# Infrastructure Requirements for Practice-Based Research Networks

Lee A. Green, MD, MPH<sup>4</sup> Linda L. White, RN, MPH<sup>2</sup> Henry C. Barry, MD, MS<sup>2</sup> Donald E. Nease, Jr, MD<sup>4</sup> Brenda L. Hudson, MA<sup>3</sup>

<sup>1</sup>Department of Family Medicine, University of Michigan, Ann Arbor, Mich

<sup>2</sup>Department of Family Practice, Michigan State University, East Lansing, Mich

<sup>3</sup>PBRN Resource Center, Indiana University, Indianapolis, Ind



ABSTRACT

**BACKGROUND** The practice-based research network (PBRN) is the basic laboratory for primary care research. Although most PBRNs include some common elements, their infrastructures vary widely. We offer suggestions for developing and supporting infrastructures to enhance PBRN research success.

**METHODS** Information was compiled based on published articles, the PBRN Resource Center survey of 2003, our PBRN experiences, and discussions with directors and coordinators from other PBRNs.

**RESULTS** PBRN research ranges from observational studies, through intervention studies, clinical trials, and quality of care research, to large-scale practice change interventions. Basic infrastructure elements such as a membership roster, a board, a director, a coordinator, a news-sharing function, a means of addressing requirements of institutional review boards and the Health Insurance Portability and Accountability Act, and a network meeting must exist to support these initiatives. Desirable elements such as support staff, electronic medical records, multiuser databases, mentoring and development programs, mock study sections, and research training are costly and difficult to sustain through project grant funds. These infrastructure elements must be selected, configured, and sized according to the PBRN's self-defined research mission. Annual infrastructure costs are estimated to range from \$69,700 for a basic network to \$287,600 for a moderately complex network.

**CONCLUSIONS** Well-designed and properly supported PBRN infrastructures can support a wide range of research of great direct value to patients and society. Increased and more consistent infrastructure support could generate an explosion of pragmatic, generalizable knowledge about currently understudied populations, settings, and health care problems.

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# INTRODUCTION

The infrastructures of practice-based research networks (PBRNs) differ widely, reflecting their varying origins and settings. Some were begun by physicians who had a strong desire to do research in community practice settings<sup>1</sup> but had no set research program, whereas others were formed around a specific research agenda.<sup>2</sup> The geographic scope of PBRNs ranges from national (eg, Pediatric Research in Office Settings, sponsored by the American Academy of Pediatrics, and the National Research Network sponsored by the American Academy of Family Physicians) to very local (eg, MetroNet, a 12-practice network in metropolitan Detroit sponsored by the Wayne State University Department of Family Medicine).

To date, very few data have been published about PBRN infrastructures. Basic survey data on the numbers and types of practices, clinician and patient demographics, geographic distribution, and studies completed or in progress are available for 86 of the 111 PBRNs identified by the PBRN Resource Center.<sup>3</sup> Other authors have described medical records and busi-

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#### CORRESPONDING AUTHOR

Lee A. Green, MD, MPH 1018 Fuller St Campus Box 0708 Ann Arbor, MI 48109 greenla@umich.edu



ness systems information technology (IT) in practices in statewide family medicine<sup>4</sup> and regional pediatric<sup>5</sup> networks, but data on the research-support IT infrastructure of PBRNs themselves are lacking. Although case studies of single-network infrastructure development exist,<sup>6</sup> at present, there is no comprehensive survey of PBRN infrastructure, much less any detailed analysis linking infrastructure elements to research productivity or efficiency.

The Agency for Healthcare Research and Quality (AHRQ) describes a set of basic infrastructure elements that must be in place for a PBRN to qualify for grant funding (eg, for RFA-HS-05-011 grants).<sup>7</sup> These elements include the following:

• At least 15 ambulatory practices and/or 15 clinicians devoted to the primary care of patients

• A statement of the PBRN's purpose and mission, including an ongoing commitment to research

• A director who is responsible for administrative, financial, and planning functions

• A support staff of at least 1 person reporting to the director

• A mechanism such as a community advisory board to solicit advice and feedback from the communities of patients served by the PBRN clinicians

• An organizational structure independent of any single study

• Communication processes such as regular newsletters, e-mails or listservs, conference calls, or face-toface meetings

In the discussion that follows, we offer suggestions for configuring PBRN infrastructure. Our suggestions are based on our own experience and discussions with directors and coordinators of other PBRNs. We hope that the data linking structure to research productivity that we now lack will become available in the future and allow suggestions to be made on a more evidencebased footing.

### INFRASTRUCTURE ELEMENTS

The PBRN is the basic laboratory for primary care research, and laboratories are designed for the research questions they intend to answer and the methods they will use to approach those questions. In our discussion, we therefore adopt the position that the infrastructure of a PBRN should be designed to support its research mission and should be designed after that research mission has been determined. In other words, the statement of mission and purpose should come first, and the infrastructure should be designed to support it. Certain elements of infrastructure will be common to all or nearly all PBRNs; others will vary depending on mission. We consider both of these categories.

#### **Common Infrastructure Elements**

Certain elements of infrastructure appear essential to support any successful PBRN: a director, a coordinator, a regular news-sharing function, some means of regular 2-way communication among the member practices, a membership roster, a provision for meetings, and an organized means of ensuring human subjects protection.

#### Director

The director is operationally responsible for the PBRN and is the individual accountable for management of the network. The director is typically a physician but may be a PhD researcher or another senior administrator. Training or experience in research is very desirable if not essential for this position.

The director is responsible for ensuring that proposed projects are evaluated in light of the network's research focus and mission, resources, and other concurrent projects. (Networks differ in whether the actual decisions on prioritizing projects are made by the director, the governing board, a project review committee, or the membership as a committee of the whole.) The director need not be directly involved in active research within the network, but should know of all projects in the network. She or he often provides or arranges for mentorship and project development assistance for network members who have research questions and need help developing them. Outreach and recruitment of potential new network members, writing press releases, and giving talks at appropriate forums to reach existing and potential new members are also the director's responsibility. If the network holds regular meetings, the director is usually responsible for leading those meetings. Finally, the director is responsible for daily administration, such as personnel and financial management.

It is essential not to underestimate the time commitment of the director. PBRNs require substantial inperson contact and hence make heavy demands on the director's involvement. It is probably not practical to commit less than 0.20 full-time equivalents (FTEs) for even a small network, and 0.50 FTEs is more realistic for a network of any size. (In some networks, a team of investigators shares the personal contact function, reducing the time commitment required of the director.)

#### Coordinator

The PBRN coordinator is the key staff person responsible for the day-to-day operations of both the network and the projects within the network, and is critical to the success of a network. Although published data do not exist, we have developed a description of the successful coordinator from discussions at national PBRN workshops. Successful coordinators often have training and experience in both health care management and



project administration. While the level of experience will vary from person to person, a basic understanding of both clinical settings and health services research are important.

The coordinator has 3 overlapping roles including, but not limited to, being a research manager, an infrastructure administrator, and an assistant to the network director. In any given network, the coordinator does not manage all elements of all the roles. For example, some networks may have specialized budget personnel, often as part of an academic department sponsoring the network.

As a *research manager*, the coordinator is responsible for managing research initiatives. Some of these responsibilities include the following:

• Identifying potential grant opportunities

• Assisting with the development and submission of grant applications

• Developing project-specific protocols and procedures

• Hiring, training, and supervising research support staff

• Organizing, overseeing, and assisting the work flow of projects

• Overseeing the management of study budgets

As an *infrastructure administrator*, the coordinator is primarily responsible for maintaining communication across the network, both between network members and between the network infrastructure elements.

The following tasks are necessary for maintaining this communication:

• Creating and distributing a PBRN newsletter or other periodical mailings

• Organizing and scheduling meetings, including board and member discussions as well as regular meetings with infrastructure staff including the PBRN director

• Developing and maintaining the network Web site

• Conducting conference calls or teleconferencing relevant and/or essential to the network

As an *assistant to the network director*, the coordinator helps the director with the recruitment and retention of practices and clinicians within the network by performing a set of tasks:

• Assisting with the recruitment of new PBRN members

• Maintaining a directory (database) for tracking both research activities and member information

• Working closely with the PBRN director to identify potential problems or difficulties within or between practices and network administration or governing organizations

• Serving as a liaison between the community and the network

The coordinator position will ordinarily require at least 0.50 FTEs in even a modest-sized network. Larger networks will require more dedicated time and may divide the coordinator roles between 2 or more people.

#### **One-Way Communication**

The 1-way communication or news-sharing function of a PBRN is usually served by some combination of a newsletter and a Web site. The content of both will be quite similar. Newsletter intervals vary with activity; quarterly publication is a common choice. A Web site has the advantage of offering archival and reference information, but members must actively check it. Both forms of communication serve to celebrate successes, prepare for upcoming possible projects, reinforce contact information, and disseminate schedules. The value of a newsletter or Web site in making the PBRN known and attractive to potential new members should also be considered.

#### Two-Way Communication

The 2-way communication function of a PBRN is often supported by an e-mail listserv; that is, an e-mail service wherein listed members can both read and post comments. Discussion boards on a Web site are also possible, but require members to actively sign in to check on them. Two-way asynchronous communication is an effective means of developing ideas, managing active projects, and sharing news as well as collaborative feedback. It also serves the intangible but vital role of community-building, particularly in PBRNs that are geographically dispersed. The same listserv can also support the 1-way news-sharing function, if all or nearly all members of the network are subscribed.

#### Membership Roster

The roster may be anything from a simple list kept in the coordinator's or director's office to a full-scale multiuser database containing extensive descriptive information. A well-designed roster database will allow identification of practices for specific studies, support the mailing list for the newsletter and other communication tools, and provide information on the network (numbers, locations, and demographics of practices) to support grant applications.

#### Meetings

PBRNs generally have some form of regular meeting among members. In small networks, meetings may be as frequent as monthly, whereas in large or geographically dispersed networks, an annual assembly may be all that is practical. Larger meetings may serve more than the communication and community-building functions: they may include presentation of research results and research proposals, training sessions for general methodologies or specific projects, and workshops on topics such as grant writing or manuscript preparation. Continuing medical education (CME) credit is often offered even at smaller meetings.

Geographically dispersed PBRNs with infrequent meetings may supplement their meeting schedule with regularly scheduled conference calls open to all members, hosted through commercial services or by hospitals or universities with telephone line resources. A new alternative, practical in only a minority of settings because of high-speed Internet requirements, is Webbased videoconferencing.

#### **Board Function**

All PBRNs require a board function, but how that function is served varies widely and depends to a great extent on whether the network functions primarily in a top-down, bottom-up, or whole-system fashion.8 Networks that are freestanding, nonprofit legal entities such as 501(c)(3) corporations, of course, have board structures dictated by their legal status. Some small unincorporated or institution-based networks function as a committee of the whole. Large institution-based networks generally require a formal board of directors, which may be appointed by sponsoring institutions or elected by the membership, or both. Patient representation on the board should be strongly considered, both to maintain patient-centered research values and because funding agencies are placing a great deal of emphasis on patient input at this organizational level.<sup>7</sup> Alternatively, a PBRN may create a community or patient advisory board that reports to the governing board.

#### Human Subjects Protection Management

PBRN members and their office staffs must have training and certification in human subjects protection.<sup>9,10</sup> At present, the required training programs vary widely and are often specific to host institutions or to funding agencies. A good starting point for an overview is the Bioethics Resources Web page of the National Institutes of Health (http://www.nih.gov/sigs/bioethics). PBRN infrastructure must include a means of knowing members' progress toward certification and, ideally, support for helping them work through required material. Some PBRNs hold human subjects certification courses at their meetings, others give talks at members' offices or hospitals, and some offer online training through their host institution.

PBRNs that are not entirely owned by or otherwise subsumed within a single health system will have to deal with multiple institutional review boards (IRBs), which typically vary widely in their procedures and requirements. A detailed database of IRB procedures and contact information, a collection of their forms, and at least 1 person experienced in working with them will be critical elements of infrastructure. This database must be well maintained, as IRB processes change relatively often.

# **Mission-Dependent Infrastructure Elements**

For PBRNs intending to do only simple observational correlation studies, no formal infrastructure beyond the basics outlined above may be needed. PBRNs intending to carry out prospective cohort studies, clinical trials, or practice change interventions will need to consider dedicated research assistants (RAs), more sophisticated information management resources, training programs for members and their staffs, and formal linkages with the statistical and methodologic expertise of academic centers.

#### **Research Assistants**

The qualification of and funding for RAs vary with the local conditions of each network and the research mission(s) they undertake. Permanent RA positions that continue from one project to the next attract and retain more capable RAs, but must be supported financially during gaps between project funding streams. That support typically requires infrastructure support from a larger institution or a means to recover indirect costs or contractually set aside direct funds from grants to cover the gaps.

In some cases, practice staff rather than RAs collect study data. This substitution may necessitate financial support or other incentives for the practices. Using practice staff has 2 risks: research activities must compete with clinical demands for staff time and attention, and office staff may not be well or uniformly trained in research data collection. Both risks have implications for the generalizability of the patients recruited as well as the quality of the data obtained. The substitution of practice staff for RAs is nonetheless done successfully in many PBRNs and is advantageous particularly when geographic dispersion of practices is large, data collection procedures are straightforward, and data must be collected from many sites simultaneously. A brief, wellthought-out training program can allow gathering of high-quality data.<sup>11</sup>

#### Information Technology Infrastructure

The elements of IT infrastructure<sup>12</sup> can be considered in 2 categories, according to whether they function primarily at the practice level or at the network level. Here we will consider only those IT elements that directly relate to PBRN research, deferring practice business operations<sup>4</sup> and general research issues such as statistics software to other authors.

At the practice level, electronic medical records (EMRs) can be helpful in PBRN research.13 They may be very helpful in providing practice demographics to support grant applications, identifying patients as candidates for studies, and providing data for retrospective chart review projects. Commercial EMRs are generally not designed for research; some proprietary systems do not even allow practices to access their own data for research without payment to the vendor. Choosing an EMR carefully, however, can maximize its usefulness in PBRNs. Practices contemplating the purchase of an EMR may wish to consider whether the data are structured in a manner that supports research queries, the ease of access for ad hoc gueries, and whether data elements or forms can be added for specific research projects. At the network level, PBRNs may need to consider Web and file servers, shared databases, networking, and data collection equipment.

PBRNs desiring a Web site, listserv, or shared files require some form of server infrastructure. A wide variety of arrangements are possible, depending on local resources, expertise, and needs. A simple desktop computer with an always-on Internet connection may suffice; at the other extreme, the network may have space in a commercial or academic server-hosting operation. Regardless of the specific arrangements, 3 needs must be addressed: backup, security, and support. If any information of operational importance is kept on the server, a regular practice of backing up the data and server configuration should be in place, this practice protects against loss of data in unforeseen circumstances. Security needs will vary with information content: for example, a newsletter-type Web site is not sensitive, but a roster of practices with private office telephone numbers is. As a rule, PBRN Web sites themselves are not targets of hacking (illegal access), but any server is a target for takeover as a "zombie,"14 including home computers connected to the Internet by a cable modem or a digital subscriber line (DSL). Security features should therefore be turned on and patches should be kept up to date. Support can be in the form of a person in the PBRN with suitable expertise, someone in an academic or organizational setting who supports the PBRN, or a commercially purchased support service, which may be included with space on an institutional server system.

As the size, scope, and sophistication of their research designs increase, PBRNs can find themselves hamstrung by what initially appeared to be the simple task of database design. Attention to relational design will save the growing PBRN a great deal of repeated work later. Multiuser databases (both for PBRN operations and for specific research projects) containing potentially sensitive information must be shared with, but restricted to, appropriate personnel, with careful attendance to security principles as described above. Off-the-shelf database systems designed to be userfriendly can present wide-open portals for unauthorized intrusion.

The PBRN whose research mission includes highintensity activities such as clinical trials will require a means of highly secure communication. Each PBRN will arrive at its own solution based on its members' preferences and the technical expertise available to it, ranging from fax to virtual private networks (VPNs).

PBRNs with research missions that necessitate the collection of field data often equip research assistants with *laptop computers*. Infrastructure must then be in place to back up these computers frequently and reliably and to ensure that information contained on them remains secure in the event that one is lost or stolen.

#### **Regulatory Compliance**

PBRNs whose missions include health services research, quality improvement, or translation of research into practice will have to access medical records to measure physician practice patterns, and that access requires a system for ensuring compliance with the Health Insurance Portability and Accountability Act (HIPAA).<sup>15,16</sup> HIPAA compliance can be maintained by negotiating a business agency agreement between the PBRN's host institution or nonprofit corporation and its member practices, wherein the PBRN is privileged to patient data for purposes of a quality audit or other business reason. An example of such an agreement is provided in Appendix, available online only as supplemental data at http:// www.annfammed.org/cgi/content/full/3/suppl\_1/ S5/DC1. Use of these patient data for research must still be specifically approved on a project-byproject basis, but a business agency agreement can at least credential a consistent set of PBRN research assistants to be able to abstract records across practices when a project receives IRB and HIPAA approval.

#### **Research Consulting Expertise**

PBRN projects usually require some level of statistical consultation and methodologic expertise. This expertise can be in the form of academic or private-sector researchers who are members, or nonmember experts who are retained by formal consulting arrangements. Specific forms of expertise are called for based on research mission. A PBRN planning clinical trials and one focused on epidemiology will have different needs. In most cases, these needs are addressed by an affiliation with an academic center.

PBRNs with research missions that require pursuing federal or equivalent grant funding will also benefit from holding regular mock study sections. A mock study section is a panel of 3 or more senior researchers with national study section experience who review PBRN members' grant applications before submission. The reviews must take place far enough before the submission deadlines to allow sufficient time for revisions before the application is due. They are typically conducted in a realistic study section format, but with the researcher(s) present in a "fly on the wall" fashion—listening and gaining insight into how the various components of their project may be received, but not permitted to explain or defend. That is, the application must stand on its own as it will in the actual study section. Written feedback is then provided to the researcher(s).

Closely related to the mock study section is mentoring and development.

PBRN researchers have traditionally relied on their own initiative and had minimal resources, but as the pool of experienced researchers grows, it becomes more feasible for PBRNs to offer mentorship to new investigators. Mentorship is particularly useful to community practitioners whose important research ideas and perspectives can be thwarted by lack of training or experience in research methods.

Project-specific mentorship and guidance in development of a research project can be facilitated by a regular program of *concept paper* review (for an example and format, see http://www.ahrq.gov/about/cpcr/cpcrconc.htm). A concept paper serves as a tool to refine a research idea and present it to potential collaborators and funding agencies. It also aids the PBRN staff and membership in assessing proposed projects for consistency with the PBRN's mission and resources, as well as in ensuring that projects running concurrently avoid unnecessary interferences.

If a PBRN's mission calls for studies requiring specific skills, such as clinical trials, the network will have to develop or arrange for research training for members. These programs will be specific to the research needs in question, and few useful generalizations can be offered, except that they will typically involve faculty from outside the PBRN. Programs may take place at a central meeting site or may convene at members' practices. An offering of CME credit will improve acceptance and be appreciated by members.

# **INFRASTRUCTURE COSTS**

The costs of sustaining infrastructure have been perhaps the greatest single barrier to successful PBRN operations, from the earliest days of network research<sup>17</sup>

Element	Approximate Annual Cost, \$	
	Basic Network	Moderate-Complexity Network
Director (0.20, 0.50 FTE)	32,000	78,000
Coordinator (0.50,1.00 FTE)	32,000	64,000
Research assistants (2.00 FTE)	NA	83,000
Secretarial support (0.50 FTE)	NA	21,400
Computers and software	1,000	2,200
Technical support	500	11,000
Printing and mailing	400	1,800
Telephone and fax	300	1,200
Travel	NA	8,000
Meeting costs	3,500	17,000
Total	69,700	287.600

# Table 1. Simplified Infrastructure Costs for Hypothetical Research Networks of Differing Complexities

FTE = full-time equivalent; NA = not applicable because the basic network does not have these elements.

to the present. Funding agencies have long recognized that traditional bench and academic-center clinical research requires major infrastructure support to cover expenses ranging from building depreciation to the costs of retaining critically important trained staff during funding fluctuations, and have recognized that that support must be substantial. Those expectations are built into academic centers' negotiated indirect rates. At the present time, however, few academic centers are willing to pass even a portion of these indirect rates to their PBRNs as they would to their clinical research centers, and funders are unaccustomed to thinking of PBRNs as the laboratories that they are, analogous to bench research edifices. As a result, PBRNs are often chronically underfinanced, operating on shoestring budgets and depending heavily on volunteer labor.

Costs of infrastructure vary with the research mission of the PBRN, but some commonalities across missions may be illustrative. Even a small network doing only simple epidemiology studies and other observational research (ie, a basic network) will require a half-time coordinator and a 0.20-time director, a laptop computer with a typical 3-year lifespan, a desktop computer, some technical support, a newsletter, and meeting, telephone, and fax expenses. A network with a larger membership, wider geographic dispersion, and a mission that includes intervention studies and externally funded research (ie, a moderate-complexity network) will require more director and coordinator time, 1 or more research assistants, travel expenses, secretarial staff with the skills to prepare competitive grant applications, and a sophisticated technologic infrastructure. Table 1 displays a simplified financial requirements for these 2 scenarios; the actual costs are only rough approximations of course and will vary



widely by locality and specific setting, but serve to illustrate the challenge. Networks taking on high-complexity projects (not shown) may easily require more than \$500,000 annually in infrastructure resources. The moderate-complexity network modeled in the Table or a high-complexity network will recover some, but by no means all and possibly less than half, of those expenses in allowable direct costs on grants.

Even the costs reflected in the Table involve substantial hidden costs of volunteer labor on the part of PBRN members and their staffs, a phenomenon observed since the early days of PBRN operations.<sup>16</sup> Fairly compensating members and their office personnel for their time and effort is the next major funding hurdle in infrastructure maintenance, and will require education of funders to recognize those costs as allowable direct expenses.

# CONCLUSIONS

In this article, we have attempted to describe briefly the infrastructure requirements for divergent types of PBRNs and to describe a range of possible configurations. As yet, no inventory of PBRN infrastructure establishes clearly what the most common elements are. More importantly, there is no data-based way to determine what elements directly bear on the success of a PBRN. The work of Bland and Ruffin<sup>18</sup> on successful research environments is based on studies in traditional academic settings. We recommend that a similar analysis of PBRNs be conducted so that best practices can be identified for nascent and evolving PBRNs to emulate. Finally, both increased and more stable funding for PBRN infrastructure is needed to support research on the important and understudied problems and settings that only PBRNs can address.

#### To read or post commentaries in response to this article, see it online at http://www.annfammed.org/cgi/content/full/3/Suppl\_1/S5.

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