SPECIAL ARTICLE

Single Community Research Networks

The HARNET Experience

David C. Slawson, MD; James M. Herman, MD, MSPH; Joshua H. Bennett, MD

Clinical research performed in family physicians' offices is critical for building an expanded knowledge base for modern health care. Practitioners do not usually have the time, funds, or research expertise to conduct clinical studies. Organized networks can accomplish this goal. Large-area networks, composed of many separate practice sites from a wide geographic area, are valuable sources of information for describing the natural history of disease. These observational studies usually consist of data collection during clinical practice. Experimental trials include evaluations of new protocols, diagnostic tests, or therapies, often in a randomized and blinded fashion. Because of the difficulties in adhering to a standardized protocol, experimental trials are rarely undertaken in the busy clinician's office. Similarly, it may be difficult to standardize these studies in large-area networks. Smaller networks, often in a single community, can feasibly perform more complex studies. Important strategies are required to avoid loss of interest, lack of continuity, and conflict of interest. *(Arch Fam Med. 1993;2:725-728)*

Clinical research performed in family physicians' offices can address broad-based practical questions from the primary care setting. Many practitioners do not have the time, funds, or expertise in epidemiology to conduct valid clinical studies.

Organized networks of physicians can perform research and minimize each member's work load. Central administration provides expertise in research and statistics and is responsible for obtaining and managing funds. Pooling data from multiple practice sites can ensure adequate sample sizes and offer a wide range of clinical heterogeneity.

Examples of well-known networks include the British General Practitioners Network, the Ambulatory Sentinel Practice Network (ASPN), the Missouri Network, the Primary Care Cooperative Project (COOP), the Wisconsin Research Network (WREN), and the Michigan Research Network (MIRNET). Large-area networks such as these are composed of members from separate practice sites from a wide geographic area and have several advantages. First, there is access to a large population of patients with a wide spectrum of disease severity, enabling research on relatively unusual conditions. Second, by combining patient populations of different sociodemographic groups as well as different practice styles, these attributes can be studied.

Two significant disadvantages of large-area networks are also noteworthy. First, geographic separation of physicians' offices makes coordination and standardization of research protocols difficult. Second, such networks are structured well before a project is anticipated, requiring a well-organized central administration before a project is developed and undertaken. This entails significant costs. A recent review of network research by Green and Lutz[1] estimated the required initial investment to be $50 000 per year for at least 3 years. For many groups of physicians, community hospitals, and residency

From the Department of Family Practice, Harrisburg (Pa) Hospital (Drs Slawson and Bennett), and the Department of Family and Community Medicine, Pennsylvania State University/The Milton S. Hershey Medical Center, Hershey (Drs Slawson, Herman, and Bennett).

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programs considering research, these costs are prohibitive.

Green and Lutz[1] also provide useful commentary on the types of studies best suited for large-area networks. These include (1) descriptive and natural history studies that document what actually happens to people with a given condition in the real world of primary care and (2) studies that investigate the most appropriate methods for network research. Experience with nonobservational and/or interventional studies in large-area networks is much more limited.

Smaller networks, often located in a single community and based at a particular hospital or residency program, have a different profile of advantages and disadvantages. Advantages include the following: (1) The proximity of network members allows for familiarity and a shared enthusiasm ("critical mass"). (2) The smaller local networks and the geographic proximity of their members allows performance and standardization of complex studies, such as randomized trials and testing of new diagnostic procedures. (3) Smaller networks do not require large financial outlays when organized around a specific project or group of projects.

Smaller networks cannot duplicate, however, the large sample sizes possible in large-area networks. One cannot assume without analyzing the sample that results are generalizable to other populations. In addition, the practices will be geographically and often culturally more homogeneous, making practice variables more difficult to study.

In 1992, the Harrisburg Area Research Network (HARNET), a single community network, published results of its first collaborative project.[2,3] We describe our experience in forming a single community research network. We do not intend to provide a rigorous scientific study of research networks, instead we want to delineate the problems and potential biases we encountered in this setting and our solutions.

THE HARNET EXPERIENCE

The HARNET came into existence as an outgrowth of the Harrisburg (Pa) Hospital Family Practice Residency Program. In 1988, clinicians from six local practices (four suburban and semirural private practices and two residency-based family practice centers in urban and semirural areas) met to discuss their mutual interest in practice-based research.

Clinicians from these practices teach in the family practice residency program. Initial discussions held at monthly faculty meetings centered on a list of clinical research questions arising from the members' practices. At this early stage, the list included many types of questions, such as the optimal management of elevated cholesterol levels in the elderly and the treatment of purulent rhinitis. Two questions related to the evaluation and treatment of cervical disease. The first concerned women who were found to have atypical Papanicolaou smears. The second considered the use of a cervical acetic acid wash as an adjunct to the Papanicolaou smear for improving the detection of cervical disease.

There was agreement among group members that many cytologic reports noted the presence of cervical atypia and that there was no consensus in the community regarding treatment. Gynecologists in the community seemed to split into three factions: those recommending doing nothing, those recommending repeating the cytologic study in 3 or 4 months, and those insisting on immediate colposcopy.

Several factors were important in choosing a final project. First, as most network members were relatively new to research, the protocol needed to be reasonably simple to perform in a standard way at each site. Second, data collection in the busy office setting required a minimal interruption of patient care flow. Third, a sample size appropriate to answer our question needed to be available. Finally, the cost of the study had to be reasonable.

After consideration of these factors and a review of the relevant literature, the research director (D.C.S.) refined the research question into the following protocol. Women presenting for a health maintenance examination in network offices underwent a cervical acetic acid wash in addition to the Papanicolaou smear. Consenting subjects with either an abnormal acetic acid wash or a Papanicolaou smear demonstrating cervical atypia underwent a second examination 4 to 6 months before a colposcopic examination. Women with a Papanicolaou smear showing a squamous intraepithelial lesion underwent colposcopic examination without further delay. The results were recorded at each office site in a research log.

Performing an initial pilot study can help identify potential problems early and prevent frustration and invalidation of the study results at a later date. We tested the acceptance of the acetic acid wash by patients before beginning the study within the network offices.

Participating members of the network approved the project during a monthly faculty meeting, with follow-up confirmation in writing. Residents provided approval and feedback during weekly resident-faculty meetings. One of the residency faculty members with experience in research and training in epidemiology was designated as director of the network and principal investigator. This research director was salaried by the hospital. One day per week was protected from other responsibilities by the residency director and hospital administration for the development and management of the network. This allowed for planning the project, overseeing data collection, performing data analysis, and preparing and presenting the final results.

The hospital Institutional Review Board approved the project, and a grant was obtained for $25 000 from a local foundation for a 2-year study period. The majority of the funds supported a part-time research assis-

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tant. The research director hired and trained the research assistant. Important attributes of the assistant included medical training (at the medical assistant level), computer literacy, a penchant for strict attention to details, and a pleasant and engaging personality.

The research director and assistant visited each network office to introduce the protocol to the staff members. The importance of the study and its potential to have a positive impact on patient care in their office was highlighted. This occurred during lunchtime, with food provided by the network.

A KEY CONTACT person was identified in each office. Several factors considered in choosing these individuals included the amount of time that they had available for the research project, their commitment to research, and whether they occupied a position of authority within the office. Although a formal authoritative role was not necessary, it was important that the contact person be well respected by the other staff members and clinicians. Each office's manager committed the contact person to from 1 to 2 hours each week for the recording of data. To maintain close, ongoing monitoring of the protocol, the research assistant made biweekly visits to each office. The assistant monitored data collection by reviewing the research log and discussing problems and questions with the office staff and clinicians. This helped to maintain interest and enthusiasm for the project.

Network clinicians received regular feedback in several ways. First, on-site evaluation of the data collection process occurred as discussed above. Second, the research director received and initiated numerous telephone calls with the clinicians regarding questions and problems. Third, discussions of relevant issues occurred at each monthly network/faculty meeting and residents' meeting. To avoid bias, data results were not released to the network members before completion of the study. Finally, letters were written on several occasions when problems with individual practitioners threatened the overall validity of the study.

The research director and assistant performed regular physician compliance studies. They compared the number of actual patients enrolled in the study with the number of eligible patients encountered by each participating clinician. The research assistant contacted clinicians with low scores, resulting in the identification of several interesting problems. For example, on several occasions, female clinicians had lower compliance rates. Their patients preferred female clinicians and, because the study colposcopists were male, objected to participation in the study. This problem resolved with the addition of a female colposcopist to the study personnel.

The importance of authorship and credit to network members was addressed. Under current guidelines, we reserved authorship for the network members involved in the major planning, writing, and review of the project and manuscript. Other network members were credited with notation as members of HARNET. Each office site received a certificate of appreciation with reprints of the publication presented to clinicians and staff members.

POTENTIAL BIAS IN NETWORK RESEARCH

During the management of this project, we noted a number of issues that could have invalidated the final results.

Selection Bias

The first priority of a busy practice is to efficiently handle patient flow. Without a continued sense of the importance attributed to the research project, it is easy for network office staff members to commit errors in the selection of participants for the research protocol. Patients may be scheduled for procedures or follow-up visits at the wrong time or with the wrong person. Clinicians may not be reminded that a person with a particular test result is a candidate for the study. Finally, data may be incorrectly recorded in the research log. Regular review of patient selection techniques and data collection by the research assistant minimized this potential bias.

In a similar manner, noncommitted clinicians influenced the entry of study participants. During our study, several office-based clinicians began to perform colposcopy themselves. Because reimbursement for procedures is relatively generous, an immediate conflict occurred between our study and the financial incentive to not enroll patients. In addition, each practitioner had "special patients" who they did not wish to enroll. Usually, this was because the patient was well known or of a relatively high social status. In these cases, the clinicians did not wish the patient to be a "guinea pig."

Most important, the clinicians often did not understand that selective patient enrollment would jeopardize the validity of the study by introducing selection bias. To minimize this, we spent several group sessions explaining the importance of avoiding selection bias and the role of each clinician and office staff member. Most individuals complied after understanding the concept and avoided selective enrollment. One individual persisted, however, in a referral pattern highly prone to bias. This placed that entire office's population of subjects at risk for noninclusion in the final results. Fortunately, the network negotiated a settlement with the individual, allowing him some control over the procedures performed on his patients, with supervision by study personnel.

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Misclassification Bias

Misclassification of subjects to an incorrect outcome group can significantly bias the final results. In our protocol, practitioners used an acetic acid wash of the cervix to identify potentially abnormal areas. This procedure was initially unfamiliar and therefore had a learning curve associated with its use. Wrong decisions regarding the normalcy of an acetic acid wash can misclassify a patient. This misclassification would lead to obvious distortion in the predictive value of an abnormal acetic acid wash. Several methods for educating the clinicians minimized this form of bias. First, photographs of normal and abnormal cervices after acetic acid washes were distributed to each office site. Second, slides were shown at several network meetings showing the same material. Within several months of having seen definitely abnormal washes in several patients, practitioners became more comfortable with their decisions, thus minimizing misclassification.

Confounding

The question of confounding in this study is difficult to ascertain, but several interesting possibilities exist. For example, the effect of other cancer risk factors, such as the proximity of the Three-Mile Island nuclear plant to all the practices in our network might be a factor. Fortunately, long-term studies have failed to demonstrate any changes in the expected frequency of cancer from this area.

CONCLUSION

In summary, performing clinical research in a single community network is feasible. Certain types of projects, including randomized trials and testing of new diagnostic procedures, are especially appropriate for this setting. The continuous feedback and constant monitoring necessary to prevent bias is difficult to achieve without proximity of network members.

Important strategies are necessary to avoid loss of interest, lack of communication, and conflict of interest, all of which may lead to biased results. Individuals with knowledge of clinical epidemiology and research methods must direct the project. The interpersonal "glue" binding the network members must supply continued motivation despite differing levels of understanding and motives among the research participants. Ongoing negotiation of disagreements and conflict is essential.

Initially, HARNET included only full- and part-time faculty members from the local area. Other physicians from the community have shown interest in participating in future projects. Questions posed for the future include pain control for otitis media, treatment for purulent rhinitis, and additional studies of the methods involved in doing research in the single community setting.

Our research assistant is funded only when a project creates a need for time. Thus, continuous funding to maintain the network is unnecessary. Although we had no direct involvement with our state's Academy of Family Physicians, networks similar to HARNET could form with support from these organizations.

Research involvement has raised our community-based clinicians' and family practice faculty's and residents' knowledge and respect for clinical epidemiology as a tool for answering important practice-based clinical questions. They see themselves more as scientists/clinicians, and have found that participation in research is motivating and fun.

Our hospital's primary care image benefits from the tighter affiliation of these practices as a result of their collaboration in research. Research in the single community setting is practical, rewarding, and important for expanding the primary care knowledge base.

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Reprint requests to Department of Family Practice, Harrisburg Hospital, 205 S Front St, Harrisburg, PA 17105-8700 (Dr Slawson).

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