



NATIONAL ASSOCIATION OF
COMMUNITY HEALTH CENTERS, INC.®

Monograph

RESEARCH IN COMMUNITY HEALTH CENTERS

by Robert A. Fried, M.D.

Vice President for Research and Development

Ambulatory Innovations, Inc.

Indianapolis, Indiana

For many primary care clinicians, "research" is a dirty word. It brings to mind laboratory benchtops crowded with equipment, a mindset more concerned with molecules than with people, and all that is wrong with the ivory-tower outlook of the confirmed academic. Choosing a primary care career, in fact, often is a reaction to the research-oriented, highly competitive environment that characterizes most schools for health care professionals.

At the same time, health center practice inevitably leads to important questions about real problems: What is the most effective treatment of a given problem for the people we serve? What would happen if we evaluated this symptom differently from how the textbooks recommend? How can we practice in a more cost-effective manner — that is, how can we

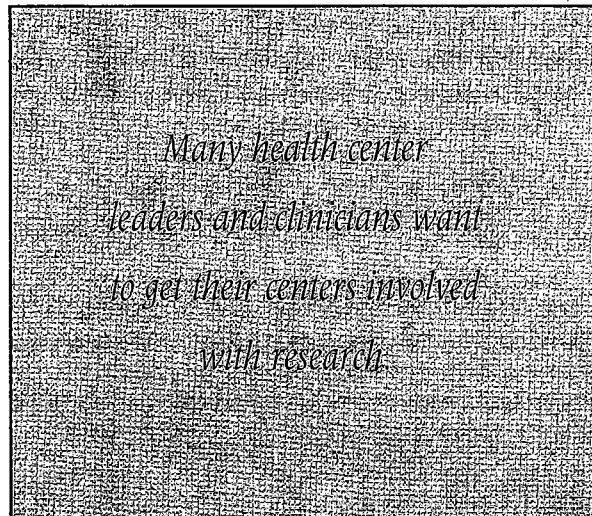
get more health with fewer dollars? Research is about answering questions like these. Research can be thought of as the process of asking answerable questions and *systematically pursuing* the answers in a manner that yields *trustworthy results*. Doing research in the course of caring for patients provides benefits for patients, clinicians, and communities.

Asking questions, collecting data, analyzing the results, making changes based on the analysis — if that sounds like continuous quality improvement, it should. Clinical research has a lot in common with CQI. Although research studies usually collect more data in a more rigorous fashion, quality improvement projects can be thought of as research studies on process improvement. Clinical research is a natural fit for health centers with CQI experience.

Many health center leaders and clinicians want to get their centers involved with research. Some already are pursuing one or more projects; others are just getting started. As with any change, successfully implementing a research program requires planning, attention to detail, and assuring buy-in by key stakeholders.

PRIMARY CARE RESEARCH

It's important to distinguish between research in primary care and research about primary care. A clinical drug trial is an example of research in primary care. The health center serves as a source of patients and clinical expertise, but the question being studied — is this drug more effective than other drugs? —



does not arise from the practice of primary care. On the other hand, research about primary care — which is what this monograph means by “primary care research” — is generally characterized by:

- a concern about the health problems that most people have most of the time;
- a focus on the individual, not an organ system or disease, and an interest in the individual in the context of family and community;
- a reliance in many cases on epidemiology, the same skill needed to produce a community needs assessment.

Why Do Primary Care Research?

Health centers have some special reasons to get involved with primary care research:

- **A research program can help with the recruitment and retention of clinicians.** High-quality clinicians are likely to be asking the kinds of questions that primary care research tries to answer. Being involved in research helps clinicians answer their own questions.
- **Research activity can make a health center more attractive to medical schools and residency programs.** A research program is evidence of a climate in which schools can feel comfortable sending their students and trainees.
- **Research can sometimes generate extra funds for a health center.** Most studies include compensation for overhead or indirect costs. While not “primary

care research” in the sense used in this monograph, clinical drug studies can be quite lucrative for participating health centers. (See “Funding Research” below for more details on the financial impact of research.)

- **Patients who participate in clinical research can enjoy improved access to care as well as earlier access to new drugs and therapies.** (These benefits are more often seen with studies in primary care — drug trials, for example — than with what this monograph has labeled as primary care research.)
- **Most important, primary care research can have an impact on your health center’s clinical mission.** Much traditional academic research is not relevant to the complex task of caring for patients and their families in community health centers.

For these and other reasons, research is likely to provide a sufficient “return on investment” to justify the resources needed to get started.

A Case Study: Patients with Headache

As an example of the above point, consider a common problem in primary care: when to perform a head CT scan in patients complaining for the first time of a headache. The clinical concern is that a new headache can be a symptom of a brain tumor or hemorrhage. Traditional textbooks of neurology, basing their suggestions on patients referred to academic centers from many locations, recommend that patients who state their new-onset headache is severe ought to have a CT scan. Primary care research has provided a thoughtful response to this idea. In a practice-based study, only two percent of persons presenting in primary care with a new headache actually had a CT scan, although 46 percent of the patients said their headaches were severe.¹ This cost-effective approach to diagnostic testing made clinical sense. The risk of serious disease causing headaches — brain tumors and hemorrhage — was only 12 per 100,000 patients per year.²

The neurology textbooks, in other words, don’t tell the full story. Primary care clinicians can rely on

*research is likely to provide
a sufficient
“return on investment”
to justify the resources
needed to get started.*

¹ Becker L, Iverson DC, Reed FM, et al. Patients with new headache in primary care: a report from ASPN. *J Fam Pract* 1988;27:41-7.

² Becker LA, Green LA, Beaufait D, Kirk K, Froom J, Freeman WL. Detection of intracranial tumors, subarachnoid hemorrhages, and subdural hematomas in primary care patients: a report from ASPN, part 2. *J Fam Pract* 1993;37:135-41.

their basic clinical skills to detect those patients with new-onset headache who require sophisticated testing. Dollars that might have been spent on unnecessary CT scans could be reallocated to other health needs. In an environment increasingly dominated by managed care, practice-based primary care research can help health centers develop policies that emphasize quality and cost-effectiveness.

What is the Scope of Primary Care Research?

Naturally, not all primary care research studies will focus on cost-effective imaging techniques for selected clinical problems. The research issues are diverse. Health center leaders who are considering research should understand the range of topics that might be researched in their centers.

A recent report³ suggested that most studies would concern the core elements of primary care: the practitioner, the patient, the problem, and the clinical process of care:

- Research on the *practitioner* might look at variation in practitioners' decisions and their practice styles. What motivates practitioners to practice in certain settings and to take certain actions, and what sustains them over time? How do practitioners assimilate new knowledge into their work? Which communication styles are most effective, and which create barriers between practitioners and patients?
- Some investigators will study the characteristics of the *patient*. How do cultural, social, and ethnic factors influence the health-seeking behavior of patients? What leads some patients to modify behaviors and others to continue unhealthy habits? What outcomes of care are most desired by patients, and how do they measure those outcomes for themselves? What are the unmet needs of special patient populations such as the elderly, homeless persons, or those with disabilities?
- The *problem* for which patients seek help in primary care often is ill-defined and hard to diagnose. The practitioner must distinguish serious from self-limited disease and develop a plan to manage the problem, while working within the constraints of time and money. What is the optimal diagnostic approach to selected patient com-

Health center leaders should understand the general characteristics of different research designs because each type has a different potential impact on center operations, staff, and patients.

plaints? How do physical, psychological, and social factors interact to distort signs, symptoms, and responses to treatments?

- Researchers also study many aspects of the *clinical process of care*. How can the distinction be made between benign and dangerous symptoms, so that cost-sensitive decisions can be made without jeopardizing patients' health? Are some treatments as effective in unselected primary care populations as they are in controlled clinical trials? Can unrecognized mental illness be diagnosed earlier so that treatment may be prescribed earlier?

Some investigators may want to conduct primary care research on questions that do not fit neatly into these categories. Successful research depends on curious people asking questions and setting out to find the answers. The so-called "research agenda" ultimately is a bottom-up, grassroots phenomenon. Since not all worthwhile research can be funded, reports such as the one mentioned above do serve as a guide to funders' interests.

Types of Research

Because the scope of primary care research is so broad, investigators use a number of different types of studies. Health center leaders should understand the general characteristics of different research designs because each type has a different potential impact on center operations, staff, and patients.

The least intrusive study design is a record review, which resembles an audit conducted for quality

³ Nutting PA. A research agenda for primary care: summary report of a conference. Agency for Health Care Policy and Research, administrative publication 91-08, 1991.

management purposes. Many excellent studies have been accomplished just by reviewing patient charts or administrative records. In highly computerized centers, the impact on operations may be quite minimal.

More intrusive than record review is the observational study. In this design, someone — a patient, a clinician, or a support staff member — completes a data collection form during or near the time that a patient is seen. Perhaps the patient fills out a questionnaire while waiting to be seen. Or a clinician may be asked to carry a small pocket-sized card and record certain data elements on selected patient encounters. In some cases there is an actual observer — a research assistant or staff member — and in others there is a surrogate for an observer, like a tape recorder. Most published primary care research studies have been observational.

The most intrusive design is the intervention study. In this case the investigator wants to compare two or more things — say, treatment A with no treatment, or treatment A with treatment B. Intervention studies can require significant changes in health center operations and policies.

THE ETHICS OF RESEARCH

Past abuses have heightened the public's sensitivity to ethical issues in research. To assure that the public is protected, researchers must submit their proposals to an appropriate *institutional review board* (IRB). An IRB has institutional and lay representatives. Its purpose is to assure that the rights of patients are respected and protected in any research study. All medical schools and many large university-affiliated hospitals have their own IRBs.

IRBs usually require patients who participate in research studies, observational or interventional, to sign an informed consent. The consent form must, at a minimum, describe the purpose of the study; detail the benefits and risks of participating; and provide patients with access to investigators if they need more information. (In general, studies that only involve chart review are exempt from the informed consent requirement, provided that identifying information is removed from patient records before they are shared with investigators.) Health center leadership should assure that any study in which they participate has been approved by an appropriate IRB. If your center is one of many sites involved with a study, then the principal investigator is responsible for securing IRB

approval. If, on the other hand, a study originates from your center, then you will need to present the proposal to an IRB in your community.

SECURING A COMMITMENT TO RESEARCH

It may be a cliché, but it still rings true — a journey of a thousand miles begins with a single step. Sometimes an individual clinician decides to lead by example with a small project using record reviews or collecting observational data on his or her own patients. Some health centers have grown successful programs from the seeds of such efforts.

Other centers have chosen a more formal route of discussion and debate before any projects were undertaken. But regardless of the pathway, starting a research program ultimately requires the "buy-in" of several key stakeholders. These include health center clinicians; administrative and support staff; the executive and finance directors; the board of directors; and the community being served. Buy-in is important regardless of whether your center intends to be part of research *in* primary care (for example, a drug trial sponsored by a pharmaceutical company) or research *about* primary care (what this monograph has labeled primary care research).

Support for a research program should be thought of as a two-part process — getting agreement to a research program in general, and then securing buy-in separately for each given research study. The questions and needs of stakeholders are sometimes different for both halves of the process.

To assure that the public
is protected,
researchers must submit
their proposals to an
appropriate institutional
review board (IRB).

Clinicians

As noted earlier, many clinicians chose primary care careers in part as a reaction to the unpleasant aspects of academic medicine. Active resistance by the clinical staff will make any research project impossible. To overcome such resistance, emphasize these key points:

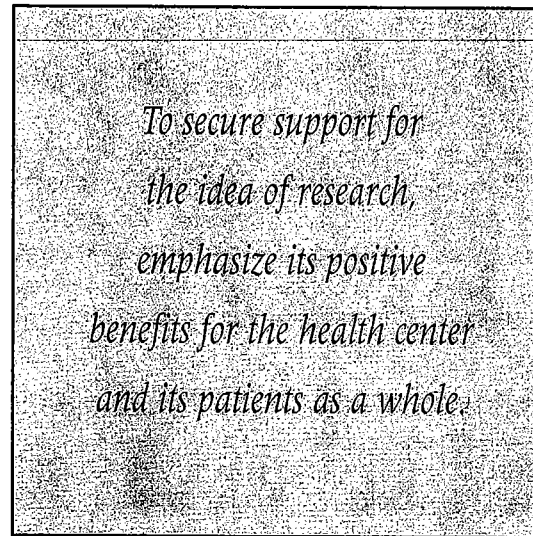
- Health center research offers a creative outlet for clinicians.
- The research program will help the health center by facilitating recruitment and the other issues summarized above, and help clinicians take better care of their patients.
- Some studies will allow underserved patients better access to care and to new drugs and other therapies.
- The mechanics of any specific study will be reviewed in advance with clinicians to assess their impact on their workloads and clinical routines. Of course, this promise must be kept!

A key to building support for research is the presence of a clinical champion. The champion should be a respected clinician who can articulate the case for research with authority. Often this is the medical director, but it need not be.

Many centers have a designated *clinical* coordinator in place. This individual, usually a registered nurse, works with physicians, other clinicians, and support staff to assure that patient care is optimized. If your center has a clinical coordinator, his or her support for research can be beneficial.

Clinician support for any particular study will depend in large measure on the specifics of the project. Good research questions — ones that are more likely to be supported by health center clinicians — have characteristics summarized by the mnemonic FINER:⁴

- The study is **feasible** — adequate numbers of patients can be recruited; there is available technical expertise to complete the study; the project is affordable and manageable.
- The study is **interesting** to the clinical champion and the clinical staff.



- The research is **novel** — it has the chance of proving something new and isn't just about confirming someone else's findings.
- The project is **ethical** — there are no unacceptable physical or privacy risks.
- The study is **relevant** to the work of the clinical staff — that is, the answer to the research question could affect the way care is delivered at the health center.

Any proposed study should be reviewed against the FINER criteria with clinical leadership before the center agrees to participate.

Administrative and Support Staff

Both for research in general and the specifics of any given study, support staff will focus on the impact on patient flow and their own workflows. To secure support for the idea of research, emphasize its positive benefits for the health center and its patients as a whole. As noted earlier, there are many analogies between research and continuous quality improvement. Researchers often fail to realize how disruptive of office routines their study requirements can be. For any particular study, a detailed analysis of its impact on patient flow should be done before the center agrees to participate. Any change in the care process should be mapped out with a flowchart. Research staff who will be present at the center should meet support staff before the project begins, and all logistical questions — where will the researcher sit? where will supplies for the study be stored? how much longer will patients wait as a result of this study? — should be addressed.

⁴ Cummings SR, Browner WS, Hulley SB. Conceiving the research question. In Hulley SB, Cummings SR. Designing clinical research: an epidemiologic approach. Williams & Wilkins, 1988:14-5.

One support staff member should be designated as the research project liaison. All questions and issues from center staff about the project should go through the liaison to the research team. Larger health centers with an active research agenda often hire a full- or part-time research coordinator to play this role. If the center has a clinical coordinator, he or she also can be a good choice for the research liaison role.

Administrative Leadership

Like other stakeholders, the health center's administrative leadership will want to understand the impact on center operations of engaging in a research program. Naturally they will be concerned about its impact on productivity and financial performance. Any specific research project should have a budget available for review by the center's finance director.

If your center contemplates making a major commitment to research, it may be wise to consider appointing a research oversight committee that includes representation from key stakeholders. This committee should review all research projects and be accountable to health center leadership for the overall conduct of studies. There are pros and cons to giving veto power to an oversight group. On the one hand, its approval can be an important part of the buy-in process. But committees can, and sometimes do, veto interesting and valid research projects. Naturally, the organizational culture of your health center should guide a decision about the creation and authority of your own research oversight committee.

Board of Directors

Boards everywhere are responsible for assuring that organizations behave in a manner consistent with their mission and legal responsibilities. A health center board is no exception, and its endorsement of the idea of research will depend on the directors' ability to connect a research program to the center's larger purpose. The specifics of board approval will vary greatly from health center to health center. Presentations to the board about research should, of course, take into account the personalities and aspirations of individual directors. In general, it is wise to seek an understanding with the board that its approval is not required for each specific project, and that new studies are to be listed as "information-only" items on board meeting agendas. If you create a research oversight committee at your center, consider appointing one or two directors as *ex officio* members.

The Community

As noted above, the lay public is now aware as never before of the ethical issues surrounding medical research. No one wants to be thought of as a "guinea pig"; everyone wants confidential medical information kept secure. It is critical that the health center's community — the people it serves — supports or at least does not object to any contemplated research at the center. Many centers already have community advisory boards or other established mechanisms for soliciting input. These entities should be given an opportunity to review and comment on the idea of research in general.

As for specific studies, health center leadership must strike a balance between advancing a project in a timely manner on the one hand and assuring full buy-in on the other. Less intrusive study designs — record reviews and observational studies — may not require advance review by a community advisory board or similar committee, as long as concerns about confidentiality and other issues have already been addressed internally. On the other hand, intervention studies are most likely to raise the "guinea pig" issue, particularly if a given treatment is being compared to a placebo. There is no easy formula for securing community support of an intervention study, and health centers are advised to gain experience with other research types before participating in an intervention study.

FUNDING RESEARCH

It's important to develop a comprehensive budget for any research project. Some or all of the following items⁵ may be necessary:

- Staff assistance such as secretarial support or research staff;
- Consultants;
- Special equipment or tests;
- Supplies such as photocopying, printing, software, postage, telephone, miscellaneous office supplies;
- Office space and furniture;
- Travel to collect data;

⁵ Bass MJ, Orr VJ. Checklist for conducting research in the practice setting. In Bass MJ, Dunn EV, Norton PG, Stewart M, Tudiver F, eds. *Conducting research in the practice setting (Research methods for primary care, volume 5)*. Sage Publications, 1993:245-52.

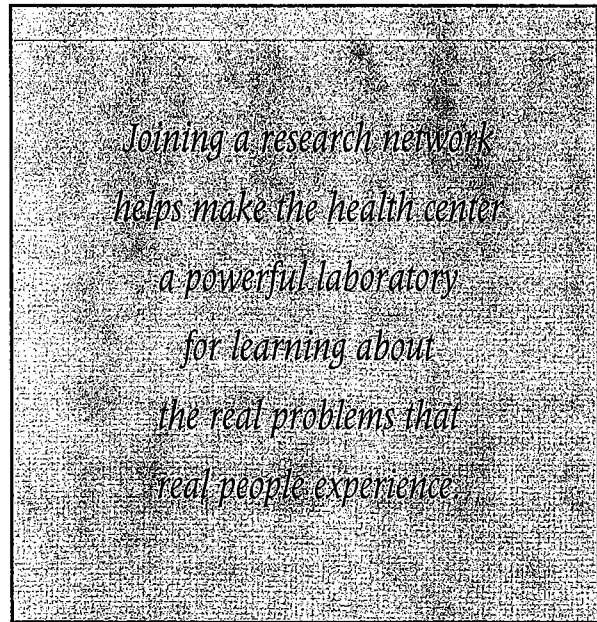
- Data analysis;
- Travel to present results;
- Other costs such as reprints, Internet access, reimbursement of subject expenses, honoraria to office staff collecting data.

One cost that rarely appears in research budgets is lost time by health center staff. Both clinical and support staff who participate in studies will devote some hours to meetings, data collection, and related research activities. Time spent at meetings is time that will not be devoted to patient care or health center administration. If the study will require large amounts of clinician or support staff time, it is wise to assign a cost to their lost productivity. In this way, funding proposals for the project can be viewed against a complete understanding of the study's actual cost impact on the health center.

A complete discussion of research funding is beyond the scope of this monograph. It is worth noting that potential funding sources include at least the following:

- Special interest organizations such as the American Cancer Society or the American Heart Association;
- Professional medical organizations including the national office or state chapters of the American Academy of Family Physicians;
- Foundations;
- State-funded initiatives that are often administered through state health departments;
- Federal agencies such as the National Institutes of Health, the Centers for Disease Control and Prevention, and the Agency for Health Care Policy and Research;
- University departments or research offices;
- Industries such as pharmaceutical companies and medical equipment suppliers;
- Individual donors with particular interests in primary care.

⁶ Hickner J. Practice-based network research. In Bass MJ, Dunn EV, Norton PG, Stewart M, Tudiver F. Conducting research in the practice setting. Research methods for primary care, volume 5. Sage Publications;1993:12639.



PARTNERSHIPS: A WAY TO GET STARTED

Health centers need partners to help them get started in research. Among the strongest potential partners are *practice-based research networks*.⁶ Networks allow primary care practices to pool their data and produce large sample sizes. This increases the generalizability of research done in practice settings. Joining a research network helps make the health center a powerful laboratory for learning about the real problems that real people experience.

Doing research in this way is not new. For years the National Institutes of Health has funded multi-center trials, usually involving a number of medical schools working together on a single high-tech research study. And for more than 20 years, groups of practitioners (usually in the same city) have banded together to test particular hypotheses.⁷ What is new is the growing number of practice-based research networks and their growing popularity as living laboratories for primary care research.

One of the oldest and best-known research networks is the Ambulatory Sentinel Practice Network (ASPN).⁸ A U.S.-Canadian endeavor, ASPN investi-

⁷ Perrin J, Charney E, MacWhinney JB Jr, McNerny TK, Miller RL, Nazarian LF. Sulfisoxazole as chemoprophylaxis for recurrent otitis media: a double-blind crossover study in pediatric practice. *N Engl J Med* 1974;291:664-7.

⁸ Green LA, Wood M, Becker L, et al. The Ambulatory Sentinel Practice Network: purpose, methods, and policies. *J Fam Pract* 1984;18:275-80.

gators have published 50 studies on topics ranging from the management of headache and miscarriage in primary care, to the epidemiology of non-work-related carpal tunnel syndrome and the impact of the Clinical Laboratory Improvement Act on primary care practice. Networks need not be large organizations to produce high-quality research. As small an area as the Upper Peninsula of Michigan has its own practice-based network that has published several studies on the prevalence of selected diseases in rural practice.⁹

Health centers can "jump-start" their research programs by affiliating with existing practice-based research networks. Enrollment requirements generally are modest, and most networks allow individual practices to opt out of participating in any given study.

Medical schools also are potential partners for health centers wishing to get started in research. Finding one's way inside the academic center can be challenging, though. Health center leaders might begin by calling department chair offices in family medicine, pediatrics, or internal medicine and asking if any faculty members are doing primary care research. If so, then those faculty members could be approached directly.

FINAL COMMENT

Half a century ago, Will Pickles, an English country doctor, discovered through careful observation that jaundice could be separated into several distinct illnesses.¹⁰ His laboratory was his rural practice setting; his research instruments were a pencil and notebook. Closer to home, a family doctor in south

Georgia, doing epidemiologic research while caring for patients over a course of 30 years, has contributed significantly to our understanding of coronary artery disease.¹¹ Opportunities abound for primary care practices to add to our knowledge of the human condition. Health centers can and should be part of that effort.

RESOURCES

An excellent and detailed introduction is the series collectively entitled "Research Methods for Primary Care," a six-volume collection published by Sage Publications. The series editors (Moirra Stewart, Peter G. Norton, Fred Tudiver, Martin J. Bass, and Earl V. Dunn) are among the most respected names in primary care research. Particularly valuable to health center leaders contemplating research programs are the first (*Primary Care Research: Traditional and Innovative Approaches*) and fifth (*Strategies for Implementing Research in the Primary Care Practice Setting*) volumes in the series.

Another useful text is *Designing Clinical Research: An Epidemiologic Approach*, edited by Stephen B. Hulley and Steven R. Cummings (William & Wilkins, 1988). It contains a great deal of information on the specifics of study design, but also has chapters on ethical issues of research, implementation of studies, and writing and funding research proposals.

The Federation of Practice Based Networks can provide a list of primary care research networks as well as other assistance. The Federation can be reached in care of the Ambulatory Sentinel Practice Network, 1650 Pierce Street, Denver, Colorado 80214.

⁹ Root DT, Hickner JM, Nelson TC. Prevalence and prediction of chlamydial cervical infection in a rural area: an UPRNet project. *J Fam Pract* 1991;33:369-74.

¹⁰ Pemberton J. Will Pickles of Wensleydale: the life of a country doctor. Royal College of General Practitioners;1984.

¹¹ Hames CG. In the eyes of the beholder: a thirty-year odyssey of research in primary care. In Stewart M, Tudiver F, Bass MJ, Dunn EV, Norton PG. Tools for primary care research. Research methods for primary care, volume 2. Sage Publications, 1992:1-13.

Publication of this monograph was supported by the Bureau of Primary Health Care, Health Resources Services Administration, Department of Health and Human Services.