
Conducting Clinical Trials in Practice Settings

Research in Progress by Family Physicians

Paul A. Nutting, MD, MSPH, and Gregory P. Alexander, MD

Rockville, Maryland

Most family physicians are familiar with the frustration of reading the results of a new randomized clinical trial using a particular intervention in a very highly selected group of patients. It is not the results that are frustrating per se, but the implicit assumption of the researchers and journal editor that such results are directly applicable to the varied patient populations of other practice settings. Most large randomized trials are conducted in tertiary care centers using patients who are often quite unlike those routinely seen in family practice settings. Such trials are highly selective by design, excluding large numbers of potential patients, to achieve a homogeneous group of patients who are middle-aged, have fully developed diseases and no comorbid conditions, and in whom adherence can be carefully controlled. Endpoints of the study are usually limited to pathophysiologic measures and rarely reflect the patient's functional status and quality of life.

Few physicians would deny the importance of such carefully controlled clinical trials in understanding the diagnosis and treatment of specific diseases. Such research alone, however, is not adequate to guide the decisions made in the care of heterogeneous patient populations. Additional information is needed when care involves patients of all ages, with various comorbid conditions, and in whom adherence to medical advice varies.

The need for information directly relevant to the clinical practice of family medicine has given rise to intense interest in practice-based research. Organizations that support research in practice settings have taken several forms, but all have the central purpose of providing a laboratory for study of health and health care events

in relatively unselected populations of patients and practitioners.¹

Formal networks of practicing primary care physicians committed to collaborative research have been in existence in other developed countries for a number of years, receiving substantial governmental support, and filling significant roles in research and disease surveillance. In the United States, state and regional practice-based research networks appeared in family medicine as early as the mid-1970s. The early networks included the Michigan Research Network, the Dartmouth Primary Care Cooperative Information Project (COOP), the Minnesota Academy of Family Practice Research Panel, and the Colorado Family Medicine Information System. In 1978 the Ambulatory Sentinel Practice Network (ASPEN) was established as the first national network. Initial support of ASPEN was provided by the North American Primary Care Research Group, the Rockefeller Foundation, and more recently, the American Academy of Family Physicians. Subsequently, the Pediatric Research in Office Settings (PROS) was formed as the second national practice-based network, with support provided by the American Academy of Pediatrics.

The Agency for Health Care Policy and Research has emphasized the need for practice-based research in its research agenda for primary care² and has emphasized practice-based research in its small grants program.³ Practice-based research is also earning respect among other research agencies of the US Public Health Service. Three practice-based clinical trials currently in progress by family physicians serve to illustrate the diversity of research possible in practice settings as well as the breadth of potential funding sources.

Submitted, revised, August 7, 1992.

The views expressed herein are those of the authors and do not reflect the official policy of the Agency of Health Care Policy and Research, the US Public Health Service, or the Department of Health and Human Services.

From the Division of Primary Care, Center for General Health Services Extramural Research, Agency for Health Care Policy and Research, US Public Health Service, Department of Health and Human Services, Rockville, MD.

Improving Early Detection of Cancer

With funding from the National Cancer Institute, Allen Dietrich, MD, of the Department of Community and

Family Medicine of Dartmouth Medical School, is studying the effect of minimal and intensive dissemination strategies to improve early cancer detection services provided in primary care. Through the Cancer Prevention in Community Practice Project, Dietrich's research team is using an intervention designed in an earlier project⁴ to reach all 400 family physicians and general internists in Vermont and New Hampshire. The intervention involves assisting individual practices in designing a series of office routines that support early cancer detection and preventive care. The routines involve use of manual flow sheets and require the active participation of office staff. In the previous project, volunteer practices that were provided such assistance improved mammography screening rates for women aged 50 years and over from under 60% the previous year to almost 80%. The impact of the dissemination strategies will be assessed over 12 months through patient exit questionnaires, medical record reviews, and physician and office staff questionnaires. The project is cosponsored by the New Hampshire and Vermont state chapters of the American Cancer Society and the New Hampshire and Vermont chapters of the American Academy of Family Physicians.

The Effect of Brief Physician Intervention on Alcohol Abuse

Michael Fleming, MD, of the Department of Family Medicine at the University of Wisconsin, has recently received support from the National Institute on Alcohol Abuse and Alcoholism to conduct a randomized clinical trial to test the effect of briefly delivered physician advice on problem drinkers. This is the first large-scale randomized controlled trial of an alcohol abuse intervention to be conducted in the United States using practice-based primary care physicians. The study will be conducted in the practices of 60 family physicians from the Wisconsin Research Network (WRn). Problem drinkers will be identified by a self-administered questionnaire on general health habits, and randomized to an experimental group and a control group. The experimental group will be offered services according to a standard protocol that includes a diagnostic interview, a brief, intensive counseling session, a self-help manual, a prescription to change drinking habits, and two follow-up visits. Fourteen outcome variables will be used to assess changes in drinking patterns, utilization of inpatient and outpatient services, legal events, accidents and injuries, family and social relationships, and self-reported health status. It is expected that the study will provide additional evidence to support the inclusion of screening for heavy drinking in health maintenance protocols for all adults.

Outcomes Associated with Routine Use of Prenatal Ultrasound

Bernard Ewigman, MD, and his associates in the Department of Family Medicine, University of Missouri, are conducting a large randomized trial of the outcomes associated with routine use of ultrasound examination in low-risk pregnancies. The study is being funded by the National Institute of Child Health and Human Development.⁵ This trial overcomes the weakness of the nearly 30 studies conducted in the last 20 years by attaining adequate statistical power. Over 15,000 low-risk obstetrical patients have been recruited and randomized into the two arms of the trial. In one group, patients receive two screening ultrasound examinations during the pregnancy; in the other group, ultrasound is used only when specifically indicated. Outcome variables will include pregnancy management and perinatal morbidity and mortality. To achieve statistical power, Ewigman has recruited over 100 practices in seven states, of which 17 are family practices and 92 are obstetrics practices.

Clinical Trials in Practice-Based Research

Each of the studies described above represents a different application of practice-based research. Ewigman has adapted the principles and methods of large multicenter clinical trials to practice settings to achieve large enough numbers of patients to study clinical problems in screening. Although the study was designed originally to enroll patients from tertiary care centers, it quickly became apparent to the investigators that adequate numbers of low-risk patients could be generated only by involving practicing obstetricians and family physicians.

Dietrich is randomizing practices in a classic health services research study to develop and test strategies to assist practicing physicians in the implementation of cancer control activities. The study directly addresses the dilemma faced by family physicians who find that the pace and logistics of their practice environment compete with their desire to increase health promotion and disease prevention activities. Using the patients and physicians in actual practice settings, his study will produce information that should be directly applicable to a wide audience of practicing primary care physicians.

Fleming is using a randomized design to study the effect of a brief intervention for alcohol abuse on unselected primary care patients. His study will enroll problem drinkers from the practices of family physicians and should produce results that will translate easily into the work of practicing family physicians.

The studies also illustrate the various strategies for organizing randomized trials in practice settings. Fleming is using volunteer practices from WRen, a large and well-established statewide practice-based research network with an impressive history of research. Dietrich's initial work was done with the Dartmouth COOP, another well-established practice-based research network. By expanding to the larger group of primary care practices in New Hampshire and Vermont, he is increasing the sample size while retaining the value of research in practice settings that is particularly critical for understanding strategies for dissemination of practice guidelines. Finally, Ewigman has recruited over 100 practices for his study, and he believes that for large-scale trials, recruitment of new practices may be as efficient as using existing networks (Bernard Ewigman, personal communication, July 1992).

Although the studies described vary in a number of important ways, all three were designed specifically to produce information useful to family physicians in their everyday practice. This is logically accomplished by using practice settings as the laboratories in which the practice of family medicine can be observed.^{6,7} These and other studies currently in progress in practice-based settings demonstrate the importance of practice-based research in building the knowledge base required to improve the care family physicians provide to their patients.

References

1. Nutting PA. Practice-based research: laboratories for outcomes and effectiveness research. In: Hibbard H, Nutting PA, Grady ML, eds. Primary care research: Theory and methods. Proceedings of the Second Annual AHCPR Primary Care Research Conference, San Diego, Calif, January 1991:277-81.
2. Nutting PA. A research agenda for primary care. Rockville, Md: Agency for Health Care Policy and Research, 1991.
3. Agency for Health Care Policy and Research. Health services research priority areas for accelerated small grant application review. NIH Guide 1991; 20:12-5.
4. Dietrich AJ, O'Connor GT, Keller A, Carney PA, Levy D, Whaley FS. Improving cancer early detection and prevention: a community practice randomized trial. *BMJ* 1992; 304:687-91.
5. Ewigman B, LeFevre M, Bain R, Crane JP, McNellis D. Ethics and routine ultrasonography in pregnancy. *Am J Obstet Gynecol* 1990; 163:256-7.
6. Green LA, Lutz LJ. Notions about networks: primary care practices in pursuit of improved primary care. In: Mayfield J, Grady M, eds. Primary care research: an agenda for the 90s. Proceedings of the First Annual AHCPR Primary Care Research Conference, Colorado Springs, Col, March 1990:125-32.
7. Green LA. How can family practice and primary care practice-based research networks contribute to medical effectiveness research? In: Hibbard H, Nutting PA, Grady ML, eds. Primary care research: theory and methods. Proceedings of the Second Annual Primary Care Research Conference. San Diego, Calif, January 1991:283-6.

NOTE: References 1, 2, 3, 6, and 7 are available from the Publications and Information Branch, Center for Research Dissemination and Liaison, Agency for Health Care Policy and Research, Room 520 EOC, 2101 East Jefferson, Rockville, MD 20852.

Announcement

THE SOCIETY OF TEACHERS OF FAMILY MEDICINE

26th Annual Spring Conference

April 24-28, 1993
Hyatt Regency San Diego

For further information, contact:

The Society of Teachers of Family Medicine
8880 Ward Parkway, PO Box 8729
Kansas City, MO 64114
800-274-2237, Ext. 4510, or 816-333-9700