Primary Care Research Revisiting Its Definition and Rationale

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Too often the questions of basic biomedical research have been mistaken to represent the critical scope of all medical research, and traditional laboratory methods have been seen as necessary and sufficient methods for understanding human health and illness. As a result, approximately 90% of National Institutes of Health (NIH) funding is spent on research within the traditional biomedical sciences (anatomy, biochemistry, genetics, microbiology, molecular biology, physiology, and so forth). The smaller amount of federal funding available for clinical research has been spent primarily on specific disease entities, such as cancer and heart disease. These funding decisions have resulted in the neglect of a large proportion of the problems and issues that confront primary care physicians and their patients.

Clinical Research

Perhaps not surprisingly in an era of academic medical centers' increasing dependence on clinical revenues, the amount of clinical research and the number of clinical investigators have decreased. It has been difficult to track the magnitude of this trend, however, because a concise definition of clinical research is lacking. To address this concern, a national consensus-building conference, the Clinical Research Summit, was held in November 1998, and a working definition was adopted. Clinical research was defined as "a component of medical and health research intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health." Attendees further agreed that "clinical research embraces a continuum of studies involving interactions with patients, diagnostic clinical materials or data, or populations in any of the following categories: (1) disease mechanisms; (2) bidirectional integrative research; (3) clinical knowledge, detection, diagnosis, and natural history of disease; (4) therapeutic interventions including clinical trials of drugs, biologics devices, and instruments; (5) prevention (primary and secondary) and health promotion; (6) behavioral research; (7) health services research, including outcomes and cost effectiveness; (8) epidemiology; and (9) community-based and managed care trials."

Primary Care Research

In the broader context of clinical research, primary care research remains a fledgling enterprise with many institutions and funding agencies still having difficulty understanding what it includes and what its potential value might be despite a considerable body of supportive literature. The need for primary care research, the research traditions of relevance to primary care and the scope of its methods, and efforts to elevate primary care research to a national priority have been documented. However, only 0.4% of NIH funding (up from 0.3% in 1984) and only 4% of the funding from the Agency for Health Care Policy and Research (down from 4.4% in 1984) goes to departments of family medicine. Both private (eg, the American Academy of Family Physicians) and public (eg, the Agency for Health Care Policy and Research) organizations have formulated working descriptions of primary care research. Nonetheless, primary care researchers still lack a coherent definition with which most can agree. We believe it is particularly important to address this problem now, during a time of concern about and advocacy for clinical research. The definition and examples provided here should be useful for those who are trying to explain the importance of this work to academic administrators and funding agencies. Primary care has most recently been defined as "the provision of integrated, accessible, health-care services by clinicians that are accountable for addressing a large majority of personal health-care needs, developing a sustained partnership with patients, and practicing within the context of family and community." This definition was debated and was based on a comprehensive literature review and multidisciplinary input. It has been widely adopted since its publication and offers a sensible, if not perfect, definition to guide research in primary care. One of its most important aspects is the concept that primary care is a function that does not necessarily belong to a particular discipline but is dependent on knowledge from many sources. On the basis of this definition, primary care research can be as defined as research directed toward the better understanding and practice of the primary care function.
categories of research Primary care research has traditionally included studies that fall into the following overlapping categories.

Theoretical and Methodologic Research This category includes the development and testing of theoretical models, operational definitions, and measurement tools relevant to the primary care function. Included in this category are such things as: classification systems designed to capture the phenomena of primary care; ways to measure concepts, such as integrated, accessible, and accountable care; methods for distinguishing the separate and combined effects of primary care on individuals, family units, or the community; and ways to observe and measure important relationships (eg, the physician-patient relationship) and their impact on outcomes. Other investigations involve generating and testing alternative conceptualizations of the tasks and methods of primary care (eg, goal-directed care, family-centered care) and efforts to expand the methods available to primary care researchers (eg, mixed methods research, complexity theories).

Health Care Research This is the large and important area of primary care research focused on direct investigation of the primary care function itself. Questions directed toward improving the quality and effectiveness of primary care practices fit in this category. Although health care research has historically emphasized the analysis of large data sets, primary care research often employs both qualitative and quantitative methods to examine relatively small numbers of individual physicians and practices to determine which methods seem to work best.

Clinical Research Studies in this category are focused directly on the effects of the primary care function on patients. It includes research on the factors that determine why patients become ill and seek medical attention, the meanings of presenting symptoms and signs in a primary care setting, the most effective and efficient diagnostic and treatment strategies, and the natural histories of health problems with and without intervention. The outcome measures used are often those that are directly meaningful to patients, such as quality of life, mortality, health of the family unit, and cost and convenience of care (outcomes research).

Health Systems Research This category extends the first 3 to the larger systems level. It encompasses educational research, research on dissemination and adoption of new discoveries, implementation of quality improvement systems into primary care settings, and health policy.

THREE EXAMPLES

Night Sweats Many diseases and health states are thought to be associated with night sweats (eg, tuberculosis, menopause, nocturnal hypoglycemia in people with diabetes, autoimmune diseases, malignancies, and medications). However, for the primary care physician who is faced with an undiagnosed patient with night sweats, the following questions arise that currently lack answers: (1) What are the incidence and prevalence of night sweats in a primary care patient population? How often does this symptom go unreported? (clinical); (2) What are the most likely causes of night sweats in a patient presenting in a primary care setting? (clinical); (3) What is the most effective and efficient path to the correct diagnosis? (clinical); (4) What is the natural history of idiopathic night sweats in otherwise healthy patients? (clinical); (5) How much of an impact do night sweats have on the quality of life of patients and their bed partners? (clinical); (6) If common and significant but underrecognized, how can clinicians reorganize their assessment methods to systematically screen patients for night sweats? (health care); and (7) If night sweats are an important symptom of potentially serious disease, how can the population be educated to pay attention to and report them? (health systems).

Cognitive Impairment Cognitive impairment is a prevalent and serious problem for older people. Early diagnosis and treatment are becoming more important as effective treatment strategies have become available. To provide optimal care for these patients, primary care physicians need answers to the following questions: (1) Is systematic formal screening for cognitive impairment necessary in primary care settings in which patients and their families are well known by their physicians and staff and are seen frequently? (clinical); (2) Does earlier detection result in better outcomes? (clinical); (3) What are the outcomes of greatest importance, and how can they be best measured? (theoretical/methodologic); (4) What would it cost to screen all patients [over] older than a specified age? (health systems); (5) Should we train primary care physicians to complete the evaluation and direct treatment, or should patients who screen positive be seen by a neurologist, geriatrician, or psychiatrist or psychologist? (health care); and (6) How can caregiver education programs, which have been shown to delay institutionalization and save money, be organized and funded? (health systems).

LABORATORY TEST RESULTS

Another set of questions involves laboratory test results. What is the best way to manage (tracking, notification, documentation, follow-up) laboratory test results in a primary care setting? Before this health care question can be answered, several others must be addressed: (1) What is meant by “best”? How should patient preference,
physician preference, cost efficiency, and legal requirements be balanced? (theoretical/methodologic); (2) How would we answer such a question even if “best” could be adequately defined? (theoretical/methodologic); and (3) Assuming that an answer can be found, what is the most efficient way to help clinicians incorporate the method into their practices? (health systems).

EDUCATION FOR THE FUTURE

Primary care research is directed toward the better understanding and practice of the primary care function. It is further distinguished from other types of research by an emphasis on effectiveness rather than efficacy. It is often immediately applicable to primary care practice and widely generalizable.

The science base of medicine, including primary care, has improved significantly during the 20th century. Overall, however, primary care has been neglected because it was not seen as requiring an intellectual engine. The mismatch between the focus of research efforts to date and the need for research in primary care can be understood to derive from an unbalanced effort focused on understanding specific diseases and molecular mechanisms. To improve primary care, a more robust enterprise embracing the full scope of research in this setting is required. We hope that our attempt to define and describe the scope of primary care research will help its advocates educate those who are able to make this happen.

REFERENCES