

## A Framework for Primary Care Research

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Primary care research consists of four types: basic, clinical, health services, and health systems. Basic research addresses the development of methods to study subjects relevant to primary care services, regardless of whether they deal with a clinical problem or a characteristic of services delivery. Clinical research involves issues relevant to the processes of delivering services, including recognition of people's problems, diagnostic approaches, and types of therapy and their outcomes. Health services research concerns the relationships associated with the organization and financing and their impact on the processes and outcomes of care. Health systems research focuses on understanding how the

economic, political, and social milieus influence the structures and processes of the health services system, with specific relevance to its primary care infrastructure. The literature on primary care, as reflected by publications in three major general journals, is notably lacking in many specific areas of study within these types of primary care research, particularly with regard to basic and health services research.

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The Institute of Medicine's Committee on the Future of Primary Care is grappling with the concept of primary care and where primary care fits in the edifice of clinical practice. Its interim report<sup>1</sup> proposes a definition that captures the essence of what primary care has come to mean among those who practice it, both in the United States and abroad. Its essence is that primary care is continuous, coordinated, and comprehensive care provided over time to populations undifferentiated by a particular disease, organ system, or gender.<sup>2</sup> The words used in the Institute of Medicine definition are somewhat different, but the meaning is clear. The Committee now must come to grips with the challenge of defining primary care research so that it leads to clear directions for building the scientific basis for clinical practice. As national attention is increasingly focused on the importance of primary care

and of research to inform its organization and provision of services, we are witnessing a bandwagon phenomenon. Research agencies and their constituencies are discovering that portfolios can now be described as "primary care" portfolios; research on the most esoteric of diseases has become research on primary care, on the grounds that the diseases are occasionally seen in primary care. Clearly, if everything that ever appears in primary care is defined as a primary care issue, there will be no meaningful distinction to the term "primary care research."

### What Is Primary Care Research?

In my view, the only meaningful definition of primary care research is "research done in a primary care context." Not all research conducted on primary care problems constitutes primary care research, but all research done in primary care *is* primary care research. That is, it is not the nature of the problem studied that makes it primary care research but, rather, the context and the way in which the research is conducted. Since primary care is the point of first contact for all problems, it follows that these problems are potentially and properly the subject of primary care research. That does not mean, however, that they can

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be studied in contexts other than primary care settings and remain primary care research. The fallacy of concluding that primary care research can be done in settings other than primary care settings is amply documented by the following examples.

*Example 1.* The first edition of an important book on the subject of ambulatory pediatrics included a chapter on anemia in which the author claimed that 14% of all anemias were due to iron deficiency. The author was a hematologist in a premier medical teaching institution. In his experience, it was probably the case that only one in seven anemic children had iron deficiency. However, his experience was in a referral center, not a primary care setting. Most anemias in most primary care settings for children are iron deficiency anemia, and only research considering the context of primary care settings would give the correct spin to this issue.

*Example 2.* Pediatricians attending a continuing education course were asked to indicate the usual presenting findings for several genetic diseases. The vast majority cited the pathognomonic sign, which they all had been taught by "experts" in the respective diseases. The pathognomonic sign, however, rarely figures in the picture during the early stages of diseases, when they are most often seen by primary care physicians. Rare metabolic diseases are encountered in primary care, but knowledge about their recognition and management in primary care cannot be gleaned from research conducted in tertiary medical centers.<sup>3</sup>

*Example 3.* Conventional wisdom, as passed down by the specialty of obstetrics and gynecology, is that patients with pelvic inflammatory disease should be hospitalized. The Ambulatory Sentinel Practice Network (ASPN) has demonstrated that although 43% of patients meet published criteria for hospitalization, only 9% are hospitalized, without adverse effect among those not hospitalized. This results in a savings of more than \$12 billion nationally.<sup>4</sup> Similarly, conventional wisdom is that patients with spontaneous abortion accompanied by bleeding and pain for 6 hours or more require hospitalization for dilation and curettage or induced labor. ASPN showed that 40% of such patients could be managed completely at home or in the office without either intervention and without adverse effects. This saves \$145 million per year for the country as a whole.<sup>5</sup>

Many more examples of the fallacy of deriving primary care wisdom from research in non-primary care settings can be found in the April 1994 issue of *The Journal of Family Practice*, which is devoted to studies conducted in ambulatory practice-based research networks.

Specifying a research agenda for primary care is not difficult because of the paucity of research that has been done and the volume that remains to be done. The chal-

lenge is to be judicious in setting priorities and to set an agenda that builds incrementally toward a truly sound primary health care infrastructure in our health care system. To be judicious in our priority setting and to build incrementally, we must know where we are starting and where we are going. That is, there must be a framework that guides the agenda.

Research in other markets has its own framework, which deals with performance, design, engineering, workmanship, safety, and service. It addresses most of the things we want to know about primary care, but this research model does not suffice for health care research because medical care involves something that commercial products do not: person-to-person interactions.

## Types of Primary Care Research

It is useful to divide health care research into three types: basic research, clinical research, and health services research. It is possible to understand the differences among these three levels of research by referring to the components of the health services system.<sup>6</sup> The health services system itself is composed of structural and process elements which, with the contribution of social, physical, economic, and political influences, determine the state of health of populations and individuals within these populations. Structural components are aspects of the health services system that do not involve individual practitioner-patient interactions, although they may influence them. Personnel, facilities, equipment, mechanisms to achieve accessibility, information systems, definitions of benefit packages, specification of eligible or enrolled populations, mechanisms of governance are all features of health services systems.

In contrast, the process forms the substance of practitioner-patient interactions. Process is composed of two parts: aspects primarily under the control of the physicians, and those primarily under the control of patients. Practitioners, for their part, bear the responsibility for recognizing the complaints, problems, and needs (including those for health promotion and disease prevention) of people with whom they are associated. Having recognized these needs, practitioners formulate them into a working hypothesis, or diagnosis, that enables them to embark on the next step: an appropriate course of intervention or action. The cycle is completed when the impact of this intervention is determined, ie, the process of reassessment to determine how the original problem has changed. People, for their part of the process, decide whether to use the health services system for their perceived needs; they then decide whether to accept the interventions that are proposed and determine how satis-

Table 1. Types of Research and Research Settings in 97 Original Articles Published in 1994

Journal (n)	Type, %			Setting, %			
	Basic	Clinical	HSR	Primary Care			
				Clinic	Office/HMO	Inpatient	Other
<i>The Journal of Family Practice</i> (34)	18	59	23	24	15	15	45
<i>The Journal of General Internal Medicine</i> (33)	36	55	9	12	12	34	42
<i>The Journal of the American Medical Association</i> (33)	37	43	20	0	3	28	69

HSR denotes health services research; HMO, health maintenance organization.

fied they are with them. Once the large impact of the environment is taken into account, the adequacy of the process is represented by its outcome.

*Basic research* either is devoted to *one* component of structure, process, or outcome, or is designed to develop methods to study the components and their interrelationship. In the context of primary care, basic research addresses challenges such as developing methods to measure health status, to study physician-patient communication in primary care, to study the organization of services, or to characterize case-mix (either for the purposes of controlling for differences in morbidity burdens in quality of care studies, or for the purpose of prospective budgeting).

*Clinical research* involves one or more of the processes contributed by practitioners and either one of the other processes or a facet of health outcomes. Examples of clinical research are a study of the relationships between diagnostic methods and subsequent treatments, and research to elucidate the impact of treatments on health outcomes. Conducted within primary care settings, clinical research elucidates these relationships in primary care.

*Health services research*, in contrast, is research in which at least one of the proposed explanatory variables of interest is not framed in conventional biomedical terms: that is, it is not confined to consideration of the processes contributed only by practitioners. This definition was developed by an early Institute of Medicine committee<sup>7</sup> and, I believe, has served well. Examples of health services research can be found in the literature concerning the impact of various types of organizational formats on patients' satisfaction with services; the impact of methods to reimburse physicians on the use of diagnostic tests or methods of treatment; and the impact of patients' acceptance of, satisfaction with, or participation in the care provided on the outcomes of care. Health services research also includes factors that determine why and how people use the health care system. In the context of primary care, health services research elucidates these relationships within primary care settings.

*Health systems research* focuses on understanding the relationship between components of the environment and the design and operation of the health services system. That is, it elucidates the political, social, economic,

and other similar types of influences that have an impact on how health services systems are organized and how they function. There can also be health systems research on primary care; in particular, this type of research addresses how these determinants influence the primary care infrastructures of health services systems.<sup>8</sup>

The distinctions among these types of research are not always absolutely clear, and there may be legitimate disagreement on the assignment of particular research topics to any particular one of these categories. This reality does not detract, however, from the more general usefulness of specifying research in this way if the purpose is to decide on priorities when priorities must be set.

The categorization of research in this way is not limited to primary care, since research on other levels of care can be conceptualized in the same way. However, if it is to be appropriately labeled as primary care research, investigation into any of these topics must explicitly consider the primary care context.

## Challenge to Primary Care Researchers, Journal Editors, and Funding Agencies

How well are we doing in the conduct of primary care research? Is current research focusing on a reasonable range of issues, and is it doing so in a way that meets the definition of primary care research; ie, is it being conducted within a primary care context?

To approach an answer to this question, I classified all original research articles in three major journals published in 1994. Under the assumption that the greatest concentration of primary care research would be contained in journals that are primary care oriented, I selected *The Journal of Family Practice* (JFP) and *The Journal of General Internal Medicine* (JGIM). For comparison, I also targeted *The Journal of the American Medical Association* (JAMA). Six issues of JFP and JGIM and eight issues of JAMA were required to obtain a comparable number of articles, arbitrarily preset at between 30 and 35. Table 1 reflects the similarities and differences in proportion of these research contributions that were basic, clinical, and health services research. Between 40% and

Table 2. Primary Care Research Topics, by Basic, Clinical, and Health Services Research Types

Non-Policy-Related Research	Policy-Related Research	
Basic Research	Clinical Research	Health Services Research
<ul style="list-style-type: none"> <li>• Measurement of health status</li> <li>• Measurement of case-mix and severity of illness</li> <li>• Procedures for assessing quality of care</li> <li>• Measurement of the need for referral and characteristics of referral care</li> <li>• Development and adaptation of methods to manage presenting problems</li> <li>• Techniques to measure the effectiveness of care and assessment of patients' cooperation</li> <li>• Procedures for assessing the responsiveness of patients to medical recommendations</li> <li>• Improving the accuracy and efficiency of data collection and recordkeeping</li> <li>• Development of a method to estimate the community served by a primary care practice</li> <li>• Development of methods to facilitate the use of community data in primary care practice</li> <li>• Development and testing of ways to examine the effectiveness of primary care training, certification, and educational activities</li> </ul>	<ul style="list-style-type: none"> <li>• Descriptions of the practice of primary care in various organizational configurations, settings, and communities, including the incidence and patterns of diseases seen, services provided, and resources employed</li> <li>• Evaluations of the effectiveness of the drugs, devices, and procedures common in primary care practice</li> <li>• Design and testing of protocols for screening, diagnosis, and treatment</li> <li>• Evaluation of prevention, patient education, and self-care activities</li> <li>• Analyses of the process of medical decision-making, including both careful descriptions of how diagnostic and therapeutic choices are being made, and the development and testing of methods to improve the process</li> <li>• Examinations of the interrelationships between the physical and psychosocial aspects of illnesses, particularly as they are seen in primary care</li> <li>• Examinations of differences between users and nonusers of health services by comparing individuals, families, communities, or practices</li> <li>• Descriptions of the natural history of illnesses commonly encountered and managed in primary care practices</li> <li>• Can good primary care reduce the likelihood of comorbidity in certain individuals or in particular population subgroups?</li> </ul>	<ul style="list-style-type: none"> <li>• Studies related to longitudinality of care</li> <li>• Studies related to first-contact care</li> <li>• Studies related to comprehensiveness</li> <li>• Studies related to coordination</li> <li>• Studies concerning the relationships among the essential features of primary care</li> <li>• Studies related to referral practices</li> <li>• Studies related to modifying pattern of referral</li> <li>• Studies concerning the roles of primary care physicians and those of specialists</li> <li>• Studies related to teamwork in primary care</li> <li>• Studies related to the organization and financing of primary care services</li> <li>• Studies related to the use of technology in primary care</li> <li>• To what extent can concerted efforts to deal with problems in a family context facilitate the process of care as well as its outcome?</li> </ul>

60% fit into the category of clinical research, with the percentage slightly higher for JFP and JGIM than for JAMA. About one fifth of the contributions in both JFP and JAMA were health services research, with only one half that proportion in JGIM. Slightly over one third of JGIM and JAMA contributions constituted basic research, twice the proportion found in JFP; for JAMA, these were almost all represented by studies of the epidemiology of disease.

When the place of the research was categorized as inpatient, hospital clinic based, emergency department based, HMO or doctor's office, or other, there were clear differences in the journal contributions. About 40% of studies published in JFP were conducted in community-based practice, ie, in doctors' offices outside hospital clinics or in HMOs, compared with approximately 25% in JGIM and 3% in JAMA. JGIM had the highest proportion of research (just over 33% ) conducted in inpatient settings, compared with 15% in JFP and 28% for JAMA. Two thirds of the studies in JAMA were on populations of people rather than practice populations. Since studies of community populations inform *all* levels of care, not only

primary care, this type of epidemiologic research, while important in forming decisions about the organization of the health services system, is not specific to primary care. Just over 20% of the research studies in JFP and just over 25% in JAMA were conducted using existing national, regional, or local data sets, as compared with only 6% in JGIM.

There were also differences when the studies were characterized according to the subjects of study. In both JFP and JGIM, 40% of the studies concerned primary care physicians (family physicians, general internists, pediatricians, or a combination), compared with only 3% in studies published in JAMA. JAMA's relatively heavy focus on epidemiologic studies was represented by 83% of its contributions involving subjects other than practitioners. Most of these, as noted earlier, were studies of populations undifferentiated by their source of care.

My proposed primary care research agenda, from the book *Primary Care: Concept, Evaluation & Policy*,<sup>9</sup> contains 32 specific topic areas within the three types of research. The topics that were specified were deemed to be of high priority because the literature concerning them

was so sparse and because the subjects were of high relevance to policy decisions that must be made in our health care system (Table 2). In fact, 15 of the 32 areas that were specified are not represented at all in the 97 research contributions to the three journals mentioned above.

The research agenda developed by the Agency for Health Care Policy and Research divides the research questions into three areas: reducing costs by improving access; understanding the differences between various types of practitioners purporting to provide primary care; and studying the impact of differences in the organizational and financial arrangements of providing primary care. As is appropriate for a health services research agency, each of these areas fits the definition of the health services research type of primary care research. These are the areas that are most underrepresented in the literature review just summarized: 5 of the 12 specific areas under the health services research agenda for primary care (Table 2) are not represented by any of the articles contained in those journal issues. Basic research in primary care is also underrepresented: 6 of the 11 specific areas are not represented in the reviewed literature.

While not systematic or necessarily representative, this review suggests that many high-priority issues are not being addressed in a major way, at least in these three journals most likely to be read by primary care academicians and practitioners. Journals, even those with high primary care focus, seem to dwell most heavily on clinical issues, particularly concerning the biomedical aspects of diagnostic and therapeutic methods. Even primary care continues to be dominated by conventional models that emphasize biomedical determinants of problems and their management. The areas most lacking in the existing research literature are studies of attributes that are clearly

specified in all definitions of primary care: person-focused care over time (longitudinality), care for all but uncommon problems in the population (comprehensiveness), and integration of all aspects of care (coordination), as well as first-contact care. Highest priority for a research agenda in primary care is research that addresses functions that are unique to primary care, primarily since this country is now undergoing a major experiment in the form of managed care, which is designed to improve the provision of primary care.

The challenge for primary care research is to place greater priority on these issues. Only then will it be possible to enhance the effectiveness and efficiency of our health care system by building its primary care infrastructure.

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