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AHCPR CONFERENCE PROCEEDINGS

PRIMARY CARE RESEARCH: AN AGENDA FOR THE 90s



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Conference Proceedings

Primary Care Research: An Agenda for the 90s

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Foreword

This volume contains keynote and plenary presentations, as well as luncheon and dinner addresses, given during the conference, "Primary Care Research: An Agenda for the 90s," which was held March 28-30, 1990, in Colorado Springs, Colorado.

The conference was originally conceived in early 1989 as a means to communicate the funding opportunities currently available to the primary care research community at the National Center for Health Services Research and Health Care Technology Assessment (NCHSR). It quickly grew to include the participation of several other Federal agencies and a private foundation.

These proceedings are proffered not as a definitive summation of the accomplishments of primary care research, but rather as a representation of the broad scope and variety of primary care research. We hope that this compilation will provide stimulation for increased research in primary care that will further the delivery of appropriate and effective health care.

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Preface

When the idea for a primary care research conference first took shape, it was conceived within the National Center for Health Services Research and Health Care Technology Assessment (NCHSR). Three months before the conference, Congress passed a major piece of legislation that changed both the administration and organization of NCHSR, with enormous implications for primary care research. Section 6103 of the Omnibus Budget Reconciliation Act of 1989 dissolved NCHSR and replaced it with the Agency for Health Care Policy and Research (AHCPR), with expanded authorities and budget. This agency was born from the simultaneous pressures for guideline development and more practice-relevant research, including the medical treatment effectiveness program. Most importantly, for the first time, a Federal agency was authorized to conduct and support research, demonstration projects, evaluations, training, guideline development, and the dissemination of information on health care services with respect to clinical practice, including primary care and practice-oriented research.

This legislation afforded an opportunity to expand the scope and authority of the conference; at the same time, the conference provided an ideal forum in which to develop a primary care research agenda for the new agency. Thus, it was with renewed enthusiasm and an increased mandate for primary care research that AHCPR-along with its cosponsors-continued with plans for this first primary care research conference. A paper was commissioned for each of the topic areas, and authors were asked to provide a summation of the field, with emphasis on future directions needed for research. Presentations by current funded investigators involved in primary care research rounded out the program.

Near the close of the conference, ten working groups were formed to assist in the development of a primary care research agenda for AHCPR. On the final morning of the conference, the comments and recommendations developed by the working groups were presented to elicit comments from the entire group. The results of this exercise, including the revised agenda, will soon be available from AHCPR as a separate publication.

In deciding to convene a primary care research conference, AHCPR had several objectives. The conference was designed to (1) foster increased communication, cooperation, and collaboration among the disciplines that comprise primary care; (2) obtain input from the field for the formulation of an updated primary care research agenda; (3) enhance dissemination of information about the funding opportunities available from Federal agencies that sponsor primary care research; and (4) stimulate the field to submit additional high-quality research proposals for primary care studies.

The success of this conference in meeting these goals has led to plans for a second primary care research conference that will be held in January 1991. Within the pages of these proceedings are the topical papers and keynote addresses that comprised the 1990 conference. While this volume is not intended to be an exhaustive review of primary care research, it does present state-of-the-art information and identify some provocative topics for future primary care studies.

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Toward a New Agenda in Primary Care Research

Jennifer Mayfield, M.D., M.P.H.
Conference Chair

Background

This discussion will focus on the history of primary care and primary care research and delve into some of the constraints that have hindered the growth and development of the discipline and its research. It will also explore some of the new opportunities for programs and funding that are emerging, especially from Federal sources.

To begin with, it must be remembered that primary care is a very young field, less than 20 years old, with few established research programs or experienced mentors. Primary care researchers have not had an identifiable funding source for their investigations and often have felt that their values and goals are misunderstood by the basic-science orientation at the National Institutes of Health (NIH). The field's struggle to develop a credible research effort has been hampered by inadequate financial resources, the absence of established researchers, and the lack of sophistication in grantsmanship, all of which are available to other disciplines.

Definitions

However daunting such resource constraints may seem, of greater consequence is the definitional and perceptual dilemmas inherent in a field dedicated to generalism and integrating others' work. To start with, hardly anyone agrees on a definition of primary care. Furthermore, no one agrees as to who delivers primary care, especially primary care practitioners. The field is an amalgamation of different disciplines that prefer labels such as "family physician," "general internist," "general pediatrician," and "nurse practitioner." Some include the disciplines of gynecology and emergency medicine. All appear to have evolved from strikingly differ-

ent disciplines to a practice that is almost indistinguishable in approach and values.

If the practice of primary care is difficult to define, primary care research is even harder to describe. The research, which overlaps and integrates many disciplines, is often perceived as having no agenda or methodology of its own. Every time a piece of work can be categorized differently, such as "prevention" or "rural research," it is relabeled as such, leaving primary care with the remnants of the undefinable. Thus, it is not surprising to hear many charge that "primary care research has no agenda of its own." It could also be argued that primary care research has a meta-agenda—that is, an agenda of agendas.

In a similar fashion to practitioners, researchers have conducted their work and published in isolation. This behavior, necessary to develop a cultural identity and support specialty journals, has also hampered the development of the field. This problem was noted in the early 1980s when the Rockefeller Foundation published the collected abstracts from several primary care organizations. As Mack Lipkin¹ explains in the introduction to the 1982 volume,

We began the first of these annual volumes, *Primary Care Research in 1980*, after discovering that workers in primary care were often unaware of each other's work and organizations. (p. viii)

Unfortunately, those collections were published for only 3 years, and the problem of isolation continues.

This segregation occurs not only between different types of practitioners, such as physicians ignoring the research done by nurses, but also between practitioners and the methodologists aggregated under the rubric "health services research." Much of the primary care research conducted by health services researchers is ignored in the reading and education of the primary care practitioner and clinician-researcher.

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A common misperception by the primary care clinician-researcher is that health services research has nothing in common with his or her research interests. While health services research is not the same as primary care research, the two have much in common. Both are relatively new fields of endeavor that attempt to integrate and implement the knowledge from a number of disciplines. Health services research often functions as the "basic science" discipline for primary care research. For example, health services researchers have developed a number of important tools for primary care research, including severity of illness and functional status measures, survey instruments, decision analysis and medical record systems, measures of patient satisfaction, and population measures of health.

Health Services Research and Primary Care Research

The association of primary care research with health services research has not been an easy or natural process. Perhaps the only group of primary care researchers who felt comfortable within the old National Center for Health Services Research and Health Care Technology Assessment (NCHSR) in the late 1970s and early 1980s were the general internists who were attracted to the decision-analysis field.

In 1983, a family physician sent a Dr. Edward Brandt, Assistant Secretary for Health, requesting greater support of primary care research. That letter stimulated the formation of a working group of primary care researchers in family medicine, internal medicine, and pediatrics and health services researchers to develop a research agenda for NCHSR under the chairmanship of Bob Haggerty, M.D.

NCHSR published the program note, "Health Services Research on Primary Care,"² in October 1985 to announce its interest. And, during the late 1980s, several institutes at NIH shifted their funding emphasis to include research in primary care settings, particularly with regard to cardiovascular disease, cancer prevention, and mental health in the primary care setting. However, few proposals were submitted to NCHSR, NIMH, or NIH, and many of those lacked the necessary sophistication to be funded. Thus, the primary care research field continued to feel that they had inadequate support for their research.

This volume contains the proceedings of a conference that was conceived, initially by AHCPR, to address the misperception that the Federal funding system was not supporting primary care research and to encourage the

submission of quality proposals. The agency enlisted the collaboration of a number of Federal organizations that currently are supporting primary care research, including the National Institute of Mental Health (NIMH), the National Institute of Alcohol Abuse and Alcoholism (NIAAA), the National Cancer Institute (NCI), the National Institute of Child Health and Human Development (NICHD), and the Health Resources and Service Administration (HRSA). All of these organizations and agencies were interested in publicizing the excellent work that is currently being supported and to encourage both the quantity and quality of proposals that are submitted by primary care researchers.

In organizing the conference, a working definition of primary care was agreed on, based upon a report issued in 1978 by the Institute of Medicine (IOM),³ which cited "first contact, comprehensive, coordination, and continuity" as the important features of primary care. The sponsors agreed that the focus of the conference would be research on the kind of care generally provided by, but not limited to, family physicians, general internists, general pediatricians, and nurse practitioners. The conference organizers felt it was important to address the differences in backgrounds and interests of the major primary care disciplines and how they perceive their research.

Conclusion

By any standard or measure, the conference would have to be deemed a great success. Its agenda included notable experts in pediatrics, general internal medicine, family practice, and health services research, as well as legislative experts, organizational representatives, and Federal spokespersons. Nearly 300 attendees benefited from the diverse experiences and perspectives on primary care research of these policymakers, researchers, and practitioners.

This conference and its proceedings are proffered not as a definitive summation of the accomplishments of primary care research but rather as a representation of the broad scope and variety of primary care research. It is hoped that the insights and views of these outstanding presenters will be informative, provocative, and energizing to all who read these proceedings and that this compilation will represent a step forward in the legitimate reclamation of an agenda for primary care. Most importantly, AHCPR is publishing these proceedings in the hope that they will provide stimulation for increased scholarly efforts in primary care research that will further the delivery of appropriate and effective health care for all.

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Primary Care Research: Where Have We Been? Where Are We Going?

E. Harvey Estes, Jr., M.D.

Introduction

This conference and these proceedings have three stated purposes: to review the accomplishments of primary care research, focus on the challenges and opportunities facing primary care research, and advise the U.S. Public Health Service and the new Agency for Health Care Policy and Research (AHCPR). All those who attended the conference, and those whose papers appear in these proceedings, have an opportunity to lead and to mold the future of the primary care disciplines. There is now a new Federal agency, created with a purpose that can only be viewed as a dream come true for primary care research.

The following statement is from Section 6103 of the Omnibus Budget Reconciliation Act of 1989,¹ as it relates to AHCPR.

The purpose of the agency is to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.

Section 6103 continues with a list of some general authorities and duties. These include research on:

1. the effectiveness, efficiency, and quality of health care services
2. the outcomes of health care services and procedures
3. clinical practice, including primary care and practice-oriented research
4. health care technologies, facilities, and equipment
5. health care costs, productivity, and market forces

6. health promotion and disease prevention
7. health statistics and epidemiology
8. medical liability.

All of those associated with primary care will no doubt agree that these topical areas have direct relevance to daily tasks in patient care. Likewise, the field has a great opportunity to shape the manner in which this new authority will be used.

Primary Care: What Is It?

The researchers, practitioners, and allied professionals who attended this conference know what primary care is, but there are many who do not. A brief definition of primary care and primary care research is, therefore, in order.

Dr. John Millis is often credited with the first use of the term "primary care."² In the "Millis Report" of 1966, he spoke of a new type of physician—the primary physician—who was to be a person highly qualified in comprehensive care—that is, a functional specialist instead of a subject-matter specialist or a technique specialist.

In 1978, a committee of the Institute of Medicine (IOM) spent many months trying to define primary care.³ In their report, the committee concluded that it was not a discipline or a type of training and that it could only be defined by the style and array of services offered by a practice. This array of services could be described by such terms as comprehensive, available, responsible, and so on. The descriptors implied a concern for the population being served and a willingness to meet its members halfway in providing the needed services. Prevention was emphasized; also, physical and temporal accessibility and cost and convenience of services were highlighted. It was agreed that primary care could be directed at a given age or other group—children, old people, women, and so forth—but the acid test was

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whether the whole spectrum of services was provided to that target population.

Primary Care: Who Does It?

The IOM report recognized that one trained as a primary care physician could practice in an emergency room and not practice primary care. It also recognized that the practice of good primary care requires specific knowledge and skills and cannot be learned from a series of experiences in a variety of specialties.³

To summarize, primary care was defined as a practice that recognizes the dignity and personhood of the patient and assumes the responsibility of combining this with good preventive, diagnostic, and therapeutic skills. Primary care can be provided by a physician with any background, but usually it is provided by those trained in general internal medicine, general pediatrics, or family practice.

Representatives from all of these disciplines, plus others, attended this primary care research conference. Ten years ago there were acrimonious debates about the "turf" of primary care, in which those from each discipline claimed to be the only "true purveyors" of primary care. This, for the most part, has been replaced by an ecumenical movement. There appears to be a growing feeling that the primary care disciplines have a great deal in common, and that there is much more to be gained from working together than engaging in turf battles.

There are now regular meetings between the leaders in these three major disciplines. There are long-range strategic discussions among the leaders, and there are even occasional voices speaking for common training programs for residents in the three disciplines. The new legislation and the new agency, AHCPR, can have a profound effect on this movement.

At this time, there is no clear consensus on the issue of a single joint training program. Discussions on this topic can quickly generate frictional heat, but there does appear to be a genuine consensus regarding the value of cooperation in research.

There is nothing that generates cooperation as quickly as common adversity, and this has been the fate of the research communities in all three disciplines over the past two decades. All have felt embattled and misunderstood among the research communities within their own institutions, receiving less than their share of dollars, space, and recognition compared with those engaged in more basic research activities. All have looked with envy on the organ system- and disease-specific research

enterprise sponsored by the National Institutes of Health (NIH), in which established investigators receive stable support-often over decades-and, in turn, are able to provide support for junior investigators while serving as role models for future generations of investigators.

Primary Care Research: What Are Its Characteristics?

But, it is more than adversity that binds together investigators in the primary care fields. Other, and equally powerful, forces are at work. The most fundamental of these is the nature of primary care research: it is very different from other research within the medical center.

The major difference is that primary care research deals with the individual as the principal focus, rather than an organ system or an abnormal physiology. This focus has inherent problems. Individuals have their own priorities and desires, which may confound the design of the research. Individuals have the same life span as the investigator, and results are often seen over years or decades, much too slow to allow quick results and many published papers (often, these are criteria in tenure decisions involving the investigator).

Primary care research is generally based on principles and techniques of epidemiology as a basic science. The experts and role models for this discipline are often found in the school of public health, not in the school of medicine. While this distinction is less important than in the past, it still adds to the isolation of those engaged in primary care research within a medical school.

There are several other characteristics of primary care. There is a large preventive emphasis; natural history of illnesses and outcomes of treatment plans are other themes. These features make primary care research a natural "fit" within the new agency. Indeed, a strong case could be made that the primary care physician is the only professional who can truly and objectively assess the outcomes of therapy, including the therapies carried out by organ-specific or disease-specific specialists.

An alternative to the very cumbersome, slow, and expensive controlled clinical trials is a network of primary care physicians, systematically judging outcomes in the course of normal care of their patients. One such network could carry out several evaluations simultaneously. Several primary care networks are already in place and appear to be effective, but they need more support.

Still another key emphasis of primary care research is the relationship between doctor and patient. This is a powerful relationship. It can confound a research study, requiring that double-blinding be a feature of the design. The relationship also can be a powerful tool, activating

the patient to engage in preventive programs. The doctor-patient relationship is, within itself, a highly relevant subject for research that deserves a great deal of emphasis, since most treatment requires patient involvement and cooperation in order to achieve lifestyle change.

Increasingly, it is being recognized that no physician can provide a complete spectrum of primary care for a population of patients. A team is required. Traditionally, this has been a primary care doctor, the doctor's nurse and/or office assistant, and the doctor's secretary. Now, more complex organizational structures are being used.

In cities, there are multispecialty clinics, health maintenance organizations, and satellite clinics. In rural areas, there are networks supporting midlevel practitioners, with telephone consultations and circuit-riding physicians. The management of these complex systems is a growing area for fruitful primary care research. For example, what methods can be used to ensure that a diffuse organizational team is providing the complex set of services needed by the people to be served?

Health Care in the United States: What Are Its Strengths and Weaknesses?

Primary care exists for a purpose—to meet the health and sickness needs of a population. True primary care recognizes the fact that it exists to serve that population. The IOM definition³ was emphatic in stating that the primary care practice must meet the patient and potential patient halfway by (1) anticipating the hours and location most convenient for those served, (2) providing services without undue delay, (3) eliminating barriers to access, and (4) in many other ways. The responsibility for continuity was also emphasized by the IOM committee, including responsibility for effective preventive services.

It seems logical, then, that AHCPR shares this same type of responsibility at a higher organizational level. It has the charge of ensuring that primary care is available to everyone, and that, when obtained, it is as effective as possible. The enabling legislation is quite specific in calling for research regarding the extension of these services to those now poorly served—persons living in rural areas, low income groups, minorities, and the elderly. At the societal level, the new agency has the same responsibility for the total population as the primary care physician has for his or her patient population.

With this responsibility in mind, an examination of the Nation's overall health care system, in terms of its strengths and weaknesses, is in order. These strengths

and weaknesses must be addressed if AHCPR is to achieve its objectives.

There can be no question as to the extraordinary successes that have been achieved in understanding basic physiology and the pathophysiology of disease and in applying these principles to patients. NIH and its extramural programs are the acme of research and **technologic** advancement.

At the same time, it has not as yet been possible to translate this knowledge into sensible programs of intervention that would be available to the entire population. Basic prevention and basic treatment are not available to those underserved groups previously cited. Perinatal mortality, perhaps the best single index of the adequacy of the primary care system, is lagging behind that in other nations and is rising in many areas of the Nation.

Uve Reinhart, the Princeton-based health economist, has pointed out that America is a kind and generous nation, but it has chosen \$100,000 liver transplants as the evidence of this generosity, applied-of course—to only one patient in a million (personal communication). **Reinhart** has noted that other nations have chosen less expensive evidence, and that they can afford to apply this choice to many more who are in need. **Reinhart** goes on to suggest that the United States adopt a two-tiered system of care, admitting that the country cannot afford the expensive items, but strengthening support for the less expensive, more widely needed services for those unable to pay for their own care.

Surely everyone recognizes the innate wisdom of **Reinhart's** advice. Politically, the Nation may not be ready for a two-tiered system, but it should be obvious that provision of good primary care services would be a far more effective and humane way to spend the public funds that are available.

How Can Primary Care Research Help?

One of the objectives of this conference and these proceedings is to inform the field about the new agency and to provide AHCPR with assistance in setting its research policy for the future. It is heartening to realize that this agency combines many authorities, all of which are necessary to develop an effective system for health care. Participants at this conference should think, not about how they can get funding for individual research projects, but instead, about how they can assist the new agency in meeting the enormous challenge that has been placed before it.

Likewise, it is important to think, not of family medicine or pediatrics or internal medicine, but rather of primary care and its improved availability and quality.

Primary care research can find answers for most of the problems facing the country's health care system. The need for primary care is enormous, and good primary care research is essential to make this more evident and to make health care as effective as possible.

Primary care research can help by guiding research in other fields of endeavor. A research enterprise without primary care research is analogous to exploring the stars without a constellation map and a scanning telescope or examining a tissue specimen with an electron microscope without first examining it with a low power light microscope. Primary care research should direct efforts to the most important objectives. Research as a pure, undirected search for truth is laudable, but most would agree that the bulk of the Nation's limited health care research resources must be directed at solving the most pressing problems.

The exact nature of the research was the pivotal topic of the conference. The following research topics appear to be among the most needed in solving the health care problems that face the country:

1. promotion of an understanding of illness
2. promotion of an understanding of the natural history of common diseases
3. promotion of prevention in the primary care setting
4. study of the effects of the provider-patient interaction

5. translation of new biomedical advances into practical patient care programs
6. recognition of the role of family, support groups, workplace, and community in health, disease, and treatment
7. promotion of improved clinical decisionmaking
8. enlistment of the patient as an active partner in the health care plan
9. restoration of balance in the country's system of health care.

The fate of the new agency and primary care are closely linked together. If primary care research can assist AHCPR in effectively addressing the problems of unmet health care needs in an era of restrained funding, its hand will be strengthened and improved health care in the future will be virtually assured.

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The Legislative Perspective on Primary Care Research

Peter P. Budetti, M.D., J.D.

Introduction

Everyone who attended this conference is an expert in primary care research in one sense or another. Why, then, is it necessary to have this particular presentation? The sad truth is that public entities, including most legislators and their staff, have virtually no perspective on primary care research.

What the public and its officials do have, on the other hand, is something of a perspective on primary care itself. And a few of the legislators and staffers who were responsible for the new Agency for Health Care Policy and Research (AHCPR) actually had a sense of what kinds of research projects the field of primary care ought to be involved in, as well as the kinds of studies that are needed about the field of primary care itself.

These two factors—a sense of what legislators and staff think about and expect of primary care and a sense of the kinds of research that might be generated by such a perspective—will be the focus of this discussion. The purpose here is to describe the political context that surrounds efforts to fund and conduct primary care research, with the hope that an understanding of the political context will assist efforts to produce the kind of research that will be valued by policymakers and, further, that will help to assure future funding for the field.

To appreciate where primary care research fits into the operations of AHCPR, it is important to understand the origins and structure of the recent legislation and also to see the degree to which primary care was specifically considered in that process and framework. Accordingly, this discussion will begin with a description of what this legislation is all about. Next will be a review of how the drafters of the legislation thought that primary care might appropriately relate to the major provisions of the law. The conclusion will include some general thoughts

on the political perspective of primary care research and what that might mean for researchers in the near future.

The Legislation and Primary Care

This legislation was the product of two separate political waves that, happily, came together in a productive way. One was the growing interest in taking a serious look at the effectiveness, appropriateness, and outcomes of medical care. The other was the dedication of many health services researchers to pushing the Federal Government to expand its support for the field.

The first movement, to evaluate medical care, was largely generated by the well-known efforts of Jack Wennberg and Bob Brook that were aimed at improving the quality of care and the equally well-known efforts of the Office of Management and Budget (OMB) aimed at reducing federal spending. This interest in evaluating medical care for two different purposes created a tension between quality-driven and budget-driven solutions.

The fundamental difference between these two approaches translated into two pragmatic political issues. One was whether the work should be done by or through the Health Care Financing Administration (HCFA) or through the Public Health Service (PHS). The second was how the relevant Congressional committees would deal with the jurisdictional conflicts, since one set of House and Senate committees has principal jurisdiction over health affairs and the PHS, while two House committees and one Senate committee have jurisdiction over the Social Security Act and HCFA.

The second movement, to expand Federal support for health services research, was generated by people who were frustrated with hearing that health services research hadn't done enough to solve the big health care issues of access, costs, and quality. The frustration, of course, was that the critics were demanding monumental results from a relatively tiny program. AHCPR's predecessor, the National Center for Health Services Re-

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search and Health Care Technology Assessment (NCHSR), just couldn't have been expected to solve all of the Nation's health care problems with barely \$18 million in direct appropriations. Even counting funding from all public sources, the total for health services research was only about one-ten-thousandth of the **\$500 billion** being spent on health care in this country.

The fact that both these waves were cresting simultaneously meant that it was possible for the drafters of the legislation to take a comprehensive approach. There developed a consensus on both sides of the aisle that it was a conflict of interest for HCFA to be funding research and developing guidelines for improving the quality of care, since it was also involved in paying bills and watching its budget. There was also consensus that it was unfair to ask NCHSR, as it had existed, to undertake the task of running a major new initiative that would be constantly scrutinized by HCFA, OMB, and the entire medical community. Since there was also a consensus that the overall health services research effort needed far greater support, it became possible to create a structure that could build on NCHSR's accomplishments and reasonably take on both new tasks as well.

Here's the vision represented by the new legislation: within the PHS there was to be a broad base of health services research, conducted as well as supported by AHCPR. Much of that research would deal with health services issues such as organization and financing, with no direct relevance for the outcomes of care. At the same time, there would be a large body of research aimed precisely at a better understanding of the effectiveness of medical care.

The research on medical care would be available for use in developing medical practice guidelines, standards, performance measures, and review criteria. But these activities should be done in a particular way that balances public interest and private expertise. On the one hand, it was determined that guidelines should not simply be developed by the concerned specialty societies. On the other hand, guidelines should not be developed by the government as such.

To strike a balance between these two opposite approaches, there should be a governmental entity charged with stimulating, supporting, and overseeing the development, dissemination, and updating of guidelines by the private sector. That entity is the Forum for Quality and Effectiveness in Health Care, a component of AHCPR (but one that has been given a degree of insulation from the rest of the Agency's activities). The notion

is a public-private joint enterprise with public support and scrutiny and private participation.

The development of the guidelines is always to be based on the best available information. That information is part of AHCPR's overall responsibility for generating new information through research. So there is to be feedback between the Forum and the Agency, based on research on the use and effects of the guidelines themselves, as well as research on medical care outcomes.

What all of this means is that AHCPR has different but interrelated tasks. All the components of the Agency must be able to carry out their own functions while at the same time relating continuously to the other components. This is a difficult task, but at least there was an underlying legislative vision.

Impact of the Legislation on Primary Care Research

Primary care is an identified priority for research, demonstration projects, evaluations, training, guideline development, and the dissemination of information. It is reemphasized in the legislation as a priority with respect to the recommendations to be made by the National Advisory Council for Health Care Policy, Research, and Evaluation. This was conscious and deliberate; it was intended to short-circuit conventional thinking that might well focus on high-tech medical care and instead shift the focus to emphasize the need to address primary care. The report by the Committee on Energy and Commerce¹ states:

The committee has identified certain high-priority areas for the Agency. These include medical liability and clinical practice, specifically primary care and practice-based research.

Research on primary care, particularly research based in clinical practice, is another area of health care that has not received adequate attention. Fostering practice-based research requires a series of activities. Individuals already engaged in, or just entering, active clinical work must be adequately trained in research methodologies. Collaborative networks must be established to have a representative base for research. Research agendas should be developed. All of these activities are necessary for the Agency to have an appropriate program in primary care and office-based research.

The special needs of primary care also were taken into consideration with respect to outcomes research. The legislation establishes four criteria to be used in setting priorities for the diseases, disorders, and other health

conditions for which research and evaluations are to be conducted. Those four criteria deal with the number of individuals that could benefit, the amount of clinical variation found, the level of expenditures, and the availability of data. Thinking through the criteria, it is clear that primary care is likely to meet the first three very often. Because of concern that the fourth criterion might disadvantage primary care, the committee said:

While these factors are always to be considered, it is not the committee's intent that all four factors necessarily be fully satisfied before an area is identified as appropriate for research. For example, research on the outcomes of primary care might well be considered a high priority, even though the data necessary for such evaluations are not readily available or readily developed, if the other three factors weigh heavily.

These comments were meant to emphasize the importance of research on the outcomes of primary care.

There was also specific consideration given to the need for removing barriers to new researchers entering the field. Such new and future researchers would include "those from institutions with future promise but limited track record, as well as those from clinical-practice situations rather than research-based institutions." These comments also took into account the special circumstances that characterize primary care research.

Topics that are of specific concern to primary care researchers were also discussed by the committee. For example, the committee said:

The committee also expects the Agency's activities to include research on methods of improving communications between physicians and patients and of encouraging patient compliance with treatment and prevention regimens.

Finally, in addition to the comments quoted above, the committee highlighted the importance of protecting the interests of primary care in the establishment of the Advisory Council. The committee stated:

The council is to consist of both Federal and private individuals. The majority are to be distinguished researchers in related fields of health policy and practice. These researchers can and should include physicians, particularly physicians involved in primary care and clinical practice research.

What does all of this mean? First, it must be said that although most of those in the legislative bodies of the Congress don't identify primary care research as an issue, the intent of the individuals most intimately involved in drafting and passing this legislation was very clear. Primary care is to be a full partner in the future activities of the Agency. This is true not only for re-

search, training, and dissemination, but also for the development of medical practice guidelines, standards, performance measures, and review criteria. To emphasize this intent, primary care was specifically mentioned in several places in the legislation where this intention might otherwise be misconstrued.

Primary Care Versus Primary Care Research

What follows are highly personal views about what the public and its representatives think of and expect from primary care. These views make no pretense of being documented by health services or any other research—and that's just the point. These are no more nor less than the attitudes that probably will determine the reaction of public policymakers to proposals for primary care research. Therefore, it would be reasonable to say that these are the attitudes that will make or break public support for primary care research.

First, primary care itself evokes generally positive feelings. It's something down to earth and good, something basic that people think they understand. It is not readily associated with high technologies or hospitals. This is quite unlike the more complex responses evoked by phrases like "subspecialists," "MRI scan," "DRGs," and "physician payment reform."

Second, primary care is not considered a pressing health policy issue. Skyrocketing medical care costs, 37 million uninsured, the annual proposals for Medicare and Medicaid budget cuts, hospitals complaining that Medicare is putting them out of business, AIDS, biomedical research, nursing home conditions, long term care—these are recognized as issues. Not primary care; no background noise, no problem.

Third, primary care is thought to be "cheap," as in inexpensive. No one expects to see "routine office visit to pediatrician" on the list of overpriced services. People who care about how much money physicians make are concerned about gastroenterologists and other subspecialists, not internists—and they don't always appreciate the lack of distinction between those two. There is the vague expectation that an increased role for primary care might somehow save money—modified somewhat by the caution that it might be all too easy to buy far too much primary care.

Fourth, primary care is viewed as the dependable part of medicine. This is related to the view that primary care is "low-tech" in character. People who recognize that there are serious concerns about medical care have grown accustomed to hearing questions raised with respect to new advanced technologies. They are not com-

for-table with the idea that routine office care needs careful scrutiny.

Finally, although people generally think positively about primary care, it is not what they want when they are really sick. When cancer or rare diseases strike, people want the super-subspecialist. They have visions, accurate or not, of England, or even Canada, where everyone can get to the general practitioner, but only a few people can get the most advanced care-and they don't like that vision. Primary care is seen as relevant for routine and preventive care, but as not being up to taking care of the most sophisticated health care problems.

Five characteristics of primary care, then, dominate public thinking: primary care is considered familiar, not in serious trouble, cheap, and dependable but only moderately sophisticated.

What are the implications of these characteristics-grossly unfounded stereotypes, if you will-of primary care for research? The first two, familiarity and lack of urgency, have similar consequences for research-that is, why bother? Because it is a field of medicine that people feel they are familiar with means that primary care is taken for granted. This grows out of the same attitude that results from the awareness that there are major health policy issues that need to be confronted, combined with the perception that primary care is not one of those issues.

Being taken for granted means being confronted with arguments such as, "It is clear why research is needed to cure cancer, save premature infants, and treat heart attacks-or to build the star wars defense system, for that matter-but it is not at all clear why research on primary care is necessary." The practical effect of this attitude is that the National Institutes of Health budget strikes a more sympathetic note than that of the new Agency. Budgets are limited; therefore, shouldn't the research resources be applied to solving the biggest problems?

The third and fourth perceptions, that primary care is relatively cheap and dependable, have another serious consequence for research. This consequence relates to a certain conflict of interest that is present in virtually all clinical research. This is a conflict that includes primary care, although it certainly is not at all peculiar to this field. This is the conflict wrought by the fact that many primary care researchers are also primary care practitioners. The conflict becomes particularly problematic as more emphasis is placed on patient outcomes research, studies of the effectiveness and appropriateness of care, and the development of medical practice guidelines.

Why raise this issue in this forum? Everyone here knows that primary care researchers would never bias their results to justify their clinical salaries. The issue is raised because this kind of work will be politically inflammatory either way. If the research shows that primary care is ineffective or extremely costly, the researcher's future at the "Medical School of the Perpetual Grant" is threatened. Show that primary care is effective and extremely cheap, and the policymakers will snicker. After all, one thing politicians understand is conflict of interest. For physicians or other health professional researchers who make a substantial part of their living from clinical practice, this could be a serious issue.

If this is an issue for all clinical research, why highlight it for primary care? The answer is simple; primary care is more vulnerable politically to the consequences of highly critical research than high-tech medicine is to negative findings in biomedical research. This would apply equally within academic medical centers and in the public image. The challenge is to continue to ask appropriately tough questions and to be able to stand the heat when the answers might undermine some of the good feelings people have about primary care and, further, might threaten some of the incentives to do research on primary care.

The fifth characteristic-that primary care is only moderately sophisticated and not what people want when they are really sick-is one of the potential strengths of primary care research. For example, research that demonstrates that high-tech or very costly medicine is not as effective as had been anticipated still leaves sick people to be cared for. If more basic care is just as effective, and that same care is more acceptable to patients, primary care would be bolstered. Or, as another example, if research demonstrates that primary care physicians are the best judges of when to expose patients to high-tech care, the relative unsophistication of primary care could be recognized as a positive feature. As a final example, it may well be demonstrated that primary care can, in fact, be highly sophisticated in many cases, thus reducing the demand for subspecialists, again to the benefit of primary care.

Conclusion

In conclusion, this is a moment of real opportunity for primary care research, but not one that is free of political hurdles. The field can make a real contribution, but it

will have to make a name for itself. In the process, it must be resilient enough to deal with some adverse reactions, and everyone must make a real effort to see that primary care research remains an appropriate priority. The **legislative intent** and the structure are there; now primary care researchers must do good work.

Reference

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Family Medicine Research

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Introduction

This article will review key issues that affect primary care research from the viewpoint of a family physician. It will begin with a discussion of the origins and history of family medicine research and proceed to the four major needs shared by all primary care researchers, whether they are from an internal medicine, pediatrics, family medicine, obstetrics, community medicine, or epidemiology background. These needs relate to research career development and support; the creation of a primary care research agenda; the development of research tools, including adapting those of other disciplines; and the development of a research community that crosses specialty boundaries. Recommendations are included for further development of primary care research.

Origins of Family Medicine Research

In 1961, White and colleagues reported on the distribution of patient care between tertiary centers, community hospitals, and office practices.¹ The absolute numbers may have changed some since then, but the conclusions still hold. On average, 1,000 individuals in a United States community make approximately 5,000 visits annually to physicians, resulting in 100 hospital admissions, 10 of which are to a university hospital. About 194 million visits each year are made to family physicians; this accounts for 30 percent of all visits to physicians in the United States.² Approximately 50 percent of these visits are for symptoms related to 20 to 30 problem areas, depending on the diagnostic classification used.³ Between 1.6 and 2.5 percent of patient contacts result in referrals, and only .5 percent of family medicine contacts require referral to a tertiary care center.^{4,5} Thus, 99.5 percent of patient contacts in family medicine deal with problems outside the tertiary care

arena, which has been the locus of most biomedical research.

The intellectual development of family medicine in the United States began with the unrest of the early 1960s, which led to the creation of the specialty. Its founders were not satisfied either with the evolution of the specialty approach, entrenched in the biomedical model, or with the current approaches of general practice.^{6,7} Early priorities of family medicine academicians were to establish organizational, political, and educational support for teaching family medicine principles.⁸ The development of this teaching base has remained a major priority to the present, in keeping with the national need to increase the number of primary care physicians available in the country. As the specialty has matured, a major need for new knowledge to guide family physicians in their patient care activities and a better understanding of the origins of illness as it presents in the family physician's office have become driving forces of family medicine research.^{6,7,9,10}

Two themes predominate in family medicine research.¹⁰⁻¹⁶ The first involves applicability of the research question to the clinical practice of family medicine. Studies following this theme involve illnesses commonly encountered by family physicians and problems that typify the special aspects of primary care practice. These include, for example, investigations of symptoms and the presentation of illness at an early stage, when findings may be subtle and diagnosis difficult. The integration of prevention into clinical practice is a major research focus, as are approaches to modifying health behaviors.

A second major research theme in family medicine has been to move beyond questions that can be answered completely within the strict biomedical paradigm and to integrate biological changes with individual perceptions, feelings, and values and with interactions between

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the individual and his or her environment. This broader integrative view is being pursued in three major areas.

The first area relates to the daily practice of family medicine and includes interactions between patient and physician and patient responses to medical interventions. Second, is the investigation of interactions between the family and an individual family member's health.^{5,11} Third, is investigation of the community and its effects on health and the ways in which the family physician may impact on health by working at this level.^{6,17-19} Given this spread of investigational foci, a reasonable definition of family medicine research is:

Family medicine research addresses the need for new knowledge by family physicians in order that they may better manage their patients, their patients' families, and their practices and fulfill their health care roles at the community level. Further, family medicine research particularly seeks to answer those questions that arise in the family practice setting or the relationship between family physician, the patient, and the patient's family and community. Family medicine research investigates issues from the family physician's perspective.

This definition is soft and many improvements could be suggested. However, it is equally applicable if "primary care" is substituted for "family medicine" and "primary care physician" is used instead of "family physician." The demarcation between what is called primary care research and disease-oriented or basic science research will continue to be vague. As the agenda for primary care research is developed and implemented and a national community of primary care researchers is assembled, the meaning of primary care research will become clearer.

As a footnote to the definitional issue, it bears saying that family medicine research, as well as other primary care research, does address a large number of the major health policy issues of the country today, but it is not limited to any one of these issues.^{10,12,13,16,20,21} Primary care research is interested in the problems of all social and economic classes, including the poor and the urban and rural underserved. It is concerned with the problems of the elderly, with problems that affect adults and youths, and with the problems of families in their reproductive years, problems that have led to the Nation's abysmal standing internationally with regard to infant morbidity and mortality.

In all of these areas, there is potential for significant new knowledge that could improve the health status of all Americans.** However, to capitalize on this potential, a number of fundamental needs of the primary care

research field must be met. To stimulate the development of primary care research, it is necessary to attend to the development of human resources.

Human Resources

Medical students. Students entering and progressing through medical school can generally be divided at the outset into two groups: (1) those with aspirations to enter a person-centered, integrative, primary care field and (2) those who are disease, organ, or technology focused and, therefore, destined to become subspecialists. While there is considerable changing of initial career choice during medical school, it is mainly a change within these two general categories rather than between them. The human resource challenge for primary care research is to identify those students with an interest in research and then nurture the intense drive to discover new knowledge that characterizes successful researchers. This requires above all role modeling, as well as specific curricular and elective opportunities.

Residents. About 65 percent of family medicine residency programs are located at community hospitals and function with little input from university faculty.* This creates a family medicine residency faculty with very different priorities and viewpoints from those of traditional university faculty. Among these faculty are a number who have actively pursued research, most driven by an internal desire for new knowledge. Such researchers and their community hospital settings provide excellent research opportunities outside of the university confines. However, they do not enjoy the support of the university environment, including access to a research community that can be helpful in conducting high-quality research.

The development of the trainee through medical school and the residency years currently is in the purview of the Health Resources and Services Administration (HRSA) and is a domain controlled in large part by department chairmen and residency program directors for the primary care disciplines. The new Agency for Health Care Policy and Research (AHCPR) needs to establish working relationships, both with the academic community and HRSA, to stimulate new opportunities to sustain research career interests of those entering the primary care fields.

Recommendation. At the residency level, there is a need to increase opportunities for working with experienced researchers who can role model successful academic careers. The special opportunities presented by this environment suggest that investment in developing its research potential may provide excellent returns. A

national program of primary care research electives for students and/or residents to involve them in properly designed projects with the Indian Health Service, in 330 funded neighborhood health centers, or other urban or rural high-need sites, may be highly motivating.

Fellowship. Support is also needed beyond the residency years in order for budding researchers to develop into independent investigators. Currently, there is almost no fellowship base for developing the skills of research-oriented family medicine faculty.²³

Until recently, no family physician faculty member had ever received a National Research Service Award (NRSA) or any other type of federally funded research career development support. In 1988 this finally changed with the implementation of programs originally mandated by Congress in 1986. At that time, Congress legislatively directed that .5 percent of all NRSA funds be set aside for primary care positions and that another .5 percent be set aside for health services research positions. This created approximately 25 primary care NRSA new starts annually. Of these, about eight are in programs accepting family physicians. In addition, family physicians can compete for many of the health services research NRSA positions.

Because of the magnitude of skills to be developed, fellowships ideally should be structured in keeping with the recommendation by Dr. Wyngaarden, during his tenure as Director of the National Institutes of Health (NIH). Wyngaarden recommended that fellowships be of at least 3 years duration, with 80 percent of the time devoted to research.²⁴ Although individuals in nonprimary care areas completing such 3-year positions have been self-selected, more than 40 percent go on to careers that are principally research-oriented, in contrast to the 20 to 25 percent of those who complete a 2-year research fellowship. It is noteworthy that only about 2 percent of NIH career researchers do not have research fellowship backgrounds.²⁵

In addition to the eight NRSA positions, a variety of other nonresearch fellowship opportunities exist for those interested in family medicine academic life. These generally integrate exposure to research methods with a curriculum oriented at clinical, teaching, and administrative skill development.

Paradoxically, in spite of the growing interest in research within family medicine, the support available for research career development has contracted over the last decade. Both the Kellogg Foundation and the Robert Wood Johnson Foundation have withdrawn support from family medicine fellowship programs. These fel-

lowship programs were very influential in stimulating research within family medicine departments and producing faculty with a basic research orientation.^{13, 26, 27}

Recommendation. Because of the critical need for research fellowship positions, it must be a priority to increase the number of primary care NRSA starting positions available nationally from the approximately 25 currently available to at least 100. This should be coupled with a push to include 3-year fellowships. This would require increasing the .5 percent NRSA set aside to 2-3 percent. In addition, private foundations should initiate investment in research career development, perhaps through innovative strategies. Such might include coupling institutional fellowship support to the support for early faculty years that is necessary for fellowship graduates to blossom into independent investigators.

Early faculty years. Carole Bland, a researcher at the University of Minnesota Department of Family Practice, has conducted an in-depth evaluation of factors related to faculty 'research productivity.'^{28, 29} Bland has identified the characteristics of a successful researcher. In addition to having adequate research skills, a successful researcher needs:

1. a mentor relationship
2. a minimum of 20-40 percent of time protected for research
3. a parent institution whose administrative and academic leadership sets research productivity as a high priority
4. a community of colleagues locally
5. a community of colleagues nationally.

The magnitude of the tasks to be accomplished by a research-oriented faculty member without fellowship training (currently, the vast majority of early career faculty) at the beginning of an appointment are daunting.^{23, 24} First, there is the need to master the clinical literature related to a specific research field of interest. In contrast, the young subspecialist moving into research does so out of a training background that has imparted a state-of-the-art understanding of the field and exposure to its clinical tools. Such is not the case for the primary care researcher who, instead, has developed a broad set of primary care clinical skills. Not only must the aspiring primary care researcher develop an in-depth understanding of his or her chosen clinical area, but he or she also usually must acquire an understanding of key behavioral and social science knowledge.

For example, the new researcher wishing to improve the effectiveness of the primary care of patients with low back pain, including decreasing progression to chronic disability, must master a number of fields. These include the orthopedic and neurosurgical view of the low back, the psychophysics of pain measurement, the psychology of pain, and an understanding of illness behavior and its involvement in the development of chronic disabilities, as well as an understanding of the primary care environment and disability compensation systems. However, it should be pointed out that, to be successful, a researcher should concentrate on one conceptual area, rather than trying to span the breadth of clinical primary care.

Second, the aspiring primary care researcher must develop skill with research methods including study design, instrument selection or development, analytic techniques, research management, and writing. He or she must learn how to manage research processes, including consultative relationships with specialty colleagues. Finally, the aspiring researcher must be introduced to and take an active part in the community of researchers which he or she is joining.^{23,30}

In summary, there are a number of factors that impede the ability of academic departments to support early career faculty research efforts. These include inadequate funding, competing priorities, academic promotion criteria, and a shortage of mentors.

Funding

Through the early 1980s, research funding nationally averaged only about \$1 million annually to primary investigators located in family medicine academic units. Over the last 3 to 4 years, approximately 10 family medicine investigators have received R01 or FIRST awards. Even with these, it is estimated that the total Federal health research dollars awarded to family medicine annually is less than \$7 million, or less than 0.1 percent of the NIH Federal health research budget.²³

The impact of such minimal Federal funding for research in family medicine is worsened by the current emphasis on curtailing health costs and by the nature of funding for family medicine generally.^{31,32} Family medicine does not control a lucrative procedure such as catheterization or gastroscopy. Its labor-intensive, ambulatory nature is only beginning to be recognized in reimbursement formulas. Only about 30 percent of residency costs are offset by direct patient income.^{33,34} While the low-cost nature of family medicine is highly desirable in the context of national policy, it precludes

development of substantial in-house support to prime faculty research activities.³⁵

Recommendation. The HRSA 780 Department Development Grants Program has been the major source of funding to establish research beachheads within family medicine departments. These funds are the life blood of research activities in most family medicine departments, and they must be continued. Their decrease or termination would be devastating nationally.

Competing priorities. The impact of the paucity of research funding on the ability of young faculty to pursue substantial research is worsened by the intense pressures created by the major need for additional family medicine faculty nationally. Most departments and residencies have one or two vacant faculty positions. The lack of faculty and the financial austerity of family medicine academic units create adverse conditions for most early career faculty.

Even fellowship-trained faculty, when looking for positions nationally, find that most departments are not able to protect more than 10 percent of their time for development of research during their early academic years. Those that join academic departments find the more immediate competing pressures of clinical, administrative, and teaching responsibilities such that the creation of a substantial research program is very difficult. As a consequence, a disturbingly large number of family medicine faculty—even those who are fellowship-trained—have not pursued development of a research component to their careers.

Perkoff²⁶ surveyed 42 graduates of Robert Wood Johnson Fellowships and found that over half did not have interested colleagues (51%), consultants (54%), financial support (73%), or time (84%) to help them with their research; 62 percent spent less than 10 percent of their time on research, and 18 percent spent no time on research. Only 18 percent could spend more than 20 percent of their time on research. This was despite the fact that 67 percent of those surveyed indicated that research was a high priority; only 23 percent were satisfied with the time they had to spend on their research.

Promotion Criteria

Those who occupy leadership positions within family medicine, including many who participated in this conference, contribute to the problem by adopting the traditional myths of academic medicine, which suggest that all academicians should engage in substantial research, and that this is the highest measure of academic productivity. As a consequence, instead of producing triple threats, triple non-threats are produced.

Recommendation. Instead of paying lip service to the premise that all faculty should have a few hours a week to devote to research, more benefit may accrue if departments focus their research resources on those few individuals most highly motivated to conduct substantial research. There is a broad range of other scholarly activity from which primary care would benefit greatly that could be the focus for those faculty who are less motivated to do research. Such a focusing of research resources also will raise the stakes for young researchers: the field of primary care cannot afford to provide long-term support to the nonproductive individual.

Mentors

A major difficulty for the primary care field, particularly for family medicine, is the dearth of senior investigators. The number of family physicians nationally with the skills to be senior independent researchers and mentors is probably between 50 and 100, depending on how "mentor" is defined. These individuals are distributed nationally, with a few universities having achieved a critical mass of perhaps four or five, along with the resources needed to support them. But, many more are distributed one or two to an academic department. Encouragingly, where there is a senior researcher, there are generally several junior faculty who are working with the senior scientist as their mentor to develop their skills.

These problems suggest a need for specific types of research support. Support for the development of the human resources for primary care research cannot be viewed as the sole responsibility of the new Agency for Health Care Policy and Research. It requires a commitment of State and private institutional dollars, diversion of some of the scarce clinical income that is available in academia, and substantial private foundation and industry investment.

Recommendation. First, a "center's program" is needed to support the 10-20 institutions that have achieved a critical mass of researchers and, thus, could become major sites of research and research training. Second, and just as critically, support must be provided that specifically targets departments and community residencies where one or two senior researchers have been successful and are contributing to the development of junior faculty. Support is also needed for practice-based, non-academic research units, such as the Ambulatory Sentinel Practice Network and the Dartmouth Coop Network, that will allow them to maintain research and career development as part of their activities.

The Primary Care Research Agenda

A second major requirement to stimulate the development of primary care research is the development of the research agenda, the focus of this conference. The development of a research agenda is necessary for a number of reasons. First, it stimulates development of dynamic intellectual communities invested in a common set of problems. The exchange within such communities is critical to the evolution of theory necessary to expand the frontiers of knowledge and to development of research methods and tools. In addition, it labels an area of investigation as suitable for investment by Federal and non-Federal funding sources. It also identifies areas in which individual researchers, research teams, or academic departments may wish to invest substantial time and effort.

Several issues related to agenda development also must be considered. The first is that it should not be a static process. While an initial agenda must be set, there is also a need to put in place the process by which the agenda will be modified as the field evolves.

Second, primary care research should respond to the major sources of morbidity of the American people for which primary care can lead to better health. For example, in the area of maternal and child health, a major research focus is on the development of an understanding of the causes and the means of preventing low birth-weight and its sequelae. Researchers in the field continue to search for the final common pathways, but many have adopted a multifactorial model of causation. The latter includes stress levels, socioeconomic issues, adequacy of prenatal care, social support, and health habits such as smoking and alcohol and drug abuse as major contributors to low birthweight. All of these are problems in which the primary care physician, providing care to families prior to conception as well as prenatal care, may be in an excellent position to intervene.

Third, the agenda should be set based on the current status of the primary care research field rather than the standards or expectations appropriate to established fields that have enjoyed many years of Federal support. For many areas of primary care, there remains a need for basic descriptive and exploratory work: these include a greater understanding of the natural history of medical conditions as they present in primary care and the impact of current primary care activities. In many areas such basic work is required before proper intervention research can be designed.

A fourth important issue is that primary care research must become theory-based. Because of the broad rang-

ing nature of primary care, the paucity of investigators with substantial backgrounds in research, and the lack of established research tradition, much past primary care work has investigated isolated insights, rather than contributing to the development of a coherent set of theories. In this regard, work on the underlying characteristics of primary care, as described by the Institute of Medicine study,³⁶ may be of particular value. These include comprehensiveness, continuity, coordination, access to care, and accountability.

A fundamental requirement for a study area to make it into the primary care research agenda in the near future is the availability of a critical mass of researchers who have the competence and the interest needed for research progress. Another requirement is that understanding of the disease processes or health issues be at the level where major breakthroughs in the primary care setting are possible. For example, until there was an understanding of the viral basis for AIDS, development of primary care-based prevention efforts were not feasible.

The last issue pertaining to development of the research agenda relates to the creation of appropriate research methods. This is so important that it is described below as a separate major need.

Development of Research Tools

Given the youth of the field, a substantial investment must be made in refining the research tools, including the assessment and, if necessary, modification of tools developed outside of primary care. Indeed, the lack of appropriate research tools may be a limiting factor for much of the research in primary care. The range of tools required is broad, in keeping with the breadth of primary care concepts. However, several categories deserve mention.

Recommendation. Primary care researchers have developed and must continue to refine data collection³⁷⁻⁴⁰ and classification systems.^{11,41,42} The first version of the International Classification for Health Problems in Primary Care was published in 1975. It followed 3 years of development, including piloting and evaluation in 15 countries involving over 200,000 patient contacts. It subsequently has gone through several revisions. The latest version is ICHPPC-2 Defined,⁴³ which gives definitions for the 378 rubrics in the classification and is published with an accompanying glossary of terms for primary care research.⁴⁴ Maurice Wood in the United States, working with European community collaborators, has used this code as a basis for developing a multi-dimensional classification system for primary care epi-

sodes that includes “reasons for encounter,”⁴⁵ and the International Classification-Process-Primary Care (IC-Process-PC) as additional dimensions.⁴⁶ It has been cross-indexed with ICD-IO. This system of classification, the International Primary Care Classification,⁴⁷ has been adopted enthusiastically in the European community as a major primary care research tool, but it is only now beginning to receive attention in the United States.

Recommendation. Support for further development of classifications is necessary. In particular, improved methods are needed for classifying psychiatric morbidity and psychological problems as they present to primary care physicians. Also, work that will help provide a primary care perspective to DSM-4 should be a high priority.

Another major tool needing support for further development is network research.⁴⁸⁻⁵¹ Networks provide a mechanism for rapidly collecting large numbers of patients and identifying geographic, urban/rural, and physician-specific sources of variation. They also provide an efficient means of conducting multiple research projects. Finally, networks provide a means for engaging a large number of primary care physicians in research collaborations that give valuable insight into the questions which arise in true non-academic practice settings.

Recommendation. Support for research networks, and for methodologic studies of network research, should be a high priority.

With regard to research design, primary care research has a long history of adapting epidemiologic design principles and quantitative analytic techniques. Alvin Feinstein has contributed tremendously to the adaptation of such instruments, and to the identification of problems in their use.⁵² More recently, primary care researchers have begun to adapt a very different set of research tools, those of the social sciences commonly referred to as “qualitative research techniques.”⁵³ These appear to be of particular value when used to develop a conceptual understanding of health-related behaviors.

Recommendation. Such qualitative techniques should be viewed as complimentary to quantitative technique, of equal importance, and worthy of support for some areas of primary care research. These techniques may be of particular value in developing theory that subsequently can be tested using quantitative techniques.

Tools are being developed to explore the doctor/patient relationship, physician behavior, and other primary care processes. Associated conceptually is the development of tools related to clinical decisionmaking, al-

though the latter often involves very different research approaches.

Finally, the field is beginning to develop or adapt measurement tools for use in primary care. Such tools are exemplified by functional status scales and measures of overall health status. They also include measures of symptoms and disability of both an organic and a psychiatric nature. Such measures have generally been adapted from researchers outside the primary care arena.

Of note, even when tools are adapted from other fields, a number of steps are required for them to be used most effectively. These include a reassessment of psychometric properties using primary care populations, an assessment of the appropriateness of scale weights and interpretive criteria, and a reassessment of sensitivity, specificity, and associated parameters.

Primary care populations are different from other populations in aspects that may be critical to the performance of such measures. First, the primary care population is usually experiencing a current illness. This may have a major impact on the performance of tools that were developed for use in general community populations. Other tools have been adapted from specialist colleagues. Patients in primary care settings frequently are seen earlier in their disease process than those seen by specialists. The diagnosis may not be clear, and the patient's understanding and acceptance of the diagnosis also may be at a very different stage from that of patients in the specialist's office. This may affect an instrument's performance.

Recommendation. The investment required to modify existing or create new research measurement tools can be very substantial and needs to be a part of the initial primary care research agenda. For all of the reasons outlined above, the development of research tools should be a major focus in primary care research for the next 5 to 10 years. The ability to develop high quality research programs will be dependent in large part on the quality of the tools that are available.

Creating a Primary Care Research Community

Finally, the expansion and integration of the national primary care research community is a particularly critical need. Currently, family medicine researchers are torn between meetings outside the specialty devoted to their research interests or to a variety of family medicine meetings, including those of the North American Primary Care Research Group, the Society of Teachers of

Family Medicine (STFM), and STFM special topic workshops, such as its annual family conference.

In many areas, family medicine researchers and those from general internal medicine and pediatrics are pursuing common research themes. Family medicine researchers have valuable insights to share, particularly from their biopsychosocial integrative framework, while primary care internal medicine and pediatric researchers have skill with research methods and analytic approaches that would be valuable to family medicine researchers. For instance, the work of Barbara Starfield has been valuable in defining the care of children in communities and the content of pediatric primary care. And, the work of Sheldon Greenfield provides superb insights into the doctor/patient relationship.

Unfortunately, there is little opportunity for primary care researchers to share such strengths. In addition, all primary care researchers would benefit greatly from the contributions that Federal research program staff, advisory groups, and the peer review process bring to establishing research priorities and standards and disseminating information to a research community.

Family medicine is considering a restructuring of its academic organizational structure to better coordinate the efforts of department chairmen, residency directors, STFM, and researchers. While this step will be important to those within family medicine, it does not address the need for increased interaction among researchers in the three primary care disciplines.

Recommendation. One bold move in this direction would be to create an annual primary care **federation**-type set of meetings analogous to the AAMC meeting each fall. If the Society of General Internal Medicine, the Ambulatory Pediatric Association, STFM all held concurrent meetings in one location each spring, this would provide an exceptional opportunity for the researchers and educators to interact. It also would have the major benefit of allowing leadership from all three groups to discuss and evolve consistent policies and initiatives that would strengthen all primary care.

Conclusion

The work needed to develop primary care research is indeed formidable. Appropriate research environments and a national community of primary care researchers must be created, they must be able to sustain experienced researchers and lead to the development of new researchers. The development and implementation of a research agenda that addresses major health problems must be accomplished without delay. For a number of areas this will have to start with exploratory descriptive

work that can inform development of theory and, subsequently, theory-based development of primary care interventions. Finally, given the newness of the field, a substantial investment must be made in the development of the research tools that will be the basic instruments of primary care research.

These enhancements are likely to impact substantially on the practices of the 200,000-plus physicians in primary care in the United States, and through them contribute significantly to the improvement of the health status of the American people.

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Commonalities in Primary Care Research: A View From Pediatrics

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Introduction

There would be no need for this session if the three primary care disciplines recognized their **commonalities**, were aware of each other's work, and otherwise established some mechanisms for collaboration. For several years in the early and **mid-1980s**, representatives from each of three primary care research **organizations**—the North American Primary Care Research Group (NAPCRG), the Society for Research and Education in Primary Care Internal Medicine (SREPCIM), and the Ambulatory Pediatric Association (APA)—**met** regularly to consider various mechanisms for collaboration. Included in these discussions were budding plans for a joint research journal but it never happened, and the general internists formed their own journal. The joint discussions did lead to one tangible bit of sharing; each of the three primary care research societies now offers complimentary registration at its annual meeting to a representative of the other two societies. This represents progress, but more can and should be done.

In trying to set a stage for more substantive collaboration, this presentation will briefly cover the **state-of-the-art** in primary care pediatrics research and some special “struggles” characterizing the field of general pediatrics, before turning to some areas of shared research interest, challenges to primary care research, and approaches to dealing with the challenges.

Research in General Pediatrics: The State of the Art

There is no journal devoted to general pediatrics. The closest is the journal **Pediatrics**, which is a monthly journal with occasional supplements. **Pediatrics** is owned by the American Academy of Pediatrics, to which the vast majority of pediatricians belong. Since

the organization includes both clinicians and academicians, its journal might be expected to carry a range of articles. What might be the appropriate balance of articles on primary care versus specialty pediatrics? It is difficult to understand why it is that well under 15 percent of the research papers in a journal read largely by practitioners of pediatrics deal with anything remotely connected to primary care pediatric practice.

Pediatrics published 265 original research articles in 1989, of which 40 were concerned with primary **care**—that is, they covered issues in practice settings dealing with general pediatric populations. (Reports of epidemiologic surveys and studies conducted in non-health community settings—such as schools—or by home interviews were not considered primary care settings.) Eliminating articles on research conducted in the normal newborn nursery brings the total down to 32 articles, and after eliminating the three articles focusing on prenatal settings, the total comes to 29, or 11 percent. Half of the remaining research articles described research done in hospital outpatient departments; the remainder—15 articles, or 6 percent of the total—reported research conducted at least in part in office-based or community clinical facilities serving general pediatric populations.

Virtually identical findings result from an analysis of articles during 1989 in the **American Journal of Diseases of Children** published by the American Medical Association: 17 percent of these articles dealt with a topic in primary care. After excluding the newborn nursery and prenatal clinics, only 13 percent are in outpatient pediatric facilities, and only 5.5 percent focus on office practice settings.

There are many other pediatric journals: the **Journal of Pediatrics**, **Clinical Pediatrics**, **the Journal of Adolescent Health**, **the Journal of School Health**, **Pediatric Research**, **Pediatrician**, and others. For the most part, they do not have well delineated differences in the focus of

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their articles, and their style derives more from the predisposition of individual researchers to submit articles to one rather than another.

It is not surprising, then, that health services researchers in other primary care disciplines fail to notice primary care articles in pediatrics journals. The frequency with which the journals publish such articles is too small to make it worthwhile even to peruse the journals. Pediatric primary care articles are, of course, published in health services research and public health journals, but here, too, the frequency is low. In 1989, 14 percent of research articles in the *American Journal of Public Health* concerned children, but only 3 percent were on a topic in primary care. In the same year, *Medical Care* published 99 articles, only three of which dealt with children and only two of the three with a primary care issue. This is not because pediatric primary care research isn't done, but rather that the literature is probably smaller than that concerning adults, widely dispersed, and not easily noticeable.

General Pediatrics, Ambulatory Pediatrics, Primary Care Pediatrics, and Pediatrics

A brief comment about the terminology of primary care pediatrics may clarify some of the current "struggles" in pediatrics.

The American Academy of Pediatrics maintains that pediatricians are specialists. It recognizes that there is a separate role for pediatric subspecialists—that is, in the care of problems that are too infrequent for the non-subspecialist to maintain competence in their treatment. Even though the term "generalist" is often used for the non-subspecialist pediatrician, it is not a comfortable term for the profession of pediatrics because of its insistence that all pediatricians are specialists. The problem seems to be that "generalist" implies trivial. Another problem may be the reality that specialists command better reimbursement rates than generalists. The field of primary care has not yet been defined by the profession of pediatrics, despite society's expressed need for the primary care pediatrician. One approach to dealing with this situation is to do away with the term "generalist pediatrician," substitute the term "primary care pediatrician," and get on with the task of building a credible research and educational base for it.

Primary care pediatrics means care for a population of children that are unselected by age or type of problem, aiming at easy access, comprehensiveness, and coordi-

nation. It may include care in the hospital for common problems that do not require specialist expertise.

The research society with the most noticeable primary care focus is called the Ambulatory Pediatric Association (APA). Although APA meetings are where most of the primary care research is reported, there is an increasing trend for the group to divide into subsections on particular aspects of ambulatory pediatrics. These subspecialties include developmental and behavioral pediatrics, adolescent medicine, chronic illness, injury control, child abuse, and AIDS, all of which have the status of "special interest groups." More important, however, is the fact that there are separate societies for behavioral and developmental pediatrics and for adolescent medicine, thus indicating much more fragmentation in primary care pediatrics than appears to be the case in either internal medicine or family medicine.

Ambulatory care is care delivered in outpatient settings. It may be primary care or specialty care. There is virtually no information on the balance between primary ambulatory and secondary ambulatory care in the United States. The situation is further confused by an apparently increasing tendency of ambulatory care pediatricians to mix primary and secondary care. A national survey recently conducted by Dr. McCrindle at Johns Hopkins University indicated that 18 percent of pediatricians in practice have a subspecialty interest, and another 7 percent practice solely as subspecialists (McCrindle B, Starfield B, in preparation). If academicians are included, about one-third of all pediatricians have at least a subspecialty interest. The situation is becoming more muddled with time, as an increasing proportion of pediatric residents are opting for fellowship training in a subspecialty. Of the 40 percent of residents planning to take a fellowship last year and the year before, 90 percent intended to do a subspecialty fellowship. Therefore, the whole concept of the primary care physician may be increasingly diluted in pediatrics, even in ambulatory pediatrics. It can only be hoped that increasing legitimization of a primary care role, buttressed by a better knowledge base, will reverse this trend.

Areas of Interest Shared by Pediatricians, Family Physicians, and General Internists

In this part of the discussion, it may be helpful to distinguish two main types of primary care research: basic research and policy-relevant research. Both are health services research to the extent that they involve at least one characteristic that is not biomedical in type, or they

are directed toward the development of methods useful in health services research.

In primary care health services research, basic research consists of methods or theory development. For example, work directed at developing health status measures is basic research. So are efforts to devise a means of conceptualizing and measuring primary care, its components, and its differences from emergency, secondary, and tertiary care.

Clearly, the three primary care disciplines share an interest in basic research. There has been some sharing, and some recognition of the overlap of interests. Those who have been interested in health status measurement cannot have failed to be aware of the work done in the past decade with adults. The clustering methodology developed by Schneeweis, Rosenblatt, and colleagues at the University of Washington¹ is another example of research recognized across the disciplines. Similarly, efforts to develop ways to measure continuity and coordination of care have been based upon recognition of lines of work in the other disciplines. However, this is true more for internists and pediatricians, who seem better attuned to each other's work than family physicians, who seem to be a bit apart. Research to develop a framework for analyzing physician-patient communication seems to have gone three separate ways, with little awareness of the contributions of the others. Unfortunately, the seminal collaborative project organized under the auspices of the Society for General Internal Medicine did not include any pediatricians, despite early planning to do so.

The other kind of primary care research, policy-relevant research, is of three types: clinical research, health services research, and primary care training research. Policy relevance means that the findings of the research might be influential in informing decisions, although it may not be specifically designed to do so. Clinical research (often classified as clinical epidemiology) is policy-relevant because it can inform clinical policies. For example, practice standards for methods of problem recognition, diagnosis, management, and reassessment might develop from research findings. All of the work on practice-based screening, technology assessment for diagnosis and therapy, and follow-up fails in this realm. Much of this work is necessarily problem- and diagnosis-specific and therefore would be expected to be different for adults and children. Family physicians, however, would be expected to overlap with internists when adults are of concern and with pediatricians when children are the focus.

There certainly could be productive collaboration in clinically-relevant, policy-related research. Consider, for example, the work on comorbidity, just recently reaching journal readers. Are the pediatricians aware of the work of Pompeii and **Charlson**² and that of Greenfield and **colleagues**?³ Are these internists aware of the work concerning children's comorbidity? How familiar to internists and family physicians is the thinking concerning the concept of severity of illness proposed by Stein and **colleagues**,⁴ and how does this work relate to thinking about severity of illness in the other two primary care disciplines? So far, there has been little sharing of philosophies and ideas and much less collaboration in research.

Although a developmental focus, with an eye toward understanding early determinants of later health problems, is most characteristic of pediatricians, family physicians and internists also share an interest in the natural history of illness and the way in which it is shaped by medical care. To what extent do particular illnesses tend to recur or persist, and what implications does this have for the organization of services?

The second type of policy-relevant research is research on health services organization and delivery. It is in this area that there is, perhaps, the most shared interest and the most potential for collaborative endeavor. Health services research is not limited to primary care, of course, but health services research should be an important component of primary care research. Think of all the possibilities concerning the relationship between various aspects of process of care and outcomes of care:

- the impact of continuity on response to management and various ways of achieving continuity
- **the roles** to be played by other types of **personnel**—nurses, social workers, and others—in outreach and in management of problems
- the impact of various types of financing on recognition of patient's problems
- the extent to which group practice facilitates management, referral, and follow-up and patient satisfaction
- various approaches to coordinating information from referrals and their impact on patient empowerment in responsiveness to medical therapy
- the potential contributions to satisfaction and health outcomes of the client-held record

- the extent to which community-orientation can be achieved and its potential for improvements in problem recognition and health status.

All of these issues are relevant to the effectiveness and efficiency of health services, and they are common to all of the primary care specialties. Despite the enormous number of possibilities and the apparent lack of obvious barriers to joint conceptualization and conduct of research, there is little collaboration.

However, the first step toward increased interaction has been taken. A few years ago, members of all three disciplines were convened for a working session to conceptualize the area of health services research in primary care. The result was a document published by the then National Center for Health Services Research and Health Care Technology Assessment (NCHSR).⁵ In that document, needed research was divided into three types: methodologic studies, clinical and epidemiologic studies, and organizational, regulatory, and economic studies. Over 25 specific, important areas of study were identified within the three broad types. Despite the careful thought that went into its preparation, with joint participation from the three disciplines and a special solicitation for primary care research proposals that was based on it, the document has not received the attention it deserves.

The third area subsumed under policy-relevant research concerns research on primary care training. What characterizes primary care training? What should characterize primary care training? Are primary care training programs providing adequate training for primary care practice? How can this be measured? Does primary care training do a better job than traditional training in preparing practitioners for primary care practice? A first collaborative step concerning this topic was taken by the Division of Medicine in the Health Resources and Services Administration (HRSA), which awarded a contract for an evaluation of the impact of the federally funded primary care training programs to a team of internists and pediatricians. (A contract had been awarded previously for evaluation of family practice training, so there was no possibility for collaboration with family physicians.) The study was conducted using the same methodology in both specialties; the results were remarkably similar in that primary care residency training programs in both medicine and pediatrics did much better in teaching issues relevant to primary care than traditional residencies (Noble J, Friedman R, Star-field B, et al, in preparation).

Challenges to Primary Care Research and Collaboration Across the Specialties

There are three major challenges to primary care researchers, quite apart from any inherent difficulties in conceptualization of research topics or availability of appropriate methodology. The first of these is **generalizability** of findings. Generalizability is a challenge in any kind of research, but it is particularly so in primary care because the characteristics of the particular setting are so influential that they become a constellation of variables in and of themselves. Research is traditionally done in single settings by individual researchers and their immediate colleagues. Collaborative research is still uncommon and is most often undertaken to increase the number of observations in situations where the events are rare. This is not the case in primary care, so this impetus to collaboration is absent. Nevertheless, collaboration should occur for reasons of **generalizability**. The study in the single office or, more commonly, in the single outpatient unit will continue to be useful in developmental efforts—that is, in hypothesis generating efforts. Studies with potential policy **relevance**—whether clinical, health services research, or training evaluation—should be done in more than one setting, unless the findings are intended to be applied only in that one site. Grant proposals that involve collaboration should receive extra “points” for doing so.

A second challenge concerns the relatively poor training of primary care researchers. It is accepted practice in the clinical subspecialties for trainees to undertake postdoctoral fellowships, with mentoring from more senior researchers. At least in pediatrics, the requirements for research training in subspecialty fellowships are being codified, it will soon no longer be possible for fellows to spend most of their time in clinical care. With the exception of some important postdoctoral training programs, such as the Robert Wood Johnson Clinical Scholars, most primary care fellowships have been overwhelmingly clinical. The demand for clinical time in medical centers is so great that fellows are typically given a day or so a week to learn and do research. This just isn’t enough.

A third challenge concerns the rewards to primary care researchers themselves. These researchers are often so consumed with clinical demands that the time devoted to research is inadequate. The situation may be even more problematic in pediatrics because of the relatively greater frequency of acute events in the care of children. It is not as easy to schedule pediatric patients as it is in the general care of adults where so many of the problems

are chronic and do not need immediate scheduling. Balancing patient care needs with research demands is a delicate art.

Dealing with the Challenges

There are at least several approaches for dealing with the challenges of primary care research. The first is research training. Better use should be made of the National Research Service Awards (NRSA), The Agency for Health Care Policy and Research (AHCPR) already provides NRSA awards. AHCPR needs to expand its capacity; it needs to work with the field to publicize the availability of the fellowships, identify more candidates, and place them where they can be trained, full time, for a minimum of 2 years. The institution of research career development awards and research scientist awards could go a long way towards legitimizing such research in academia and could provide the means for young and promising researchers to devote more time to developing and practicing their research skills.

The second approach is encouragement of collaborative research. There are now practice-based collaborative networks in family medicine (Ambulatory Sentinel Practice Networks, ASPN) and in pediatrics (Pediatric Research in Office Settings, PROS). Academic researchers should be participating in these networks as collaborators. The networks should be collaborating with each other too; ASPN and PROS have representation on each other's steering committees, More focus on office-based practice could facilitate attention to community-oriented primary care (COPC) and, in addition, lead to improvements in the relevance and representativeness of the research and its findings. A major problem for these networks is core support to sustain the infrastructure from one study to the next. A consortium of funding agencies might undertake to provide such support; perhaps AHCPR could provide leadership here.

The 1988 solicitation in health services research on primary care⁵ should be widely disseminated. Special solicitations requiring collaboration among primary care researchers on topics of common concern could also be useful.

A third approach concerns the standardization of terminology and measurement. The concept of primary care and its components needs translation to measurable qualities. The concept should mean the same thing to all researchers as should the methods to measure it. Biomedical and clinical research would not be where they are today if researchers did not agree on the meaning and measurement of a blood sugar or a blood pressure.

A fourth approach is to encourage the submission of proposals from all three branches of primary care. The current study sections receive very few applications from pediatrics or family medicine. Part of the problem is that much of the focus of health services research has been on issues related to hospitalization, which is relatively infrequent in childhood; furthermore, many solicitations are limited or highly targeted to the elderly population. As a result, the leading experts in primary care research (those who serve on study sections from time to time) are rarely exposed to the work done in pediatric settings. A substantial amount of the funding for pediatric health services research is provided by HRSA's Maternal and Child Health Bureau (MCHB). It would be very useful for AHCPR to establish some means of joint review or other collaboration with MCHB, just as it does with the National Institute on Aging and other entities of the National Institutes of Health. Better collaboration and joint funding with foundations supporting pediatric health services research would also be valuable.

Finally, a joint journal would be very useful in fostering collaboration, even in the presence of separate journals. It could be devoted mostly to health services research in primary care. Perhaps it would be worth starting with a joint research newsletter devoted to health services research in primary care.

Conclusion

This primary care research conference has provided a forum for researchers from all three disciplines to interact and share ideas. Indeed, the field owes special thanks to AHCPR, not only for organizing this conference, but also for the continuing support, encouragement, and assistance the agency has provided to the field of primary care research.

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Primary Care Research: A Perspective from General Internal Medicine

Robert M. Centor, M.D.

Introduction

General internal medicine is succeeding, albeit slowly, in primary care research. This statement may seem bold; to some, it may seem inaccurate, and to others it may seem unfounded. A brief look at the history and growth of general internal medicine will validate the opening statement and set the stage for this presentation.

During the 1970s and early 1980s, departments of internal medicine created divisions of general internal medicine. The divisional names differ—some are called general medicine, some outpatient medicine, some primary care internal medicine. The “job description” of these divisions has differed greatly. Some divisions have a different charge from other divisions; these divisions provide clinical care and teaching without any explicit or implicit expectation of research. Some divisions have grown from the older concept of the consulting general internist and do not focus as clearly on primary care, but rather traditional internal medicine. However, in general, today’s divisions of general internal medicine provide primary care to patients, teach students and residents, serve significant administrative roles in their departments and schools, and perform a variety of research.

The Society of General Internal Medicine (SGIM), which was born the Society for Research and Education in Primary Care Internal Medicine (SREPCIM), first began meeting in 1978. The first several years found a small meeting (less than 200 participants) primarily focused on how to build a division and a self-examination of its reason for existence. This meeting would occur on the Friday before the American Federation for Clinical Research/American Society for Clinical Investigation/American Academy of Pediatrics (AFCR/ASCI/AAP)

meetings. Little research was presented at SREPCIM, the real research meeting was the clinical epidemiology/health care research sessions at the AFCR.

In the early 1980s, it seemed that the way to succeed in academic general internal medicine was to emulate the basic scientists. That is, the researcher would have to develop a research theme and acquire the tools to examine a clinical question in a rigorous and defensible manner. The AFCR meetings emphasized the commonality between academic general internal medicine and the rest of internal medicine. Attendance at that meeting, and especially presentation at that meeting, provided legitimacy. While academic general internists were different from most subspecialists in the way they did their research, research, nevertheless, was carried out.

Early Successes in Internal Medicine

The focus of primary care internal medicine research does not differ from pediatrics or family practice—all are concerned with patient care. Research concerning patient care can take many forms; to illustrate this, the following paragraphs will focus on early successes in internal medicine.

Early research successes centered around those projects that fit into the rubric of clinical epidemiology/health care research. Many researchers focused on a single problem—for example, chest pain, sore throat, syncope, or back pain—and designed research projects to improve understanding of various aspects of these problems. This kind of problem-oriented research generally required the prospective collection of clinical data. Once the investigator had collected a prospective clinical database, he or she could analyze the data in a variety of ways. Such studies yielded a number of smaller studies and often spawned additional research. Other investigators have concentrated on retrospective data collection to answer classical clinical epidemiology

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questions. Still others have examined issues of health care delivery, focusing on quality of care.

What stimulated the involvement of general internists in this research? A significant number of academic general internists had and continue to have post-residency training. The major supporter of this training has been the Robert Wood Johnson Foundation. Their Clinical Scholars Program has enabled a large number of primary care physicians to obtain advanced training and skills such as clinical epidemiology, biostatistics, and business administration. While these programs are not restricted, it seems that general internists have taken advantage of the Clinical Scholars Program in disproportionate numbers. This program and other training programs like the Milbank Scholars and the shortlived Kaiser Fellowships helped to create a critical mass of researchers.

Having a place to present research (the aforementioned AFRC meetings), which department chairs valued, gave these young investigators a chance to flourish and to network. Those who were without such training were able to benefit by attending excellent research presentations and to learn from the critical review of those presentations. Thus, these meetings served to focus on quality, stimulating the attendees to both perform more research and improve their research designs.

A core of researchers gained skills, and some gained national recognition. When this group published articles, all general internists felt pride. Each publication instilled new confidence in the field.

Thus, in 1985, the future looked pretty rosy for the quantitative types. Funding was difficult, but many investigators were learning how to find funding for their research. Prominent sources for funding included foundations, the National Center for Health Services Research and Health Care Technology Assessment, and the National Library of Medicine.

However, this story also has its downside. Many academic general internists were asking questions that didn't fit into either the clinical epidemiology/health care research or medical decisionmaking paradigms. These academicians were doing serious work but had difficulty finding a forum for presentation or for publication. Two prominent areas of inquiry were the doctor-patient relationship and medical education.

In 1985, two major events occurred that are still having a positive influence on academic general internal medicine. First, Steve Wortman, in what was considered a radical and bold move, increased the duration of the SREPCIM meeting from 1 to 2 days. This opened the

door for more presentations and more workshops. Over 500 people attended that 1985 meeting, and the enthusiasm during the conference was palpable. Still at that time, the "best" research went to AFRC, and the percentage of accepted abstracts at SREPCIM remained unacceptably low. The second important event was the announcement of the Society's journal—the *Journal of General Internal Medicine*. Thus, there would be a special place to publish, where all of the articles would come from colleagues in the field. Having a place to publish encourages researchers that their research will "see the light of day."

Primary Care Internal Medicine Today

Today, academic general internists can be roughly divided into the quantitative types and the "soft" types. The quantitative academic general internists, as a group, are flourishing. The national SGIM meeting (with an attendance of 1000) provides a forum for research presentations. This meeting now shares abstract presentations with the AFRC in joint sessions. Each year, the quality of the research improves, and the quantity increases. For many in the field, the journal has provided more than a place to publish, it has presented a first opportunity for participating in peer review.

Research funding is finally starting to improve. The new Agency for Health Care Policy and Research (AHCPR) has increased funding this year. The patient outcomes initiative has opened up funding opportunities for a large number of general internists.

Why have these general internists succeeded in obtaining funding for their grant proposals? Several points seem to be pivotal. First, successful grantees respond to "pink sheets" positively, taking the study section's suggestions and using them as guides for improvement. Second, there seems to be a cooperative/collaborative spirit. These grantees often have internists from other institutions as co-investigators or consultants, and they frequently benefit from co-investigators outside of general internal medicine. These successful grantees forge alliances with subspecialists in internal medicine, biostatistics, sociology, and so on, and they often strive for multidisciplinary research. This model seems to have the highest probability of success for general internal medicine researchers.

However, even for the quantitative types, there are still problems. Funding of fellowships continues to lag. Only the Robert Wood Johnson Clinical Scholars program provides consistent funding of which some general internists can take advantage. The old National Cen-

ter for Health Services Research and Health Care Technology Assessment (NCHSR) had no explicit program for funding fellows. If primary care research, whatever the discipline, is important, then AHCPR should help create the next generation of investigators. Fellowship support is needed which is analogous to National Institute of Health (NIH) support for basic science fellowships. In addition, a program is needed for career development awards.

The “soft” types have had much greater problems in establishing their academic (read “research”) credentials. Research that includes measurable outcomes and statistical comparisons is more readily acceptable. Thus, general internists who are interested in psychosocial concerns or improvement in educational programs have had more difficulty in finding places to present or publish their work and in obtaining support for their research. SGIM, for many years, seemed to be biased against work that was not quantitative. Recently, the national meeting has set aside simultaneous abstract presentation time for such work. This represents a start. The opportunity to present begins a critical dialogue that leads to more work and stronger work. However, the Society still seems to have prejudices against these important areas of research. Even so, SGIM responds more positively than most journals and virtually all funding agencies.

There is definitely a need for improvement, including a better understanding of how to evaluate, investigate, and teach “the soft stuff.” While such investigations might face more difficulties, the subject matter of these areas of inquiry has great importance. It is necessary for the rest of the field to work with these innovators to better understand where they need to go and how they can be helped along on their journey.

Conclusion

In summary, general internal medicine is slowly succeeding in its research mission. AHCPR can help by

expanding its emphasis on primary care. As society’s greatest need for physicians remains in primary care, so are the greatest research needs. In particular, critical needs include:

- a better understanding of how to deliver care in a humane and effective manner
- more insight into appropriate management and diagnostic tests; it would be a mistake to rely on a continuing uncritical proliferation of new technology. Patients need new technologies; physicians need new technologies; but, both physicians and patients need to know the implications of these technologies
- more knowledge about the best ways to deliver care
- an understanding of the impact of the relationship between a primary care physician and a patient.

Obviously, there are many important questions that must be answered. The primary care disciplines need the opportunity to focus on the questions and produce the answers.

Finally, divisions of general internal medicine should fit well into departments of internal medicine. **Subspecialists** need general internists; patients need general internists; and research needs general internists. While the special skills of general internal medicine are different, and department chairman and other divisions in the department don’t always understand them, these skills do come from the intellectual tradition of internal medicine. This tradition has given the field its start; now it is up to general internists, themselves, to chart the future.’

‘In 1985, the Regenstrief Institute for Health Care sponsored a conference titled “Research in General Internal Medicine.” The proceedings of this conference, published as a supplement to the *Journal of General Internal Medicine* (Vol. 1, No. 4S), are highly recommended.



The Federal Investment in Primary Care Research

Fitzhugh Mullan, M.D.

Introduction

Primary care research is important to many programs of the Federal Government because of its relevance to both clinical care and health policy. Although the definitions of “primary care” and “research” vary from agency to agency, there are a number of programs within and outside of the Public Health Service (PHS) that support primary care research.

Funding for Primary Care Research

A summary of the levels of funding and the numbers of projects sponsored by these agencies during fiscal year (FY) 1989 is found in Table 1. This analysis indicates that the \$15.38 million spent by the National Institutes of Health (NIH) during 1989 is the largest single contribution to primary care research. This figure was arrived at by searching the NIH grant files using the terms “family medicine,” “general practitioner,” and “primary care physicians.” While little of this research was undertaken with primary care as its focal issue, much of it supported investigators whose identity and issues were primary care-relevant.

The Health Resources and Services Administration’s (HRSA) \$7.4 million allocation for primary care research was divided between SPRANS (Special Projects of Regional and National Significance) of the Maternal and Child Health Program, Family Medicine Grants and National Research Service Awards in the Bureau of Health Professions, and five rural health research centers supported by the Office of Rural Health Policy. The most specified primary care research investment in the PHS was made by the Agency for Health Care Policy

and Research (AHCPR), formerly the National Center for Health Services Research and Health Care Technology Assessment (NCHSR). The agency spent \$5.13 million on investigator-initiated research relating to the practice of primary care. The \$3.43 million in Indian Health Service funding was spent on intramural projects related to health care of Native Americans.

Current and Future Opportunities in Primary Care Research

This brief analysis provides some tentative insights into the nature of Federal funding for primary care research that may be of use to future investigators. While the NIH support for primary care research could be considered tangential, it is, nonetheless, the richest source of funding for investigations of clinical matters normally considered a part of primary care. This observation emphasizes the importance of exploring, understanding, and using the NIH grants programs.

The AHCPR funding for “targeted” primary care research is significant and growing. The transformation of NCHSR into the new agency, along with a significant budget increase in FY 1990, should bring this agency to the attention of primary care investigators. Moreover, the medical effectiveness and patient outcomes research mandate of AHCPR are pragmatically oriented and well suited to issues traditionally of interest to primary care researchers. Major studies are already underway on clinical entities, common to primary care practice, such as back pain and prostatism, and others are contemplated on issues such as otitis media and sickle cell disease. The medical effectiveness initiative offers major opportunities for primary care researchers.

This funding analysis indicates that very little support is currently being provided for primary care researchers by agencies traditionally concerned with public health

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Table 1. Agency totals

	Investments (millions)	N 89 Projects
Public Health Service		
ADAMHA	\$3.50	19
AHCPR	\$5.13	37
CDC	\$0.22	1
HRSA	\$7.40	53
NIH	\$15.38	60
IHS	\$3.43	25
Total	\$35.06	195
Other Agencies		
HCFA	\$0.33*	31
VA	\$1.30	12
Total	\$1.63	43
Grand total	\$36.69	238

*Dollar figure not available for 27 HCFA projects.

SOURCE: The respective agencies.

practice. The public health-primary care interface is of growing interest in the wake of increased concern about access to care at the State and local levels and the broad criticisms of the public health system articulated in the Institute of Medicine (IOM) report, *The Future of Public Health.* The Centers for Disease Control (CDC) is a potential area for expansion of research in the population-based aspects of primary care. Community oriented primary care (COPC) is an approach to the delivery of clinical services that combines the population-based science of epidemiology with the practice of clinical medicine. It is an ideal instrument for undertaking primary care research with a population perspective on a community level. Various programs within HRSA, the Indian Health Service, and the CDC have shown an interest in COPC.

Summary and Recommendations

In summary, the following concepts might be explored and implemented in the interest of upgrading the national approach to research in the area of primary care.

1. An annual short but intensive course in primary care health policy and research methods might be offered for the purpose of developing a network of primary care research and policy leaders. This concept has been referred to as the “primary care/epidemic intelligence service.”
2. Primary care research networks such as the Ambulatory Centennial Practice Network (ACPN) or the Dartmouth Coop might be expanded and replicated.
3. The “common front” between family medicine, general pediatrics, and general internal medicine might be nourished and strengthened by an ongoing set of collaborative activities (conferences, journals, research projects) that would make use of the important commonalities between the three disciplines.
4. A program of research and educational activities might be undertaken between primary care researchers and public health researchers in areas such as prevention and population science.

Primary care research, in all, stands to be an important new laboratory for clinical medicine and health policy in the United States.

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The Future of Primary Care Research

Robert Graham, M.D.

Introduction

This presentation will focus on three basic points related to primary care research and explore them from two perspectives: (1) that of a professional organization and (2) that of an individual who has spent some time in the public sector in Washington dealing with issues that are somewhat related to research funding.

It will begin with a definition of primary care research, followed by a discussion of the new Agency for Health Care Policy and Research (AHCPR) and its importance for primary care research. Finally, some ideas and recommendations will be put on the table regarding what can be done to “make it all work” by the two distinct constituencies represented at this conference—those interested primarily in health services research and those interested principally in primary care research.

What Is Primary Care Research?

To some hard-line academicians, primary care research is an oxymoron. They say it’s soft, it’s trivial, it’s complicated, it’s not urgent, it’s not a center of excellence, and so on. That viewpoint is part of what the field is up against. The fact that each of the presenters on the first afternoon of the conference felt it was appropriate to develop a definition of primary care research indicates that the field is really at the starting gate in the process of building an initiative.

Between the two groups of researchers—the health services researchers and the primary care **researchers**—there is a general sense of shared endeavor and shared priorities; yet, the semantics (the way the two groups look at the world) are not exactly the same. So, they keep checking with one another to establish some ground rules and areas of agreement: “This is what we think it is. What do you think it is?”

Presently, the field is in a developmental stage; individuals are coming together to share ideas and experiences in an attempt to formulate a definition of primary care research. Larry Culpepper (in this volume) cited Kerr White’s 1960-61 article, “The Ecology of Medical Care.” Those who have read the article will recall the hierarchy of “nested boxes,” **that** is, the box within a box within a box, and so on. To illustrate how this point applies to primary care research, assume that in a given month 750 individuals out of 1,000 report feeling unwell; 250 of these will see a physician. Thirty-three will be admitted to a community hospital, and one will go to a university or to a shared-care center. Those numbers may have changed somewhat in the almost 30 years since White’s article but probably not all that much.

What is the domain of primary care research in this scenario? It’s every one of those boxes from number 1,000 through number 33. Sometimes this research is gathered or conducted through research systems, sometimes there are research teams, and sometimes there are just little bits and pieces of information scattered about. Whatever the case, this is the domain of the primary care provider, whether the provider is a family physician, general internist, pediatrician, nurse midwife, or any one of those who are included in the definition of provider.

One of the critical elements of this definition of primary care research is the question, “What is the focus of the research?” This includes consideration of the nature of the community, the context or setting of the patients, and their individual and group risk factors. The research must also take into account the nature of the encounter between the patient and the professional and the setting or context in which it takes place.

The single most critical element of primary care research—that is, what sets it apart from other types of research—is the encounter of an unselected patient with a provider. As they go from one patient encounter to

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another, primary care providers can't know what they are likely to see next. In primary care there is no predictive element that says, "because this kind of patient was just seen, it follows that this kind of patient will appear next."

The next critical element of primary care research is the assessment of the patient. At this point, a number of questions must be asked, namely: What data should be collected? How should the data be assembled and analyzed? How can a conclusion be reached? Is this patient acutely ill? Emergent? Nonurgent? The determination of treatment strategies—choosing intervention, nonintervention, support counseling, management of a patient, and significant other strategies—is clearly a major domain of primary care. Even in individual cases, the determination of a treatment strategy is not necessarily exclusive to one particular provider. Other primary care providers are drawn into these encounters, because few patients exist in a vacuum.

So, the scope, type, and function of the medical practice are cardinal elements of what constitutes the domain of primary care research. These elements should be included in the definition of primary care because they emphasize what primary care providers have in common while downplaying their differences.

Interest and Support for Primary Care Research

One major characteristic shared by all who attended this conference is an interest in and a commitment to pursuing primary care research issues, as well as the conviction that primary care research issues are important. In that respect, primary care researchers stand very much apart from the rest of the medical research complex. The support for primary care research today from any source is inadequate. Indeed, this type of research has low priority if it has any priority at all. The fact that it has such low levels of support is another important element of what it has become. Due to its low priority and resulting funding inadequacies, there are relatively few working in this field.

The paltry amount of aid available for primary care research in this country is a very important part of the reason that the Nation's health care system has some of the major flaws and problems that it has. As excellent as the system can be for most of the people much of the time, it is inadequate. This shortfall in the health care system is due, at least in part, to the fact that primary care researchers have not had an opportunity to investigate basic medical questions. As a result, the dynamics at

work in America's health care system are not fully understood; more effective ways of reaching and involving people have not been devised; and ways have not been found to influence, cure, and support them.

In this country, much of the Federal and private support for research goes into reductionistic models of research. This direction in research funding has created a centrifugal force of sorts that has led research enterprises into ever more narrow categories. This is not meant as criticism of the National Institutes of Health (NIH), nor of the biomedical research model that has become standard. Rather it is a plea for balance in the Nation's research efforts. That balance does not exist today. The NIHs of the world are certainly necessary, but an NIH-type approach is also needed for primary care research, especially in terms of investment strategy.

The Impact of AHCPH on Primary Care Research

It could be said that AHCPH is a marriage of the National Center for Health Services Research and Health Care Technology Assessment (NCHSR) with the hopeful and glorious new crown of "effectiveness research." Many at this conference have been in the NCHSR's constituency and will agree that the Center and its work were not adequately funded. For years, health services researchers have felt that the Center and its research programs did not receive enough attention or funding and, indeed, that the research might have done better if it were under the NIH or at some other agency.

The movement for effectiveness research, which had been going on for a number of years, suddenly found an opportunity to advance as a result of Congress' desire to insert another cost-control solution into the relative value scale (RVS) debate. This other solution was to say, "let's not just put a rigid limit on what can be spent, let's understand how to spend wisely." So the Congress decided to combine effectiveness research and primary care research.

There is some room for disagreement with this approach of categorizing primary care research as a function of cost control. First, it seems as though primary care research was added to the legislation in a late draft, at nearly the last minute. That is not necessarily bad; at least it is a part of the legislation. Credit is due to those who made sure it was included: the staff of the committee that sponsored the legislation and advocates of primary care research. Credit also goes to the committee for its perception that embracing primary care research

would allow them to expand on their major agenda issue, effectiveness research.

Second, the committee's approach has made AHCPR into something that is essentially a graft of primary care research and effectiveness research. Because primary care research was an afterthought, it will never receive consideration at the same level of priority or the same level of interest as other issues. It remains to be seen where primary care research will come out compared with effectiveness research in the agency's efforts.

In the long run, effectiveness research probably will take greater priority because that's the hot topic. It may very well be that 10 or 11 months from now, someone from Congress will pick that bill up and say to the AHCPR, "all right, you owe us three guidelines. Do you have them?" It is very doubtful that anyone in Congress is going to pick up the bill and say, "you owe us a primary care research strategy, do you have it?" So, there is a basis for concern about how the agency will respond and to what it will respond.

AHCPR: Its Strengths and Weaknesses

What has primary care research gained from the creation of this agency? As a constituency group, primary care researchers must be concerned about AHCPR's strengths and its weaknesses. If the agency is going to succeed and the interests of primary care research are going to be advanced, then the strengths will have to outweigh the weaknesses. First, the weaknesses:

1. The fact that the agency is new is a weakness. It hasn't taken form yet. Many will have major expectations of it, yet the agency has no clear track record. Perhaps too many expectations have been developed too soon. After all, something can be written into legislation, it can be published in committee reports, and results can be promised in 8 months. But if it doesn't get done in 8 months, who looks bad? Not the person who wrote the committee report.
2. The second weakness is that this agency will have a major core of new staff with new responsibilities. How should those responsibilities be handed out? How does anyone even know what all those responsibilities will be? And, with all of these new ideas and new responsibilities, how can it all be done in a year as the legislation requires? There are many other questions that must be answered within the context of a limited budget. For example, hundreds of new employees must be recruited, but will the new people all have appropriate expertise? Prob-

ably not. That's a common **difficulty**, but it doesn't necessarily mean a new agency will end up with a bad staff.

3. A third weakness is that, at least for a period of time, there will be uncertainty about the leadership of the new agency. Until a lengthy search process has been completed, AHCPR's administrator will have "acting" in front of his name, and that introduces a bit of uncertainty. Such uncertainty can get in the way of the agency's ability to hit the ground running and accomplish its assigned responsibilities for the first 12 months.
4. The final weakness, and perhaps the most important in terms of the primary care research agenda, is that our interpretation of the agency's mission might differ from Congress' interpretation. The wording of the Congressional charge to this agency, particularly in the area of effectiveness research, indicates that AHCPR is to undertake directed research and deliver a specified set of goods to Congress within a defined period of time. In other words, this is not to be investigator-initiated research. Yet, the research model that will bring forth the finest fruits of American ingenuity and creativity is investigator-initiated. The Congress has invested heavily in this agency and it is one of AHCPR's major constituents; the question is, did Congress envision the agency as working with people like those who attended this conference—that is, people who are interested in primary care or health services research and those who are interested in support for development of fellowships and faculty?

Now for the agency's strengths. These are strengths that can and should be built upon.

1. There are great expectations for this new entity, and its creation has aroused great enthusiasm and energy. If this were not true, the agency would not have had to turn away 150 additional people who wanted to attend this conference.
2. The agency represents a source of fresh leadership and a new perspective on research. Whether the people are new to the agency, or whether they were part of NCHSR's staff, there is now an opportunity to examine the issues differently and creatively.
3. Congress has given AHCPR the resources to complete at least part of its assigned task. It is debatable whether the resources will be adequate to the task.

But, there is an indication that achieving a measure of success during the initial honeymoon period may give the agency a fighting chance for greater resources down the line.

4. An additional strength is that this agency has the opportunity to act in areas of high visibility, such as patient outcomes, treatment effectiveness, and clinical guidelines. These **are** the “sexy” terms in medicine today. It is difficult to predict where these terms will stand 3 years down the road. They may be an integral part of medical practice, and this may be called a watershed period. On the other hand, in a few years these terms may be all but forgotten. But right now, for many people, patient outcomes and medical treatment effectiveness are where the action is. Certainly, this is true for AHCPR.

Creating an Iron Triangle

Finally, what can primary care practitioners, researchers and other interested parties do? It is important to recognize that the current situation could provide an opportunity to form an “iron triangle,” a term heard often in Washington. An iron triangle is made up of the following: (1) a constituency that is interested in a cause, (2) an executive agency that has the authority to do something, and (3) a congressional advocate. Together, these three entities form an iron triangle that can produce money, authority, and product.

Past experience has shown that a Federal health care research entity is generally ineffective unless an external constituency group has provided a major reason for that entity’s existence. This does not mean that all successful Federal research agencies were formed as a result of external constituencies, although many were. Why is the National Cancer Institute a \$2 billion-plus program, or why is the National Heart, Lung, and Blood Institute a \$1 billion effort? It is because of their constituencies and the effective working relationships that have evolved in their respective iron triangles. It is not going to be any different for the primary care research community and AHCPR.

As a constituency of this agency, the primary care research community must push hard on the opening that has been provided by Congress for funding primary care

research. Priorities include funds for investigator-initiated research, not just funds for directed research; fellowships; faculty development; and centers of excellence.

Conclusion

In closing, some thought must be given to alternatives if this new opportunity doesn’t work out. It will take a year or more of “watchful waiting” to see if the promise embodied in the legislation and AHCPR will bear fruit. Will there be more grants to departments of family medicine, divisions of general internal medicine, and divisions of ambulatory pediatrics? Will opportunities for collaboration increase? Will research training and faculty development be available? Will there be fellowships? These are some of the criteria that will be used to measure progress in primary care research.

But, it might not happen. There are a variety of possible scenarios in which this agency might be unable to live up to its advance billing in terms of primary care research. If that happens, primary care physicians and researchers may need to do their own outcome assessments. Another option is to seek legislation to create an institute of primary care research. The constituency represented at this conference must find a way to work through present opportunities or, failing that, to make its own opportunities to get more Federal support for primary care research. Certainly this conference has shown that advocates from all three disciplines can and must come together as a committed group to confront and work through these issues.

Primary care research, its advocates and practitioners, are still on the bottom of the totem pole in academic medicine, and that’s bad for everyone: the patients, the providers, the researchers, and the system. The formation of this agency may be a very important first step in addressing the neglect of primary care research. The agency deserves the support of all those who are interested in primary care research. This is the first step, it’s a major step, but there are many more that have to follow.

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The Agency for Health Care Policy and Research: Relevance for Primary Care Research

J. Jarrett Clinton, M.D.

Introduction

The Agency for Health Care Policy and Research (AHCPR) was established by the Omnibus Budget Reconciliation Act in December 1989.¹ This legislation gave the new agency a broad mandate that expands upon the activities of its predecessor, the National Center for Health Services Research and Health Care Technology Assessment (NCHSR).

AHCPR's mission is to enhance the quality, appropriateness, and effectiveness of health care services and to improve access to those services through a broadly based scientific research program and through the promotion of improvements in clinical practice.

The agency's mission is directed toward several broad goals:

1. promoting improvements in clinical practice and patient outcomes through more appropriate and effective health care services
2. promoting improvements in the financing, organization, and delivery of health care services
3. increasing access to quality care.

AHCPR will continue to support research, demonstration projects, evaluations, training, and technology assessments. In addition, AHCPR will continue to pursue a vigorous health services research program, including primary care research. These are the predominant activities that were carried out formerly by NCHSR. New and expanded responsibilities include medical treatment effectiveness research and clinical guideline development, the dissemination of information on health services and health care delivery systems, and data standardization.

AHCPR will give special attention to health care services in rural and frontier areas and also to the health of low income groups, minorities, and the elderly. This is a prominent theme in AHCPR's agenda, and the agency is eager to develop a research and evaluation portfolio that adequately reflects these priority areas.

A specific section of the new legislation directs AHCPR to develop and support a research program on the outcomes, effectiveness, and appropriateness of health care services and procedures common to Medicare beneficiaries.

AHCPR's activities and resources are focused on the following concerns:

- effectiveness, efficiency, and quality of health care services
- outcomes of health care services and procedures
- clinical practice, including primary care and practice-oriented research
- health care technologies, facilities, and equipment
- health care costs, productivity, and market forces
- health promotion and disease prevention
- health statistics and epidemiology
- medical liability.

AHCPR's Niche in the Public Health Service

AHCPR is the eighth, and by far the smallest, agency of the Public Health Service. The other seven are well known; they are the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); the National Institutes of Health (NIH); the Centers for Disease Control (CDC); the Health Resources and Services Administration (HRSA); the Food and Drug Administration (FDA); the Indian Health Service (IHS); and the

Dr. Clinton is Assistant **Surgeon General** and **Acting** Administrator of the Agency for Health Care Policy and Research, U.S. Public Health Service.

Agency for Toxic Substances and Disease Registry. Representatives from many of these agencies attended this primary care research conference, indicating strong Federal interest in issues related to primary care.

What does it mean to be an agency? This status provides greater opportunity to talk with the leadership of the Public Health Service about effectiveness and primary care. Agency status means that AHCPR's Administrator is on equal footing with the leadership of the other seven agencies, making it easier for us to discuss overlapping responsibilities and also to explore potential areas for collaboration. Agency status is a definite asset for AHCPR, but it does bring with it additional administrative obligations and issues that we will have to resolve in the months ahead.

Budget Issues

AHCPR's budget stems from three sources. First, there is an appropriation from the Social Security trust funds. Second, AHCPR receives funds through budget authority money. And third, the agency has a source of money that is a transfer from other components of the Public Health Service-this is known as 1 percent evaluation money.

The overall appropriation for the Agency grew from \$50.7 million in FY 89 to \$98.8 million in FY 90. The Administration's request to Congress for the Agency for FY 91 is \$110 million.

Obviously, this is a small fraction of the \$600 billion spent each year in America's health care system. But, with productive work on the part of researchers and practitioners in the field and AHCPR staff, the picture is hopeful that AHCPR will have sustained growth.

National Advisory Council

AHCPR receives advice from many groups; the Congress regularly specifies direction; and events like this conference are convened to provide advice, additionally, about AHCPR's direction. By virtue of the new legislation, AHCPR will have a National Advisory Council for Health Care Policy, Research, and Evaluation. This Council will be composed of 17 members, and it will make recommendations for research, demonstration projects, and the review of technology assessments. In addition, the Council will review AHCPR's research agenda on outcomes, procedures, and services.

Organizational Structure

Four centers and four offices have been established within AHCPR. The centers are:

- Center for General Health Services Extramural Research
- Center for General Health Services Intramural Research
- Center for Medical Effectiveness Research
- Center for Research Dissemination and Liaison.

The Center for General Health Services Extramural Research continues to be the agency's focal point for the entire spectrum of investigator-initiated health services research, including primary care, technology and quality assessment, cost and financing, AIDS, and rural health. Within this center, AHCPR has established a Division of Primary Care to coordinate and administer the agency's primary care research portfolio and other activities-such as this conference-related to primary care.

Health care technology assessment is a responsibility that has been carried forward over the years. The major components of AHCPR's technology assessment program are: identification of needs, establishment of priorities, development and evaluation of criterion methodologies and health care technologies, research activities, and education, training, and technical assistance on the spectrum of technology assessment. These activities will continue as a major component of the agency's extramural research portfolio.

The Center for General Health Services Intramural Research includes about 40 health services researchers who work with two very powerful data sets. The National Medical Expenditure Survey (NMES) provides data on the uninsured and poorly insured, as well as the adequacy of insurance, access issues, and the rates of health care utilization in America. The second data set is the Hospital Studies Program, in which AHCPR researchers analyze data from about 60 million hospital discharge summaries compiled over the last two decades. This data base will grow rapidly to 100 million summaries in the near future. Using these data, AHCPR researchers can examine variations in **treatment, outcomes, health care utilization, and other related health care issues.**

The Center for Medical Effectiveness Research is responsible for the extramural research component of the agency's medical treatment effectiveness program, known as **MEDTEP**. **MEDTEP's** major goal is to improve the effectiveness and appropriateness of medical practice by developing and disseminating scientific information regarding the effects of presently used health care services and procedures on patients' survival,

health status, functional capacity, and quality of life. Research conducted under this program addresses fundamental questions about what difference medical care makes: Do patients benefit? What treatments work best? Are health care resources well spent?

MEDTEP research emphasizes evaluation of the outcomes (what resulted) of health care services, rather than the processes (what was done). The production and documentation of scientific findings through health services research, together with active dissemination of these findings, will lead to more informed clinical decisionmaking and a more effective and efficient health care system.

MEDTEP projects include multidisciplinary approaches to address variations in health care delivery and patient outcomes. Outcomes research includes studies involving both cross-sectional and longitudinal analyses, prospective and retrospective data collection, clinical and nonclinical data, and a variety of approaches that permit demonstrations and evaluations of the relationship between health care and its outcomes. Priorities include research that will benefit a significant number of people and projects that address high expenditures for health care.

The Center for Research Dissemination and Liaison is responsible for the agency's entire research dissemination effort, including its linkages with public and private institutions. AHCPR's efforts in this area, which have been ongoing for some time, are being greatly expanded. The agency is already working with State legislators, and this group will be broadened to include county legislators and the business community.

AHCPR has an extraordinary charge to disseminate the information that grows from the agency's research, guideline development, and overall research investments, and we have been directed through the new legislation to promptly publish and disseminate as broadly as possible our research findings, results, guidelines, and other materials. Our mailing lists of some **30,000-plus** individuals and institutions enable us to reach our constituents to let them know what the agency is doing, why it's being done, and what is being found through research. In addition, AHCPR will provide indexing, abstracting, publishing, and other related services.

AHCPR has recently initiated discussions with the National Library of Medicine (NLM) to bring health services research and technology assessment information into the MEDLARS system. This is the start of a major 2-year investment that will allow users to access the MEDLARS system as easily for health services research

and guideline information as they do now for biomedical information.

In addition to these four centers, AHCPR also has four offices.

The Office of the Forum for Quality and Effectiveness in Health Care will arrange for the development, review, updating, and revision of clinically relevant guidelines for physicians and others in the health care system, including patients. It is to accomplish the same for standards, measures, and criteria for assessing the quality of care in America's health care system. As outlined in the legislation, three sets of guidelines are to be produced and submitted to the Congress in January 1991. AHCPR has been in contact with a number of groups, specialty societies, and others in the field to identify work that is well underway in guideline development; the goal is to identify efforts that, with further assistance from AHCPR, can be accelerated into a reasonable set of guidelines that can be ready for use in 1991.

AHCPR has been provided with a broad set of opportunities to construct these guidelines. It must be pointed out, however, that the guidelines will not be written by the Federal Government. They will be written by American clinicians, including primary care providers, for the American people. AHCPR's role is to facilitate that process.

The Office of Science and Data Development has been established to facilitate the development of a consensus and understanding of the commonness and the variations in the way health care data are identified, counted, and sorted. This is an extraordinary challenge that will take a decade or more and require a sustained effort.

In fiscal year 1990, AHCPR will transfer \$5 million to the Health Care Financing Administration (HCFA) for the establishment of a service center for the data sets that exist within that agency, since HCFA is not financed to meet data requirements for outcomes research. The need is clear for HCFA to develop a data service center for researchers who want to use those data bases, and AHCPR has begun to work toward that goal this year. Hopefully, this effort will blossom as our collective efforts begin to form data linkages and move us forward toward health data that is characterized by commonness in definitions and "shorthand" codes.

The Office of Health Technology Assessment carries out the department's review of health care technologies in response to the specific requests of HCFA and **CHAMPUS**. AHCPR makes recommendations to **Fed-**

eral health care reimbursement programs directed by HCFA and CHAMPUS with regard to the safety, efficacy, and cost-effectiveness of specific technologies. These assessments are carried out by the Office of Health Technology Assessment within AHCPR.

Office of Planning and Resource Management.

Under this management umbrella are several important functions, including the Office of Program Development. The office focuses on management functions and budget systems, which must be enhanced considerably in light of the agency's new status and anticipated growth.

Conclusion

The goal of this presentation was to provide a brief overview of the Agency for Health Care Policy and Research and to show the relevance of its legislative mandate and programs to primary care. Although I have described AHCPR in an organizational fashion, I do not want to leave you with the impression that these entities work in isolation. Even though the agency is comprised of eight distinct organizational units, there is a great deal of collaboration and interaction among the centers and offices that make up AHCPR.

Hopefully, this overview has provided sufficient information to relate AHCPR's goals and activities to the sessions that comprise this conference (described in this volume) and the issues that are paramount on the primary care research agenda. These issues include:

- changing provider behavior through physician decision support systems
- research with disadvantaged populations and AHCPR's charge from Congress
- medical treatment effectiveness in primary care mental health

- research on community-oriented primary care
- health services research and prevention-disease prevention and health promotion are still prominent themes in the agency's programs
- outcome measurement issues in primary care research
- the effects of financial and organizational changes—market forces in general are an important facet of AHCPR's program initiatives
- the development of practice based networks, which need to be expanded in primary care and other health care systems
- research on primary care and rural health—this area presents a special challenge for AHCPR, since Congress has given AHCPR a specific charge in this area.

The recommendations developed during this primary care research conference* by primary care practitioners will provide AHCPR with a challenging agenda and a clearer sense of direction to set the course for the agency's primary care research program in the months and years to come.

Reference

1. The Omnibus Budget Reconciliation Act of 1989. Public Law 101-239, Title IX, Public Health Service Act, Section 6103. Washington: US Congress.

*Recommendations were developed and presented during this conference to help formulate AHCPR's agenda in primary care research. Some of these recommendations can be found scattered throughout these proceedings. A more complete discussion of the agenda development process that took place during this conference and the recommendations which arose from that process will be published in the near future as a separate volume (available from AHCPR in late fall 1990).

Changing Physician Behavior

J. Sanford Schwartz, M.D., and Stuart J. Cohen, Ed.D.

Introduction

Medical practice is both difficult and complex. The volume of information that must be learned and assimilated is huge. Much of the information is characterized by high levels of uncertainty and rapid change. Application of this information is complicated by its often contradictory nature and by the conflicting needs and preferences of patients, payors, and different classes of providers. Thus, there are few absolute indications and contraindications. Rather, the physician's task is characterized by the need to flexibly individualize decisions within the framework of rather broad guidelines and parameters.

At the same time that the physician's task and his or her environment are becoming ever more complex, the pressures on the physician are increasing. The ever rising costs of medical care (now approaching 12% of the Nation's gross national product); the accelerating development, diffusion, and use of medical innovations; and the increasing recognition of large variations in practice content that, at present, cannot be adequately explained by differences in case mix, patient preferences, or health outcomes have focused attention on developing and implementing interventions to improve physician practice and patient health.

Improvement of physician practice requires an understanding of: (1) descriptive decisionmaking (how physicians make decisions), (2) prescriptive decisionmaking (how physicians should make decisions), and (3) how to change physician behavior. This paper will review these three topics and then discuss the implications of current efforts to improve physician behavior as it impacts on

the quality of care, focusing on how these efforts might be made more effective and how they can be guided by further research in these areas.

How Do Physicians Make Decisions?

We literally make thousands of decisions daily, most with little if any conscious thought or awareness. Yet these decisions are influenced by a variety of obvious and subtle factors. It is the combination of these factors that determine what others have referred to as "practice style".^{1,2} Understanding physician decisionmaking draws on an extensive, multidisciplinary body of research (Table 1).

People suffer from significant limitations in the ability to process information. Most people are unable to consider in their short-term memory more than three to seven alternatives or hypotheses at any one time.³ Much of the information collected and available for decision-making purposes cannot be assimilated and interpreted correctly. We tend to adopt ineffective, limited search strategies and to inadequately consider alternative hypotheses.^{4,5}

There is excessive reliance on heuristics (psychological shortcuts) to make complex, probabilistic judgments under conditions characterized by substantial uncertainty. This leads to incorrect and biased decisions, the na-

Table 1. Disciplines contributing to understanding how physicians make decisions

Cognitive psychology
Communications
Diffusion of innovation
E c o n o m i c s
Education and adult learning theory
Management
Marketing and survey research
Medical decisionmaking
Sociology and social learning theory

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ture of which, in many cases, is predictable.⁶ The most common cognitive errors that lead to biased decisions include: (1) representativeness, (2) recall and salience, (3) anchoring and adjustment, and (4) framing. Thus, physicians are likely to incorrectly estimate the probability of an event if the event is similar in appearance to other conditions and events, if the event is especially easy or difficult to recall, if the frame of reference from which one is starting is incorrect, and by the context in which the issue is raised. This leads to misclassification and misinterpretation of information.

How Should Physicians Make Decisions?

Prescriptive decision aids are based on the premise that unbiased methods of decisionmaking can improve upon human decisions, given the inherent limitations in human working memory, information processing, and social behavior. Prescriptive decisionmaking methods rely on standardized (usually quantitative) methods to summarize and synthesize information for the decisionmaker, often identifying the best (or a limited set of optimal) decision options. The objective of these systems is to provide decisionmakers with unbiased analyses of problems and decision options, formally integrating a much wider range of inputs and alternatives than would be possible for an individual to consider.

The most widely used prescriptive decision aids are guidelines and algorithms, decision analyses, computer simulations, and artificial intelligence. These models usually are characterized by: formal specification of the problem; standardized, probabilistic evaluation of a broad range of information inputs (both objective and subjective), incorporating the degree of information uncertainty; and mathematical weighting of information and probabilities in determining optimal solutions. Some methods incorporate consistent application of heuristics. Artificial intelligence systems often draw on an extensive internal information base. The best systems are interactive, permitting the user to modify all aspects of the model, as deemed appropriate. The simplest systems are programs that provide automated feedback to users (such as prescription ordering systems that identify drug interactions and laboratory test ordering systems that suggest interpretation of results and subsequent work-up recommendations). While prescriptive decision support systems have significant potential as decision aids, their use has been limited thus far to highly selected, rather narrow problem domains.

Changing Physician Behavior

Behavior is a complex phenomenon. Actions are precipitated by stimuli or cues. These cues are integrated with existing knowledge through a complex series of cognitive steps referred to as information processing. The result is a judgment. In the presence of sufficient motivating factors, these judgments are transformed into decisions (intention to act). When the environment is sufficiently supportive, decisions are transformed into actions (Figure 1).

According to this model, behavioral change might be facilitated by improving knowledge, strengthening cues and stimuli, optimizing information processing, altering motivations, or modifying the environment. Improving physician decisions and decisionmaking alone may not be sufficient to improve physician practices.

Methods to change physician behavior have been classified into five categories (Table 2).^{7,8} A variety of evidence suggests that efforts to change behavior are likely to be most successful when several of these methods are combined. Most behavior is too resistant to change to be altered consistently by any one method, except in unusual circumstances or with implementation of particularly strong forms of some of these methods. Thus, efforts to alter behavior must address the multiple complex factors that influence decisions and actions (Table 3).

Administrative structure. Administrative structure may influence behavior. Changes in test-ordering forms

Figure 1. Model of factors influencing behavioral changes

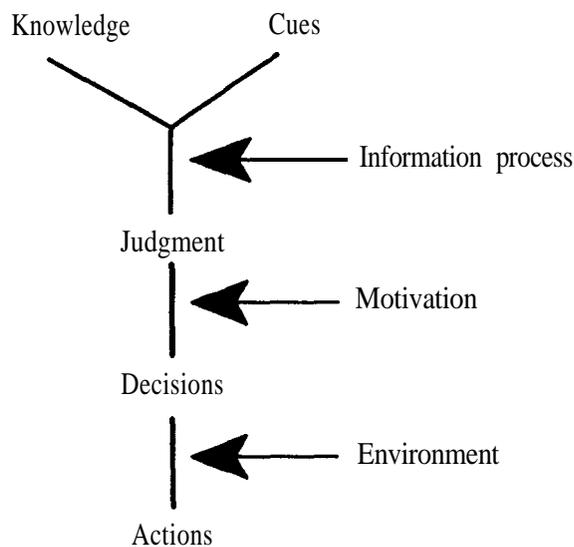


Table 2. Methods to change physician behavior

Administrative structure/process
 Education
 Feedback
 Incentives
 Regulation

requiring justifications, indications, or just additional information are a burden, and implementation of required preprocedure approval to obtain services (laboratory tests, diagnostic services, operative procedures) have been shown to influence utilization. However, use of administrative barriers to reduce utilization is limited by the induced inefficiencies and resistance engendered among providers. If the administrative barriers are not carefully targeted they will become too burdensome for providers and for those responsible for enforcement. While less well studied, changes in administrative structure also may increase provision of underutilized services, such as recommended screening tests or even recommended physical exam components. **Computer-generated reminders** have been shown to be effective in increasing the use of desired services. The use of changes in administrative structure to encourage desired behavior is underexplored and represents a potentially fruitful area for investigation.

Education. Education (provision of new information), while often necessary, usually is not sufficient to change behavior. Education lays the basis for recommended actions. Moreover, given the paradigm of scientific medicine, physicians often require strong evidence before they will even consider changing behavior. Interventions that rely solely on education and do not address the complex behavioral, social, and organizational factors that influence behavior usually are not

successful in changing behavior, underscoring the strong influence that these other factors exhibit on behavior. However, one should avoid the popular tendency to dismiss the importance and potential impact of education when combined with other factors, such as peer input. Medical practice over the past 20 years has been characterized by profound changes, most of which occurred primarily as a result of changes in clinical knowledge and information. Now there is the need to put education in perspective and to recognize that certain aspects of practice, particularly those that lie outside of the classic medical model (prevention, cost, cost-effectiveness), are more resistant to change on the basis of education alone.

The form and context in which information and innovations are presented are extremely important factors in influencing behavioral change. Thus, education must be focused in terms of appropriateness of topic, communication of the message, receptiveness of the recipient, and specificity of the message (the two or three primary points). Reinforcement of the central message through repetition and feedback is especially important. Education may be particularly effective when it is related to past **experiences**.⁸

Receptivity to change is influenced by factors that affect motivation—that is, attitudes, habits, perceptions, and values—as well as by social and organizational factors (patient demand and preferences, institutional norms). Attitudes and perceptions may overwhelm evidence. Physician attitudes and perceptions may be influenced by those of patients, other physicians, and **payors**, as well as by institutional or societal norms. Habits are particularly resistant to change. Environmental factors such as regulation and competition also can affect motivation for change.

Table 3. Relationships between decision processes and methods to change physician behavior

Decision process	Method to change behavior
Knowledge	Education (targeted)
Information processing	Education (targeted, decision support) Feedback (reinforcement)
Judgment	Education (targeted) Feedback (reinforcement)
Motivation	Incentives (behavioral, financial, social)
Actions	Administrative (structure, process) Feedback (performance) Incentives (behavioral, financial, social) Regulation

Feedback. Feedback provides an effective mechanism to reinforce the message for desired change. Given the complex set of factors that influence behavior, such reinforcement often is required to remind the **decision-maker** of the desirability, opportunity, or need for change. Feedback can be provided via impersonal means (computer profiles or reports) or by personal interaction (peer review groups, committees). Feedback is most effective in changing behavior when it is provided in a timely fashion, when provided relative to peers, and when combined with education and either incentives or administrative changes.

Incentives. Incentives are particularly powerful motivators of behavior change. Incentives may be financial or social/behavioral and either positive (rewards) or negative (penalties). In general, positive incentives are thought to be more effective than negative incentives.⁹ However, for a variety of reasons (often political in nature), there has been a reluctance to use positive incentives in medical care. Therefore, most interventions have used negative incentives. Financial incentives are among the strongest, most generally accepted, and most widely used intervention methods because of their ease of implementation. The impact of the implementation of Medicare's Prospective Payment Systems for hospitalized patients on physician use of hospitals and the effects of health maintenance organization (HMO) incentives and risk-sharing on physician use of ancillary services¹⁰⁻¹² represent examples of the power of financial incentives on physician behavior. Social and behavioral interventions also are powerful motivators of behavioral change. Peer pressure (professional acceptance, respect, and prestige) and appeals to social norms (patient expectations, societal duty, moral responsibility), while more abstract than financial incentives, may be very effective motivators of change.

Regulation. Regulation attempts to alter behavior by fiat. It is particularly resisted by professionals, such as physicians, who highly value their specialized knowledge, experience, and expertise and resent the intrusion on their professional sovereignty. Thus, regulation tends to be difficult and expensive to implement. It is often necessary to establish new administrative bodies to implement and enforce the regulations, which sometimes unintentionally restricts the rights and benefits of the intended beneficiaries of the regulation. Moreover, over time, regulated groups often gain control over the regulating body and administrative structure. Thus, at times, regulation may become counterproductive. Regulation may be effective in altering behavior, especially

when tied to strong incentives that are strictly enforced. However, it is associated with high hidden economic and social costs. Thus, its use is best limited to carefully selected and targeted areas, where the need justifies the costs and where strong social and political consensus exists.

Models for Changing Physician Behavior

There is a need for a paradigm shift (Table 4) in how we model and frame the issue of improving provider practices and, thereby, patient outcomes. Currently, much of the emphasis on changing physician practices is directed toward improving physician decisionmaking. This model places the physician at the locus of behavior. It focuses on knowledge, information processing, judgment, and motivation. Thus, interventions are weighted toward education, feedback, and incentives (social and financial). This model, however, is incomplete. While knowledge, cues, judgment, and motivation often are necessary to change behavior, frequently they are not sufficient.

An alternative model is based on the practice ecology metaphor. The practice ecology metaphor focuses on the environment in which the physician practices. It emphasizes administrative and organizational factors to change that environment, along with incentives and regulation. The environment interacts with the physician at both a micro and a macro level. For example, on a micro level, most physicians recognize that they should examine the feet of diabetics who are prone to foot infections. However, most physicians do not perform such an exam. Merely having such a patient take off his shoes or socks when placed in the exam room substantially increases the likelihood that the physician will examine the patient's feet.¹³ The patient scheduling practices employed by HMOs and **preauthorization** of services for hospitalized patients used by many insurance companies represent examples of macro environmental policies.

The difference between the two metaphors, while largely one of emphasis, has substantial implications for research and policy development and implementation. The paradigm used alters the nature of the questions

Table 4. The paradigm of changing physician behavior

Metaphor	Locus
Decisionmaking	Physician
Practice ecology	Environment

asked, how such questions are perceived and framed, and what resources will be used to address them. While the practice ecology model recognizes the importance of physician decisionmaking in improving many physician practices, it also recognizes the limitations of such a model for facilitating some changes and emphasizes the necessity of environmental factors to sustain behavioral changes, especially if motivation is lacking or if incentives are mixed or ambiguous.'

Intervention implementation. Even when an individual is motivated and interested in changing behavior, a number of barriers may inhibit such change. These may be individual (habit, lack of recall) or institutional (routine procedure) barriers that require special initiatives to be overcome (reminder systems, institution of new procedures). Organizational barriers and time pressures are especially potent and insidious and require special attention if behavior change is to be accomplished.

Thus, behavioral change is a function of the manner in which an intervention designed to change behavior is implemented, as well as the composition of the intervention. In other words, the medium is as important, if not more important, than the message. The factors that influence the effectiveness of interventions to change physician behavior include (1) communication, (2) messenger, and (3) setting.

The way in which information is communicated has significant impact on the potential effectiveness of interventions to change physician behavior. The likelihood of successfully changing physician behavior is greatly increased if the physicians who are the target of the intervention are involved in its design and **implementation**.⁷ People learn best when they are actively engaged in the learning process ("people listen best when they are talking"). Thus, interventions should be designed so that there is interactive (face-to-face) communication with learner involvement. Moreover, people become committed to the success of an intervention when they are involved in its development. The tone of the intervention also influences its effect. Success is greatest when information is presented in a collaborative, constructive fashion.

The messenger used to implement the intervention is an important factor in its success. The messenger should be a **neutral**, objective, authoritative, competent, and credible source. Innovation is facilitated by respected peers and opinion leaders.¹⁴ Professional societies, local and national opinion leaders, academic faculty, re-

searchers, and independent, nonprofit institutions are effective messengers for changing physician behavior.

The success of an intervention will be facilitated by a setting that reinforces the message. Such an environment is characterized by an aura of prestige and an informal, comfortable, constructive, and **collegial** tone and process. Personal interaction and an absence of bureaucracy further facilitate success. Especially important is the need to be efficient with the time of the target physicians. Interventions are best implemented at the local level, facilitated by well-known change agents. The great success of agricultural extension agents in changing farmers' behavior provides a promising model for changing physician behavior that warrants further evaluation than has been provided to date.

Implications for Improving Quality of Care

Based on research in this area, what can we anticipate to be the impact of alternative proposed programs designed to change physician behavior? What areas for future research are likely to be most promising and warrant highest priority?

Practice guidelines. Practice-based guidelines have attracted a great deal of attention recently as a potential mechanism for changing physician behavior. Guidelines are primarily an educational intervention, attempting to improve physician practice by reducing uncertainty in controversial areas of practice based on expert analysis of the best available information. Current proposals focus on guidelines developed by professional societies, thus drawing on the advantages derived from professional participation in the process and from the presence of an authoritative, credible, respected source.

Informational guidelines used to change physician behavior are unlikely to be successful in and of themselves. There is little consensus of how guidelines should be implemented, beyond as an educational tool. Although the use of practice guidelines to develop regulations by payors has been widely advocated, it has not as yet been convincingly demonstrated and it is likely to be of limited effectiveness. Practice guidelines are most likely to be successful when they are developed and implemented at the local level. Such guideline-driven regulation is likely to be most effective in those areas where there is substantial consensus and limited uncertainty **regarding appropriate practices, but where there remain large** deviations from these well accepted norms. However, to the degree that guidelines focus on the most difficult aspects of medical care where there is substantial

uncertainty and controversy, they are likely to be less successful or even counterproductive to the degree to which they become incorporated into regulation. Medical practice is **difficult** in such circumstances, even under the best of conditions. It is unlikely that quality medical care can be practiced by algorithm-driven, nonphysicians devoid of patient input about their values and preferences among the risks and benefits involved. Moreover, regulatory programs, despite their original intent to be administered flexibly, often drift into rigid implementation as a result of the bureaucratic tendencies of regulatory organizations. The frustrations that often accompany the less-than-anticipated success of these programs may antagonize the decisionmakers with whom a collaborative effort is sought. Administrative burdens are increased. Finally, such programs are expensive to administer and operate and entail risks of reducing efficiency, reducing quality of care, and jeopardizing professional **cooperation**.⁹

Practice guidelines may reduce uncertainty through explicit articulation of professional consensus, and they may identify priority areas for clinical, epidemiological, and health services research. Guidelines may predispose physicians to consider changing their behavior, but unless coupled with other incentives and interventions, they are unlikely to effect rapid change in actual practice.

Physician payment/financial incentives. Financial incentives have been demonstrated to cause large behavioral changes when of sufficient strength and when coupled with generally accepted practice and theory. Perhaps the most striking recent example of this is the change in practices that occurred subsequent to implementation of Medicare's prospective payment-based diagnosis related group (DRG). There were large, sustained reductions in hospital length of stay associated with implementation of the program. The impact of financial incentives directed at physicians is less clear. Managed care systems (HMOs, PPOs) have adopted financial incentives for physicians of variable strength, with limited documentation of their effects. Thus, most of the efforts in this area are being driven by economic theory, in the absence, thus far, of convincing empirical evidence of their impact.

It is likely that financial incentives of sufficient strength will alter physician behavior, although the degree to which such changes occur and the pattern of the changes are not known. Also the impact of such changes on quality and outcomes of care is unclear. There is the danger that strong financial incentives might dominate

practice decisions to the detriment of patient care. Of particular concern is the potential physician conflict of interest between what is in his or her financial "best interests" and the health interests of the patient, in which the patient is protected only by the physician's values of duty to the patient.¹⁰⁻¹² Given the subtlety and complexity of most medical decisions, this is of considerable concern.

Financial incentives are highly political. Opportunities for their adoption will be increased to the degree that interest groups are recognized and balanced, to the degree that the rationale for such incentives is consistent with the medical model (take into account differences in case mix factors such as disease severity and comorbidity), and to the extent that providers have meaningful input into the development and implementation of such programs. Financial incentives may provide an effective mechanism to improve quality and the cost-effectiveness of care when combined with practice guidelines, if the incentives are not too strong.

Regulation. Regulation, while expensive, intrusive, and cumbersome, will continue to play an important role in health care.^{15,16} The effectiveness of regulation (certificate-of-need for hospital capital expenditures) has been **demonstrated**,^{17,18} although its impact has not been as great as was expected, and often it has led to unintended and undesired effects.¹⁹ In part, this is due to the tendency of the targets of regulation to control the regulatory process over time, the difficulty and expense of enforcement at the level of physician **decisionmaking**, and the ability of local decisionmakers to find ways around even the most carefully crafted regulations within their unique local **environments**.²⁰⁻²² The financial and organizational costs of regulation have led to widespread dissatisfaction and discontinuation of regulatory programs, such as certificate-of-need. Regulation of physician decisionmaking is especially difficult and likely to be even less successful and more frustrating than regulations aimed at organizations and institutions.

Outcome assessment. Another major initiative involves determination of the impact of medical practice on health outcomes. Documentation of large variations in patterns of care across small and large areas unexplained by other factors has highlighted the need to assess the impact of health **practices**.^{1,2} However, variations are a problem that is worthy of interest only to the degree that the variations indicate misuse of health care resources and reduced levels of outcome. Information about the relationship between physician practices and

health outcomes is only a preliminary step to changing physician behavior and improving health outcomes.

A broad range of important research issues must be examined if the knowledge gained through outcome assessment is to result in improved quality of care. What are the most effective methods for presenting this information to physicians, other providers, patients, and payors? How often is this new information used by providers or patients? How often does such information identify new problems? How often does it lead to altered management of patients? How often is patient health improved by the induced changes in physician behavior? What factors influence and determine the use, impact, and value of such information?

Organizational and administrative structure. Organizational structures have the potential to alter physician practice through their combination of methods to change physician behavior and are the focus of a great deal of interest by those seeking to change physician behavior. Organizations, such as HMOs and other managed care groups, permit financial incentives, education, participation, guideline development, peer pressure, and regulation to be applied concurrently and in an integrated fashion at the level of the practice. Components of organizational change, such as utilization review, local guideline development, and second opinion programs, have been adopted by many local medical groups and institutions.

There has been considerable growth of new provider organizations and in the adoption of various administrative components. However, the characteristics that are associated with adoption of these interventions and the impact of the interventions on physician practice have not been well studied. Those studies that have been performed tend to be nonexperimental and do not use state-of-the-art quasi-experimental and nonexperimental designs. Adjustment for baseline characteristics, regression to the mean, and case mix (disease severity and comorbidity) are uncommon.

Research Strategies

Topic selection. The potential issues and practices available and in need of study to change physician behavior far exceed the health services research resources available. Thus, the limited available research resources should be allocated to those practices that offer the greatest potential to improve the health of the public. The factors to consider in determining the potential clinical value and policy impact of health services research

include the prevalence of the condition, the costs (direct and indirect) associated with the condition, the potential impact for changing practices, the potential impact on patient health, and the generalizability of the results;

Generalizability. Most efforts to change physician behavior have been focused on house staff and teaching hospitals. Most likely, this focus has occurred because investigators, who are concentrated at these institutions, feel more comfortable at and better understand these institutions and find them to be more receptive to study. However, the vast majority of clinical medicine is practiced in the general community, not in teaching hospitals. Thus, the generalizability of the results of interventions to change physician behavior is unknown and, probably, rather limited. Future studies should be focused on routine, nonteaching practice settings.

Effectiveness vs. efficacy. Research to change behavior should focus on the effectiveness of interventions (the impact under average conditions), rather than upon efficacy (impact under ideal or optimal conditions). Performance of studies and interventions in community settings represents one aspect of effectiveness vs. efficacy. Similarly, effectiveness requires intervention designs that are subject to replication in other settings and environments.

Practice organization and structure. The impact of practice organization and structure on physician practices warrants much greater investigation. The microenvironment of practice offers the potential to alter physician behavior in an effective, efficient, and acceptable fashion. This will require a better understanding of the impact of administrative structure, nonphysician inhabitants, local resources, and local barriers on physician behavior. A related area of study deals with intermediary organizations, those groups that are interposed between physicians and either patients or payors. Such organizations appear to be growing rapidly and have not even been adequately described. Very little is known about their roles in medical practice and their impact on physician behavior.

Impact vs. mechanism studies. Interventions to change physician behavior and practice can focus either on the impact of the intervention (Does it work?) or on the mechanism of the intervention (Why does it work?). While mechanism studies often are more attractive intellectually, the current limited state-of-the-art and the difficulty in changing physician behavior argue for a focus on impact studies until effective methods to change physician behavior are identified, developed, and implemented.

Funding Sources

There are many needs and opportunities for research into changing physician behavior, and there are significant research resources available. The Agency for Health Care Policy and Research (AHCPR) has funds to support both basic and applied research in changing physician behavior. The new Patient Outcome Research Teams (PORTs) have, as a major objective, study of mechanisms of changing physician behavior and development, implementation, and evaluation of effective programs to change physician behavior to improve the outcomes of care. Health services research funds from the AHCPR and funds from the National Science Foundation (NSF) support research to improve understanding of how physicians actually make decisions and the nature of the factors that influence such decisions, although the commitment to funding research in these areas is not as strong as that for outcomes research. AHCPR, along with the National Library of Medicine, funds research on the development of improved prescriptive decisionmaking and decision support systems. The National Institutes of Health (NIH) fund similar research in the disease areas related to individual institutes. Nonprofit health care foundations likewise fund demonstration programs in selected areas, through which such research can be conducted.

Summary

There is a consensus that the current health care system suffers from problems related to cost, quality, and sub-optimal practice patterns that have been resistant to change. Given the central role of the physician in the medical care system, fundamental changes in these areas of medical practice will require substantial changes in physician behavior. This is a complex and difficult task under any circumstances, made even more complicated and difficult by the need to ensure that such changes ideally result in improved medical care and health outcomes (or, at a minimum, do not jeopardize patient health in the long or short run).

A great deal is known about the elements required to change physician behavior. However, many of these principles often are ignored, while quicker, easier fixes are sought (usually with disappointing results). As we enter an age in which substantially more information will be available regarding the outcomes of medical practices, there is an urgent need to learn how to change physician behavior more effectively and efficiently.

To facilitate changing physician behavior, there must be a paradigm shift from a focus on the physician to a focus on the environment in which medical care is delivered. While behavior change may occur without concurrent environmental change, such environmental change often is required to reinforce the behavior change and to make it permanent.

Research on changing physician behavior is complex, and the issues are multifaceted. As such, a multidisciplinary approach is required to develop and implement effective interventions. The state-of-the-art of changing physician behavior is such that research should be impact-oriented (what works) rather than mechanism oriented (why it works). If the goal of such research is to change the behavior of practicing physicians, the research must be generalizable to these physicians.

There are many needs and opportunities for research into changing physician behavior. Fortunately, significant research resources are available to support this work.

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Policy Research with a Disadvantaged Population

Lawrence Miike, M.D., J.D.

Introduction

What makes a particular population disadvantaged, and why are minorities disadvantaged? With regard to health, the term “disadvantaged” is characterized by health deficiencies, which may be defined broadly or within a particular context.

Within the Federal Department of Health and Human Services, two offices have been principal contributors to the definition of “disadvantaged populations.” These are the Office of Minority Health and the Division of Disadvantaged Assistance within the Bureau of Health Professions, Health Resources and Services Administration. These Federal entities have defined disadvantaged populations as “those disadvantaged by **race/ethnicity**, socioeconomic status, or gender.”* In the programmatic context, there are such programs as the National Cancer Institute’s Special Populations Studies Section, whose efforts are focused on populations at high risk for cancer—namely, blacks, Hispanics, Native Americans (Alaska Natives, American Indians, Native Hawaiians), Asian Americans, the aging, blue-collar groups, and low-income groups.*

These definitions show that, although the “disadvantaged” label is wide-ranging, grouping on an ethnic basis predominates. The increased health risks of minorities result from a combination of their socioeconomic status and incompatibilities between their cultures and mainstream health care. There are financial barriers to receiving care and cultural barriers to using the care for which disadvantaged persons are eligible or entitled.

Socioeconomic and cultural/ethnicity factors are usually intertwined. The basic factors underlying the “disadvantaged populations” label are usually economic and social. Ethnic groups that are at an economic and

social disadvantage often have the additional factor of cultural barriers and conflicts that contribute to their relative disadvantage. A common finding among certain ethnic groups is low income and its sequelae, which reduce access to health services and may contribute to less concern over behaviors that are risky to health. Low use of health services may also be partly a result of cultural influences that are ethnicity-based, such as suspicion of or incompatibility with mainstream health services; or, the cultural factor may be primarily socioeconomic rather than ethnic, such as a “blue collar” culture.

While each disadvantaged population is certainly unique, they also share common characteristics. For example, poor health manifests itself in similar ways among all disadvantaged populations. Commonly, they suffer the same major diseases as the general population, but more severely, because of poor access to and utilization of health care.

Similarly, common health care policy and research issues are found among all disadvantaged populations. **By** examining a specific disadvantaged population in some detail, policy and research issues clearly emerge that are also found when other disadvantaged populations are examined. This discussion will focus on the Native Hawaiian population residing in Hawaii. In the interests of brevity, commonalities between the health problems of Hawaiians and those of other disadvantaged populations will not be explored. However, these commonalities do exist, and they will emerge whenever **disadvantaged** populations are studied.

Health Care Policy and Research Issues

The following policy and research issues are of particular concern with regard to disadvantaged populations. This list is not exhaustive; instead, it puts forth a variety of issues that will be discussed from the perspective of health care for Native Hawaiians.

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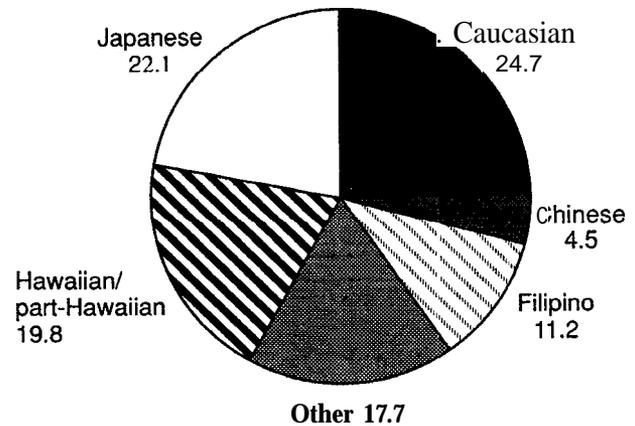
1. Data limitations
2. Methods for developing organizational capacity at the local level to plan for and provide services
3. The community's role in and concern about research conducted in the community
4. Effectiveness of alternative methods of treatment (including traditional versus Western methods) for selected conditions
5. Effects of legislative and administrative environments on programs that attempt to implement health care policies
6. Health services provided in nonmedical settings
7. Effectiveness and cost-effectiveness of health promotion and disease prevention programs

The Health Status of Native Hawaiians

Native Hawaiians, or persons of Hawaiian ancestry (Hawaiians and part-Hawaiians), presently comprise approximately 20 percent of the residents of the State of Hawaii (Fig. 1). Native Hawaiians are also the fastest-growing ethnic group in Hawaii because of a high rate of intermarriage between Native and non-Native Hawaiians (all offspring from such unions are part-Hawaiian and thus Native Hawaiian). While the part-Hawaiian population is young and growing rapidly, the Hawaiian population is old and rapidly diminishing. In 1986, there were less than 700 Hawaiians 18 years of age or younger compared with nearly 93,000 part-Hawaiians in the same age group; Hawaiians comprise less than 4 percent of the total Native Hawaiian population residing in Hawaii, as shown in Table 1.

In the State of Hawaii, Native Hawaiians as a group are overrepresented in the lower income categories and underrepresented in the upper income categories. Figure 2 reveals that in 1986 Native Hawaiians comprised 36.4 percent of families with yearly gross incomes under \$10,000, but only 14.4 percent of Native Hawaiian families were in the over-\$40,000 bracket.

Figure 1. State of Hawaii, 1986; ethnic percentage distribution



SOURCE: State Department of Health, Health Surveillance Program

On an age-adjusted basis, Native Hawaiians have a mortality rate that is 34 percent higher than that of the United States as a whole (Table 2). Because of the overwhelming number of part-Hawaiians compared with Hawaiians, the Native Hawaiian mortality rate largely reflects the part-Hawaiian population. Indeed, if mortality rates were calculated separately for the Hawaiian and part-Hawaiian populations, Hawaiians would have an overall mortality rate that is 146 percent higher than the US mortality rate, while the part-Hawaiians' mortality rate would be 17 percent higher.³ Relative to each other, Hawaiians have an overall age-adjusted mortality rate more than 100 percent higher than part-Hawaiians (Table 3).

There is much evidence that this high mortality rate can be reduced substantially. For example, Native Hawaiians have cancer incidence rates comparable with whites in Hawaii (i.e., 380.4 per 100,000 among whites and 387.02 per 100,000 among Native Hawaiians, a 2% difference). However, mortality rates from cancer among Native Hawaiians are **211.73** per 100,000, compared with a white mortality rate of 165.4 per 100,000—a difference of 28 percent (Fig. 3). Certainly a plausible hypothesis would be that this difference in mortality is due to late diagnosis and/or inadequate treatment.

Like other ethnic groups (such as other Native Americans, blacks, and Hispanics), Native Hawaiians have high prevalence rates for diabetes.⁴ For this disease, there is little difference between Hawaiians and part-

Table 1. Age frequency distribution: 1986 Native Hawaiians vs. other ethnic groups

Age groups	Total Hawaiians	Pure Hawaiians	Part Hawaiians	Other ethnic groups
Total	204,716	7,892	196,824	827,738
0- 9	48,422	202	48,220	120,185
10 - 18	45,160	450	44,710	114,731
19-24	24,742	817	23,925	83,702
25 - 34	32,154	1,260	30,894	163,265
35 - 44	20,283	1,235	19,048	102,700
45 - 54	17,536	1,629	15,907	84,793
55 - 64	9,748	1,021	8,727	83,280
65 +	6,671	1,278	5,393	75,082

SOURCE: Analysis based on data tapes provided by the Health Surveillance Program, Hawaii Department of Health, November 1989

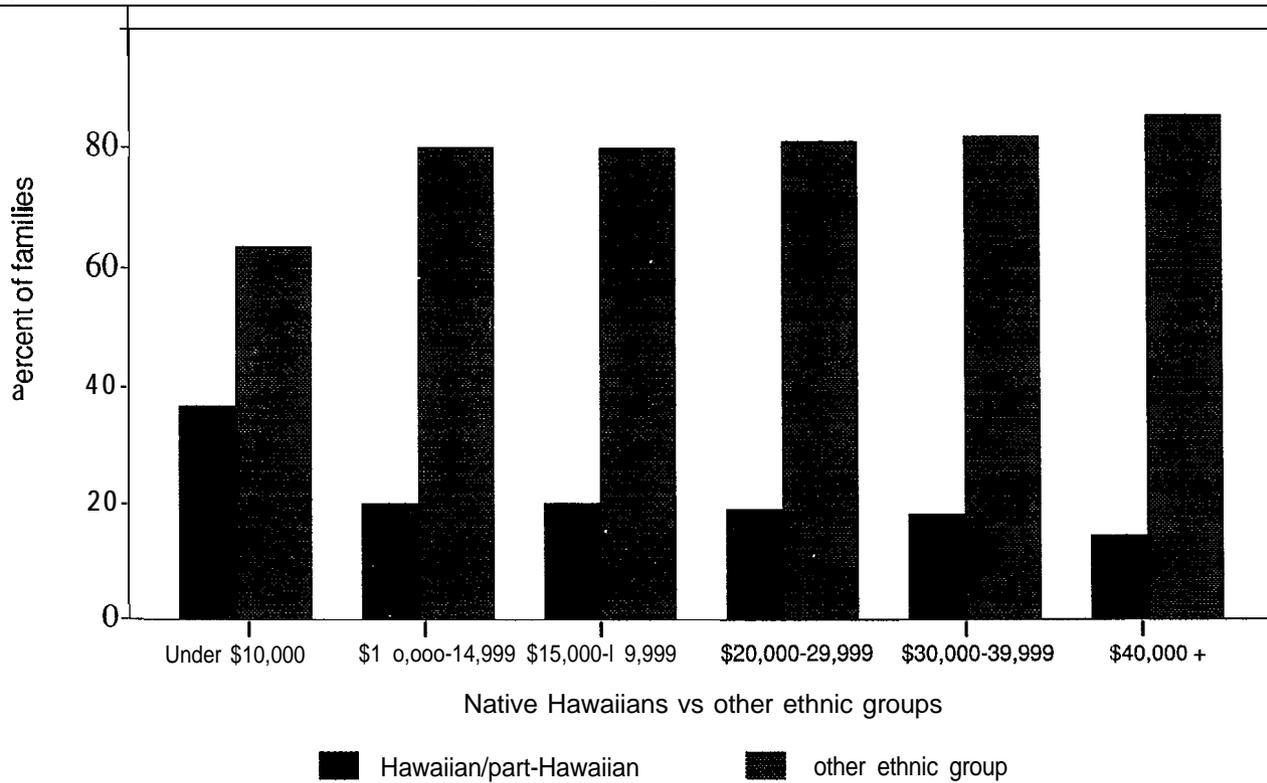
Table 2. Native Hawaiians, both sexes: Leading causes of death and comparison with all races in the United States

Rank	Cause of death	No. of Deaths	Age-adjusted death rate		
			Hawaiian	U.S.	Ratio
	All causes	888	739.2	552.2	1.34
1.	Diseases of the heart	297	273.0	189.7	1.44
2.	Malignant neoplasms	204	183.9	132.6	1.39
3.	Accidents & adverse effects	55	33.0	36.0	0.92
4.	Cerebrovascular disease	50	46.1	35.1	1.31
5.	Diabetes Mellitus	32	29.0	9.8	2.96
6.	Certain conditions originating in the perinatal period	28	8.9	8.5	1.05
7.	Pneumonia & influenza	21	18.1	11.4	1.59
8.	Congenital anomalies	17	6.1	5.6	1.09
9.	Suicide	17	9.4	11.5	0.82
10.	Other diseases of arteries, arterioles, and capillaries	11	9.6	5.3	1.81
11.	All other infectious and parasitic diseases	10	8.3	1.6	5.19
12.	Homicide and legal intervention	10	6.3	9.2	0.68
13.	Chronic liver disease and cirrhosis	9	7.7	10.4	0.74
14.	Chronic obstructive pulmonary disease and allied conditions	8	6.5	16.8	0.39
15.	Nephritis, nephrotic syndrome, and nephrosis	6	5.5	4.6	1.20
	All other conditions	113	87.8	64.5	1.36

Note: By age-adjusted deaths per 100,000 population, 1980-1985 (yearly average).

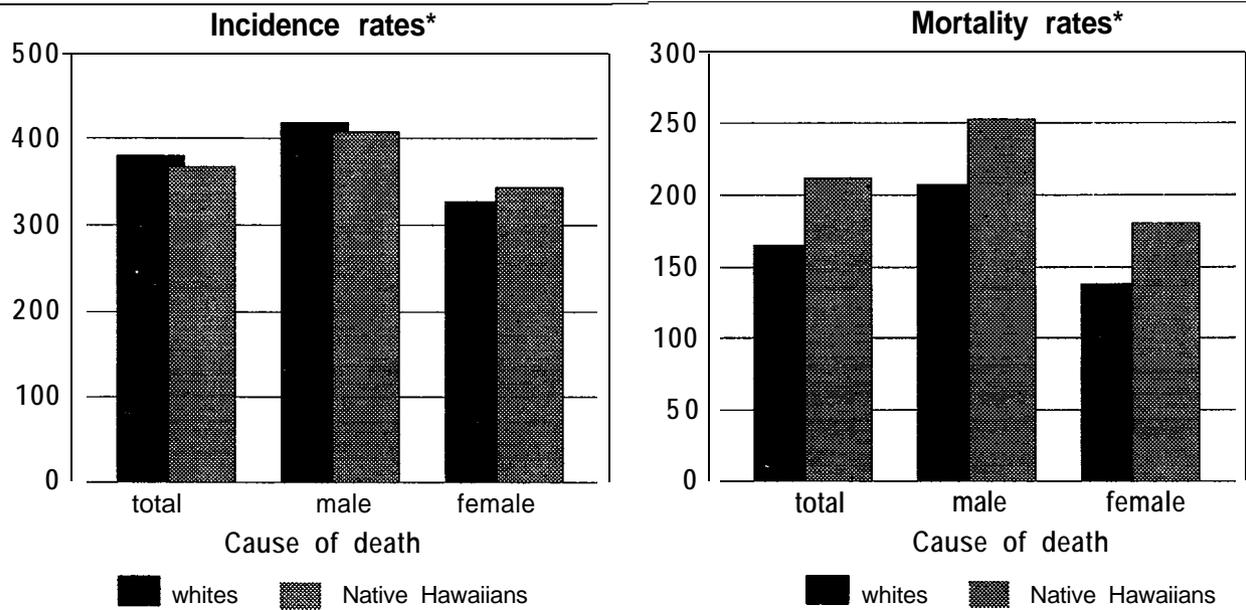
SOURCE: United States Congress, Office of Technology Assessment, "Current Health Status and Population Projections of Native Hawaiians Living in Hawaii" (Staff Paper), Washington; April 1987.

Figure 2. State of Hawaii, 1986; family gross income per year



SOURCE: State Department of Health, Health Surveillance Program

Figure 3. Rates for all cancers per 100,000 persons



*age-adjusted incidence

Source: State of Hawaii: 1982-86
State Department of Health, Tumor Registry

Source: State of Hawaii: 1982-86
State Department of Health, Vital Statistics

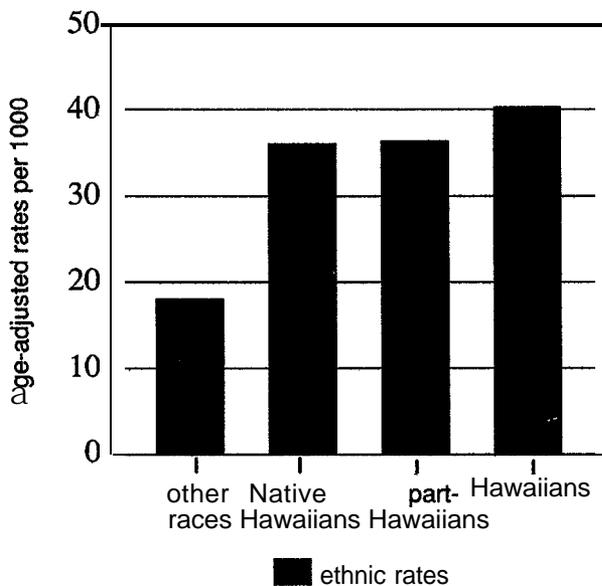
Hawaiians (Fig. 4), and nearly all of the diabetes among Native Hawaiians is noninsulin-dependent diabetes mellitus (NIDDM), or Type II diabetes (Fig. 5). Thus, the most important risk factors for the high diabetes rate among Native Hawaiian and other ethnic groups are probably external and not genetic (e.g., obesity and other lifestyle/environmental factors).

In fact, Native Hawaiians lead all other ethnic groups in Hawaii in six of eight selected behavioral risk factors—seatbelt nonuse, obesity (an astounding 41.9% of Native Hawaiians consider themselves overweight, compared with a Statewide average of only 18.1%), smoking, acute drinking, heavy drinking, and drinking and driving. Native Hawaiians are second to the Japanese in hypertension, and below average only for sedentary lifestyle (Fig. 6).

The Native Hawaiian Health Care Act of 1988

Under Public Law 100-579, the Native Hawaiian Health Care Act of 1988, up to nine Native Hawaiian health care systems have been authorized: two on the island of Kauai that also will serve Niihau; two on Oahu; one on Molokai that also will serve Lanai; two on Maui; and two on Hawaii.

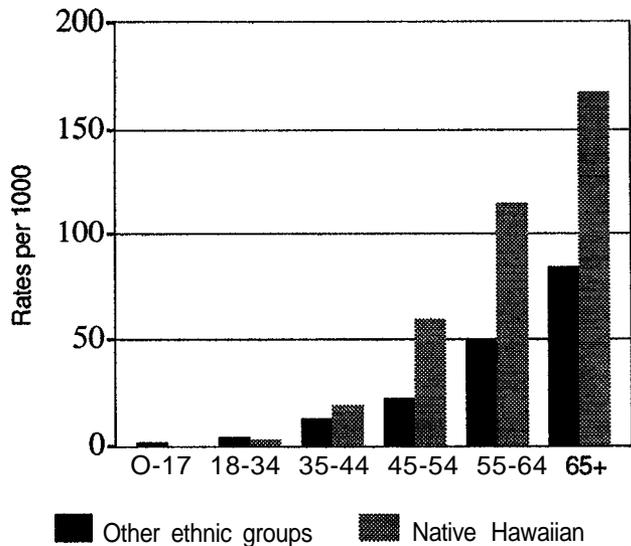
Figure 4. Age-adjusted prevalence of diabetes; State of Hawaii, 1986



Note: Standardized by population of other races.

SOURCE: State Department of Health, Health Surveillance Program

Figure 5. Prevalence of diabetes by age groups; State of Hawaii, 1986



SOURCE: State Department of Health, Health Surveillance Program

In essence, the Act provides for the establishment of supplemental health services in primary care, health promotion, and disease prevention. Each system will be governed by the Native Hawaiian community, with substantial participation by health practitioners of Native Hawaiian ancestry, including traditional healers. The legislation stipulates that the following services must be provided:

- outreach efforts to inform Native Hawaiians of the availability of health services
- education in health promotion and disease prevention among Native Hawaiians by Native Hawaiian health care practitioners (whenever possible), community outreach workers, counselors, and cultural educators
- services of physicians, physicians' assistants, or nurse practitioners
- prevention and control of diabetes, high blood pressure, and otitis media
- prenatal and infant care
- improvement in nutrition.

In addition, the following services may be provided:

- other services within the meaning of the terms “health promotion,” “disease prevention,” and “primary health services,” as defined in the Act
- provision of health care services by traditional Native Hawaiian healers
- identification, treatment, control, and reduction of the incidence of preventable illnesses and conditions endemic to Native Hawaiians.
- collection of data related to prevention of diseases and illnesses among Native Hawaiians.

During the first year (fiscal year 1990), planning for these health care systems will take place through Papa Ola Lōkahi, a new organization created by the Act. This organization also has the responsibility to develop an overall Native Hawaiian master plan and provide policy guidance and technical assistance once the health care systems are established. Papa Ola Lōkahi (literally meaning “board of health in unity”) consists of:

1. Alu Like, Incorporated, a private nonprofit Native Hawaiian service and training organization
2. E Ola Mau, a private, nonprofit organization of health professionals of Native Hawaiian ancestry
3. the Office of Hawaiian Health of the State Department of Health
4. the Office of Hawaiian Affairs of the State of Hawaii
5. the University of Hawaii.

Following the planning year, community-based Native Hawaiian organizations will apply to the Federal Department of Health and Human Services (DHHS) for service delivery funding. Papa Ola Lōkahi must recognize and certify the organizations as having the capacity to provide the services, and DHHS will make its funding decisions in consultation with Papa Ola Lōkahi. Figure 7 summarizes the relationships between DHHS, Papa Ola Lōkahi, and the community-based Native Hawaiian service delivery organizations; authorization levels; and actual fiscal year 1990 appropriations.

Data Issues

Underlying the population and health statistics summarized above are specific assumptions on who comprises the Native Hawaiian population and which one of

two quite different population estimates should be used. For the purposes of this analysis, “Native Hawaiians” will be persons with any degree of Hawaiian ancestry on a self-identified basis. (The degree of Hawaiian blood quantum that a person of Hawaiian ancestry has is important in the State of Hawaii for the purpose of determining eligibility for benefits derived from Hawaiian Homelands, where a person must have at least 50% Hawaiian blood quantum to qualify. Blood quantum is also an issue among many American Indian tribes insofar as tribal membership is concerned.)

Self-identification on the basis of any degree of ethnic-specific ancestry is also the method of identifying and quantifying other ethnic groups. But, questions about the validity of data sources arising from self-identification may not be as apparent with other ethnic groups as they are in the Native Hawaiian population.

Prior to the 1970 Census, there were separate reporting categories for Hawaiians and part-Hawaiians. Beginning with the 1980 Census, the “short form” filled out by all persons asked only that the subject select the ethnic group that best described him or her. The “long form” asked some persons additional questions about their ancestry. In the 1980 Census, an estimated 118,251 persons identified themselves as Hawaiians, and an estimated 136,341 persons answered that they had some degree of Hawaiian ancestry.

In contrast, the Health Surveillance Program (HSP) conducted annually through Hawaii’s Department of Health on 2 percent of households in the State, estimated that there were 175,909 persons of Hawaiian ancestry residing in Hawaii in 1980 and that more than 90 percent of these were part-Hawaiian.³ In the HSP, respondents are asked to identify the race or combination of races of their father and mother. Respondents are placed in one of eight possible ethnic categories as derived from their fathers’ and mothers’ ethnicity: 1) Caucasian, 2) Japanese, 3) Filipino, 4) Chinese, 5) pure Hawaiian, 6) other pure unknown, 7) mixed: part-Hawaiian, and 8) mixed: non-Hawaiian and others. Anyone who is of mixed ancestry that includes “Hawaiian” is placed in the “mixed: part-Hawaiian” category.

During the period 1980 to 1985, the HSP estimated that an annual average of 184,841 Native Hawaiians lived in Hawaii, 8,134 Hawaiians and 176,707 part-Hawaiians.³ The difference between HSP’s 8,134 Hawaiians and the Census Bureau’s 118,251 persons who best identified with the “Hawaiian” category reflects the fact that the HSP’s estimate was blood quantum-derived

(persons with both parents identified as “Hawaiian” only), while the Census estimate was of those persons who considered themselves Hawaiian, probably through cultural affinity as well as through their degree of Hawaiian blood quantum. For example, in a mid- 1980s survey conducted by the State Office of Hawaiian Affairs, even though more than 95 percent of Native Hawaiians were part-Hawaiian and less than 40 percent of Native Hawaiians had 50 percent or more Hawaiian blood quantum, 69 percent believed they had a Hawaiian lifestyle.⁵

Determining how many Native Hawaiians reside in Hawaii and selecting data sources are crucial issues in providing supportive information for the Native Hawaiian Health Care Act of 1988. The HSP estimates were used because they could be checked for consistency through the yearly surveys, and they seemed more reliable than the Census estimates. Another consideration was that use of the HSP would result in significantly lower morbidity and mortality rates for Native Hawaiians, because the estimate chosen would provide the denominator for calculating rates, and the HSP estimate was significantly larger than the Census estimates.

Thus, the resulting estimates of health status might be an understatement of the health problems of Native Hawaiians, but they could not be criticized for advocating special treatment for Native Hawaiians by overstating their health problems.

Another limitation of even the HSP data is that Native Hawaiians are subcategorized into Hawaiians and part-Hawaiians. This places statistical limitations on some of the data analyses. For example, the Hawaiian mortality rates reflected in Table 3 are based on an annual average of only 2 13 total deaths among the Hawaiian population (total deaths among the part-Hawaiian population was an annual average of 673). “Hawaiian” could be acting as a proxy for poor access to medical services due to cultural barriers, low income, living in rural areas, and so forth, as well as the possibility that there could be a genetic aspect to the difference in health status between Hawaiians and part-Hawaiians. On the other hand, the part-Hawaiian population is a very diverse group, many of whom would be indistinguishable from non-Native Hawaiians socially, economically, and even culturally. Collective analyses of Native Hawaiians would reflect the characteristics of the part-Hawaiian

Table 3. Comparison of age-adjusted yearly average death rates per 100,000 population for Hawaiians and part-Hawaiians (both sexes) by selected leading causes of death, 1980-1985

Causes of death	Age-adjusted death rate		
	Hawaiian	Part-Hawaiian	Ratio
All causes	1,357.5	645.2	2.10
Diseases of the heart	525.1	230.1	2.28
Malignant neoplasms	299.1	162.8	1.84
Diabetes mellitus	67.4	26.6	2.53
Cerebrovascular disease	86.1	38.3	2.25
Other diseases of arteries, arterioles, and capillaries	12.1	9.2	1.32
Nephritis, nephrotic syndrome, and nephrosis	10.2	4.4	2.32
Accidents and adverse effects	76.8	30.1	2.55
Suicide	11.8	9.1	1.30
Homicide and legal intervention	19.4	5.6	3.46
Pneumonia and influenza	35.6	14.7	2.42
All other infectious and parasitic diseases	15.0	7.9	1.90
Chronic obstructive pulmonary diseases and allied conditions	15.4	5.4	2.85
Chronic liver disease and cirrhosis	7.9	7.9	1.00

SOURCE: United States Congress, Office of Technology Assessment, “Current Health Status and Population Projections of Native Hawaiians Living in Hawaii” (staff paper): Washington: April 1987.

population, so whether or not it is statistically valid, there are sufficient reasons for providing collective analyses of Native Hawaiians and separate analyses of Hawaiians and part-Hawaiians.

For policymaking purposes, such as the Native Hawaiian Health Care Act of 1988, this level of analysis is sufficient. For program implementation and effectiveness, the challenge will be to identify and address those within the broad category of "Native Hawaiian" who are most in need.

Developing the Community's Organizational Capacities

Not surprisingly, local communities resent centrally directed programs. Under the Hawaiian Health Care Act, each of the health care systems to be established will be governed and administered by local Native Hawaiian organizations. In the planning stages, this translates into dual objectives: (1) developing the organizational capacity at the local level to plan for and provide services, while simultaneously (2) planning for such services through these local organizations. Each island differs in the extent to which its Native Hawaiians are already organized, and that issue must be confronted. However, local and island-specific efforts must also proceed within a larger Statewide system. So there must be a substantial degree of local and island autonomy in determining the extent and configuration of services to be provided, but these individual efforts must somehow comprise a Statewide system that contributes to the sense of community among the State's Native Hawaiians.

These empowerment, organizational, and capacity-building objectives are somewhat akin to two health services research issues:

1. building the capacity in a disadvantaged population to determine and provide appropriate health services to its community
2. making more effective use of existing resources, especially in rural areas, where there is a relative lack of services and where systems-building and coordination are especially crucial.

These are difficult concepts to convey in this brief analysis, but the gist of the issues will become more apparent in the following section.

The Community's Role in Research Activities

In February 1990, Papa Ola Lōkahi sponsored a meeting of researchers interested in Native Hawaiian issues. During the meeting, the community's role in and concerns about research conducted in Native Hawaiian communities were addressed by a panel of Native Hawaiian community leaders and organizers.* Discussions focused on the following areas: governance of the research project, project design, benefits to the community, ownership or control of information generated by the research, **followup** activities, and implications for the agencies funding the research. The following message emerged from the meeting. Communities want to participate in all phases of the project, from initial conceptualization to completion and followup, and they want to do more than provide advice, they want to share in the governance of the project. This is embodied in community representation on the governing board of the project, not just on a community advisory board.

Researchers should not assume that Native Hawaiians are not capable of understanding the underlying science and the research methods. The grant application and research methods must also be acceptable to the community. This means that researchers must allocate more time than they are accustomed to in initiating, planning, and putting the grant application together.

Research proposals most acceptable to the community are those with direct and immediate benefits to the community. What these benefits actually consist of is determined on a project-by-project basis. What is most important is that the Native Hawaiian community be involved in identifying what the benefits are in the research proposal. Benefits can include direct services to individual members of the community as part of the project design, or they can be more broadly defined, such as assisting in the training of Native Hawaiians so that more Native Hawaiians are available to serve Native Hawaiians.

Information generated in the community should be under the control of or at least available for reasonable use by the community. The various aspects of this issue include: 1) who keeps or has copies of the data, 2) reasonable and limited access to data before research results are published, and 3) confidentiality concerns. Finally, researchers need to identify the purpose of the research and specify the **followup** activities that will take place within the community.

Table 4 is the unedited, original attempt by the Waianae District Comprehensive Health and Hospital Board, Inc., the governing body of the Waianae Coast **Compre-**

hensive Health Center (WCCHC), to develop criteria for a proposed cancer research project at the WCCHC by the Cancer Research Center of Hawaii. The goals and objectives expressed here reflect the goals and objectives of minority initiatives in the agenda of research programs in general, including that of the Agency for Health Care Policy and Research (AHCPR) -for example, to be culturally sensitive, provide appropriate services through community input, and increase the capacity and numbers of ethnic researchers.

Effectiveness of Alternative Methods of Treatment

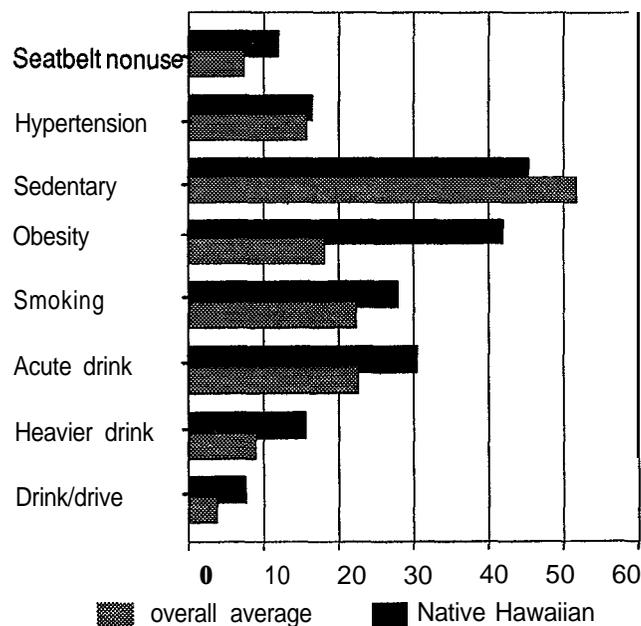
Inclusion of the services of traditional healers in the forthcoming Native Hawaiian health care systems has generated interest in many Native Hawaiian communities. Many traditional healers have kept a low profile while continuing to serve Native Hawaiians, but there are now initial efforts by traditional healers to develop voluntary guidelines/standards on what such practices consist of and who is capable of providing such services. Difficult issues as yet unaddressed and unresolved include validation of these practices and the exact role of traditional healers in the Native Hawaiian health care systems, such as types of diseases and conditions they may treat, either as an alternative to or in conjunction with Western medical care.

It would be a mistake to focus solely on the validity and appropriateness of traditional healing practices. It is also important to learn about the validity and appropriateness of specific Western-based approaches to selected conditions and diseases. Traditional healing practices and the respect many Native Hawaiians have for these healers may provide an avenue to substantially address the high-risk behaviors that threaten the health of many Native Hawaiians (see Fig. 6).

The Legislative and Administrative Environment

Even the most well-thought-out policies will fail if the environments in which they are implemented and have to operate are not supportive. These are difficult times for new domestic initiatives. Getting over the legislative hurdle is difficult enough; additional difficulties await in the form of year-by-year appropriations and reauthorizations of legislation, which are typically authorized for 3-year periods.

Figure 6. Selected behavioral risk factors; morbidity and mortality



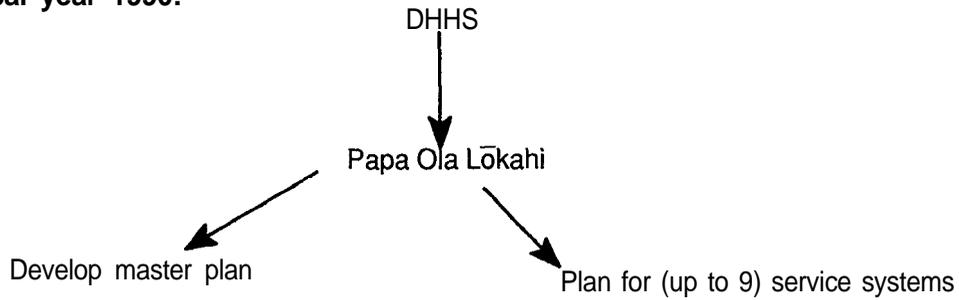
Source: State Department of Health, Health Promotion and Education Office, Telephone Survey, 1987

Furthermore, the time allocated for program implementation also leads to difficult situations. For example, with the Native Hawaiian Health Care Act, organizational activities and operational planning for the service delivery systems are supposed to be accomplished, starting from scratch, within the first fiscal year. On the other hand, if it takes a little longer, the Native Hawaiian communities will become increasingly dissatisfied with promises unfulfilled. (For example, the Act was enacted in October 1988, too late to provide appropriations for fiscal year 1989, which began in October 1988. Thus, questions have been asked as to why this initiative is still in the early stages of planning, more than a year after the Act was passed.)

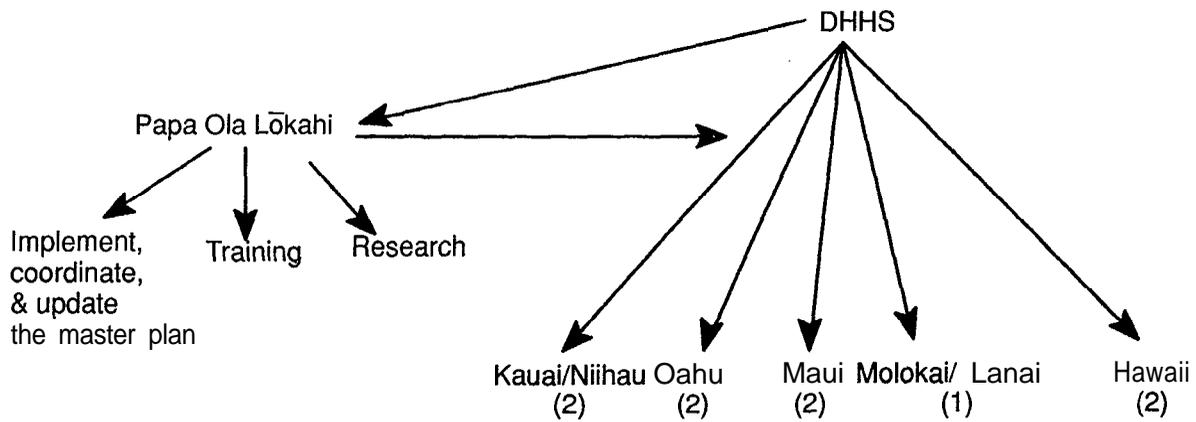
Figure 7 shows that appropriations for fiscal year 1990 were at minimal levels, and that, 7 months into the fiscal year, no Federal funding had been received. Simply stated, how is it possible to plan rationally for new systems of health services when there is no reliable indication as to what the yearly budgets will be or even whether the authorizing legislation for the program will be renewed after the fiscal year? This observation is made, not out of a belief that the situation can be changed, but as a reminder to policymakers and health services re-

Figure 7. Appropriations for Native Hawaiian Health Care Systems

Fiscal year 1990:



Fiscal year 1991+:



	FY 1990	FY 1991	FY 1992
Planning:			
Authorized:	\$1.6 million	none	none
Appropriated:	\$700,000 * (actual is \$684,000)		
Papa Ola Lōkahi:			
Authorized:	\$1 million	\$1 million	\$1 million
Appropriated:	\$100,000**		
Services:			
Authorized:	none	\$5 million	\$10 million

. Actual is \$684,000.
 **actual is \$98,000; State provided \$200,000 as of July 1, 1989.
 Note: FY '90 appropriation not available until at least May 1990.

Table 4. Waianae Cancer Research Project, 1986-1987: Goals and objectives (Draft)

The Wainae Cancer Research Project will:

1. Be sensitive to the culture of the study participants.
 2. Provide direct and immediate benefits to the study participants and the community as a whole.
 3. Educate community leaders and residents about the high cancer rates among Native Hawaiians (causes and prevention).
 4. Organize and empower community leaders and residents to identify and communicate their health concerns and to generate appropriate communicate their health concerns and to cancer prevention and control.
 5. Organize community advisory committee to advise and assist the WCCHC and the cancer research center with planning and implementing the project.
 6. Involve Native Hawaiians in the planning and implementation of the research project.
 7. Create a sense of ownership of the research by the community.
 8. Review and revise instruments, protocols and procedures at the community level.
 9. Provide job training opportunities and experience to community residents, especially young Hawaiians; ask the Center to cooperate in summer job placements for youth so they can learn first hand about cancer research and health careers.
 10. Involve participants in the project, not only as “subjects,” but also by offering health education sessions to any clubs or church groups they may belong to and possibly involving participants in conducting the research.
 11. Generate useful, meaningful data concerning the possible causes of the high cancer rates among Hawaiians.
 12. Develop a draft grant proposal for submission to the National Cancer Institute for cancer prevention; the proposal will reflect the ideas and experiences of a cross-section of Waianae coast residents.
 13. Establish a cooperative working relationship between the Waianae community and cancer researchers as a basis for future research.
 14. The cancer center should be asked to involve a representative of the advisory committee in the early planning phases of future CC grant proposals.
 15. The community advisory committee should be designed so it can continue after the project is finished as a resource to both WCCHC and the cancer center; study participants should be invited to join the advisory committee.
 16. Research study participants will be adequately informed of the results of the research as soon as these results are available.
-

Note: Project application made to the National Cancer Institute in 1989 and approved early in 1990.

searchers that factors, which have nothing to do with the content and merit of programmatic initiatives, can have a strong influence on whether a program will succeed.

Health Services Provided Through Non-Medical Settings

Current concepts of primary care are too physician-oriented. This is detrimental to physicians as well as to the community of patients. To quote from the prepared remarks of Dr. Harvey Estes (in this volume):

No physician can provide a complete spectrum of primary care for a population of patients. A team is required. Traditionally, this has been a primary care doctor, his secretary and his nurse and/or office assistant, but more and more complex organizational structures

are being utilized . . . Primary care exists.. . to meet the health and sickness needs of a population. . . How can we ensure that a diffuse organizational team is providing the complex set of services needed by the people to be served?

The answer, of course, is that the burden is being placed on the wrong actors. The physician’s role in primary care is crucial, but the physician’s practice is not the sum total of primary care. Nor is it appropriate to continue to assume that the physician is the entry to primary care; certainly this is not true for many ethnic populations. who, when they do seek “primary” care, end up in emergency rooms.

Physicians are being set up for failure because they are expected to be both the entry point and the patient-facili-

tator for “the complex set of services needed by the people to be served.” Moreover, the physician-oriented model is dominated by economic concerns; hence, his or her “gatekeeper” role, when what is needed are “gate-finders” and “gate-openers,*” roles that can only be played by more broadly based and representative community organizations.

The Effectiveness and Cost-Effectiveness of Prevention

The resources and services that will be made available under the Native Hawaiian Health Care Act were determined by what is politically and economically feasible at this time—that is, no sharing of the Federal Indian Health Service with other Native Americans and no purchase or subsidizing of health insurance. Instead, Native Hawaiians are to be provided services that supplement ambulatory and inpatient medical care services, assuming that such medical care services are already available to them. Native Hawaiians therefore find themselves in the peculiar position of being a test population for the often-stated proposition that primary care, health promotion, and disease prevention services are, in the long run, more effective and cost-effective than acute medical care.

It does not make sense to encourage Native Hawaiians, especially those who have not availed themselves of mainstream medical care, to use the forthcoming Native Hawaiian health care system if it is not also possible to help them gain entry into mainstream medical care if they subsequently choose to do so or if they need such care (for example, of what use is it to detect cancer among Native Hawaiians if it is not possible to find proper treatment for them?). Therefore, Papa Ola Lōkahi will be attempting to help its clients gain entry to already available services as well as to provide the services authorized by the Native Hawaiian Health Care Act.

Hawaii has advantages most States do not:

1. Hawaiians receive liberal Medicaid benefits and extensive health services provided directly by the State.
2. Hawaii is the only State that is exempt from the Federal ERISA (Employee Retirement and Income Security Act)-derived restrictions on mandatory employment-based health insurance, so that any employee in Hawaii working 20 hours or more a

week must be provided health insurance. Consequently, the uninsured population in Hawaii is 3-7 percent, compared with 15-17 percent nationwide.

3. Hawaii is in the initial implementation stages of a new State health insurance program, directed at the remaining “gap” group of individuals without any private or public health insurance coverage.

The Native Hawaiian Health Care Act provides an opportunity to evaluate whether prevention is effective and cost-effective, subject to the impediments mentioned previously (e.g., a grassroots effort in need of much technical assistance and severe problems of implementation concerning the amount and timeliness of Federal appropriations).

Conclusion

It might take decades for fundamental changes to occur in the country’s health care delivery system. A more realistic, near-term scenario features: 1) greater access to currently available services that are more efficiently managed and (2) supplemental services on a more modest financial scale. Native Hawaiians have been offered the latter—that is, modest supplemental services; the next step is to see if Native Hawaiians can efficiently access currently available services. It is probably safe to say that this system has implications for the direction that the overall health care delivery and financing system in the United States will take.

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An Overlooked Resource: The Black Patient

Lolita M. McDavid, M.D., M.P.A.

Introduction

The task of bringing more blacks as participants into clinical research studies reminds one of the Pirandello play, "Six Characters in Search of an Author." In searching, it isn't necessary to go far, as blacks are twice as likely as whites to use hospital clinics for their care, have six disease categories that account for 80 percent of their deaths, have an age-adjusted overall mortality rate which is 1.5 times that of whites, and the black population is growing faster than the white population.^{1,2} Thus, the actors are there, the scenes are set, all that is needed is an author, or in this case, a researcher.

Areas Fertile for Research

Blacks as possible participants in research studies and clinical trials cannot be ignored for three primary reasons: (1) blacks are disproportionately impacted by certain diseases/diagnoses, 2) blacks often receive care at academic hospitals located in central cities, and 3) the black population is growing faster than the white population. It is expected that the black population will grow from its current 11.5 percent to an estimated 16.9 percent of the Nation's population in 2050.³

In almost any area of clinical or psychosocial research, there is a need to know if blacks are affected differently than whites and if so, why. Conversely, it is important to know for which diseases, such as breast cancer, that blacks may be at no greater risk.⁴ Since research has shown that blacks and Hispanics are less likely to participate in surveys and clinical studies, there is little information about risk groups within these minority populations.^{5,6}

In their monumental work released in 1985, the Secretary's Task Force on Black and Minority Health² outlined six causes/diagnoses that contribute to over 80 per-

cent of the excess deaths suffered by blacks: they are heart disease and stroke, homicide and accidents, cancer, infant mortality, cirrhosis, and diabetes. All of these are fertile areas for investigation.

Heart disease and stroke account for 30 percent of the excess deaths among blacks, with blacks having a stroke mortality rate that is 66 percent higher than that of whites.⁷ Because 30 percent of excess deaths among blacks can be attributed to heart disease and stroke, the area of cardiovascular disease is ripe for exploration. While blacks have higher mortality rates from coronary heart disease (CHD) than whites, they are less likely to be hospitalized for CHD and less likely to have angiographic studies done or to have coronary artery bypass surgery performed.* Even after controlling for age, sex, payor, income, and primary and secondary diagnoses, whites undergo significantly more coronary artery bypass grafting procedures.^{9,10} There are several possible points of inquiry here: perception of symptoms in terms of severity and implications, the effects of previous experiences with health care providers, and poor understanding of the possible interventions—that is, "all my family dies of heart disease and there's nothing that can be done about it."

In addition to the diseases/factors responsible for excess deaths described in the Secretary's Task Force Report,² there also are areas that have long been ignored or neglected. One such area is mental health. A long-held belief was that mental illness could be linked to heredity or genetics – a theory that made the inclusion of blacks in studies of mental illness moot." It has been stated, not so tongue-in-cheek, that until recently in psychiatric research even the rats had to be white!¹²

The impediments to involving blacks in psychological studies or psychiatric trials arise from these long-held perceptions and beliefs. Researchers in the past focused on negative behaviors and social deviancies in relation to mental health problems in the black community, if at

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all. Few, with the exception of minority researchers, have looked at those strengths and supports that allow many blacks to function in a society which is often foreign and hostile. It is important to identify the positive supports that help the majority of blacks to function as a source of direction for new programs and interventions.

As important as it is to develop sensitivities on the part of the researcher, black patients must be willing to enter into treatment programs or therapy modalities that may seem new or strange to them. For many in the black community, psychological or psychiatric problems are handled through religious faith or family and social supports.

Reasons for Nonparticipation

Why don't minority patients participate more in clinical research trials? Are they more likely to be "clinic" patients and less likely to be approached by researchers than "private" patients? Do past patterns of discrimination affect both the researcher and the patient? Is there a reluctance to join studies because there is fear of being a "guinea pig"? Are there folk beliefs—such as herbal medicines and religious healing—that must be tried first when a condition is diagnosed? Are there long-held taboos about revealing "personal business" that must not be breached? It is probably all of these reasons and more.

A historical awareness of the ways in which blacks have obtained health care is important to understanding the current dilemma. During slavery, the slave-owner was responsible for the health care, such as it was, of his slaves. With the end of the Civil War, slaves became responsible for their own medical care. Because many slaves already practiced herbal and folk remedies that had African origins, blacks often turned to each other rather than formal **medicine**.¹³ Historically, many white physicians would not accept blacks as patients. This, coupled with the dearth of black physicians, has resulted in many blacks who have no identified physician and/or no regular source of care except hospital clinics or emergency rooms.

Because of this historical perspective, researchers must also have a knowledge of factors that influence the health-seeking behaviors of blacks; among them, the respect for authority figures, the role of religion, and the strong family structure in the black community, especially as it relates to older patients.

Design Issues

In studies that involve blacks, there is the need to separate race, with its implications of genetics and inheritance, from socioeconomic questions and ethnic/racial origin. For example, studies have shown no difference in breast cancer mortality rates when comparing black and white women, but blacks at all ages and socioeconomic levels have higher rates of **hypertension**.^{4,14} Thus, while race is not a risk factor for breast cancer mortality, there does seem to be a relationship between race and hypertension. For reasons of treatment modalities, patient education, and health care delivery issues, it is important to identify those diseases and processes that are linked to socioeconomic factors rather than race alone.

Traditionally, studies have often "matched" on sex, age and race. Two of these variables are easily defined—sex and age. However, "race" is ambiguous as most blacks are not of pure African ancestry. Blacks may be of American, Caribbean, Central or Latin American, or African origin. In the few studies that have controlled for migration, significant differences were **found**.¹³ Studies that enroll urban blacks from cities such as New York, Newark, or Miami, usually do not distinguish country of birth. Yet, this may be significant when looking at health beliefs and/or health care-seeking behaviors. Poor blacks who have grown up in New York are probably closer to poor whites in respect to health beliefs and health care-seeking behavior than Haitians who have migrated to Miami.

In looking at minority populations, researchers must be willing to depart from traditional tomes. Traditionally, "good" studies have control and experimental groups. Traditionally, studies that compared blacks with whites often viewed the whites as the controls, with the implication of normalcy. As a colleague once remarked, when whites are used as the "gold standard," they may be instead "fool's gold." Instead of case-control studies, research addressing blacks may be more valid if a quantitative/descriptive method is used. In such studies, the usual statistical concepts—rates, correlations, and proportions—are utilized. However, subjects are not randomly assigned to control and experimental groups. Such studies can thus yield information for small groups or even a single **case**.¹⁵

It is also important for the researcher to be cognizant of conclusions drawn from studies involving treatment modalities that impact blacks and other minorities. When Svensson looked at racial differences in clinical

drug trials, he found that blacks were underrepresented. Even in trials that were testing anti-hypertensives, only 47 percent of those reviewed reported the racial composition of the study population.¹⁶

Recruitment Issues

Hospital clinics, staff patient panels, and resident continuity practices are sources of patients. However, there are other potential sources of patients that are often ignored.

Because black physicians have traditionally cared for black patients, black doctors are an obvious source of potential study participants. With the opening of previously segregated medical institutions, more black physicians are admitting patients to both community hospitals and academic centers. Methods must be identified to assist and encourage black physicians, especially those who do primarily clinical work, so that they can acquire the skills necessary to participate in primary care research. Including local black physicians as adjunct clinical researchers serves two purposes: (1) it provides an opportunity for the physicians to participate in an academic exercise that they may not otherwise seek, and (2) it provides the research staff with an entree to the physician's patients. Many black physicians belong to their local chapter of the National Medical Association (NMA), because historically they were not welcomed in all local AMA chapters. This Association can also serve as a conduit to the community, as well as a source of community-based clinicians who may be interested in participating in clinical research.

It is important for researchers to investigate other community groups or agencies in their respective communities that can provide participants and/or support for projects. Programs such as the Maternity and Infant Health Projects provide obstetrical and well-baby care and may allow research involving their patient populations. Programs like the Department of Agriculture's Women, Infants, and Children's Program (WIC), senior citizens organizations, and community based health centers also can be sources for participants.

The black church, as one of the few institutions that is controlled by the community, can be a source of patients and information and a means of program implementation. In Oakland, California, a program was established with the churches in which fecal occult blood testing was carried out.¹⁷ Churches are often willing to allow groups to conduct programs, such as hypertension screening, and the ministers can function as a link with the congregations and the broader community.

Data Collection Issues

Data collection instruments should be assessed to determine appropriateness for use with a black or other minority population. Care should be taken to eliminate or modify instruments that have been designed and validated for use in whites. This does not mean that, because an instrument has been validated in a white study population, it cannot be used. It does mean that use of terms or indicators that measure areas with cultural variability—such as health beliefs, self-esteem, parenting practices, family supports, or **folkways** and religious beliefs—should be examined for racial/cultural appropriateness.

Traditional methods used to obtain data need to be scrutinized for appropriateness. An example is the use of telephone surveys. Because blacks, especially those in poor neighborhoods, are less likely to have telephones, they may be less likely to participate in telephone surveys due to what has been called “**noncoverage bias**.”⁴

Interviewing Issues

It has been noted that there appears to be an observational bias introduced when the interviewer is white and the participant is black? Every effort should be made to utilize black interviewers in studies that enroll large numbers of blacks.

Like many other minority or ethnic groups, blacks often feel that physicians and health care workers are omnipotent and not to be questioned. This is directly related to a respect for education, and thus, to question is to challenge. Patients should be encouraged to ask questions.

Blacks, and particularly elderly blacks, often have a social support network upon which they **rely**.^{18,19} Therefore, when carrying out interviews, researchers should inquire about such supports, and a friend or relative should be allowed to be present for support and as a source of additional information.

Analysis Issues

The subject of confounding will impact significantly upon the analysis of research that includes blacks. Obviously, low socioeconomic status (**SES**), poor access to health care, alcoholism, and risk-taking behaviors are associated with high rates of homicide, and some diseases are associated with alcohol and tobacco use, such as cirrhosis, pancreatic cancer, and cancers of the esophagus and larynx. It has been suggested by other authors that differences in the prevalence rates, and therefore

excess deaths rates, for these behaviors and conditions can be better explained by SES than race alone.^{2,13} An example of this is seen in studies that examine the spread of the AIDS virus and possible intervention strategies. Comprehension of taboos regarding sexual preference, condom use, educational levels and economic constraints of IV-drug users will be important in determining how to design intervention and education programs. In one study, white IV-drug users, who had more education and were less likely to be on public assistance, were twice as likely to use new needles than blacks and Hispanics.²⁰

Comment

Once the data are analyzed and the conclusions are drawn, care must be taken not to generalize the results to all blacks. The assumption that affluent blacks and poor blacks share the same risks cannot be made on the basis of race alone. Findings for poor rural black women cannot be assumed to apply to middle class urban black women; the social supports that poor blacks utilize may be the same supports that poor whites rely upon. Blacks are no more homogeneous than whites—they are poor, middle class, educated, uneducated, rural, and urban—with all the risk factors ascribed to each of those subgroups. Data collection must reflect this, just as interpretation of data and resulting conclusions are restricted by this.

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Mental Disorders in the Primary Care Setting: Research Priorities for the 1990s

Herbert C. Schulberg, Ph.D.

Introduction

Health services research has long been conducted by Federal agencies concerned with the clinical, organizational, and economic aspects of medical care. The significance of this research and its policy impact will grow as cost containment remains a dominant influence during the coming years. In considering priorities for the 1990s, studies of how mental illness is diagnosed and treated within primary care settings will assume ever greater importance on the health services research agenda. This area for investigation was spawned in the 1960s by England's National Health Service, which requires that patients seeking specialist care be funneled through the generalist system.

Many of the clinical and economic issues generated by this gatekeeping mechanism are now equally prominent in the United States. For example, the pattern in prepaid practices of limiting patient access to specialists is intensifying concerns as to whether psychiatric illnesses are being properly diagnosed and treated, and whether outcome suffers when treatment is provided by primary care physicians rather than specialists.

The Federal Government has sponsored studies addressing such questions since the mid- 1970s. However, the research typically has been funded by the National Institute of Mental Health (NIMH) alone and pursued from a psychiatric perspective. Rarely have other Federal agencies joined in sponsoring these clinical and policy-oriented analyses. Past bureaucratic boundaries should dissolve, however, due to recent legislation assigning the comprehensive Agency for Health Care Policy and Research (AHCPR) a major responsibility for **primary** care studies. Effective grassroots **collabora-**

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tion among psychiatric and primary care researchers is also eliminating fruitless distinctions between the initiatives and interests of specialists and generalists.

In anticipation of nationally facilitated multidisciplinary ventures, what cutting edge studies regarding mental illness in primary care practice warrant the health services researcher's attention? What are the pressing conceptual and clinical issues, and which are methodologically feasible to investigate in the coming years? This paper reviews what is known and not known about the epidemiology and classification of psychiatric morbidity in primary care practice, physician recognition of mental disorders, and the efficacy of treatment strategies in ambulatory medical settings. Additionally, priorities for a future health services research agenda are suggested.

Epidemiology and Classification of Psychiatric Morbidity

The starting point in constructing a meaningful knowledge base for studies of diagnosis and treatment is data regarding the prevalence of psychiatric illnesses in primary care practice. These rates may be derived from patient self-reports on screening questionnaires, physician assessments, psychiatric interviews, and standardized interview schedules. The significance of the researcher's information source is highlighted by Von Korff and colleagues' finding that only 5 percent of primary care patients met criteria for an anxiety or depressive disorder when assessed by the primary care physician, a screening instrument (the General Health Questionnaire), and a standardized interview schedule (the Diagnostic Interview Schedule). Primary care physicians and the screening instrument generated the highest prevalence rates (33 and 39%, respectively); the interview schedule generated the lowest rate (8%).

Standardized interviews are thought to produce the most reliable diagnoses, and so they have been administered in approximately one dozen primary care studies conducted in the United States, England, and other countries. Schulberg and Burns² analyzed reports based on structured assessment procedures and found the resulting mental illness prevalence rates to range from 11 to 36 percent. The reasons for this three-fold variation remain unclear. It appears unrelated to the particular diagnostic instrument used, the country studied, or the organizational structure of the primary care system in which patients were assessed.

Disparities in prevalence continue to interest health services researchers, but they, as well as epidemiologists and clinicians, are now focusing on the related issue of whether existing classification systems validly diagnose mental illness in primary care practice. This concern stems from uncertainty as to whether psychiatric nosology founded largely upon studies of mentally ill hospital populations is also valid for establishing "case-ness" in ambulatory medical practice.³ The dilemma is readily illustrated with regard to depressive disorders. DSM-III contains several subcategories for this disorder; nevertheless, a sizable number of primary care patients reporting extensive affective distress are not readily diagnosed within this nomenclature. For example, Barrett and colleagues⁴ found 4 percent of primary care patients to display mixed anxiety-depression and an additional 6 percent with suspected depression, but all 10 percent failed to meet criteria required by DSM-III for the diagnosis of affective disorder.

Since psychiatric treatments (particularly of the pharmacologic type) are linked to diagnosis, what are the clinical implications when a syndrome fairly prevalent in primary care practice fails to meet diagnostic criteria? One possibility is to view such morbidity as subclinical and self-limiting and, therefore, to be treated with watchful waiting alone. The alternative is to consider such morbidity as clinically significant and warranting treatment, despite the lack of nomenclature for its classification. Both approaches, however, suggest the need for research which tests the predictive validity of definable non-DSM-III syndromes. For example, a clinical trial could compare outcomes for patients with mixed anxiety-depression who received a standardized psychiatric treatment with those followed naturalistically. Barrett and colleagues⁴ note that such outcomes research could determine whether definable syndromes common to primary care but defying current classification warrant a new DSM-III code. Outcome data also

would clarify which conditions primary care physicians must diagnose promptly and treat aggressively and which are transient, subclinical, and spontaneously remitting.

Another example of DSM-III's limitation in primary care practice is its inability to classify the clinically significant psychosocial problems troubling patients. Stumbo and colleagues⁵ found that approximately one-third of adult family practice patients were assigned psychosocial diagnoses; almost 20 percent of this group were prescribed antidepressants and 11 percent tranquilizers. If "psychosocial" episodes are to be properly assessed and treated, valid and relevant classification systems are required.⁶ Frameworks considered during recent years include the triaxial system, the problem-oriented approach, and the reason-for-encounter system. Presently, the American Psychiatric Association is deliberating whether DSM-IV should include as clinical disorders the V codes "for conditions not attributable to a mental disorder that are a focus of attention or treatment," for example, marital problems leading the primary care patient to present with ill-defined symptoms or conditions. Descriptive epidemiology and outcomes research could clarify the conceptual validity of classifications addressing psychosocial problems and determine whether they sharpen strategies for clinical care.

A second classification dilemma pertains to the validity of DSM-III criteria for particular disorders that fail to identify primary care patients of its presumed type. For example, physicians regard somatization disorder as rather common in ambulatory medical practice, and yet its point prevalence is minimal. Schulberg and colleagues' administered the Diagnostic Interview Schedule to a primary care population and found fewer than 1 percent meeting DSM-III criteria for somatization. A possible reason for this surprisingly low rate is that the DSM-III diagnosis requires at least 13 symptoms sufficiently severe to warrant medication or physician visits. Deeming this symptom threshold unduly high, Escobar and colleagues* used a cut-off score of only four symptoms for men and six for women. They found that this preserves the predictive value of the standard DSM-III diagnostic criteria in community samples. The effect of lowering symptom threshold for somatization's prevalence in medical practice is seen in Kapoor and colleagues' study with syncopal patients.⁹ Only 2.9 percent of those with syncope of unknown origin met full DSM-III criteria for somatization, but 12.4 percent were so diagnosed within Escobar and colleagues' less

restrictive definition. Researchers should now investigate whether primary care patients classified within an abridged somatization construct resemble or differ from patients meeting the full DSM-III definition on such variables as risk factors, service utilization patterns, functional disabilities, and course of illness.¹⁰

A still further epidemiologic issue warranting the attention of health services researchers is the degree to which physical and psychiatric morbidity coexist in primary care populations. Such comorbidity raises complex diagnostic issues, given uncertainties about underlying etiologic mechanisms and the validity of assessment procedures. When medical patients present with emotional symptoms, the clinician must determine whether there are causal associations between the two forms of pathology, a joint vulnerability mechanism, and/or processes whereby emotional problems are expressed through somatic symptoms. Given the significance of these clinical dilemmas and widespread speculation about strategies for their resolution, it is striking that few primary care researchers have empirically examined comorbidity's prevalence and clinical manifestations.

The psychiatric-physical illness relationship receiving the most attention is that of depression and various organic disorders.¹¹ Primary care patients with a major depression often present with neurovegetative symptoms that might be misattributed to physical illness. Conversely, medical problems such as hypothyroidism produce organic affective syndromes. Research is needed, therefore, to determine the prevalence of various comorbid patterns and to ascertain whether the medical morbidity of depressed patients resembles or differs from that of nondepressed patients.

A cross-sectional study of this type was conducted by Coulehan and colleagues¹² in an academic primary care center. They found the prevalence of specific physical illnesses similar among depressed and nondepressed patients, but "ill-defined conditions" were significantly more common in the former group. The severity of diagnosed medical illnesses also was judged significantly higher among the depressed patients. More extensive research of the longitudinal type is urged, therefore, to determine (1) whether primary care patients with various DSM-III diagnoses also have more severe physical illnesses, (2) the causal direction of comorbidity, and (3) whether the symptomatology and disability caused by a psychiatric illness adds to the burden of physical illness. Strategies for investigating the latter issue are exemplified in the RAND Medical Outcomes

Study,¹³ which compared the functional impact of depression to that of other illnesses.

Physician Recognition of Mental Disorders

Despite persisting uncertainties about the validity of psychiatric nomenclature in ambulatory medical practice, scores of researchers have investigated the primary care physician's recognition of mental illness. The resulting work may be classified into four types:

1. studies comparing diagnostic formulations from the psychiatric perspective and the perspective of a primary care physician
2. studies experimenting with procedures for increasing the frequency with which primary care physicians assign psychiatric diagnoses
3. studies analyzing the physician's diagnostic process with the aim of discerning factors that enhance or detract from clinical accuracy
4. studies investigating the relationship between diagnosis and treatment.

Analyses of clinician accuracy and procedures for improving it have prevailed to date. Research into the diagnostic process and the diagnosis-treatment linkage is still relatively uncommon.

Clinician Accuracy

Given that approximately 25-30 percent of ambulatory medical patients have a diagnosable mental illness, how accurately is it assessed by primary care physicians? Schulberg and Burns² review of pertinent studies concluded that degree of clinician accuracy relates strongly to the criterion measure's content and psychometric characteristics. Thus, several investigators utilizing structured assessment instruments generated undetected psychiatric illness rates in the range of 70-90 percent. When a psychiatrist's formulation has constituted the yardstick, physician nonrecognition has ranged from 45-60 percent. Highly variable rates of undetected morbidity were obtained by researchers using screening instruments as the assessment yardstick, since each such instrument has differing sensitivity and specificity rates and positive and negative predictive values.

Another framework for analyzing the earlier research on clinician accuracy is whether the study focused on the physician's assessment of any psychiatrically diagnosable illness, or whether it was specifically concerned with diagnosing depression. With regard to recognizing

broader morbidity, Wilkinson's¹⁴ review of earlier English studies found undetected psychiatric illnesses in general practice to range from 33-60 percent. More recent studies in American primary care settings determined that up to 80 percent of the psychiatric diagnoses assigned to patients were undetected by physicians.^{15,16} Studies of the physician's ability to recognize clinical depression per se accurately have generated a wide range of rates, extending from a low of 15 percent to a high of 80 percent.

Thus, it is clear from much of the earlier research that primary care physicians significantly underdiagnose mental illness. The frequency with which this occurs probably relates most strongly to the study's criterion measure. Further research on clinician accuracy potentially could establish more precise estimates of unrecognized psychiatric morbidity, but the utility of additional data is unlikely to warrant this effort. The research focus should shift, instead, from a concern with whether physicians accurately diagnose mental illness to the more complex issues of whether recognition can be improved and the cognitive-behavioral processes whereby physicians formulate psychiatric diagnoses.

Improving the Recognition of Psychiatric Illness

Strategies for increasing the frequency and accuracy with which primary care physicians diagnose psychiatric illness are best designed within an educational framework including the elements of knowledge, interviewing skills, clinical decisionmaking, and attitudes.¹⁷ This model is rarely implemented in its totality, however. Efforts to improve physician recognition typically are limited to providing these clinicians with psychiatric knowledge and then investigating whether it produces an incremental gain in diagnostic accuracy. Thus, many researchers have investigated the power of screening score information in sensitizing physicians to a psychiatric disorder that might otherwise be overlooked in the clinical formulation. This educational strategy assumes that physicians select the most probable cause of a patient's complaint as the working diagnosis; improbable conditions are considered only if extremely serious and not to be missed. Physicians provided with a patient's score on a psychiatric screening instrument presumably are alerted to the heightened likelihood of mental illness.

Numerous researchers have studied whether screening scores indeed influence the primary care physician's diagnostic strategy with regard to psychiatric illnesses

in general, or depression in particular. However, their findings are inconclusive. Some earlier investigators determined that screening scores do increase sensitivity to psychiatric illness, but others determined that such information is neglected or rejected.¹⁷ This inconclusive pattern continues in several recent studies as well. Thus, Rand and colleagues¹⁸ determined that feedback of General Health Questionnaire (GHQ) scores doubled the number of psychiatric diagnoses assigned by family practice residents. However, Shapiro and colleagues¹⁹ found that feedback of GHQ information produced only marginal effects on the overall detection of psychiatric problems by faculty internists and residents. Of interest in the Shapiro group's study is that GHQ scores did increase markedly in the detection of psychiatric morbidity among the elderly, blacks, and men, subgroups among which such disorders are detected infrequently.

Possible reasons for the inconsistent influence of screening scores on diagnosis range from the failure of physicians to even note the information to the physician deeming it irrelevant. The latter possibility has provoked much debate among physicians and researchers weighing the clinical utility and economic feasibility of screening for mental illness in primary care practice. The opposing sides of this controversy are summarized by Kamerow²⁰ and Campbell.²¹

The advisability of screening for depression in ambulatory medical settings has stimulated particular attention.^{12,22} Supporting Frame's²³ negative view, the United States Preventive Services Task Force²⁴ has recommended not screening for depression in asymptomatic patients. However, the Task Force urges a high index of suspicion for depressive symptoms among persons at high risk for an affective illness, for example, those with a current sleep disorder or a history of prior depressive episodes. In this light, studies are needed of the frequency with which physicians recognize such high-risk patients, whether screening instruments are then administered, and whether screening scores are utilized in the clinical assessment and diagnostic formulation. Physician-based and practice-based variables affecting the screening score's utility require study as well. Variables of the latter type merit particular scrutiny given the finding by Wells and colleagues²⁵ that recognition rates for depression are significantly higher in fee-for-service than in prepaid medical practices.

The Physician's Diagnostic Process

Studies of the manner in which screening data contribute to the diagnostic process will be useful, but analyses of clinical decisionmaking in primary care practice are

even more vital. The need for research regarding characteristics of the patient-physician interaction that facilitate or hinder diagnostic accuracy has been repeatedly emphasized. Nevertheless, few investigators have yet analyzed the details of how physicians assess a patient's presenting complaint and determine whether its etiology is organic, psychological, or both. For example, Jones and colleagues²⁶ found that physicians' expectations about normative illness behavior influenced recognition of emotional factors in the illness presentation more than mental status characteristics. Physicians attributed greater emotional morbidity to patients judged to have less severe medical illness and to be less satisfied with their care.

Studies like that by Jones' group,²⁶ which analyzed retrospective data from questionnaires administered to patients and physicians, are useful. However, investigators must also scrutinize clinical encounters to determine whether and how primary care physicians elicit information, interpret cues, and formulate hypotheses about mental illness in ambulatory medical populations. Studies of this process should consider that the physician's problem-solving strategy consists of both cognitive and behavioral elements. The cognitive components include preconceptions regarding the probability, severity, and treatability of psychiatric and organic illnesses; probabilistic models regarding the utility of screening, laboratory, and treatment procedures; and "concept-driven" perceptions that increase the likelihood of diagnosing those conditions the physician is comfortable treating. The behavioral component of a clinical assessment includes interviewing style and other aspects of the physician's verbal interaction with the patient.

A conceptual model incorporating these cognitive and behavioral variables is guiding Badger and colleagues (personal communication, November, 1989) in their pilot study to explore reasons for the underrecognition of depression in primary care practice. Key features of this University of Alabama research into the microelements of the assessment process are its use of a standardized clinical presentation by actors to control for patient variability and its emphasis upon diagnostic practice among community-based physicians rather than academic faculty or residents. It would be useful as well to investigate within this conceptual model how organizational variables influence the physician's interpretation of cues and formulation of hypotheses given the findings by Wells and colleagues²⁵ that payment method is significantly related to recognition rate.

Relationship of Diagnosis and Treatment

A fundamental premise in studies of physician recognition of mental illness is that proper diagnosis guides the physician to effective treatments. As a corollary, it is assumed that inaccurate assessment produces adverse clinical consequences. These premises underlie NIMH's Depression/Awareness, Recognition, Treatment Program²⁷ that teaches primary care physicians how to diagnose and treat affective disorders within state-of-the-art standards. While the diagnosis-treatment linkage is widely accepted, its validity has been questioned.²⁸ For example, studies of the diagnosis-treatment relationship in psychiatric settings indicate that these two elements of clinical care are not necessarily linked. Longabaugh and colleagues²⁹ found the various DSM-III diagnoses of depression to poorly predict the clinician's use of both somatotherapy and psychotherapy. Furthermore, very few diagnostic factors in the Keller and colleagues'³⁰ study predicted treatment intensity, even though their research involved psychiatrists at prestigious academic psychiatric hospitals.

The relationship of psychiatric diagnoses and treatment in ambulatory medical settings remains poorly understood. Magruder-Habib and colleagues³¹ found that when physicians were informed of their patient's depression, 75 percent of the patients received psychiatric treatment. However, 60 percent of depressed patients were treated even when the physician was not informed about the mood disorder. Both patient groups were treated primarily with drugs, but one-fourth of the dosage levels were judged therapeutically inadequate. Ormel and colleagues³² similarly found that 70 percent of patients recognized by Dutch general practitioners as psychiatrically disturbed were provided some treatment. Only 36 percent of the nonrecognized cases received some treatment.

What is the implication for primary care practice of this uncertain linkage between the assignment of DSM-III diagnosis and psychiatric intervention? It emphasizes that clinical decisionmaking is a multifaceted rather than singular process in which physicians utilize any of the following paradigms:

1. selecting a nonspecific diagnosis but initiating a specific treatment, e.g., prescribing an anxiolytic for subclinical anxiety
2. assigning a specific diagnosis but pursuing a non-specific treatment; e.g. engaging in "watchful wait-

ing” for a major depressive episode of moderate severity

3. assigning a specific diagnosis and a particular treatment, e.g. prescribing lithium for a bipolar affective disorder.

Intrinsic to each of these paradigms is the physician’s judgment about the efficacy of available treatments, their clinical side effects and economic costs, and the degree of risk associated with not formulating a definitive diagnosis and/or not initiating a specific treatment.

Utilizing this framework, it could be speculated that the widely noted findings by Jencks³³—that the majority of psychiatric interventions occur during primary care office visits when no psychiatric diagnosis is recorded—exemplify the first decisionmaking paradigm (listed above) rather than poor clinical practice as some have alleged. It also may be speculated that diagnosis poorly predicts treatment for milder psychiatric disorders but does so more effectively for the severe disorders, a clinical pattern observed previously by Williams.³⁴ These uncertainties suggest the need for studies of what patient, physician, and/or practice-based factors lead to the use of specific therapies for nonspecific diagnoses, and the converse. Furthermore, researchers should investigate whether symptom groups and problem lists better define treatment strategies, given that such formulations convey needed information with a clarity often obscured in formal diagnosis.

Treatment Outcomes in Primary Care Practice

Studies of whether and how therapies are provided to primary care patients are needed only if it can be assumed that patients treated within standardized guidelines have better outcomes than those left untreated or treated inadequately. How valid is this assumption? Presently, it is far from robust, since outcomes research has lagged behind other studies of psychiatric morbidity in primary care practice. The resulting dearth of effectiveness data led participants in the 1988 NIMH/University of Pittsburgh Research Conference on “Treatment of Mental Disorders in General Health Care Settings” to urge a priority for studies of patient outcomes, quality of care, and clinical effectiveness. Such endeavors typically have gained little support from practitioners, but third-party payers are pressuring for data to substantiate the benefits of covered services. Given this impetus, support is growing for studies of the outcomes of psychiatric treatments provided to primary care patients and the quality of such care in routine practice.

With regard to whether psychiatric treatments benefit primary care patients, it has been thought that interventions proved effective with psychiatric patients are equally beneficial when prescribed for ambulatory medical patients. However, the propriety of transferring clinical technologies from one sector of caregivers to another is being increasingly questioned. For example, Schulberg and colleagues³⁵ have noted that depressed ambulatory medical patients possibly are experiencing a disorder that differs in etiology, symptomatology, severity, and duration compared to the disorder experienced by depressed psychiatric outpatients. If the clinical disorders differ, treatments may need to be revised. Given this possibility, it is striking how little empirical evidence exists as to whether pharmacologic and psychosocial treatment standards validated with depressed psychiatric patients are equally valid with depressed medical patients. Research is needed, therefore, to establish the effectiveness of therapeutic agents within the setting and with the patients where they are to be employed.

Randomized clinical trials are the preferred strategy for investigating this issue of ecological validity. Formidable gaps remain, though, between the scientific requirements for an experimental design and the investigator’s ability to control needed aspects of medical practice in primary care facilities. “Hybrid” methodologies should be considered, therefore. For example, outcomes for the heterogeneous intervention of “usual care” by a physician constitute a possible clinical standard against which the benefits of standardized pharmacotherapy and psychotherapy can be compared. While placebos often are the comparison condition in a clinical trial, it presently would be unethical to prescribe them to depressed patients. The use of a mixed rather than pure comparison condition surely will cause discomfort to scientific purists, but this strategy potentially has the compensating virtue of producing findings that will be perceived as practical and meaningful by primary care physicians.

While the findings from outcomes research remain to be generated, administrators and third party payers already are demanding treatment pattern data for utilization review and quality-of-care decisions. From their bureaucratic and economic perspectives, it is vital to know about types and duration of psychiatric interventions so that costs and outcome may be properly balanced. Implicit to quality of care analyses is an appropriate “gold standard” against which routine practice can be compared. Indeed, a criterion yardstick was vital

to Keller's group³⁰ in formulating the previously described findings about inadequate treatments for depression in academic psychiatric centers.

Despite their relevance, quality of care investigations regarding management of psychiatric morbidity in primary care practice remain unusual. A key reason is the lack of a "gold standard" acceptable to both psychiatric and primary care physicians. For example, Uhlenhuth³⁶ contended that the low level of psychiatric treatments provided patients by community physicians do not constitute inadequate care, but rather the good judgment of generalists about effective interventions for patients using their services. The issue of what works best increasingly is being analyzed from the economic as well as the clinical perspective.³⁷⁻³⁹ After reviewing these contributions to the quality-of-care literature, Smith⁴⁰ concluded that it would appear simple to identify effective aspects of psychiatric care in general medicine settings. In reality, however, this task is quite complex and the need remains, therefore, for well designed quality-of-care research.

In designing analyses of how physicians routinely practice in the majority of community settings, investigators should consider methodological guidelines offered by Kupfer and Freedman.⁴¹ The design should include descriptions of the ethos prevailing in the studied treatment setting, the rationale of clinicians in selecting particular interventions, and the demographics and clinical characteristics of treated patients. Only when such multidimensional information is assembled, can valid, generalizable, and practical conclusions be drawn about treatments, courses of illness, and outcomes.

Summary

Earlier studies have established that approximately 25 percent of primary care patients meet criteria for a psychiatric diagnosis. Epidemiologic studies to refine the prevalence rate continue, but of more pressing concern is whether particular DSM-III categories validly classify the particular forms of psychiatric morbidity presenting in ambulatory medical settings. Researchers, therefore, should focus on the predictive validity of modified criteria for disorders such as somatization and mixed anxiety-depression and new classifications for psychosocial problems. Physician recognition of mental disorders, as defined from various perspectives, has occupied researchers for two decades. While a sizable literature consistently indicates underrecognition to be the prevailing pattern, little is known about the clinician's deci-

sionmaking process and even less about whether and how diagnosis formulations influence treatment decisions. Research on these latter issues is long overdue. Vitaly significant, but equally lacking, are outcome data for primary care patients treated for a mental disorder. Little research has been conducted on the effectiveness of treatments transferred from the specialist to the generalist sectors, nor has much attention been devoted to methodologies for studying whether practitioners meet quality of care standards. Both types of treatment outcomes research should be major priorities on the agenda of funding agencies if mental illness in primary care practice is to be properly managed.

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Community-Oriented Primary Care: A Critical Area of Research for Primary Care

Paul A. Nutting, M.D., M.S.P.H.

Introduction

Among the many challenges facing primary care research are those that involve methods for meeting the specific need for health services of defined populations. These several approaches to the organization and management of primary care practices and programs for this purpose have become known under the rubric of community-oriented primary care (COPC). Originally explored as a strategy for improving the health status of underserved populations,^{1,2} this approach more recently has begun to catch the imagination of primary care practitioners and researchers.³⁻⁸

What Is Community-Oriented Primary Care?

The basic model of COPC is quite generic and easily adaptable to a variety of practice settings.⁹⁻¹¹ The model consists of three elements, namely (1) a primary care practice or program, (2) a defined target population, and (3) a systematic process that addresses the priority health problems of the target population with both primary care and public health strategies. The COPC process, that is the third element, in turn consists of four functions. These include:

- defining and characterizing the target population
- identifying priority health and health care problems of the population
- mounting intervention strategies or modifying practice patterns
- **monitoring** the impact of interventions.

COPC is a particular approach to organizing, delivering, and monitoring the impact of primary care to a defined target group. There are a number of important misconceptions about COPC. For example, it is not in itself a research method. It is not a form of epidemiology, nor a replacement for epidemiology, although it draws heavily on the rich tool chest of epidemiologic methods.¹² It is not limited in application to underserved populations, although for disadvantaged populations it holds great promise. Rather COPC is an application of the principles of epidemiology to the organization and management of primary health care for a defined population; as such, it expands the potential of primary care to rationally and economically meet the health care needs of a particular population.

One of the great sources of confusion in COPC results from the wide variety of faces that a COPC practice or program may assume. This results from the many appropriate ways in which the COPC practice or program may define its target population, or in the idiom of COPC, its community. Certainly, the most obvious application of COPC is when the target population is an entire community—this is the closest approximation to the classical use of the tools of epidemiology. Where the target population is defined in other ways, the applicability of epidemiologic methods becomes more of a challenge.

The fundamental principles of COPC can apply to a wide variety of practice settings, and in this lies its great potential for the pluralistic health care system of the United States. The potential diversity in application of the fundamental components of the COPC model were clearly demonstrated in the national study of COPC conducted by the Institute of Medicine in the early 1980s.⁹ There are many excellent examples of COPC in the public sector, including the community health centers and the various programs of the Indian Health Service.

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There are, however, fewer examples of the principles of COPC applied in the mainstream of primary care medical practice.

Obstacles to Widespread Application

Several authors have written eloquently of the several obstacles to more widespread implementation of COPC in the mainstream of primary care in this country.^{13,14} Among the obstacles most frequently cited are the following:

- difficulty in defining a target population
- difficulty in accessing individuals in the target population
- lack of practice resources for COPC
- lack of available data on the target population
- scarcity of skills, knowledge, and experience in COPC
- limited tools for application of COPC in a practice setting
- inability to obtain reimbursement for COPC processes.

One of the concerns most often expressed is that most primary care physicians would have difficulty in defining a “community” that does not include large numbers of patients of other practices. In the many situations in which a “true” community is difficult to define or address, a target population consisting of the household members of a physician’s active patients is an ideal place to start.^{4,8} While not a community in a sociopolitical sense, such a practice population represents an excellent opportunity for primary care physicians to expand their scope of clinical concern beyond the stream of patients that visit the practice. Such a scenario may represent the best opportunity for COPC (as a particular strategy for organizing and managing primary care) to realize its great potential to change the way medical care is delivered in this country.

Defining and addressing the health problems of a practice population will have different implications for the various primary care specialties. The most direct application will be to family medicine and mixed specialty practices that are able to offer comprehensive services to all members of a household independent of age and sex. An internal medicine practice however, could define its population as all adults in each household of its active patients. Similarly, a pediatric practice could address

the health needs of all children in the household of active patients.

The remainder of this presentation will focus on two issues: First, a discussion of how-by addressing a practice population as defined above-the fundamental processes of COPC can be applied to a target population in virtually any primary care practice or program. This is not meant to detract from the important applications of COPC to underserved populations or from the importance of capitalizing on opportunities to serve a total community. Rather, it is offered to demonstrate that the principles of COPC can be a vital force in primary care in a variety of practice settings. Second, a COPC research agenda will be proposed to help define the costs, impacts, and strategies needed to overcome the obstacles to a more population-based approach to primary care.

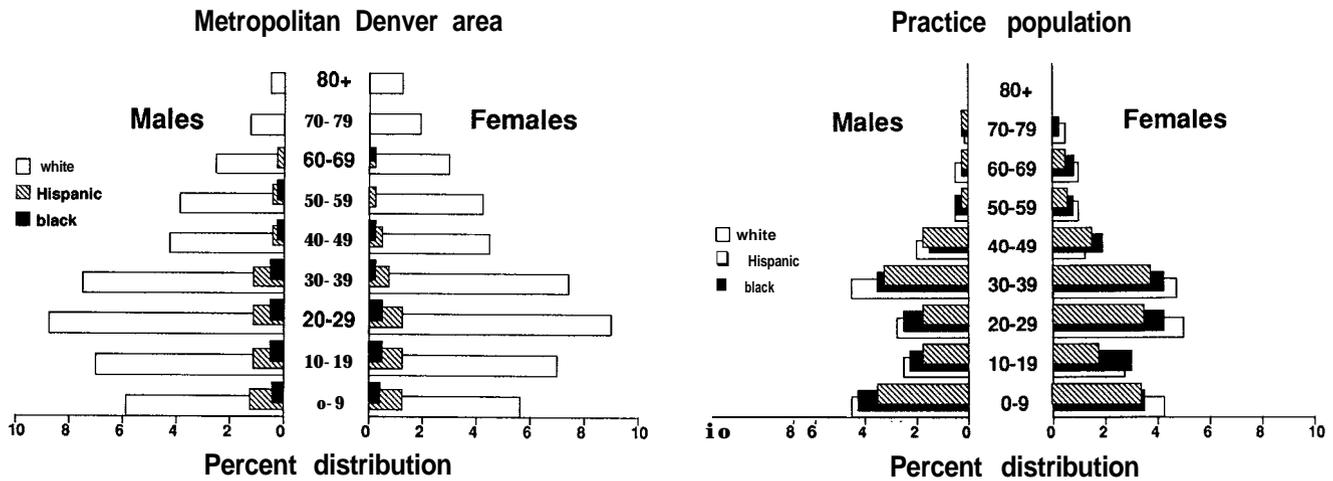
Addressing the Health Needs of the Practice Population

Application of the COPC process to a practice population can be illustrated with data from a mainstream practice setting, in this case from a family medicine center that trains residents in Denver, Colorado. This particular practice serves a mixed ethnic, urban population. Third party coverage for the population includes a mix of public and private plans, both fee-for-service and prepaid. Consistent with accepted primary care practices, each new patient is assigned to a primary physician at the time of registration. In addition, the name, date of birth, and sex of all members of the patient’s household are collected and entered in the commercial data system that supports practice billing. This information, along with diagnostic and procedure data, was downloaded from the commercial system in flat ASCII files and subsequently managed on a microcomputer.*

Defining the Practice Population

The practice population was defined as all members of the households of the active patients of the practice. Active patients were defined as those making contact with the practice within the previous 24 calendar months. Thus, the practice population included all 1,147 members of 559 households, which in turn were made up of 615 (54%) active patients, 366 (32%) inactive patients, and 166 (14%) nonpatients. The age-sex profiles of the three components of the practice population are shown in Figure 1. These distributions suggest a preponderance of females of childbearing age and children among the active patient population. Young adult males are

Figure 1. Age-sex distributions of active and inactive patients and nonpatients in the practice population



common in the inactive patients and dominate the non-patient population. There also appears to be a relative abundance of adolescents among the inactive patients.

Figure 2 compares the age-sex profiles of the practice population with that of the metropolitan area of Denver and confirms the impression that the practice serves a relatively larger proportion of minorities and of women and children than expected from the composition of the general population. With data on all members of the household, it is possible to describe the types of households that constitute the practice population, as shown in Table 1.

By far the most common household consisted of a single adult under age 50 (42.9%), yet most of the people in the practice population lived in households consisting of two adults with children (42.3%) or a single adult with children (24.6%). This was surprising to all physicians in the practice who felt that they rarely saw anything resembling a nuclear family.

Prior to planning outreach activities beyond the active patients, two characteristics of the practice population were investigated. First, the physicians were concerned that reaching out to nonactive patients might appear to be aggressive marketing intended to “steal” patients from other practices in the area. An informal survey of active patients provided an estimate for each individual in each household (that is each individual in the practice population) as to whom they looked for primary medical care. The results are shown in Table 2 and suggest that

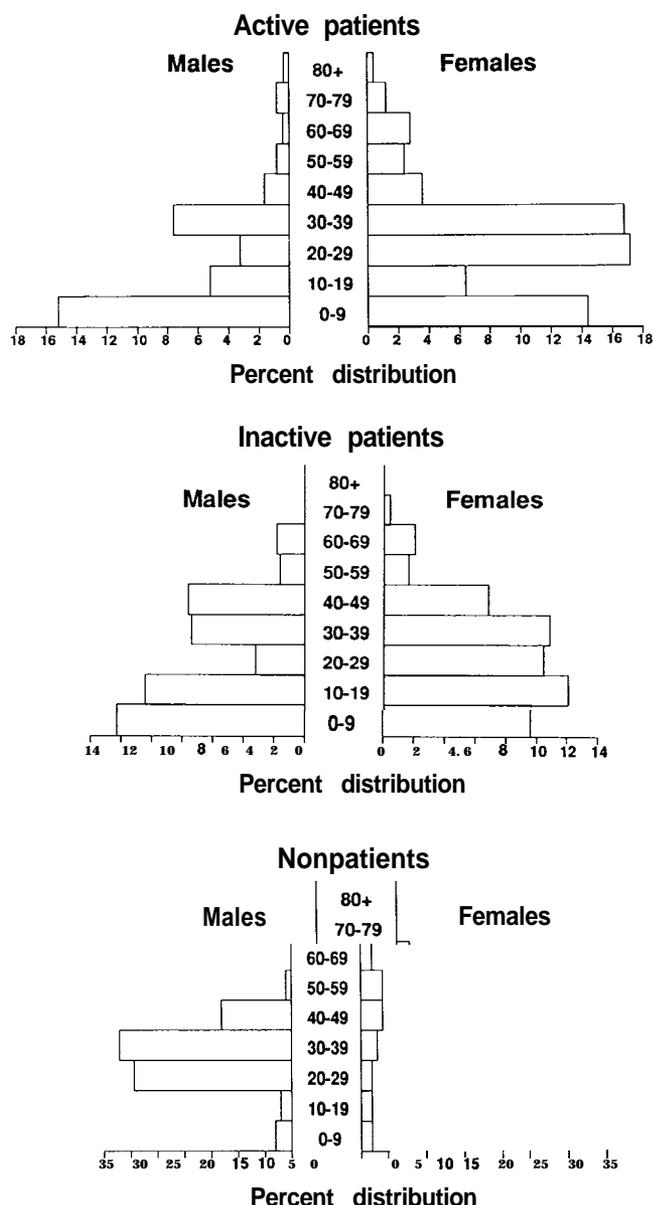
all the active and inactive patients and over 85 percent of the nonpatients identified the residency practice as their primary source of medical care. While based on a non-random sample, these results provided sufficient reassurance that reaching out to this group of nonpatients should not be construed as marketing targeted toward the patients of other practices in the vicinity.

Second, the practice managers were concerned that the physicians might reach out to a population that would further increase the already strained financial liability of the practice. Data collected in the survey also suggest that the active patients and nonpatients did not differ markedly by method of payment for services. Comparing active patients with nonpatients, commercial insurance was in place for 40.5 percent compared with 43.3 percent, respectively; Medicaid covered 27.0 percent compared with 21.6 percent; Medicare covered 0 percent compared with 4 percent; and 32.4 percent compared with 31.6 percent had no form of third-party coverage. It was somewhat reassuring to the practice management that reaching out to the nonpatients would not further strain the financial liability of the practice.

Identifying Priority Health Problems

There are many approaches to identifying priority health problems among a target population. Population-based surveys are a common method, and they are particularly easy to do by mail if the names and addresses of all members of the target population are known.

Figure 2. Age, sex, and race distribution of the practice population compared with the population of Metropolitan Denver



Note: Data for the metropolitan area of Denver is based on the Denver-Boulder Standard Metropolitan Statistical Area (SMSA)

Often, surveys yield interesting information as was discovered from a small sample of the individuals in the practice population used in this example. It was discovered that the proportion of smokers varied with the activity status of the patient. Smoking was reported in 33 percent of the active patients (near the national average),

50 percent of inactive patients, and 63 percent of nonpatients. Since these rates are not age-sex adjusted, the differences may be in part a reflection of the differences in the age-sex profiles among the active, inactive, and nonpatients; nonetheless the apparent increase in rates of reported smoking among the nonactive patients suggests a topic for outreach.

Another interesting approach that was used in this example involves comparing the number of expected cases of a given health condition with the number observed within the practice population. Figure 3 shows the differences between the expected prevalence and the observed prevalence of hypertension among different groups in the practice population. These data were derived by indirect age-sex adjustment, a process illustrated in Table 3. The reference age-sex-race specific rates were multiplied by the number of individuals in each age-sex-race group within the practice to produce numbers of expected hypertensives in each group. This was compared to the number of hypertensives actually diagnosed within the practice, based on the coded diagnoses available in the data system. Both expected and observed prevalence rates were computed by sex for blacks and Caucasians. When 95 percent confidence intervals were computed for the observed prevalence, the rates were compared. Displayed graphically, these data suggest that there might be a substantial number of young males (particularly black males) in the practice population with undiagnosed hypertension.

This example demonstrates application of the first two steps in the COPC process to a practice population. It appears to be feasible and to yield information that could form the basis for the development of intervention strategies. Although the particular program was organized according to some important principles of primary care, the salient features are not beyond the reach of any primary care practice wishing to duplicate the process.

Community Participation

No discussion of COPC is complete without mention of the participation of the target population. Community involvement is an important feature of COPC and one that should not be abandoned. While highly desirable, participation of the target population may be difficult to accomplish in many instances. Addressing a practice population will also pose the challenge of attempting to incorporate systematic input from a target population with no inherent organizational structure and little propensity to develop one. Nonetheless, there exist excellent examples of how this might be accomplished.

Table 1. Distribution of the practice population by composition of the household

	Number of households		Number of children		Total number of individuals	
	number	percent	number	percent	number	percent
Two adults with children	110	19.6	265	58.2	485	42.3
Single adult with children	92	16.5	190	41.8	282	24.6
Two adults with no children						
over 50 years	17	3.0	--	--	34	3.0
under 50 years	6	1.1	--	--	12	1.0
Single adult with no children						
over 50 years	94	16.8	--	--	94	8.2
under 50 years	240	42.9	--	--	240	20.9
Totals	559	99.9	455	100	1147	100

In his suburban Minneapolis practice, **Seifert** has managed to organize the individuals in his practice to provide a broad range of important support and information functions for the practice.^{15,16} Practices addressing a practice population might use Seifert’s approach to organizing a “patient advisory council” for gaining valuable input in identifying priority health problems and for broadening the range of support in implementing interventions. Seifert’s experience further suggests that the patient advisory council may be an important source of additional help for those nonreimbursable tasks involved in COPC.

A Research Agenda for COPC

In my opinion, the potential value of applying the principles of COPC in the mainstream of primary care is compelling enough to justify further research in COPC. The researchable issues in COPC can be thought of in four categories. These include the economics of COPC, systems issues, behavioral issues, and the methods or science of COPC. Examples of researchable questions in the economics of COPC include:

- What are the impacts achievable on the health of the target population and at what cost?
- Can the revenue generated by providing needed services offset the fixed costs of the COPC process in a fee-for-service practice?
- In what ways might volunteer help from the target population be used to cover fixed costs of the COPC process?

- Research into the systems issues will address questions such as the following:
- What systems (human and nonhuman) need to be in place, and what existing systems can be used?
- What are the existing sources of data that would be useful in the COPC process? How can these data be used in:
 1. characterizing the community
 2. identifying a cluster of addressable problems
 3. setting priorities among problems in the cluster
 4. determining modifications needed in interventions to enhance impact
 5. determining when to stop an intervention
 6. community perceptions of priority problems
 7. community perceptions of appropriate interventions?

Table 2. Survey of 102 individuals in 35 households regarding primary source of medical care

	Persons surveyed		Residency practice primary source of care	
	number	percent	number	percent
Active patients	48	47	48	100
Inactive patients	17	17	17	100
Nonpatients	37	36	32	86
Total	102	100	97	95

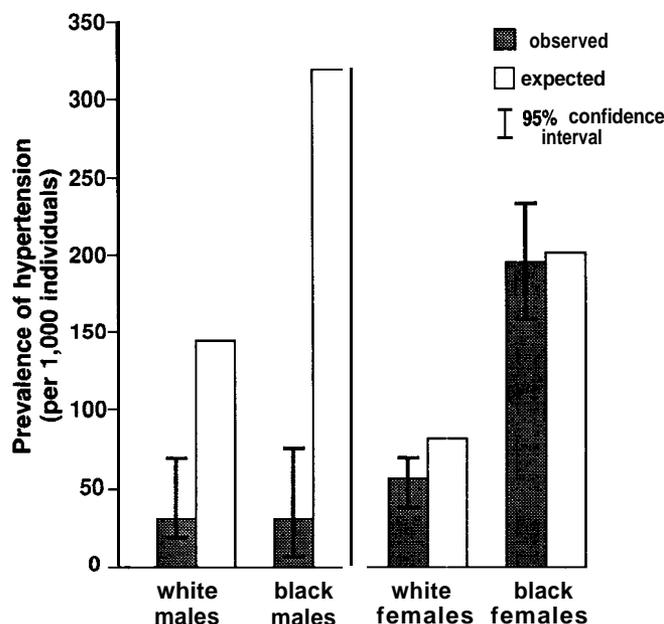
Table 3. Indirect adjustment of prevalence rates for hypertension

	Total patients	Standard rate* per 1,000	Expected cases	Individuals with hypertension
White males				
25-34	163	75	12.2	1
35-44	48	140	6.7	2
45-54	32	226	7.2	0
55-64	26	252	6.6	3
65-74	43	308	13.2	6
Subtotal	312		45.9	12
Black males				
25-34	96	164	15.7	0
35-44	68	363	24.7	2
45-54	32	367	11.7	1
55-64	36	586	21.1	5
65-74	7	433	3.0	1
Subtotal	239		76.2	9
White females				
25-34	348	22	7.7	3
35-44	190	66	12.5	6
45-54	48	139	6.7	4
55-64	46	276	12.7	13
65-74	39	349	13.6	11
Subtotal	671		53.2	37
Black females				
25-34	268	124	33.2	29
35-44	103	238	24.5	26
45-54	29	397	11.5	11
55-64	38	456	17.3	14
65-74	16	463	7.4	8
Subtotal	454		93.9	88
Total	1,676		269.2	147

*From the National Health and Nutrition Survey, National Center for Health Statistics.

- What existing organizations within the community can become the force behind COPC (e.g., community hospital, local health department, primary care practice)?
- Can a practice billing system provide data that are useful in the COPC process?

Figure 3. Observed and expected prevalence of hypertension in the practice population



Researchable questions relating to the behavioral issues include the following:

- What are the motivating factors that involve providers and community participants?
- How is motivation maintained over time?
- What are the training requirements for primary care physicians?
- How does an interest in and commitment to COPC diffuse among the practice and the community?
- How can the target population participate if it is not an organized community?

Finally, the methods and science of COPC involve a number of important research questions as well, including:

- What methods/techniques are required to carry out the COPC process?
- How well does COPC work, in terms of achieving an impact, for different classes of problems (e.g., maldistribution of diagnostic or treatment services, addressing “hidden” problems, reducing behavioral risk factors, increasing functional level, and so forth)?

Table 4. Research issues on the process of COPC

Defining and characterizing the target population

- Is the practice population a reasonable target population for COPC activities in a variety of practice settings?
- What proportion of individuals in a practice population consider the practice or program to be their primary source of care? Does this vary by practice? Does this vary by age and sex?
- Does the “baseline” epidemiologic study of the target community lead to any new information about problems, priorities for intervention among problems, feasibility, or projected impact of specific interventions?

Identifying priority health problems

- Does the problem profile of the “practice population” accurately reflect the status/needs of the larger community in rural areas?
- Can the underdiagnosed problems in a practice population be inferred from epidemiologic analysis of the active patients in the practice population?
- Development of nominal group processes that use existing data and identify a range of important problems, aggregate them in a meaningful way, identify a range of strategies, estimate the impact of strategies, and choose among the strategies one or more to employ.
- Methods for estimating the impact of intervention strategies under consideration during the process of setting priorities.
- What is the difference in the prioritization of a group of problems from the perspective of the community (or its several groups) and the perspective of the professional (or group of professionals)?

Designing and implementing an intervention strategy

- Methods for estimating the projected impact of an intervention strategy under consideration.
- Methods for comparing projected impact of alternative intervention strategies for the same problem and across different problems.
- Development of a nominal group process that identifies health problems.
- When addressing a practice population, how might intervention strategies be structured to take advantage of natural family dynamics?

Monitoring impact of the intervention

- How can an intervention strategy be economically monitored for effectiveness?
 - What information is available (or which data can be collected) to assist decisions to modify or discontinue the intervention?
 - When can a successful intervention strategy be discontinued?
 - Can nominal group processes be developed to assist in assessing the effectiveness of an intervention strategy?
-

- What tools and techniques are needed for measuring need and monitoring the effectiveness of an intervention?
- How much analysis is needed, and how rigorous should it be?

- Are nominal group techniques useful in conjunction with existing data for the analytic functions of **COPC?**

More specific research questions related to the four functional components of the COPC process are detailed in Table 4.

Conclusion

From another perspective, COPC represents the application of the tools and the principles of epidemiology to the organization and practice of primary care. The question here is not whether COPC can apply to the mainstream of primary care in this country; rather the question is, why has it taken us so long to explore the possibilities?

In most of the world, the notion of primary health care explicitly involves the organization and management of primary care for a definable population. The ability to look beyond the individual patient to the health and health care needs of families and the community is one of the cornerstones of good medical practice. The application of epidemiologic techniques to managing the health care of a defined population makes COPC a relevant innovation in primary care for the 1990s.

The fundamental principles of COPC have the potential to contribute to the effectiveness of the mainstream practice of primary care by expanding the perspectives of primary care physicians beyond the stream of individuals passing through their examining rooms to a target population whose health can be improved through strategies that combine primary care and public health. To embed into the practice of primary care the ability and expectation that primary care include concern for a target population larger than the individual or family will greatly improve the capacity of this Nation's health care system to address the priority health concerns of its people.

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Health Services Research and Prevention in Primary Care

Charles E. Lewis, M.D., Sc.D.

Introduction

This discussion will examine current research efforts focused on prevention in the primary care setting; offer suggestions for researchers, agencies, and review groups dealing with this topic; and propose a new research agenda for primary care prevention research. It will close with a list of ten recommendations on how to obtain funding for research.

There are three types of questions related to prevention that are of interest to primary care practitioners and researchers. First, there are the “what” questions; for example, “What are the risk factors that are predictive of the major causes of morbidity and mortality in society?” The answers to such questions are derived from epidemiologic studies, and as with all research, the degree of precision varies widely from study to study.

Take, for instance, the problem of adolescent pregnancy. The research question might be “What are the antecedents to early unprotected sexual intercourse?” and the answer would be “A whole list of variables ranging from poor self esteem, faulty decisionmaking, lack of social support, lack of education, desire for escape from the family, ignorance of physiology, peer pressure,” and so on. It is slightly different in this case than in the case of coronary artery disease, where the answer to the “what” question is more clearly defined. Other “what” questions are: “What do doctors do in terms of prevention? or “What do people do to protect their health?”

Next come the “how” questions: “How well do providers know the population for whom they are providing care, including the prevalence of various risk factors among that population?” “How can we intervene?” “How can we reduce the incidence of adolescent preg-

nancy?” “How can we get individuals to stop smoking?” “How can doctors be persuaded to use a vaccine for hepatitis B?”

These questions presuppose an answer to the third question—that is, the efficacy question: “What works?” Is there anything that (a) changes the antibody structure of individuals or (b) reduces their propensity to smoke or engage in other harmful behavior? If there is a specific intervention—whether it is a vaccine, counseling program, educational program, or whatever—then the subsequent question is “What is the effectiveness of the effort to use such an **efficacious** intervention?”

As illustrated in Figure 1, prevention research efforts can be classified into four categories: causality, providers, interventions, and patients. The figure also lists some questions that research projects under each major heading attempt to answer. For example, in causality: “What are the risk factors for X?” Current knowledge in this area comes from epidemiologic studies, both large (e.g., the Framingham heart study’) and small (derived from practice networks).

Research involving providers may focus on what they know about risk factors and interventions, what they believe about the validity of the data on risk factors and their own efficacy in reducing risk factors, and what questions they ask their patients. In most cases, history taking is an important step that precedes intervention. For the pragmatic, the basic question is, “What do providers do to reduce the risk for their patients?” For interventionists, the question would be “How can providers’ practices be changed?” presuming their practices are less than optimal.

With regard to interventions, the basic question is simply, “What is worth doing?” Is a particular intervention worth spending time, effort, and money on, in terms of pursuing risk reduction?

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Figure 1. A classification scheme for research in primary care prevention

A. Causality	• What are risk factors for X?
B. Providers	• What do providers: know (1) believe (2) ask about (3) do to reduce risk? (4) • How can providers' practices be changed? (5)
C. Interventions	• What is worth doing?
D. Patients	• What do patients: know (1) believe (2) do? (3) • How can patients' practices be changed? (5)

The final category relates to patients. In a format similar to the provider question, it is also important to determine what patients know about risk factors and prevention, what they believe in terms of the truthfulness of the data and the relevance of the risk to themselves, the personal consequences of taking action or not taking action, and finally, what their current practices are.

As a parallel to prevention with providers, patient-oriented prevention research can examine ways to change patient's practices to reduce their risk.

Research Methods

A brief review of the research methodologies applicable to each of these four domains reveals some of the prerequisites for conducting research in this area. Epidemiologic studies generally require fairly large populations. In terms of experimental design, longitudinal studies that provide observations over several points in time may facilitate inferences with regard to causality. For the sake of discussion, it will be assumed that most health services researchers concerned with prevention in the primary care setting have neither the resources nor interest to pursue questions related to this area.

Interventions have been studied rather extensively by those health services researchers who enjoy doing meta-analyses. Reviewing the existing literature and analyzing the relative merits of published studies does have a certain appeal for some investigators. While information arising from such studies is essential, given the recent US Preventive Services Task Force report? this probably will not be a high-priority funding area, at least for the next few years.

The two remaining areas, which should be the most familiar and of most interest to health services researchers in the field of primary care, focus on what happens in the dyadic relationship that exists between health care, disease prevention, and health promotion. Such studies may involve surveys of providers and patients to determine their knowledge base, belief structures, and current practices. A prerequisite for such surveys is access to a defined body (sample) of providers and patients, preferably those with characteristics that permit generalization to a larger universe, and the ability to analyze reasonably large data sets. These studies require experienced surveyors who can design appropriate questionnaires or interviews that yield reasonably **nonambiguous** information about a specific variable. They also require the political clout or economic resources to obtain a high participation rate that will offset the usual threats of selection bias due to **nonresponse**.

Preventive Services Provided by Internists

A study conducted in 1987 by Lewis, Schwartz, and Clancy, with support from the Centers for Disease Control, provides an example of the kind of research described above. A random sample of the membership of the American College of Physicians (ACP) was surveyed to determine what internists do, believe, and know about preventive services and how this is related to thenature of their practices (i.e., subspecialist vs. general internist), gender (male vs. female), and their own personal health practices. Previous studies^{3,4} had demonstrated that a physician's counseling practices were significantly associated with his or her own personal health practices; the study described here provided an elegant sample to retest that hypothesis.

With the endorsement of the ACP (essential for bidding on this contract), a random sample was drawn of approximately 12 percent of the male members of the College and 40 percent of women members and Fellows of the College. Women were intentionally oversampled to provide the number of respondents needed for **ade-**

quate statistical power in comparing their practices with those of men.

This stratified random sample was selected from 22 of the College's 55 regions to ensure adequate representation of all geographic areas. Sampling was done by region to facilitate use of the Governors' offices as "reinforcers." Those members who failed to respond to the initial survey were sent a second questionnaire and a reminder letter; nonresponders to the second notice were called and/or sent a reminder notice from their Governors emphasizing the importance of responding to the survey. A 75 percent response rate was achieved, with a total of 1,359 internists returning the questionnaire.

The questionnaire was designed to collect data on internists' practices with regard to immunizations, the use of screening tests, and counseling practices, as well as information on the organization and nature of their medical practices and their personal health habits. An overall summary of the survey is forthcoming,⁵ as is a more specific analysis of the counseling practices of internists as related to their personal health habits, specialties, and gender.⁶

Results

Table 1 summarizes some of the characteristics of the respondents in this study. The average age of responding internists was 42.9 years, and 85.9 percent of their time was spent in patient care. Of the 4 1.1 percent of these physicians who reported no formal subspecialty training, 36.5 percent stated that they are in the full-time practice of general internal medicine. Only 12 percent of subspecialists indicated that they spend 100 percent of their time functioning as a subspecialist, suggesting that there are many subspecialists who function as generalists. It would be interesting to learn whether they do primary care as well. The average number of patients seen in an office in the average week was 72.2, while the median was far lower (50), indicating that this distribution has a long narrow tail to the right. Almost three-quarters of these internists reported that they saw no nursing home patients during the week prior to the survey.

A variety of dimensions were examined related to providers' personal health, some of which are illustrated in Table 2. Despite the known hazard of nosocomial infection due to Hepatitis B, only 29 percent of these physicians have been immunized against the virus. Almost

Table 1. Characteristics of Respondents

Age (years) (x)	42.9
Subspecialty training	41.4
Patient care time (x)	85.9
Full-time generalist	36.5
Full-time subspecialist	12.1
Patients seen in office (x)	72.2
Patients seen in nursing home (x)	19.2
Note: Number of respondents = 1,359; 71.5 percent see no nursing home patients	

half have no personal physician, 40 percent have not had a physical examination in the past 5 years, and nearly 50 percent have never had a stool occult blood examination.

A greater proportion (72.1%) have never had a sigmoidoscopy, but approximately one-quarter of the men say they examine their testicles (without reference to frequency). As a hint of the effect of gender on personal health practices, only 4 percent of the women state that they do not examine their breasts, and less than 1 percent have never had a pap smear.

Obtaining information for the purpose of establishing risk is the first step in the practice of clinical preventive medicine. Table 3 shows the proportion of physicians who indicate they routinely obtain and record various elements of the history. While almost all ask their patients about smoking, seven of eight obtain and record alcohol histories, and 46.6 percent state that they do the same for exercise. A review of their medical records in other facilities would probably suggest that there has been considerable over-reporting with regard to these and sexual history questions. This is an inherent problem in self-reports of socially desirable behavior.

Screening tests are important to those who would detect disease early. However, in contrast to tests not obtained, there is also the issue of changing provider behavior when tests are ordered that have been documented to be of no value or when they are done

Table 2. Provider's personal health

Immunized against hepatitis B	29.2
Do not have personal physician	47.9
No physical exam in past 5 years	40.8
Never had stool occult blood exam	49.7
Never had sigmoidoscopy	72.1
Never examined testicles	23.8
never examined breasts	4.0
never had pap smear	0.3

Table 3. Percentage of providers who routinely obtain and record a history

Smoking	94.1
Alcohol use	87.5
Exercise	46.6
Seatbelt use	7.0
Sexual functioning	26.9
Sexual orientation	24.7

with a frequency that suggests a concern with economic rather than preventive issues. Table 4 illustrates the practices of surveyed physicians with regard to four common screening tests. Recent position papers from the ACP suggest that an annual ECG is totally **unwarranted**.⁷ Despite the Nation's obsession with cholesterol, it is doubtful whether most internists would agree that serum cholesterol needs to be measured annually, at least in the average patient; the frequency for performing sigmoid-oscropy is also somewhat out of line.

Finally, with regard to counseling, Table 5 summarizes the proportion of internists in this sample who never, or only at the first visit, raise the issue of smoking, alcohol use, lack of exercise, and failure to use seat belts among their patients who have these risk factors.

This study is illustrative of research that focuses on providers. Studies also continue to be done that examine the same questions with regard to patients: What do patients know about risk factors? What do they believe about them? What do they actually do (self-reported behaviors)?

Intervention Research

Perhaps the most important and most difficult area of prevention-related health services research involves the testing of specific interventions designed to prevent "X." Investigators who are action-oriented may find this to be a methodological mine field, and before undertaking such research, they should read the pink sheets from rejected projects to identify the problems that are often found in proposals for this kind of research.

Perhaps the most common problem is the failure to specify exactly what the intervention will be. Often this fault derives from a more fundamental problem—that is, failing to have an adequate conceptual framework to support the intervention proposed. Conceptual frameworks are important, but they are like beauty; they are in the eyes of the disciplinary beholder. Thus, many investigators submit grants that contain an inventory of conceptual frameworks to appease reviewers and fail to settle on a specific framework.

If there is one cardinal ground rule related to interventions, it must be, "make it simple." For not only must the intervention be delivered again, again, and yet again, it also must be constant over time. Only by monitoring the interventions and interveners and providing some data on quality control over the treatment period can the contention be supported that a constant dose of "X" has been delivered to the subjects.

A second dilemma facing researchers who seek to intervene has to do with the nature of the population involved. Evaluating the impact of interventions requires pre- and post-test measures, hopefully on the same subjects and hopefully with a control group. While the randomized controlled trial may be the gold standard in this area, this gold may tarnish if there is significant attrition from the population involved. Incidentally, such attrition is most likely to occur in those groups where evidence of the effect of intervention to reduce risk is most needed, i.e., in disadvantaged populations.

Another truism is also applicable: "it takes a difference to make a difference." While complex interventions are difficult to maintain at a constant level, interventions that provide only minimal treatment may well provide minimal impact.

Table 4. Percentage of providers who do screening tests annually

Chest x-ray	9.2
EKG	24.1
Serum cholesterol	49.2
Sigmoidoscopy	12.6

Table 5. Percentage of providers counseling those with specific risk factors: never, or at first visit only

Smoking	2.0
Alcohol use	6.4
Exercise	19.8
Seatbelt use	83.7

A third and significant problem facing those concerned with research in prevention is the very nature of the problem of counting “nothings.” Prevention is successful when events do not occur; often the events that researchers are trying to prevent are not common, at least within a reasonable period of observation, say 1 to 3 years. Therefore, in dealing with the basic problem with statistical power, several alternatives are present: (1) recruit a very large population, (2) pray for stability and no bias due to attrition, or (3) find a group that has a lot of events and try to prevent some of them. This often brings the charge of nongeneralizability.

Conclusion

Primary care physicians must begin to look at prevention as a way to improve the quality of life for **people**—either one at a time (e.g., in their patients) or in groups (e.g., regional or national campaigns). We must design primary care research that is concerned with prevention, test the efficacy and effectiveness of interventions, and plan programs that can effectively deliver interventions.

Some of the more provocative questions that deserve attention (but may not be at the top of the priority list for funding agencies) include:

1. Why don't physicians do what distinguished groups, such as the US Preventive Services Task

Force or the American College of Physicians, recommend?

2. Why is the teaching of preventive medicine to medical students assigned to Saturday mornings, weekends, and 5 o'clock on Wednesdays?
3. Why is the teaching of preventive medicine not interwoven into the clerkships where it becomes part of the business of patient care?
4. Why is the National Board of Preventive Medicine examination not taken seriously by promotion committees, and why are the questions on that Board so irrelevant?
5. Why don't third-party payers pay for preventive services?

In summary, there are a number of research questions related to prevention in primary care settings that are ripe for investigation. This discussion has focused on some of these questions, and hopefully, it has sparked renewed interest in prevention research among primary care and health services researchers—that was certainly the intention.

But prevention research, like any other kind of research, also has a practical side. The following are suggestions, based on many years of experience, on how to obtain funding for prevention research, especially Federal research grants.

1. Get an idea.
 - test it on your friends
 - do a literature review
 - summarize what's been done
 - reexamine your idea—test it on nonfriends
 - find a suitable framework
 - ask senior investigators from other institutions to listen to you talk about it
2. Get a copy of a grant recently funded by your target agency.
 - read it and reread it
 - imagine your idea dressed up in that rhetoric and logic
3. Get a list of the members of the study section that will probably review it.

- do a citation index review of their work
 - get copies of at least three papers published by them
 - be sure and cite anything written by them that is remotely related to your idea
4. Make contact with a staff member of the agency.
 - send them a brief description of your idea
 - be sure to make an obvious error of omission so they can “save” your idea-thus making it theirs
 5. Write a first draft of the proposal and remember you will rewrite it at least ten times before it is submitted.
 6. Don't forget to:
 - consult a statistician about sampling estimates, power calculations, and an analysis plan
 - ask someone who writes/teaches English to review the proposal for intelligibility
 - get help in putting together a budget (from your organization)
 7. Ask someone old and cranky and experienced to tear it apart.
 - look for every single question-regardless of how ridiculous-that someone might ask
 - prepare yourself for the result of this review
 8. Start all of this months ahead of the deadline for the grant.

- while time does not ensure success, trying to do steps 1-7 by working 24 hours a day is impossible
 - make sure you allow time for all institutional clearances
9. Ask yourself one last time-do I really want to do this if they give me the money? (What if they only give me half the money?)
 10. Be prepared to have the project rejected or not funded; be committed to a rewrite or get anew idea-after a good cry, resubmit.

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Outcome Measurement Issues

Sheldon Greenfield, M.D.

Introduction

The measurement of outcomes in general, and particularly in primary care, is in its infancy, yet great progress has already been made.¹⁻⁴ This discussion will include some general comments about outcomes, describe some very promising work from the Medical Outcomes Study (MOS), and outline a research agenda for the measurement and use of outcomes in primary care.

The use of outcomes to judge medical care or effectiveness is inherently treacherous because of the probabilistic relationship between process and outcomes and the many factors that are beyond the physician's control. However, it is important to note that research into the use of outcomes has begun to deal with the major problems that stand in the way of high validity, reliability, and feasibility for outcomes. Generic outcomes may not be applicable in certain situations, such as common complaints when almost all patients get better or with adverse drug reactions, which are very rare. However, the potential usefulness of outcomes in many, if not most, clinical situations—especially chronic disease—can make them a valuable part of medical practice.

It should be noted that generic patient outcomes, such as functional status and quality of life, allow for maximum comprehensiveness in assessing quality of care, because they reflect not only the technical but also the interpersonal aspects of office-based care—persuading patients to take medication, return for followup, and undergo noxious procedures; eliciting patients' psychosocial problems or **concerns** or beliefs about care that may impair medical treatment; and accounting for patients' values when setting on a course of action. Measures of the process of patient care cannot adequately reflect the interpersonal dimension. This is best reflected in measures of patients' functioning and quality of life.

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The National Study of Medical Outcomes

Evidence is building that patient outcomes provide valid and reliable estimations of the quality of care provided by individual physicians. In the context of the MOS,^{1,2} scores for patient outcomes (controlling for case mix) are being generated for individual physicians. Those scores will be used to compare the care provided in different health care delivery systems, in practices with a wide range of resource use, among different physician specialists, and in different geographic areas. Preliminary evidence from this study suggests that a generalized score can be obtained for an individual physician that is an accurate and stable estimation of that physician's care. Further studies are needed to determine whether and to what extent these individual "patient outcome scores" must be adjusted (by patient characteristics, system of care characteristics, or physician characteristics) before fair comparisons of care can be made.

Patient Functioning and Quality of Life As Outcome Measures

Are patients' functioning and quality of life reasonable indicators of the outcomes of care provided by an individual physician? The most desirable evidence to address this question is not available—that is, that physicians differing on some known criterion of excellence ranked identically when patient outcomes were used to assess quality of care. Recent evidence suggests, however, that these measures, as they are being increasingly refined, are valid for discriminating between the care provided by individual physicians.

Early studies used patients' functional status to predict use of health care services and mortality. More recent studies have shown that patients' functional status correlates with traditional physiologic outcome measures, such as forced expiratory volume in 1 second (FEV),⁵ blood sugar,²⁻⁴ and blood pressure.^{6,7}

A 1989 study of 9,385 patients in the offices of 362 physicians in three major United States cities shows the clinical validity of a functional status measure. Patients and their physicians were asked to indicate whether they (the patient) had specific medical conditions and symptomatic complaints.¹ Patients were also asked to complete a 20-item functional status questionnaire. The results of the association between patients' reports of the presence of specific illnesses, physicians' confirmations of the presence of those illnesses, and patients' functional status are shown in Figure 1. The broken line represents "well patients," those who denied having chronic disease and whose physicians confirmed that they were disease-free. Each disease condition is graphed according to its mean level of impact on physical function, role function, social function, mental health status, health perceptions, and reported pain. As shown in Figure 1, the more severe the disease, the greater the dysfunction. Further, each condition generates a unique signature.

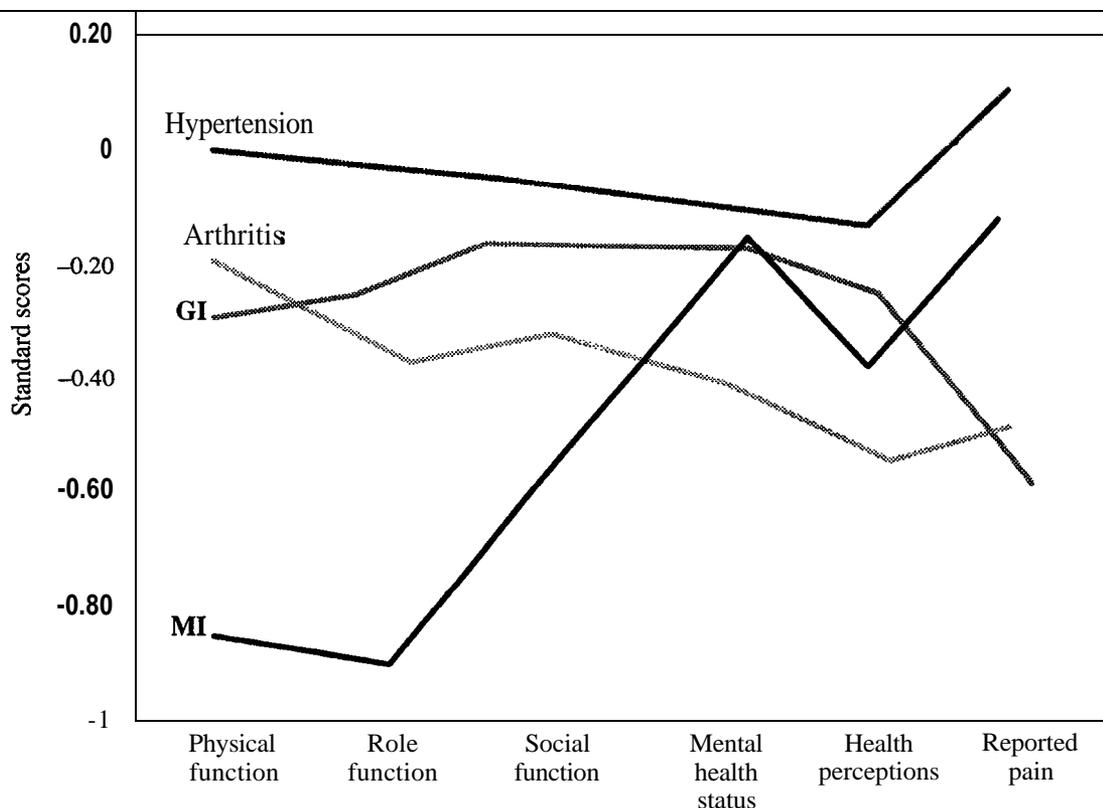
The demonstrated association between patient functioning and physiology indicates that what the physician

does (to manage blood sugar, control blood pressure, treat chronic obstructive pulmonary disease, and so forth) has a direct impact on patient outcomes. These health status measures have achieved the level of validity required to include them, along with traditional outcome markers, in the monitoring of care for chronic diseases. They differentiate between those patients with and without chronic disease and fit the clinical patterns of disease. They show more dysfunction for the more severe disease conditions. The mean for each category of patient functioning (physical, role, social) for each disease condition could be used as the standard of care, below which physicians' performance would be subjected to additional scrutiny.

Outcomes Measurement in Office Practice

Feasible methods now exist for measuring patient functioning and quality of life in the context of busy office practices. In individual office practices, these measures could be used to evaluate the quality of the physicians' performance and provide maximum opportunity for improving patient care through feedback.

Figure 1. Health profiles for patients with four conditions



NOTE: GI = gastrointestinal; MI = myocardial infarction

As with traditional methods for measuring the process of care, the procedural steps for using patient outcomes to evaluate the quality of care include obtaining scores for individual physicians, setting standards below which care will be reviewed, and obtaining the consensus of groups of physicians regarding the standards to be used in defining quality. To obtain interpretable quality assessment information using patient outcomes, the scores of individual physicians, groups of physicians, systems of care, and so forth, must be adjusted for the factors that may cause errors—that is, variations not due to differences in the quality of care provided. Such factors include case mix and optimal time window for making judgments about care. These factors can be overcome. With respect to case mix, for example, there are several techniques for modifying scores in order to render accurate judgments about care provided. “Baseline” measures of patients’ functioning can be used to adjust any scores obtained at some later period. Independent measures of the clinical severity of patients’ health conditions can be used to adjust “baseline” measures of patients’ functioning.

The total clinical disease burden of the patient (the aggregated comorbid conditions the patient has) also can be used to adjust patients’ functional status. Recent evidence indicates that the conclusions drawn about the quality of patient care may be very sensitive to case mix **adjustment**.⁸⁻¹⁰ Further research is needed to identify and adjust for factors that cause inappropriate conclusions about an individual physician’s performance when it is judged using patient outcomes.

Limitations

There are three basic limitations to the use of patient functioning and quality of life as measures of the quality of medical care. First, they are nonspecific. They may reflect factors other than the medical care received by the patient. Second, they do not provide targeted information to improve patient care. Outcomes do not give behavioral feedback regarding the specific elements of physicians’ performance that must be changed. Third, research has not shown that quality of life can be improved. These limitations do not discredit the use of patient outcomes in quality of care assessment. Rather, they suggest that patient outcomes must be used judiciously, nonpunitively, and in conjunction with other measures of the quality of care, including structure and process.

The promise of outcomes, particularly in the area of health status, offers new opportunities in research and

demonstration. First, while the MOS and other studies have provided (and will continue to provide) considerable evidence for the value of outcomes, more research into the tailoring of outcomes to specific conditions, particular kinds of doctors, specific situations (such as emergency rooms), and certain populations—such as poor people and people living in rural areas—must be carried out before they can be generally useful. This will require further research into the relationship of the outcomes to each other and their sensitivity and specificity to process.

Conclusion

Once these measurement studies are done, either as methodologic studies or as part of other policy studies, a host of important primary care research areas can be explored. These areas include the relationships to outcomes of costs, quality of care, discrete processes, new technologies, interpersonal care, systems, and specialties, as well as the characteristics of specific populations, such as socioeconomic status. The dawn of this era of outcomes is a very exciting one and should lead to a great deal of progress in the understanding and improvement of primary care.

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The Impact of Financial and Organizational Changes on Primary Care

Thomas R. Konrad, Ph.D. and Gordon H. DeFrieze, Ph.D.

Introduction

American health care is undergoing rapid and dramatic organizational changes that affect the provision of primary health care. The whole set of issues related to the provision of routine, nonspecialty, health care services is of importance during the present era because primary, health care providers play a critical role in addressing the following policy issues:

- Is it possible to differentiate between necessary and unnecessary use of health care services; can unnecessary use be reduced or eliminated?
- Is it possible to assure that the services received are appropriate to meet requirements and of adequate quality?
- Can access to care be guaranteed for those who actually need health care services?

Primary care providers and facilities shoulder a large burden with respect to all of these issues but play an especially important role with respect to access to care. Unfortunately, in the present period of rapid cost escalation and apparent surpluses of health care practitioners, public policies giving emphasis to the accessibility of basic health care have a distinctly secondary priority.

There are two distinct issues with respect to access. The first is what might be called coverage, or the proportion of the population in need who actually receive a given service. The second is equity, or the extent to which coverage is extended to all elements of the population, without discrimination or preference.* These two issues are obviously related, because efforts to bring those

groups with the lowest level of coverage up to the average level will presumably improve equity as well. But the concept of coverage is much more easily understood and has been the predominant theme in most programs designed to increase access to care.

Among the most important efforts of the past 20 years to guarantee access to health care in the United States has been the effort to ensure that every person, regardless of social status or characteristics, has a regular source of primary medical care. This has involved two types of interventions. First, there are the programs intended to affect the balance between specialists and generalists in clinical medicine through efforts to improve the quality and quantity of primary care training for physicians and to make this level of medical practice a viable and attractive career option. Second, there are efforts to design and promulgate new types of health care programs to serve heretofore underserved populations where primary care is the centerpiece.

Federal, State and local governments, as well as private philanthropy, have devoted much energy and resources to both types of efforts. For example, the development of residency programs in family practice and general internal medicine and the promotion of the nurse practitioner for rural communities are examples of this "personnel" emphasis. The establishment of community health centers in underserved areas and efforts to develop group practices in internal medicine residency programs and hospital outpatient departments exemplify the "organizational" approach. Occasional efforts to coordinate these two approaches have also occurred, as when the National Health Service Corps was proposed as the "staffing" arm of the Rural Health Initiative in the late 1970s.³

At the same time that these planned efforts to increase the volume of primary care practitioners and the options for primary care practice are taking place, the American health care scene has experienced expansion in the scale

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and diversity of the medical care marketplace. Many of these developments seem to run counter to the traditional ideology of what constitutes “good” medical care. Instead of giving emphasis to the notion of a single, regular source of primary care, American health care consumers are being offered a bewildering array of discrete services and service providers who are able to advertise their convenience and accessibility. While employers and other purchasers of health care seem to be looking for ways to “bundle” consumers of health care and to purchase organized programs for meeting their basic health care needs, the health care “industry” is offering—and the consumer seems to be demanding the right to select from a wide range of health care services. Consumers want to protect their right to define specific health care services as relevant to their immediate and specific health care needs. The health services market seems to be headed in the direction of “unbundling” these services and individually marketing them to defined segments of the lay public.

These two trends have quite different implications for the way in which primary health care, as a level of care and as a set of defined relationships between consumers and providers, can develop in the decade ahead. Primary care physicians, for example, increasingly find themselves in roles that have shifted from advocacy for their patients to more emphasis on their responsibilities in the allocation of health care resources.^{4,5} This is especially true as physicians find themselves working as the salaried employees of large multispecialty health care organizations. Coupled with a rapid increase in the volume of prepaid health care, the current era has produced a highly complex environment within which physicians relate to the large practice organizations for which they work.

Investigators at the University of North Carolina’s Health Services Research Center have been studying these trends for more than 20 years. This article draws on the work accomplished at the center during the past two decades in order to make some observations about the kind of studies that are needed to unravel the long-term implications of these transitions in American medical practice.

Starting in 1969, Madison, Konrad, and Tilson⁶ began a study of 40 of the largest multispecialty practice organizations in the United States. The intent was to uncover the history of these organizations and determine the role they were playing in diverse medical markets throughout the Nation. Second, there was interest in the career orientations and pathways of the physicians who chose

to work (largely for salary) in these organizations. Finally, an important part of that study was an effort to understand how the then emerging concept of “primary care” fit into the multispecialty group practice organization.

In 1987, Madison and Konrad were joined by other colleagues (**DeFriese, Kory, Lee, and Pathman**) in a much broader study of all of the largest multispecialty groups in the country and the physicians who were employed by these practice organizations. The differences that emerged in the environment for large group practice over this 20-year period were astounding. Dramatic changes had occurred, both in the motivations of physicians to work in such an environment, as well as in the professionalization of the medical leadership of practice organizations.

The organization of these large-scale practice groups reflects an important and exciting dialectical tension between the imperatives of management, on the one hand, and the priorities of clinical practice on the other. Although, this tension is not absent in other forms of medical practice, it is more acute in the large medical group. Examination of how these groups cope with such tension may provide important lessons and models for the development of innovative methods for organizing and delivering services.

With generous support from the National Center for Health Services Research and Health Care Technology Assessment (**NCHSR**)—now the Agency for Health Care Policy and Research (**AHCPR**)—investigators at the University of North Carolina have studied these transitions in medical practice over quite a number of years. The papers from the second of these studies are just beginning to come out, and this discussion will include some observations from these studies about important developments in the organization and financing of care as they impact on the practice and provision of primary health care.

Methods

The study focused on physicians employed in large medical practice organizations which were defined as having all of the following characteristics:

- employed at least 40 different full- or almost full-time physicians on a nontemporary basis who constituted a majority of all physicians at work in the organization
- could be defined legally as a single entity for purposes of medical practice and could demonstrate ad-

ministrative unity by: (a) self-identification as a unified staff; (b) a designated medical leadership position (e.g., medical director, chief of staff); and (c) a centralized physician recruitment and selection function

- identified the delivery of medical care as its primary **purpose**
- numbered at least half of its physician staff from among the specialties of internal medicine, pediatrics, family medicine, obstetrics-gynecology, and general surgery
- existed as an organization for at least 2 years at a minimum staffing level of 30 or more full-time physicians
- was not a unit of the Federal government
- served clientele that was not restricted in choice or movement.

These criteria established definitional boundaries for the type of physician groups the study targeted—that is, large groups, having some degree of administrative hierarchy and looking toward generally similar, though not identical, goals. The criteria effectively excluded others that might employ large numbers of physicians but were clearly dissimilar: most general short-term hospitals—organizations that are staffed mostly with part-time physicians (who are in full-time private practice but only function part-time in the hospital); physicians in temporary postgraduate training status (e.g., interns, residents, and fellows); the physician tenants of medical arts buildings and other cooperative configurations of separate proprietorships; organizations that engage in patient care secondary to or in support of another principal mission (e.g., research, medical education); **locum tenens** and other kinds of contract staffing firms; certain very large single specialty groups (e.g., in anesthesia or psychiatry); recently formed groups that may be experiencing organizational instability as a result of intensive development and rapid initial growth; patient care settings operated by the Veterans Administration, the public Health Service, and the military; and the medical staffs of asylums, prisons, and student health services of large **universities**.^{7,8}

The data were collected in three phases: (1) identification of potentially eligible organizations, (2) interviews with the leaders of participating groups, and (3) mailing of questionnaires to staff physicians. In phase one, a brief screening questionnaire was mailed to 826 **poten-**

tially eligible organizations who were selected from group practice and health maintenance organization (HMO) directories and Federal sources. From these screening questionnaires, 163 organizations were identified that, in 1986, appeared to satisfy all seven criteria. All were invited to participate in the study.

The second phase of the study took place between fall 1987 and July 1988. In this phase, 30-minute telephone interviews were obtained with key administrative and medical leaders of each of these organizations. From the administrator, data were collected on the group's history and organizational structure, leadership, size and staff configuration, participation in **HMOs** and other managed care programs, and method of physician payment. The medical directors' interviews focused on the medical director position, leadership structure, the locus of decisionmaking for several clinical and program areas, the scope of the clinical services program—including preventive services, physician remuneration at various career stages, the mode of medical staff supervision, quality assurance, productivity expectations, and career guidance. A variety of documents were also **examined**—for example, organizational charts, staff rosters, recruitment literature, resumes of medical leaders, and organizational histories.

In phase three, which began in the fall of 1987 and ended in November 1988, a 16-page questionnaire, the Physician Staff profile, was mailed to physicians in five common specialties—family medicine, internal medicine, pediatrics, obstetrics-gynecology, and general surgery. Issues addressed in the questionnaire included professional background, recruitment, current professional activity, perceptions of the group as an employing organization, clinical and administrative routines, typical hours worked per week, and patient load.

Of the entire population of 163 groups invited, 88 percent (n = 143) provided either executive interviews or physician surveys, while 72 percent (n = 117) participated in all three phases of the data collection. Up to four mailings of the physician questionnaires were conducted yielding a per group average physician response rate of 87 percent.

Findings

Several trends became evident as the surveys progressed. First, large groups have been growing both in number and in complexity, and doing so at an accelerating rate, particularly during the 1980s. Second, these groups are expanding **geographically**. The 163 large medical groups participating in this study staffed nearly 1,300 distinct medical care delivery sites in which **phy-**

sicians practiced. Yet, growth and expansion are harbingers of even more fundamental changes in the structure of these groups; organizational forms seem to be shifting so that older categories of “group practice” no longer apply.

Research conducted in the early 1970s distinguished two major types of large medical group practice organizations. The first was the private multispecialty clinic. Often patterned on the Mayo Clinic, and not infrequently staffed with physicians who had trained there, this kind of group was located disproportionately in the upper Midwest and often was, or aspired to be, a regional or national referral center. These groups were “autonomous” and very individualistic in their orientation. They were owned by their physician partners who broadly shared policymaking authority among themselves but were seldom concerned with establishing clinical regimens of care. They received income exclusively on a fee-for-service basis and paid physicians that way, avoiding overt competition with other medical entities. Collectively they tended to identify with the American Association of Medical Clinics (now known as the American Group Practice Association). The conception of how to maintain quality medical care was basically through attempts to selectively recruit well-trained specialists who “fit into” the organizational milieu of the group.

The other type of medical care organization was called in words that sound almost archaic today—a “closed panel prepaid group practice.” Today it is called a group or staff model HMO. These organizations have been described as “heteronomous” because they often had been founded by or received substantial direction from an external agent that might exercise key staffing decisions. Because this arrangement served to represent the interests of a consumer constituency, policies about the scope of services, staffing, and the delivery of medical care were formulated “proactively” in anticipation of demands from a defined patient population. Decisions about clinical policies were centralized and transmitted to the medical staff through some form of clinical hierarchy with a medical director at its apex. These organizations had a limited range of organizational forms, among them Kaiser Permanente medical groups, Group Health Cooperative of Puget Sound, and the Health Insurance Plan of New York. Many of these organizations were members of the Group Health Association of America. Because they operated on a prepaid basis, they were somewhat out of the mainstream of American medicine’s traditional fee-for-service orientation.

The environment in which these organizations functioned then was also much simpler—geographically, organizationally, and legally. Thus, with the exception of the Kaiser Permanente system, no corporate medical organization operated in more than one metropolitan market area. Independent practice organizations, group practice sponsored HMOs, employer sponsored PPOs, and organized business coalitions seeking volume discounts had not yet arrived on the scene. In many jurisdictions, legal barriers prevented non-physician stockholders from owning shares in organizations employing physicians, and advertising was discouraged by professional ethics and practice acts. More importantly, however, the distinctive potential of the primary care physician, especially the family physician, was not yet recognized.

The more recent study described here, however, revealed dramatic changes not only in the structure of these groups, but in the strategies they use to cope with this changing environment. These trends have been examined elsewhere* using a new typology of large medical practice organizations. That study revealed a new organizational form of group practice that has emerged which is intermediate between the traditional “individualistic autonomous” fee-for-service group and the group or staff model HMO. These newer groups take a “reactive” position in the current medical care market and have adopted the “heteronomous” staff model HMO that has been characterized as usually proactive in seeking out clients and marketing its services. Although this form of organization is typically owned by the physicians working there, it is controlled by an internal medical staff hierarchy. This structure is described as having “administered autonomy.” In addition, many of these same groups also have a dynamic market response strategy which has been characterized as “transitional.” Although they are heavily involved with HMOs and PPOs, which constitute between 20 and 60 percent of their business, such organizations are not overwhelmed by them. Because of their large size and high visibility in a local medical care market, these “transitional” groups can obtain favorable terms from HMOs, PPOs, and others who want to engage in volume discount purchasing. They can secure their position by negotiating with several different HMOs or by starting their own.

There are many other aspects of these organizations that have been examined, but this discussion will highlight the lessons that have been learned through encounters with large groups that bear on defining an organizational research agenda for primary care in the 1990s.

Growth in Scale of Practice

First, when the three prototype organizational forms are examined in terms of how they relate to primary care, an interesting fact emerges. About one-third of the physicians in the “traditional individualistic **autonomous**” groups identify themselves as “generalists” within their specialty of practice. At the other end of the spectrum, in the staff and group model **HMOs**, almost two-thirds of the physicians have such a “generalist” identification. In the “transitional” groups the proportions of subspecialists and generalists are about equal. Physicians’ practice locations reflect their primary care functions. About two-thirds of the physicians in the “**heteronomous/proactive**” groups practice in satellite clinics, while just the reverse is true in the case of the “individualistic autonomous” groups. The transitional multispecialty groups, in particular, are extending themselves geographically and broadening their service mission. This is represented in terms of more satellite and “walk in” clinics, more hours per week of service, and a stronger emphasis on the primary care physician, especially the family physician.

Although many of these groups still think of themselves as major referral centers, they are aware that having their own primary care physicians widely distributed helps ensure that their own subspecialists get the referrals they need to survive. Overall, higher proportions of prepaid medical care are associated with greater use of generalists and broader geographic access. This suggests that an organizational orientation toward a defined population will translate into a pattern of physician staffing and deployment that emphasizes primary care. At the same time, unless there is a consistent understanding between the generalists and specialists of their respective organizational roles, there is a potential for competition for patients between them.

New Medical Leadership Roles

Almost without exception, the growth in size of these groups and greater involvement with third parties have led to more centralization of policy formation in the traditionally individualistic medical group, while geographic expansion has fostered some decentralization of operational control in the group and staff model **HMOs**. The result has been to make physician leadership in these two formerly divergent types of organizations become more similar in outlook and to increase the depth of the executive cadre of physicians.

There is an emerging realization that medical management involves not just a representation of organizational

interests to the outside world but the actual control of medical work. This means more than merely documenting and reporting on physician behavior; it also means developing mechanisms to plan what physicians will be doing and ensuring that it gets done in a way that is consistent with corporate goals and strategy. This tendency in management is being strengthened through mechanisms such as the use of executive discretion in the awarding of salary bonuses—long a feature of other American corporations but comparatively new in medicine.

Further, for these executives, the impending implementation of the resource-based relative value scale (RBRVS) means that accurate monitoring of physician behavior has assumed a whole new importance, since thousands of distinct medical decisions by hundreds of individual physicians may have quite unanticipated financial consequences for the entire organization as well as its various specialists and subspecialists. Changing the value of primary care and the “cognitive” specialties could promote friction between generalists and **subspecialists** within these groups. This possibility is likely to strengthen the role of medical administrators in mediating the different interests in their organization and establishing the “rules of the game” for the internal division of labor. Medical executives also have an interest in examining health services in a different way than do clinical practitioners or medical researchers. Their perspective draws upon the work of the health care economist and clinical epidemiologist. They need to play a role in identifying and selecting from the ever-proliferating stream of medical technology (both hardware and procedures) those in which an organizational investment is warranted,

The strengthening of the primary care function does not necessarily mean that the individual autonomy of each practicing primary care physician is increased. In fact, the enhancement of the collective autonomy of the primary care physicians in these settings may be accompanied by a diminution of their latitude of **decisionmaking** as individuals. The active participation—even dominance—of primary care physicians in the establishment of practice guidelines or protocols within their groups serves to establish a distinctive pattern of care and a style of practice for an organization out of what previously had been idiosyncratic initiatives by individual physicians or specialties. Generally, such rationalization of practice patterns strengthens the collective hand of the primary care divisions of the organization over the **subspecialties**. Yet, because primary care involves those

diagnoses and procedures that are most frequently used in medical practice (and hence the most susceptible to routinization), it is primary care physicians as individual practitioners who are most affected by practice guidelines once they are established and institutionalized. Primary care physicians may have a stronger voice in determining the collective balance between quality and efficiency, but once their voice is heard, they may also experience stronger constraints on their traditional autonomy as individual practitioners.

New Financial Interests

The significance of concerns about striking the right balance between quality and efficiency becomes evident with the realization that new financial interests have established a firm presence in the provision of primary care and projected that presence to more than one metropolitan market area. Some, like FHP, Inc., have established their own medical groups owned outright by stockholders. Others, like PruCare, have contracted with well-established multispecialty groups to acquire a reliable, direct-service capacity. Still others-like CIGNA, HealthAmerica, and Maxi&e-have used both strategies, sometimes merging preexisting groups with “primary care networks” in the same community that had been a group’s competition. Even where ownership arrangements are not involved, HMOs can possess substantial leverage as purchasers. Most of the medical group informants participating in the study reported that employer coalitions and individual practice association (IPA)-type HMOs were communicating to them their desire for specific packages of services, although few had set any quantitative targets. At the same time, some traditionally independent medical groups have established their own HMOs in order to compete with IPAs developing in their areas. Whatever particular form these developments take, they have promoted a “clash of cultures” in which corporate and medical interpretations of economic and clinical phenomena are often at odds.

There has emerged anew category of physician executives who serve as “boundary-spanners” between the two perspectives. As a consequence, the function of the primary care physician has been strengthened, not only because primary care physicians are perceived by all concerned as providing or arranging for more cost-efficient services, but also because generalists are disproportionately likely to occupy these strategic leadership roles. This tension between the imperatives of management (efficiently organizing the delivery of health ser-

vices) and the priorities of clinical practice (ensuring that physicians have an opportunity to exercise their craft) has always been there, and traditionally respected clinicians, using common sense and informal techniques, were able to reconcile these competing demands. But the presence of corporate interests (competitive positioning, strategic planning, major capital acquisition, stockholder return) and more explicit efforts by third parties aimed at ensuring the organizations’ accountability, through the inspection of their processes and outcomes, has made this process of managing simultaneously more difficult and more necessary.

Yet, clinical leadership must be exercised if medicine’s clinical autonomy is to be preserved in practice settings that integrate a viable governance structure with a sensitive and sensible quality control process so that both are palatable and effective. In interviews with medical directors during this study, many individuals were encountered who are “muddling through” despite the difficulty of developing effective clinical leadership, uncertainty about methods and criteria for assessment of the “medical director” role, and an absence of grounding in organizational lore or theory. What they do have now is the increasingly sophisticated capacity of information technology to record and display the parameters of clinical decisionmaking in their medical staffs to measure medical practice variation. In the future, however, they will have results from health services research focused on outcomes, some of which may have been generated out of their own organizations in collaboration with other similar medical groups. Given these conditions, it seems likely that important, possibly irreversible, changes in the delivery of primary care will ensue.

As stated earlier, the medical executive is also a boundary spanner who often directs or assists in the formulation of clinical policies meant to balance the demand for quality and the need for cost-effective application of resources. The medical director is also the advocate for the medical staff in negotiating with the other elements of the large practice organization that are no longer as subservient to medical dominance as they were in former times. Just as the primary care physician’s clinical role combines allocative and advocacy dimensions, so does the medical director’s. Only in this case it is allocation of resources between the different segments or specialties on the clinical staff and advocacy for the medical practice in its competition with other organizational and environmental interests.

Defining the Content of Primary Care Practice

In this study, one area was examined in more detail than others, and it bears directly on the delivery of primary care in these settings. This was the formulation and implementation of policies dealing with clinical protocols or practice guidelines. First of all, ambulatory care “practice guidelines” specifying expectations for physicians to provide certain curative medical services for the care and treatment of acute illness were relatively atypical in all these settings. On the other hand, there were a number of organizations with medical staff policies in the area of preventive health services. Variability in the scope of these policies could come from a number of sources, including the nature of the service delivered and the practice specialty of the physician. Some services may be easy to deliver or hard to forget in the normal routine of primary care; some specialties may be more assertive in developing and promulgating recommendations to their practitioners than are others. Consequently, four broad areas were chosen as indicators because (1) it was thought they might encompass the work of practitioners in different primary care specialties, (2) discussion focusing on guidelines was ongoing, and (3) uniform professional consensus about the content of such guidelines was lacking. These areas included immunization, smoking cessation, colorectal cancer screening, and breast cancer screening.

In each of these areas, the “proactive/heteronomous” groups were most likely to have a strong set of expectations that their physicians provide preventive services and be fairly specific in the content of that policy. For example, all of the “proactive/heteronomous” groups, had an immunization protocol, and virtually all of them had a protocol for breast cancer screening for women aged 50 to 59 (96 percent) and colorectal cancer screening (89 percent). In addition, almost three-quarters of these highly structured medical practices encouraged their primary care physicians to suggest smoking cessation initiatives to their patients and routinely recorded patients’ smoking status in their charts—a process that helped physicians to implement this preventive service. Medical groups that were less structured internally or less involved with HMOs were markedly less likely to do these things. For example, only 69 percent of the “individualistic/autonomous” groups had an immunization protocol; 65 percent had a breast cancer screening protocol for women aged 50-59; and only 46 percent had a protocol for colorectal cancer screening. Fewer than half of these groups (42 percent) had an explicit

expectation that primary care physicians should initiate smoking cessation counseling with their patients who smoked, and even fewer (38 percent) facilitated this process by ensuring that they had a smoking history from all their patients. Further, the intermediate groups—those with some centralization and intermediate levels of HMO participation—ranked in between the two extreme types in the percentage that had well-defined preventive service delivery policies in three out of the four areas described above.

What is the significance of this variability and what accounts for it? Of course, because it was not possible to examine record data from the patients of more than 6,000 physicians in settings across the country, it is impossible to say for certain that the presence of a preventive services protocol leads to a higher proportion of patients receiving these services. However, it was found that physicians’ self-reported volume of preventive services delivered was higher in organizations that had more formal preventive service policies. These data are consistent with the hypothesis that substantial effects are due to organizational variables. Over 80 percent of the organizations surveyed indicated that they included their groups’ provision of preventive services as a part of their marketing strategy. A logical interpretation of these findings is that an organization with a strategy of involvement with HMOs has a reason for emphasizing preventive services, while an organization with a structure that centralizes clinical policy decisions has a mechanism for ensuring their delivery.

Access to Care

It should come as no surprise that large medical care organizations possess the resources to deliver quality care relatively efficiently. However, whether they can effectively reach all the population in need, given the current system of paying for (or not paying for) medical care, remains questionable. Of the 117 organizations surveyed, 113 reported estimates of the percentage of their patient care paid for through Medicaid. Of these, 21 (18.6%) indicated that they did no Medicaid business at all, and among those who served Medicaid clients, 31 said that Medicaid accounted for 2 percent or less of their revenue; at the other extreme, there were 10 large group practices that identified Medicaid patients as representing 10 percent or more of their revenue. A variety of environmental correlates of provision of Medicaid services were examined, and it was found that such characteristics as the level of Medicaid reimbursement in the State, the size of the Medicaid population, and the level of per capita income in the metropolitan area were not

correlated with the organization's relative emphasis on the Medicaid population. On the other hand, a significant negative relationship ($r = -0.37$; $p < .001$) existed between the proportion of care provided to Medicaid patients and the care paid for through prepayment contracts. Further, despite the fact that internal hierarchical structure and low organizational autonomy are highly correlated with HMO involvement, Medicaid participation is not related to those structural features of the organization. This pattern suggests that medical groups of all kinds that target HMO clients are less likely to serve a Medicaid population, and this appears to result from strategic marketing decisions rather than any inherent responsiveness to local community needs. For example, 13 of the 28 reporting groups who had 60 percent or more of their patient population in HMOs did no Medicaid business at all, yet most of these organizations are located in major metropolitan areas with high numbers of Medicaid patients and where payment policies are on the more generous side (for this reimbursement source). Of course, Medicaid patients might have access to care from other institutions in the area that were not included in this survey. It is worth noting, however, that almost invariably the proportion of a practice's patients who are Medicaid patients is lower—generally far lower—than is the case for the State as a whole. Further, among those with a high volume of prepaid service, organizations that were founded more recently (since 1972) are especially less likely to have a Medicaid clientele. On the other hand, older HMOs also have aging populations, and their competitive disadvantage is likely to make it more difficult for them to provide the volume of services demanded by their beneficiaries as they age into eligibility for Medicare.

The physicians who work in these organizations are not unaware of this problem of access. In this study, physicians were asked: "How do you feel about the amount of attention your practice organization gives to concern with providing care for the poor and uninsured?" and gave them the option of answering on a seven-point scale indicating whether they thought their organization placed too much emphasis, too little emphasis, or the right amount on this medically indigent population. Almost 60 percent of the physicians in groups that did no Medicaid business thought their group did too little for the poor and uninsured. Even in those groups with 10 percent or more Medicaid business, about 30 percent of the physicians expressed the same opinion. Conversely, even in practices with high proportions of Medicaid patients, only 10 percent of

physicians think their organizations are doing too much for the poor. This situation leaves unanswered the question of how these large scale organizations, with their potential for efficient delivery of quality services, might be able to bring to bear their considerable health care resources in extending their services to the more economically vulnerable sectors of the population.⁹

The fact that organizations may be unable or unwilling to provide broad access to care, while the physicians who work in these practice settings might wish it were otherwise, highlights another theme that is worth stressing: providers are not the same as practitioners. Provider is a term used to designate an individual or entity that supplies health care services for use by patients or groups of patients. Practitioners, on the other hand, are always individuals—people who are trained and licensed to provide personal health services. Traditionally, not much thought has been given to this kind of a distinction because the provider of ambulatory care has usually been conceptualized as a physician in solo practice. With the growth of complex organizations in the delivery of inpatient care and the rise of the prospective payment system, a divergence of economic interest between the hospital and the physician has become more evident. And as group practices become larger and more complex, a parallel process is happening in the area of ambulatory care. Thus, the way in which medical practice organizations (i.e., providers) are compensated is not necessarily the basis on which practitioners are compensated for their services. More structures are being interposed between the incentives and controls of the reimbursement system and the incentives and controls of the employment system. Then it becomes more difficult to predict the consequences of any of the changes in reimbursement policies on any of the outcomes of concern in primary care—efficiency, quality, and access.

Conclusion

When an individual has a charge from Congress, such as Dr. John M. Eisenberg does, to sift through information and make substantial policy recommendations, our common recognition that we are not exactly sure how to define an "intermediate visit," is not just a curious omission, but a vital piece of missing information. Dr. Eisenberg (in this volume) describes the wide range of sources and methods of information that the Physician Payment Review Commission (PPRC) takes into consideration in making such decisions. Dr. Barbara Statfield (in this volume) and her research team rely on extensive secondary data analysis to construct profiles

of patients who present different kinds of requirements for service. These efforts are clearly needed if there is to be any progress in the right direction.

As these efforts begin to bear fruit, the intuitions that researchers and practitioners have about how different types of patients make use of primary care may be validated, and understanding may increase about how to more successfully manage the care of those with **particular** patterns of chronic or acute problems. These efforts could be enhanced through illustration with some concrete cases-longitudinal profiles that simultaneously portray the clinical problems **while** also telling the patient's story.

Eliot **Freidson**¹⁰ has recently noted a curious paradox in health services research that is especially applicable to the field of primary care, and his observations are worth quoting at length. After remarking on the extensive amount of research on the health care system that has been developed over the last two decades, Freidson states that really there is little reliable information about the way the health system works, because we

... lack data obtained by direct, firsthand observation carried out systematically by trained investigators. The data that are available in bewildering profusion are primarily indirect, secondhand data collected for administrative and accounting purposes but treated as if they represent what actually goes on in health care settings. There are also documents produced by task forces, commissions, and other tourists after they have visited some country or institution, been led on officially conducted tours, and chatted briefly with officially selected informants under institutionally-controlled conditions. By far the smallest proportion of all the words available report systematic and direct study designed and carried out independently of the institution by skilled researchers, and even there most of them are surveys long on representativeness and reliability but short on validity. In all, the primary resource on which we rely in order to make sense of health services is not so much sound information as our sense of plausibility, which varies by personal experience and theoretical, moral, and political prejudices.¹⁰ (pp. 231-232)

The observations are incisive, if not flattering, about the current state of the field of health services research, especially in the area of primary care where the content of services actually delivered is not always obvious and their import is often not immediate. Research in primary care may have to make a few forays into ethnography in order to color in the thick sketchy outlines drawn from secondary analysis of large administratively oriented databases and add to them a "sense of plausibility."

Primary care research has almost always been more likely to be conducted in organized ambulatory care set-

tings, at least partly because it is easier to "round up" patients and doctors in such systems. Yet, the findings of such studies have not been as convincing to practitioners or policymakers as they might otherwise have been because of limited generalizability to the "real world" setting of the busy and independent solo practice physician. As organized systems become more mainstream, significant portions of this "real" world are being transformed, often with a speed and subtlety that eludes us.

Clearly, a role for organized groups in the delivery system exists and has been recognized at least since the report of the Committee on the Costs of Medical Care¹¹ over half a century ago. If there is to be any kind of coordinated national effort to make the delivery of primary care more efficient, assure a minimal standard of quality, and reduce the inequities in the delivery of health care, some kind of involvement of large scale group practice will be required. As this occurs, satisfactory explanation of these processes will require that more emphasis be placed on identifying the role of organizational factors in the explanation of physician practice patterns.

While there is still a need to broaden our perspective to see the context in which these decisions are made, it also might be necessary to narrow the focus to those few key elements in the system that seem to have the capacity to make fundamental changes in the content and function of primary care. While the following list is not exhaustive, there are at least three issues that underpin the others:

- How will primary care physicians come to deal with the inherent contradictions of the gatekeeping activity?
- How will the role of the medical executive **evolve**—more strongly in the direction of advocate or allocator?
- To what extent will the emerging ethic of commercial marketing of medical care undermine efforts to assure access to care for vulnerable population groups?

The development and testing of models of organizational behavior, both at the micro and macro levels, as well as the ongoing monitoring of how these large scale health care organizations actually behave in the real world, will become crucial to an understanding of how to link broad national health policy objectives to the myriad decisions made in the consulting room of primary care physicians every day in their patient care.

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AIDS and Primary Care Research: Marcus Welby vs. the Green Eyeshade Boys

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Introduction

It seems that a couple of decades ago, there were many more articles and conferences about primary care than there have been lately. The reasons for this are unclear, but hopefully, this conference is an indication that primary care is indeed alive and well and making a comeback. The purpose of this presentation is to examine how primary care research is related to the current AIDS crisis.

The title of the presentation, “Marcus Welby vs. the green eyeshade boys,” may be a bit confusing. The term “green eyeshades” refers to accountants who, at least in the old days, used to actually wear green eyeshades and sleeve garters and other trappings of their trade. These two images reflect the dichotomy that exists today with regard to primary care. There are two fundamentally different notions of what primary care is now in America and how it relates to HIV/AIDS.

This discussion will focus on three topics: (1) the different views of primary care, (2) some fundamental tensions about the attributes of good primary care, and (3) some lessons learned from the AIDS epidemic about primary care research as they apply both to HIV disease and other diseases.

Perspectives on Primary Care

‘There are several different concepts of primary care. To begin with, the notion of primary care **really** emerges from the 1960s and early 1970s as an ideology. It comes from a kind of wistful remembrance of the way medicine used to be or the way it was supposed to have been. Was it ever really like that? One of the most prominent

features of the “good old days” is that they are always better in retrospect than they were at the time.

What is primary care? Most of the presenters at this conference provided a definition of primary care, each of which differed slightly from the others. Some of the definitions that have been used to characterize primary care include:

1. Primary care connotes access, continuity, and comprehensiveness.
2. Primary care provides medical and psychosocial support.
3. Primary care facilitates communication of information about health status and disease to patients.
4. Primary care is responsive to the community.’>

Organizational viewpoint. Several decades ago, there were organizations, such as the American Medical Student Association, and various health activists who were greatly concerned about access to care. That was the period, after all, of Medicaid and Medicare. It was then, too, that many other innovations were responding to the message, “Americans don’t have access to the kind of care that they need.”

Patient’s viewpoint. There was a sense that American medical care was becoming too specialized, too compartmentalized, too difficult to figure out, and too hard for patients to maneuver their way through. Americans needed doctors that were, in essence, like Marcus Welby. Marcus Welby was everyone’s favorite doctor; he was the ideal doctor. A clear message emerged from patients: they seemed to be dissatisfied with the American health care system, and many providers echoed this dissatisfaction as well. A general feeling emerged that Americans wanted to go back to the way things were before. And so, the notion was born of what primary care was supposed to be.

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The hospital administrator's perspective. Hospital administrators certainly have their own notion of primary care. If asked, a hospital administrator is likely to say that the role of a primary care physician is to keep the hospital beds full. In other words, a primary care physician is to patients as a whale is to plankton. Advertisements by hospitals to recruit primary care physicians usually claim that they want their patients to have continuity and comprehensiveness; in reality, they want to keep the beds full. Hospital administrators, for the most part, perceive primary care physicians as part of the transmission path from illness walking around in the community to someone in a hospital bed.

Academics. Once upon a time, there was funding for primary care training programs, and there were conferences on primary care in the academic setting. It's pretty clear that a lot of the people who went through primary care residency programs found that they could not survive in academia, let alone get promoted, by spending an hour and a half with Mrs. Jones going through the prognosis of her hypertension. And so, somehow, academia turned "primary care" into arcane decision analyses. So people are calculating patient utilities and somehow this is translated as primary care. What this has to do with Marcus Welby is hard to fathom. But to some extent primary care became that set of disciplines that didn't have another home in academia and about which a researcher could get papers published.

Often the people who did the primary care were also doing other research, and they became melded together as general internists, general pediatricians, and family practice people. Medical interviewing, patient attitudes, and related activities are reflective of aspects of primary care.

But the latest and probably most powerful notion of primary care is as gatekeeper. Some time ago, John Eisenberg published an article in the *Annals of Internal Medicine* entitled, "The internist as gatekeeper."³ It was prophetic; over the past 10 years, managers of health care systems and insurers of health care have increasingly come to see primary care as the savior of the health care system. They certainly view the primary care physician and his or her attributes very differently from the "warm and fuzzy feeling" described earlier.

The "ideal" primary care physician. From the patient's perspective, the ideal primary care physician is available 24 hours a day. He or she is knowledgeable about all diseases; has unlimited time to chat about any subject; makes house calls; treats adults (pregnant and nonpregnant), children, and pets on occasion; is kind

and compassionate; and is never concerned about money.

The average health maintenance organization (HMO) medical director's idea of an "ideal" primary care physician is quite different. He or she follows about 4,000 patients with ruthless efficiency, seeing one every 12 minutes, and is very stingy with prescriptions and even stingier with referrals to subspecialists. This is a physician who occasionally orders x-rays, has heard of CT scans but has never actually ordered one, and has never heard of MRI.

The question is, where does this schizophrenia come from? In part, it comes from the split between the normative prescriptive notion of primary care-Marcus Welby-and the day-to-day operational realities of the bizarre health care system in this Nation. Most people recognize and understand both sides of the story. And that, in fact, is the problem; it is difficult to reconcile what is clearly desirable-not only for patients, but also for the health care system and ourselves-with what is necessary in terms of the way the system is working today.

Renewed Interest in Primary Care

What were the reasons for holding this primary care research conference? There are three important factors that provided the major impetus for this meeting.

1. The health care system is financially out of control. It is now recognized by private payers, hospitals, unions, businesses, and by the biggest insurer of all—the Government—that the health care system's financial order is in trouble.
2. Most people are now convinced that there is no practical solution at hand; all of the measures that have been tried—managed care, preadmission screening, utilization review, second surgical opinions, and so on—have failed to halt the rise in costs.⁴
3. The closest thing there is to an official policy about what will be done in this area is an agreement between the Government and the payers and insurers that effectiveness research must increasingly guide reimbursement—that is, those health care practices which are not effective must be separated out from those that are effective, and payment for ineffective treatments must be denied.

And so a pressing priority has emerged to pay much more attention to what works and what doesn't, in part because of concerns about quality. But, in reality, **effec-**

tiveness research seems to be the only avenue open at this time for keeping health care expenditures under control. Therein lies the schizophrenia that characterizes discussions about primary care practice: is a primary care physician supposed to be Marcus Welby or should he or she be a skinflint? It is probably impossible to have it both ways, and pretty soon, a decision will have to be made.

Primary Care and AIDS

Now, how does the foregoing relate to AIDS? This won't be a discussion of the pressing health services research issues in AIDS.* Instead, the following will focus on the priorities for primary care providers and health services researchers with regard to AIDS.

Who treats AIDS patients? Why is it that certain doctors—that is, certain types of doctors—seem to take care of patients with particular types of diseases? It seems that there are certain features of diseases that have an impact on why one doctor takes care of them instead of another.

First is prevalence—take, for example, diabetes compared with Wegener's granulomatosis. With conditions such as these, it is easy to decide who would and would not be expected to take care of patients.

Another issue is difficulty of diagnosis, a factor not often considered. There are a fair number of patients who, if they have a wart or a lesion on their skin that has changed recently, are going to go directly to a dermatologist. If a man gets hit by a truck and a bone is sticking out of his leg, he knows enough to go to an emergency room and consult an orthopedist. He's not going to start with his family physician and then be referred through the network. On the other hand, if a man is feeling tired and doesn't know where to go, he will probably visit his primary care doctor, if he has one.

Then, there is the rate of change in the therapy. When a therapy is changing quite fast (e.g., therapy for some cancers), many doctors won't feel very comfortable taking care of such a patient unless they know the latest information and therapies. With hypertension, on the other hand, the therapy changes very glacially; there is a new calcium channel blocker—so what?

The nature and toxicity of the therapy also helps to determine who will treat a patient. Most primary care phy-

sicians probably feel uncomfortable handling therapies that are themselves toxic and with which the physicians don't have a lot of experience. For this reason, they are reluctant to do much with methotrexate or bleomycin, because they don't want to kill patients in the course of trying to take care of them.

And lastly, the demographics of the population with a particular condition or disease also have an impact on who will provide care. Clearly, obstetricians are professionally prepared to take care of poor women who are pregnant. But most poor women who are pregnant wind up going to other places for care rather than to private obstetricians.

So, in looking at why it is that people with AIDS come to the HIV outpatient clinic at Johns Hopkins Hospital in Baltimore instead of to neighborhood health centers, it became apparent that not enough is known about why one doctor treats a certain condition and not another.

Why have repeated calls for neighborhood health care centers to take care of people with AIDS fallen on deaf ears until recently? In order to answer this question, it is necessary to understand why certain doctors take care of colon cancer in some communities and not in other communities. This perplexing question certainly applies to AIDS patients and the physicians who do and do not treat them.

There don't seem to be a great many health care providers who are willing to take care of AIDS patients, despite the fact that many people have called HIV/AIDS a primary care disease. If the kind of warm and fuzzy definition of primary care is used—that is, continuity, taking care of all their problems, available 24 hours a day—that's what the physicians at the Johns Hopkins HIV outpatient clinic try to provide for their patients.

But, it is troubling to realize that calls for every general practitioner, every family practitioner, and every neighborhood health care center to take care of people with HIV infection don't seem to be answered. If this phenomenon is common, not just in Baltimore but in other cities as well, it signals a serious problem that will only get worse.

Public health and AIDS. A second set of issues has to do with the role of clinical public health services with regard to AIDS. In this context, clinical public health services include STD clinics, TB clinics, and neighborhood health centers. There are now many public health departments around the country that are talking about setting up "seropositive reactor clinics" or clinics to take care of the HIV-positive individuals who feel well. And they are contemplating this on the basis of existing mod-

*For a thorough discussion of AIDS in the context of health services research (including severity of illness, statistical projections, quality of care, and other issues); see *New Perspectives on HIV-Related Illnesses: Prowess in Health Services Research*, proceedings from a conference held May 17-19, 1989 in Miami, FL. Rockville, MD: Agency for Health Care Policy and Research; 1989.

els of clinics that take care of poor people with TB or STDs; they legitimately perceive that **no one** else is taking care of poor people with HIV/AIDS. Why is it that the medical market has failed in this regard, and it has been left to the public health departments at the city or State level to step in and take care of these people? Given the differences between HIV/AIDS and TB, for example, will the health department that does a good job of taking care of TB and STDs be able to do a comparable job in taking care of HIV/AIDS patients?

Quality of care. A third factor concerns the meaning of quality. Many of those who do health services research and have been concerned about quality of care have seen quality as something rather narrowly defined from a medical or surgical perspective. But what about the notion of quality as something that the consumer perceives? Does the patient have a place to park, does the nurse speak English; is the food any good? Researchers tend to dismiss these considerations as amenities or trappings; nevertheless, they can be the deciding factors that make patients choose one hospital over another. So patients perceive these “nonmedical” concerns as elements of quality in a way that health services researchers usually do not.

For example, there are 58 HIV-positive women who have given birth at John Hopkins Hospital and have children that are being followed by the pediatric HIV center. Of these, only nine are being followed by the Hopkins’ HIV outpatient clinic. They all have been referred to us, but they haven’t shown up or they haven’t stayed in care. There is no question that, if they came in, they would get the right dose of AZT or pentamidine at the right interval; the “quality,” narrowly defined, would be there. But there’s something about the services at the outpatient clinic that is not attractive to these patients, factors that are often ignored in considerations of quality. Thus, there is one set of quality definitions that applies to the technical aspects of care and another that is much more difficult to quantify and, unfortunately, may be dismissed.⁵

Other health care providers. Fourth, what is the role of nonphysicians, not only nurses but also physicians’ assistants and nurse practitioners? Most of the care at Johns Hopkins’ outpatient HIV center is delivered by nonphysicians. At a time when there was a physician shortage, either real or perceived, there was interest in and money for training for these “midlevel support people.” Now that there is a perceived physician surplus, it’s not popular anymore; money for training nurse practitioners and other personnel is less available.

The future of HIV care almost surely will depend a lot on **midlevel** personnel, especially as many States pass laws restricting the working hours of house staff. Certainly the role of nurse practitioners and physicians’ assistants in today’s medical arena is an issue that deserves renewed **attention**.⁶

Consumer support for research. And lastly, what is the role of consumers in affecting the agenda, site, and methodology of research? Peter Budetti (in this volume) maintains that it is important for those who have an interest in health services research to be politically active. Nowhere is this more important than in connection with HIV/AIDS. The consumers of this research (particularly HIV/AIDS patients and the gay community) have played a pivotal role in AIDS research, not only in securing funds for it, but also in defining the subject of the research, the sites of the research, and even the research methodology. To the extent that the constituency for health services research is limited to health services researchers, the field will always be in a weak position relative to biomedical and basic science research. If a health services researcher goes to a local neighborhood church or a senior citizens’ organization and asks them to write their Congressman in support of a decision analysis program, it’s a safe bet that they are not going to be all that interested or motivated to help. Health services research suffers not so much from a lack of direction or data as from a lack of commitment of public will and funds. It boils down to an inability to communicate the urgency of the research to consumers.

That’s not to say that more research is unnecessary in areas such as infant mortality, but a great deal is already known about how to lower the infant mortality rate; this is information that for the most part has not been acted upon. And so, understandably, the potential constituency for health services research is perhaps not so eager to be supportive of those areas of research that earn academic credit because, from their standpoint, these issues are not the main barriers to increased services and better outcomes for health care consumers.

Conclusion

All five of the areas described above concern AIDS and primary care; they are not new issues, but they are being revisited in light of the ongoing schizophrenia that now characterizes health care planning and financing. Is primary care really desirable because it serves a patient-driven, quality-driven, **comprehensiveness-of-care** agenda, or is it something that can help to reduce

health care expenditures, control utilization, and distinguish the effective from the ineffective?

These two missions-providing quality care and controlling costs and utilization- are not fundamentally incompatible, but there are some conflicts. For example, concerning the mission of AHCPR, the new agency will face a conflict between the psychosocial “softer” primary care agenda and the need to issue three sets of practice guidelines fairly soon. This ongoing tension probably will continue for some time.⁷

Focusing on AIDS, it would certainly be worthwhile to examine whether medical treatment effectiveness and cost control can't be compatible, or to the extent that they are incompatible, to quantify what the trade-offs are. What are the trade-offs in cost for higher quality care? What are the trade-offs in quality for more cost-effective care?

Hopefully, in the area of AIDS research, towards which there is, I believe, some resentment among some academics about what they believe is overly generous funding, researchers can begin to supply some answers to the broader areas of health services research that are chosen not because they're special to AIDS but because there may be a special urgency to resolving them in this field.

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Alcohol and Substance Abuse in Primary Care Settings

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Introduction

In recent years there has been growing concern about the prevalence of alcohol and drug abuse in the general population. While this concern is often expressed as a need for greater law enforcement, it is also being translated into a strong mandate for action by the health professions. At the Federal, State and local levels there is a general consensus that health professionals should be more involved in the identification and management of persons at risk of alcohol and other drug problems. Beyond the conviction that more should be done, there is little concrete guidance at the policy level to indicate how good intentions should be translated into action. Fortunately, this situation is changing with the development of expert consensus recommendations and the mobilization of resources for research, training, and program planning. One sector of the health care system that is being targeted for increased attention is the primary care setting. This is reflected in the recent publication of several important expert committee reports,¹⁻⁵ each of which defines new roles and responsibilities for primary care with respect to alcohol and drug abuse. Two reports recently released by the Institute of Medicine (IOM)^{4,5} merit special attention.

The first study, entitled *Broadening the base of treatment for alcohol problems*,⁴ is a critical review of available knowledge and experience regarding the provision of treatment services for alcoholism and alcohol abuse. During its deliberations the IOM study committee was guided by a vision of the probable structure toward which treatment for alcohol problems seems to be evolving. That structure comprises a continuum of services in which a broad community-wide screening effort is coupled closely with a comprehensive specialized treatment network. The proposed role of community

agencies includes the identification of individuals with alcohol problems in primary care settings, the provision of brief interventions to a portion of those identified, and the referral of others to specialized services.

The second recent IOM study? *Prevention and treatment of alcohol-related problems: Research opportunities*, contains an important chapter on early identification and treatment. The chapter specifies a research agenda needed to develop the knowledge base for screening and brief intervention. Because this agenda is so relevant to the study of secondary prevention in primary care settings, the discussion here borrows heavily from its recommendations, while attempting to extend the agenda to other psychoactive substances like marijuana and cocaine.

Primary Care and the Burden of Illness from Psychoactive Substances

A substantial portion of society's burden of illness is associated with the misuse of alcohol and other substances. Many of the people who misuse these substances are encountered in primary care and other medical settings.

One recent study, for example, found a prevalence of alcohol problems of 20.3 percent among new patients in an ambulatory medical care setting.⁶ The emergency room is another medical setting in which there is extensive contact with alcohol problems. Between 10.8 and 32 percent of casualty cases seen in emergency departments have had substantial alcohol involvement.^{7,8} Prevalences of 3 1.9 percent in males and 23.1 percent in females were found among consecutive new admissions for inpatient and outpatient psychiatric treatment.⁹ A prevalence of 30.1 percent was reported among consecutive admissions to an orthopedic service for acute injuries.¹⁰ Alcohol problems are likely to be important in other medical care specialty settings as well. Internists, and particularly gastroenterologists, frequently see pa-

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tients whose medical problems are directly related to alcohol consumption (for example, peptic ulcer and hypertension). Given the high prevalence of alcohol and other drug problems among adolescents," pediatric and school settings may be another area of particular relevance.

Between one and three million Americans are considered to be regular users of cocaine, which has been implicated in a number of medical conditions such as seizures, myocardial infarction, and respiratory arrest." Marijuana, a drug that is smoked regularly by more than 10 million Americans, is known to contribute to pulmonary disease and accidents associated with acute intoxication.³ The use of psychoactive substances by adolescents has become a major issue in both pediatrics and child psychiatry.

In sum, a significant proportion of persons who seek medical care either have alcohol or drug problems or will be consuming these substances in a way that contributes substantially to their medical problems. This disturbing trend has been a major driving force in efforts to incorporate screening and brief intervention procedures into routine practice at the primary care level.

Screening

Screening is typically used to differentiate among apparently well people, separating those who may have (or may be at risk of having) a medical condition from those who do not. It applies best to conditions that are categorical entities—that is, they are either present or not present. Screening is conceptually different from "detection" or "case-finding," although these terms are often used interchangeably. The aim of case-finding is to identify active cases that have already developed a diagnosable disorder. As will be discussed below, many screening tests are designed more for case finding than early detection. Implicit in the concept of screening is the assumption that there will be significant benefit to the health and well being of the individual from having the condition detected at an early stage.

A variety of assessment procedures have been developed to facilitate the early identification of persons with harmful or potentially harmful alcohol consumption.¹³ Unfortunately, there has not been as much research attention devoted to the detection of other psychoactive substance use. Although most procedures have been developed to identify active cases of drug dependence or "alcoholism," many are useful for early identification. These procedures include self-report instruments, objective tests of body fluids, and clinical examinations.¹³

Because verbal report methods can be easily falsified by defensive patients, there has been strong interest in the identification of biological markers that reflect recent substance use or early onset of physical consequences.^{14,15}

Screening for alcohol problems. **Self-report screening procedures.** Two of the more widely used brief screening tests for alcohol problems are the Michigan Alcoholism Screening Test (MAST) and the CAGE questionnaire. The MAST is a 25-item interview that asks questions about the medical consequences of chronic drinking, attempts to stop or control drinking, social problems arising from drinking, and symptoms of alcohol dependence. It is the most widely investigated instrument of its type, probably because it is easy to administer and has been shown to be valid in distinguishing between known groups of alcoholics and nonalcoholics. However, its sensitivity has varied between 57 and 100 percent when used in different populations.¹⁶ Shortened versions of the MAST, including the 1 O-item Brief MAST (BMAST), have been used successfully to discriminate alcoholics from other psychiatric patients. However, its ability to identify "problem drinkers" is poorer than that of the MAST.¹⁶

The CAGE Questionnaire is very brief and fits unobtrusively into a standard clinical interview or examination, an important consideration in determining a test's acceptability to primary care practitioners. The four items are: 1) Have you ever felt you ought to Cut down on your drinking? 2) Have people Annoyed you by criticizing your drinking? 3) Have you ever felt bad or Guilty about your drinking? 4) Have you ever had a drink first thing in the morning to steady your nerves, or get rid of a hangover? (**Eye-opener**).¹⁷ A positive response to two or more of these items identifies a problem drinker.

Biological markers. Many clinicians are skeptical about the truthfulness of heavy drinkers when they are asked to give an honest report of their alcohol consumption or alcohol-related problems. Biological markers are potentially more objective, though they are subject to the vagaries of laboratory technique. Some are influenced by the time elapsed between the individual's last drink and the venipuncture. A variety of standard laboratory tests performed on blood samples have been evaluated.

Gamma-glutamyl transpeptidase (GGT) and mean corpuscular volume (MCV) of red blood cells have commonly been used for both screening and confirmatory diagnosis, but their values are affected by sub-

stances other than alcohol as well as physical conditions not related to drinking, and the values are not always elevated in heavy drinkers. Serum transferrin and new immunological tests developed to measure acetaldehyde bound to hemoglobin show promise as more specific markers of heavy drinking, but further research is needed to confirm their usefulness in routine screening.¹⁸⁻²⁰ The ideal marker would be one that is highly accurate and has the ability to identify gradations in alcohol use. Such a precise indicator is not yet available. Use of markers could identify problem drinkers during visits to physicians offices and thus point out those who could become subjects for more intensive intervention efforts.

Recent research on the use of biochemical indicators in the early detection of alcoholism suggests that:

1. A single, powerful biochemical marker may never be found, given the diversity of biochemical systems affected by alcohol, the different nutritional habits of alcoholics, and the probable genetic differences in susceptibility of those systems.²¹
2. A combination of tests, including GGT, MCV, and SGOT is likely to provide, at relatively low cost, a strong indication of recent excessive alcohol consumption.²²
3. The widespread applicability of newer biochemical measures (e.g. desialotransferrin) will depend on subsequent work that supports their utility.

Clinical signs. Le Go²³ and others²⁴ have developed clinical examinations to identify alcoholics. These procedures estimate severity of alcohol dependence by rating the degree of tremor and physical stigmata. Although the medical and psychiatric impact of heavy drinking is widespread,²⁵ clinical signs appear to be of limited value for early intervention. This is because detectable changes tend to develop late in the natural history of alcohol dependence. Other correlates of chronic drinking, such as hypertension, are not sufficiently specific to be of much value in screening. However, they may help to confirm an impression that alcohol consumption is problematic; and, this kind of feedback may serve to motivate a patient to change his or her habits for the sake of health.

Combined procedures. There is some research suggesting that the combination of a brief interview, clinical examination, and biochemical tests may enhance the sensitivity of alcohol screening.²⁶⁻²⁸

These elements are all combined in AUDIT, the **Alcohol Use Disorders Identification Test**. In 1982 the World

Health Organization asked an international group of investigators to develop a simple screening instrument for use in primary care settings. Its purpose was to identify persons with alcohol problems, using procedures that were suitable for use by health workers in both developing and developed countries. The investigators reviewed a variety of behavioral, laboratory, and clinical procedures that had been used for this purpose in different countries. They initiated a cross-national study to select the best features of these various national approaches to screening.^{29,30}

Unlike previous screening tests, the new instrument was aimed at the early identification of harmful drinkers rather than alcoholics. Special emphasis was given to measures that discriminate between social drinkers and nonalcoholic excessive drinkers whose use of alcohol results in harm and who are at high risk for future alcoholism. Two instruments were developed that can be used individually or in combination. The first is a ten-item "core" self-report screening instrument.³¹ Only questions that refer specifically to alcohol are asked. As shown in Table 1, the core instrument contains three questions on the amount and frequency of drinking, three questions on alcohol dependence, and four questions on problems caused by alcohol.

Because the core AUDIT questions are subject to denial by defensive or uncooperative patients, a second, or "clinical," AUDIT was developed to provide corroborating evidence that does not require direct questions about alcohol use. As shown in Table 2, this consists of two questions about traumatic injury, five items drawn from clinical examination, and a blood test, the serum GGT. This procedure was devised for situations where it is considered advisable for the initial screening process not to refer directly to problems with alcohol.

The WHO Collaborative Project provides an example of an effort to develop a simple, widely applicable method for the early identification of harmful drinking. The AUDIT focuses on the identification of specific kinds of alcohol-related problems, rather than assuming the more ambitious role of predicting who eventually will develop the "classic" syndrome of progressive alcoholic deterioration.

Screening for drug abuse. Considerably less research attention has been devoted to the development of screening tests for substances other than alcohol. Like alcohol screening tests, screening for drug abuse has been conducted by means of self-report procedures and objective analysis of body fluids. Two examples of self-report screening tests for drug abuse are the POSIT and

Table 1. The audit questionnaire

1. How often do you have a drink containing alcohol?
(0) never (1) monthly or less (2) two to four times a month (3) two to three times a week (4) four or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?
[code number of standard drinks] *
(0) 1 or 2 (1) 3 or 4 (2) 5 or 6 (3) 7 to 9 (4) 10 or more
3. How often do you have six or more drinks on one occasion?
(0) never (1) less than monthly (2) monthly (3) weekly (4) daily or almost daily
4. How often during the last year have you found that you were not able to stop drinking once you had started?
(0) never (1) less than monthly (2) monthly (3) weekly (4) daily or almost daily
5. How often during the last year have you failed to do what was normally expected from you because of drinking
(0) never (1) less than monthly (2) monthly (3) weekly (4) daily or almost daily
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?
(0) never (1) less than monthly (2) monthly (3) weekly (4) daily or almost daily
7. How often during the last year have you had a feeling of guilt or remorse after drinking?
(0) never (1) less than monthly (2) monthly (3) weekly (4) daily or almost daily
8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?
(0) never (1) less than monthly (2) monthly (3) weekly (4) daily or almost daily
9. Have you or someone else been injured as a result of your drinking?
(0) no (2) yes, but not in the last year (4) yes, during the last year
10. Has a relative or friend or a doctor or other health worker been concerned about your drinking or suggested you cut down?
(0) no (2) yes, but not in the last year (4) yes, during the last year

*In determining the response categories it has been assumed that one "drink" contains 10g alcohol. In countries where the alcohol content of a standard drink differs by more than 25 percent from 10g, the response category should be modified accordingly.

Note: Numbers in parenthesis are scoring weights. See manual for scoring procedures and interpretation (Babor et al 1989).

Table 2. Clinical screening procedure

Trauma history

Have you injured your head since your 18th birthday? [___]
 (3) yes (0) no

Have you broken any bones since your 18th birthday? [___]
 (3) yes (0) no

Clinical examination

Code as follows:
 (0) not present (2) moderate
 (1) mild (3) severe

Conjunctival infection [___]
 abnormal skin t - 1
 vascularization

Hand tremor [___]

Tongue tremor [___]

Hepatomegaly [___]

GGT values
 (0) lower normal (0-30)
 (1) upper normal (30-50)
 (3) abnormal (50-or higher)

Note: Numbers to be inserted in parenthesis are scoring weights. See manual for scoring procedures and interpretation (Babor et al 1989).

the DAST, which were designed for adolescent and adult populations, respectively.

There are no generally accepted assessment protocols for screening adolescent substance users. For this reason a procedure was recently developed by an expert committee of clinicians and scientists commissioned by the National Institute on Drug Abuse.³² The 139-item screening questionnaire is termed the Problem-Oriented Screening Inventory for Teenagers (POSIT). The POSIT is designed to measure problem severity in ten domains that have been found to be related to substance abuse and amenable to treatment intervention.

The ten domains are alcohol and other drug problems, mental health, physical health status, delinquency, social skills, family system, school adjustment, work habits, peer relationships, and leisure interests. A quick-scoring procedure provides an estimate of the severity of each problem area, as well as a global severity score. Graphic profiles can be constructed that identify areas requiring comprehensive diagnostic assessment.

The Drug Abuse Screening Test (DAST) was designed to provide a brief procedure for clinical screening and treatment research.³³ The 28 items ask about various consequences that are indicative of drug abuse and dependence. Like other self-report measures, the accuracy of this procedure depends on the cooperation and veracity of the patient.

Laboratory analysis of body fluids has become a major approach to screening for drug abuse. These tests can provide evidence of recent drug exposure but may be of limited value in determining whether the drug is being used chronically or during hazardous activities. Because the metabolites of drugs like cocaine and marijuana can be present in urine for days to weeks following a single exposure, it is often impossible to determine the regularity of drug ingestion, the degree of intoxication, or the amount of risk or harm connected with drug use. These methods have also been subject to sensitivity and specificity problems.³

Opportunities for research on screening. More attention should be devoted to the evaluation of low cost, rapid, and reliable screening procedures that are likely to be used routinely by primary care practitioners in a variety of health care settings. However, no matter how sophisticated the biochemical test or how reliable the self-report interview, neither may be incorporated into routine clinical practice if it lacks face validity, is inconsistent with the expected role of the health professional, or is difficult to use or interpret. This brief review suggests the following agenda for future research on screening for alcohol and drug abuse in primary care settings. (See the 1989 IOM report⁵ and Babor et al.,³¹ for additional suggestions.)

- Which of the currently available biochemical, clinical, and self-report screening procedures are best suited to the identification of alcohol and other substance use disorders in primary care settings?
- Is there a biological or biochemical marker with sufficient sensitivity and specificity to identify adults

and adolescents at risk of future alcohol- and drug-related health problems?

What is the accuracy of verbal report screening methods (interviews, questionnaires, **computer-assisted tests**) compared with clinical and laboratory procedures? How can their accuracy be improved? Under what conditions are these methods inaccurate for the purpose of early identification?

Building on the evidence for early childhood risk factors that predict adult alcohol and drug **problems**,^{34,35} can these indicators provide useful information when incorporated into routine screening tests?

Intervention Strategies in Primary Care Settings

Screening should not be conceived in isolation from intervention and treatment, but rather as the first in a series of elements. Its contribution to secondary prevention is dependent on the availability of effective treatment strategies. A secondary prevention approach to problem drinking and drug abuse must include not only the search for screening tests, but also the testing of intervention techniques and management strategies. Only then can it be evaluated in terms of its impact on the morbidity and mortality of the population at risk. In this section brief intervention procedures that have been developed for problem drinkers are reviewed to illustrate approaches that have proven to be promising for the early management of alcohol abuse. Their implications for the management of drug abuse are also discussed in the context of a research agenda for primary care.

In an effort to implement a public health approach to the secondary prevention of substance-related problems, research and demonstration programs have been instituted in several countries to link a new generation of screening technologies to low-cost early intervention **strategies**.³⁶ Part of the impetus for these programs comes from broader-public health concern with the relationship between lifestyle-related behavioral risk factors and disease **prevalence**.³⁷ Because lifestyle risk factors—such as cigarette smoking, recreational drug use, and heavy drinking—are often amenable to behavioral interventions, increasing attention has been devoted to the development of educational alternatives to costly medical care. Some of the more promising research opportunities in the area of alcohol consumption are described below.

Controlled trials and program evaluations. During the 1970s, a number of studies evaluated the effectiveness of broad-spectrum behavioral treatment techniques with nondependent problem **drinkers**.^{38,39} In general, the results of early studies were encouraging, with success rates at 1-year **followup** averaging between 60 and 70 percent.³⁹ Unfortunately, the behavioral approaches used in these studies were time-consuming, sometimes involving as much as 45 hours per client. Later studies have employed a less time-consuming approach, referred to as behavioral self-control training. This approach typically includes specific behavioral techniques such as goal setting, self-monitoring, controlling rate of consumption, functional analysis of drinking behavior, self-reinforcement, and the learning of alternative behavioral competencies to substitute for drinking?

One finding that emerged from this work was that self-help manuals may be as effective as self-control training provided by a therapist.⁴¹ This suggests that low-cost interventions that provide information, encouragement, and brief counseling may be appropriate as the first attempt to intervene with patients who drink heavily but are not dependent on alcohol. Common features of these interventions are their low cost, the modest investment of time and resources, an emphasis on self-help and self-management techniques, and minimal training requirements for professional service providers. The results of other studies support this conclusion.

In one investigation, Kristenson and colleagues in Malmo, Sweden, studied 529 middle-aged men who had been identified as “heavy drinkers” as part of a general health screening **project**.^{42,43} Men identified as having elevated levels of gamma-glutamyl transpeptidase were randomly assigned to either a counseling group or a **control group**. Although the GGT values of both groups decreased significantly, over a 6-year period the intervention group improved more in terms of absenteeism, sick days, and days hospitalized. The study showed that a simple intervention based on regular feedback about a biochemical marker had a beneficial effect on the drinking habits and physical health of a population considered at risk of future alcohol problems.

Elvy and colleagues⁴⁴ conducted a trial of referral to treatment among a heavy-drinking, non-dependent sample of general hospital patients in New Zealand. Problem drinkers identified in hospital were randomly assigned to either a referral condition, in which they were confronted with their drinking-related problems and referred for alcohol counseling, or to a control con-

dition, in which no action was taken. The results indicated that a substantial number of those patients (62%) who were offered treatment accepted the referral, and those referred showed significantly greater improvement after 12 months.

A related study was conducted in Scotland at the Royal Edinburgh Infirmary to assess the effectiveness of brief counseling and a self-help manual with nonalcoholic, socially stable problem drinkers. These patients were identified in a general hospital.⁴⁵ Screening was conducted by a trained nurse using a 10-minute interview that asked about drinking habits, medical history, and social background. While both the counseling and control groups reported significantly less alcohol consumption at the 1-year follow-up evaluation, the counseling group indicated fewer alcohol-related problems and greater reduction in GGT values.

Another study conducted in Scotland evaluated an early intervention program designed to involve primary care physicians in the identification and management of problem drinkers.⁴⁶ Known as the DRAMS Project (Drinking Responsibly and Moderately with Self-Control), the program consisted of screening procedures, interview guidelines, and patient-education materials aimed at reducing the patient's alcohol intake to nonhazardous levels. The DRAMS package was introduced to general practitioners (GPs) in the Highlands area of Scotland. At the end of a 21-month evaluation period, 52 participating physicians reported counseling a total of 161 eligible patients. A review of case records indicated that there was a significant increase in the identification of alcohol-related cases during the DRAMS project. But while the GPs generally agreed with the DRAMS approach, the evaluation indicated that only a minority actively employed it.

The DRAMS program was also subjected to a controlled trial using 16 GPs who screened all patients aged 18-65 visiting their surgeries. Males drinking above 35 drinks per week and females drinking more than 20 drinks per week were considered eligible for the intervention. There was a general reduction in the alcohol consumption of the DRAMS group (from 182 to 148 drinks), especially among patients who complied completely with the DRAMS protocol.

Wallace and colleagues⁴⁷ conducted a controlled trial in England to determine the effectiveness of advice given by GPs to heavy drinkers. Patients either received advice to reduce their alcohol consumption (N = 450) or were assigned to the control condition (N = 459), in which advice was not offered. Followup assessment at

one year revealed a greater than two-fold reduction in alcohol consumption in the experimental group, compared with controls. The reduction in consumption was positively associated with the number of advice sessions attended.

In a related line of research, concern about the effects of alcohol on the fetus has increased interest in how brief intervention techniques might be employed with pregnant women who drink.⁴⁸ Prevention of fetal effects has focused on educational activities, social support, and early identification of problem drinkers. In general, studies have demonstrated positive effects on maternal drinking behavior and smoking, as well as positive effects on the fetus.^{48,49}

Finally, the World Health Organization⁵⁰ is currently conducting 'a multi-center trial of advice for heavy drinkers. Centers in Norway, the United Kingdom, the Soviet Union, Bulgaria, Kenya, Zimbabwe, Australia, Cost Rica, Mexico, and the United States are employing a single-blind, controlled, randomized design to examine the effects of either simple advice (requiring approximately 5 minutes) or brief counseling (approximately 20 minutes) to reduce consumption among heavy drinkers. While the results from this project are not yet available, preliminary findings suggest the utility of this approach in widely different cultural settings.^{50,51}

Summary. Not only is the concept of secondary prevention attracting widespread interest, the development of effective, inexpensive, early interventions is moving beyond clinical trials to the evaluation of demonstration programs and community-based initiatives.⁴ Before these findings can be used to develop training and intervention procedures for primary care practitioners, further research is needed on the behavioral processes that underlie the effectiveness of these interventions, as well as the practical barriers that may limit the widespread initiation of early intervention. As indicated by the results of some demonstration projects and small-scale clinical trials, there are a number of logistical, technical, and professional issues that need to be addressed before the promising findings from early intervention research can be applied to clinical practice and public health programs. There is now a pressing need to study how best to implement and disseminate early intervention programs. These research needs are discussed below in terms of recruitment, behavioral change strategies, and program implementation.

Recruitment. A major challenge to the development of brief intervention programs is the crucial transition be-

tween identification of a drinking problem and involvement of the problem drinker in the change process. Many problem drinkers will not voluntarily submit to even a short-term intervention program.⁴⁶ One procedure found to attract large numbers of heavy drinkers who are likely to be motivated to change is routine health and lifestyle screening in medical settings.⁵²

The success of recruitment will also be affected by the duration of the intervention. Interventions requiring only a brief counseling session or the provision of an informational booklet may reach a much wider audience than those demanding regular participation in a series of counseling or educational sessions. The goals of the intervention are likely to affect recruitment and compliance as well. Almost all of the programs reviewed here recognized the need for flexibility in setting treatment goals. Moderation rather than abstinence is often the preferred initial option for most patients.

Finally, a common characteristic of these interventions is the avoidance of labeling. The terms “alcoholic” and “alcoholism” are inappropriate for heavy drinkers who do not manifest cardinal signs of alcohol dependence. Less stigmatizing terms such as heavy drinker, hazardous alcohol use and problems related to drinking are used instead.

As recommended by the IOM Research Agenda Report,⁵ the following questions should be considered for further research:

- What kinds of recruitment (e.g., self-initiated vs. initiated by a health worker) provide the greatest likelihood of engaging high-risk drinkers in an early intervention program?
- How effective are different types of primary care workers (e.g., doctors, nurses, social workers, etc.) and different types of screening information (lab test results, estimates of alcohol consumption, clinical examination findings) for initially engaging heavy drinkers in an early intervention program?
- Is there a relationship between health beliefs, **perceptions of risk, fear of alcoholism, and motivation for change?**
- **What motivational techniques are most effective in producing commitment to change drinking behavior?**
- How can persons who use psychoactive substances other than alcohol best be recruited into intervention and referral programs?

Behavior change strategies. Behavior change strategies that have been successfully used in early intervention studies^{36,38,40,46,53,54} share a number of common theoretical assumptions. The more promising approaches utilize strategies that take into account the multiple determinants of both human motivation and drinking behavior. These “broad spectrum” or multi-component interventions typically incorporate behavioral, cognitive, and social psychological principles into the intervention technique. The following research questions should be pursued in order to provide a better knowledge base for primary care interventions.

- How well do these techniques apply to the secondary prevention of other substance abuse, especially marijuana smoking, cocaine use, and prescription drug abuse?
- What kinds of alcohol and drug users respond best to brief interventions? For example, do children of alcoholics respond differently than children of non-alcoholics?
- What are the unique contributions of screening, assessment, and information feedback, regardless of advice and counseling?
- What are the personal and professional characteristics of effective change agents? Is the status, authority, gender, or degree of empathy of the change agent a factor in the drinker’s response to an intervention program?
- Which strategies work best for heavy drinkers and other drug users?

Implementation. Finally, there are a number of logistical, technical, and professional issues that need to be addressed before the promising findings from early intervention research can be applied to clinical practice in primary care settings. More research attention should be devoted to the evaluation of screening and brief intervention procedures that are likely to be used routinely by primary care practitioners in a variety of health settings. No matter how sophisticated the biochemical test or how effective the intervention, neither may be incorporated into routine clinical practice if it is difficult to use or inconsistent with the expected role of the health professional. Research is needed to identify barriers to effective screening and intervention.

Conclusion

One of the reasons that alcohol-related problems are under-diagnosed in primary care settings is that physi-

cians do not feel responsible to intervene once a drinking problem has been identified.” Nor do they feel any less competent to intervene when a drug problem is evident. With the development of screening and early intervention procedures that are effective and easy to use, the reluctance of primary care workers may no longer be warranted. Nevertheless, research is needed to determine the best methods to implement and disseminate early intervention programs. One area worthy of research is the training of medical students in screening and brief counseling. Another is the development of continuing education materials for medical professionals.

Effective, inexpensive, brief screening procedures and interventions are still in the early stages of development. Whereas promising results have been reported with heavy drinkers and cigarette smokers, there has been little attention devoted to other psychoactive substances.³ In addition, there have only been a few studies on the behavioral processes that underlie the effectiveness of such strategies. In addition to the research needed in these areas, further exploration of screening, recruitment, and implementation processes is important. More research attention should be devoted to the evaluation of low-cost, rapid screening procedures that can be used routinely by primary care practitioners. And, if studies continue to show the effectiveness of early identification and treatment, the next generation of research should focus on how best to train health care professionals in screening and brief intervention and on the development of materials for continuing education.

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Notions About Networks: Primary Care Practices in Pursuit of Improved Primary Care

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Introduction

There is no universally accepted definition of a practice-based research network. It is widely understood, however, that a practice-based research network is a group of practices devoted principally to the care of patients but also affiliated with each other and perhaps with academic or governmental enterprises for the purpose of investigating the phenomena of clinical practice occurring in communities. Practice-based research networks are characterized by an expectant organizational framework that transcends a single study, enduring through time to address multiple or recurrent questions. A primary care practice-based research network is distinguished by its ongoing commitment to understanding primary care. This article is focused on primary care practice-based research networks and discusses starting such networks, essential components, major impediments, advantages and limitations, and promising opportunities.

Background

The feasibility of practice-based research networks is now established. Extensive worldwide experience over the past 30 years supports this claim. Practice-based networks in Australia have assessed prescribing patterns of clinicians.* Using hand-held computers in the United Kingdom, British general practitioners have investigated adverse effects of various drugs. The viral watch of Canada has persistently forewarned North America of the existence and nature of influenza epidemics.* The "French connection" electronically unites general practitioners in France in pursuit of instant surveillance of communicable diseases.³ Within New Zea-

land there are now two practice-based networks, one based on a modern information system and the other based on randomization by physician. Some 14 national primary care practice-based research networks have formed a consortium and successfully investigated otitis media as it is managed in 9 of these networks in Europe, the Middle East, North America, South America, and the South Pacific.⁴

In the past 15 years, there have been multiple examples of regional primary care research networks within the United States, such as the Cooperative Information Project (COOP) in New England,⁵⁻⁶ the Family Medicine Information System (FMIS) in Colorado,⁷ Wisconsin Research Network (WREN), the Pediatric Practice Research Group in the Chicago area,⁸ and other important groups in Virginia, California, Minnesota, Alabama, Washington, and elsewhere.

Two national primary care networks have been established in the United States, the Pediatric Research in Office Settings Network (PROS) sponsored by the American Academy of Pediatrics, and the Ambulatory Sentinel Practice Network (ASPN)^{9,10} launched under the auspices of the North American Primary Care Research Group. The work of these American networks has been reported with a few exceptions in primary care journals and may have escaped detection by other audiences. During their relatively brief existence, practice-based research networks have demonstrated remarkable versatility in providing surveillance of problems seen in primary care, descriptions of the problems and processes of primary care, and investigation of questions of importance specifically in primary care. Furthermore, these networks have identified methodological problems associated with their enterprise and stimulated the pursuit of improved methods.

The Dutch pioneered sentinel practice networks. The Dutch sentinel stations" are perhaps the most experi-

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enced system in existence, and this network can serve as an instructive example of investigating problems in general practice defined by either governmental agencies or primary care physicians. A permanent government grant for the Netherlands Institute for General Practice in 1965 and the establishment of the first chair in general medicine in Utrecht in 1967 encouraged a group of innovators to start a set of cooperative studies. The initial work described morbidity as encountered by first-contact medical professionals and clarified that a standard practice of 2,500 patients produced 7,500 spells of illness of which 5,000 were submitted to a general practitioner, and 750 of these required referral.

Other recognized sources of epidemiological information about the Dutch people already existed and included mortality statistics, hospital statistics, and population surveys. Each of these other sources had recognized advantages and disadvantages. Health interview surveys provided subjective information but lacked professional judgment. Health examination surveys required substantial organizations and huge resources. Mortality statistics provided information about death but not about the diseases and ailments that caused only suffering and inconvenience. Furthermore, in many cases, there was no clear cause of death, and multiple pathologies coexisted, perhaps none of which actually explained a death. Hospital statistics attached a diagnosis to a discharge but did not always attribute the information to a person or a population. Furthermore, hospital statistics usually concerned more serious illnesses providing at best an incomplete picture of morbidity in the population.

Of course, not all morbidity within the Dutch population presents to general practitioners, but the threshold for the general practitioner's services was known to be much lower and less selective than for the other points of entry into the Dutch health care system.

The early work in this system was promising and an agreement was made to establish a national network of sentinel stations to gain insight into the health problems of the Dutch people as could be determined by general practitioners.

The sentinel stations of the Netherlands have reported continuously since 1970 and now consist of 45 practices with 61 general practitioners caring for 1 percent of the Dutch population. The distribution of these practices covers four regions and three degrees of urbanization, and the age and sex distribution of patients seen in these practices approximates the age and sex distribution of the Dutch people.

Approximately 60 subjects have been investigated using a systematic process of weekly reporting. The conditions studied include spontaneous abortion, alcoholism, the suspicion of battered child syndrome, pregnancy despite contraception, and bites by pets. Circumstances such as requests for ultrasound examination, requests for the morning after pill, contacts with recently discharged psychiatric patients, requests for referrals, and requests for euthanasia have been studied. Also included were reports of Parkinson's disease, depression, diabetes mellitus, acute unusual headache, measles, psoriasis, and suspicion of myocardial infarction. Often the topics investigated are selected because there is a suspicion that other sources of information do not cover the whole domain or are selectively biased.

After some 20 years of experience, the sentinel stations of the Netherlands report that the strong points of their practice network are:

1. cost-effectiveness because of the ability to sustain within practices positive attitudes toward accurate and meticulous work for multiple investigations rather than coping with ad hoc recruitment and participation
2. access to professional judgment close to the onset of physical and mental problems in the population, organized as part of existing clinical services
3. exposure of special selection and observer biases associated with front-line clinical work.¹¹

Sentinel stations also report as their principal weakness variation in recording that remains unexplained despite age and sex adjustments and standardization of methods. This Dutch experience of some 20 years confirms that a practice-based network can present an alternative approach to developing knowledge about health and illness as it exists in communities.

Getting Started

Starting a primary care practice-based research network, like most other human enterprises, requires commitment and leadership. It is reasonable to begin with five to forty practices focused on an initial project that is almost certain to succeed. Buttressed with a strong spirit of volunteerism, approximately \$50,000 per year for each of at least 3 years is sufficient seed money to launch a network and determine its feasibility. The early days of a network should be viewed as a time to establish foundations on which incremental progress can be made with further time and financial support. Minimal return

on investment can be expected during this time. Maintaining such a network and establishing a sustained research agenda requires considerably more committed resources.

Essential Components

There are at least six essential components in a practice-based research network. The first is an accepted statement of common purpose and a pervasive sense of mission. The second is a mechanism of governance that assures fair decisionmaking which is faithful to purpose and mission. The third is a set of unifying symbols that make the network a perceivable reality, such as a name and address, letterhead, a logo, and designated officers. Spanning time and space, these networks require multiple communication systems such as the US mail, dedicated telephone lines, regularly produced newsletters, and face-to-face meetings of various combinations of network members. A staff with at least one person principally identified with the network is necessary, and finally, a set of key processes must be established. These processes must accomplish seven tasks:

1. identify questions important to the network
2. refine ideas and researchable questions
3. facilitate design of investigations to answer these questions
4. provide a linkage between the network's questions and funding
5. implement investigations throughout the network
6. conduct and monitor network studies
7. report results with appropriate credit to all participants.

Impediments

One of the most important impediments to realizing the potential benefits of primary care practice-based research networks is the reluctance of the better established research enterprises to recognize the importance of questions and answers related to family practice and primary care. This, in turn, precipitates "over reaching" by these networks to draw attention to their efforts. The relative disinterest by "the establishment" also allows an environment to persist that remains relatively unwilling to fund either the infrastructure necessary to establish centers of primary care research or investigations specific to primary care. Once a practice-based research

network is established, the major challenge is sustaining collaboration for extended periods across geographic barriers without disrupting clinical practice.

Advantages

Among the advantages of practice-based research networks, three stand out. There is the opportunity to access neglected phenomena of great importance to people, with attention to the special selection and observer biases of primary care and the opportunity to generalize results to practice. There is an efficiency in these networks analogous to the efficiencies inherent in a reusable space shuttle. The same "apparatus" can be used repeatedly, and it can conduct multiple studies concurrently, even interweaving investigations to complement each other. Furthermore, these networks by virtue of their size, make it possible to investigate infrequent events and frequent events with short periods of data collection. Thirdly, there is a synergism in these networks that links the community and the academy and links questions from practice to answers from practice that are applicable in practice.

The consequences of seizing these advantages are exemplified by some of ASPN's earliest work concerning headache, pelvic inflammatory disease (PID), spontaneous abortion (SAB), and chest pain. While at least 46 percent of ASPN patients with a first visit for headache would be predicted by expert consensus to need CT scanning, only 2 percent were scanned, representing a \$2.1 billion financial risk to the Nation.¹² And, 43 percent of ASPN patients with presumed acute PID met published criteria for hospitalization, but only 9 percent were hospitalized. This rate was consistent with randomly collected data for family physicians and obstetricians/gynecologists and represents a \$1.2 billion financial risk to the Nation.¹³ Standard texts recommend dilatation and curettage (D&C) for women with SAB, but only about half of women miscarrying in ASPN practices had a D&C, representing at least a \$140 million per year annual financial risk.¹⁴ When seeing patients with chest pain, regardless of diagnosis, utilization of services increased in ASPN practices whenever the doctor was uncertain of diagnosis, and proportionately more electrocardiograms were done for patients with chest pain thought to be of gastrointestinal origin than chest pain thought to be of cardiac origin.¹⁵ Whether these decisions and other daily decisions in practice are appropriate or optimal is largely unknown, and answers await careful investigation.

Limitations

In the United States, research related to primary care has not kept pace with research in other specialized areas of medicine. Consequently, inadequate guiding theory, lack of description of the basic phenomena, and mistaken assumptions inhibit the formulation of relevant questions about primary care. For example, it could be assumed that family physicians are rarely involved with miscarriage because of a lack of involvement in obstetrics, that the important clinical concerns relate to infection and hemorrhage, and that miscarriage is a phenomenon of the emergency department. These assumptions could guide the formulation of investigations, but it can be stated with reasonable confidence that all of these assumptions are wrong. Perhaps the compelling questions in the primary care of miscarriage have to do with discriminating operative management and the psychosocial impact of miscarriage on people and their caretakers.

In addition, methods are inadequately developed. The dimensions of assuring the quality of data from practice-based networks include assessment of the accuracy of data reported, the appropriateness of the reported data, and the completeness of reported data. When ASPN was investigating miscarriage, one of the questions asked related to the rate of miscarriage, and complete reporting was viewed as essential. Appropriate statistical formulas were used to calculate the number of charts that would be required to know confidently that—with an error value associated with an individual response of .01—there was no underreporting of miscarriages in the network. Assuming that there were only 100 clinicians reporting in the network and that each did only 3,000 visits per year, this calculation suggested that 15,772 charts would have to be audited, a formidable task. To be additionally conservative, a multinomial correction factor could be applied, further increasing the sample size. Of course, these numbers can be reduced dramatically if higher error values are accepted—for example, to use only 665 records with an error value associated with an individual response of .05. In this same investigation a 100 percent review of subjects to identify misclassification found that 35 of 226 initially enrolled patients failed inclusion criteria or had inadequate documentation in their medical record to make a determination. These were deleted from the study. Which was a better gold standard: the medical record or the ASPN clinician's immediate report of the clinical event of mis-

carriage? For now, the best methods to assure the quality of data from practices are not fully resolved.

There is often confusion about the unit of analysis. Doctors, patients, problems, and diagnoses commingle on a day-to-day basis, and what seems to be a logical choice in reality may not be straightforward. For example, an analysis of CT scan utilization for patients with headache in ASPN revealed that 2 percent of patients making a first visit for a headache had a CT scan ordered.** For patients making a second visit for a new headache, the rate was 5 percent. Utilization declined with three or more visits and averaged 2.5 percent for all visits. The rate of utilization varied not only for the symptom and patient but also for the order of visits over time. It seems likely that the use of episodes of illness rather than office visits will provide a better characterization of primary care. For now, they are poorly understood.

The most useful descriptors of practices and providers are uncertain. ASPN collects a registration data set for each practice (Table 1) and each clinician in each practice (Table 2). Some practices are located more than 50 miles from a CT scanner, and others are across the street from the full range of imaging services. Some practices have existed for over 30 years, and others are new. Some practices exist within an HMO, and others have fewer than 10 percent of patients in HMOs. Some practices are in States with vigorous Medicaid programs, others are not, and some are in Canada. It is not known with sufficient confidence how variables such as these affect the questions and answers of primary care, but they almost certainly influence results.

Mechanisms are inadequately developed to conduct followup studies in the chaotic environment of practice. For example, when ASPN launched an investigation of adult onset diabetes, followup data were required. Despite highly motivated clinicians and a facilitating reminder within the medical record, only 46 percent of enrolled patients had sufficient followup data to allow analysis [unpublished data]. Using a different method that shifts the process of recognition of the need for followup to central staff, ASPN noted improved followup in a study just completed on carpal tunnel syndrome. Adequate followup methods are needed, and perhaps the progressing computerization of practices will offer new, testable options.

These networks have other limitations, such as limited experience with intervention trials. Furthermore, gen-

Table 1. ASPN practice registration data

Name
Phone and address
Founding date
Rural, suburban, urban
Type of practice: solo, 2-person partnership, family practice group, multispecialty group, corporate, other
Practice coverage arrangements
Site most patients are seen
If Canadian, percentage of practice that is Canadian medical
If us:
a) percentage of fee-for-service, closed-panel HMO, open-panel HMO, PPO, contractual
b) National Health Services Corps or Robert Wood Johnson practice site
Practice limitations by age, sex, presenting problems
Office visits per week
Days/week patients are seen in office
Computer capabilities for billing and data base management
Ability to completely enumerate the age and sex of the practice's visiting patients
Number and type of employees
Obstetrical services: prenatal care, deliveries, postnatal care
Home visits per month
Nursing home visits per month
Teaching of health profession students and residents
Involvement in practice-based research in addition to ASPN
Distance in miles and minutes to services for admission, ER, consultation, selected procedures
List of all providers in the practice
Staff contact person and phone number
Physician contact person and phone number

eralizability, while almost certainly superior for practice applications, remains largely unassessed. It has been encouraging, however, to find ASPN frequencies correlating **with** randomly collected data in the National Ambulatory Medical Care Survey.

Finally, there are significant management challenges that must be overcome to succeed with practice-based research networks. The issues known to impact other approaches to multicenter research apply in prac-

tice-based research networks-that is, standardization, control, credit, and dependency on stability in multiple environments. At least three challenges are more specific to these networks:

1. Creating linkages to other research enterprises can connect primary care research to what is already known and further complete imperfect pictures of human suffering; but such linkages can divert the

network from the fundamental purposes of primary care research.

2. The practice environment must be protected while pursuing answers with methods sufficient for the questions. The practice environment can be disturbed but not disrupted.
3. The clinicians within the network can easily generate 100 ideas from their daily experience, but from these, perhaps four or five researchable questions may emerge. Uniting these questions that have “come up” from the network with requests for proposals that “come down” for research projects, is no mean feat, and writing an achievable proposal may not create an approvable proposal.

Striking a responsible balance with each of these three management issues challenges the managers of practice-based research networks.

A Network Versus a Large Single Practice

Networks of practices make feasible studies and analyses that are not attainable in a single practice. Surveillance of disease is an obvious prototype. Examples of surveillance include monitoring infectious diseases, such as influenza and AIDS and also environmentally induced diseases, such as those caused by air pollution. Results from multiple sites can be stratified over several variables, such as the degree of urbanization or access to medical technology—for example, distance to mammography. A network also allows intervention studies with clinicians as the object of study and permits analysis of the impact of practice and community variables. Using different practice settings opens the door for widespread participation of clinicians in research, allowing them to realize directly how results affect their practice. Results obtained from a spectrum of practices rather than one location enhance generalizability. Networks are appropriate laboratories for studies that characterize presenting complaints, such as headache, while avoiding selection biases associated with a headache clinic or a fully insured population. These opportunities are counterbalanced by the problems and limitations previously discussed. Furthermore, the characterization of the population under care in multiple sites is more difficult than, for example, in a single large multi-specialty practice or an HMO with a defined population. Age/sex registries offer at best a partial solution.¹⁶

Opportunities

It is important to recognize what should **not** be done in primary care practice-based research networks. These networks are not the place to do unpiloted work, pursue questions for which methods are inadequate, or answer questions that can be answered in one or two practices. It may be catastrophic to use such networks as “go-phers” for other researchers with personal needs or agendas focused entirely on the tip rather than the base of the iceberg of human suffering.¹⁷ On the other hand, current dissatisfaction with health care systems calls for attention to (1) the unknown effectiveness of most interventions and (2) unexplained variations in the clinical enterprise without apparent change in quality. Calls to develop and test practice guidelines require a shift in emphasis toward patients that cannot be accessed in hospitals and then toward the determination of what is actually happening and what should be happening in practice.

At the beginning of the 1990s, there are two particularly promising sets of opportunities for these networks. The first is the characterization of primary care. The focus has been defined adequately* and includes identifying the circumstances associated with the onset of illness, determining the reasons people present themselves as patients when they do, characterizing presenting complaints, measuring the contribution of various tests to the resolution of patients’ problems, and assessing the interfaces between levels of clinical enterprise from home to office to hospital to alternative care sites. Of course, the same systems required to characterize primary care can monitor the impact on practice of changes in policy, demography, and clinical problems.

The second set of opportunities is related to developing and improving methods to establish a solid foundation for further generations of work in primary care research. These methods need to delineate episodes of illness as a unit of analysis, further improve primary care classification, and invent additional methods for followup studies in practice. Existing methods for measuring accuracy, reliability, and validity of data must be tested further in practice-based research networks, modified if necessary, and new methods created if required. Resolution of these methodological issues could be abetted by the appropriate application in these networks of the current advances in electronic technology that can facilitate data collection, data transmission, standardization, and communications throughout networks.

Table 2. ASPN clinician registration data

Name
Sex
Birth date and place
Graduate training
Board certification
Membership in professional society
Employed by governmental agencies
Primary professional activity
Faculty status
Income status: salary, salary plus incentive, residual after expenses, other
Percentage of time in direct patient care
Number of years in practice since completing formal training

A Modest Suggestion

What then can be suggested about family practice and primary care practice-based research networks to those committed to investigating family practice and primary care? Perhaps these networks can evolve into the primary care research laboratories of the 21st century. One strategy would be to replicate the establishment of clinical research centers, an approach that has been successful in other clinical disciplines. For example, a competition could be held to authorize the establishment of at least ten primary care research centers. Each of these centers might have:

1. access to at least 20,000 free-living people receiving care within community-based practice
2. systematic approaches to collaboration with at least ten community-based practices
3. a core staff directed by a primary care clinician, to formulate and execute careful research with particular attention to advancing methods for primary care research
4. optional initial support for further training of staff, e.g., in clinical epidemiology
5. fellowships of 2 to 3 years duration for young primary care investigators

6. definite linkages to an experienced coordinating agent to assure rapid dissemination of advances and cooperation as needed to address promising opportunities.

The hallmarks of these centers would include a commitment to sound methods; collaborative **relationships** among practicing clinicians, academicians, and relevant agencies; and a focus of research on a mix of problems seen by generalists.

It is likely that a primary care research center with these characteristics could be established and operated for an annual cost of approximately \$500,000 divided between practice support and central support. Each center would be expected to conduct a minimum of three, **and eventually** as many as ten, investigations per year. In addition, approximately \$40,000 per center, per year, would be required for coordination (i.e., communications, travel, and coordinating staff). In an era of \$80 million investigations that may not work out, this can be perceived as a good business decision.

Conclusion

Practice-based research networks are feasible and versatile. A small network limited in scope can be initiated with \$50,000 and considerable volunteerism, but sustaining a network and consistently pursuing a research enterprise requires considerably larger commitments of resources. Such networks must have a clear purpose and sense of mission, adequate governance, unifying symbols, communication **systems, dedicated** staff, and processes sufficient to complete careful research. Such networks offer access to important but neglected phenomena, uncommon efficiencies, and synergism linking communities and science. Yet, these networks are limited by the Nation's largely overlooked, collective ignorance about both the nature of primary care and methods relevant to primary care research. The entire enterprise is impeded by a widespread failure to understand the intrinsic value of family practice and primary care.

Practice-based networks hold great promise as the primary care research laboratories of the 21st century. Here, primary care can be characterized, adequate methods can be devised, and answers can be developed to many neglected clinical concerns. Perhaps the growing enthusiasm for these networks can be merged with the concerns of Federal agencies, and specific steps can be taken to respond to the public's urgent need for improved primary care.

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Research on Primary Care and Rural Health: Opportunities and Challenges

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Introduction

The considerable changes within the health care delivery system witnessed over the last decade has placed particular stress on the environment for rural health care. These changes have created enormous pressures for new approaches, new methods, and new systems for delivering health care in rural areas of the Nation. In addition, these changes have precipitated an expectation that the health services research community will respond to the many questions that remain unanswered on health care services for rural America.

Over the last several years, rural health has received increasing attention from the Nation's policymakers. The interest of these policymakers must be translated into policy-relevant research that can assist in developing programs to alleviate the problems of rural health in the future.

This discussion of rural health care research is based on three premises:

1. The research community is in a unique position to assist in meeting the greater needs of society. Academic medical centers, as the purveyors of research and education, are responsible for meeting certain societal needs. The responsibility also extends beyond the confines of traditional research models.
2. Rural people, who represent 25 percent of the Nation's population, deserve access to the same level and quality of health care as their urban counterparts. Although simple in concept, the notion of equity is an important element in the consideration of solutions for meeting the challenges of rural health care delivery. The major dilemma is the paucity of

research on primary care and rural health; such research would assist in developing possible solutions for existing health care problems in rural America.

3. Any research conducted on rural health issues must, *a priori*, involve the consideration of broader issues related to rural society. In rural America, the health care delivery system cannot be readily separated from other elements of rural society. The success or failure of other rural systems—such as education, commerce, and government—are interrelated with health care delivery concerns. Small, isolated research efforts have not met the challenge in answering the many health care questions that continue to constrain health care delivery in rural communities. In an era of constrained resources, the health services research community has a particularly important role in examining the needs of society.

Overview of Rural America

Before proceeding, it would be useful to have a context for the notion of rural health. The provision of health care for rural Americans is a community investment requiring community development through cooperative venture. Health care issues cannot be considered in isolation from the many other issues that affect the fabric of life in rural America.

Rural health is an investment, not only from the perspective of people's health, but also from the perspective of community viability. Without a health care system, the ability of a rural community and the people who reside in it to sustain themselves is quite difficult. Rural health also involves community development; addressing the viability of rural hospitals and the training of rural physicians serves no useful purpose if rural America is dying. Community development means not only providing certain services but also using the community investment for further development. Finally, it is a coop-

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erative venture, since very few services can be maintained in isolation in rural American.

Rural America is complex and diverse. For example, Vermont and Wyoming are similar in population but vastly different in terms of heritage, resources, and economic base. The differences between these two States typify the contrasts that characterize rural America. Those who are familiar with urban areas will agree with the notion that Kalamazoo, Michigan is vastly different in resources and problems from New York City. Yet both communities are classified as urban based on national definitions. The same type of individual characterization is needed when analyzing rural settings.

Over the last decade, several attempts have been made to classify rural areas. These topological efforts are an important process, since much confusion has existed in the past related to defining rural America. The issue of common definitions was highlighted as a major concern at the 1987 conference on rural health services research sponsored by the National Rural Health Association and the Foundation for Health Services Research.⁷ In fact, the issue was identified as the number one cross-cutting issue for the conference. In identifying the issue, the summary report stated:

There are numerous definitions of "rural" as well as other equivalent or nearly equivalent terms, such as "nonmetropolitan," "frontier," and "rural-farm." The divergent definitions of these various terms make data from one government agency incompatible with data from another in analyzing rural populations. The development of systems of community definitions of rural areas should be standardized or coordinated, and should also reflect the diversity of rural communities, which range from very isolated, sparsely populated areas to communities adjacent to urban areas.* (p. 1054)

Rural areas can be classified according to four categories based on population density and locale:

1. adjacent rural areas are those which are rural by definition (i.e., communities of less than 2,500 population or counties of less than 100,000 population)³
2. urbanized rural areas of those communities that are rural by any definition yet sustain services that are clearly tertiary in nature
3. countryside rural areas, the traditional rural areas of the Nation that predominate in both population and total number of rural areas
4. frontier areas, which by definition are those counties of less than 6 people per square mile.⁴

The ability to more clearly define rural areas seems to be an important factor for determining the level of services that are needed for a given area. For example, a frontier region is usually incapable of supporting more than basic primary care services (in rare instances, the services for an entire region may be coordinated). An urbanized rural area, like Marquette, Michigan-which is located in a frontier region but is a relatively large community-can support extensive secondary and, to some extent, tertiary care services.

The cost of services can vary according to the degree of rurality. In a study conducted by the Department of Health for the State of Colorado, the costs for providing emergency medical services in Denver were \$8.00 per capita; for rural Colorado, about \$25.00 per person; and, for frontier counties, in excess of \$50.00 per capita (Metcalf W, personal communication, July 1988). Fewer people result in an inability to defray fixed costs over a sufficient population base to keep costs down. These considerations require an awareness of the degree of rurality and the diversity of rural areas in the Nation when considering policy options in rural health.

Changing demographics within the rural environment have a profound impact on the health care system and the viability of rural health services. For example, the US Department of Agriculture has documented a marked loss of population in certain sections of the Nation.⁵ The loss of population-especially younger, working-age cohorts-is markedly affecting the ability of rural America to sustain an infrastructure that can attract members of all professions, including the health professions.

This depopulation also has a marked impact on the tax structure for many rural communities. Often, those left behind are the elderly who are dependent upon passive income sources such as Social Security. The end result is that active income generation and recycling are diminished resulting in an ever downward spiral of economic capacity within the rural community. The downward spiral results in further tightening of the already constrained resources and services.

The demographic shift just described is creating a population of elderly persons in rural areas. In nonmetropolitan areas, 13.1 percent of the population is over age 65, compared with a national average of 11.2 percent for the general population.⁶ It is predicted by the Census Bureau that the over-age-65 population cohort will reach 17.3 percent of the Nation's population by the year 2020. Many rural communities already exceed such demographic patterns. Furthermore, the more rural the

community the greater the number of elderly. Data from the 1980 Census reports show that 12.9 percent of the population is over age 65 in communities of 10,000 to 50,000 persons; the figure is 14.7 percent for a population of 2,500 to 10,000; and 15.4 percent when the population is 1,000 to 2,500.⁷

Further, the traditions of rural America in caring for the elderly are eroding. The informal network for elderly care—long a hallmark of rural society in this country—is disappearing. The end result is that rural communities, like the rest of America, are beginning to rely more on institutional resources as the mode for delivery of this care. Many rural areas lack sufficient resources to sustain the diversity and complexity of elder services required in a contemporary society. The impact of the rural demographic shift upon the health care system is crucial, since the type and level of services required for the elderly differs vastly from the patterns of care that have been provided in rural areas in the past. Also, the training of providers for such an environment differs.

Aside from these rural health delivery issues, a number of other health-related concerns must be addressed. For example, what will be the impact of the technological revolution on the delivery of health care services for underserved rural populations? The new, evolving technologies will radically alter the standards of medical practice over the next decade. How will these new and innovative health care approaches be implemented and received in rural areas?

In addition, the issues of technology development are potentially interrelated with the health problems of the rural populace. Roemer noted that the intensity of health problems in rural areas is often exacerbated by transportation difficulties, housing problems, poverty, and nutritional deficiencies, as well as limitations in the availability of health services.⁸ Could a substantial impact be made on these problems through the use of existing or evolving technologies?

Beyond the issues associated with technology development are the continuing health problems of rural people. Cordes and Bruce have outlined a number of general health care issues that are important in any rural health services research discussion.⁹ They noted that nonmetropolitan areas exhibit:

- a greater incidence of chronic conditions in comparison to urban areas, with an associated increased incidence of disability
- higher rates of infant mortality

- a greater proportion of the population without health insurance
- a substantial portion of the population who have no “regular source of care”
- health status indicators for rural blacks, Native Americans, migrant workers, and selected geographic areas (e.g., Appalachia) that are more comparable to many Third World countries than the United States.

These pressing issues are summed up in today’s major concern: addressing the many unresolved questions related to the delivery of health care in rural areas of the Nation. There is an expectation that health services researchers will assist in critically examining these rural health problems. Such research will assist policymakers in developing viable solutions to rural health delivery problems. What follows is a discussion of these issues and an overview of several potentially fruitful areas for further research.

Rural Health Research Areas

Physician supply. Despite a near doubling in the supply of physicians between 1960 and 1985—a total physician increase of 210,000 or 64 percent of all active physicians¹⁰—rural America continues to be underserved. The supply will continue to increase from 227 physicians per 100,000 population to a ratio of 280 per 100,000 by the year 2010, yet without changes in physician distribution, rural America’s physician shortage will continue.” Although considerable debate has evolved over the question of physician diffusion in rural areas, recent studies support the notion that most rural areas have experienced either a stable or declining number of physicians over the last several decades. Kindig cited evidence that the rate of physician growth in rural areas was about one-fourth the rate of growth for urban areas and, further, that the growth was insufficient to meet physician human resources needs due to death, disability, retirement, and outmigration of rural physicians. Kindig also noted that up to 25 percent of the rural physicians in sparsely populated areas will retire or relocate within the next 5 years,¹⁰ a prediction that has been supported by other recent studies.*¹ Kindig concluded that:

There remain geographic areas of the country which are relatively undersupplied with primary care physicians. This is certainly the case for certain subspecialties as well but this has been less well documented. Most areas have shown increases over the past decade as the result of the overall increase in physician supply, but rural and inner city areas have shown lower rates

of increase for primary care physicians. There is significant variation in MD/100,000 population for counties with less than 50,000 population, with the Southern States having the lowest regional levels.¹⁰ (p. 50-51)

Minnesota can serve as an example of the rural health dilemma. Despite a 60 percent increase in the State's physician supply between 1965 and 1985, the nonmetropolitan counties of the State exhibited a 2 percent decline in overall primary care physicians and an 11 percent decline in family physicians." The declines occurred despite several notable rural-oriented programs at both the University of Minnesota and the University of Minnesota at Duluth.

Most rural health professionals agree that it is more difficult to recruit physicians to rural areas today than it was 5 years ago. The reasons for this are numerous, including: changes in delivery patterns, increased reliance upon technology, unavailability of ancillary professionals in many rural areas, lack of financial incentives for rural practice, and an educational system that emphasizes subspecialization rather than primary care as the model for future practice.

In particular, it must be noted that the most important change in health care in recent years is that it is no longer an isolated exercise practiced by the solo doctor of yesteryear. Today, health care is a complicated enterprise practiced by a team. The delivery of high quality services requires the availability of many health professionals who can provide many sets of services in many different settings. Concomitant with the Nation's failure to meet physician manpower needs in rural America is the failure to train ancillary health professionals for rural practice. Critical research issues include:

- the impact of the demise of the National Health Service Corps on physician dissemination to rural settings
- the socialization process of medical school and points of maximal influence on career choices of future rural providers
- the effect of training environment on future rural providers
- the impact of group practice on decisions by providers to seek certain practice environments
- the degree to which interdependence upon other health professionals affects physician decisions on practice locations.

Rural hospitals. The rural hospital is a particularly crucial institutional resource in the rural health care delivery system. It serves as an essential cornerstone in the economic infrastructure of most rural communities. Doeksen, in ongoing work on the subject at Oklahoma State University, has concluded that: "... the projected impact of closing a rural hospital upon the economy of a rural community could be quite devastating"¹³ (p. 64). Until about 2 years ago, the rural health policy debate revolved around the status, future, and problems associated with the rural hospital. The need for more research on the many issues affecting the rural hospital seems obvious. As a focal point for those research efforts, the following suggested research categories are evident in the literature as common themes in research related to the future of the rural hospital.

Organizational structure. The structure of hospitals in rural communities has rarely been addressed in the research literature. This issue is particularly challenging in the changing hospital marketplace. Patton¹⁴ has noted that: "... very little information was available regarding rural hospitals by type of ownership. For example, what difference, if any, has it made that half of all rural hospitals are publicly owned? Also, what has been the impact of multihospital system or alliance affiliation?" (p. 1017). These questions of organizational structure will be particularly important during the early 1990s, since new legislative efforts seem to be advancing an agenda of multihospital networks. The Omnibus Budget Reconciliation Act of 1989¹⁵ includes specific reference to a new program of "Essential Access Community Hospitals." These facilities will develop over the next year without the benefit of significant health services research on some of the critical questions related to institutional/area relationships or service sets for these hospitals. Other important questions related to organizational structure include:

- What is the most effective organizational relationship between rural hospitals and tertiary referral facilities?
- What types of connections are crucial for maintaining hospital services in the community?
- Which services should be removed from the rural community and tied to the referral center?
- Is the existing relationship between the public health and hospital sectors the most effective in rural settings? How can services be amalgamated for the purposes of sustaining programs in rural areas?

- Are multi-institutional relationships beneficial? If so, how? Is there a difference in the benefits of geographic multi-institutional partnership arrangements vs. partnerships arranged on some other basis (e.g., Catholic facilities arranged in consortia)? Are both types of relationships important?

Access and availability of services. Some have argued that the existence of the hospital in a rural community determines the availability of health care services. From a policy perspective, the issue of access and availability represents the major consideration in the debate on maintaining the viability of rural hospitals. In essence, it is the “So what?” question: So what if the rural hospital closes? Does it make any difference where people seek services, or more importantly, does hospital closure impact on the morbidity and mortality of the populace? These few central questions are critically important to policymakers, and few research efforts have concentrated on them.

Other important research questions include:

- What specific services of the rural hospital are of such critical importance that they affect the health status of the rural populace? Is there a minimum cluster of services that are important as a safety net?
- Do access and availability differ in rural areas compared with urban areas for the financial component of the issue?
- What happens after the rural hospital closes? Where do people migrate for services? Who provides those services, and how are they delivered? Are there substantive differences in the quality of the services?

Quality concerns. The myth exists: the quality of health care delivered in rural areas is less than the quality of services provided in urban settings. It is a common myth without backing or substance in the literature. The converse, however, is also questionable. Professionals involved in rural health have long recognized that the perception of quality problems, regardless of the reality, significantly affects the utilization of local services. Few studies have been completed by the health services research community that attempt to measure the quality of comparable services provided in rural and urban settings.’ An issue related to quality is the concern directed at issues of volume in determining quality. Luft and colleagues¹⁶ linked the volume of surgical procedures to the mortality rate, but the research was not concerned

specifically with rural hospitals. Three groups were identified: (a) Group I, where no threshold effect could be identified (e.g. coronary bypass surgery); (b) Group II, where a clear volume relationship existed—that is, beyond a certain number of procedures the mortality rate was not affected (e.g., vagotomy and pyloroplasty); and (c) Group III, where increased volume did not impact on mortality (e.g. cholecystectomy). No application of the study has been made to determine which services can be provided in rural hospitals without jeopardizing quality of care.

One of the major questions to be addressed in quality studies for rural hospitals is the issue of small numbers. It is quite difficult to develop a reasonable methodology from a research standpoint for most rural settings because of the small number of services provided for the health problems in question.

Other specific questions in need of further research include:

- Is there a set of services that can be delivered in a variety of settings, including rural hospitals, where outcomes do not vary regardless of volume? What are the parameters of those services? How are they delivered? Who provides the services and under what circumstances?
- Is there any benefit to measuring quality outcomes in rural hospitals as a geographic group rather than individual entities?
- What is the impact of providers on quality of care provided in rural institutions compared with urban facilities? Does the support system for the providers impact on the quality of services (e.g., solo vs. group practice and rural practice tied to urban practice vs. independent)?

Aside from these three critical areas, there are a host of other rural hospital research questions that need further analysis. In general, the sparsity of rural health research on hospitals allows for significant contributions to be made in any number of areas.

Organizational Issues

The health care system in the United States is generally recognized as disjointed at best. The integration of services is more a concept than a reality except in a few isolated instances. It can be anticipated that the structural component of the health care debate will take on ever-increasing importance as more proposals for change are considered and adopted by policymakers at both the Federal and State levels. Certainly, the health

services research community could perform a valuable service by initiating more research related to the organizational structure of health care systems.

Financing Problems and Special Populations

The current knowledge base on rural health financing considerations is markedly limited. The field offers a plethora of possibilities for the health services research community. Financing health services is tied to the extent of insurance coverage available to the individual and personal income levels. In general, it has long been documented that persons residing in nonmetropolitan areas suffer from a higher rate of poverty compared with urban residents (i.e., 18.3% vs. 13.8%, respectively) and higher rates of underemployment (i.e., 18.1% vs. 12.3%, respectively).¹⁷ These two factors result in a population that has less health insurance even when employed¹⁸ (Wisconsin Rural Health Research Center, in preparation), and when they do have health insurance, they usually have less coverage than their urban counterparts.¹⁹

Such issues are of particular importance in the current health care policy debate, since many of the proposals espouse a health benefits package tied to employment. These proposals are of particular importance to the majority of Americans, because most are covered through some type of employment-related health insurance.²⁰ Furthermore, many of the proposals currently being debated tie a health benefits package to employers with a certain number of employees (e.g., five or more employees). If implemented, proposals like these could skew coverage toward urban areas. In recent testimony before the National Advisory Committee on Rural Health, preliminary survey data were presented showing that average business size is smaller in rural settings compared with urban settings.²⁰ As a result, passage of new laws mandating coverage for employees will probably have less impact in rural areas than in urban communities.

The issue of special populations is intimately tied to questions of financing. In particular, the health problems of the homeless and chronically mentally ill; Native Americans, Hispanics, and other rural minorities; and the impoverished elderly often are directly intertwined with financing considerations.

The seminal work on financing issues in health care was completed in 1987 by Rowland and Lyons.¹⁹ In defining future research in rural health, they identified

economic and health status, insurance coverage, and access to care as the predominant issues for future health services research. Examples of specific, unanswered research questions highlighted by Rowland and Evans include:

1. How have economic changes—such as industrial shifts and institutional closings—affected rural health status and the use of health care services?
2. What is the impact of Medicaid coverage on the rural poor compared with their urban counterparts? Are there ways to enhance the effectiveness of Medicaid in rural areas?
3. Are there specific aspects of the occupational and employment structure of rural areas that influence the financing of health care?
4. Do the rural uninsured receive less health care services than the urban uninsured? If so, why? What is the specific impact of health care financing on the availability of services?

Conclusion

There are a substantial number of health services research questions in the area of rural health. The issues described above provide a cogent agenda that requires the attention of the research community. Since much of the health services research emanates from the academic medical center, it is important to recognize the limitations of these institutions in accomplishing this most important research agenda.

Many academic medical centers are incapable and others are unwilling to respond to primary care needs and research questions. Lewis and Sheps,²¹ in *The Sick Citadel*, recognized the dilemma when they observed:

... the academic medical center must give high priority in its teaching, research, and patient-care programs to the major health problems of the population of its area and to practice in the community. (p. 22)

Unfortunately, most of the academic medical centers are not located in areas where the rural populace is readily available for research. In part, the efforts to establish the rural health research centers through direct funding of such programs resulted from this oversight by the health services research community. Although these research centers are proceeding with both individual and cooperative research agendas, surely more studies can be accomplished if the health services research community becomes more involved in mining the rural health field.

Finally, there is also a need to encourage a pluralistic, interdisciplinary approach in rural health services research rather than an approach with a unified paradigm. As such, it is important to recognize the impact of non-health concerns in conducting research related to rural health. Perhaps this issue represents the major departure from more traditional research on health care for urban areas.

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Primary Care Research: Impressions of the Conference

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The proceedings of this conference provide a thoughtful commentary on research related to primary care. How can the organization and financing of medical care be evaluated from the perspective of primary care? How can provider behavior be changed? What is known about research related to prevention? All of these topics are covered in this volume.

Still, despite the in-depth discussions of the role of health services research in primary care, a gnawing concern remains. If a man from Mars were to have landed here at the beginning of this conference and sat through the sessions, would that Martian conclude that primary care research exists? Would he understand it any better than he might have before he had landed? Or put another way, do your parents understand what you do for a living?

It may be that the conference attendees have failed to sufficiently describe what primary care research is in distinction to other types of health services research. It also may be that it is time to recognize the possibility that primary care research is not a distinct entity.

The discussions over the course of the conference, in defining primary care, have described it as a function. Its characteristics—including continuity, comprehensiveness, access, and first contact, among others—were elucidated by Estes, Smith, and other speakers (in this volume). The nature of primary care as a type of medical care that is provided by health professionals to the public was made clear. But less clear was the distinction of research related to primary care from other types of clinical research.

A strong case could be made that primary care research is really not about primary care but is more often about the components of primary care—its continuity, its access, and so on. Yet primary care does not have a lock on

these characteristics of high quality medical care. Certainly, urgent care and emergency care offer access and first contact care. Many other physicians provide continuity of care for their patients. What does distinguish primary care is that it provides these characteristics in a well-organized package. The combination is clinical primary care, yet the elements of primary care are the focus of research investigations.

Primary care is a means to an end—or a set of ends—not an end in itself. By suggesting that researchers study primary care, there is a risk that the essence of clinical primary care—that is, its functions—will be overlooked.

As a result of the overlap between research about primary care and research about other medical care, the focus has been not so much on primary care research as on clinical research, on studies that evaluate the comprehensiveness, the continuity, and the quality of medical care, as well as the access to medical care and its effectiveness. If the man from Mars had been asked if the primary care research agenda is substantially different from the clinical research agenda, he most likely would respond with skepticism.

“Is clinical research dead?” is a question often asked in academic circles these days. Will the concerned clinician, who is interested in the effectiveness and outcomes of medical care, be able to carry out this research in a high-quality fashion and receive funding to do so?

The Agency for Health Care Policy and Research (AHCPR) has an opportunity to provide leadership in clinical research, in order that all health professionals, not just primary care health professionals, will find themselves guided by effective, scholarly investigations that enable them to provide higher quality care to their patients. Certainly, some of the most important work will relate to the care provided by primary care professionals, who attempt to combine all of the characteristics of primary care. But much important clinical research will also be done in more narrow areas. It is

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probably no coincidence that the National Center for Health Services Research and Health Care Technology Assessment has had its name changed to the Agency for Health Care Policy and Research. The emphasis is on care, on care research, on medical care, and on the evaluation of medical care.

This focus on medical care research can take many forms. It may evaluate the outcomes of medical care—whether it is primary care or not—in particular, the cost, effectiveness, and adverse effects of care. Medical care research may also focus on the types of methods that are used, such as clinical epidemiology, clinical decision-making, or clinical economics. What is essential, though, is that this type of research emphasize the clinical encounter, that very special relationship between clinician and patient in the context of an environment and health care system that shapes the relationship.

Primary care research, then, is an application of research to an important clinical area. As a result, it is imperative to keep in mind the fundamental building blocks of research related to primary care, for that is where support must be provided by AHCPR; it is unlikely that support will be provided by anyone else.

Although many who would see primary care research as its own discipline may complain, identifying primary care research as an application and not a primary form of research itself is not unusual in other health research areas. This is certainly the way that much other research in this country is organized—for example, cancer research, heart disease research, and AIDS research. These are convenient ways to package the research, to keep it purposeful, and to keep it directed.

Moreover, packaging research along the lines of its applications rather than the more fundamental methodology of the research is a demonstrated way to develop a constituency. Will primary care give health services research its constituency? Those who are in the primary care disciplines have not been very effective in convincing the public, nor its elected officials, that primary care research deserves much more attention than it has received. More successful have been programs to emphasize some of the components of primary care, such as the evaluation of continuity and prevention, or some of the characteristics of primary care, such as its effectiveness or its cost. In many ways, primary care clinicians and their patients are users of health care research. Only some are doers of health care research, but all should be its advocates.

In addition to the need to recognize that primary care is an application of research rather than a form of research

itself, it is also necessary to recognize the potential risks of claiming that the important issues of clinical research belong to primary care. First, doing so would risk divorcing primary care researchers from the rest of the health services research community. Primary care physicians, carrying out research related to primary care, desperately need to develop a link with their colleagues in the basic sciences of primary care. Just as the cancer investigator depends upon linkages with cellular biologists and immunologists for advances in state-of-the-art of cancer-related research, so do primary care researchers rely on advances in decision analysis, economics, and sociology to further their field.

Second, by claiming this form of clinical research as their own, the primary care specialties would allow other specialties to abrogate their responsibility for using epidemiology, economics, and the other tools of health services research to evaluate their own effectiveness and outcomes. Some specialties have moved ahead, beyond the expertise of many primary care scholars. For example, take note of geriatricians evaluating functional status, rheumatologists evaluating the improvement in health status, and cardiovascular or cancer clinicians evaluating prevention.

What is needed most is not so much an initiative in primary care research alone, but the development of a new science of clinical practice. This would represent a rejuvenation of clinical research that recognizes its potential contribution to evaluating the effectiveness and efficiency of medical care, while also recognizing the need for strong methodologic skills and clear thinking in research design.

Another risk of overemphasis on the primary care applications of research is that AHCPR could become overly pragmatic, losing whatever commitment it has had to the support of basic research in this area. If basic research in the fields underlying primary care research is abandoned by the Agency, it is unlikely that it will be picked up by any other program in the Federal Government.

A final concern about claiming medical care or clinical research as “primary care research” and narrowing its focus of application is that most physicians do not understand the implications of this type of research for their practices. Certainly, new forms of dissemination are needed to provide findings from this kind of research to all types of practicing physicians and nurses—not just primary care clinicians—findings that are important in their roles as clinical policymakers.

The Consequences of Success in Primary Care Research

Daniel M. Fox, Ph.D.

Introduction

My goal is to describe what happened at this conference and explore some of the implications of the conference for the future of primary care research. To be more precise, I will describe and interpret what I heard during the conference about the purposes of primary care research. In telling this story, I will address my central concern as a researcher: the relationship between scientific knowledge and policy. Indeed, -you might think of what follows as the report of a 2-day research project called something like “The Consonance and Dissonance of Normative Models of Primary Care Research.” The methods used in this pseudo-study were participant observation and textual analysis.

My hypothetical study reached two conclusions. The first conclusion is that there are two superficially similar, but actually very different, normative models of primary care research in good currency among this population. The second is that each of these normative models is politically volatile in a different way.

After I report the results of this empirical study, I will summarize the pertinent research literature that suggests why it will be difficult to make policy using research that is based on these normative models. The conclusion I have drawn from this analysis may seem to be pessimistic, but it is pessimistic only if you believe that complicated problems can have simple answers.

Normative Models of Primary Care Research

The first model used at this conference is based on the assertion that the health care system in the United States is in dreadful condition. The model then assumes that the purpose of health services research, and research on **primary care in particular, is to devise ways to remedy that condition.**

The alternative model used during the conference is based on the assertion that primary care in the United States is in dreadful condition. (A variant of this model: some participants would also say that the US health care system is in trouble because of the condition of primary care.) The model then assumes that the purpose of health services research is to remedy the condition of primary care: both how it is now practiced and how it should be practiced in the desirable future when more resources are allocated to it.

Here are some data-statements and impressions taken from the presentations at this conference-that exemplify each of these models. First, the model that asserts that the central problem is the terrible condition of the Nation’s health care system:

- The health services research community has an important role in examining the needs of society.
- Primary care is a means to an end, which is broad reform of the health care system.
- We are in the early stages of a revolution in the way American physicians practice medicine.
- The current health care system suffers from problems related to cost, quality, and suboptimal practice patterns that have been resistant to change.
- There is a consensus that the health care system is “out of control” and that “nobody knows what to do about it.”

The following are statements in support of the second model-that is, the purpose of research is to improve the condition of primary care:

- We really stand apart from the rest of our medical research complex, and as a result, our health care system has many of its major flaws.

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- We must restore balance in our system of health care.
- As society's greatest need for physicians remains in primary care, so are the greatest research needs in primary care.
- The goals of primary care research are for physicians to better manage their patients and support their health care role at the community level.

I hope that no one who has followed me this far has concluded that the trouble with primary care research, or health services research itself, is that it has normative models. I assure you that the consensus among leading researchers in the history, sociology, and philosophy of science is that all scientific work (including their own) is based on normative models.

The Political Consequences of the Two Models

Each of the normative models I have described is politically volatile. Before I explore the potential political consequences of each model, I want to describe briefly how normative models become politically controversial, even when the investigators who employ them believe they are doing reasonably objective research using the best theories and methods of the medical, social, and behavioral sciences.

Normative models become controversial in several ways. Sometimes the results of research based on the models are critical of powerful individuals. A good example would be a randomized clinical trial that demonstrates the ineffectiveness of a treatment that has been used for many years. At other times, the impact of a normative model is more subtle. An example would be finding that a problem with access to care for certain people increases their morbidity. Here the normative model is critical by implication: some readers of the research results might want to redistribute resources in order to improve access.

People who are sensitive to politics have little difficulty identifying the normative models driving any scientific research that affects their interests. This is so because the values that underlie the normative models are widely held and often controversial. The normative basis of the science is communicated symbolically—through key words, inflections and even body language. This communication, and the political responses that are based on it, occurs even though none of the participants

in a discussion recognize the theoretical differences between normative and descriptive models.

The political consequences of the two normative models of primary care research are somewhat different. The model that asserts that health care in the United States is in terrible condition puts its adherents at considerable risk of facing mobilized opposition throughout the health care sector. When we study the quality, effectiveness, and efficiency of health care, we are evaluating the behavior of people who have names and constituencies, as well as interests and feelings. This is in contrast to laboratory scientists who, in most cases, look at the behavior of microorganisms and organs and clinical scientists who study patients.

What the proponents of the first model are suggesting is as startling as it would be to examine the HIV epidemic from the point of view of the virus. Such an examination would begin by asking what the human species did to change the formerly quiet and epidemiologically ineffective lifestyle of this retrovirus.

The danger of the second model, research that seeks to fix primary care rather than the whole health care system, has been artfully described by Peter Budetti (in this volume). Dr. Budetti identified the dangers of special pleading by a researcher that what he or she does deserves additional support at a time when the consensus of powerful people in health affairs and general politics is that there are more important issues.

This model also puts researchers who work on primary care in danger of being isolated from other constituencies within and outside the health sector. I include in these constituencies people who argue that policy for every aspect of health care should be based on the best available science—on the gold standard of the age at the bench, in the clinic, and in the population. But more importantly, I am talking about isolation from those who argue that improving health is less a matter of better primary care than of better policies to address the economy, the environment, housing, race, social class, and other stigmatizing factors.

Those who embrace the first model will most likely have more enemies within the health care sector. They will have fewer outside it if they are willing to acknowledge that one of the reasons the health care system is in terrible condition is that this society does not address significant causes of impairment, disability, and handicap.

I should point out that there is a more optimistic view of the political consequences of the second model. Dr. Robert Graham (in this volume) put this view very well

when he said that we have “an opportunity to act in an area of high visibility.” Sometimes visibility is not desirable, however.

The Consequences of the Models for Policy

What do we know, as a result of research, about the problems of making the policies that are likely to be derived from research on either of the two normative models that have been advocated at this conference? This research question could be restated in order to provide a broader definition of the pertinent literature: What do we know about the causes of continuity and change in health care policy?

Actually, we know a great deal about this broader question as a result of research that has been conducted over many years, although this area of research has not been particularly popular in health affairs. Indeed, when I consider the complaints aired during this conference about the funding that has been available for primary care research, it reminds me of the more severe funding problems of investigators who study systematically how institutions and political systems operate.

Here is a summary of that underfunded and hard-won knowledge, compressed into four alliterative points. Understanding both continuity and change in health care policy involves knowing about the interaction of some or all of these factors:

- ideas
- interests
- illness
- interventions.

As I define these factors more precisely, you will realize that the alliterative statement is a device for communicating some very complicated matters. The term “ideas” in this context means beliefs, values, and operating assumptions.

Beliefs include unexamined commitments about the goals of medical care, the way new knowledge is created and disseminated, and how the definitions of diseases are arrived at (some would say negotiated). Values are a more familiar concept after two decades of heightened concern about medical ethics. Operating assumptions are our views (which we rarely examine systematically) about such matters as how Congress and the executive agencies operate, or how priorities are set in medical school budgets, or how and when a teacher communicates successfully.

I use the term “interests” to stand for the familiar behavior of individuals and groups to maximize their satisfactions or benefits without making an unsupportable number of enemies. I will pass over this concept quickly because it has the richest and most familiar literature.

By “illness” I mean two things. The first is the pressure of particular causes of morbidity and mortality on the institutions and resources of the health care sector. Secondly, it means the way important interest groups perceive illnesses—for instance, the definitions of onset, etiology, and course among health care professionals and the general public at any time.

One example of the pressure of illness on policy will suffice. It has mattered enormously for health policy in this century that, in about 1920, more people began to die of chronic disease than of infectious diseases and injuries. How it has mattered involves, among other considerations, changing definitions of onset, etiology, and course. A dramatic recent example is AIDS, which was redefined as a chronic disease, HIV infection, in 1989 and 1990.

The final point is “intervention,” by which I mean what health care professionals do as a result of ideas, interests, and illnesses. Interventions create their own constituencies of providers, educators, researchers, and in some powerful examples (like penicillin, cortisone, transplants, and AZT), of consumers.

Applying the Concepts to Normative Models

Now, I will apply these four concepts to the two normative models of research on primary care that have been current at this conference. I will compare policy based on these models with three rather well known policy initiatives of the past 40 years (each of which was driven by a normative model of research). The three policies, in chronological order, are the establishment of the National Institutes of Health (NIH) Extramural Grants Program (1940s), the expansion of medical education by State and Federal subsidies (1960s and 1970s), and the inception of price-based reimbursement (DRGs) in the 1980s. The conclusions drawn from the following analysis are summarized in Table 1.

The NIH extramural grants program. The creators of this program—an alliance of Public Health Service officials, Congressmen and their staffs, and academic researchers—addressed the four factors as follows:

1. They based their claim on broadly accepted ideas about the progress of medical knowledge and how that progress came about.

Table 1. Four policies: a history

	Ideas	Interests	Illness	Interventions
NIH extramural Medical education	Accept consensus	Narrowed definitions	Chronic disease	
DRGs	“	Selective	“	
Primary care	Challenge consensus	Challenge array	Challenge conception	Target Challenge priorities

2. They very deliberately established a narrow definition of concerned interest groups, convincing most practicing physicians (and the American Medical Association), for example, that they would gain reflected glory from the new program at no personal cost.
3. They justified the program as a response to the increasing incidence and prevalence of chronic disease. The purpose of the policy they advocated was to learn more about the biology of the degeneration of organ systems that was the basis of chronic disease.
4. They carefully ignored interventions, as most physicians and the public defined them. But they implied that research on the biology underlying chronic disease would have a benign influence on interventions in the future and that the research would contribute to medical progress (which, they believed, had been uninterrupted since the previous century).

The expansion of medical education. Here is how the advocates of this highly successful set of policies addressed the four factors:

1. Like the advocates of the NIH extramural grants program, proponents of expanding medical education amplified the symbolic value of broadly accepted ideas about the progress of medicine and the increasing prowess of physicians.
2. They chose selectively among the interest groups in each State. In States where medical interest groups opposed starting or expanding schools, proponents built support among banking, construction, union, and chamber of commerce constituencies.
3. Advocates of expanding medical education used ominous projections of increasing morbidity from chronic disease to bolster their arguments for increasing the physician-to-population ratio.

4. They ignored interventions, except to say that whatever leading physicians did-especially in teaching hospitals-was in the patients' (and the public's) interest.

Diagnosis-related groups. In this instance, the political calculation was simpler than either of the others. The premise of the politics was: if an array of interests can be changed by changing incentives, then it is possible to influence interventions. Advocates of price-based reimbursement appeared to be arguing that neither ideas nor illness, as I have defined them, mattered to the new policy.

Policies Derived From Normative Models

With this background, the policies that would be driven by either of the two normative models can be examined. Policy based on either model would require major changes in all four of the factors: in fundamental ideas (beliefs, values and operating assumptions); in the array of interests in what seems to have become the Nation's largest industry; in the professional and public perception of what an illness is and how it should be managed; and in the relative value that is assigned to various interventions.

According to this analysis, neither of the two normative models is likely to lead to policy in the foreseeable future. We are not close to a national consensus that the health care system is in terrible shape and perhaps even further from a broad-based political agreement that primary care is in dreadful condition. Advocating your favorite model will be a long and frustrating process. Indeed, you are likely to fail if your criteria for success are outcomes (changes in policy) rather than process (how many grants have been awarded, the size of the research budget, or how many guidelines have been issued).

Conclusion

We are all eager for the new Agency for Health Care Policy and Research to succeed. Each of us wants our favorite normative model for research to drive policy.

But we must be patient, and our expectations must be low. Those of us who have been committed to health services research for the past several decades are familiar with low expectations, Now we must work hard and in an analytic fashion at the politics of raising researchers' expectations.

One way to work at these politics would be to select normative models for research that are more likely to lead to policy in our professional lifetimes. One alternative model would be to build support for modest changes

in ideas and the array of interests by examining, with the best available science, one intervention (or the interventions directed toward one segment of the population) at a time, **For** example, emphasis could be placed on managing the disabling **results** of chronic disease, because these place the greatest burden on people and therefore on resources, Assume that neither the health care system nor primary care is in dreadful condition, but rather that, for the moment, it is the only health care system that we have.

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