Commentary on the Federal Role in Clinical Prevention Research

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ABSTRACT: Effective clinical prevention practice is the objective of the long journey from laboratory and epidemiologic studies to clinical understanding, interventions, and prevention practice with individual patients. The ability to ask ever more fundamental questions about the molecular basis of disease, as is rapidly being developed by NIH's Human Genome Project, promises to make this journey even longer and more complicated, but eventually to make screening and intervention for preventable disease even more amenable to clinical intervention. As we expect in the future, much of what we currently do in clinical prevention practice had its genesis in earlier federal support for basic and clinical research.

We comment on the content and major points of the papers on the federal role in prevention research. These papers, in addition to describing the past accomplishment, current state, and future opportunities for prevention research, raise questions about the ultimate application of the enormous and successful national investment in prevention research. A fault line exists among the increasing knowledge of prevention practice, the rapid changes in the way services are delivered, and demonstration of the effectiveness of prevention procedures applied for the good of the whole population.

The federal agencies most concerned with the application of prevention knowledge are those most limited in their research budgets: the Agency for Health Care Policy and Research (AHCPR) and the Centers for Disease Control and Prevention (CDC). The National Institutes of Health (NIH), with the greatest research dollars for investment, also has the broadest mandate for investment in research. Meeting all the demands to fund high-quality research is challenging; however, NIH may have review procedures that disadvantage clinical researchers and, among these, applied prevention researchers. The restructuring of the health care system by managed care promises opportunity for more effectiveness research. However, the same competition that fosters the development of managed care may limit the extent of prevention experimentation and the dissemination of results. Current national concerns for the weakening of support for clinical research are in part due to the reduced availability of patient care revenue to support clinical research brought about by managed care. The academic and practice communities that share concern for prevention research should recognize the increasing gap between basic and applied prevention knowledge. Those committed to the clinical application of this knowledge should encourage increased federal research support to assure that what we think we know is indeed so, that what is efficacious is available to all in the society that so generously supports research.

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Should this country invest in prevention research? If exploring the efficacy of preventive approaches and testing the application of preventive measures ultimately improves the health of our citizens, is it worth the taxpayers' money? Charles C. Colton dealt with the relative importance of health and money when he stated:

> There is a difference between the two temporal blessings—health and money; money is the most envied, but the least enjoyed; health is the most enjoyed, but the least envied; and this superiority of the latter is still more obvious when we reflect that the poorest man would not part with health for money, but that the richest would gladly part with all his money for health.[1]

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In a world that values highly technologic advances, the benefits of prevention research, which could facilitate a higher level of health of our population, have often been underestimated. Scientists interested in pursuing prevention-related problems have generally had relatively fewer sources of funding, especially on the Federal level where the percentages of research budgets devoted to prevention have historically been sparse. But the world of health care is changing and the importance of prevention is more widely recognized today in both the health care literature and the practice arena. Philip Lee, MD, former Assistant Secretary for Health, points out that ". . . behavioral and lifestyle factors are major causes of morbidity and mortality, contributing to all 10 of the leading causes of death in the United States."[2] Yet, in spite of the evidence that the leading determinants of disease and death are rooted in behavioral choices, relating to risk factors such as tobacco, diet, exercise, and alcohol,[3] a paucity of evidence exists on the factors that influence people to adopt healthy behaviors. And according to Dr. Lee, this evidence ". . . cannot be achieved without support for basic, clinical, and applied research efforts."[4]

With this in mind, the National Coordinating Committee on Clinical Preventive Services (NCCCPS) devoted their meeting on May 11, 1994, in Washington, DC, to the Federal Agenda and Funding Opportunities for Research on Clinical Preventive Services. The NCCCPS, convened by the U.S. Public Health Services and chaired at that time by J. Michael McGinnis, MD, then Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion), consisted of representatives from 33 organizations representing practicing primary care providers, academic and public health communities, and health care financing organizations. Its overall mission was to provide leadership in the implementation of clinical preventive services by examining barriers to service delivery in primary care and by developing potential solutions to overcome those barriers. At this meeting, most of the authors of the following papers presented as a panel addressing opportunities and funding sources for clinical preventive services research within their agencies. Following this meeting, these experts presented as a panel again at the Prevention '95 conference on the Federal Role in Research. It was envisioned at that time that the papers be prepared for publication. This issue of the *American Journal of Preventive Medicine* is the fruition of that intent.

The organizations within the NIH that contributed papers are the Office of Disease Prevention and the National Heart, Lung and Blood Institute (NHLBI). Other government agencies represented are the Centers for Disease Control and Prevention (CDC), the Agency for Health Care Policy and Research (AHCPR), and the Office of Disease Prevention and Health Promotion (ODPHP) of the U.S. Public Health Service. The Foreword is written by a former federal official who previously was Administrator of the Health Care Financing Administration (HCFA) and Director of the CDC. The final paper represents a response from a private-sector primary care research organization.

Because the genesis of these papers was the panel of speakers at the NCCCPS meeting, and because there are multitudes of Federal funding sources, it was not possible to represent all governmental sources of funding. For example, additional institutes within NIH, such as the National Institute of Nursing Research, National Institute on Aging, National Institute of Child Health and Human Development, National Institute of Neurological Disorders and Stroke, National Institute of Mental Health, National Center for Human Genome Research, National Institute of Deafness and Other Communicative Disorders, and numerous other Federal agencies conduct prevention-related research but were not included in this collection of papers. Among those agencies are the Veterans Administration, the military, and the Health Care Financing Administration, which, with the exception of the last, continue to invest in prevention research, albeit with more discrete populations and issues than the agencies represented here. Their contributions to prevention-related research must also be recognized. We will briefly comment on the papers, beginning with the Foreword by Dr. William Roper.

The Foreword by William L. Roper, MD, former White House Aide to Presidents Bush and Reagan, and also head of first the HCFA and then the CDC, looked at prevention research from his perspective when head of the Prudential Center for Health Care Research. From that perspective, carrying out research in a managed care setting, he provides a rosier picture of the future of prevention practice than that later discussed by Dr. Kleinman. Dr. Roper feels that the landscape for the study and implementation of prevention research has shifted with the emergence of managed care. Implicit in this shift is the focus on prevention services, which have promise of being cost-beneficial. Also implicit is the availability of defined covered populations for study of both the implementation and outcomes of prevention research. These hold major implications for current and future prevention practice, perhaps the most important of which is to force clinicians, through managed care oversight, to shift their focus from individual patient care to population concerns of the payer of services when making care decisions. Concern for population need is critical to carrying out significant prevention research, providing a larger, more diverse and more accessible population than previously available to researchers. Dr. Roper argues that the emergence of managed care, and its eventual collapse into a smaller number of large organizations that can success-

fully provide appropriate and high-quality services, will be accompanied by both a need to pose questions on the provision of effective prevention services and the emergence of a public-private partnership to answer them in the larger, increasingly diverse populations served by managed care.

The largest investment in federal prevention research in its broadest definition has been made by the National Institutes of Health (NIH). Dr. William R. Harlan, Director for Disease Prevention at NIH and whose overall contributions were helpful in the publication of these papers, provides an overview of NIH support for prevention research, the functional relationships affecting prevention research within the agency, and useful background information for prevention researchers. He emphasizes the relevance of the major NIH investment in genetic research on prevention and gives examples of the continuity among molecular medicine, clinical research, and population research. This relationship between genetic research and prevention has not been readily recognized by prevention researchers but has great significance for their work. Also, Dr. Harlan acknowledges that the structure of NIH, in which most Institutes were formed to address specific diseases or life stages, can be a challenge for prevention research because prevention often requires holistic and populational perspectives. His examples of Institutes joining together to conduct prevention studies are encouraging. An example is the Women's Health Initiative, a longitudinal study involving 40 clinical centers. Such prevention studies that are larger with more generally representative populations and that occur over a longer time period are sometimes required to provide results that have clinical or public health implications. NIH's commitment and capability to conduct large clinical trials and to promote methodologic advances in design, conduct, and analysis can significantly impact prevention efforts. Dr. Harlan further addresses the importance of capturing benefits and risks of prevention interventions. Knowledge of both is necessary to provide balanced prevention advice, especially when applied to populations at nominal risk of disease with diverse individual risk. This perspective is important as we look at U.S. prevention guidelines and associated research issues that became apparent in guidelines development, as discussed in the DiGuiseppi and Atkins (ODPHP) paper. Finally, Harlan emphasizes the need for integration of scientific findings and clinical perspectives to maximize the utility of prevention research.

An illustration of a specific NIH research program is provided by Drs. Jeffrey Cutler and Denise Simons-Morton of the National Heart, Lung and Blood Institute (NHLBI). In their paper, they focus on cardiovascular disease (CVD), one element of NHLBI prevention research, which represents the most extensive and long-standing area of prevention research activity in that agency. Further, study of CVD has led to significant individual and population interventions, which have decreased mortality from coronary artery disease, perhaps the most significant advance in chronic disease control. Using CVD examples, they provide a clear, concise description of the research process within NHLBI. Eighty-six percent of new extramural NHLBI research funding is investigator-initiated. The remainder, institute-initiated projects, often involve large-scale multicenter studies, for which the authors explain the planning, development, and implementation process. Concise descriptions of primordial/primary prevention studies and secondary CVD prevention studies are provided in this very informative paper.

Prevention researchers will find the paper authored by Drs. Dixie Snider and Stephen Thacker useful in its discussion of the CDC mission, historical perspective, breadth of concern, and description of current CDC prevention research activities. Congress determines areas of CDC prevention research by targeting funds to program-specific areas. Many prevention researchers will find that their area of interest fits within these broad program areas; however, CDC also funds a number of investigator-initiated grants. CDC's emphasis on partnerships can also provide opportunities for researchers who work with some of the partners, such as the Association of State and Territorial Health Officials, University Prevention Centers, Injury Control Research Centers, Association of Schools of Public Health, Association of Teachers of Preventive Medicine, Minority Health Professions Foundation, and a network of health maintenance organizations. The Federal Register is the source of regular announcements of CDC research funding for interested researchers. A current CDC initiative involves development of "laboratories" for population-based prevention research. These Urban Centers for Applied Research in Public Health are being proposed by CDC to bridge the gap between local public health authorities and epidemiologic research and prevention effectiveness activities. Snider and Thacker explain that through these Urban Centers, multiple studies can be conducted without the need to create a separate study "population" every time a new study is contemplated.

Continuing and emerging research priorities of CDC are improvement of health of children/adolescents, women's health, identification and control of emerging infections, vaccine-preventable diseases, prevention of intentional and unintentional injury, and exploration of tools of public health, such as risk assessment, risk communication, and informatics. The importance of and emphasis on intervention studies are also addressed in the CDC paper.

The Agency for Health Care Policy and Research (AHCPR) is concerned with improving the delivery of

preventive services known to be efficacious. The determination of efficacy is done by research funded by other agencies and endorsed by groups such as the U.S. Preventive Services Task Force. James Cooper, MD, and Carolyn Clancy, MD, discuss AHCPR's prevention research agenda. They argue that the restructuring of the health care system through increased payment by managed care provides increased opportunity for service accountability. As there are both increased knowledge of effective prevention practices and interest in prevention research, AHCPR solicits proposals that facilitate the transfer of prevention knowledge into practice. The authors identify three general areas of needed research—effectiveness (including cost effectiveness), quality, and access. In doing so, they describe research issues that require study in each of the areas.

By effectiveness they mean the study of how efficacious procedures can be translated into actual preventive service provision in diverse real world situations. Cost effectiveness is a particularly important aspect of such research as the health care system is increasingly driven by short-term cost considerations. These considerations raise issues as to how the payer of services benefits from the provision of many preventive services whose full benefit may not be apparent until far in the future, past the likely time of patient enrollment in the provider's plan. With cost considerations an increasingly explicit aspect of care provision, less costly and time-consuming ways of providing prevention services and efficient packaging of services, particularly counseling services, need to be developed. The authors argue for research on improved patient risk adjustment and outcome measures to facilitate comparison of service provision. These concerns relate directly to the research area of quality. More service provision is meaningless unless done in an appropriate and acceptable manner. Here, too, development of better measurement methods is necessary to identify not only that timely and scientifically effective services are provided, but also that indicated follow-up procedures are done. The development of quantitative measures for prevention systems performance connotes improvement in prevention service provision only if the services are provided to those for whom the service is appropriate and only if findings are communicated to patients who act upon them. These questions lead to the concern with access, which remains a major concern of AHCPR. Access issues relate not only to the uninsured or underinsured, but also to those who are financially, socially, or psychologically distanced from service provision. Such people, often those at highest risk of avoidable disease development, may not receive prevention services even though insured by an organized system of medical care. Many researchable access issues requiring study concern restructuring of service delivery through division and delegation of responsibility among the diverse providers seeing patients. The delivery of prevention services may also be enhanced by improved use of technology when services are delivered. Their paper should stimulate researchers to appreciate the many researchable problems relating to procedures with known efficacy whose provision is an increasing priority.

The paper by Drs. Carolyn DiGuiseppi and David Atkins is particularly relevant to this issue of providing efficacious services. They reflect on this issue following the intensive review of the prevention literature occasioned by their staff work reviewing the published prevention literature for the prevention recommendations of the Second Edition of the *Guide to Clinical Preventive Services*.[5] One of their important findings is the lack of scientific evidence for the benefit of many prevention practices. The paucity or poor quality of the evidence limits the number and certainty of recommendations for prevention practice. Because of the absence of research data, numerous recommendations in the *Guide* received a grade of "C," denoting insufficient evidence to recommend for or against providing the preventive intervention as part of the periodic health examination. For example, the authors found that evidence on the effectiveness of counseling to change behavior is scarce. As much primary prevention depends on behavior change, and counseling is time-consuming and costly, the absence of such evidence will impede investment in counseling by cost-conscious providers. In their paper, they provide valuable guidance to researchers on the types of research questions that need to be addressed to provide more evidence in this crucial area of prevention. Other areas they identify as prevention research priorities are periodicity, patient preferences, risk assessment, and cost-effectiveness analysis. The authors identify critical evidence needed to make informed judgments about the appropriateness of many procedures. Recognizing the difficulties of conducting randomized controlled trials that yield the strongest evidence, the authors recommend potential solutions for researchers: studies of single linkages in the causal pathways, observational studies, and increased use of meta-analysis. Finally, they stress the importance of identifying effective strategies to implement recommended preventive services and evaluating the effectiveness of clinical practice guidelines in improving patient outcomes. Their paper is notable because of its emphasis on applied prevention research and the unique perspective they provide on the paucity of convincing evidence for many prevention interventions. The quality of future studies, not their quantity, will be critical in advancing prevention practice to include a larger number of services.

The last paper, authored by Dr. Lawrence Kleinman, is a thoughtful commentary on the current focus on practicing evidence-based medicine. The article is par-

ticularly relevant given the emergence of managed care in the context of the sparse research base on effective prevention practice documented in the previous paper. He provides a model illustrating the conceptual relationship between traditional medical care and evidence-based medicine. Kleinman argues that the current lack of an adequate research base for many customarily provided prevention services makes a move to purely evidence-based care premature for primary care and prevention services. While he illustrates this issue with examples from pediatric practice, the issue is as relevant for medical practice for patients of all ages. He substantiates points made by DiGuiseppi and Atkins regarding the limited scientific basis for predicting outcomes and effectiveness of care, and indeed the limited science underlying much of medical practice, but discusses the dilemma this poses for the clinician.

Kleinman observes that the private sector is driven by competitive pressures that increasingly affect the way primary care services, including prevention services, are provided. These practice incentives promote productivity, not quality, which may conflict with providing some prevention services. Further, competitiveness promotes secrecy, not openness, implying that if better ways of providing prevention services are identified by organized providers, they will not necessarily be widely communicated and, therefore, added to the knowledge base for all providers. The issue of dissemination of knowledge of prevention services is of even greater concern with the increasing budgetary constraints on agencies, such as AHCPR and CDC, particularly concerned with the effective delivery of prevention services. Such constraints imply that the pace of development of knowledge about effectiveness will be slowed, prolonging dependence on the small body of existing evidence-based medicine.

Assuming that some proportion of extant but not yet scientifically proven prevention practice is indeed effective, excessive reliance on evidence-based medicine may compromise delivery of needed prevention services to some people. Kleinman illustrates his assertion by raising questions from pediatric practice, where little is known of the process and outcome of prevention counseling and education practice for children, yet well-child care constitutes a large proportion of the content of pediatric practice. Current prevention research is particularly deficient in measurement of social and behavioral outcomes, both for the individual and for social environments, yet much pediatric clinical intervention has as its aim increasing the likelihood of a child's being in a nurturing environment and making healthful life choices. Kleinman's paper is a provocative discussion of the prevention service implications of financing health care through managed care and the risks of relying only on evidence-based medicine as the basis for medical practice.

Discussion

A new element in prevention practice and research is managed care. These papers have presented both the positive and possible negative effects of managed care in the context of providing clinical preventive services based on what we currently know regarding efficacy. Those papers addressing clinical practice issues argue the need for applied prevention research, efficacy research, and effectiveness research, and describe some of the federal mechanisms by which this research can be done. The availability of managed care enrollees as populations for prevention research is an attractive prospect that undoubtedly will lead to improved methods of providing selected prevention services. However, managed care is likely to improve preventive care for a limited number of effective procedures, as dictated by cost considerations and managed care organizational or external standards, such as prevention practices identified as quality markers by groups such as HEDIS. As a result, only a subset of effective prevention procedures will be adopted and studied, if at all, by the internal funding mechanisms of managed care organizations. These issues are confounded by the concern that programs funded internally may provide a competitive benefit for a managed care organization, but may not be disseminated as widely as other prevention knowledge, a concern that may be justified. Increasingly, federally supported studies will be done in managed care organizations because of the ready availability of a population, as has long been the case for studies in closed-panel HMOs. However, as in the case of previous research, it is only a small number of HMOs by type and by site that will undertake the research. It is not at all clear how representative these findings are.

It is also apparent that managed care, by making clinically or economically based but not experimentally based decisions about health care use, creates issues that demand research to assess their consequences. A current example is the movement by managed care to shorter post-partum stays. This move is clearly cost saving. While the shorter stays are warranted in many cases, they are associated with higher short-term rehospitalization rates for several conditions, including jaundice, where delay may be deleterious to infant well-being.[6] Ideally, the health effects of newer policies, such as shorter post-partum stays, should be assessed prospectively. Further, in anticipation of likely increased morbidity ensuing on the lessened clinical observation of patients at a time of high expected morbidity, patient education and outreach programs might be provided and assessed for effectiveness in detecting anticipated morbidity before deleterious effects could ensue for otherwise preventable morbidity.

Regardless of the managed care issue, government has responsibility for doing research that is relevant for

meeting the prevention needs of the entire population. The population includes a fluctuating but substantial number of non-insured and underinsured people, many of whom are particularly vulnerable to preventable illness. Further, for the foreseeable future, many people will obtain fee-for-service care, including most elderly, for whom prevention screening programs are particularly important. Already known is that for the nation's one universal financial access program, Medicare, use of prevention services is far less than ideal, both for initial as well as repeat procedures, whether for mammography screening[7] or for immunization.[8] As might be expected, those of highest risk are less likely to receive screening.[9] Learning how to motivate people to seek prevention services, getting providers to recommend procedures to patients, and setting up systems to assure that procedures are done and then followed through, requires costly and difficult research in the community, which needs to be done. Ideally, such studies should be done in multiple clinical settings. Even managed care organizations vary greatly in their organizational structure and populations of both providers and beneficiaries, which will affect care. Not all of these interventions offer likelihood of commercial gain; therefore, government support is needed for such applied prevention research. Counseling interventions, if proven effective, will also most likely require federal support, as these interventions are time-consuming initially and need reinforcement if behavior change is to be sustained. If not proven effective, federal support would be needed for studies to determine what is effective. Ultimately, however, organized systems of care should be better able to adopt effective prevention services, particularly those such as counseling services, through use of less-costly providers, use of computer technology for providers and patients, targeting of interventions, patient reminders, and sustained follow-up, little of which can readily be done by traditional solo or small group providers.

These papers comment on the current status of prevention research from its major sources of federal support and on current issues in clinical prevention services. Providing these services is the fruit of much of prevention research, and it appears as though the fruit is not yet fully ripened. Given the enormous and successful investment in prevention research, *few* proven prevention practices and relatively *little* technology are actually available to be used with confidence that in their application human benefit will result. In the review of the U.S. Preventive Task Force's experience, in Dr. Kleinman's paper, and in AHCPR's priorities for research, there is discussion of this discrepancy between this prevention knowledge and its application. It is clear that despite enormous and continuing national investment in the entire spectrum of prevention research, a major deficiency in our research enterprise is in closing the loop among molecular and epidemiologic knowledge of prevention risks, development of clinical interventions, demonstration of their efficacy, and their implementation in clinical practice and application in health services. What is most lacking is the behavioral and economic research necessary to assure that what is known is applied to the benefit of the society that so generously sponsors this research. There is substantial governmental support for basic research, but there is more uncertainty about the investment in research funding for applied prevention research. The Institute of Medicine recently held a public meeting on clinical research, and its report made a plea for continued and expanded investment in clinical research in the laboratory and in experimental clinical care.[10] Less addressed is the need for translational research from the medical center to the diverse population at risk. As a society and as preventionists, we must assure that what is developed is effective in clinical use for those with need: those insured as well as those uninsured, those who regularly use medical care, and those socially isolated from the health care system. The many underimmunized adults, undiagnosed hypertensives, poorly controlled diabetics, and patients diagnosed with invasive cancers in the United States are testimony to the discrepancy between attainable health and actual health status.

It is ironic that we are the nation with the greatest investment in prevention research and the developed nation with among the greatest discrepancies between what can be attained and what is attained in prevention services. Given this discrepancy, in part but not entirely due to lack of insurance coverage, a larger part of the federal prevention research budget in the future should be devoted to proving the efficacy of prevention interventions and in learning how these services can be more effectively provided through diverse health care systems.

There are structural aspects of NIH that may affect how such research is funded. Recent indication that patient-oriented research is less likely than laboratory-oriented research to be well ranked and ultimately funded by NIH, and that the composition of NIH study sections affects these funding decisions, substantiate the belief that the structure of NIH review affects funding outcome.[11] It has long been alleged that this is so for prevention research applications, particularly for clinical prevention research. Since primary and secondary prevention are the preferred clinical approaches to disease, at least equitable, if not at this time preferential, funding of high-quality clinical prevention research should be assured.

Another reason for considering preferential funding of clinical prevention research is our past success in

laboratory research. Given the enormous amount of nearly known and known, inadequately applied prevention knowledge, and of likely but incompletely researched prevention practices, an increasingly important aspect of research should address the closure of this gap rather than the widening of it. As a nation, we are more inclined to develop than to apply knowledge. We have, as a result, more and more incompletely digested prevention science. Clinical prevention is the concern of clinicians devoted to individual and population health. It is we who must be the bearers of the message that more clinical prevention research should be done. We should be the advocates for giving a higher priority to research on the application of existing knowledge than to the laboratory and therapeutic clinical research that are traditionally funded, particularly at NIH. AHCPR remains a grossly underfunded agency and CDC has greater potential than resources for applied prevention research, particularly for hard-to-access populations.

The interest in prevention is here now, and the motivation is ever more explicit to promote prevention services. Through managed care, accountability is increasingly possible, at least for proven prevention procedures. Preventionists should argue for more funding for all prevention research and for federal research priorities that permit evaluation of effectiveness and implementation of prevention knowledge through more efficacious ways of providing care.

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