# BIOMEDICAL INNOVATION: THE CHALLENGE AND THE PROCESS

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As a nation, we have not, to date, established a comprehensive strategy for understanding and guiding the origins, development, transfer, and dissemination of medical technologies and practices. Recently, attention has been focused on the validation of medical practices and the assessment of the costs and benefits associated with their use. While attention to these particular aspects of problems facing health technology is encouraging, it is discouraging that most of the evaluative research has been limited to the later stages of the innovation process, when the technology is already being transfered into widescale use.

Since the second world war, the biomedical field has simultaneously experienced an information explosion and remarkable technical advances in the detection, diagnosis, therapy, rehabilitation, and prevention of disease. These advances are broadly referred to as biomedical "technology." Today, highly sophisticated technology is available for some medical problems; but, for other problems technology is either inadequate or non-existent. Advances such as the evolution of sulfa antibiotics may be a model of the appropriate adoption, utilization, and displacement of a biomedical innovation over a relatively short time period.*

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*A new era of medicine and specifically pharmocologic therapy for bacterial infections began to evolve in 1932 when Gerhard Domagk discovered that prontosil rubrum, a red dye, protects animals from streptococcal infections. After three years of exhaustive animal studies and clinical trials, he made this important discovery public. In 1936, French researchers found that the bacteriostatic component of the dye was actually sulfanilamide. English physicians then published reports of positive therapeutic results with the drugs Prontosil and sulfanilamide in patients with meningococcal infections, and the use of sulfanilamides spread rapidly. Their success was reflected in a dramatic decline in morbidity and mortality from bacterial infections. Meanwhile, penicillin, first discovered in 1929 was being tested during the early 1940s. Penicillin was so efficacious that it soon became an indispensible therapeutic agent, and the use of sulfanilamide began to decline. Although sulfanilamides and other sulfa drugs are still available, penicillin and many new families of antimicrobial drugs today have displaced sulfa for treatment of most infectious diseases.

Unfortunately, the development and dissemination of medical innovation does not always occur in such a optimal fashion. Some efficacious medical practices have been adopted too slowly; some practices have been displaced too slowly; and others, though clinically valuable, have been too costly. Such problems are a disservice to the public in need of responsive health care regimens. Therefore, a high priority for policy development must be to make the management and conduct of our biomedical research and development system maximally responsive to the health care needs of the population.

Appearing before the Senate Subcommittee on Health and Scientific Research in 1978, Dr. Julius Richmond, then Assistant Secretary for Health, expressed the Administration's perspective on the need for a policy on the dissemination of biomedical technology. He noted that:

> .....while the Department (DHEW) is extensively involved with technology as a developer, an evaluator, a purchaser, and a regulator, it has no comprehensive strategy to link, systematically, stages in the life cycle of technology development, evaluation, transfer, diffusion, utilization, and phaseout. (1)

A similar view was presented by Representative Henry A. Waxman at a hearing on the establishment of the National Center for Health Care Technology:

> We must find ways to reduce the time it takes to transfer medical discoveries into daily practice once we know they will improve patient care. We must prevent premature use of technology which may have unproven value, and which may trigger long-term side effects in the patient. (2)

## THE CHALLENGE

In the 1980s a major challenge for those who manage biomedical research will continue to be the guidance of the research and development

systems so as to produce technology responsive to health care needs. To respond to that challenge, those who make desicions about the funding and management of the biomedical innovation process might benefit from a more complete understanding of the process itself and of its components.

## Conceptual Model

At this time, any description of the process of biomedical innovation must be considered highly theoretical because definitive empirical data simply to not exist. How, then, do we address ourselves to the objective of better understanding the process? We propose a conceptual approach to describe the process, but we present it as a hypothetical model which must itself be time-tested for validity. The model presents a framework constructed on theoretical and empirical research from fields outside the biomedical area. We do not know whether the findings from other fields are transferable to the biomedical field, but this model is presented as a useful instrument for organizing a discussion of the effectiveness of the biomedical research and development system and for initating future research directions.*

We identify two components in our model of innovation. The first component is the progression of technology from ideas to products, that is, health care devices, drugs and practices. The second component consists of the interactions among people that bring these ideas to fruition. These two components are highly interrelated but distinct.

The overall flow of innovation is through four distinct stages. The first is the generation of ideas in basic, clinical, and applied research. These ideas are prompted by the goal to more fully understand

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life processes and the causes and cures of disease. The second stage is communication of ideas. Researchers must communicate ideas among themselves to integrate the essential pieces of knowledge that will eventually be developed into a specific technology. At the third stage, development of clinical applications, researchers and technologists respond to societal needs with practical applications of ideas for the diagnosis and treatment of disease. In private industry, the economics of the marketplace are highly influential on the directions of research applications. During the fourth stage the packaged technology or medical practice becomes a market good that moves out of the research community toward adoption or diffusion in society.

Linking the four stages and spurring or deterring the progress of an innovation is evaluation. In one sense, evaluation is integral to each stage of the innovation process because at all stages of research some component of evaluation is built into a research design. It is the nature of the scientific method to test and of the peer-review system in the biomedical research community to evaluate. Formalized evaluation and validation, however, in the form of clinical trials or other validation research, often occurs at the third stage, clinical applications, before a technology is disseminated for adoption. Existing technology is continually evaluated and re-evaluated by practitioners and patients and, in some cases, regulatory and research agencies of the federal government. Evaluation identifies needs, successes, and failures that can be fed back into any of the previous stages of the process. This feedback maintains the dynamics of the system, forcing the improvement of technology and motivating the search for more detailed knowledge of health and disease. Figure 1 is a diagram of the biomedical research spectrum that depicts its program planning concepts. The top arrow

identifies the first four stages of the model, the middle arrow specifies the categories of research currently funded to advance the biomedical research continuum, and the third arrow states the primary objectives of each phase of the research continuum.

Several conceptual questions are apparent in our theoretical model. The first question is how to structure and characterize the flow of skills and personnel as integral and transitional to each stage of the model. The health care industry, from the generation of ideas to the evaluation of health care technology, may be different from other industries in its use of research skills. In at least one subset of the biomedical researchers there is a close relationship between the idea generators and those who put the technology into practice, namely physicians. In industries related to consumer goods, such as the automobile and electronics industries, researchers come from diverse basic disciplines such as chemistry and metallurgy. These researchers certaintly use the ultimate products of their research but cannot be considered to promote or prescribe them in the marketplace. In the health sector, however, practitioners often enjoy the opportunity of a close relationship with researchers. The majority of biomedical research in the United States takes place in universities which combine research settings with practice settings. A clinical researcher might have an office next door to a physiologist and not far away might be a cardiac disease clinic. Interacting with both individuals are medical students who provide, perhaps, the fastest link to practice. Of course, other subsets of researchers are not as close to clinical practice, for example, device manufacturers and the pharmaceutical industry. Neither are the federal government's health policy, regulatory, and other related

agencies close to clinical practice; yet, to do their work, they must reach out and involve clinicians in their program and policy development and decision-making. While this conceptual view of technology development is appealing with its double stream of ideas and skills, we have little research to indicate whether this view is useful or valid. Some evidence does exist however about the nature of the flow of ideas and the relationship between this flow and health care skills and personnel. A study by Comroe and Dripps which characterizes major advances in the fields of cardiovascular and pulmonary medicine has shown that research advancement relies on bringing together disparate pieces of information and various skills at the right time in the right setting. (3)

The second question is how to identify those factors within the flow of innovations that determine whether an innovation skips a stage, is unduly detained at a stage, or never proceeds beyond a certain stage. We do know, for instance, that considerable lag time has existed between discoveries and their eventual validation and application. We do not know why. Whether lag time exists today is essentially unanswerable now and can be determined only retrospectively, but it is a concern we must continually explore. We also know that some innovations have been adopted too early and have had a negative impact on society. In our greatly increased capacity to communicate through the literature and electronic media is the potential for over-rapid communication or over-rapid development and adoption of technology before it is appropriately or adequately evaluated. At the same time, we must recognize that validation is an exceedingly expensive procedure and that our financial and manpower resources are finite.

The succeeding section of this article gives the background, rationale, and proposed future research directions for each of the four stages of

of the biomedical innovation model. We do not consider the proposed research directions definitive or complete. We suggest that the challenge is to translate these ideas into a coherent research framework, one that we in the biomedical community can use to continue, if not accelerate, the major improvements in health status witnessed during the past eight decades.

## THE PROCESS: RESEARCH BASE AND FUTURE DIRECTIONS

Meeting the challenge of guiding research and development systems to produce technology responsive to health care needs involves exploring new approaches. In understanding the stages of technology development in health, we can best benefit from previous research in other fields by carefully examining health-related patterns rather than quickly accepting the applicability of those findings to the health field. Several specific differences seem to justify this caution: 1. Greater uncertainties are involved in natural science research and development than in the physical sciences, including issues of biomedical variability and efficacy determination; 2. The federal government sponsors much biomedical research but, unlike defense, is not the direct customer for the products of that research; 3. Among scientific and technical fields, biomedical research has a high degree of academic dominance; 4. Biomedical technology has a high degree of government regulation of product acceptability and diffusion; and; 5. The market for biomedical technology usually involves the responses by medical practitioners as intermediaries and only then the public as the ultimate consumers with health care needs.

To construct a framework for considering these cautions and new approaches, we overview in this section the existing research bases and proposed future directions for the successive, interrelated communication of ideas and knowledge, development of clinical applications, and

diffusion and adoption of technology, and for the multi-stage process of evaluation of medical technology.

Stage One: Generation of Ideas

The generation of ideas, the first stage in the biomedical innovation process, begins with the decision to pursue one line of research instead of another and is influenced by characteristics of the ideas themselves, the innovators, the research organizations, and forces external to the organizations and science.

Research Base. The bulk of research on the generation of ideas has related to the creativity of individual researchers--how they arrive at new ideas and follow through to innovation. In the late 1950s, attention turned to the innovation process in industrial and governmental research and development (R&D) organizations. The basic assumption behind this research was that the quantity and quality of work performed by scientists and engineers are affected by the organizational settings in which they work. A research goal was to explore how the organizational setting influences the researcher's utilization of basic talents; a policy goal was to find ways to enhance desired types of scientific performance by modifying organizational factors. Most of the research was done in industrial settings and little in the biomedical area.

Pelz and Andrews (4) and Andrews with other colleagues (5) studied the effects of various organizational and individual factors on technical performance by 11,200 members of R&D groups in the U.S. and six European countries in universities, medical schools, government laboratories, and industrial settings. Their research identified a number of factors which had a significant positive correlation with scientific performance: diversity of professional activities, the age of the research group, the quality of research planning, and the skills of

supervisors. The correlations, however, do not resolve the issue of causality. It is still uncertain, for example, whether diversity of function is a factor that contributes to higher performance or whether high performance is responsible in part for the diversity.

A small interview survey of 50 academic physicians reported by Finkelstein and colleagues is more specific to the issue of research productivity in the medical community. (6) Here the findings on how diversity contributes to performance were interpreted to be a limited corroboration of the Pelz and Andrews work. In health research, productivity also relies, we believe, on an adequate pool of physician-researchers. To determine the characteristics of medical students that indicate a strong potential to become physician-researcher, the Association of American Medical Colleges has been conducting a longitudinal study of the class of 1960 at 28 U.S. medical schools. Findings from this study show that a combination of high ability, aesthetic and theoretical values, and a preference in college for the humanities and mathematics indicates strong potential to become a physician-researcher. (7) Two measures are correlated with the quality of innovative ideas: the success of a first grant application and post-doctoral training of M.D.s and Ph.D.s, particularly at major research centers.

Future Directions. The following important questions about the generation of ideas in the biomedical setting need research study. What is the relative role of universities, medical schools, government laboratories, and small and large companies in generating ideas? Are processes for generating radical breakthroughs in medicine similar to or different from those for generating incremental improvements? Do successful and unsuccessful clinical investigation, diagnostic and therapeutic techniques, and drugs arise in the same way or in different ways? Can a better understanding of idea generation lead to developing technology that improves the productivity

of the health care system and reduces its costs? These and other questions should be approached systematically, perhaps beginning with a comprehensive description of the conditions under which biomedical research is currently done and an exploration of methodologic strategies for measuring research productivity in medical settings.

Stage Two: Communication of Ideas and Knowledge

Communication of ideas and data among researchers has, no doubt, various motivations, including the desires to advance a discipline, to enhance professional stature, to adhere to the established scientific practices, and to potentiate further idea development. The communication of ideas and technical knowledge occurs through a myriad of channels among and between basic and clinical researchers, technical developers, practitioners, hardware entrepreneurs, and drug manufacturers. Formal channels, such as publication in scientific journals and presentations at scientific meetings, are distinct from the less formal ways in which scientists and engineers exchange information.

Research Base. Early research in this area has been largely outside of fields related to medicine and has been aimed at better understanding the patterns of technical communication. This work has been based on the assumption that timely and effective communication of information among researchers can significantly enhance research productivity.

In comparing the patterns of communication of research scientists and research engineers, Allen found that formal documentation, books, journals, and reports were not important communication channels of innovative ideas for engineers in industrial settings. (8) Research scientists, however, relied heavily on these formal channels. Allen attributes the difference in patterns to the difference between science and technology: science is universal and scientists can effectively

communicate with others throughout the world, whereas technology is local with its goals defined in terms of local cultures and interests as perceived by a specific organization. Although the nature of technology generally renders communication outside the organization difficult, a subset of researchers do actively take the lead in communicating with the outside world. These technological gatekeepers appear to be the most effective means for informally bringing technology into and out of technology-oriented organizations.

Can these findings about communication patterns among scientists and engineers be applied to the biomedical research field? The organizational patterns of academic medicine may be different from than those of industrial settings. The fact that the academicians' recognition system is nationally linked to their disciplines or specialities may foster a special set of communication patterns. Thus, the communication habits of engineers may not match or be transferable to those of biomedical researchers. However, there may be less of a differences in patterns of communication among scientists and biomedical researchers in technological innovation where the boundary between the generation and application of new scientific knowledge is less distinct.

Basic and clinical researchers in medicine read the biomedical literature, but a paucity of data specifies the effects of that reading. One approach to enhancing communication among biomedical researchers is currently being attempted by the National Library of Medicine (NLM). (9) Because publications accumulate at such a rapid rate, NLM is studying how to connect researchers quickly and efficiently with proper information channels. NLM has set up a data base of reviewed literature about viral hepatitis. An intermediary group of experts distills the mass of information on hepatitis to a manageable size and system. It is estimated that 70-100

such data bases would provide a fairly comprehensive coverage of (a) diseases of high morbidity and high mortality requring frequent physician-patient interaction; (b) diseases causing high expenditures, and; (c) of diseases about which information changes rapidly. However, we still lack measures of the likely effects of these data bases on researchers' productivity.

Future Directions. The important research questions about communication of ideas and knowledge in the biomedical field deal with the patterns and alternatives of communication. What, specifically, are the communication patterns among basic and clinical researchers? What channels do they predominantly use for communicating ideas? To what extent do they use alternative channels? How can the communication process be improved and fostered? The same questions should be asked about communication between researchers and practicing physicians. Also, the applicability of models developed outside the biomedical research sphere should be questioned because of the possibly unique characteristics of the sciences, scientists, and practitioners in biomedical research.

## Stage Three: Clinical Applications and Development

Only a fraction of the knowledge generated from biomedical research is selected for the development of applications in the clinical setting. The procedure for selecting future developments involves a number of factors, including need, efficacy, cost, and profit. Transforming that research knowledge into applied clinical technology involves the cooperative participation of the research and health practice communities, the public, industry, and the government.

Research Base. Studies within and outside the health field have addressed the issue of the advisability of supporting targeted basic or applied research to produce technology with high social impact. The approach typically adopted in these studies has been retrospective,

tracing major advances back to their origins. The ideal approach would probably be to follow a number of basic research ideas prospectively through the stages leading to widespread use. However, prospective studies are impractical because research ideas historically have a high mortality, as has been documented in the literature of industrial management.

Among the earliest studies of this type was Project Hindsight, commissioned by the U.S. Department of Defense and reported in 1966. (10) A team of scientists and engineers analyzed retrospectively how 20 important military weapons came to be developed. Two conclusions were that the contributions of research and development in the nonprofit sector, particularly universities, were no greater proportionately than in other sectors, and that scientists and engineers contributed most effectively when the effort was mission-oriented. Many other studies of industrial innovation support the importance of market or need-pull as an initiating factor for successful development.

Subsequently, some studies of research outcomes in the medical, physical, and social sciences arrived at conclusions contrary to those of Project Hindsight. The study of Comroe and Dripps (3) was devoted entirely to innovations in cardiovascular and pulmonary medicine occurring from 1945-1975. The conclusion in which these investigators had the highest confidence was that a diversity of clinical and basic research, including all types of early innovative process activity, was important in the development of ten most important cardiopulmonary clinical advances. They could not identify a single type of early innovative activity whose productivity overshadowed all other types.

As in studying the generation of ideas, determining the environmental factors that contribute to the individual's and organization's performance is a useful approach to understanding development of clinical applications.

In interviews with 66 faculty members in engineering and science departments at a leading technological university, Roberts and Peters explored the demographic and environmental characteristics of researchers who had ideas for applied technology as well as the characteristics of those who also attempted to transfer their technologies into use. (11) The following characteristics distinguished the idea exploiting faculty from others: being a first-born son; writing a book; obtaining a patent; being aware of potential financial support. (12)

In successful commercially oriented development, Roberts and Fusfeld argue that several staff roles are key: idea generators; idea exploiters or entrepreneurs; gatekeepers, or linking communicators, who bring ideas into the organization; program managers, and; sponsors or coaches. (13) Roberts has also assembled evidence that indicates commercial development appears to be most successful when it is strongly tied to market needs or demands. Frequently, innovative users of products implement their own solutions to needs, and subsequently manufacturers adapt them for more widespread production. New companies are especially prolific in product innovation. (14).

Future Directions. Knowledge about these aspects of commercial innovation point out the gaps of knowledge in the biomedical area. Do these findings apply to health and biomedical innovation? Innovations in drugs, devices, and clinical practices might well be subject to different or similar factors; however, systematic empirical studies rather than anecodotal group experience and speculation should be conducted to and compare the development processes relevant to medical practices and products. A particular focus for the retrospective study of the development of selected health technologies might be the factors that influenced the process after the scientific base was clearly established. Another focus

might be the structural linkages related to successful biomedical development, for example, the mechanisms of the idea transfer from universities to industry, with special emphasis on the role of academic medical centers; the role of new company formation in transferring biomedical knowledge into use; the relationships between pharmaceutical research laboratories and their own commercial development activities. A further focus might be on the various incentives for development, including the role of regulatory standards for efficacy and safety, the availability of capital for development, and the role of third-party payers. Once data from such studies are available, useful managerial and government policy implications can potentially be derived.

Stage Four: Diffusion and Adoption of Technology

Once new technologies have been developed and initially applied to health care and health delivery systems, information about their usefulness needs to be made available to prospective users. Formal and informal dissemination channels exist and may be operational. The decision by prospective users to adopt or not to adopt a new technology may relate to both characteristics of the technology and characteristics of the users. In addition, evaluative information, continuing medical education, and media publicity may affect patterns of adoption. The dissemination process is the stage that has received the greatest research attention within the biomedical field. (15)

Research Base. Research on the process of information dissemination has well established the existence of several aspects of the process. (16) The classic model of diffusion recognizes the gatekeeper or near-peer as the primary determinant of diffusion of commercial ideas. The hierarchical structure of an institution or an organization also influences technology diffusion. A clear distinction has been made between the initial

adoption process of a new technology and its acceptance or even eventual institutionalization. The trend of adoption and decay has been described as an S-shaped curve for some technologies but may not be universally applicable. It is not known, for example, whether equipment-embodied goods and software diffuse differently. Re-invention, or adaptation of technology to local circumstances, has been recognized, as has the fact that adoption does not necessarily imply proper use. (17) Finally, the role of a marketing component, such as advertising, has been studied. (18)

A classic study of innovation dissemination conducted in the biomedical field is assumed to have general applicability. Coleman, Katz and Menzel examined the patterns of adoption of a new antibiotic by physicians practicing in three small communities. (19) They determined that the information was most effectively disseminated through informal communication networks among physicians within each community. The informal channels were more effective than the formal channels of journal reports, scientific meetings, and drug promotional activity. The Office of Technology Assessment of the U.S. Congress is said to have reviewed numerous studies of the diffusion and adoption of medical technologies and concluded that among the most important factors determining whether and how rapidly a physician will adopt a new technology are his or her own clinical experience and that of colleagues.

A few studies have examined behavioral change by health practitioners and the public, for example, Finkelstein and colleagues examined the change in use of certain drug therapies as a function of clinical validation efforts. (20) Other sources of information such as advertising campaigns, technical literature, and programs of continuing education can have an important secondary impact on health-related behavior. Farquhar and colleagues, in their three-community study of the dissemination of

individual health behavior information for the prevention of cardiovascular disease, suggest that it is possible to alter an individual's health behaviors by a mass media campaign alone or in concert with other educational strategies. (21) Data from the NIH-sponsored National High Blood Pressure Education Program whose objective is to disseminate high blood pressure information to practitioner and patient alike suggest that in 1971 only 50 percent of the millions of Americans known to have high blood pressure were aware of their condition. By 1974, this figure had risen to 70 percent as health providers began to develop the skills needed to effectively communicate health information. Similarly, only 4 million of those hypertensive Americans were under adequate control in 1971; by 1974, that figure had apparently doubled. In addition, there has been a very marked increase in the number of total patient visits to physicians for hypertension and hypertensive heart disease, while total patient visits for all causes have increased only slightly. (22)

Other work in the medical field has attempted to identify the characteristics of the innovation process that favor the adoption of technological innovation by hospitals. Gordon and colleagues considered the importance of organizational factors affecting the adoption of technology by hospitals. (15) Russell has demonstrated that the S-shaped curve is applicable to the adoption by hospitals of some of the most costly technologies. (23)

Future Directions. More study is needed of the factors that encourage or impede the diffusion of clinically validated drugs, devices, and techniques to the practice community. How do medical practitioners presently learn about new drugs, diagnostic tools, and advances in clinical practice? How, for example, do the characteristics of the technology and the health care environment of potential users affect the

dissemination of ideas and practices? Are peer relationships the primary determinant of diffusion of clinical practices? What is the nature of peer relationships in diffusion? How important are organizational factors and marketing approaches? What are the relative roles of formal and informal diffusion channels? What is the impact of political, economic, social, and ethical factors on the public and on the health care professional's behavior?

Evaluation of Medical Practices

Growing public concern about the adequacy of health care and health costs and the ever faster pace of biomedical research have made evident the complex nature of the entire process of biomedical innovation. Evaluation of medical practices, which does not and should not necessarily occur at the end of the innovation process, encompasses those activities which determine the safety and efficacy of the practices and their social impact. It may serve as a predictor of the success of a technology. Evaluation may provide feedback that influences other aspects of the process, for example, the extent of dissemination of a medical practice or the decision by a commercial developer whether to select a technology for later marketing.

Research Base. A number of researchers and several government agencies are taking the lead in evaluating the safety, efficacy, and social impact of health technology on medical practice. Considerable work has been reported on the experimental methodologies for conducting clinical validation studies. (24) Others have written about efforts to rationalize clinical decision-making as to the choice of specific therapies or diagnostic tests for patients. (25) The case for evaluating medical practices has most often been based upon the increasing costs of health care delivery and the scarcity of societal resources that can be expended on human services. (26,27,28) Researchers have responded with reports of

cost/benefit analyses or cost/effectiveness studies of particular practices or programs which were of interest. (29) At least one author has recently called for evaluating not only technology, but also the research process that leads to it. (30)

Efforts by government agencies have included the major study of the cost-effectiveness of a large number of health technologies that have been undertaken by the Office of Technology Assessment. OTA staff were among the first to publicly recognize the importance of dealing systematically with problems associated with the use of medical technology. The Institutes of the National Institutes of Health and its Office for Medical Applications of Research have embarked on a program of "Consensus Development" designed to resolve controversy and uncertainty in the use of certain medical practices. Conferences of experts are convened, followed by the dissemination of their consensus opinion about a use or practice. An important activity undertaken by the National Center for Health Care Technology, in cooperation with other health agencies is the attempted development of means to evaluate emerging medical practices before they are widely disseminated. Products of this work, if successful, could lead to models for predicting whether emerging technologies will have a significant effect on the health status of the population or whether their potential will ever by fully realized.

Future Directions. Evaluating the efficacy of the products of research is very expensive. Typical clinical trials cost on the average of $1,000 to $2,000 per patient per year; some clinical trials for cardiovascular disease therapies involve thousands of patients and hundreds of investigators and cost as much as $100,000,000. With such extensive research required it seems that alternative means must be found for validation, such as data from registries, data from physician practice, or the use of

retrospective data. While none of these alternatives compares with the randomized controlled clinical trial in precision of results, these or similar alternatives can help to provide much needed information on the efficacy of regimens.

The use of concensus development in formal conferences to assess the state of knowledge concerning the appropriate use of regimens is promising, but much remains to be learned about how to manage the consensus process as well as the validity and the impact of the results. The effect that evaluation data has on basic research has not been investigated, although Levy and Sondik note in at least one instance, blood pressure reduction, that clinical trials that demonstrate the efficacy of a medical practice have lead to a rebirth of interest and new knowledge development into the basic causes of the disorder. (31) Clearly, a relationship should exist between validation and basic research, and that relationship must be well understood if the research process is to be as effective as possible.

## CONCLUSION

With health care costs in the United States along nearly $400 billion annually and with a federal biomedical research budget of only $4 billion, we have every incentive to make the best use of our resources and to learn how to guide appropriate scientific developments to follow comparably successful pathways. The process as outlined in our model is only a tentative first attempt at a description. Knowledge of each stage in the innovation process is severely limited. The challenge seems clear: if we are to address the toll of disease most effectively and efficiently our efforts need to include the establishment of policies which encourage an understanding of how the biomedical system functions.

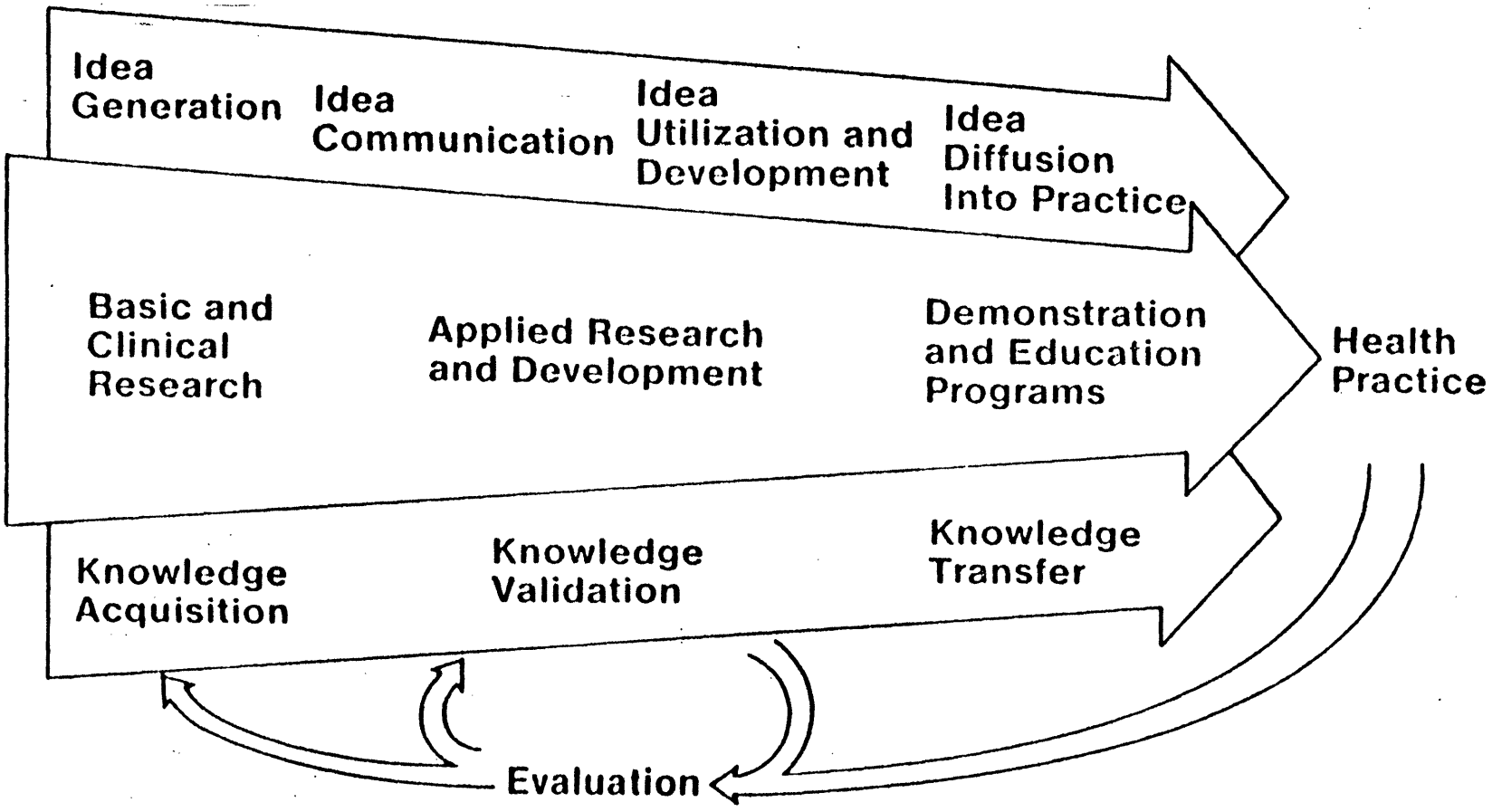


Figure 1

The Biomedical Research Spectrum

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