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THE RESPONSIBILITIES OF NIH AT THE HEALTH RESEARCH/HEALTH CARE INTERFACE

From the

Office of the Director
National Institutes of Health
Bethesda, Md., 20014

The Responsibilities of NIH at the Health Research/Health Care Interface

February 1977

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SUMMARY

1. Steeply rising health care costs and wide disparities in health care quality and availability point to major weaknesses in the Nation's health care system. While research clearly has no direct answers for main "systems" problems,[1] Congressional and other observers look increasingly to the research community for help.

2. The National Institutes of Health, as principal supporter of biomedical research, recognizes its leadership responsibility in this regard. This paper, therefore, identifies ways in which the research community--by systematizing, formalizing, and extending present procedures for handling research information--can make modest but helpful contributions in several areas:

o Formal identification and recommendation of new clinically relevant research information will help the practicing community to gain maximum direct benefit from national research programs.

o Appropriate parts of this recommended information flow could provide a basis for standards setting by the health care community, with implications both for cost and quality of care.

o New formal procedures could act as a further safeguard against premature or lagging transfer of new research knowledge into health practice.

o New procedures could also assure that possible cost, ethical or other social impacts of new research findings are taken into account in research community recommendations.

3. The NIH proposal would require each NIH Institute[2] to formalize and extend existing procedures--or to devise new ones--to assure that pertinent

1/"Systems" problems beyond direct research impact include: absence of mechanisms to establish national health policy and to orchestrate components into a coherent whole; inadequate cost control incentives in charging and payment for services; physician distribution and continuing education problems; deficiencies in regional resource planning and control; difficulties in obtaining public support on "life style" issues, involving cigarettes, alcohol, drugs, diet, exercise; etc; etc.

2/Throughout this document, the term "NIH Institute is used generically and is intended to refer also to NIH Bureaus and program Divisions; the term "Institute Director" should be interpreted to have similar breadth.

information in its research area is processed as completely as possible for effective transfer to the health care community. Knowledgeable members of the research community would be expected to seek a "technical consensus" on these points: the clinical significance of new findings; whether validation for efficacy and safety has been adequate, and if not, what more needs to be done; whether cost, ethical or other social impacts need to be identified as points for caution when formal recommendations are made; whether the technical complexity of the new findings suggests the need for further demonstration of feasibilities in local community settings; whether recommendations are phrased for ready understanding and acceptance by health practitioners, and include all appropriate cautions.

o Each Institute would be free to tailor its "technical consensus" and related procedures to specific problems and competencies in its research area; and to draw upon representatives of government and non-government lay and professional groups when their contributions might be useful.

o To provide guidance, central support and coordination, an office established in the Office of the Director, NIH, would maintain essential links among Institute efforts, the Director, NIH, the Office of the Assistant Secretary for Health, and health care agencies. It would assist in the development of effective procedures common to all Institutes, and in evaluation of the success of transfer processes; it would also have available the requisite competence in science writing to assist Institutes in "translation" and "packaging" of information for transfer across the interface; and would coordinate these activities with the communications role of the National Library of Medicine.

4. The NIH proposal also recommends the establishment of a consensus-building mechanism on the health care side of the interface,[3/] to include representatives of major participants in health care delivery, financing, and regulation. If echelons above NIH should decide to create such a mechanism, these, in the view of the NIH would be useful functions to assign it:

o Responsibility for assessing research community recommendations for new diagnostic, therapeutic or preventive measures in terms of health care feasibility (including costs and technical complexity); and for providing authoritative "feed back" to the research community on those or related matters.

o Principal responsibility for "getting out the word" to individual members of the health care community on useful new information from research.

5. Other points about the NIH proposal warranting mention:

First, a critical assumption: that broadened responsibilities will not draw NIH into activities inappropriate to its primary research mission,

3/ See attached diagram "NIH Responsibilities at the Health Research/Health Care Interface"

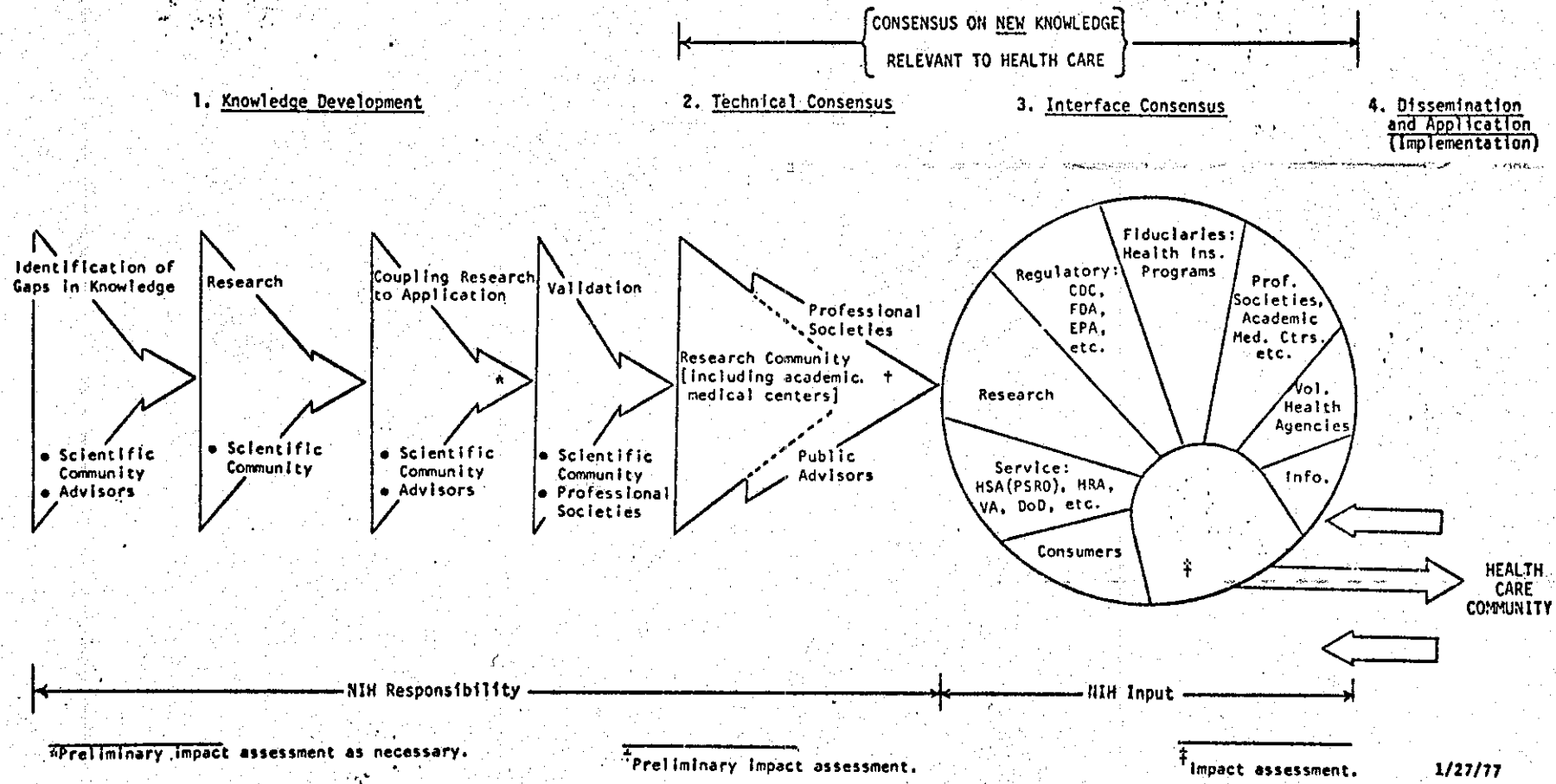
such as regulation, direct health care, or authoritarian establishment of health care standards.

Second, conspicuous strengths exist upon which NIH may draw: The structuring of NIH Institutes, their associated National Advisory bodies, and the network of collaborating investigators and research institutions within the research community provides an adequate framework for addressing issues. Also, medical school teaching hospitals and main disease research centers currently represent the most effective transfer points for the movement of research knowledge into health practice. Their strengths and expertise must underpin new processes. The archival and communication resources of the National Library of Medicine are major assets.

Third, significant dollar and personnel costs are associated with proposed "technical consensus" activities. Provision for these costs should be a part of implementing policy decisions.

Fourth, the new "transfer" processes would not replace or interfere with existing processes for research information dissemination, which would continue to depend mainly on publication in the open literature. Rather, they would assure that the most "useful" part of this information flow goes through an identification/validation/recommendation process to reinforce its ready acceptance in health practice.

NIH RESPONSIBILITIES AT THE HEALTH-RESEARCH/HEALTH-CARE INTERFACE



*Preliminary impact assessment as necessary.

†Preliminary impact assessment.

‡Impact assessment.

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THE RESPONSIBILITIES OF THE NATIONAL INSTITUTES OF HEALTH
AT THE HEALTH RESEARCH/HEALTH CARE INTERFACE

February 1977

DRAFT

I. ISSUE

What should the role of the NIH be in assuring effective introduction into the health care system of new knowledge pertinent to disease prevention, detection, diagnosis, treatment, and rehabilitation: What new organizational approaches are needed to discharge this role?

II. BACKGROUND

In recent testimony 1/ before the Senate Labor and Public Welfare Subcommittee on Health, the Director, NIH, commented on the above issue as follows:

> It seems clear that in the future, the NIH and the rest of the scientific community must assume greater responsibility for the effect of research on the quality and cost of health care. The need for assuring effective transfer of useful new knowledge across the "interface" between biomedical research and the health care community and systems is a major issue.

What in fact are the dimensions of the problem to be addressed? Appendix A deals with these matters in some detail; in summary form, pertinent background includes the following:

1. Currently, within the research community, formal processes are lacking to assure systematic identification and evaluation of clinically relevant research information, and its effective transfer to the health care community when this would be appropriate:

- Over most of the spectrum of disease and health problems, there is no provision for formal, systematic, informed identification of new research knowledge with potential usefulness in diagnosis, treatment, or disease prevention. Similarly, formal processes are lacking to assure that: (1) cost, ethical, and other social impacts of new knowledge are taken into account systematically; (2) the technical complexity of new findings is assessed in terms of the need to recommend additional feasibility demonstrations at the community level; and (3) wherever possible, a "technical consensus" is achieved among those most knowledgeable on

1/ Hearings before Senator Kennedy's Health Subcommittee on June 17, 1976.

best current approaches to prevention, diagnosis, or treatment of specific diseases.

• When important new clinical information has been identified, the traditional methods used by the research community to "get out" this word work much better in some parts of the practicing community than others. Communication is most effective with those working in medical school or main research/care settings or who are members of medical specialties with a direct incentive to keep up with latest information in their area. It works less well with those who have minimal medical school or research contacts, and have little time to spare from busy general practices. These inadequacies on the transfer side are complicated by related inadequacies in information feed back from the practicing community to research.

2. Just as gaps are evident on the research side in terms of processing clinically relevant research findings, the health care side of the interface has disparities in the application of new findings: Some validated interventions may diffuse too slowly through the health delivery system; others, in the absence of validation and consensus, may be applied prematurely or inappropriately. Again, a problem seems to be the lack of effective mechanisms and processes for information handling at the interface.

3. Neither Congress nor the Executive Branch has assigned specific agency responsibilities for correcting these health spectrum deficiencies. However, a number of members of Congress as well as the President's Biomedical Research Panel have urged NIH leadership in seeking solutions at least on the research side of the interface. For the moment, general agreement is lacking within the research community on whether or not it would be feasible for that community to take on new responsibilities for consensus building and assessment--and whether, if feasible, this could be done without undue risk to the primary research mission. The principal concerns are that NIH and the research community might be drawn into direct health care, regulation, or authoritarian standard setting (any of which would be viewed as a major threat to the research mission); or that new activities would seriously diminish resources for research.

4. The key questions for the NIH thus relate to the extent to which NIH should assume responsibility for:

• validation of new or established methods for diagnosis, treatment, prevention and rehabilitation of disease problems; done through Contract

• improvement of the informal system whereby consensus is reached concerning the validity and significance of new findings from research, and their readiness for wide clinical application;

• assessment of the non-medical implications (e.g., social, ethical, economic) of new findings; Technology assessment the increase of

• evaluation of cost containment, where research advances may appear to lead to costly treatments;

• dissemination of research results, beyond traditional channels of scientific communication.

III. PURPOSE AND SCOPE

Against this background, the NIH has undertaken to determine more appropriate mechanisms for translating the output of biomedical research and development into knowledge, products, and techniques which can be effectively employed in the practice of medicine and public health. A specific response is offered to the basic question: "What should the role of the NIH be in assuring effective introduction into the health care system of useful new knowledge from research?" A preliminary phase of full discussion is viewed as essential for this proposal. Significant elements of feasibility, acceptability, and cost need to be considered both within the research community and at public policy levels. Because of intrinsic inter-relatedness of research and care activities along the health spectrum, suggestions are also offered on mechanisms that might be useful on the care side of the research/care interface. These might assist in moving component elements toward a coherent health system, and are recommended for consideration within the health care community and at appropriate levels above the NIH.

done by a free market

IV. PROPOSAL

This section recommends a series of process changes and specific task assignment through which the biomedical research community (including the NIH) would be able to meet added responsibility for the effective introduction of relevant research information into health practice.

Basic Assumptions. This document is based on several critical assumptions:

Reverse of tech. transfer

1. That runaway cost increases and wide variations in the quality and availability of health care signal unacceptable difficulties within the Nation's health care system.

done by a free market

2. That it is reasonable to expect, therefore, that in the future, the NIH and the rest of the biomedical research community will have added responsibilities related to the effect which research ultimately has on the quality and costs of health care available for delivery.

O.K. but inconsistent w/ tech. assessment suggestion.

3. That for effective pursuit of national health goals--including the identification of definitive ways to prevent or treat major disease and health problems --these new responsibilities must not encroach upon the basic research mission of the NIH or erode resources (both funds and manpower) committed to that mission.

4. That additional resources as required must be provided to the NIH to enable it to discharge new assigned responsibilities.

Inconsistent w/ tech. assessment suggestion.

5. That in assigning new responsibilities, care must be taken to minimize NIH involvement in activities inappropriate for an agency with a primary research mission,--specifically the establishment of

authoritarian standards for health care, direct regulation, or commitments to provide direct health care.

6. That an important area of "health system" need that NIH and the health research community might appropriately address is improved processing of research information. More specifically, the need is to assure that clinically applicable new information flowing from research is: (a) systematically identified; (b) validated for efficacy and safety; and (c) assessed (where appropriate) for cost, ethical, and other social implications. Further, the results of these evaluations should be provided in the form of recommendations to the health care community and the public, in useful and readily accessible form.

Concepts. Concepts underlying this proposal include:

The importance of "consensus building" activities. While within the research community, the existing range of mechanisms for identification of research needs, opportunities and gaps seems to work reasonably well, a deficiency exists in what might be called "consensus development". The absence of formal well-developed mechanisms for this purpose in most research areas appears to be a major factor affecting appropriate diffusion of new knowledge. [A further discussion of this problem will be found under "Background", Appendix A]. "Consensus building," as used here, is viewed as a series of processes, extending the length of the health spectrum, beginning with an effort to achieve agreement among those most knowledgeable about particular research problems (i.e., the "technical experts" in a disease area.) These experts in turn can interact with informed professionals capable of providing value judgments in other areas, such as economics and ethics; and finally, the results are shared fully with all the participants in the delivery system. From the logic of its place in the health spectrum, the NIH has a prime responsibility for the first or "technical" phase of consensus development; but its responsibilities diminish as the technical aspects become subordinate.

- In this sequence of consensus development, the research community may be viewed as a potential "seller." A distinction between those who develop new research information (the "sellers") and those who accept it for general use in health practice (the "buyers") increases the integrity of transfer processes: There is less likelihood of premature or unnecessary transfers; a basis for "feedback" and critique, from the user's perspective, is provided; and the research community is insulated to some degree from direct care, standard setting or regulatory activities.

Maximum involvement of the research community in the advisory process. To assure maximum credibility and impact of recommendations within the practicing health community, the advice from technical experts should reflect--to the maximum degree possible--a research community position rather than that of a particular Federal agency or individual scientist. To this end, the broad participation of professional societies, voluntary health agencies, academic and categorical medical centers, etc. is essential. Processes adopted for generating advice on a particular disease or health problem should have as a principal objective the obtaining of the best achievable consensus among those in the community viewed as most knowledgeable in the problem area. They must also be constructed to avoid intrusion into judgments of self-interests of any specialty group or professional or lay organizations, or the appearance of same.

Building on existing strengths and processes within the research community. A number of conspicuous strengths may be drawn upon:

- A framework for addressing the comprehensive range of disease and health problems is already provided by the structuring of NIH Institutes, their associated National Advisory bodies, and the network of collaborating investigators and research institutions within the research community.

- Medical school teaching hospitals and research centers currently represent one of the most effective transfer points for the movement of research knowledge into health practice. These provide an underpinning of strength and expertise on which any new process must build.

- Professional societies and voluntary health agencies have a broader and more direct relationship to the practicing community at large. They should be encouraged to expand their roles in seeking consensus and to assume a principal responsibility for dissemination and demonstration.

- A number of programs to improve the dissemination of research results into health practice have already been mounted by various NIH components, including the Office of the Director. These have been instructive and provide reason for optimism about expansion of such exercises. All (including formally mandated control and demonstration programs) warrant continuing assessment of their value in achieving community-wide improvement in the movement of research findings into practice.

Principal Features of the Proposal. In summary form, these are the main features of the NIH proposal:

Identification of relevant clinical research knowledge. Require each NIH Institute Director--in concert with appropriate public advisory bodies--to formalize and extend existing procedures (or to create new ones) to assure that new research knowledge pertinent to disease prevention, detection, diagnosis, treatment, or rehabilitation in his area of concern is adequately identified and appropriately processed for effective transfer to the health care community. Essentially, this involves recognition that findings in a particular area have progressed to the point that authoritative analyses would be appropriate on validity and significance. This responsibility, on occasion, will include identification of new clinical interventions not yet ready for introduction into the health care system, but which nevertheless present issues needing broader analyses in anticipation of that readiness.

How does this overlap on requirement to report inventions?

Technical consensus development. To carry out these tasks, each Institute Director (with his appropriate expert council) would be responsible for designing credible identification/validation/consensus-seeking processes to meet the needs in his specific research areas. It is expected that a variety of processes might be needed within an Institute, particularly if the Institute has multiple major disease problems within its purview. Similarly, there might be considerable variation among Institutes in terms of approaches adopted. It is likely that certain problems will require cooperative interactions among several Institutes and their constituencies. In any case, these processes would address certain common elements, e.g., adequacy of the scientific base, validity, state of readiness, and anticipated impact on the delivery system.

How will this interface with invention evaluation already institute responsibility?

- Participants. There are numerous obvious sources of advisory competence upon which Institute Directors might draw in one combination or another to meet new responsibilities. These include the Institute scientific staff; members of the National Advisory Council; principal investigators at recognized centers of excellence (including comprehensive centers); other research or health care consultants in workshop-conference formats, etc. Where international input and participation are essential, the Fogarty International Center could play a useful role.

In most circumstances, Institute Directors may decide that the exercise in consensus must extend beyond the usual limits of the research community itself, and include especially interested outside groups, such as the general and specialized professional organizations and lay-professional groups oriented toward specific health problems (e.g., the American Cancer Society, American Heart Association, and the Cystic Fibrosis Foundation). Where there are prominent and influential bodies of this latter kind, whose interests include both research and care, a collaborative effort both in designing processes and in implementation would be essential. In fact, when appropriate, such bodies might be encouraged to sponsor (or co-sponsor) efforts in technical consensus development.

This is already part of invention evaluation

The process should involve participation, by invitation, of representatives from the PHS and other agencies in the Government, including those concerned with other aspects of health care delivery (e.g., fiduciary and service) in order to alert them to new developments and to utilize their technical and value judgments in the consensus development process.

Is an inventor going to be estopped from proceeding without a consensus

There must be no reluctance to confront difficult and complex issues in this technical consensus development process. Willingness to take rational and prudent positions on such issues should be inherent in the responsibility assumed when organizations agree to participate.

One of the hazards in the proposed mechanism is a potential for conflict of interest when a participant organization represents a constituency that stands to gain if a certain course is recommended. However, as in other situations of this kind, this hazard can be obviated by assuring that participants are representative of all the diverse but relevant elements concerned with a given question.

Tech. assessment not technology transfer.

- Preliminary impact assessment. Some clinically relevant research findings undergoing validation and consensus development will raise important legal, ethical or economic questions.[2/] These may lead to an overt recommendation that the "transfer" of such new research knowledge be deferred pending resolution of these questions. For biomedical science in general, and NIH in particular, this type of action has in the past been highly unusual, but may be expected to become more commonplace in the future.

As the primary source of biomedical research support, NIH has a responsibility for involvement in some level of impact assessment for innovations arising from its research. The expertise residing in the biomedical community, National Advisory Councils, and the NIH staff, encompasses some of that required for impact assessment, conspicuous exceptions being the economic, legal, ethical and fiduciary aspects of some problems. Although NIH can provide itself with such expertise, the health care sector, with its diverse components (see chart) would ordinarily be in a better position to make many such assessments.

Special Cases. Two of these are of special concern in consensus development.

- Complex Technology. Some new technology coming from research is so complex that community hospitals require additional resources

2/ Technology assessment or impact assessment as it is used in this document "is a class of policy studies which systematically examines the effects on society that may occur when a technology is introduced, extended, or modified with special emphasis on those consequences that are unintended, indirect, or delayed." Coates, J.F.: Some Methods and Techniques for Comprehensive Impact Assessment. Technology Forecasting and Social Change 6:341, 1974.

and local health professionals need special training before it can be applied effectively. (For example, certain treatment regimens for childhood leukemia fall into this category). Where such a complex new subject is identified--and the priority of the disease problem would appear to warrant the effort--the creation of a specialized training or control and demonstration program would be a suitable recommendation. Responsibility for this program might be assigned to the NIH Institute with cognizance for the disease area. But when the requisite competence is available elsewhere within the PHS, transfer to that agency should be encouraged. When such program responsibilities are most appropriately retained by or assigned to the NIH, special earmarked funds and other resources will be required.

• Trans-NIH Issues. Not infrequently, research concerned with a given disease cuts across Institute lines. For example, there are at least ten Institutes where research on diabetes mellitus is either conducted intramurally or funded in extramural programs. The situation is similar in cystic fibrosis, nutrition, genetic diseases, arthritis, etc. Such consensus exercises are likely to be cooperative ventures with need for consultation and coordination from the Office of the Director, NIH.

Development of "Interface" Consensus. The future will bring an increasing number of problems requiring a forum at which technical consensus could be rationalized with health care delivery issues in order to develop guidelines for eventual use by the providers of health care. Here innovations must undergo appraisal by all constituencies in the light of the many factors which enter into health care delivery. The oversight of such an interchange mechanism logically lies at a level above NIH--in the Office of the Assistant Secretary for Health, or higher. A possible interface consensus mechanism is depicted in the chart (attached). In this interface activity, the NIH and the research community must play a critical role (in that recommendations as a result of technical consensus would often provide the impetus for meetings). The NIH input would be technical--taking the form of recommendations on new modes of diagnosis, therapy, or prevention deemed ready [see "Technical Consensus" above] for application in health care. To repeat: the role of research must be carefully delineated to avoid implications that the NIH is moving toward a regulatory mode or that it represents the "source" of all knowledge relevant to these complex issues.

Potential Problems and Limitations. Apart from problems and limitations already noted (e.g., possible conflicts of interest on the part of contributors to the consensus and the danger that NIH might be drawn into regulatory activities), there are other concerns: Inherent in consensus development is compromise. There is danger that recommendations will destroy flexibility or create rigid standards inappropriate in many situations. It is essential that the mechanism be able to adjust and react with appropriate rapidity to advances as they affect previous recommendations which have emerged from the consensus development process. The process may be lengthy but every effort must be exerted to maintain the currency of recommendations evolving from this mechanism. There can be no guarantee

There will be every possibility that the State of the art will move past the innovation during delay.

against consensus reached on the basis of inadequate facts, but if the processes become part of a continuous system, refinements and improvement should be steady. While results of consensus building should be useful in meeting continuing education needs of physicians and other health professionals, this process will not resolve the problem of individuals who are unable or unwilling to involve themselves in such activities.

Dissemination of Research Information. The proposed new processes are not intended to replace or to interfere with normal pathways for dissemination of research information which would continue to depend mainly on publication in the scientific and medical literature. New mechanisms would be expected to assure that portions of this current information flow are highlighted by identification/validation/recommendation processes to enhance acceptance and utilization in health practice. Apart from proposed new processes, the technical and archival resources of the National Library of Medicine (NLM) would be expected to play an increasingly important role in providing assistance and facilities for dissemination activities of other NIH components. Specifically, the research and development staff of the Lister Hill National Center for Biomedical Communications will be encouraged to work on new models and systems of information handling to improve the efficiency and effectiveness of the information transfer process. For items of unusually high priority, and for those involving more than one NIH Institute, the Office of the Director, NIH, may act as the focus for dissemination activities. Details of proposed improvements in the dissemination process as they relate to the research-health care interface will be provided in another document to be developed.

Role of the Office of the Director, NIH. The main role of the Office of the Director, NIH, in processes to develop and implement the translation of research findings would be one of coordination, overview, and facilitation.

An office in the Office of the Director, NIH, working with representatives of the Institutes, would develop broad guidelines for the process and mechanisms to be utilized in the identification of new knowledge pertinent to health care, in consensus development and in dissemination. Such an office, established at an appropriate organizational level (e.g., Associate Director), would denote the importance and priority which the NIH attaches to the issue.

This office would serve to reinforce an awareness of individual Institute endeavors in this area and would coordinate efforts involving trans-NIH issues. It should be a relatively small office, headed by a clinician-scientist who would chair an NIH group composed of designated representatives of the Institutes which would meet on a regular basis. Such meetings would provide a forum for discussion of issues and policies related to the transfer process, with responsibility for conveying relevant policy

recommendations to the Director, NIH. The proposed office would be expected to evaluate the effectiveness and progress of the transfer process from the perspective of the NIH.

The office must also have available the requisite competence in science writing for professionals to guide and assist Institute activities in "translation" and "packaging" of information for dissemination and to coordinate these activities with the communication role of the National Library of Medicine.

Communications and the Consensus Exercise. It must be emphasized that no technical consensus exercise can achieve a useful purpose until the results of its deliberations are understood by those who need to know. There are several elements to this requirement:

- Reporting of the conclusions with the facts necessary to show not only the basis for decision, but the degree of unanimity or shades of opinion surrounding it.

- Conveyance of this information in terms understandable to the uninitiated, as well as the experts. It usually means preparing abstracts of several kinds; the greatest care must be dedicated to the summaries prepared for the layman.

- Time is precious. The promptness of the report is no less important than its quality in regard to matters which will be quickly reported by the public media to an audience exceeding that reached by any official communication other than the concluding press conference.

It is no small problem to achieve the most desirable form of reporting meetings of the kind we are dealing with here. The "official" view of the proceedings and their outcome is potentially subject to distortion no less serious than the version written by a reporter seeking the editor's attention for space. Both have institutional interests that may not be the public's. It would be ideal to have the services of a "communicator," gifted with both skeptical coolness and editorial skills, who could be insulated from self-interests and any form of censorship. At NIH, this could be provided by the Office of the Director better than within any Institute. Even in the OD, the "reporter" needs to have a quasi-independent role, such as that of the exceptional editorial writer shielded from the vested interests of a publisher or owner. This voice-of-the-public can be the greatest guarantor of the success of technical consensus.

Attachments

Background: The Responsibilities of NIH at the Health Research/Health Care Interface

1. The problem of how best to assure effective transfer of new knowledge from research to practice is not a new concern. However, interest in achieving a more effective interface between biomedical research and health care delivery has intensified in recent years due to a number of factors: increased societal expectations and demands for better health care; greater pressures for improved access to best available health care; greater complexity and sophistication of new technologies and their attendant effect on health care costs.

- Abraham Flexner, in the early years of this century, was an astute and persuasive commentator on this problem. His proposed solution was the coupling of research with medical education responsibilities in medical schools, so that development of new knowledge and its dissemination could proceed together.* To this day, the teaching hospitals of medical centers represent far and away the most effective settings for transfer of new clinically relevant knowledge from research into practice. Any proposed solutions to the dissemination problem will have to utilize these strengths already in place.

- During the 1950's and early 1960's, a number of so-called "control and demonstration" programs were developed by NIH and other PHS components to deal with facets of the knowledge transfer problem. These programs differed from the earlier control activities in the infectious disease area (which depended on mass protective approaches) by seeking to demonstrate in community settings the feasibility of new diagnostic or therapeutic techniques arising from research. The accomplishments of these demonstration activities were often controversial (differences of opinion on the cost effectiveness of the "Pap Smear" program is an example) and during budget tightening in the late 1960's, most of the major activities in these programs were terminated.

- The Regional Medical Programs (RMP), authorized by Public Law 89-239 in 1966, represented a new and highly structured attempt to build avenues for the dissemination of knowledge from major teaching and research centers to community hospitals and local practitioners. A number of dissemination approaches were tried in the various RMP regions, but program emphasis eventually centered on continuing education of practicing physicians. The limited success of this ambitious program in achieving its principal objectives (i.e., broadening access to the highest quality health care, particularly for the major diseases--heart disease, cancer and stroke) had much to do with stimulating passage of the National Cancer Act in 1971, and the National Heart, Blood Vessel, Lung and Blood Act in 1972. In both of these Acts, Congressional determination to broaden access

*Flexner, A.: Medical Education: A Comparative Study, The MacMillan Co., N.Y., 1925, pp. 283, 291.

to quality care in cancer and in heart, lung and blood disease was made clear by the direct assignment to the respective institutes of responsibility for control and demonstration programs, and by the authorization for multiple comprehensive categorical research and demonstration centers, in which research, training and care--with support from appropriate sources--would take place.

- The National Library of Medicine was established in the Public Health Service by Public Law 941 - 84th Congress "In order to assist the advancement of medical and related sciences, and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health...." Subsequently, Public Law 90-456 designated the Lister Hill National Center for Biomedical Communications as part of the National Library of Medicine to find means for the improvement of communications necessary for health education, research, and practice.

- The President's Biomedical Research Panel, called into being by P.L. 93-352 to "review and assess" the biomedical and behavioral research programs of NIH (and ADAMHA) included, as an important facet of its studies, the role of NIH in the dissemination of new knowledge. The Panel recommended (in part) that:

> "Each Institute of the NIH (and ADAMHA) should organize a formal structure for knowledge application and dissemination activities. Each must provide leadership in this effort to assure that the latest scientific findings bearing on health care are made available to the professional community....*

- Finally, NIH concern with the transfer problem is far from a new thing. Many examples of effective Institute efforts may be cited, including the vaccine development program of the NIAID; NCI control and demonstration activities in diagnosis and treatment of certain malignancies; NINCDS efforts through support of the Joint Committee for Stroke Resources; the NHLBI program in hypertension; etc; etc.

2. Long-term concern about ineffective transfer of new knowledge from research to health care (as noted above) has been accompanied by more recent but growing concern over the impact of new research knowledge on the already enormous costs of health care. There is concern, for example, over the high cost of such "half-way technologies" as renal dialysis and some of the complex therapies in cancer. While many of the cost-impact criticisms of research results are arguable, these concerns may not be dismissed lightly.

*Report of the President's Biomedical Research Panel, April 30, 1976, page 8.

In identifying options for NIH in dealing with the general problem of dissemination of research results, deficiencies in processes by which the research community transmits its findings to the health care delivery system and to the public must be taken into account.

While many Federal health actions are directed at problems perceived in the organization, funding and delivery of health services, these deficiencies are a subject of increased scrutiny and debate. At the recent hearings dealing with "Basic Issues in Biomedical and Behavioral Research," members of the Senate Subcommittee on Health questioned the effectiveness of the dissemination process for discoveries ready for general use. It was suggested that deficiencies in the information flow in the health system are partly responsible for unevenness in the quality of health and medical care across the nation. It has been suggested that the research community and the NIH have a responsibility to help assure that the best medical interventions are widely utilized. Deficiencies exist not in delay between development of an intervention and its application, but rather in the absence of a mechanism which fosters the widest and most effective utilization.* At present the prior evaluation by research and medical communities of what is transferred is quite uneven and often inadequate.

At least a dozen Federal agencies possess capabilities for clinically testing, disseminating and utilizing information pertinent to health care delivery and patient management. These programs in aggregate are very large and encompass delivery, regulation, and research. Yet the roles and responsibilities of these agencies are not synchronized to eliminate the deficiencies under discussion here.

The "gap" between research programs and health service delivery thus reflect more than one defect: a piecemeal apparatus for dissemination; a lack of formalized programs both within the government and between the Federal agencies and the health care community for transfer of new technologies; and a paucity of structured and orderly mechanisms for reaching consensus on the validity, effectiveness and usefulness of many products of biomedical and health services research.

In delineating the role and responsibilities of the NIH and the research community, the broad range of activities comprising the health spectrum may be classified into three major categories:

- Research and Knowledge Development. The search for and use of knowledge:

a) Identification of opportunities, gaps, and lags in research applicable to health and disease problems.

*Report of the President's Biomedical Research Panel, April 30, 1976 page 9.

b) Developing the information base in response to this need.

c) Inter-relating new knowledge with previously existing knowledge.

d) Coupling research findings to application.

e) Validation of research results - Encompasses questions of safety, usefulness, and superiority to interventions already available.

- Consensus Development. Agreement among all parties concerned that a new intervention in the delivery of health care is scientifically sound and technically feasible and involves two discrete types of consensus development:

a) Technical consensus - scientific/medical agreement on the scientific facts that a given innovation is deemed optimal and potentially feasible for introduction into practice. There are actually two phases in this step - agreement among the experts followed by agreement between the experts and those in the health care community concerned with application. This includes anticipation of possible misuse of new technologies and preparation of correctives to offset such possibilities;

b) Interface consensus - the information and recommendations emerging from "technical consensus" are considered by all relevant parties (see attached chart) to reach an agreement concerning the suitability of a given intervention for introduction into practice. This includes awareness of economic, ethical, and other practical problems that will be created by such interventions.

- Dissemination and Application.

a) Diffusion

b) Acceptance and application by the practicing community and the public.

Research and Knowledge Development. Research is clearly an NIH responsibility, but are there shortcomings in the research process itself? There may be gaps in the information base which must be identified and there may be delays in the transfer of research information among disciplines. Additionally, there may be research knowledge which could be coupled more rapidly and more effectively in moving the products of research toward practical application for the benefit of man. A critical element in research is the evaluation and validation of results as to their scientific merit and the initial assessment of their potential for introduction into the health care system. This phase is often uneven in its implementation.

Consensus Development. Adequate formal structures do not exist for consensus development among experts and appropriate members of the medical community on the readiness of innovation for transfer to the.

health care delivery system.* Similarly, formal processes do not exist to bring together parties involved in the delivery of health care with representatives of the research community to arrive at a determination that a given innovation--in terms of health care delivery issues--is ready for wide application in care.

Clinical trials are an integral part of the consensus building process. Clinical trials (a component of clinical research) are a blend of research and health care activities aimed usually at defining prospectively the efficacy and safety of a new medical regimen or device. They provide a portion of the evaluation process which should be carried out prior to the widespread introduction of an intervention into the health care system. Although clinical trials do not ordinarily address the many social, ethical, and economic concerns that may be relevant to transfer, they play an important role in the transfer process because they are among the few formal mechanisms which foster identification of best available clinical interventions. The knowledge gained from a successful, well designed and conducted clinical trial is directly applicable to man, and may enhance the quality and duration of life. Ideally, the trial leads to identification of a new, superior intervention. When a clinical trial is conducted to compare an innovation with a conventional or standard procedure, the outcome may result either in the validation or discrediting of the established intervention.

As do other research findings, the results of clinical trials diffuse into the practicing community by many different pathways, including publications in medical and scientific journals, professional meetings, seminars and continuing education programs, and control and demonstration activities. A common defect in many of these diffusion processes is that they do not make clear the degree to which the new information reflects the opinion of the best informed among the research community.

Aside from the evolution of a consensus based on results of clinical trials and control and demonstration programs, academic medical centers and research hospitals provide practicing physicians with guidance which involves participation and concurrence from the research area. When mandated by the Congress, specific control and demonstration programs are implemented by the NIH on the recommendations of expert advisors from the academic and research communities. The interventions chosen for those programs have been identified by the advisors as the best available for a given disease. Academic medical centers and research institutions, with responsibility for continuing professional education, undertake to provide the best existing opinions concerning health and

*It should be noted that there have been successful efforts in consensus development on medical care issues as a result of meetings or workshops organized with such an objective in mind. The most recent example, under the sponsorship of the NHLBI, occurred when relevant major professional and voluntary organizations reached a consensus on the diagnosis and treatment of hypertension. (See the Report on Detection, Evaluation, and Treatment of High Blood Pressure. J.A.M.A. 237:267, 1977).

medical care. However, it is generally recognized that the vast majority of practitioners do not have a regular relationship with academic medical centers. Of the approximately 7,000 hospitals in the United States, only 250 are teaching hospitals.

Highly regarded textbooks and review articles in medical/scientific journals also reflect common or concurrent opinions of recognized investigators in a field. They continue to be useful and important traditional means for achieving and disseminating authoritative information, but as discussed below, they may have major shortcomings.

3. Diffusion and Application.* More remote from NIH research activities but nevertheless not divorced from them, is the diffusion of new knowledge throughout the system and its adoption by the practicing community. The National Library of Medicine plays a major role in this diffusion process. It is responsible for acquiring, organizing, and disseminating biomedical information in hard copy and audiovisual form, and via an extensive computer-based information system. Thus, it provides information services to the health community, both directly and through its nationwide Regional Medical Library Network.

This diffusion process is critical, for if it is defective, the entire enterprise tends to be faulted. Perceived deficiencies in this phase have aroused criticism in recent years, but as discussed above, the failure to recognize the importance of consensus development in its two steps, i.e., appropriate prior attention to the substance of what is to be diffused, is a major contributor to this deficiency.

Medical knowledge is communicated to the practicing physician by a variety of means:

Publications

a) Books and journals

b) Advertisements, circulars, handouts

Professional meetings and conferences

Postgraduate courses, continuing education and self-assessment tests

Contacts with other physicians

a) Consultations on clinical problems

b) General conversation with opinion leaders

Contacts with individuals representing pharmaceutical or medical products.

Media other than the printed word: films, computer assisted instructions, audio or audiovisual tapes, etc.

*A detailed discussion of the diffusion of medical information by Dr. Martin L. Cummings, Director, NLM, appears in Appendix B.

As a means of communication, each of these modalities has inherent advantages and disadvantages. Their effectiveness is also related to both the characteristics of the producers of the new information and of the recipients, the practitioners, although there are wide variations among individuals in both categories. The quality and validity of the information communicated varies greatly for each of these means of communication. There are also important differences in the rapidity with which information is conveyed depending on the modality.

Many physicians (particularly, specialists) are able to keep abreast of new developments in their areas of interest, but for the average physician, faced with the constant deluge of new information, this becomes an extraordinarily difficult task.

The responsibility for translation has been assumed variously by different organizations (medical centers, professional societies, etc.) with varying degrees of effectiveness. It seems appropriate that prime responsibility for this process should remain with the professional societies and it is encouraging to note that most of the societies have become more active in this area and have greatly improved their educational programs. However, this final and essential step in the transfer of new information pertinent to health and disease is not being approached systematically. To accomplish this translation in a more effective fashion, a close collaboration between Federal agencies and the professional societies becomes essential.

THE DIFFUSION OF MEDICAL INFORMATION TO PRACTITIONERS

Medical knowledge is communicated to the practicing physician by a variety of means. Any discussion of the efficiency of this diffusion process will have to be concerned not only with the intrinsic strengths and weaknesses of the several means of communication but also with the characteristics of both the producer (of new knowledge) population and the applier (practitioner) population. Moreover, it will be necessary to emphasize that while generalizations about these two populations may have some validity there is a wide variation among individuals in both categories. Thus, some scientists (producers) are acutely aware of the medical and social implications of their work; others are little concerned with those implications. On the other hand, some practitioners acquire new information with greatest facility through personal contact with opinion leaders while others prefer the printed word as a source; some are visual learners, some audio.

The major modalities of medical communication can be tabulated as follows:

1. Publications
   a. Books and Journals
   b. Advertisements, circulars, handouts
2. Professional meetings and conferences
3. Postgraduate courses
4. Contacts with other physicians
   a. Consultations on clinical problems
   b. General conversation with opinion leaders
5. Contacts with individuals representing pharmaceutical or medical products

6. Media other than the printed word: films, computer assisted instruction, audio or audiovisual tapes, etc.

Each of these modalities has inherent advantages and disadvantages viewed as instruments for the diffusion of new knowledge to the practitioner. Scientific and clinical books and journals, often called "original sources," offer the advantage of editorial selection, review and control. This process provides some degree of assurance of validity of the information which reaches print. On the disadvantage side is the commonly observed lag time between observation and publication which frequently renders journal articles months behind and books years behind the currency of knowledge generation. Further, the charge is often levelled that the printed literature serves the purposes of the writer more than it does those of the reader. Be that as it may, at least it is true that much scientific literature has as its main purpose the further elaboration of the conceptual structure of science and is little concerned with the applicability of that same information to the care of patients.

Advertisements, circulars and handouts do not suffer from the problem of lag time but on the other hand are not validated by the editorial process. They are generally easily and quickly readable and may be quite informative but by reason of the fact that they are written to sell a product or an idea their objectivity must be suspect.

Meetings and Conferences offer both audiovisual transmission of information from speakers and corridor conversations with peers, the stimulation of fellow learners. The rapid-fire ephemeral nature of most medical meetings is not conducive to learning for many participants. The series of 10 or 15

minute papers in a darkened room serves more to exalt the speaker than to inform the audience.

Postgraduate courses too often are given in the academic tradition of conveying to the student what the professor thinks he ought to know rather than what the student (practitioner) needs to know to solve his clinical problems. However, courses which provide for interaction and which elicit effort on the part of learners probably are an important channel for the diffusion of medical knowledge.

Interpersonal contacts with subject specialists is probably the most used channel for dissemination of medical information. This may take the form of either formal or informal consultation with a respected colleague or a conference with a detail man. This channel has the great advantage that, being initiated by the practitioner with a problem, the transmitter of information consciously or unconsciously goes through the processes of analysis, synthesis and translation of knowledge into an application to solution of the problem at hand. This channel, however, has the implicit disadvantage that the inquirer may not be right in his choice of consultants.

Media other than the printed word include films, audio tapes, video tapes and computer assisted instruction (CAI). These offer wide and easy distribution, reinforcement of the learning process by projection of the personality of the producer, easy repeatability for review and, in the case of CAI, an interactive capability which directly involves the learner in intellectual effort.

All of these modalities suffer from the fact that an adequate reward system has not yet been developed to motivate systematic production on a large scale. In addition, there is not yet in place a review and evaluation system comparable to the editorial and invisible college control over scientific printed literature.

These general remarks about the means and modalities at hand to convey medical knowledge are not meant to be comprehensive. Rather they are introductory to the point that improvements can be made in the flow of medical knowledge. A variety of conveyances are and probably should continue to be used. The nature of a particular message has some influence in the choice of best media to communicate it; and individual learners life style and study habits differ widely. These are reasons for the continuation of a plurality of modes of information diffusion.

Whatever the mode or the information product, however, there is a need for a regularly updated summation of clinically relevant information in each major disease area. To accomplish this the information must be examined for its scientific accuracy (analysis); it must be selected and condensed from the total biomedical data base or pool (synthesis); and it must be validated for its clinical applicability and presented in a language which is understood by the practitioner (translation). The processes of analysis and synthesis are the responsibility of subject matter experts. The responsibility for translation has been assumed variously by different organizations and accomplished with uneven effectiveness. To accomplish this translation in a systematic fashion a close collaboration between Federal agencies and professional societies is necessary. The prime responsibility for content, validity, organization, and

assessment of learning products should remain with the professional societies. It is our judgment that this final but essential step in the information transfer process is not being approached systematically. Thus, it seemed appropriate to explore new ways, and to develop system models, to improve the organization and distribution of analyzed and synthesized biomedical information. The organization should facilitate translation emphasizing new knowledge which has applicability to the problems faced by the practitioner. The first basic requirement is that the information provided must be clearly responsive to the practitioner's immediate needs. Moreover, it must be available essentially on demand. Experience justifies the assumption that the physician is more likely to act on and learn from information supplied in response to an inquiry regarding an immediate clinical problem. Finally, the information must be transmitted in terms which are readily understood.

Our goal is to develop a new process by which we can identify, organize and distribute information relevant to clinical problems which, if applied, will improve outcome in a meaningful and measurable way. The design of each step of this process requires experimentation. There is the total sum or pool of information available on any given topic. We designate this as the *data base*. If examined, it will be found to contain a very large amount of information, some original and much that is repetitious; some that is valid and much that is of dubious worth or in error. Some of the information will be well integrated into accepted postulates, but much will not be well correlated with the existing state of understanding. This *data base* can be examined for validity or "analyzed." It can be reduced in volume or "synthesized." This process of

analysis and synthesis will yield another and smaller pool of information which we designate the *data bank*. If an appropriate index discipline is used in assembling the contents of the *data bank*, new entries into the total *data base* can be appropriately assessed for inclusion or exclusion. Furthermore, inherent in computer managed information *data banks* is the capability to update, retrieve on demand and display or print as required, any line or lines of stored text. This bank would be the resource for the production of a variety of information *products*. The bank would consist of essentially two elements; the first would be syntheses of the information in the *data base* as current as the literature itself; and the second would be identifications of the validity of, or strength of belief in, these synthesized statements. These elements within the *data bank* are called *clinical hypotheses*. We have used the term "hypothesis" in two senses. The first is our hypothesis that it is possible to reduce the *data base* to a series of elements which we call the *data bank*, and that such a reduction would markedly simplify the development of information *products* for the ultimate user. The second use of the term "hypothesis" emphasizes the fact that the elements of the *data bank* are summary statements, each with some assessment of the confidence levels of its validity. These summary statements have varying degrees of uncertainty. It seemed, therefore, advantageous to make these statements not in the form of simple declarative sentences, but in the form of postulates or hypotheses. It is in that sense that this term "hypothesis" is used to describe the elements with the *data bank*.

Finally, in the development of *products*, we have used the word *translation*. We mean by *translation* the transformation of the contents of the *data bank* into

a *product* suited to an end user. It is not necessary, indeed, it is probably undesirable, for the *data bank* itself to be viewed as something to be accessed by the ultimate user. It should be viewed as the resource from which many *products* could be derived. One product might be sets of answers to common questions of practitioners; another product might be the data to be used in a "state-of-the-art" lecture or short course; another, the authority base against which to measure the wisdom of certain practice behaviors.

We are attempting to explore the process of creating such a *data bank* on a specific subject, namely, infectious viral hepatitis. We do not anticipate that all of medicine should or could be treated in this fashion. The magnitude of such a task is probably prohibitive. Rather, the candidate subjects for similar manipulation would be identified in the following ways:

- o First, the topic should represent a very common or very important entity.
- o Second, the area should be one in which there is a great deal of research activity with rapidly changing concepts.
- o Third, the area should be one in which knowing what to do, and what not to do, has apparent and measurable significance for the patient's welfare.
- o Fourth, there must be a body of subject experts willing to collaborate in the *construction of hypotheses*.

Infectious (viral) hepatitis seemed to meet all of these descriptors. When such a data bank is created it will be used to create products to meet health practioners needs. The achievement of optimal user acceptance of a new information product or service is, in large measure, dependent upon: (1) detailed knowledge of the health practitioner's existing information needs and sources;

and (2) consideration of these user and product characteristics that are associated with, and hence predictable of, acceptance by the community of health care practitioners. Such knowledge will ideally be utilized in the design and definition stage of any new product or service, and in the planning of an effective promotional strategy intended to inform and educate the potential user as to the benefits and utility of the new product or service.

For a given subset of the health care community targeted for attention, a survey of user needs would include as its objectives:

(1) A description of the general use made of the above modalities;

(2) Indices of satisfaction with each as mechanisms for transmitting biomedical research results; and

(3) Objective measures of the quality and quantity of such information now received, and the user's perceived satisfaction with it.

Knowledge of this kind would greatly facilitate the design, development, promotion, and ultimate acceptance of a new information product or service by the intended user community.

Factors Influencing Product Acceptance

The act of deciding to subscribe to or purchase a new information product or service, and in continuing its use, is a complex process involving two broad sets of factors: (1) social and psychological characteristics specific to the intended user, be it an individual or an organization; and (2) characteristics or attributes intrinsic to the product and relative to the other dissemination mechanisms currently in use.

It may be particularly useful to consider these sets of factors within the

framework of diffusion theory, that is, to conceptualize the new information product or service as an innovation, itself to be diffused within a given community of health care practitioners. In so doing, we bring to bear a large body of research findings and fruitful research paradigms that speak to the acceptance, or in diffusion terminology, the adoption of a new information product or service.

Tannon and Rogers (1975)* provide a good state-of-the-art summary of the classic diffusion model, and much of the following discussion is based upon their presentation. They identify four key elements as being central to the study of diffusion: (1) the innovation; (2) communication channels, (3) time, and (4) the social system. The Innovation. An innovation's characteristics as perceived by its potential users will affect its rate of adoption. Thus, in attempting to predict the likely acceptance (or account for the nonacceptance) of a new information product or service, one should consider the following variables:

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* Christian P. Tannon and Everett M. Rogers, "Diffusion Research Methodology: Focus on Health Care Organizations," in The Diffusion of Medical Technology, edited by Gerald Gordon and G. Lawrence Fisher, Ballinger Publishing Company, Cambridge Massachusetts, 1975. The proceedings of an NIH sponsored conference held at Cornell University in September 1972.

- o relative advantage - the degree to which the information product appears better than whatever it supercedes
- o compatibility - the degree to which the information product seems consistent with the existing values and past experiences of the health practitioner
- o complexity - the degree to which the information product seems difficult to understand and use
- o trialability - the degree to which the information product may be experimented with on a limited basis
- o observability - the degree to which the results of using the information product are visible to others
- o authoritativeness - the degree to which the product and its sponsor are seen to represent high standards of scientific accuracy and validity

Communication Channels Channels of communication are the means by which information about an innovation gets from its source to various receivers. Using the notion that a sequence of distinct stages is involved in the decision to adopt something new (i.e., the adoption process is conceptualized in five stages or steps: awareness, interest, evaluation, trial, and adoption), researchers have attempted to distinguish among various channels of communication (interpersonal and mass media) in assessing their relative impact at each stage in the adoption process. Thus, studies on diffusion of drug information* indicate that the original source of physicians' awareness of new drugs is generally commercial (i.e., detail men), but that scientific sources of information become increasingly important in the actual decision to prescribe a new drug.

Generalizations derived from diffusion research suggest the following promotional approach: If one simply wishes to inform a particular segment of the health care

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* see for example, Coleman, J.S., Katz, E., and Menzel, H., Medical Innovation; A Diffusion Study. Bobbs-Merrill Co., Indianapolis, 1966.

community about a new information product, mass media channels are often most rapid and efficient. If, however, the intent is to persuade a potential user to form a favorable attitude toward the product, an interpersonal channel (i.e., face-to-face exchange) is more effective.

Time Time is one of the most important considerations in the process of diffusion. The time dimension is involved in the innovation - decision process; in the relative innovativeness of the individual; and in the innovator's rate of adoption within a social system. Remote physicians receive new knowledge later than those in an urban setting.

The innovation - decision process is the mental process through which the health practitioner progresses from initial awareness of a new information product, to a decision to adopt or reject, and finally to confirmation of this decision. The diffusion researcher conceptualizes four main functions in the process: knowledge, persuasion (attitude formation and charge), decision (adoption or rejection), and confirmation.

Innovativeness is an individual's earliness in adopting new ideas relative to the other members of a social system. Five idealized adopter categories have been postulated: innovators, early adopters, early majority, late majority, and laggards. Research has shown that earlier adopters in a social system tend to be younger in age, have higher social status, a more favorable financial position, more specialized operations, and a different type of mental ability from later adopters. Earlier adopters utilize information sources that are more impersonal and cosmopolite than later adopters, and that are in closer contact with the origin of new ideas. They also utilize a greater number of different information

sources than do later adopters. Finally, the social relationships of earlier adopters are more cosmopolite than for later adopters, and earlier adopters have more opinion leadership.

It would seem reasonable to say that the extent to which one can characterize a target practitioner group on a dimension of innovativeness, one is not only in a better position to select the most effective communication channels for promotional purposes; but also to more accurately predict the actual time of adoption of the information product -- a dimension frequently expressed in terms of years! Thus, in practical terms, the product sponsor can gauge beforehand the magnitude of promotional resources likely to be needed in order to achieve the desired level of user acceptance; and also avoid the potential pitfall of prematurely withdrawing the new product as a presumed failure.

The Social System

While it is generally true that innovations that are perceived by receivers as having greater relative advantage, compatibility, etc., have a faster rate of adoption than others, the same innovation may have different adoption rates in different social systems. Diffusion researchers describe the relationship between a social system and the decision to adopt an innovation in terms of three distinct types:

- optional decisions - are made by an individual regardless of the decisions of other members of the system
- collective decisions - are made by consensus among individuals in the social system
- authority decisions - are forced upon an individual by someone in a superior power position, such as a supervisor in a bureaucratic organization.

It has been observed that the fastest innovation rate is by authority decisions, while optional decisions can be made more rapidly than collective decisions. Although made most rapidly, authority decisions are more likely than others to be circumvented; and they often lead to a high rate of eventual discontinuation of the innovation.

To the extent to which members of a target practitioner group are subject predominantly to the influences of one type of social system than another (e.g., a practitioner in solo practice vs. a member of a hospital's house staff), one can predict not only a different rate of acceptance of a newly introduced information product, but perhaps also the likelihood of its consistent use over time.

Given appropriate resources, the National Library of Medicine can coordinate the Federal effort, support research on the process and operate and maintain the data bank. NLM can also contribute production expertise to the development of products. The Health Science Community through its Professional Societies must contribute the content experts, fix the educational objectives and determine the effectiveness of the activity.

Martin M. Cummings, M.D.
National Library of Medicine
November 30, 1976