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MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : BID Directors

DATE: OCT 2 2 1976

FROM : Director, NIH

SUBJECT: Draft issue paper: "The Responsibilities of NIH at the Health Research/Health Care Interface"

Attached for your consideration is the draft program paper on "technology transfer," about which I spoke to you at our meeting on Tuesday the 19th. My intent is that we devote a large share of our next meeting (on Tuesday, November 2) to discussion of this document.

The issue addressed is one of exceptional importance to the NIH and to the larger biomedical research community:

> *What should the responsibility of NIH be in assuring effective introduction into the health care system of knowledge pertinent to disease prevention, detection, diagnosis, treatment and rehabilitation? How should the NIH organize--what processes must be put into place--to discharge these responsibilities?*

The document proposes the addition of major new responsibilities for NIH Bureaus, Institutes, and program Divisions, and for their respective National Advisory Councils or Boards. Specific implementing procedures are not proposed (though a general approach is outlined) because it is assumed that different processes might need to be worked out for widely variant research problem areas.

Your views will be most welcome on all aspects of this document, including in particular the feasibility and probable usefulness of the proposals made. If you have the opportunity to put your thoughts down in writing, this would be helpful, but it is not essential.

I hope in our discussions we will be able to agree upon the generalities of an NIH position on these critical interface issues, and to decide how best to move promptly toward its implementation.

Donald S. Fredrickson

Donald S. Fredrickson, M.D.

cc: OD Staff

The document proposes the addition of

DISCUSSION DRAFT

October 21, 1976

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

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SUMMARY

1. The manner of introducing new knowledge derived from research into the health care system has become an issue of major concern.

2. The National Institutes of Health, as principal supporter of biomedical research, and the rest of the scientific community, must assume greater responsibility in the selection and use of that knowledge pertinent to disease diagnosis and treatment, which is to become accepted health practice.

3. In order to discharge this responsibility, a mechanism is proposed whereby each NIH Institute, in concert with its National Advisory Council or Board, assumes an obligation to identify and foster evaluation of appropriate new knowledge on the verge of transfer to the health care community.

4. This mechanism requires the creation by each Institute of more formal and systematic processes for identification of important new clinically relevant research information and for development of consensus concerning its usefulness. These processes must encompass participation by representatives from relevant non-governmental professional and lay organizations as may be required in both consensus development and dissemination of recommended new knowledge through existing and possibly new pathways. It is anticipated that dissemination would also occur through the Office of the Assistant Secretary for Health and health agencies.

5. To provide overall advisory assistance to the B/I/Ds in this process, a small locus should be established in the Office of the Director, NIH. This locus would serve to maintain the essential links among Institute efforts, the Director, NIH, the Office of the Assistant Secretary, and health care agencies. Its activities would also include evaluation of the progress and success of transfer processes.

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

I. ISSUE

What should the responsibility of NIH be in assuring effective introduction into the health care system of knowledge pertinent to disease prevention, detection, diagnosis, treatment, and rehabilitation? How should the NIH organize--what processes must be put into place--to discharge these responsibilities?

II. BACKGROUND

In recent testimony* before the Senate Labor and Public Welfare Subcommittee on Health, the Director, NIH, made the following statement pertinent to the above issue:

> "It seems clear that in the future, the NIH and the rest of the scientific community must assume more responsibility for the effect of research on the quality of the health care delivered. The need for accelerating the transfer of new technology across the "interface" between biomedical research and the health care community and systems is a major issue." [Underlining added].

What in fact are the dimensions of the problem to be addressed? Pertinent background includes the following:

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

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 more effectively interfacing 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 optimal health care, greater complexity and sophistication of new technologies and their attendant effect on health care costs.

a. 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 this effective process already in place.

b. During the 1950's and early 1960's, a number of so-called "control and demonstration" programs

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

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 (the "Pap Smear" program being an example) and during budget tightening in the late 1960's most of the major activities in these programs were terminated.

c. 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 and Lung Act in 1972. In both of these Acts, Congressional determination to broaden access to quality care in cancer and heart disease was made clear by the direct assignment to the respective research institutes of responsibility for control and demonstration programs, and by the authorization for multiple comprehensive categorical centers, with major health care, as well as health research responsibilities in each.

d. 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....*

2. Long-term concern for ineffective transfer of new knowledge from research to health care (as noted above) has been accompanied by a more recent but growing concern for the impact of new research knowledge

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

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 are arguable, these concerns may not be dismissed lightly.

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 most Federal health actions are aimed at the broad array of problems perceived in the organization, funding and delivery of health services, these deficiencies have become 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 raised questions concerning the effectiveness of the dissemination process for those discoveries ready for general use. It was suggested that a lack of uniform information flow in the health system is in part responsible for serious unevenness in the quality of health and medical care across the nation. There are many reasons for this, more related to inadequacies in the health care system than to the dissemination of information, but this does not relieve the NIH of its responsibility to play an important role in helping to assure that the best medical interventions are widely utilized. As has been clearly demonstrated, the problem is not one of delay between the final development of an intervention and its application; the deficiency lies in the absence of a

mechanism which fosters wide utilization.* To this we should add the observation that the prior evaluation of content transferred is extremely uneven.

The potential for disseminating, clinically testing and utilizing information pertinent to health care delivery and patient management is embodied in at least a dozen Federal departments and agencies ranging from the Department of Defense to the National Science Foundation. The cumulative programmatic scope of these agencies is vast, encompassing major areas of health care delivery, regulation and research. Within this array of Federal agencies, as was pointed out by a member of the Subcommittee, roles and responsibilities for dissemination and utilization functions are not clearly defined at this time.

The widely perceived gap between research programs and health service delivery is in large measure due to the piecemeal apparatus for dissemination and the lack of formalized programs and offices for transfer/utilization within the government and between the Federal agencies and the health care community. There are few structured mechanisms for interagency exchange and communication that are directed to deal with information validation, transfer, and utilization.

Clinical trials, the research activity which undertakes to determine the primary efficacy and safety of a new medical regimen or device, lie at the interface between research and health care delivery. They provide a portion of the evaluation process which should be carried

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

out prior to the widespread introduction of an intervention into the health care systems. Although clinical trials do not directly assess the broader concerns of technology assessment - social, ethical, economic - they play an important role in the transfer process since at present they are the only formal mechanism which fosters the identification of optimal interventions. They thereby contribute to the limited and poorly structured consensus-making process which exists at present. The knowledge gained from a successful, well designed and conducted clinical trial is directly applicable to man, and when applied, may enhance the quality of life, its duration, or both. Ideally, it may lead 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 often results 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.

There is an element within these diffusion processes that is usually missing: the recipient frequently has no way of establishing the degree to which the new information is authoritative or reflects the opinion of the most informed among the research community. At

present the development of such a consensus follows a highly informal process which is often longer and more tortuous than if it were better structured.

Aside from the evolution of a consensus based on results of clinical trials, control and demonstration programs, academic medical centers and research hospitals provide practicing physicians with guidance which involves at least some participation and concurrence from the research arena. Once mandated, 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 take their responsibility for the continuing education of professionals seriously; this responsibility encompasses the provision of the best existing opinions concerning health and medical care.

Highly regarded textbooks and review articles in medical/scientific journals also reflect common or concurrent opinions of recognized investigators in a field. They remain a useful and important traditional means for achieving and disseminating authority, but they are not an adequate solution. Not infrequently, the position expounded may be the author's own or representative of a minority view. There is no minimum standard of authority save the orthodoxy of processes used to derive information, and many value judgments are purposely excluded from this technique. It should also be noted, of course, that in

many situations in medicine, no consensus exists, not because there is no mechanism to assist the experts to come to an agreement, but because the necessary data are not available to permit the development of a clear recommendation.

In any field of technology where rapid change is occurring, it is the rule that gaps exist between investigators responsible for the changes and the appliers of the technology. This is no less true in medicine than in solid state physics. While many physicians (particularly specialists) are able to keep abreast of new developments in their areas of interest, for the average physician this becomes an extraordinarily difficult task. The changes are many, varied, and rapid and the demands on his time by his practice make it impossible for all but a few to keep up. Even if a physician had time and energy, there is no available mechanism as indicated above, which would enable him to assess new medical innovations except from his own circumscribed perspective.

The present diffusion process leads to a situation in which the practicing community at large is not prepared to react promptly and in the best informed state to rapid advances in technology. This is in spite of the fact that the vast majority of physicians are anxious to apply the latest and best information available and to provide their patients with optimal care.

If the existing process for dissemination of new information may allow undesirable lag in its application, it also fosters the premature or inappropriate application of new interventions. This was a

special concern of the President's Biomedical Research Panel.* While the Food and Drug Administration has stringent requirements for safety and efficacy of drugs, biologics, and devices, many procedures existing in current medical practice and new interventions entering the medical care arena and adopted by practitioners are not amenable to such regulatory action and require more critical appraisal of effectiveness.

In summary, the major deficiencies in the present process for the dissemination of new clinically relevant research knowledge and for its wide application are:

1. Within the research community, there is inadequate structure in the current mechanisms for evaluating clinically relevant research information for dissemination to the health care community.

   a. There is no system for formally distinguishing <u>especially</u> useful new clinical information flowing from research so that it is recognizable to the practicing physician.

   b. Similarly, there is need for better information processing within the research community for identifying <u>optimal</u> clinical procedures (diagnostic, therapeutic, etc.)--whether these represent new information flowing from research, or interventions already in practice. When there is controversy

*Report of the President's Biomedical Research Panel, April 30, 1976, pg. 10.

over the optimal intervention for prevention, diagnosis, or treatment of a disease, there is no acknowledged responsibility and more formal process in place to resolve conflicting claims.

c. Even when clinically important information is identified, there is basis for doubting the efficacy of traditional mechanisms whereby the research community passes this information to the health care community and for the holder to make the best-informed decision to accept such information for wide application. Here one must make an important distinction. The problem is in wide application in the health care delivery system as opposed to: (1) the transformation of research findings into practical application (as in clinical trials); or (2) the utilization of clinically important knowledge for the management of patients in clinical research centers. There is abundant evidence that the mechanisms in (1) and (2) function relatively well.*

d. Neither Congress nor the Executive Branch has assigned to existing government agencies or proposed creation of new agencies with specific responsibilities with respect

*Battelle-Columbus Laboratories:Analysis of Selected Biomedical Research Programs, Jan. 31, 1976; Comroe, J.H., Jr.:Lags Between Initial Discovery and Clinical Application to Cardiovascular Pulmonary Medicine and Surgery, Dec., 1975. Both studies were commissioned by the President's Biomedical Research Panel.

to these deficiences in the health spectrum. However, members of Congress, as well as the President's Biomedical Research Panel (cited above) have urged the NIH to provide leadership in the dissemination and application of research knowledge.

e. There is no general agreement within the research community that creation of a new system (for identification of new clinically important knowledge, or the achieving of consensus on optimal clinical procedures) is feasible, or that acceptance of responsibility for them would be appropriate or desirable.

2. Just as there are gaps on the research side in processing clinically relevant research findings, there are deficiencies in the application of new findings on the health care side of the interface.

a. As indicated above, some validated interventions diffuse relatively slowly through the health delivery system.

b. In the absence of consensus, new interventions may be applied prematurely or inappropriately.

With these deficiencies in mind, the key questions for the NIH relate to the extent to which NIH should assume responsibility for:

- o validation of new and established medical and surgical interventions;
- o improvement of the informal system whereby consensus is reached concerning the validity of the interventions arising from research;

- o assessment of the implications of new findings and their readiness for clinical application;
- o cost containment, where research advances may lead to costly treatments;
- o dissemination of research results, beyond traditional channels of scientific communication.

It seems clear that the time has come for NIH and the rest of the research community to assume more responsibility for the effect of research on the quality of the health care delivered. The need for accelerating the transfer of new information across the interface between biomedical research and the health care community and systems is a major issue for the NIH. Its actions on this issue are of great interest and concern to many.

III. PURPOSE AND SCOPE

Against this background, the NIH has undertaken a study to determine the most appropriate mechanism 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.

This document is based on several critical assumptions:

1. That in the future, the NIH and the rest of the biomedical research community must assume greater responsibility for the effect of research on: (a) the quality of health care available for delivery; and (b) its potential costs.

2. That these new responsibilities must not carry NIH and the research community into regulation, direct health care, or establishment of rigidly authoritorian standards.

3. That to achieve these purposes, the principal need is for further processing of research information within the research community itself. More specifically, the need is to assure, with involvement of appropriate members of the research and relevant communities, that clinically applicable new information flowing from research is: (a) systematically identified; (b) validated for efficacy and safety; (c) assessed (where appropriate) for cost, ethical, or other social implications; and (d) then recommended to the health care community in readily accessed form.

The specifications for the mechanism to discharge this responsibility of the NIH and the biomedical research community are:

1. Assumption of obligation by NIH bureaus, institutes, and division (B/I/Ds) for the planning, conduct or support, and evaluation of activities leading to the identification and dissemination of new research knowledge deemed optimal for the prevention, detection, diagnosis, and treatment of disease.

2. The effective utilization of the expertise of the B/I/Ds, their advisory bodies, academic medical centers, professional societies and others from the broad community of scientists, relevant lay groups, or other organizations as appropriate, in the performance of these activities.

3. Provision for public participation in this process relative to impact assessment and to the dissemination process.

4. Creation of a central focus in the O.D., NIH, to provide guidance and advice in these activities and to effect coordination in issues crossing B/I/D lines.

To achieve these goals, the essential functions required in the innovation process have been examined and means for strengthening each of these functional areas are suggested.

In the course of preparing this document, a number of options were considered, but were rejected in favor of the single comprehensive approach presented here. It thus becomes a baseline for discussions--first within NIH, then more broadly with the larger research community and others having an interest in these matters.

IV. PROPOSAL

This section recommends a series of process changes and specific task assignments through which the biomedical research community (including the NIH) would be able to handle proposed new responsibilities for the effective introduction of relevant research information into health practice.

A. Concepts - Concepts underlying this proposal include:

Co-equal and separate "sellers" and "buyers". A reasonably clean separation 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 liklihood of premature or unneeded transfers; a clear basis for

"feedback" and critique, from the user's perspective, is provided; and the research community is protected from the temptation (and onus) of direct setting of health practice standards or regulation.

Maximum involvement of the research community in the advisory process. To assure maximum credibility and impact of recommendations from research within the practicing health community, that advice should reflect--to the maximum degree possible--a research community position rather than that of a particular Federal agency or individual scientist. Processes adopted for generating advice on a particular disease or health problem should have as a principal objective the obtaining of a reasonable consensus among those in the community viewed as most knowledgeable in the problem area.

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

- o 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.
- o Medical school teaching hospitals and categorical research centers currently represent the single 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 processes must build.

- o A number of efforts to improve the dissemination of research results into health practice have been mounted by various NIH components, including the Office of the Director. Some of these efforts will warrant retention or even expansion. All (including formally mandated control and demonstration programs) will warrant study by any group attempting community-wide improvement in processes for moving research findings into practice.

B. Principal Features - These, in very summary form, are the main features of the proposal:

1. Identification of relevant clinical research knowledge. Assign each NIH Institute Director[1/] -- in concert with his National Advisory Council or Board--responsibility for surveying the national research scene in the Institute's area of concern, and for assuring that "useful" new research knowledge (i.e., pertinent to disease prevention, detection, diagnosis, treatment, or rehabilitation) is adequately identified and processed for effective transfer to the health care community. This includes responsibility for identifying and recommending optimal modes and processes for dealing with particular disease or health problems, where a reasonable and useful consensus in these matters can be achieved.

1/ This phrase is intended to include all Bureau, Institute, and Program Division Directors at the NIH.

2. Consensus Development

To carry out these tasks, each Institute Director (with his Council) would be responsible for designing a credible identification/validation/consensus-seeking process, to meet needs for his specific research areas. It would be reasonable to expect considerable variation among Institutes in terms of approaches adopted, since each Institute encompasses a unique sector of biomedicine. (Several different approaches might need to be taken within a given Institute if it has multiple major disease problems.) Irrespective of problem area, involvement of knowledgeable members of the research community would be an objective in all processes adopted.

- o There are a number of obvious sources of advisory competence that Institute Directors might want to draw on in one combination or another in meeting new responsibilities. These include the Institute's own scientific staff (especially clinical investigators in the intramural program); clinicians on the National Advisory Council; principal investigators at recognized centers of excellence (including comprehensive centers) in the particular disease area; other research or health care consultants who could be engaged in a contract or other suitable basis.

be an objective in all processes adopted

- In many instances, Institute Directors may decide that the process must extend beyond the usual limits of the research community itself, to include consultation with other agencies of the PHS and the Government; also with especially interested outside groups, including the general and specialized professional organizations and lay-professional groups oriented toward specific health problems, such as the American Cancer Society, National Heart Association, Cystic Fibrosis Foundation, etc. 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 addition to existing support mechanisms, Institute Directors may want to consider new types of awards for assisting in carrying out new responsibilities. For instance, there might be attractiveness in a special category of "Research Extension" grants (or perhaps, preferably, contracts) through which a specific center of competence within the research community could be induced to carry out, on a continuing basis, a major segment of "research information transfer" activities.

3. Role of Clinical Trials

An important consideration for Institute Directors in developing effective processes for transfer of research findings to the health care community is the appropriate role, availability of expertise, and required levels of support for clinical trials. Again one must expect considerable variation among program areas. However, additional clinical trials may be essential to the validation of promising new research findings. They may also be required, if reasonable consensus is to be obtained, for the identification of optimal interventions. [There is a real potential for a breakdown of research transfer processes at this point. If funds are not available to mount needed trials, or if available expertise cannot assure that the right questions are asked and answered, effectiveness is likely to be impaired.]

4. Complex Technologies

Some new knowledge is so complex in its technology that community hospitals would require additional resources and local health professionals would need special training before it could be applied effectively. (For example, certain complex treatment regimens for childhood leukemia clearly fall in this category.) Where such a problem of technologically complex new knowledge is identified--and the priority of the

disease problem would appear to warrant the effort--the creation of a control/demonstration program would be a critical recommendation. Responsibility for this program might be assigned to the appropriate NIH Institute, although when the requisite competence is, or can be made available elsewhere within the PHS, responsibility would more properly belong there. (When any such program responsibilities are most appropriately retained or assigned to the NIH, it is the NIH position that special earmarked funds should be provided. This is essential if resources for the other research missions of the Institute in question are to be protected.)

5. Impact Assessment

Some clinically relevant research information undergoing the validation and consensus development process may raise questions concerning potential legal, ethical or cost impacts.[1/] Where doubts of this nature cannot be resolved quickly, the recommendation for transfer of the new research knowledge should be deferred for an assessment of these implications. As the primary source of biomedical research support, NIH has a

1/ 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.

responsibility for involvement in some level of impact assessment of the innovations arising from its research. The expertise residing in the biomedical community, National Advisory Councils, and the NIH staff, encompasses much of that required for impact assessment,[1/] conspicuous exceptions being the economic and legal aspects of some such problems. Although NIH can provide itself with such expertise, the health care sector, as the funder and provider of health care, is in a better position to make such assessments. For NIH to assume limited assessment responsibility, acting as an advisory and evaluative body, would be a logical utilization of NIH's field of expertise and mission. In-depth assessment of legal, fiducial or economic impacts should rightfully be placed in the hands of those agencies more intimately involved with such issues.

6. Dissemination of Recommended Information

When appropriate, and perhaps periodically, once or twice a year and according to an agreed-upon schedule, Institute

1/ Such assessments have been arbitrarily divided into at least three types: Macro-technology assessments "are comprehensive analyses. They generally take about two to three years to complete at a cost of approximately $300,000. Mini-assessments are about an order of magnitude smaller than a comprehensive technology assessment. They generally focus on depth or breadth but not both. A mini-assessment might be used to structure (or determine the utility of) a comprehensive assessment, which may be undertaken at a later time, or it can be used as a pilot or supplementary study to examine a single effect or problem area associated with a comprehensive TA. A micro-assessment is an order of magnitude smaller than a mini-assessment. It relies heavily on approaches such as brainstorming sessions or nominal group techniques." From Arnstein, S., "Technology Assessment: Opportunities and Obstacles," a draft paper, May 1976.

Directors would compile pertinent recommendations for their research areas, and forward them through the Director, NIH, to the Assistant Secretary for Health, and to other agreed-upon points. These recommendations would be made in the name of the appropriate National Advisory Council, and with the weight behind them of reasonable consensus within the research community. It would also be the responsibility of the Institute Directors to foster the dissemination of such information through existing pathways, particularly those already employed by groups who had participated on the consensus development process, journals, medical schools, principal grantee institutions, relevant professional societies, the AMA, etc. The technical and archival resources of the National Library of Medicine (NLM) might also play an important role. On rare occasions, for items of unusually high priority, the O.D., NIH, might be the focus for dissemination. In the absence of other appropriate mechanisms, the principal responsibility for effective dissemination to the practicing health community would lie with the Assistant Secretary for Health, or with agencies or bodies designated by him.

The proposed new "transfer" processes are not intended to replace or to interfere with normal processes for research information dissemination, which would continue to depend mainly

on publication in the open literature. The new mechanisms, if put into place, would merely assure that some part of this current information flow--the most "useful" part--goes through an identification/validation/recommendation process which enhances its use and acceptance in health practice.

7. Role of the Office of the Director, NIH

The role of the Office of the Director, NIH, in developing and implementing transfer processes would be one of overview and facilitation. For the range of issues involved in the effective transfer of research findings to health practice, a locus of technical and advisory assistance would be created in the Office of the Director. This would be a relatively small organ with clinical orientation to provide a focus and act as a catalyst in furnishing guidance and advice to the B/I/Ds. In issues cutting across B/I/D lines it would assume responsibility for coordinating the activities of the relevant B/I/Ds. The new office would act as an administrative interface in transfer matters for the NIH with the Office of the Assistant Secretary and with Government health agencies. An important part of its activities would include evaluation of the effectiveness and progress achieved in the transfer processes.

Such an office, established at an appropriate organizational level, would provide a clear indication of the importance

and priority the NIH attaches to assuring the effective introduction into the health care system of new clinically relevant research knowledge.

In addition to, or as a part of an "office of technology transfer," there should also be a locus within the O.D. for technical and advisory assistance to Institute Directors on impact assessment issues. Its responsibility would be that of providing guidance and assistance in the initiation and conduct of technology assessment; it would not initiate such activities except in unusual circumstances (e.g., cross-cutting questions involving two or more B/I/Ds; large, sensitive issues).