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MEMORANDUM

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

TO : Study Director
Office of the Assistant Secretary
for Planning and Evaluation

DATE: November 21, 1977

FROM : Special Assistant to the Director, NIH

SUBJECT : Report, "Health Technology Management at the Department of Health, Education, and Welfare".

We have carefully reviewed the subject document and our comments are attached.

These comments reflect the opinions of representatives of the bureaus, institutes, and division of the NIH.

Seymour Perry

Seymour Perry, M.D.

Attachment

November 21, 1977

NIH Comments on the report, "Technology Management at the Department of Health, Education, and Welfare"

This report is a product of a month-long study of technology assessment/transfer activities within the Department. In essence, it proposes that a Departmental level unit be established to oversee and manage health technology activities within the Department and to provide liaison with other agencies and departments throughout the Federal Government. A Phase II study is proposed to identify organizational relationships and specific functions of the proposed Departmental level unit.

As viewed from the perspective of the NIH, the Report effectively reflects critical health policy issues which have required attention for some time. The NIH is anxious to participate in attempting to resolve these issues and while the research community has no direct answers for such problems as inadequate cost control incentives, physician distribution, etc., it can play a very important role. The NIH, as principal supporter of biomedical research, recognizes its leadership responsibility in this regard and for nearly two years worked to devise a process whereby the research community could make an effective and essential contribution. The elements of this process are described in the document, "The Responsibilities of NIH at the Health Research/Health Care Interface" (Attachment No. 1), which was forwarded to the Department nearly seven months ago. The fundamental concept described is that of technical consensus development whereby knowledge (technologies--devices, procedures, drugs, etc.) is processed and validated in a formal manner for safety, efficacy, and is assessed relative to existing technologies employed by the practicing community for the same health or disease problem. Formal identification and recommendations of clinically relevant research information will provide guidance to third-party payers, regulatory and standard setting agencies, and will help the practicing community to derive maximum benefit from the national biomedical research enterprise. The NIH has recently engaged in the first such exercise by holding a consensus meeting dealing with breast cancer screening, including mammography. A background discussion and a summary of the recommendations are attached (Attachment No. 2). This meeting has been acclaimed generally as highly successful.

The Technology Study Management Report of November 7 is a comprehensive account of DHEW-wide technology transfer activities. The problems identified by the study team are quite real but unfortunately, the

Report gives inadequate recognition to the strengths of DHEW agencies. These strengths should be mobilized and enhanced. The NIH supports the need for an appropriate locus in the DHEW to be concerned with the overall problems identified in the Report but the Report otherwise attempts to deal in a simplistic way with these very complex problems. It is naive to expect that a special unit within the Office of the Secretary can cope with these problems.

SPECIFIC COMMENTS

A. Draft memorandum to the Secretary

1. Page 1, PROBLEM - The last paragraph on page 1 speaks to the Department's organization and the coordination between "Action agencies" and "knowledge development" agencies. The question here has to do with the organization of the Department and of the capabilities of DHEW to effect coordination and extend well beyond the problems of health technologies. The question would appear to be whether establishment of a unit in the Office of the Secretary having to do with management of health technology would be an effective means of dealing with the problems that exist because of the organization of the Department, and the quite different missions of its many agencies and the difficulties in effecting communication in a very large and sprawling organization.

2. On page 2 of the memorandum, it singles out CT scanners and certain surgical procedures such as coronary bypass and tonsillectomies as examples of high cost items in health care. It also singles out other items, such as recombinant DNA research, the Privacy Act, and an item which is unclear, but which is referred to "change in the sex ratio of the population" as having impact beyond the health care field. Finally, it indicates that financial incentives are a major drive beyond the use of these technologies. There is no question that the items singled out have been much in the press and have been used as examples in many speeches, but it is extremely difficult to know how anybody Federal or otherwise might intervene in the process of changing of these existing technologies. It would seem that if cost is a major factor, it is possible to perform cost benefit analyses and to adopt policies within the Department which would tend to contain such costs.

3. Page 4, REVIEW AND SYNTHESIS - The statement that at present, "analytical results often fail to move outside the knowledge development Agencies" is untrue and demonstrates a lack of

understanding of the biomedical research process. Investigators have intense motivation in not only attacking problems but in having the results of their research disseminated as widely as possible.

4. Pages 5-6 - Professional education in its many forms does communicate, at least some degree of consensus, and the NIH has just initiated a formal process for consensus development (see above). It is hardly accurate to say that consumer education is limited, although there is a good deal of room for improvement.

   STEP 1: The NIH supports the suggestion that the Secretary endorse in principle the development of an appropriate office in DHEW. However, we suggest that he request a complete plan including organizational location, authorities, responsibilities and staffing, as well as the projected methods of operation.

   Somewhat more time might be allowed than the 45 days which were suggested or proposed, and the period of 90 days might be more realistic. It is also suggested that the Secretary reconstitute the study team to include more direct input from groups that have been previously involved in this problem such as the NIH, the National Center for Health Services Research and the CDC. The Department has had little conceptual input from these groups in the development of this Report.

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B. The Report

1. The title---Does DHEW really propose to "manage" technology? Many people who would otherwise be supportive of the idea will be turned off by this terminology.

2. Page 2 (second line). What is meant by the statement "---Intellectual curiosity of researchers---?

3. Page 2 (third bullet from bottom of page). The NIH proposal for technical consensus development (the "OMAR" proposal) explicitly indicates that there would be consultation and interaction with other agencies.

   On this page and throughout the report reference is made to the economic and social aspects of applying, or not applying, technology with virtually no attention to the first step in the process, namely, technical consensus development. Unless one can agree on what the technology is and how it might be applied, it might be rather difficult to establish economic and social implications of its application. Failure to recognize this point may underlie many of the difficulties referred to repeatedly in the report.

4. Page 2 (second line from bottom). Results of evaluations do not "trickle" out. See comment above on dissemination of research results. Recent examples which refute this statement include the wide publicity given to the diabetic retinopathy trial, results of the studies on oral anti-diabetic agents, breast cancer screening, etc.

5. Page 5 (last paragraph). If this report did not attempt to provide information on, or assess the "abilities of the knowledge development agencies to conduct or oversee the types of technical studies that need to be applied," then one would question the basis upon which the decision was made to place a "management" unit in the O.S.

6. Page 6 provides a free admission of the very limited scope of the study on the part of the study team and the absence of consideration of management and cost considerations in their recommendations. However, these are serious deficiencies which cannot be lightly dismissed in view of the complexity of the issue. The study team, by its own admission, performed only a cursory one month study and based its recommendations on fragmentary information concerning the problems, procedures,

strengths and weaknesses of the various agencies. From this sketchy data was created "average" agency profiles which did not accurately depict any particular agency and tended to emphasize agency weaknesses rather than agency strengths. Of course there are agency weaknesses; there are also agency strengths that could prompt consideration of line of action other than those proposed. Too many aspects of agency problems, activities and capabilities as well as options for solution of the problems went completely unexamined. The study team seems to acknowledge the deficits in the study, but certainly does not dwell on them. Rather, the findings seem to have been used in a selective manner to recommend a course of action (centralized management) which the study group may have had in mind from the very outset.

The study team tended to downplay the fact that the various agencies were involved in varying degrees in the "six generic components" of technology transfer. It paid little attention to the fact that "technology management" has become of great concern only fairly recently, but were quick to fault the agencies for not doing it well. They paid little heed to the realities of agency development, organization and reorganization; the knowledge development agencies and the action agencies were not created as locks and keys, one perfectly designed to complement the structure and activities of the other. Thus there is not a continuity of information transfer and action interventions. However, agency deficits to some degree may also be due to the fact that what is now being demanded of them has not been previously recognized as an important part of their mission or that they have not been given the resources necessary to completely carry out that particular objective.

Item (3) under "Important study limits" states that the analysis "..specifically did not consider which organizational elements within DHEW might be assigned the identified new functions." It stands to reason that before recommending the creation of yet another new unit (i.e. the technology management unit in the O.S.), it is imperative that such an assessment be done.

7. Page 7, A Note about Legislative Steps in the Process. The "initial steps necessary to initiate the proposed technology management process and structure" may not require new legislative authority but full implementation of this report will clash with many existing legislative authorities, mandates, etc. For example, present authorization would prevent re-allocation of funds, which would be required to conduct the necessary research studies.

8. Page 8 (first paragraph). It is inaccurate to say that technologies move into medical practice with no relationship to efficacy, risks, costs or benefits. This completely ignores the current responsibilities and activities of the FDA in licensing of drugs, devices, etc.

   The process of technology development and transfer within DHEW does tend to be fragmented and haphazard, but there are important communication links between many of the agencies (e.g. NIH and FDA, NIH and CDC, etc.). Coordination could be greatly improved.

9. Page 10-12, II. MONITORING AND SCREENING. It is true that there does not exist currently a formal system "to identify, monitor and screen" technologies. The NIH proposal does not and cannot consider all of the areas of activity which the study team has identified as being desirable, and it would appear clear that it will be necessary to identify the capabilities of the existing agencies and to carefully define the roles that might be expected of them in the future efforts in the Department to deal with the various problems relating to new or existing technologies. The NIH role as forwarded to the Department is primarily concerned with new or emerging technologies and requires intimate contact with what is going on in research in this country and abroad, whether supported by Federal or other funds, and the ability to identify the possible medical applications of developments from the research field. At the time it becomes clear that there might be adoption and usage of technological methodology or new devices, it is appropriate that the possible impact be assessed and that the Department be alerted to such impact. The items chosen for such assessment will depend on developments in the field, and not on predetermined topics related to existing technologies. It is difficult to see how a proposed office in the DHEW can cope with this element since it cannot have the broad contact with the field of science that would be required, nor is it directly involved in the assessment of clinical studies which may point the way to future impacts. It would seem only reasonable that the mechanism proposed by the NIH would meet Departmental needs in the developing technology area and it might be desirable to assign OMAR a somewhat larger role than was envisioned by NIH in its original submission. A quite different mechanism would be involved in assessment of those technologies which are in use and which contribute to the high costs of medical care. In the health care delivery system there are many contributing factors to the Nation's rising health care costs which lie outside the responsibilities of the NIH and the biomedical research community. It would not be appropriate for the NIH to assume a responsibility for assessment of these factors and technologies since the considerations are not those of patient benefit or improvement in the quality of medical care. The

Department should recognize the differences between the two areas and not try to combine them under a single office, other than charging that office with acting as a receiving point for the transmittal of information within the Department and to assist the Secretary in decisions about implementation of controls that seem necessary.

10. Page 13, III. THE ANALYTIC AGENDA and page 16, paragraph beginning "In the preceding component (setting the Analytic Agenda)...". It is inconceivable that any single relatively small unit would have the vast array of technical expertise to enable it to make decisions on "which types of technical studies should be applied to given technologies..." (page 16, line 11). The Department obviously has the major responsibility in major policy issues but beyond that, it should concentrate on insuring interagency communication and cooperation, on identifying gaps and overlaps and fostering appropriate remedial actions by the agencies. The keys to effective technology transfer we believe lies in agency initiatives such as OMAR, organizations that are sensitive to agency strengths and fallabilities.

11. Page 15, C. Recommended Approach. It should not be "management" but coordination and drawing on the strengths of the agencies.

12. Page 22, last paragraph. The first sentence which urges relating allocation of R&D resources to magnitude and seriousness of health problems is naive. It has been amply shown that it takes more than money to solve, prevent or cure disease; the scientific opportunity must be there.

    The comment concerning theoretical work on adoption and diffusion of medical technologies is inaccurate, ignoring for example, the mandate and activities of the National Library of Medicine and the Lister Hill Center.

13. Page 24, last sentence. The recommendation that the NCHSR proposal be sent to the Secretary for decision without reference to the NIH proposal, appears to conflict with the recommendation on page 29 where both proposals are to go to him.

14. Page 25, first full paragraph. The statement that DHEW decision-makers and others cannot "...effectively locate and use much of the new and existing information about technologies because they are unaware of its existence; it is not in a form understandable to them" is remarkable. Publications of all kinds have increased exponentially in recent years and are readily accessible to all. Furthermore, decision-makers in the DHEW have always been able to request from the agencies reports on any subject. Finally, if the allegation is true that decision-makers cannot now understand information about technologies, then it is difficult how the

proposed small unit of decision-makers on managing technologies in the Office of the Secretary can be expected to do any better.

15. Page 29. The NIH proposal for OMAR is discussed in a very glib fashion here. At a minimum one would have thought that the study group might have considered how such an office would interface with the "action agencies," to use its terminology. It is also fair to say that NIH probably has the necessary scientific expertise which appears to be grossly lacking in some of the action agencies.

16. Page 43 (first full paragraph). It is suggested that NIH might be "unwilling" to participate further in professional educational activities. This criticism is unjustified and fails to recognize the role of professional societies, voluntary health associations, and other groups.

17. Page 43 (second full paragraph) The DHEW does have a patent policy (consult the Office of the General Counsel). NIH, the Office of the Assistant Secretary for Health, and the Office of General Counsel, each having designated responsibilities under Department regulations, have actively collaborated in administering a well defined patent policy in both impeding and stimulating Department generated innovations through conditional licensing of patents covering such innovations. Enclosed, as Attachment No. 3, is a rapidly assembled sampling of such innovations which have either reached public use or near use through conditional licensing by non-profit organizations controlled through Department management.

18. Page 43 (paragraph A). Is the suggestion being made that R & D funds should be allocated in relationship to perceived needs for technology development? With extremely few exceptions we are not ready for such "moonshots" in health.

19. Page 47 (second bullet from the bottom). The proposal that R & D funds be allocated for "lagging medical technologies" rather than on the basis of "opportunity" is very simplistic and dangerous.

20. Page 47 (last bullet on the page). As noted previously, DHEW already has a patent policy.

21. Page 55. This report needs a great deal more work before it is released to Senator Kennedy. The problems identified are of great importance to the nation and warrant prompt attention. Unfortunately, however, the Report has too many weaknesses to permit further distribution.