
Chapter 8

Findings and Conclusions

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Findings and Conclusions

This technical memorandum has described and examined the role of the National Institutes of Health (NIH) in the transfer of technologies to the health care system. Because it is a technical memorandum and not a full OTA report, it does not present recommendations or policy options for congressional consideration.

The major finding of this study is that, despite some problems relating to the timely transfer of potentially helpful technologies, the major weaknesses of the present process for technology transfer are: 1) inadequate attention as to whether technologies being considered for transfer rest on sufficient knowledge to justify such transfer, and 2) insufficient attention to the scientific evaluation of emerging technologies to determine their potential benefits, risks, costs, and conditions for appropriate use.

Very importantly, the above finding is a general criticism of the current process of medical technology transfer, NIH is only one of the actors, although it is a crucial and influential one. And it should be noted that NIH is responsible for much of the evaluation that does take place and for a great deal of the basic science knowledge that now exists.

It is also important to realize that “NIH” is not a single, tightly structured entity. It is a loosely coordinated collection of semiautonomous organizations—each pursuing related but individual goals, facing different research and public responsibilities, and under varying types and amounts of external pressures.

Policies toward technology transfer must try to satisfy a complex mixture of objectives; they must blend a concern with basic science research directed toward eventual application with a concern for science for more immediate practical

purposes. Ultimately, these two concerns may merge—the knowledge may lead to applications in health care or even in some other field. Decisions must be made in the present, but they must take into account both immediate and long-term implications.

OTA finds that five goals should underlie policies and activities of technology transfer: 1) the identification of areas where the knowledge base is inadequate to produce effective technologies, and the setting of priorities among such areas; 2) the support and encouragement of basic and applied research in areas of inadequacy; 3) the generation of adequate knowledge about the readiness for transfer of technologies under development; 4) the creation of efficient mechanisms to demonstrate and then transfer technologies judged to be ready for use; and 5) the creation of mechanisms to monitor the actual use and effects of technologies in the health care system. Further, each of these five goals must be supported by a comprehensive and readily accessible source of information collection and dissemination.

As these five goals indicate, the transfer of technology is not in itself always a good thing nor always a bad thing. Unfortunately, however, organizations and individuals very often divide into two factions: those who believe that medical technologies should be transferred as quickly as possible, and those who believe that the rate of transfer is too rapid already. Such a generalized position is not helpful. The approach should be to examine each technology, class of technologies, or disease area and ask what is known about any technology being considered for transfer or about the knowledge base being urged for development into technologies.

FINDINGS RELATED TO THE ASSESSMENT OF MEDICAL TECHNOLOGIES

NIH's principal formal activities in the evaluation of medical technologies are its clinical trials and its consensus development conferences. It is by far the most important supporter of these types of activities. With the disappearance of the National Center for Health Care Technology (NCHCT), it remains as the only major focus for such activities.

The arguments in favor of or against NIH's involvement in evaluating medical technology are still the same as they were before NCHCT's demise. The reasons that argue in favor of its playing a large, perhaps expanded, role are:

- It has relatively greater fiscal and personnel resources at its disposal than do other agencies.
- It has strong ties to the academic medical centers.
- It has a good reputation among practicing physicians.
- It has a much higher than average institutional ability to accomplish objectives.
- It has experience in assessing medical technologies, especially their efficacy and safety.

The reasons for NIH's not becoming more involved with technology assessment activities are:

- Evaluation can be expensive in terms of time, attention, personnel, and, especially, funds. With a constrained budget, assessment directs resources away from the research mission of NIH.
- NIH's primary orientation is as a developer of knowledge and technologies, not as a "gatekeeper" or a critical evaluator of technology.
- Its personnel are more appropriate for its research mission than for technology evaluation. For example, the agency has an inadequate number of assessment methodologists, epidemiologists, and health services professionals for an expanded role in assessment activities.

- The agency has a large enough and difficult enough task as it is, without the enlargement and formalization of the complicated function of evaluation.

Nevertheless, OTA finds that the evaluation function is so critical to the successful transfer of appropriate technologies that NIH should approach assessment in a more visible and structured manner and should strongly consider expanding its assessment activities. Funding and carrying out clinical trials, for example, is a function already supported by NIH. This function is consistent with the scientific orientation of NIH. Synthesizing available information on a particular technology, especially that concerning efficacy and safety, also seems appropriate for a scientific institution. On the other hand, considering broader implications of technology use, such as socioethical and economic factors, and arriving at policy judgments such as whether a specific technology should be covered in the medicare program may be better done by those more familiar with clinical medical practice and with policies toward technology use. This function might be better assigned to another part of the government.

The National Heart, Lung, and Blood Institute (NHLBI) is an example of an institute where the assessment and transfer function has been given much thought, where formal and effective processes have been developed, and where the attention given to such activities seems to be paying off in terms of successful diffusion of information and technologies.

The identification of emerging or existing technologies in need of assessment is a crucial aspect of technology transfer and assessment. NIH, through the Office for Medical Applications of Research (OMAR), was mandated to develop a yearly list of priority technologies for NCHCT. With NCHCT no longer in existence, it will be up to OMAR and NIH whether a list will be collected in the future. If that activity is discontinued, there will be no formal procedures in place, except in NHLBI, to identify technol-

ogies in need of assessment. Of particular importance is that NIH assure the evaluation of technologies whose development it has supported. Not only would such procedures be helpful because they could lead to needed evaluations, but the process of identification itself may pay dividends in terms of: 1) setting priorities for research, and 2) building a base of experience in thinking through the criteria by which a technology is judged as ready for transfer. At the same time, the process of identifying technologies

must not be allowed to become overly burdensome to the institutes and research personnel.

The level of assessment will become even more critical in future years. Budget pressures will put even greater demands on each research dollar. This budget constraint, combined with an effort to stabilize the number of new competing grants awarded, is likely to influence negatively the number or size of future clinical trials.

FINDINGS RELATED TO THE TRANSFER OF MEDICAL TECHNOLOGIES

Only rarely does NIH actually transfer technologies. In fact, most of the Federal Government's "technology transfer" activities do not actually involve the transfer of technologies. More accurately, the vast majority of such activities are those which: 1) provide information about technologies, thus encouraging or discouraging their transfer, or 2) demonstrate in a few selected settings the potential uses of new technologies.

In the first type of activity, the Government is not involved in the provision of actual medical technologies at all. Instead, it is generating, analyzing, or disseminating information. For example, publication of the results of applied research or of clinical trials may affect the transfer of technologies in question.

With the second type of activity, funds and technical consultation may be provided to support the testing of the performance, acceptance, etc., of new technologies. Thus, some transfer of technology takes place, but the extent is usually small and the conditions of use are relatively controlled.

At NIH, the institutes that have legislative mandates to conduct technology transfer activities, especially in the form of demonstration and control programs, do more of it than do institutes without such mandates. The National Cancer Institute (NCI), NHLBI, and the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) are the clearest examples of this. Thus, it is possible

that if Congress wished to increase this form of activity it could do so by extending the mandate to other institutes.

The area of control programs often brings NIH into the fuzzy interface between biomedical research and health care delivery. Under most circumstances, this type of activity bears careful watching so that NIH is not unintentionally brought too far into the delivery aspect of health care. In certain instances, it is imperative that the agency *not* get too deeply involved in demonstration and control programs that verge on health care delivery. That can occur when the knowledge base is inadequate for the development of effective and safe technologies. *Efforts to transfer technologies prematurely are especially harmful when such transfer is not only to academic health centers (where conditions may be more controlled) but also into community hospitals and other medical practice sites.* One of these instances may be in the process of occurring if the critics who believe that NCI is moving too rapidly in its transfer of certain technologies, primarily through its demonstration and control programs, are correct. OTA did not have the mandate to study that specific example; therefore further research may demonstrate otherwise. The situation, however, is worth additional examination.

Note that OTA is not saying that NIH is *doing* an inadequate job of developing or keeping track of the state of basic science. The *finding is simply that in making decisions to support the*

demonstration and transfer of specific medical technologies, attention should always be given to the knowledge base on which those technologies rest. The basic and applied research base is not at an equal level of development and understanding across all areas of inquiry. Thus, the priority and funding given to technology evaluation becomes doubly important, for only through careful scientific evaluation of efficacy and safety (and at times of cost and social implications) can informed decisions be made about readiness for transfer and therefore about the appropriate use of demonstration and control programs.

The first type of activity mentioned above—generating and disseminating information—may not be as obviously seen as transfer supporting, but it is a crucial aspect of technology transfer and is actually a far more influential and a much larger activity than demonstration and control programs. (It should be noted, however, that in a very substantial sense, demonstration and control programs are in part also “information-related programs.”)

The current effectiveness of information activities depends on the substance of the information and the process by which it is gathered and disseminated. OTA finds that the *process by which transfer-related information is disseminated ap-*

pears to be excellent in most cases. The National Library of Medicine and its MEDLARS system have played a key role in information dissemination. Similarly, NIH and its intramural and its funded researchers have made extensive use of opportunities for disseminating information through professional/scientific journals and other publications and through professional meetings.

The substance of the biomedical information generated is generally excellent, although, in keeping with above comments, more attention could be given to clinical trials and other assessment results.

In summary, NIH is one of the primary actors in the assessment and transfer of medical technologies. It is subject to a number of internal and external constraints and pressures, some of which urge it to be more active in transfer and some to be less active. OTA'S conclusion is that a cautious approach, varying according to the specifics of each situation, would be more appropriate. NIH could devote more funds and attention to generating information on the potential benefits and risks of technologies, and then, when sufficient information exists, it could actively utilize its existing, adequate mechanisms to support appropriate transfer of medical technologies.