six-component conceptual design through which systematic action could occur, compared current Departmental technology-related activities to that design, identified deficiencies, and recommended remedial actions. It was recognized that the Department's resources could not support such thorough scrutiny of all the new, existing and developing health technologies (expert estimates of which range from 8,000 to 150,000) and that many did not require that level of attention. While the agencies would continue to address other important technologies through development of their own analytic agendas, this report proposes that the Department, through a broad-based, participatory process, annually select a small number of high-priority technologies, and subject them to an especially rigorous evaluation and action process.

The Study Team concluded that in order for such a system to operate effectively, it should be managed by an office at the Department level whose functions would include the following:

-- develops operational procedures in collaboration with DHEW agencies, other Federal agencies (e.g., VA, DOD, OSTP, NASA, NSF) and outside parties at interest (e.g., academic health science centers, medical specialty groups, providers, insurers, public interest groups, Institute of Medicine, manufacturers);

-- manages the annual process related to high-priority technologies;

-- provides technical assistance to DHEW agencies in their management of non-priority technologies (based on experience with the high-priority system and targets of opportunity);

-- serves as a catalyst for formulating Departmental policies on technology management issues;

-- functions as the Department's focal point for (though not exclusive agent of) liaison with other Federal agencies and outside parties at interest;

-- functions as a "switching point" for incoming inquiries related to health technologies being addressed within the Department and for Departmental inquiries about related activities outside the Department;

-- monitors DHEW agencies' management of technologies on an ad hoc basis to obtain feedback on agency-based techniques, and to identify gaps and targets of opportunity for technical assistance or the need for further conceptual development or formal evaluation.

Limitations of the Phase I Study

The Phase I study is not intended to result in a full-fledged prescription for DHEW technology management, but to produce a conceptual framework to be used as a foundation for designing such a system in the future. Consequently, this report does not attempt to provide information on (1) the technical abilities of the knowledge development agencies and their staffs to conduct or sponsor the types of technical studies that need to be applied; (2) the quality of such studies as are now being done; (3) the abilities of the action agencies or their staffs to wield the intervention mechanisms through which DHEW can impede or stimulate development or utilization of a technology ; (4) the various options, with their pros and cons, for resolving the deficiencies identified by the study team.

If this true

Important study limits were:

(1) information was limited to reports prepared by the agencies within ten days; the Study Team had no time to do independent data gathering or verification;

(2) activities within DHEW only were examined excluding significant and relevant activities of such Federal agencies as the VA, DOD, NSF, NASA, OSTP, and OTA, and such private entities as manufacturers, medical specialty groups, academic health science centers, the Institute of Medicine, and provider and consumer groups;

(3) analysis was restricted to programmatic and systems approaches and specifically did not consider which organizational elements within DHEW might be assigned such functions or the levels of any additional staffing or funding that might be required;

(4) medical technologies only were examined; thus, health care system management, rehabilitation, mental health and environmental technologies were excluded as were research and development activities per se.

Consequently, it is recommended that a Phase II study be promptly initiated and that it focus on those aspects which will not be included in this first report. The dimensions of the Phase II study are described in Appendix Tab 13.

Two Important Distinctions

The technical terms used in this report are presented in the Glossary (Appendix Tab I). However, two distinctions are needed at this point to sharpen the discussion:

(1) the technology system vs. "technology assessment"

This report focuses on a management process and a structure (a system) for examining and influencing technologies as they move from development into practice. The popular term "technology assessment" refers only to one type of technical study that may be applied to a given technology, and it is addressed as one part of Section IV.

(2) knowledge development agencies vs. action agencies

For the purpose of this report, the Study Team has come to view agencies (or parts of agencies) as having as a primary orientation either the development of knowledge about technologies (e.g., NIH or NCHSR) or the use of that knowledge to undergird or justify actions taken to impede, promote, or otherwise set conditions on the use of a technology (e.g., HSA or HCFA). It is recognized that this distinction is oversimplified -- most knowledge development agencies have some action dimension (even if it is confined to publication of information) and some action agencies have developed considerable knowledge development capability (e.g. OPPR in HCFA). Subsequent studies of management changes will need to weigh the desirability of maintaining these duplicative and overlapping functions. The typing of agencies' primary functions is useful for purposes of examining missing or ineffective linkages and their costs.

A Note About Legislative Steps in the Process

Several legislative authorities will expire this Fiscal Year (e.g. NIH, BHPRD, NCHSR, NCHS). The Study Team believes that no new legislative authority

actions taken to impede, promote, or otherwise

is required for the initial steps necessary to initiate the proposed technology management process and structure. They are within the Department's administrative authority, and there is considerable Congressional interest in having the Department move forward on the matter. However, should new legislation prove desirable for such proposals as targeted appropriations and positions, the time available to advance them for Congressional consideration will be very short.

I. THE CONCEPTUAL FRAMEWORK FOR A PROPOSED TECHNOLOGY SYSTEM

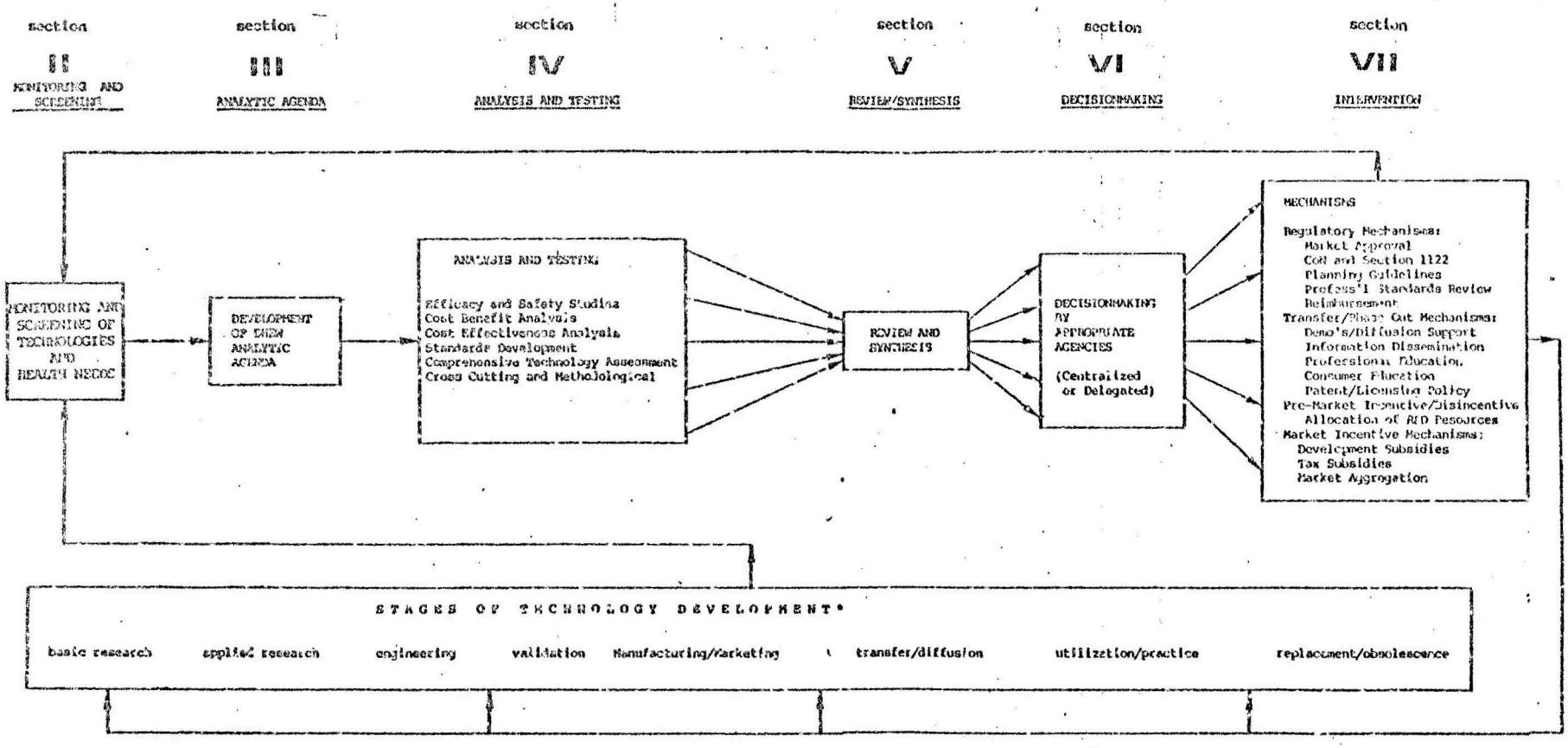
Medical technologies frequently move from a developmental stage through a fragmented and haphazard process into utilization in the health care system where they may assume a life of their own unrelated to proven efficacy, costs, risks, or benefits. Similarly, the process of technology development and transfer within DHEW is at least as fragmented and haphazard. Different types of technology studies are scattered throughout the Department, and there is no central clearinghouse to provide information about existing, new, and emerging medical technologies. Moreover, study results from knowledge development agencies are not linked systematically to action agency mechanisms to restrict or stimulate transfer and utilization of technologies, and no Departmental unit is responsible for addressing these issues comprehensively.

Recognizing that the Department currently has neither a strategy for managing medical technology nor an analytical paradigm upon which to develop such a strategy, the Study Team has designed a proposed technology system and has structured this report in terms of the proposed system. Figure 1 on the next page depicts the conceptual framework for the system which includes a six-component process:

1. Identification and screening of candidate technologies
2. Centralized priority setting of technologies to be scrutinized
3. Conduct or monitoring of the technical studies
4. Translation of technical findings for relevant users
5. Coordinated decisionmaking to restrain or stimulate the technology
6. Intervention mechanisms to implement the decisions

As shown in the following sections of this report, two of the six system components have a reasonably strong base of activities within the Department while four others are absent or very weak. The Study Team has concluded that it is important to correct the deficiencies of the existing components and to establish the absent components because all of them

FIGURE 1: CONCEPTUAL FRAMEWORK FOR HEALTH TECHNOLOGY MANAGEMENT AT THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE (section II)



* Because Technology Development is not a linear process, a technology does not necessarily pass through each of the indicated stages or pass through them in the indicated order.

are needed to assure that medical technologies are examined and that explicit decisions are made about their values and limits.

The components of the proposed system and an analysis of what is now being done, as well as what is not being done, within each component constitute the subsequent sections of this report:

Monitoring and Screening (Section II): proposes development of a technology information base, and a process for "coarse screening" of health needs and existing and developing technologies to be analyzed or tested.

Development of an Analytic Agenda (Section III): proposes a process of subjecting technologies which pass the "coarse screen" to a fine screen resulting in approval of an Annual Technology Analysis Agenda for the Department. It also includes decisions about what types of studies are to be conducted and their assignment to appropriate agencies.

Analysis and Testing (Section IV): outlines five classes of technical studies by which medical technologies might be scrutinized.

Review and Synthesis (Section V): discusses synthesis and "translation" of results of technical studies and other expert opinion into a format for policy and program actions.

Decisionmaking (Section VI): proposes development of a process for explicit departmental decisions which link findings with coordinated interventions to restrain development or stimulate technology transfer and utilization.

Implementation/Intervention Mechanisms (Section VII): outlines intervention actions flowing from coordinated agency decisions and feedback of the intervention impacts to the monitoring and screening component.

II. MONITORING AND SCREENING

- What system is available to identify and catalog existing and emerging technologies?
- How could existing and emerging technologies be screened to determine which might warrant high priority scrutiny?
- How can the Department identify and monitor the health needs in order to judge which problems warrant high priority scrutiny?

A. Description of Monitoring and Screening Component

The Monitoring and Screening component identifies those technologies which should be regarded as serious candidates for detailed study. This component consists of three elements. The first is a data base of information about existing and emerging technologies, which sets the first rough boundaries on the range of technologies to be considered.

The second element is an inventory of the causes of health impairments and disabilities. This inventory would not only rank the causes of death for various age groups, but also array the causes of various levels of impairment such as inability to work or confinement to bed. Information from the monitoring of health impairments would thus help in selecting those technologies which deserve serious consideration for intensive study. Information from the impairments inventory could also help provide guidance for new technology development efforts.

The third element in the Monitoring and Screening component is a set of criteria for "coarse screening" to identify specifically the technologies that are candidates for detailed study. The screening criteria might be based on such factors as magnitude of the health problem to

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ments and disabilities. This

which the technology addresses itself, the potential dollar and social costs of the technology, prominence of problems concerning the utilization of an existing technology, or the urgency of safety concerns. After candidate technologies have been identified through the application of "coarse screening" criteria, they would move on to the phase of Agenda-setting (See Section III) where they would be subjected to "fine screening" criteria to produce the Annual Analytic Agenda of technologies which would actually be studied in detail.

B. Agency Activities and Deficiencies

1. Monitoring and Screening of Technologies:

Analysis of the agencies' reports reveals that there is currently no system to identify existing and developing technologies or to provide the "coarse screen" to select candidate technologies to be studied. Not only is there no catalog of such technologies, either in or outside of the Department, but expert estimates of the total number involved range widely from 8,000 to 150,000 major and minor procedures and products. While none of the agencies has a systematic monitoring and screening mechanism, four of them report activities which could contribute to the development of the needed system.

NCHS reports that its 20 data systems include considerable macro data on utilization and diffusion of selected existing medical technologies and that it would be feasible to add to its ongoing surveys some questionnaire items about additional technologies. For example, NCHS can currently provide macro data which show increases or decreases over time of different types of surgical procedures such

as cardiac catheterization and hip arthroplasty. Similarly, the annual hospital survey supported by NCHS includes items which enable the center to track the diffusion rate of such hospital-based technologies as open heart surgery units, radioisotope facilities and hemodialysis (Appendix Tab 9, pages 3-6).

FDA reports that it maintains a computerized system for post-market surveillance of approved drugs. This system stores adverse drug reaction reports received from manufacturers, hospitals, physicians, the World Health Organization and other sources, including the literature. FDA also has a system that lists approved drug products.

NIH reports that developing technologies are under continuous surveillance by the Institutes as part of their ongoing cycle of program planning, but this surveillance activity is informal.

NCHSR reports that its intramural staff have developed a concept design for an "ideal system" to identify, screen, track, and forecast developing technologies, and that this concept design for a computerized system has now been embodied in an RFP in order to have an outside contractor examine both its feasibility and its cost-effectiveness. The system is designed to provide NCHSR with a systematic way of identifying the universe of public and privately funded emerging technologies that should be candidates for its technology studies program and, more particularly, to provide the base for determining the optimal time at which to conduct these studies--i.e., before the technology is too far advanced to modify through public policy intervention and yet sufficiently developed so that it is possible to obtain adequate information about the technology and its potential applications. Since

it will take some time to demonstrate the feasibility of such a system, the agency has also developed an interim informal approach for identifying and setting priorities for the study of developing technologies.

Thus, it appears that considerable work is already under way to determine the feasibility of the systematic monitoring of developing technologies which might warrant serious study, but that comparable conceptual work has not been done for existing technologies. Such a mechanism needs to be designed and tested for feasibility in the near future.

2. Monitoring and Screening of the Causes of Health Impairment

Analysis of the agencies' reports reveals that the Department also does not have a systematic inventory arraying the causes of health impairments and disabilities which could be used as a basis for the selection of high priority technologies for study. Nevertheless, there is considerable activity in the collection of mortality data and activity in the collection of morbidity data as well, and agency efforts in these areas could provide the foundation for an expanded monitoring program.

NCHS reports that it is collecting a large volume of data concerning the causes of death and, through survey questionnaires, data on the causes of illness as well. NIH, CDC, HCFA are also collecting information on the incidence and prevalence of disorders which are relevant to their missions. However, there is not enough information with which to correlate the incidence of the various diseases with the degrees or levels of impairment that they produce. For

example, one would want to know how many people with heart disease are symptomatic but working, how many are unable to work but ambulatory, and how many are so incapacitated that they are confined to bed. Determining the true "cost" of a disorder, and thus value of a technology to alleviate it, depends to some extent on knowing these impairment levels, and not simply the brute causes of death or illness. The morbidity and mortality data currently being collected NCHS, NIH, CDC, and HCFA can serve as the basis for a more systematic inventory and array of the causes of impairment levels. Such a mechanism for systematically collecting, analyzing, arraying, and displaying the causes of health impairments needs to be developed since it, together with the system for monitoring the technologies themselves, constitutes the front end of a systematic Departmental approach to technology management. Without such a system, it is quite possible that the most critical technologies will be overlooked, or that the limited funds available will be invested in the study of lower priority technologies.

C. Recommended Approaches

It is recommended that the Department determine the feasibility and cost-effectiveness of developing within one or more of the agencies, a system to: (a) identify and monitor technologies; (b) inventory and monitor the causes of health impairments; and (c) screen the existing and developing technologies to select candidates for intensive study. The system should be capable of serving both the knowledge development and the action agencies of the Department. Since it may not be possible to design and launch such a system in less than two years, an ad hoc interim approach will need to be conceptualized and employed.

III. THE ANALYTIC AGENDA

- How are the highest priority technologies selected for scrutiny from among the pool of candidate technologies?
- How can a better balance be struck between the information needs of the action agencies and the research interests of the knowledge development agencies?
- How can it be assured that those agencies capable of conducting the needed studies will apply them to the priority technologies in a timely manner?

A. Description of the Analytic Agenda Component

This component comprises the annual preparation of a Technology Analysis Agenda which reflects the Department's priority needs for technical information about existing, new, and emerging technologies. Managed at the Department level, the collaborative agenda-building process includes agency staff, representatives of other Federal agencies, and outside parties-at-interest.

The process of developing the analytic agenda serves as a "fine screen" which subjects the list of candidate technologies (identified earlier through the Monitoring and Screening component) to a more selective set of criteria such as the resources and skills of the knowledge development agencies, the information needs of the action agencies, the researchability of the problem, and the time constraints. For each technology that passes through the fine screen, the process also determines what types of studies are most appropriate to the technology to be studied, which agencies will be responsible for conducting the studies, and which potential users are likely to be most interested in implementing the study results. The Agenda formalizes the Department's intent to carry out 15-20 high priority studies per year, but does not replace the development of analytic agendas by the individual agencies. After the Agenda is approved by the Secretary, or his designate, the Departmentally-assigned studies form the core and first priority of the analytic responsibilities of the agencies.

The process of developing the analytic agenda serves as a "fine screen" which sub-

B. Agency Activities and Deficiencies

Agenda-setting occurs at the agency and sub-agency levels, influenced by priorities (not necessarily technology-related) identified through some of the following:

- the annual Departmental Planning Guidance
- OS review of the Agencies' evaluation plan submissions
- Congressional mandates and requests
- staff, peer and constituent contacts

Proposed agency agendas filter up to bureau and agency heads coordinated by review committees or by the agency planning office. Decisions are made in consideration of resource availability and perceived salience of the candidates, with the decisions then remanded to the working staff for implementation.

The primary deficiencies of this agency-based process are:

1. The needs of the action agencies for studies of specific technologies are not being incorporated into the agendas of the knowledge development agencies, and there are no interagency mechanisms to reach consensus on agency priorities or to provide arbitration in the absence of consensus.

2. There is no assurance that the types of studies initiated are conducive to policy-relevant questions being raised about the target technologies.

3. Opportunities for potentially valuable collaborative efforts are often missed because agencies are not aware of each other's capabilities and needs.

4. There is no Department-wide clearinghouse which serves as an information point for the agencies and private sector groups which need to know what studies are in progress or have been conducted on a particular technology-based problem.

These deficiencies give rise to action agencies attempting to develop staff capability to conduct studies relating to their own needs, or awarding technology study contracts that may duplicate other efforts, or remaining without the technical information to undergird their mandated functions.

C. Recommended Approach

It is recommended that the concept of a Departmental Technology Analysis Agenda be adopted, and that the responsibility for management of the annual process be lodged at the Department level.

IV. ANALYSIS AND TESTING

-- What types of technical studies should be used to examine technologies?

-- Does the Department currently conduct such studies, and where is improvement required?

A. Description of the Analysis and Testing Component

The Analysis and Testing component develops technical information and data about existing, new, and developing medical technologies. This information will include th which is now unknown, as well as the validation or refutation of what is believed.

In the preceding component (setting the Analytic Agenda), the Secretary, or his designee, would decide which types of technical studies should be applied to given technologies, and would assign responsibility for their conduct to certain agencies. Different types of studies are employed to address the diverse questions germane to different medical technologies. Classes of studies conducted are:

-- efficacy and safety

-- cost-benefit or cost-effectiveness

-- standards development

-- comprehensive technology assessment

-- cross-cutting and methodological

Each type of study is designed to provide information about a different facet of a technology; each is conducted using different methods and analytic tools; and each type requires different combinations of skills, disciplines and resources.

B. Agency Activities and Deficiencies

The one month time constraint limits this report to: (1) specifying whether or not such studies are now being conducted and (2) identifying what the agencies and the Study

Team perceive as the problems associated with their conduct. Independent judgments about the availability of resources and the quality of studies or staffs could not be mad without on-site evaluation. Problems include the following:

-- Agencies doing the analysis and testing are seldom linked effectively to action agencies. As a result, questions of interest to action agencies are usually not incorporated into the study designs;

-- Action agencies frequently do not have the time or expertise to overcome chronic state-of-the-art limitations that compromise the quality of the studies they undertake themselves. Hence, they hesitate to implement the results of studies they sponsor;

-- Similar types of studies are conducted or sponsored in several agencies, bu a "critical mass" of skills are not necessarily assembled in one place to conduct or sponsor such studies.

-- Current limitations of the state of the art of analysis and testing techniques pose barriers to obtaining definitive answers to many questions (e.g., health outcomes, long term risks).

Efficacy and Safety Testing

Efficacy and safety studies are conducted to obtain evidence about the medical usefulness and risks of drugs, devices and procedures. Since neither efficacy nor safety measures are absolute, these studies weigh probable health benefits against probable risks. Agency reports indicate a strong base for the conduct of efficacy and safety studies, particularly of new drugs and medical devices:

-- NIH, in FY 1975, conducted some 750 clinical trials at a cost of over $100 million (about 60% were solely drug, vaccine, or biologics trials);

-- FDA evaluates the results of drug and device testing conducted by applicant manufacturers. In addition, it has a small intramural program to evaluate performance of such technologies as radiological equipment, cardiac pacemakers, and intraocular lenses. The agency is required by law to determine the safety and efficacy of new drugs and devices before they are marketed; and

-- CDC attention is mainly on tuberculosis and VD therapies. These include both testing and epidemiologic studies of efficacy and effectiveness.

The major deficiency identified by the Study Team is that the vast majority of the efficacy and safety studies are focused on new or developing technologies. Rarely are studies conducted on existing technologies to determine if they are outmoded or as effective or safe as generally believed (except when they are used as controls in testing developing technologies). This deficiency is particularly applicable to medical and surgical procedures.

Cost-Benefit (CBA) and Cost-Effectiveness (CEA) Analysis

These primarily economic analytic tools are employed to (1) produce measures of costs relative to the economic value of benefits (CBA), and (2) compare costs of alternative ways of achieving a given level of effectiveness or compare levels of effectiveness when a given cost is invested through alternative approaches (CEA). Agency reports suggest that little of this kind of analysis is being conducted:

-- NCHSR spent about one-fourth of its FY 76 budget in applying such analyses to computer-based screening, diagnosis and treatment technologie as part of comprehensive evaluations of demonstration projects;

-- HCFA's Office of Policy, Planning, and Research staff have previously been involved in CBAs related to arthritis, specific cancers, and motor vehicle

accident prevention, but HCFA itself is not currently conducting such studi

-- NIH reported small scale efforts hampered by state-of-the-art problems in applying such studies to disease research. NIH's report expresses the opinion that such studies are more appropriately the responsibility of other DHEW agencies.

-- CDC reports studies on costs and effectiveness of different venereal disease tests, screening techniques, and treatment schedules.

CBAs and CEAs are highly technical, specialized techniques that should be conducted by personnel trained in quantitative and economic analysis. Considerably less is known about their reliability and methodological pitfalls than risk benefit studies. Thus, they should be located in an environment where staff can collaboratively address state-of-the-art problems, and where a "critical mass" of experience and knowledge can collegially sustain a high quality initiative. This objective suggests the centralization of such activities rather than their partition among several biomedical or health services research-oriented agencies.

Development of Standards

Standards development activities usually proceed from a base of technical information developed through one or more of the previously described types of testing and analyses. But the analysis and synthesis of that information creates new information that justifies the categorization of standards development as a class of studies.

-- FDA sets standards for the quality, efficacy, and safety of drugs and devices being considered for market approval;

-- HCFA develops medical necessity, quality, and appropriateness standards to guide PSROs in their local review activities, e.g., the agency awarded contracts totalling $1.8 million to eight health professional groups to develop sample criteria and standards sets for medical necessity of hospit-

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suggests the centralization of such

alization and appropriateness for use of a variety of procedures, tests, and drugs; and

-- BHPRD develops standards for access, supply and distribution (through the National Health Planning Guidelines) to assist State and local health planning bodies.

A major problem cited by nearly every agency developing or using standards is the need to implement and/or update viable standards as quickly as possible and the inadequacy of the technical knowledge base for doing this. It is in large part this mismatch between the important need and the lack of available data which makes this area of analysis particularly deserving of attention.

Moreover, the absence of linkages between agencies responsible for standards development and other knowledge development agencies means that the data necessary to undergird standards development is not being produced; the methodology for transferring technical data into standards is weak and the process for doing so superficial. As a result, the standards evolved are more normatively than empirically based. In part, this state of affairs can be attributed to recent pressures to produce multiple standards for PSROs and HSAs without delay. However, these shortcomings will not be overcome without a far more integrated process that recognizes the need for continuous updating in response to new data, increased study efforts including methodology, and increased realism about the current limitations of the state-of-the-art.

Comprehensive Technology Assessment

Comprehensive technology assessments examine holistically the potential future consequences of new or emerging technologies on such societal systems as the economy, the physical environment, the law, institutions, mores, ethics, and broad social fabric. These interdisciplinary assessments scrutinize what the

proposed technology is intended to achieve, whether those achievements are socially desirable, who might benefit or lose from the achievement, what unintended consequences are likely, and what policy options are available to either avert side effects or to prepare more effectively for the unintended social change likely to be triggered by the new technology. Currently, there are isolated instances of examinations of discrete societal areas:

-- economic impacts have been examined by NIH, FDA and NCHSR. (For example, FDA examined the cost to manufacturers and consumers of complying with new performance standards of x-ray machines);
-- behavioral aspects of venereal disease carriers and treatments have been studied by CDC;
-- environmental impact assessments have been conducted by NIH (on Recombinant DNA Molecule research) and FDA (on radiation technology); and
-- societal impact has been examined in three NIH studies. The study on the totally implantable artificial heart is considered a forerunner of comprehensive technology assessment despite its small scale because it involved a multidisciplinary team which analyzed a broad range of societal implications of the device.

No agencies are currently conducting comprehensive technology assessments. This deficiency should be remedied in light of the increasing recognition that societal impacts of some technologies may be more profound than their direct economic cost. Lack of technical knowledge, resources, and a mandate for such analysis have apparently precluded its development, although last year NCHSR examined the feasibility and utility of such studies (see Part D of this section) and NIH has considered "preliminary" impact assessments as part of its "consensus building" strategy (see Section V-D).

Methodological and Cross-Cutting Studies

These studies are typically undertaken to provide background information to the agency or to overcome state-of-the-art research limitations. Agency-reported activities of this type include:

-- case studies of technology adoption and diffusion by HRA and NCHSR;

-- use of computers for biomedical information transfer by NIH;

-- development of models for assessing the quality, safety and performance of drugs, devices and biologics by FDA;

-- identification of new technologies and their implications for manpower, operating costs and capital expenditures by BHPRD;

-- development of models to predict treatment outcomes, control measures, and prevalence of venereal disease by CDC; and

-- development of a model to forecast net social value of dental caries prevention procedures by NIH.

No significant work is being done to relate magnitude and seriousness of health problems to absent or lagging technology development and allocation of R&D resources. For example, heart disease is by far the leading cause of death, but it commands approximately 10 percent of the R&D allocations. Very little theoretical work is being done on adoption and diffusion of medical technologies, and this is particularly important since comparable studies in other technological fields which show slow rates of diffusion may be misleading in light of the absence of a classical market structure in the health field.

C. Recommended Approaches

It is recommended that:

-- there should be a new pilot program initiative for cost-benefit and cost-effectiveness analyses and a similar program for comprehensive technology assessment. Both efforts should be evaluated after three years to determine their reliability and utility to the health system and other relevant societal systems;

-- increased attention should be paid to studying the efficacy and safety of existing technologies, particularly medical and surgical procedures;

-- increased R&D emphasis should be placed on health problems for which the current incentive structure does not suffice; and

-- increased emphasis is needed on methodological studies to improve the reliability and validity of technology-based analysis and testing.

D. NCHSR Proposal for Comprehensive Technology Assessment

The NCHSR has advanced a proposal calling for the creation of a 3-6 person Technol Studies Group to add the capability for conducting comprehensive technology assessment to NCHSR's existing capabilities for studying cost-benefit, cost-effectiveness, and technical feasibility. The NCHSR proposal states:

> "Unlike the more discrete studies which concern themselves with particular aspects of a health technology, the new interdisciplinary technology assessment strategy provides a comprehensive analysis of their likely future effects.
>
> "NCHSR proposes to conduct holistic assessments, representing significantly different levels of effort ranging from $10,000 to $350,000 per study. The research strategy is to use micro or mini-technology assessments as a small scale screening tool to refine the research problem involved in the candidate technology and to decide what type and scope of follow-up study is really appropriate.

> "Thus, for example, a micro assessment conducted on a computerized EKG is likely to result in a judgment that it is a straight forward technology which raises no significant societal questions and the appropriate follow-up study might be a cost-effectiveness study. On the other hand, a similar assessment conducted on a nuclear powered heart is likely to reveal that it raises profound questions about the environmental radiation impacts, the psycho-social side-effects, the ethics of allocation, the dollar costs, the technical feasibility, and political-legal problems for which a full scale follow-up assessment is warranted."

The proposal for a pilot program has obvious advantages: it would provide the Department with a needed capability which is now absent, and it fits into the mission of NCHSR. There are also negative aspects: significant dollar costs are involved, and there may be overlaps in function between this proposal and NIH's OMAR proposal (see Section V). There was insufficient time to evaluate this proposal or develop alternative options for institutionalizing comprehensive technology assessment. We recommend that this be done in Phase II. If Phase II takes an extended period of time, however, we then recommend that a decision paper be prepared on the NCHSR and NIH proposals.

V. REVIEW AND SYNTHESIS

-- How can the Department collect and reduce to a useable form the technical information needed to make Departmental decisions regarding a technology?

-- How can the Department facilitate the flow of technology-related technical information to those outside the Department who effect and are affected by medical technologies?

A. Description of the Review and Synthesis Component

DHEW Decisionmakers and other users are unable to 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; or they lack the resources to integrate such information and bring it to bear in a timely manner.

This component is designed to review and synthesize (1) reports generated during the preceeding analysis and testing stage, (2) other reports and technical information, and (3) advice and recommendations from various parties-at-interest (such as manufacturers, providers, physicians, and consumers). The resulting syntheses are (1) presented to the Secretary (if it deals with a high priority technology) or other Departmental decisionmakers in a form suitable for making reimbursement, standard-setting, R&D funding, and other decisions that promote or impede technologies; and (2) transmitted to other Federal and non-Federal entities to encourage collaborative and consistent responses to technologies. The Department-level technology management unit would stimulate and coordinate the review and synthesis process for high-priority technologies, and provide technical assistance to the agencies to promote improvement in their handling of lower priority technologies.

B. Agency Activities and Deficiencies

The agency reports indicate an increasing awareness of the need for structured review and synthesis, but it is clear that additional emphasis and new initiatives are needed.

NIH, in some instances, provides the results of its studies to other agencies needing this information -- for example, vaccine research findings are given to the FDA and CDC. NIH has, as a result of their increasing awareness, recently begun to synthesize test results. A recent project involved synthesis of existing information on hypertension in order to develop consensus-based recommendations for diagnosis and treatment.

A similar exercise, on breast cancer screening, has just been completed. NIH has also submitted a formal proposal (see part D of this section) to OASH for a major "consensus-building" initiative which is designed to increase the agency's capability for synthesizing and transferring scientific findings to the health care community.

NCHSR reports that it channels the results of studies to decisionmakers and other users through two mechanisms: 1) by involving them actively in the setting of research priorities and in the development of individual projects, and 2) by issuing an ad hoc series of non-technical reports which synthesize research findings from several related projects in progress or shortly after completion.

CDC has an explicit process by which test results are reviewed and synthesized. In some cases recommendations are given to other agencies (for example, FDA or State agencies) but they are primarily used in CDC program planning.

FDA has the most formal and structured synthesizing processes. These are legislatively mandated reviews of efficacy and safety test results. These technical reviews result in recommendations to approve or not approve marketing of the product, with such recommendations then being acted upon within the FDA itself. Thus, for pre-market approval, the review, synthesis, and decisionmaking at FDA constitute a continuous formal process. No similar process exists for review of data resulting from market surveillance. FDA is aware of this deficiency and is investigating ways to solve it.

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series or non-technical reports which synthesize research findings from several

OQS. When a Medicare coverage question is triggered by a claim for a new or unusual medical service, the former Office of Quality Standards (now the Office of Health Practice Assessment) synthesizes available efficacy and safety information on that service to develop recommendations for reimbursement. The Office (which recently assumed the responsibility) reported five serious deficiencies with the current ad hoc approach to synthesis:

1) it is a reactive approach which provides no structured way to anticipate questions about technologies about to enter medical practice;
2) coverage questions are not being raised about outmoded or ineffective technologies;
3) dollar costs of the technologies are not included in the review criteria;
4) the ad hoc process of searching the literature, or telephoning experts, to respond to the coverage question, provides no assurance that the best and most reliable data are obtained; and
5) there is no pathway for raising the question of whether the technology warrants a serious study to produce currently unavailable data.

To respond to this current set of deficiencies, the Office of Quality Standards is sponsoring a Medical Practice Information Demonstration Project in collaboration with NIH, HCFA, and ADAMHA (See addendum to Appendix Tab 11). This project is an attempt to demonstrate the feasibility of gathering, validating, and synthesizing the most authoritative data on three disease categories (depression, malignant melanoma and rheumatic heart disease). The findings are designed for use in three ways: in quality assurance programs (such as PSRO), in setting biomedical and health services R&D priorities, and in medical education. If the project is successful, it may be desirable to replicate it on a larger scale.

The problems cited by OQS were also raised by HCFA, which is both a major user of

study findings and a potential feedback agent to the front end of a technology management process (by articulating the need for studies and identifying types of technologies which should be developed for more effective medical practice). HCFA is especially interested in a more structured approach to review and synthesis of the findings of cost-benefit and cost-effectiveness studies. HCFA would like this synthesized information channeled to the PSROs for use in their reviews of medical necessity, quality, and appropriateness of those health services funded by Medicare, Medicaid, and the Maternal and Child Health programs.

In addition to these agency-based problems, there are a number of Department-level deficiencies. Within DHEW, very few inter-agency agreements exist by which study findings are transferred from the agency conducting the study to an agency which will use the findings. In general, there is no mechanism for assuring systematic "translatio of bulky scientific and technical information into a form relevant for policymaking or for ultimate users such as providers and consumers. This deficiency has serious consequences for the Department. If the results of a study are not channeled to relevant decisionmakers and other users, much of the cost of conducting that study is wasted. Department decisions may be delayed or made without the benefit of information which is, in fact, available; studies may be started which duplicate existing or recently conducted efforts; and medical practice may remain unaffected by relevant findings.

C. Recommended Approaches

It is recommended that a Department-level capability be established to stimulate and coordinate the following: 1) agency-based technical review and synthesis activities; 2) translation of technical material into policy relevant form for decisionmakers and into understandable form for other non-technical users; and 3) dissemination of results to relevant parties.

D. NIH Proposal for an Office for Medical Applications of Research

NIH proposes to establish a capability in each Institute for reaching a "technical consensus" on specific medical technologies or disease areas. Consensus-building involves: 1) identifying and evaluating new information on a technology, 2) reaching technical consensus on the validity and significance of research findings and on their readiness for wide clinical use, 3) preliminarily assessing non-medical implications, and 4) producing recommendations in a form for ready acceptance and application by the health care community. Central support and coordination would be provided by an Office for Medical Applications of Research (OMAR) in the Office of the Director of NIH. The proposal has both positive and negative aspects: For example, it would complement a Department-level review and synthesis function, and is aimed at an area in critical need of improvement. On the other hand, NIH does not specify what criteria are to be used in selecting technologies for examination; significant dollar costs are involved; and the preliminary impact assessments appear to duplicate proposed activities of NCHSR (see Section IV, Part D).

In Section IX of this report, the Study Team recommends a follow-up (or Phase II) study relating to the implementation of recommendations for overcoming the deficiencies that have been identified. We believe NIH's OMAR proposal (and the NCHSR proposal) should be evaluated in the context of an array of alternative approaches to overcoming these deficiencies. If it should be decided, however, that the Phase II study should take place over an extended period, we recommend that these two proposals be presented to the Secretary as decision papers. While approval of the proposals would limit future alternatives, continued absence of the capabilities proposed would have adverse effects on the Department's interest in improving its technology-based activities.

VI. DECISIONMAKING

-- How are technology evaluation results converted into reimbursement, market aggregation, certificate of need and other kinds of technology impeding or stimulating actions?

-- Who should have the responsibility for taking the study findings and expert opinion collected during the review and synthesis process, and choosing among action alternatives?

A. Description of Decisionmaking Component

Decisionmaking is the bridge between the development of technical information about a technology and the action steps which might be taken to impede or promote use of a technology. The preceding review and synthesis component presents a technology for decision; this component assures that decisions are made and that they are coordinated.

Once the Secretary (or his designate) has reached a decision about a technology on the Department's high priority list, he would select which intervention mechanism(s) to employ, and would charge the relevant action agencies to alter regulations, draft standards, reallocate R & D funds, design a targeted practitioner education initiative, etc. Implementation would be coordinated by the Departmental-level management unit and would be related to budget and legislative decisions and integrated, if feasible, with actions of other Federal agencies and private sector parties at interest. For technologies not on the Department's high priority list, the Department-level unit will monitor the agency-based decisionmaking processes on an ad hoc basis to promote coordinated and consistent decisionmaking.

B. Current Agency Activities and Deficiencies

Where a single agency develops knowledge about a technology, internally decides on the significance of that information, and then exercises intervention mechanisms over whic

it has control to influence the use of the subject technology (a "closed loop" process), the process typically appears to be relatively well-defined, integrated and purposeful. For example, where FDA's multi-disciplinary technical staff makes a recommendation to a Division Director regarding a new drug application, the Director knows (based on its degree of innovation classification) whether he can make the final decision or must raise it to the Bureau's Associate Director for New Drug Development. The action lever--approval/denial to market, and associated conditions--lies wholly within FDA's control, and the transition from decision to action is integrated and routine. As we have stated previously, FDA is exceptional in this regard.

On the other hand, the decision-implementation relationship becomes significantly less efficient and effective where, for a given technology,

-- the pertinent response mechanisms are located outside the knowledge-development agencies; or

-- the intervention mechanisms are scattered across several action agencies; or

-- there is no external pressure (as there is from the applicant drug or appliance manufacturers) to reach a clear, timely and supportable decision.

Examples of problems culled from Agency reports include:

-- "At the NIH, explicit formal processes have not generally been utilized in dealing with decisions concerning medical technologies and assessment results." Although some interagency agreements and coordinating committees are alluded to, it is clear that NIH confines its implementation activities to the information dissemination process, and that findings are not well-linked to external action agencies.

-- Medicare obtains reimbursement guidance from the PHS Office of Quality Standards through working staff contacts. The recommendations appear to have been generated in an ad hoc manner which failed to assure that useful complementary actions are employed by other arms of the Department. (This is expected to improve under the PHS reorganization and the establishment of the Office of Health Practice Assessment which is now working on an improved process.)

-- HRA's Bureau of Health Planning and Resources Development developed technical standards and criteria monographs relating to 16 technologies as guidance for health planning agencies. While these monographs are available through NTIS, "There has been no final determination as to the value of the monographs (and) they have not been endorsed..." In addition, although case studies have been developed under contract for eight other technologies, only one has been released (in response to high demand) and it has received no endorsement.

-- PSRO: "Unfortunately, (efficacy/outcome information on medical technologies) is generally not available, and the more difficult and time consuming approach of attempting to get a (standard-setting) consensus based on practice experience must be used." "From the perspective of (HCFA's Health Standards and Quality Bureau), decisions on results of technology assessment research are not systematically occurring, nor is there a structured approach for feeding decisions into medical practice."

The Study Team believes that there needs to be a visible and predictable decision-making process which converts the weight of technical information and expert opinion into broadly coordinated interventions which affect the generation, adoption, diffusion, or phase-out of technologies. For high-priority technologies, such decisions should be made by the Secretary or his designee to lend the influence of his office to agencies' commitments to take indicated actions, and to promote collaboration by other Federal and key non-Federal entities.

C. Recommended Approach

It is recommended that one of the primary functional responsibilities of a Department-level unit be to assure that (1) Secretarial decisions on high-priority technologies are implemented; (2) relevant decisions of one agency are consistent with those of another; (3) agency decisions take into consideration potential for collaboration with other Federal agencies and non-Federal entities; and (4) that agency decisions are consistent with Departmental policies or are used as triggering devices for formulating new policies.

It is also recommended that the Department level unit monitor agency based decisionmaking processes on an ad hoc basis to promote coordinated and consistent decisionmaking.

VII. INTERVENTION MECHANISMS

-- What mechanisms does the Department have to impede or stimulate development, utilization and phase out of medical technologies?

A. Description of Overall Component

Intervention mechanisms are the Department's means to affect the development, adoption, diffusion, utilization, and phase-out of medical technologies to ensure the availability of quality health care. Specifically, policy, fiscal, educational and other mechanisms can be used to ensure that:

-- needed cost-effective technologies are brought into appropriate use more quickly;

-- existing technologies which are outmoded, inefficacious, or inappropriately used are curtailed;

-- developing technologies which may impact negatively on the health care system or on society are appropriately modified or arrested.

Four classes of intervention mechanisms need to be employed by the Department:

- o Regulatory mechanisms
- o Transfer and/or phase-out mechanisms
- o Pre-market incentive and/or disincentive mechanisms
- o Market incentive mechanisms

These classes of mechanisms and the specific types within each class come into play at different stages of the life cycle of a technology. Further, the role of responsible departmental agencies in the administration of the specific controls varies. In some cases, the agencies have direct responsibility, while in other cases, primary responsibility is at the State and local level and the Federal agencies only provide guidance, exemplary standards, and oversight.

Figure 2 is a matrix of technology life cycle stages and specific types of controls and incentives within each class of intervention mechanism which may be applied to them at various stages of development.

The potential application of current intervention mechanisms is depicted on the figure. The matrix shows that there are numerous controls applicable to the adoption, use and replacement stages and only three for the research and development stages. This apparent imbalance implies that the Department has considerably more power to affect later stages of the life cycle. In fact, this is misleading. It is not the number of controls applicable to the various stages which is important; rather it is how effectively those controls are used. R&D resource allocation controls, for example, are a powerful mechanism if their full potential is realized through effective policy and decisionmaking. These considerations are addressed in more detail in the following sections.

Further, when considering intervention mechanisms, it is important to realize that medical technology development, adoption, diffusion and utilization are driven by the following factors:

- Most hospitals are paid retrospectively and on a cost basis for technology-based capabilities, and, therefore, may tend to be indiscriminate in their purchase and use practices.

- The medical ethic essentially says that there is "nothing too good for the patient" and this, coupled with financial benefits to the physician for technology based services, contributes to overuse of technology.

- Consumers generally are not sensitive to, or responsible for financial aspects of medical care and, therefore, may be similarly indiscriminate in their demands. A large portion of medical services, for example, are

STAGES OF DEVELOPMENT / INTERVENTION MECHANISMS	BASIC RESEARCH	APPLIED RESEARCH	ENGINEERING/ FEASIBILITY	VALIDATION	MANUFACTURING/ MARKETING	ADOPTION/ TRANSFER/ DIFFUSION	UTILIZATION/ PRACTICE	REPLACEMENT/ OBSOLESCENCE
Regulatory Mechanisms								
*Market Approval/Disapproval					●	●		
*Certificate of Need/Sec. 1122						●	●	
*Professional Standards Review							●	
*Reimbursement						●	●	●
*Health Planning Guidelines							●	●
Transfer and/or Phase Out Mechanisms								
*Demonstrations				●		●	●	●
*Information Dissemination	●	●	●	●	●	●	●	●
*Professional Education						●	●	●
*Consumer Education						●	●	●
*Patent and Licensing Policy		●	●	●	●	●		
Pre-Market Incentive and/or Disincentive Mechanism								
*Allocation of R&D Funds	●	●	●	●				
Market Incentive Mechanisms								
*Development Subsidies			●	●	●	●		
*Tax Subsidies					●	●		
*Market Aggregation					●	●		

Figure 2: Relationship between Intervention Mechanisms and Stages of Technology Development

reimbursed by third party payers, and many consumers are covered by insurance programs where all or a part of the premium is paid by their employer.

Basically, these factors operate as uncontrolled incentive mechanisms. The Department presently is taking initiatives, including legislative action now pending, to deal with problems resulting from these factors.

REGULATORY MECHANISMS

A. Description of Component

There are five specific regulatory controls employed by the Department:

(1) Market Approval/Disapproval

FDA approves or disapproves the introduction of drugs and medical devices into the marketplace based upon a determination of the efficacy and safety of the technology. FDA also may issue conditional approvals which restrict where and how the technology can be used, and may recall technologies on the basis of subsequent adverse information.

(2) Certificate of Need/Section 1122

Certificate of Need (CoN) and Section 1122 require the review and approval of specified capital expenditures and proposed changes in health services. States implement these mechanisms with input from local health planning agencies and in accordance with minimum regulations established at the Federal level by BHPRD. CoN regulatory authority and practices vary across the States. Only one State has neither.

(3) Health Planning Guidelines

The forthcoming National Guidelines for Health Planning will have to be considered by local health planning agencies in developing their plans, and in conducting appropriateness reviews and the review of proposed services. Although not strictly a regulatory mechanism, the guidelines will affect decisionmaking at all levels

through their expression of national policy on the appropriate supply, organization and distribution of health resources.

(4) Professional Standards Review

Professional Standards Review, conducted by local Professional Standards Review Organizations (PSROs), determines the necessity, quality and appropriateness of health services (and, therefore, medical technologies) reimbursed under Medicare, Medicaid and the Maternal and Child Health Program. PSROs receive guidance from the Health Standards and Quality Bureau within HCFA in the form of sample sets of norms, criteria and standards but may adapt these to local practices. Of the 203 PSRO areas, there are 62 at the planning stage, and 120 are conditional. They have concentrated their initial activities on the use of hospitalization.

(5) Reimbursement

Reimbursement mechanisms employed by the Department are limited to the approval or disapproval of reimbursement under Medicare for health services and technologies. HCFA makes such determinations, which can have a multiplier effect on the reimbursement practices of Medicaid and other third party payers.

B. Agency Activities and Deficiencies

Overall roles and responsibilities of the various agencies were discussed above. Specifically, the problems reported by the action agencies are of two types: those inherent in the regulatory mechanisms themselves and those resulting from analytic deficiencies, notably the difficulty in establishing standards. Many of the regulatory mechanisms, although available, are currently in a developmental state either because their legislative mandate is relatively new (Medical Device Amendments; P.L. 93-641), or because established policies and procedures are not adequate to address the complex issues posed by modern medical technologies. As shown below, these constitute a major set of deficiencies.

HCFA makes such determinations, which can have a multiplier effect on the

The Bureau of Medical Devices has not yet completed formulation of pre-market and post-market assessment procedures and performance standards which are comparable to those of the Bureau of Drugs. Though the state-of-the-art of developing standards for technologies was identified as a limiting factor, the Bureau of Medical Devices also reported that FDA procedures and the process of promulgating regulations have further hampered the process.

Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs) are new State and local planning agencies in many cases, and the resource materials and technical assistance structure which will support their regulatory functions are not all in place. Appropriateness Review is not yet a required HSA and SHPDA function and issues surrounding its regulatory aspects are unclear. The draft National Guidelines for Health Planning are too recently issued to have had an effect on the health care system. PSROs are established in only a little more than half the designated areas and sample criteria sets have been issued only for pre-admission and continued-stay-review for hospitalization. From the agency reports, it is obvious that the newness of these regulatory mechanisms or their present state of development constitute a major set of deficiencies.

Other programmatic problems identified by the Study Team include an overall lack of coordination and the exclusion of some medical care providers from regulation. Further coordination is needed between the various regulatory mechanisms in order to assure consistency. DHEW was ridiculed when CT head scanning was approved under Medicare while BHPRD was stating it did not have sufficient information to issue guidelines about CT services even though technicians understood the Medicare decision was based on efficacy and safety data while the guidelines are based on cost-benefit and cost-effectiveness findings. The Study Team also considers that the regulatory mechanisms of CoN and Section 1122 approval are weakened by the exclusion of physicians' offices and other ambulatory care providers from the requirements.

Without the authority to control the acquisition of technologies outside health care facilities, local and State planning agencies cannot, in our opinion, effectively plan and regulate the health care delivery system for which they are responsible.

The action agencies identified the lack of technical consensus about emerging and existing technologies as a major analytic problem to their regulation. Although BHPRD has developed monographs addressing 16 health services and has a contractor working on a series of case studies describing specific technologies, neither of these efforts resulted in specific standards that planning agencies could use for decisionmaking under CoN and Section 1122 because of lack of consensus. HCFA also reported the lack of technical consensus as a major problem in the development of model sets of standards for PSROs to use in reimbursement decisions and quality assurance. The recently issued National Guidelines established quantitative standards which (when issued in final form) must be considered by health planning agencies. These may contribute to a movement towards consensus about medical technologies and assist in the development of standards on which to base CoN and Section 1122 approval.

The scarcity of data about existing technologies was identified by the agencies as a factor contributing to the difficulty of reaching consensus. Information was reported to be urgently needed for State and local health planning decisions and for PSROs. The inadequacy of the existing knowledge base and the lack of dissemination of research findings also were cited by BHPRD, HCFA, and OQS as major impediments to the development of standards.

HCFA identified a need for more comprehensive review of new technologies in order to assist in the development of Medicare reimbursement policies. In addition, HCFA reported that additional research on the appropriate conditions for use of particular technologies is needed to assist PSROs and reimbursement mechanisms in the development of standards-for-use and thus the establishment of payment policies.

Lastly, it should be noted that, while the Study Team agrees with the action agencies about the need for a more structured approach to obtaining technical information about medical technologies, we are in no position to comment on the extent to which the current lack of this information affects their performance, since evaluation of their performance and productivity is beyond the scope of this Phase I inquiry.

TRANSFER AND/OR PHASE-OUT MECHANISMS

A. Description of Component

There are five specific types of mechanisms employed by the Department to stimulate the transfer or diffusion of a desirable technology and/or to phase-out an outmoded or unsafe technology:

- o Demonstrations
- o Information dissemination
- o Professional education
- o Consumer education
- o Patent and licensing policy

Demonstration projects are undertaken primarily to obtain information from which the future course of development and application of a technology can be determined. Demonstration projects also have the potential for directly stimulating or arresting the diffusion of the technology.

Information dissemination and professional and consumer education activities, which are often interrelated, are intended to influence the decisionmaking of practitioners, other health professionals, researchers and consumers on the use of medical technologies. This is accomplished by using such media as medical journals, pamphlets, professional meetings, and conferences to inform these parties about the important positive and negative aspects of technology.

Similarly, patent and licensing policy may be used to encourage or discourage the introduction, diffusion or application of drugs and devices developed with Federal support.

B. Agency Activities and Deficiencies

The agencies' reports overall indicated only limited use of these mechanisms to systematically transfer technologies, and virtually no use to curtail or phase out outmoded or inefficacious technologies.

NIH, however, reported substantial and increasing activity in the dissemination of information, physician and consumer education, and demonstration projects. For example, NIH established a Task Force on Communications in 1975 in the Office of the Director to recommend steps to improve the dissemination of information to health professionals and the general public. The various Institutes sponsor a variety of meetings for biomedical researchers and medical practitioners; publish journals, monographs, bibliographies and pamphlets; write a monthly section for the Journal of the American Medical Association dealing with emerging technologies relevant to medical practice; produce radio and television announcements; conduct seminars for scientific writers; and operate an information clearinghouse in specific disease categories (e.g., the Cancer Information Clearinghouse at NCI). NIH also undertakes the majority of demonstration activities of the Department. The NHLBI and NCI, in particular, are required by their legislation to conduct demonstrations and education programs for professionals and the public. Further, under the auspices of the various Institutes, more than 50 research centers have been established throughout the country. In addition, the NIH's National Library of Medicine is able to provide continuously updated information from its guide to Medical Literature, Index Medicus, by means of the computerized "Medline" system. This is available nationwide through 750 terminals in hospitals, medical schools, and libraries, and is backed up by 11 Regional Medical Libraries.

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* ... bibliographies and pamphlets; write a monthly section for

NCHSR funds demonstration projects of various computer-based diagnostic, therapeutic and screening technologies. These projects focus on obtaining further information about validity, efficiency, cost-effectiveness, and user acceptance, but also aid in the diffusion of worthwhile innovations. To facilitate adoption of some of its projects and elimination of barriers to the transfer of viable innovations, NCHSR has produced user guidelines and supported "user group organizations."

An Office of Health Information and Health Promotion was established recently in OASH to provide the Department with a focus for consumer education activities. This office, which plans to concentrate its efforts in areas where there is an absence of current activities, will assist the agencies in carrying out any aspects of their missions which involve or could involve consumer education, and will develop programs for the "education of the public in the maintenance of personal and family health and in the appropriate use of the health care system." This program is likely to encounter many of the problems commonly associated with the inadequacy of hard technical information about the effectiveness of many technologies. Also, the methodologies used in affecting consumer behavior are imperfectly developed.

These same informational and methodological problems apply to professional education activities. In this case, the problems are compounded because there is no departmental focus for activities relating to the continuing education of physicians and other health professionals. Practicing physicians currently do not have an adequate source of information about the technologies that they are using or could use, and medical literature often is not directed towards the needs of practitioners or written in terms familiar to them. In fact, the quality of that literature has been called repeatedly into question.

Recently, there has been increased recognition of these inadequacies, and various DHEW agencies have been encouraged to remedy them. Several activities discussed

in this report (e.g., the Medical Practice Information Demonstration Project and the Department-level Review and Synthesis component described in Section IV) could aid in resolving these information and education problems.

NIH, however, reported that any further involvement in professional education might be inappropriate or infeasible. Since NIH currently is the most active agency in this area, it appears unlikely that substantial improvements in professional education will take place without a new locus for such activity elsewhere in the Department.

There was no explicit request in the Agency Report Form for information on patent and licensing policies or activities. Agency reports, therefore, provided no basis for discussion of these mechanisms. The Study Team is aware, however, that the Department has not articulated a policy which recognizes the dual use that patent and licensing policy can perform in encouraging or discouraging innovations resulting from DHEW-funded R&D.

PRE-MARKET INCENTIVE AND/OR DISINCENTIVE MECHANISMS

A. Description of Component

The allocation of R&D resources is an effective means for directly affecting technology development. Pre-market mechanisms can be used to stimulate, retard or redirect technology development. Decisions on the type and amount of R&D resources to be applied in any given area would be based, for example, on criteria such as the overall mission of the Department, the nature of the problem, the importance of the problem, targets of opportunity, and the availability of funds.

B. Agency Activities and Deficiencies

Agencies reported no conscious or formal use of R&D resources allocation policies

as pre-market incentive or disincentive mechanisms. Such policies, however, are de facto control mechanisms, which reflect major judgments about health needs and national priorities. The problem for the Department is that the agencies simply do not review allocation of R&D as an intervention mechanism even though the Agency Report Outline explicitly labeled it that way.

This gap in the agencies' perception and planning is particularly striking since it occurs despite the recent barrage of criticism of DHEW for overemphasis of what Dr. Lewis Thomas has termed "halfway technologies" such as renal dialysis which is palliative , and underemphasis of technologies such as vaccinations which are preventive, or nutrient therapy which is curative.

It indicates that one of the Department's most powerful intervention mechanisms is not being employed to manage technology effectively.

MARKET INCENTIVE MECHANISMS

A. Description of Component

Market incentive mechanisms are intended to encourage private corporations to develop and commercialize medical technologies which meet a unique public need but which lack a sufficiently attractive market from the perspective of the industry. Such mechanisms include:

- o Development subsidies
- o Tax subsidies
- o Market aggregation

Development subsidies essentially are direct payment schemes by which all or a part of the costs to take a technology from the "breadboard" or prototype model to the production stage are paid by the Government.

Tax subsidies basically are indirect reimbursement schemes by which all or a

part of the costs to develop actual manufacturing capabilities and/or produce a technology can be deducted from the taxable income of the organization.

Market aggregation refers to Government action to guarantee an exclusive market for a given technology which it desires, but which private corporations consider not cost-effective (i.e., manufacturing and sales costs cannot be sufficiently recovered and/or free market profit margins are too small or uncertain). This mechanism, therefore, assures a minimum sales volume and/or exclusive access to specific interested buyers (e.g., VA, PHS, DOD, GSA) for a given length of time.

B. Agency Activities and Deficiencies

Agencies essentially reported no activities to develop and apply market incentive mechanisms. The Study Team concluded, therefore, that either little was being done with this class of intervention mechanisms, or that the utility of such activities have not been recognized by agency managers. The situation appears to be comparable to the agencies' lack of a strategy for allocation and reallocation of R&D resources as an intervention mechanism.

While the agency reports demonstrated considerable concern with the problem of restricting technology use, they demonstrated no comparable concern with identifying and stimulating beneficial but lagging technologies which are not being developed because they fall between the cracks of the health care market. For example, preventative, rehabilitation, mental health and environmental technologies could reduce costs, but many are lagging in development because the normally overgenerous medical reimbursement system does not cover their use.

This gap in agency planning should be addressed at the Department level. It calls first for systematically identifying lagging or absent beneficial technologies and then, on the basis of the identification, for developing a more balanced strategy for managing technology development.

comparable to the agencies' lack of a strategy for allocation and reallocation of

It is worth noting that the Experimental Technology Incentives Program of the Department of Commerce has the explicit mission of helping Federal agencies conceptualize and implement experimental approaches to technological innovation. This Federal resource should be used, particularly because some of the lagging technologies mentioned above are likely to fall beyond the traditional purview of DHEW (e.g., air pollution and automobile safety) and these call for collaborative efforts with other Federal Departments.

The Study Team believes that there are unrealized opportunities for the Department to promote incentive actions within its purview and to influence incentive actions in areas in which it does not have direct responsibility but which may impact both departmental resources and the overall health of the American public.

C. Recommended Approaches

Overall, we recommend that the Department undertake a comprehensive review to determine why most of its intervention mechanisms are not working effectively; and then to develop and implement policies to expand their scope and improve their effectiveness. In addition, we recommend that:

- The research requirements to establish standards and policies for departmental regulatory mechanisms be clearly articulated and given consideration as research funds are allocated. All of the action agency reports identified some research needs, and we recommend that they be asked to prepare a proposed research agenda for consideration.

- Formal linkages be established between HCFA and other reimbursement organizations in both the public and private sector in order for reimbursement decisions to be more consistent, and therefore effective as a regulatory device. All third party payers should have access to information

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determine why most of its intervention mechanisms

relevant to the establishment of policies, and although private third party payers and Medicaid programs can not be compelled to act in concert with Medicare, further coordination between payers should be encouraged to increase the likelihood of a consistent approach to the regulation of technologies through reimbursement.

- o The acquisition of technologies by private physicians and other ambulatory care facilities by subject to the same CoN and Section 1122 review and approval as other prospective purchasers.

- o Current information dissemination and professional and consumer education activities be evaluated from the standpoint of their output (e.g., quality of information disseminated and relevancy of subjects covered), and their impact on the target audiences (e.g., consumers and physicians).

- o A new locus for professional education be developed to coordinate activities among the agencies and to stimulate needed new program initiatives. We recommend that the responsible organization develop a collaborative relationship with the Medical Specialty Boards and academic health centers so that departmentally-generated information may be systematically channelled to them for use by physician recertification programs and other relevant activities.

- o Specific departmental and agency policy be developed for identifying absent or lagging medical technologies and that R&D allocation plans take greater cognizance of health needs in relation to research targets of opportunity.

- o A Departmental policy be developed relating patent and licensing actions to decisions to encourage or discourage innovations resulting from HEW funded

- o A study be conducted to identify those beneficial technologies which are not being developed because current health care policy overlooks them. For example, prevention, rehabilitation, environmental and system management technologies offer the potential for improving health and reducing health care costs, yet HEW appears to be underinvesting in their development.

- o A study be conducted of other Government organizations to determine the effectiveness of their activities to promote development and commercialization of critical health-related technologies. As part of this study, the Department should identify both those technologies and activities in other fields which may impact beneficially on health problems (e. g., pollution control technologi and those technologies and/or fields where the application of appropriate incentives might be encouraged to reduce the occurrence or severity of specif health and medical problems.

VIII. DEVELOPMENT AND MANAGEMENT OF A DHEW TECHNOLOGY SYSTEM

A. Development of the Proposed Technology System

Chapters II through VII compare the Study Team's concept for a DHEW technology management system with the current activities of the Department. To consider how the Department could move from the existing fragmented arrangements to a coherent management system, it is useful to summarize the current deficiencies and the types of needed initiatives.

COMPONENTS	CURRENT ACTIVITIES	DEFICIENCIES	PROPOSED INITIATIVES
Monitoring/Screening	- Three agencies report some activities which could contribute to an identification and monitoring system for existing technologies and NCHSR has concept design for developing technologies	- no catalog of existing, new, and developing technologies - no systematized approach to identifying and screening technologies to be studied	- develop and implement system for identifying, monitoring, and coarse screening of technologies to be scrutiniz
genda-setting	- Agenda -setting occurs at individual agency levels based primarily on those agencies' perceptions of their missions, ad hoc Congressional Requests, and on resource availability	- imbalance between needs of action agencies and interests of knowledge development agencies - no assurance of agencies' focus on Nation's priority needs - no clearinghouse for information and data about technology-based studies	- create a Department-level mechanism and a fine screeni process for an annual techno analysis agenda of 15-20 hig priority studies
nalysis and Testing	- There is a strong base for technology-based studies in several agencies - NIH conducted in FY '75 clinical trials of efficacy and safety at a cost of over $100 million; FDA and CDC are also involved in efficacy and safety analysis - NCHSR spent one-fourth of its budget for FY '76 on cost-benefit and cost-effectiveness analysis as part of comprehensive evaluations; NIH, HCFA, and CDC report small-scale efforts in this area - FDA sets standards for quality, efficacy, and safety of drugs and devices, and reviews data and testing procedures of developers; HCFA develops medical necessity, quality and appropriateness standards to guide PSROs; BHPRD develops standards for organization, supply and distribution of health technologies and services. - There are isolated instances of discrete societal impact studies (by FDA, NIH, CDC, NCHSR), and NCHSR has developed a proposal for comprehensive technology assessment. - Examples of cross-cutting and methodological activities: studies of diffusion by HRA; use of computers for information transfer by NIH; development of models to predict treatment outcomes by CDC and to assess technologies by FDA.	- insufficiency of studies of existing technologies, particularly medical and surgical procedures - lack of critical mass of skills for conducting cost-benefit and cost-effectiveness studies - imbalance between action agencies' needs for standards development and knowledge development agencies' capabilities for providing them - no comprehensive technology assessments being conducted and insufficiency of discrete societal impact studies - insufficient effort to identify lagging and absent beneficial and cost-saving technologies - Little theoretical work being done on adoption and diffusion of medical technologies - Insufficient emphasis on methodological studies to improve the state-of-the-art of technology-based analysis and testing studies - ineffective linkage between study findings and agency actions to stimulate or impede technology development	- correct current imbalance of agency agendas - launch new analysis and test efforts in appropriate agenc - evaluate quality of agency studies and staff capabiliti and use findings as basis for realigning agency responsibi - consider NCHSR proposal for comprehensive technology ass ment
agency levels based		development	

COMPONENTS	CURRENT ACTIVITIES	DEFICIENCIES	PROPOSED INITIATIVES
eview and Synthesis	- NIH has begun to formally synthesize test results (e.g., on hypertension and breast cancer screening) and has developed a proposal for extensive review and synthesis activities - FDA has a formal, structured synthesizing process for reviewing efficacy and safety test results - NCHSR has begun to issue ad hoc non-technical reports synthesizing research findings from related projects in progress - OHPA has announced a Medical Practice Information Demonstration	- primarily conducted retrospectively in response to ad hoc questions e.g., reimbursement for Medicare - no mechanism for assuring systematic "translation" of scientific and technical information for DHEW policy and decision-makers or for non-DHEW users	- create a Department-level capability for oversight and management of review, synthesis and translation of study findings to relevant users in and outside of DHEW - consider NIH proposal for creation of an Office of Medical Applications of Research
ecisionmaking	- FDA has an explicit process for decision-making regarding approval for marketing of drugs and devices	- no mechanism to assure consistency and coordination of agency decisionmaking - no mechanism to assure that relevant study findings are used to formulate new Departmental policies integrated across program lines	- assign responsibility to Department-level unit to facilitate coordinated agency decisionmaking and policy development and to involve outside parties-at-interest in collaborative effort
Intervention Mechanisms	- FDA approves or disapproves the introduction of drugs and devices into the marketplace - National Guidelines with quantitative standards have recently been published in Federal Register - Planning agencies, BHPRD, and PSROs are in early stages of implementing their respective programs - HCFA makes ad hoc decisions about Medicare reimbursement for questionable technologies - NIH reports substantial technology transfer activities in information dissemination, professional and consumer education and demonstration projects - NCHSR supports user groups to facilitate adoption of validated technologies - An Office of Health Information and Health Promotion was recently established in OASH	- most intervention mechanisms still in developmental stages standards for medical devices not yet developed - PSROs not yet established in close to half of the designated areas - appropriateness review standards not yet developed - National Guidelines for Health Planning delayed, and technical assistance structure for HSAs and SHPDAs still evolving - regulatory decisions hampered by lack of technical consensus on standards for efficacy, safety, cost-benefits, and cost-effectiveness, and appropriate conditions for use of technologies - professional education efforts insufficient to needs of practicing physicians for information about appropriateness and effectiveness of technologies - information dissemination effort inadequate to need - consumer education efforts still in definition stage - allocation and reallocation of R&D not perceived by the agencies as an intervention mechanism - inadequate attention paid to market incentive mechanisms to stimulate lagging or absent beneficial and cost-saving technologies which fall between the cracks of health system incentive structure	- create a Department-level capacity for oversight and management of a balanced strategy for impl and/or stimulating technology development, adoption, and uti zation - evaluate and strengthen action agencies' capabilities for man ment, adoption, transfer, uti zation and phase-out of techn ogies - create a new locus for profes sional education on utilizatio of technology - establish formal linkages bet Department and other Federal entities and private sector to develop collaborative efforts for managing technology - launch a new initiative to id lagging and absent beneficial technologies which fall outsi of the health system incentive structure - develop a departmental policy relating patent and licensin actions to DHEW decisions to encourage or discourage innov tions resulting from DHEW-fun R&D

To emplace the proposed technology management system, there will need to be jurisdictional clarifications and realignments among the agencies as well as assignment of new responsibilities and authorities and resources. There are two general approaches to development of the proposed system:

(1) A "tabula rasa" approach is the most free form (but it might be considered politically naive). It would assume no constraints on shifting existing institutional capabilities or responsibilities, and would thus be unfettered in developing a set of jurisdictional assignments, component linkages, etc. The agencies' roles would then be reformed around the new responsibilities.

(2) An "organizational-change-on-the-margin" approach would adhere to legislated missions, existing professional skills, experience, and so forth, and would design options that fit around existing arrangements and propose marginal changes in the agencies. It is the least disruptive and quickest approach, though the one most likely to be compromised by agency momentum.

The Study Team has concluded that elements of each will be required: marginal change where agencies have demonstrated competence (e.g., efficacy and safety testing of drugs and devices; implementation of certain action mechanisms), and totally new development of such components as agenda-setting, monitoring and screening, review and synthesis, and technology transfer mechanisms.

This month-long Phase I study did not include independent assessments of agency performance or staff capabilities. To advance organizational change alternatives that attempt to overcome current agency deficiencies and, at the same time, take best advantage of existing capabilities would therefore overstep the Study Team's knowledge base. The Team believes it would be more appropriate to assign precisely this responsibility to a Phase II study as recommended in Section IX.

B. Management of the Proposed Technology System

Does the proposed system require direct management or can its operation be left to the participating agencies? Departmental systems process requirements (like the annual evaluation agenda or the forward plan) typically assume a very low priority

totally new development of such components as agenda-setting, monitoring and

for agencies which are constantly trying to discharge major substantive responsibilities. In addition, institutional histories, fragmenting constituent pressures, interagency territoriality, etc. create centrifugal forces that tend to drive agencies apart and frustrate even such simple goals as information exchange. Where they do interact, their understandable jockeying for bureaucratic advantage siphons energy away from the enterprise. For these reasons, the alternative option of leaving the management of the proposed technology system to a joint undertaking of the agencies is not presented for consideration.

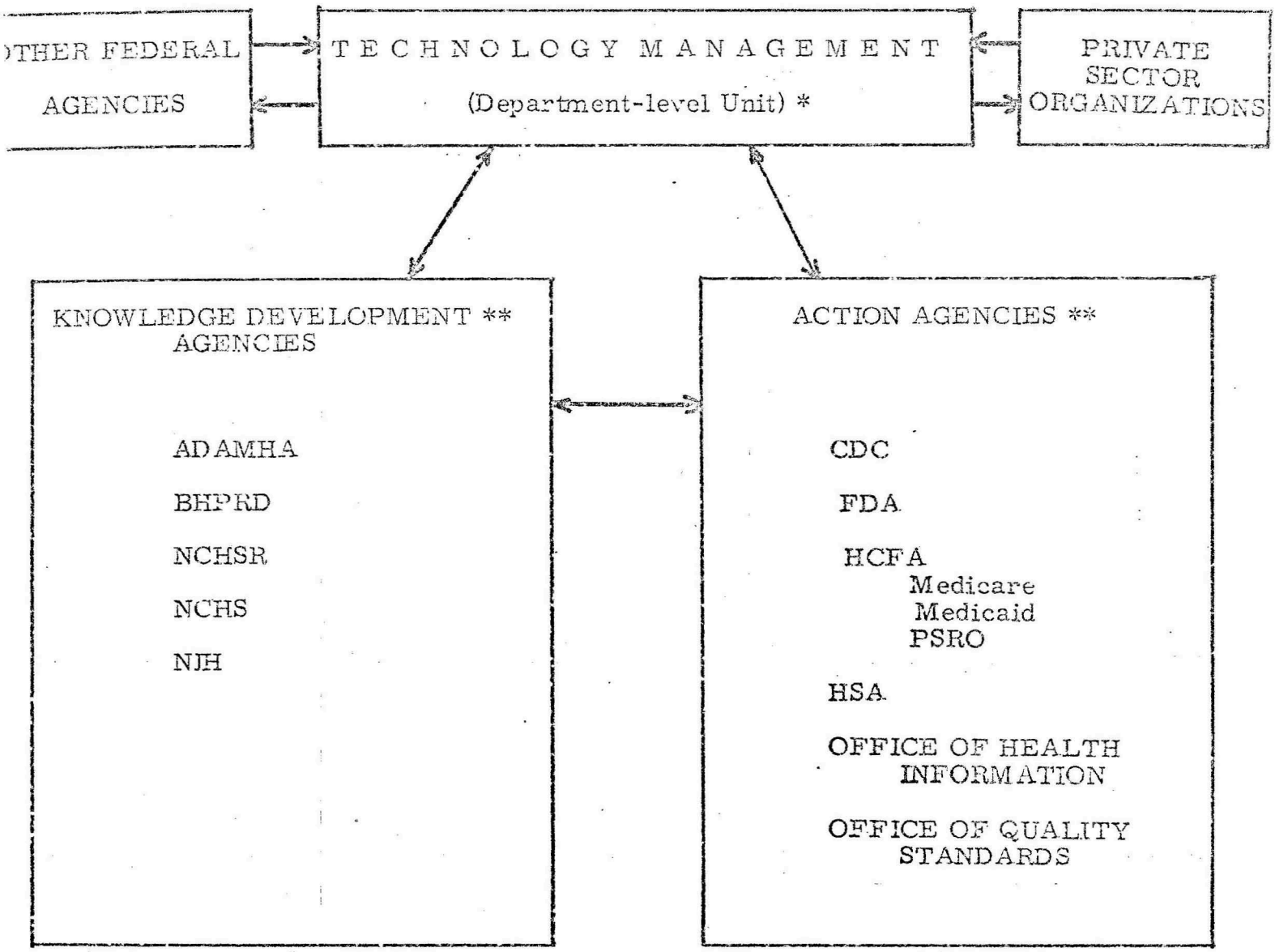
The Study Team has concluded that there is a need for establishment of a new technology management unit, and that such a unit should be located at the Department level. The functions of this unit (as shown in figure 3) might include system development, management, coordination, technical assistance, policy development, monitoring and evaluation, liaison, and information clearinghouse. The following are illustrative examples of the unit's activities; they would be more precisely defined by the Special Project Manager's decision memo (See Section IX) relating to unit location and resources, and by the unit's evolving definition of goals, functions and priorities.

SYSTEM DEVELOPMENT - The unit would initially focus on giving operational definition to the conceptual framework, and on guiding the developmental activities related to integrating the six-component system with Departmental structures and processes. Examples of the unit's developmental activities would include:

-- determination of the feasibility and cost-effectiveness of developing a system to (a) identify and monitor technologies; (b) inventory and monitor health needs; and (c) screen the existing and developing technologies to select candidates for intensive study;

Figure 3

Functions and Relationships of Proposed
Technology Management Unit



*PRIMARY FUNCTIONS
- -Management
- -Coordination
- -Technical Assistance
- -Policy Development
- -Monitoring and Evaluation
- -Liaison
- -Clearinghouse
- -System Development

** Agencies are identified in terms of their primary mission vis-a-vis technology-based knowledge development or action

-- in collaboration with the agencies, definition of the leadership, coordination and technical functions through which the agencies would participate in the technology management system and the six-component process;

-- development of a process through which the Department can collaborate on technology management problems with other relevant Federal Departments (e.g., VA, DoD, NASA, NSF, OSTP) and the private sector parties at interest (e.g., health insurers, providers, technology developers, Institute of Medicine, academic institutions, medical specialty groups and public/consumer interest groups);

-- preparation of a timetable for the annual technology agenda cycle.

These system development activities would be undergirded by information obtained from the Phase II study which is initiated by the Special Project Manager and transferred to the technology management unit staff as soon as they are appointed. As shown in Appendix Tab 13, the Phase II study would be structured so that the tasks that provide technical data and information needed for the system development activities are "front-ended", thereby giving the new unit's staff a major head start.

MANAGEMENT OF HIGH-PRIORITY TECHNOLOGIES - In the operation of the six-component system for addressing selected high-priority technologies, the unit would maintain timetables, convene or coordinate convocation of DHEW agencies and extra-Departmental participation, monitor and report progress, etc.

-- Monitoring and Screening: oversee generation of a list of "coarse screened" candidate technologies and health problems;

-- Agenda-setting: in collaboration with the agencies and outside parties at interest, convene expert judgment to "fine screen" the choice of candidate technologies; prepare an Annual Technology Analysis Agenda proposal that recommends to the Secretary the

high priority technologies to be studied, the types of studies to be performed and by which agencies, the schedule for their completion, etc.; advise relevant parties of Secretarial decisions;

-- Analysis and Testing: while the agency assigned to conduct a study will be responsible for the technical design, the unit will, where necessary, coordinate inter-agency participation in study design; it will monitor timetables of the studies and act as an information clearinghouse on studies' progress--particularly for potential extra-Departmental users;

-- Review and Synthesis: scheduling, monitoring, and providing technical assistance to the agency(ies) responsible for preparing user oriented syntheses of high priority studies and other relevant information and data;

-- Decisionmaking: prepare (in collaboration with both action and knowledge development agency staffs) a decision memo for the Secretary recommending a conclusion based upon the weight of technical findings and judgment, and a series of coordinated action steps to convert that conclusion into policy and program changes; following the Secretarial decisions, communicate decisions to relevant parties;

-- Intervention: monitor and periodically report on agencies' progress toward effecting implementation actions (e.g., reimbursement changes, professional education initiatives, new draft legislation); facilitate liaison with parties at interest outside of the Department to encourage complementary actions.

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relevant information and data;

GENERAL ACTIVITIES

-- Coordination: Where needed, the unit would help design linkages between action and knowledge development agencies to facilitate exchange of information needs, technical findings, etc. for those technologies not a part of the annual high-priority process.

-- Technical Assistance: The unit would respond to requests from the agencies for technical assistance in the operation of their internal technology management systems; it would advise agencies of the lessons learned (both positive and negative) from the operation of the high-priority system; it would request technical assistance from the agencies or from outside the Department relating to continuous refinement of the Department's technology management system; and it would provide technical assistance to other Federal and non-Federal parties on their technology management interests.

-- Policy: The unit would function as a catalyst and Departmental focal point for the development and refinement of policies relating to technology management, and would participate in preparation of legislative, budget, and management proposals to implement those policies.

-- Monitor and Evaluate: The unit would monitor (on an ad hoc basis) agencies' management of non-priority technologies and identify where technical assistance is needed and where there is need for formal evaluation activities; it would identify conceptual gaps in knowledge development and intervention activities and participate in the development of model approaches to overcoming those deficiencies.

-- Liaison: The unit would function as the Department's focal point (though not the exclusive agent of) liaison with outside parties and agencies with which to link our technology management activities; to develop collaborative working relationships through which to facilitate joint action on specific technologies; to monitor other agencies' research and technology management activities and relate them to the Department's activities; to explore opportunities for interagency agreements and joint funding; to participate in improving the evolving state-of-the-art of technology management.

-- Clearinghouse: Depending upon the capacity, location(s) and structure of the monitoring and screening component, the unit might take on "switching point" activities for incoming inquiries related to health technologies being addressed within the Department and for inquiries within the Department relating to other Federal or non-Federal health technology-related activities.

Several alternatives for the organizational locus suggest themselves: OASH (given the health orientation of this initiative) in its program unit, its policy unit, its special health initiatives office, or, because of its signal importance, in the Assistant Secretary's immediate office; OASPE if considering extending the system to educationa technology, telecommunications policy, etc.; or some direct staff arm of the Secretary or Under Secretary. The scope of this study does not permit evaluation of these and other alternatives. The Special Project Manager's 45-day analysis (see Section IX) of the unit's location, staffing, authorities, etc., should make a recommendation from among an evaluated set of options.

C. Recommended Approach

It is recommended that the Department adopt in principle both the technology system as outlined and the emplacement of a Department-level technology management unit; and that further definition of the unit and refinement of the system be sought through a 45-day analysis and a six-month Phase II system implementation study.

IX. RECOMMENDED NEXT STEPS

This report has presented a strategy for managing medical technology at DHEW. It has described a comprehensive technology system and the management of that system. In addition, it has compared the technology-based activities of the Agencies within each component of the proposed technology system and has recommended initiatives needed to close the gaps and correct the deficiencies. Those component-by-component recommendations are embodied in the following summary recommendations for next steps.

Recommended Step 1: endorsement in principle of the development of a Departmental technology system along the lines of the six components outlined, and the establishment, at the Departmental level, of a unit with the responsibility for managing such a system.

Recommended Step 2: appointment of a Special Project Manager

(a) to prepare a decision memorandum within 45 days that examines alternatives and makes recommendations regarding the technology management unit (e.g., organizational location, authorities and responsibilities, staffing); and

(b) to promptly undertake a follow-up to this study to recommend those changes in Agencies' jurisdictions and responsibilities necessary to implement each component of the technology system and to develop an approach to Departmental collaboration with outside parties-at-interest. See Appendix tab 13 for outline of the Phase II study.

Recommended Step 2: appointment of a Special Project Manager

Recommended Step 3: in addition to release of this report for broad circulation, transmission of a copy to Senator Kennedy in light of his major contribution to consideration of this subject.

Recommended Step 4: following completion of the Decision Memorandum described in Step 2 (a), establishment of the technology management unit, and transfer to it of activities begun under the Special Project Manager.

Note. On one issue related to Step 2 (b), the Study Team did not reach consensus. One opinion held that if the Department committed substantial resources to the Phase II Study, organizational change decisions could be made in six months. Consequently, the NIH and NCHSR proposals should be considered in the context of the Phase II Study, and not advanced for a separate Secretarial decision at this time. The contrary opinion held that the Phase II Study and decisionmaking process would take a full year, and that, while they might need to be altered in light of Phase II results, the NIH and NCHSR proposals should be advanced at once, recogniing that their approval would provide needed capability more quickly.

APPENDIX 1: GLOSSARY

MEDICAL TECHNOLOGIES: The drugs, devices, medical and surgical procedures used in medical care. Some definitions of this term include the organizational and supportive systems within which such care is delivered. For this study, however, only the former definition is used.

KNOWLEDGE-DEVELOPMENT AGENCIES: Those agencies in the Department whose primary mission is the development of knowledge relating to health or health care. These agencies conduct or sponsor analysis and testing activities. While their primary mission is knowledge development, they may have some significant action functions.

ACTION AGENCIES: Those agencies in the Department whose primary mission is the administration of programs which can affect the development, diffusion, or utilization of medical technologies. These agencies manage the Intervention Mechanisms. They may however, have some knowledge-development capabilities and functions.

EFFICACY: Potential benefit from a medical technology applied for a given medical problem to individuals in a defined population. Efficacy is sometimes used to refer to benefit under ideal conditions of care to differentiate it from effectiveness, which would then be benefit under average conditions of care. We have not made that distinction here; instead, we regard benefit under ideal conditions as a special class of efficacy.

SAFETY: The probability that a medical technology applied for a given medical condition to individuals in a defined population will not cause disease, injury, or harm.

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the administration of programs which can affect the development, diffusion, ...

COST-BENEFIT ANALYSIS: Analysis which compares the monetary value (usually in present value terms) of future benefits with the monetary value of all immediate and future costs (usually in present value terms).

COST-EFFECTIVENESS ANALYSIS: Analysis which relates resource costs to the levels of effectiveness of alternative technologies under study. Their goal is to identify: 1) the alternative that maximizes effectiveness for a given resource cost, or 2) the alternative that involves the least resource cost to attain a specified level of effectiveness.

TECHNOLOGY ASSESSMENT: A relatively new approach to comprehensive policy studies which has a relatively defined set of conceptual parameters. The most commonly accepted definition of technology assesment (TA) is:

> "TA 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..." (J. Coates)

This term is increasingly being used to refer to any technology-based policy analysis or planning. We have restricted our use of the term to the first sense because the term was coined explicitly by the Congressional Office of Technology Assessment to distinguish comprehensive technology assessment from other technology-based studies which examine such discrete aspects as efficacy, cost-benefit, or cost-effectiveness.