STEP 2: that you appoint 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.

approved_____ disapproved_____ date_____

STEP 3: that, in addition to releasing this report for broad circulation, you transmit a copy to Senator Kennedy in light of his particular interest in this subject.

approved_____ disapproved_____ date_____

STEP 4: following completion of the decision memorandum described in step 2 (a), that you establish the technology management unit, and transfer to it activities begun under the Special Project Manager.

approved_____ disapproved_____ date_____

Henry Aaron

Henry Aaron

Date

ROUTING AND TRANSMITTAL SLIP

TO: (Name, office symbol, room number, building, Agency/)	Initials	Date
1. Mr Latker		
2.		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested	X	For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

Attached is Sherry Arnstein's paper.

PATENT BRANCH, OGC
DHEW
JAN 3 1978

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Seymour Perry, M.D.	Phone No.

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OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

DRAFT: January 11, 1977

TECHNOLOGY ASSESSMENT: PROPOSED PROGRAM AND PLAN OF ACTION FOR NCHSR

Introduction:

Technological innovations in health and medical care have spawned both desirable and undesirable impacts. On the assets side of the ledger are such intended effects as the eradication and prevention of some diseases, the ability to alleviate much pain and suffering, the saving of lives, the restoration of unproductive lives, and the extension of productive lifetimes.

On the liabilities side of the ledger have been such unanticipated and unwanted side effects as the sharp escalation of health care dollar costs, the inequitable distribution of the benefits and disbenefits, the ability to prolong life in a degraded state, an increase in unnecessary patient risk, the introduction of coercive behavior control, the spread of social dependence, the invasion of personal privacy, and the violation of human rights.

Today there are literally hundreds of nascent technologies in the various public and private R&D pipelines, and policymakers are becoming increasingly concerned about the lack of a systematic early warning and assessment system to alert them to their potential arrival and to the myriad of positive and negative effects that they may bring in their wake. The creation of such a system would enable health policymakers and decisionmakers to plan more effectively for (1) modification or regulation of equivocal technologies, (2) improved diffusion of beneficial technologies, (3) stimulation of needed lagging technologies, and (4) arrestment, if necessary, of undesirable technologies.

In the past, ad hoc studies such as cost-benefit, cost-effectiveness, technical feasibility, and clinical trials have been used to assist decisionmakers and policymakers with these technologically-based judgments. When these studies were conducted sufficiently early in the R&D process, they generally have proved quite useful for determining the technology's feasibility, safety, efficacy, and dollar costs.

In more recent years, however, new health and medical innovations like the CAT Scanner (Computerized Axial Tomography) have been catching public policy-makers and decisionmakers off their guard -- surprising them both by their unheralded arrival and their unwelcome effects on the cost of health care.

In the future, some of the now nascent technologies -- e.g., the nuclear powered heart, the male birth control pill, biofeedback devices, computer-based diagnostic algorithms, national computerized patient records, cloning, ectogenesis, and prenatal sex selection -- auger even more profound side effects which will transcend straightforward issues of dollar cost and effectiveness into the more value laden realm of social costs and benefits to the patient, the family, and the society at large.

Thus, in the future, health decisionmakers and policymakers will need to be alerted both to the traditional dollar cost-benefits as well as to the more pervasive social-cost benefits of some nascent technologies. Moreover, in light of the interdependence of societal systems, they will need to be able to distinguish between those future technologies which are likely to affect only health institutions as opposed to those which are likely to stimulate major spillover perturbations on other sectors of society -- transportation, energy, materials, environment, religion, education, values, mores, ethics and life style.

To make these distinctions, decisionmakers and policymakers will need to be armed with data and information based on both conventional studies such as cost benefit, cost effectiveness, feasibility, and clinical trials as well as more holistic, interdisciplinary studies exemplified by the new field of technology assessment (TA).[1/]

Technology Studies Group (TSG):

In response to the need for an early warning system, the Policy Board of Health Resources Administration (HEW) recently approved the creation of a new pilot Technology Studies Group (TSG) within the National Center for Health Services Research. The mission of the new TSG is to provide cogent research based analysis and options on technology related problems to decisionmakers and policymakers concerned with the short-term impacts and long-range consequences of new and nascent health technologies. Its

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1/ Technology Assessment (TA) is an interdisciplinary form of policy research. It focuses not only on first-order impacts and consequences (namely the intended impacts of a technology) but the second and nth order effects (namely the unanticipated and unplanned long-range impacts and consequences and the interaction among them.) The analytic strategy identifies the parties-at-interest to a technology and examines their perceptions of who benefits and who loses. Moreover, a TA looks at both quantitative and qualitative effects of a technology recognizing that some of the most profound impacts and consequences may not be quantifiable. The holistic approach is designed to improve public policymaking by clarifying certainty from uncertainty about how a future technology is likely to affect society as well as how a future society is likely to affect the use or abuse of a technology. Technology assessment was conceived initially in the Congress in the late 1960's and has been pioneered by several federal agencies, most particularly the National Science Foundation, the Environmental Protection Agency, NASA, and the Department of Transportation.

decisionmakers and policymakers concerned with the short-term impacts and

multidisciplinary staff will concern itself with the following kinds of questions about a new technology:

-- When is it likely to come on line?

-- Is it feasible to produce?

-- Is it safe?

-- Is it efficacious?

-- Is it effective?

-- Does it produce clinical side effects?

-- What does it cost to produce and purchase?
-- How will it impact the cost of health care?
-- Does it improve health?

-- Does it reduce pain and suffering?

-- How might it be abused and by whom?

-- Are there better alternatives to meet the objective?

-- Are its intended and unintended impacts limited to the health system?

-- If not, what are the potential unintended impacts and consequences that extend beyond the health system (e.g., on the economy, on the culture, on the mores, on the environment, on the legal political system, on the family, on other social institutions, on balance of trade, etc.).

-- Who are the parties-at-interest and which will be benefited or disbenefited?

-- Who are the relevant decisionmakers and policymakers?

-- What public policies could avert or minimize its undesirable effects?

-- What public policies could enhance its desirable effects?

Functions and Major Tasks of TSG

The Technology Studies Group will have a two-pronged function:

1. To provide technology related information for the Bureaus, Centers and Offices of HRA (B/C/O's) on near-term problems and issues -- e.g., analysis of burn unit technology, state-of-the-art of the mini-GEMSAEC, economic impacts of computerized EKG's, or cost effectiveness of CAT Scanners.

2. To provide an early warning system for B/C/O's and other relevant policymakers on long-term technology problems and issues -- e.g., potential unintended and unanticipated effects of emerging technologies such as nuclear powered hearts, computer generated diagnostic protocols, ectogenesis, male birth control pill, biofeedback devices, and anticaries vaccine.

The first function will be fulfilled by employing such traditional studies as economic impact, technical feasibility, cost benefit, etc. The second function will be addressed by employing such newer research strategies as comprehensive (macro) and partial (mini) technology assessments. By lodging the responsibility for both functions within a single TSG, it will be possible to both improve the state-of-the-art of long-term technology assessments and to insure that these improved methodological techniques are incrementally employed in the near-term studies when they are applicable (and not naively employed when they are inapplicable).[2/]

To carry out this dual function, the TSG will assemble the requisite core of research and analytic skills to carry out the following services:

2/ Attachment A provides a Taxonomy of Technology Studies which illustrates their similarities and differences in terms of the kinds of questions they address, the kinds of analytic parameters they include or exclude, and the depth of analysis they normally employ for the various parameters.

-- Provide technical consultation to the B/C/O's on ill-defined technology-based problems and issues.

-- Define and refine technology-based issues into researchable problems.

-- Define the scope and parameters of specific studies to be performed.

-- Provide technical consultation to ad hoc intramural teams which will conduct follow-up studies.

-- Conduct or sponsor follow-up studies.

-- Monitor grantees and contractors.

-- Conduct or sponsor background studies (e.g., tracking system for identifying potential technological innovations, game simulation for communicating technical data to lay parties-at-interest, and methodology for social impact analysis.

-- Develop collaborative arrangements with other relevant federal agencies and NCHSR's Health Care Technology Center.

-- Develop collaborative arrangements with other parties-at-interest, e.g., industrial drug and device corporations, third party payors, public interest and consumer groups, contract research groups, universities, professional provider associations.

-- Create a Sounding Board (or Advisory Committee or Study Panel) to provide continuing advice to the TSG on such matters as potential technological developments and issues, methodological innovations, research strategy, dissemination of findings, etc.

Potential Users of TSG

The TSG will serve three primary clusters of potential users:

1. Internal to HRA -- Bureaus, Centers and Offices of HRA
2. Internal to HEW -- HSAs, OS, FDA, NIH, ADAMHA, SSA, NCHPD
3. External to HEW -- professional provider associations, (AMA, AHA, AAMC, ANA, ADA, APHA, MCHR, NMA, NDA) insurers, manufacturers, health researchers, consumer groups, public interest groups, and other federal agencies affected by health care technologies (NASA, DOD, NSF, OTA, EPA, ERDA, DOT).

Procedures and Work Flow of TSG

The modus operandi for the Technology Studies Group (TSG) is schematically illustrated in the Work Flow Chart (Attachment B). As shown on the chart, there will be three types of input requests to the TSG: (1) Technical Consultation for B/C/O's on ill-defined technology based issues; (2) Nomination by B/C/O's of candidate technologies to be studied; and (3) Nomination by external users of candidate technologies to be studied.

1. Technical Consultation will enable non-research staff from the B/C/O's to bring ill-defined technology-based issues to the TSG to determine if it is a researchable issue and/or whether it is better addressed via a non-research strategy, e.g., the research might have already been conducted, or the problem might not be reasonable within the available decision making time frame, or critical data might be

unavailable. This consultation will result in a decision to nominate a technology to be studied by the TSG, or to have either the Extramural staff of NCHSR or the B/C/O contract for a conventional study, or a decision that no further study is needed.

2. Nominations of candidate technologies from B/C/O's will be screened by the TSG in consultation with the Director of the Intramural Division and the Director of NCHSR using explicit criteria which are set forth in a later section of this document. After a candidate technology has been selected for study, the TSG will convene an ad hoc team (7-10 disciplines and parties-at-interest relevant to the specific technology) to participate in a Micro-Technology Assessment. The Micro-TA (a cursory and heuristic, analytic exercise for examining a technology holistically which primarily involves focused brainstorming and structured analytic modeling) will be managed by members of the TSG. Participants of the ad hoc team will be asked to devote 3-4 person days to the exercise, while members of the TSG will be responsible for the backup research and analysis of the data and information derived from the participants. The Micro-TA report will include a definition and refinement of the research problem as well as a judgment about the type and scope of study which is most appropriate to the problem. It also will include a cursory description of the state-of-the-art of the technology, its potential impact domains, its parties-at-interest, the central available literature and technical experts, the options for bounding the study, data gaps, and the key methodological problems to be faced in conducting the follow-up study. For example, a Micro-TA conducted on a computerized EKG is likely to

primarily involves focused brainstorming and structured analytic modeling)

result in a judgment that it is a straighforward technology which raises no significant psychological, cultural, environmental, ethical and political questions and thus the appropriate follow-up is a straightforward cost effectiveness study. On the other hand, a Micro-TA conducted on a nuclear powered implantable heart is likely to reveal that it raises profound questions about environmental radiation impacts, psycho-social impacts, ethical questions, and political legal problems and, therefore, a Mini or a Macro-TA is called for.

When the Micro-TA results in a decision to conduct a follow-up conventional study, the extramural staff of either NCHSR or of the relevant B/C/O will contract out for the study, monitor the contractor, and be responsible for disseminating the findings.

When a Micro-TA results in a decision to conduct either a Mini or a Macro-TA, the TSG will solicit grant or contract proposals or conduct the study intramurally. The TSG will monitor grantees and contractors of TA's and will handle dissemination of findings to all parties-at-interest.

Note that the NCHSR will be reimbursed for all follow-up studies conducted at the request of B/C/O's and that during the first year of operation, it is not expected that the TSG will conduct any TA's in-house since it will be limited to 2-3 staff members.

3. Nomination of candidate technologies from external users will follow the same work flow as those nominated by B/C/O's. However, special efforts will need to be made to obtain funding assurance to carry out such follow-up studies since these nominations may not have high funding priority for the B/C/O's.

During the first year of operation, the TSG will actively solicit candidate technologies to be studied by reaching out to relevant internal and external potential users to be sure that they are aware of the purpose and capabilities of the TSG. Different outreach strategies will be used for internal and external users:

-- Internal Users: An outreach process for internal users is already in process. The Senior Fellow in charge of the TSG has been actively soliciting candidate technologies to be studied by conducting interviews with the Director and relevant staff of the B/C/O's. Nominations received to date for the first Micro-TA's are (1) anti-caries vaccine, (2) mini GEMSAEC, (3) waste heat recovery technology for hospitals, (4) antifibrillatory drug, (5) continuous renal dialysis machine, (6) artificial pancreas, (7) hospital based mini cyclotron, (8) liquid dental decay treatment, (9) continuous (but reversible) contraceptive, (10) a blood test for cancer detection, (11) anti-gonorrhea immunization, (12) coronary artery surgery.

-- External Users: The TSG will hold a conference to brief potential external users of the creation of the group and to solicit candidate technologies which have high salience for them. To assure that the conferees are substantively equipped to focus on the complexities of the assigned topic, they will be sent an advance background paper on TA, and the conference might open with a three hour simulated Micro-TA to give the participants first hand experience with the TA concept.

Criteria for Selection of Technology Studies:

The following criteria will be used to determine not only which candidate technologies will be studied but the priority to be given to starting a study.

-- Policy relevance (importance of decision or policy that hinges on the proposed study).
-- Availability of staff or consultants' relevant to the candidate technology.
-- Availability of funds to carry out a proposed study.
-- Degree of potential controversy (Higher priority will be given to those technologies which are likely to raise significant controversial questions about dollar and social costs.
-- Time frame available (amount of time available before decision or policy choice must be made).
-- Amenability to research (sufficient data and information are available and the proposed study does not duplicate work being done by another Federal agency.)

study.

Important Caveats:

It is essential that expectations of the TSG be realistic and take into consideration the numerous constraints under which it is being launched. For example:

-- During the first year of operation, the TSG will be staffed with the equivalent of 2.5 persons and during the second year with five. Neither a three nor a five person group can be expected to conduct large studies intramurally since even one cost benefit study, for example, could easily absorb the full time efforts of three people for an entire year. If this were done intramurally it would divert, in fact preclude, the TSG from providing any of the other proposed activities.

-- No job slots currently are available for the TSG. Thus, the staff will be recruited via the Intergovernmental Personnel Act. IPA Fellows are available only within academic time frames and must come and go during a one or two year period. This in and out process will heavily impact the decisions about which technologies to study and the time frame in which they must be done. Moreover, because IPA's are by definition short-term and temporary, the TSG will not be able to develop a built-in memory, and much time will have to be devoted to recruiting and orienting new staff to lessons learned on prior studies.

-- The TSG has been created to be responsive to a set of internal and external users who may demand only studies on immediate problems

and crises and may discount future potential crises. If this occurs, the TSG will not be able to mount a coherent research strategy with a valid balance of near-term and long-term problems.

-- There are no set aside funds for the TSG to enable long-range planning and smooth functioning. Each study, therefore, will have to be negotiated separately and procedures worked out for transfers of interagency funds which are likely to cause delays and even wasted staff efforts. Moreover, the current funding strategy provides no funds for background studies which should form the basis of such a new program initiative since each of the B/C/O's will be interested in funding only those studies which are of direct and immediate interest to them. Thus, cross-cutting methodological studies designed to improve the state-of-the-art and studies to gather generic data or information are unlikely to be funded.

Accomplishments to Date:

During 1976 a Senior Research Fellow was recruited by NCHSR to design a technology assessment program which might be instituted by NCHSR. A draft design framework was circulated for comments in May 1976, and revised in October 1976. ("Technology Assessment: Opportunities and Obstacles for Health Managers" by Sherry R. Arnstein, accepted for publication in IEEE Transactions in Systems, Man, and Cybernetics, August, 1977.) This design framework reflected the research conducted by the Fellow on the state-of-the-art of the new field of technology assessment as it is being practiced by other federal agencies

and the Congressional Office of Technology Assessment. It included a rudimentary taxonomy of nascent health and medical technologies now in various stages of R&D.

Shortly after this design framework was circulated, the HRA Policy Board created a Task Force on TA which was asked to consider how a technology assessment program might be created to serve the needs of all the Bureaus, Centers and Offices of HRA. (Task Force report entitled "Technology Assessment in HRA", was presented to the Policy Board on September 17, 1976).

Following the approval of the HRA Policy Board to create a TSG within NCHSR, the Fellow has conducted personal interviews with representatives of the B/C/O's to solicit candidate technologies to be studied and has identified and recruited potential job candidates for the TSG. In addition, the NCHSR has appointed an ad hoc Work Group to develop a plan of action for the proposed TSG to provide the specific functions, tasks, and modus operandi which have been embodied in this document.

Activities for 1st Year:

-- Hire staff
-- Hold conference on TA for potential external users to solicit candidate technologies and to develop continuing lines of interaction.
-- Create Sounding Board for TSG
-- Finalize criteria for selection and procedures for TSG
-- Provide consultation and technical assistance for B/C/O's

-- Conduct 5 Micro TA's -- Intramural

-- Design and monitor 3 Mini TA's -- grant or contract

-- Design and monitor 2 Macro TA's -- grant or contract

-- Design and monitor 3 background studies -- grant or contract (e.g., early alerting and tracking system on nascent technologies, structural analysis modeling, game simulation, scenario development, adversary TA models, and techniques for public participation in TA.

-- Develop collaborative relationships with other federal agencies, e.g., NIH, FDA, NSF, President's Panel on Biomedical and Behavioral Research.

-- Monitor methodology and final TA reports from other agencies (particularly EPA, NSF, DOT, and NASA and OTA.)

-- Establish collaborative relationship with NCHSR-funded Health Care Technology Center at University of Missouri.

-- Prepare two or three technical papers and articles on TA in health care.

-- Prepare two or three non-technical articles on TA in health care.

Expenditures for 1st Year:

-- Five Micro TA's (consultants)	$ 15,000
-- Three Mini TA's	175,000
-- One Macro TA	300,000
-- Two Background Studies	150,000
-- One conference	30,000
TOTAL	$670,000

Activities for 2nd Year:

-- Continue ongoing activities of 1st year

-- Hire staff (2 additional IPA Fellows)

-- Provide technical assistance to B/C/O's

-- Conduct 8 Micro TA's intramurally

-- Design and monitor 3 Mini TA's: 1 Intramural, 2 Extramural

-- Design and monitor 3 Macro TA's

-- Design and monitor 2 Background Studies

-- Conduct conferences on completed TA's for parties-at-interest

-- Prepare two or three technical papers and articles on TA in health care

-- Prepare two or three non-technical articles on TA in health care

Expenditures for 2nd Year:

-- Eight Micro TA's (Consultants)	$ 24,000
-- Four Mini TA's	240,000
-- Three Macro TA's	900,000
-- Three Background Studies	200,000
-- Three Conferences	90,000
TOTAL	$1,454,000