

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE



ORGANISATION MONDIALE DE LA SANTÉ
BUREAU RÉGIONAL DE L'EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPA

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

INDEXED

*Technology, Medical - Copenhagen
Technology, Medical - Europe*

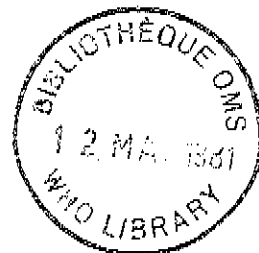
Consultation on Development of

NATIONAL MEDICAL TECHNOLOGIES
ASSESSMENT PROGRAMMES

Copenhagen, 27-28 May 1980

Report on a Consultation

Copenhagen
27-28 May 1980



→ H4/48/12
ENGLISH ONLY

3.1.5

1981

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1. Introduction

A Nordic countries/WHO (EURO) Consultation on Development of National Medical Technologies Assessment Programmes was convened at the WHO Regional Office for Europe in Copenhagen on 27-28 May 1980.

The meeting brought together 23 temporary advisers from Denmark, Finland, Iceland, Netherlands, Norway, Sweden, United Kingdom and the USA, as well as staff of the WHO Regional Office. A list of participants is given in the annex. Responsibility for chairmanship of the meeting was shared by Professor V. Gaunó Jensen, Chairman of the Danish Medical Research Council, and Dr H. Poulsen, Director of the Danish Hospital Institute. Dr R.M. Oliver and Mr R.W.B. Allen acted as rapporteurs and Dr A.H.W. Wahba, Regional Officer for Appropriate Technology for Health, as secretary.

2. Scope and purpose

An urgent need has been identified for national policies and strategies on medical technology to ensure coordination of individual and institutional efforts in this field. As a preliminary step, it was felt that the establishment of national medical technologies assessment programmes would provide a sound basis for the development of such policies and would strengthen the provision of comprehensive health services at international level.

The intention of the Consultation was to review three fundamentally different models of technologies assessment in Sweden, the United Kingdom and the USA and discuss how these might be developed to form a rational system of assessment feasible in, and acceptable to, the Nordic countries and other countries in the WHO European Region, with a view to more global application subsequently.

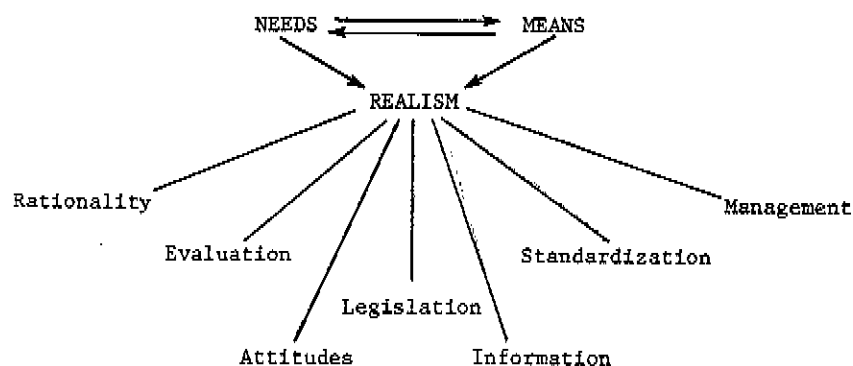
3. Definitions

Medical technologies assessment refers to the systematic analysis of the anticipated impact of a technology or group of technologies with regard to safety, efficacy and utilization and to social, economic and ethical consequences. Coupled with this is the need to define medical technologies, and though there is debate on the scope of this definition, the following formulation was agreed for the purposes of the Consultation:

"Those technologies, equipment, drugs or procedures used in the delivery of health services for prevention, diagnosis and treatment of illness and in rehabilitation."

4. Background

There have been dramatic advances in all fields of medical technology in the last 20 years, mostly geared to better diagnosis. Commercial pressures have been and remain considerable, and there is an increasing need to relate industrial medical development to the planning of health care services throughout the world. There must be a realistic balance between needs for health care and the means by which they may be met. This can be represented diagrammatically as follows:



There can be little doubt that technology improves the assessment, reporting and recording of medical conditions and has assisted in early and precise intervention. There has been miniaturization and increased mobility of equipment for use in numerous health care situations, and there are now many new and powerful means to support failing physical functions.

However, the questions must be asked whether these developments automatically lead to improved overall quality of care for the population or necessarily to improved quality of life. There are many problems. For example, the development of high-level technology inevitably leads to increasing dependence upon it. There is often overemphasis on curative care at the expense of preventive or rehabilitative care. Increasing expenditure in health services often results in rising costs of health care. All this can result in insufficient social orientation to care and lack of cost-consciousness.

5. Models of medical technologies assessments

5.1 Sweden (Mr E. Jonsson)

The unification of medical and social welfare services in Sweden became a reality when the two were combined into the National Board of Health and Welfare (Socialstyrelsen) in 1968. The decentralization of ambulatory health services was encouraged when the Government transferred responsibility for the district physicians and mental hospitals to the counties in 1961 and 1963 respectively.

Today, in terms of expenditure, 87% of medical care in Sweden is delivered at hospitals, 88% of which are operated by the 26 county councils and municipalities in the decentralized fashion defined by reforms of 1864. Thus, it is the counties which are the actual purchasers of medical equipment and, in a sense, it is they who decide whether a new technology is to be adopted.

The policy making of the counties, however, is to some extent constrained by the state. The counties' freedom of choice is also limited by cooperative agreements with other counties to provide specialized services within a regional system created in 1958 and aimed at ensuring the delivery of specific types of services at the level (local, county or regional) where they can be provided most efficiently. This regionalized arrangement of Swedish medical services is mirrored by Sweden's hospital system. There are four levels in the hospital hierarchy: health centres, community hospitals, general hospitals and regional hospitals.

Outpatient services are organized at health centres within each county on the basis of primary care districts. These centres, which form the lowest tier of the hospital hierarchy, are usually staffed by general practitioners who are in charge of ambulatory and preventive care. District nurses are active in home care and sometimes specialize as district midwives or child-care nurses.

At the organizational level above the health centre is the community hospital, which ordinarily provides four specialized services - medicine, surgery, radiology and anaesthesiology - for a population of 60 000 to 90 000.

The third tier of the hospital hierarchy is the general hospital, of which there is usually at least one per county, each serving a population of 250 000 to 300 000. These hospitals offer 15 to 20 specialized services.

The fourth and top tier of the Swedish hospital hierarchy is the regional hospital. There are seven such hospitals throughout the county, each with an average catchment area of slightly over a million people. All but one of these institutions are affiliated with medical schools and serve as centres for research and teaching. Among the specialized services they provide are neurology, radiation therapy, thoracic surgery, neurosurgery, paediatric surgery and various types of cardiac care.

Sweden's four hospital tiers provide a clear "pecking order" for determining who receives sophisticated new technologies. The regional hospitals are the first in line, and the general hospitals^a, community hospitals and health centres follow. The regionalized hierarchy of hospitals provides Swedish health planners with a strategy for optimizing the use of medical technologies and, particularly, for ensuring that highly sophisticated equipment and technology-intensive specialties are concentrated at the regional hospitals.

Medical personnel: education and employment by the State

The external organization of Swedish hospitals provides only a partial picture of the mechanisms at the disposal of Swedish planners to restrain the influx of technologies. In addition, the internal mix of medical personnel and facilities must be analysed. For the sake of

^a County councils do not necessarily feel responsible for introducing a sophisticated new technology to their county's general hospital, because residents may be referred from that hospital to the regional hospital that they also subsidize

brevery, the discussion of medical manpower will be limited to physicians and nurses. As of 1977, Sweden had roughly 15 000 physicians or a ratio of 1 per 515 population. Most Swedish physicians are employed by the State. In 1977, only 6% of Swedish physicians were in private practice.

The State not only employs, but also educates virtually all medical personnel in Sweden. Thus, it is able to match training programmes to anticipated and present needs. By 1985, the numbers of Swedish physicians specializing in long-term care and psychiatry are projected to increase by 130% and 60% respectively. Swedish policy toward the training of specialists who use technology-intensive techniques means that these physicians will be increased by only 28%.

Once physicians are educated in a predetermined fashion, the National Board of Health and Welfare can also decide to a large extent where they will work through its allocation of medical posts. This power not only facilitates planned assignment of physicians at various levels within the hospital hierarchy (from the regional hospital to the health centre), but is also the basis for ensuring their proper geographical distribution. It should not be inferred, however, that Sweden has solved the nearly universal problem of supplying rural areas with physicians. An overall physician shortage in Sweden still allows for mobility.

Mechanisms for control of medical technology

The organizational means that Swedish planners have at their disposal for controlling technology have been discussed without specific reference to who manipulates them. The three bodies that exercise control over the medical care system in Sweden are the Executive and Parliament, the National Board of Health and Welfare and the county councils.

The relationship of the State to the counties is like that of a rider to a horse: the rider can apply persuasive tactics, but, in the final analysis, it is up to the animal to decide on its movements. The steering role of the rider is played by the National Board of Health and Welfare. The Swedish Government uses its fiscal leverage by subsidizing hospital construction. Since 1864, however, counties have had constitutional power to tax their citizens and to decide whether or not to build hospitals, so they control the amount of care available. In summary, the State tries to compel the counties to follow the desired path through regulation and subsidy.

The question persists, however, of how the State decides which course to adopt when a new technology becomes available. To answer this, it is useful to examine the information on which the "rider" depends. The National Board of Health and Welfare has three principal sources of information for evaluating new methods and instrumentation: the National Bureau of Statistics (Statistiska centralbyrån), physicians who serve as consultants to the Board and the Swedish Planning and Rationalization Institute of the Health Service.

The National Bureau of Statistics assembles data concerning all Swedish patients, using their social security numbers. Since these numbers are used for medical identification, all medical services rendered to a given individual can be accounted for and used in tabulating national statistics.

Once health needs and budgetary constraints are known, the strictly medical likelihood of a new technology satisfying unmet needs must be evaluated. This general evaluation of biomedical innovations in Sweden is performed by physicians prominent in their specialties, who also often serve as consultants to the National Board of Health and Welfare. Their task is to assess whether the technology "is consistent with proven scientific knowledge and good experience". These physicians do not appraise equipment on a brand by brand basis, a task which is performed by the Swedish Planning and Rationalization Institute. Instead, they evaluate experimental techniques (such as transplants) or new diagnostic and therapeutic interventions. Overseeing research and development in order to abort innovations that could consume inordinate amounts of resources can, however, be dismissed as playing an insignificant role in Swedish efforts to control technology. Not only is it considered counterproductive to supervise basic science in Sweden, but it would also be impossible to extend such control abroad, where innovations such as the CT scanner and coronary artery bypass operations originated.

Swedish planners do employ another strategy: adjusting manpower policy so as to reduce the number of technology-intensive specialists. Particularly favoured at present in Sweden are physicians and nurses trained for chronic geriatric care and primary care.

A third possibility for control of medical technology, that of funding incentives, could play a role in Sweden's socialized system. It is conceivable that financial pressure could be used indirectly; however, this channel for technology control is rarely used.

A fourth strategy, that of regulating technologies as rigidly as pharmaceuticals, is not appropriate for use in Sweden, because it goes against the "rider and horse" mentality of the Swedish medical structure. As previously noted, the counties in this context are free to make their own decisions.

A fifth strategy, that of a national information agency issuing voluntary guidelines, would clearly be preferable. It is, therefore, not surprising that the Swedish Planning and Research Institute has undertaken to partly fill such an advisory role. The successful functioning of this purely advisory body in planning technology in Sweden goes hand in hand with the regional organization of Sweden's hospital system, since planning the rational diffusion of a technology requires a clear hierarchy in order to prevent duplication. In theory, therefore, Sweden is predisposed towards the second and fifth of the aforementioned containment strategies, namely the manpower and informational approaches. Only empirical evidence about the influx of specific technologies, however, can demonstrate whether these methods work.

5.2 United Kingdom (Dr R.M. Oliver and Mr R.W.B. Allen)

Introduction

Care is needed in the use of the words "research", "development" and "evaluation", since different interpretations can be placed upon them, which can be important for international comparisons. So far as equipment is concerned, there is probably a continuous spectrum from the initial idea to a marketable product which passes through the phases of feasibility bench-type "mock-ups", prototype models, technical and clinical evaluations, further development, production models and perhaps further clinical and technical evaluation. It is frequently difficult to define where each of these phases ends or begins, and this, too, can present difficulties if responsibilities or funding for each phase are different.

Funding of research and development

In England and Wales, over £25 million was spent by the Department of Health and Social Security (DHSS) on health service research development and evaluation in 1978. A large proportion of this - roughly £10 million - was an allocation for "commissioned medical research" administered for DHSS by the Medical Research Council (MRC) and devoted to applied biomedical work judged by DHSS to be important for health care. This is distinct from the other MRC funds, which tend to be directed to more fundamental aspects of medical research.

The rest of the DHSS research funds not handled by the MRC is applied to other defined areas of activity, such as health and personal social services research, National Health Service building, engineering, computers, equipment and supplies. Equipment and supplies research and development, which includes evaluation, accounted for about £2 million out of the total research budget in 1978-79.

A small amount of money is usually available each year for what is termed "special medical developments", which are exceptional features of the NHS that need special funding. In 1978-79, over £1 million was used for this purpose, including £600 000 for building and equipment.

Strategy

The broad strategy for DHSS research on equipment provides for:

- the development of equipment to meet a known need, either where none is available or where the existing equipment fails to meet the need satisfactorily (this may include the development of novel equipment in response to proposals if it can be demonstrated that it would bring a substantial benefit in treatment and diagnosis);
- assistance, as necessary, in improving the performances and reliability of available equipment of United Kingdom manufacture and, where appropriate, stimulation of production in the country;
- support to the activities of the DHSS Supply Division, including investigation of defects of equipment in current use and establishment of standards;
- stimulation of British industry, particularly in the production of medical equipment with export potential.

Control within the United Kingdom National Health Service

In the United Kingdom, considerable autonomy is given to the health authority regions. Most funds for health care are distributed on the basis of population size and characteristics to the health authorities for use as they judge necessary (including expenditure on equipment) within certain general policy guidelines. Although health authorities have considerable devolved powers, DHSS nevertheless does not have inconsiderable influence and makes readily available much needed advice.

Problems of evaluation

Evaluation of equipment has limitations, involving problems for the United Kingdom as elsewhere. Speed is often, though not always, of the essence. To be really useful, results of an evaluation must be available before they are overtaken by events. For example, an evaluation report is of little use if it ceases to be relevant to the equipment currently available. Similarly, if evaluations depend on comparison with other equipment or techniques, then the value is lessened if the alternative equipment has itself changed. Unfortunately, events will not stand still, and commercial considerations often dominate the scene. It is sometimes difficult to weigh up the benefit of evaluation. For example, it may be difficult to judge whether an evaluation actually influenced those for whom it was intended; nor can one easily measure such an effect. The mere demonstration of eventual purchases of recommended equipment does not necessarily imply that this has resulted from the published evaluation. These are not arguments for not making evaluations, but searching questions must be asked to ensure that money devoted to evaluation is well spent.

DHSS Supply Division

The Supply Division of the DHSS has a central responsibility for all aspects of the supply of equipment and materials used by the National Health Service. The Division also has the responsibility for monitoring the United Kingdom health care manufacturing industries and for advising the rest of the central government on the supply of health care equipment and medical consumables. One part of the Division, the Scientific and Technical Branch, has special responsibility for serving as a centre of scientific and professional expertise on almost all equipment and consumables used by the National Health Service. The Branch has a number of roles, but, in the context of this meeting, those which have a particular influence on the assessment of new medical technologies are as follows:

- giving advice to hospitals seeking information which will assist them in making a sound choice of equipment to meet their needs;
- giving advice to health care equipment manufacturers on the performance and safety requirements of the National Health Service;
- encouraging the use of appropriate quality assurance techniques and production standards by manufacturers, including the investigation of defects in hospital equipment, and follow-up to ensure that the defect is corrected both in the equipment already in routine hospital use and in that subsequently sold to the National Health Service;
- developing and ensuring the adoption by manufacturers of appropriate national and international standards applicable to medical equipment.

Evaluation

The Scientific and Technical Branch has been initiating and supporting evaluations for many years now. During the course of 1979, about £600 000 of the Branch's research and development budget was spent on evaluations. The money was used in part for the purchase of equipment to be evaluated (some is loaned by manufacturers), for the support of staff carrying out the evaluation (much of the testing in hospital departments is carried out alongside routine work and, as such, is not charged) and for the development of evaluation methods.

Evaluations which are supported by DHSS are intended to be as comprehensive as possible. They consist, therefore, of an examination of the safety standards and performance criteria met by the equipment, together with a detailed examination of the construction and design in order to assess the reliability and maintainability of the equipment in routine service use. In a limited number of cases, the cost implications are examined, in respect of both capital and revenue, for the hospital department intending to use it.

The evaluations are carried out in centres, usually hospital or medical schools, having expertise in the design and routine use of the equipment under investigation. Existing international standards are used as a basis for performance and safety tests, but if this is not possible and a suitable national standard is available, then this is used. If no relevant international or national standard is available, a carefully prepared evaluation protocol is drawn up to test the equipment. All the evaluations include results of user experience in routine service conditions over a certain period and, where possible, such testing is carried out in a number of centres to avoid personal bias. At the end of the evaluation, a detailed report is prepared by the people who did the work, and, in the first instance, a copy is sent to the equipment manufacturer for his comments, which are generally included at the end of the final report. Thus, any unsatisfactory feature identified by the evaluation can be brought to the manufacturer's attention, and if the funding is accepted by them and the fault is subsequently eliminated from the equipment, this can be acknowledged in the report. This part of the evaluation, in which there is a feedback to the manufacturer, serves an essential function in ensuring that the equipment is safe and has an acceptable performance for use in the National Health Service.

The attached table lists some major equipment evaluation programmes, the centres in which they are carried out, and the dates on which work started.

Since the beginning of 1975, when work had already been under way for a number of years, some 101 evaluations have been reported, 18 being surveys of categories of equipment and the remaining 83 being studies on individual items of new equipment.

MAJOR EVALUATION PROGRAMMES

Equipment	Location	Start	Number of reports
X-ray equipment (test centre)	London	1979	
X-ray equipment (user trials)	Various	1976	22
CT scanners	London	1978	1
Blood pressure transducers	Sheffield	1976	1
ECG recorders	Oxford	1977	1
Cardioscopes	Newcastle	1977	1
Defibrillators	Sheffield	1977	
Surgical diathermy equipment	Cardiff	1977	1
Blood gas analysers	Birmingham	1978	2
Pathology laboratory equipment	Various	1971	66
Aids to daily living	Loughborough	1974	4
Patient lifters	Edinburgh	1975	
Haemodialysis equipment	Aldermaston	1968	15
Haemodialysis equipment (user trials)	Newcastle	1975	2
Infusion pumps	Bath	1979	
Humidifiers	Birmingham	1979	
Breathing machines	Cardiff	1980	
Resuscitators	Bristol	1979	

5.3 USA (Dr C. Lowe)

With the rapidly increasing number of drugs, devices and procedures introduced in recent years, the United States Government has been steadily expanding its medical technologies assessment activities.

Generally, the technology explosion has led to two important problems: some technologies have reached the practising physician without adequate testing; and others, though properly validated, have been too slow in reaching the health care delivery system.

To attack these problems, existing federal health agencies have accelerated efforts to evaluate drugs, devices and procedures, and new agencies have been created to coordinate assessments.

One key component of the federal technology assessment network is the congressional Office of Technology Assessment. Created in 1972, OTA is an advisory arm for Congress, providing members with independent information about potential beneficial and harmful effects of technical applications.

Under the executive branch of the Government - headed by the President - the Office of Science Technology and Policy (OSTP) evaluates the scale, quality and effectiveness of United States efforts in science and technology. In the health area, OSTP has been working with the Health Care Financing Administration (HCFA) to provide a more organized and scientific basis for determining reimbursements. HCFA is the agency responsible for reimbursements for Medicare and Medicaid patients, the federally managed system to meet health costs of the aged (Medicare) and the poor (Medicaid).

In addition to the HCFA, other components of the Department of Health and Human Services (DHHS) are involved to varying degrees in technology assessment. The Food and Drug Administration (FDA), Center for Disease Control, Health Services Administration, Health Resources Administration, and Alcohol, Drug Abuse and Mental Health Administrations are all health agencies with limited capacity and marginal responsibility for evaluating technology. FDA has major responsibility for regulation of a variety of technologies and some capacity for evaluation. The sixth component of the Public Health Service (PHS), the National Institutes of Health (NIH), has a major responsibility for technology evaluation. With the exception of HCFA, all of these are under PHS.

In 1976, amid growing concern about the need for more effective evaluation of medical technologies, the President's Biomedical Research Panel and several members of Congress suggested that NIH take the lead in improving the process of translating the results of biomedical research into practice. The NIH Director, Dr Donald S. Fredrickson, agreed to accept this responsibility and, in early 1977, outlined a process he called "consensus development".

The first consensus conference (breast cancer screening) was held in the autumn of 1977 and, to date, some two dozen conferences have been conducted on subjects ranging from surgical treatment of morbid obesity to removal of third molars. At the conferences, investigators, practitioners, consumers and others are brought together in an effort to reach general agreement and formulate a statement on the safety and effectiveness of drugs and medical, surgical and dental devices or procedures. The technologies scrutinized in this way may be emerging or may already be in general use. The conferences are held in the form of an open forum, where all sides of the issues are explored by the panel and the audience. The conclusions drawn by a consensus panel are printed after the meeting and widely reported. This consensus statement provides the medical community and the public with accurate, current information obtained from experts who are in the best position to know.

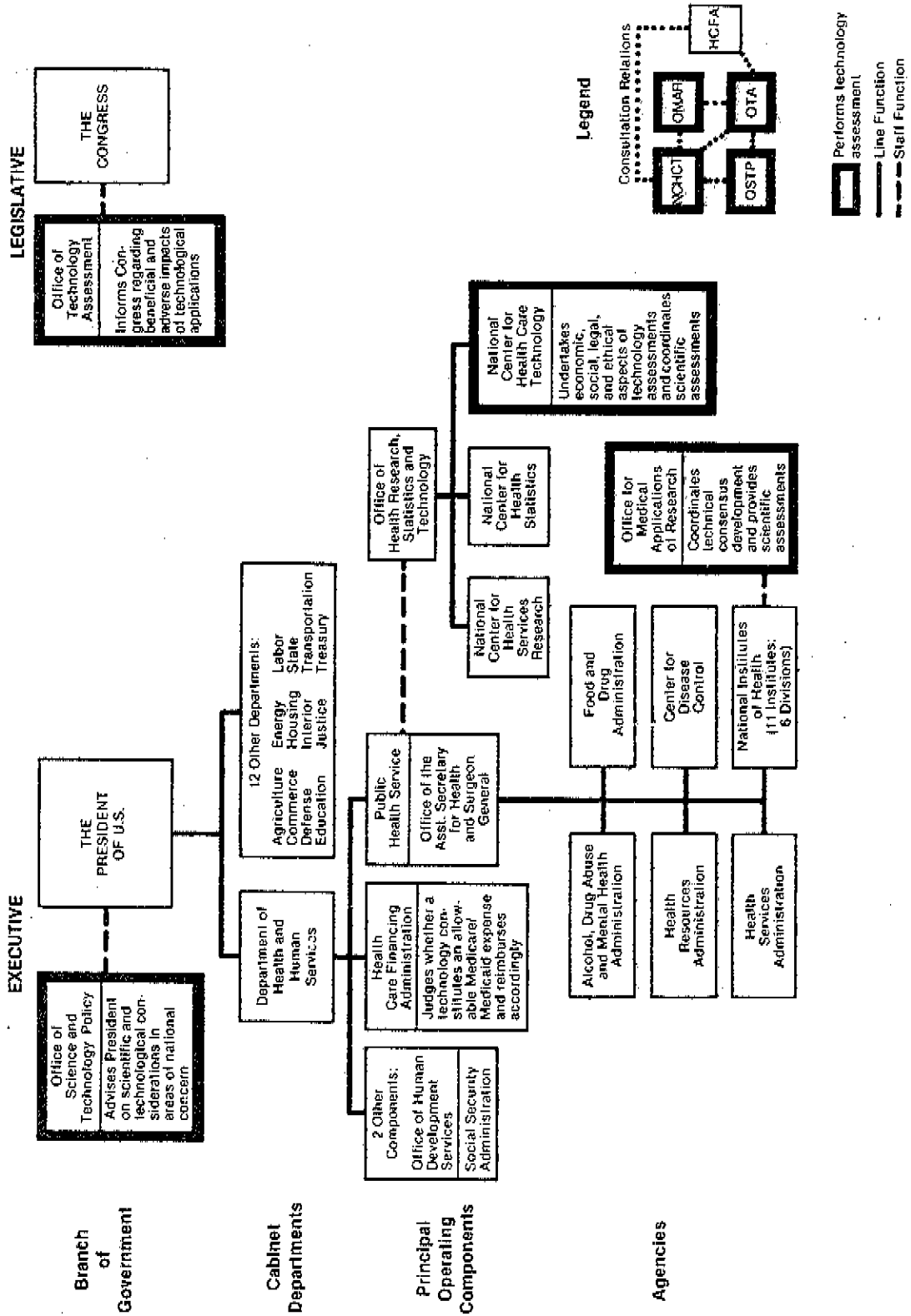
The Office for Medical Applications of Research (OMAR) was created in the autumn of 1978 to coordinate, monitor and evaluate the progress of the consensus effort. It operates out of the Office of the Director, NIH. The National Center for Health Care Technology (NCHCT) is the other important element in the assessment process. This body, the National Center for Health Statistics and the National Center for Health Services Research are all under the supervision of the Deputy Assistant Secretary for Health.

NCHCT coordinates DHHS medical assessment activities and issues recommendations on the appropriate use of new and existing technologies. It reports the results of its assessments to HCFA, which, in turn, uses this information in developing its Medicare and Medicaid reimbursement policies.

NCHCT focuses on economic, ethical, legal and social considerations and, to a large extent, depends upon the NIH consensus development programme and the NIH institutes for scientific data for assessment of safety and efficacy. Though NCHCT has the authority to conduct scientific evaluations independently, it works closely with OMAR and the NIH institutes in assessing technologies, while OMAR formulates, sponsors and manages consensus conferences. Thus, it is obvious that highly detailed planning has been necessary for consensus development.

The first step is to identify a technology for evaluation. Once this has been chosen (most often by an NIH institute), a planning group, including outside experts, is named. This group begins by framing the key questions to be asked of the consensus panel. As a next important step, the chair person is selected.

U.S. HEALTH TECHNOLOGY ASSESSMENT



The group generally begins its work by structuring the programme, identifying subjects for presentation, choosing speakers and selecting a consensus panel, usually consisting of from 7 to as many as 25 persons. After several months of planning, the conference is held. After all the data has been presented, the panel meets to write its consensus statement, which is presented in draft form on the final day of the meeting. This statement, with some revisions, is promptly printed by NIH and made available to numerous national and international medical periodicals as well as to the lay press. Representatives of professional and general media organizations also attend these sessions.

The dissemination process is critical to consensus development. If reports of the panel's findings do not leave the meeting room, the entire effort will have failed. In the early years of the consensus effort, conferences have emphasized technologies in general use. As the programme progresses, however, emerging technologies will account for a larger portion of the conference calendar. By this means, NIH will serve more effectively the objective of translating the results of biomedical research into the practice of medicine.

With the maturing of the consensus programme and the addition of NCHCT assessment activities, the USA continues in its efforts to improve the quality of health care. This should help both the physician and the patient.

6. Information needs

It is important that decision makers base their decisions on reliable, easily understood information. If such information is not used or if it is not available, there is a danger that decisions may be based on intuition, often illogically and with scant regard to the implications for the overall use of health care resources. Thus, adequate information is crucial to medical technologies assessment. Furthermore, it must be in a form suitable for use by the many groups involved in decision making - for example, the users of technology, industrial developers and producers of technological equipment, health care planners, politicians and the general public.

Many advantages would stem from the international exchange of data, but, if this is to be successful, some agreement on common methodology is necessary. Attempts at achieving this have hitherto had only limited success, and there remains considerable scope for further collaboration.

Assessment of technologies falls into two broad categories:

- assessment of safety, quality and efficacy;
- assessment of the clinical role of technology and its effects on the organization and economics of health care.

The first of these two categories is probably the one to which most attention has hitherto been devoted, both by industry and by users and developers of technological equipment. Indeed, this is probably the easiest area in which to develop standardized criteria and acceptable international comparative data. There is a need to pursue such cooperation vigorously.

It is the second category of assessment which presents the most difficulty. Whereas standards of safety, quality and efficacy are more or less commonly applicable to all nations, the clinical role of technology may depend on the local health care system and the economic development of the nation.

The economic development of countries is associated with a number of problems. In underdeveloped countries, the tendency is to provide expensive medical technology in the few main centres at a time when a majority of the population outside such centres is starved of medical facilities. This cannot be the best way to deploy limited resources for the overall benefit of the greatest number. In contrast, in developed countries, the problems are more those of reallocation of existing resources, where cost-effective considerations and public political opinion are often more delicately balanced.

Nevertheless, all countries are having to face such decisions, and it is becoming increasingly important to ensure that reliable, unbiased advice is available to governments and the general public, who, it must not be forgotten, are ultimately the consumers of health care resources.

The powerful influence that physicians have on governments and public opinion places considerable responsibility upon the medical profession. It is therefore imperative that sectional interest by the profession is, and is seen to be, unbiased and based on sound scientific and economic reasoning.

7. Methodology

One of the major difficulties facing those responsible for assessment programmes is the lack of agreed methodology for evaluating the clinical role and cost-effectiveness of new techniques or technologies in health care. Similarly, some measure of social or ethical consequences seems desirable.

Such methodology is essential if proper judgments are to be made or international comparisons attempted. This is one of the areas where further research and development of assessment techniques is needed. The objective should be to develop methods for various aspects of assessment in a form whereby it would be possible for planners to consider the individual parts of an overall technology assessment which are most applicable to their particular problems or national circumstances.

If appropriate methodology were developed, great international benefits could stem from the establishment of a reliable, preferably standardized data bank of information on safety, quality, efficacy, and the less well defined topics of cost-effectiveness, benefit, clinical role and social or ethical impact, from which health care planners anywhere in the world could draw. Such a broad objective may yet be unrealistic, but this should not deter those working in these fields from directing their efforts in that direction.

8. National medical technology policy

8.1 General

Medical technologies used in health care systems tend to require additional personnel, greater skills and more tests and equipment, thus giving rise to higher costs. Although in most industries the technology problem is one of not getting innovations into the market rapidly enough, in health care there is concern that diffusion is too rapid, insufficiently assessed and uncontrolled.

At a time when the allocation of limited health care resources is a major public issue, general guidelines for a national medical technology policy based on safety, efficacy, costs and utilization are essential. While such guidelines can be provided on an international basis, national policies have to be developed at national level according to priorities in health care, but also taking into account political and economic issues.

In order to coordinate individual and institutional efforts, national policies for medical technology appear to be urgently needed. As a preliminary step towards establishing this policy, national medical assessment programmes will provide a sound basis for constructive development and will, furthermore, reinforce the provision of comprehensive health services at national level.

8.2 Objectives and strategies

In the planning of a national medical technology policy which could be developed by a national centre or an agency, the following actions should be considered:

- the identification of centres possessing technical expertise and facilities for assessment, and the creation of a national network of centres;
- the establishment of priorities for research, demonstration and evaluation of medical technologies;
- the support (by grant or contract) of research, demonstrations and evaluations concerning the safety, efficacy, cost-effectiveness and social and ethical impacts of medical technologies;
- the support of studies on the utilization of medical technologies, alternative methods for disseminating information on medical technologies and alternative methods for measuring the quality of health services;
- the coordination of all training and manpower development in relation to medical technologies.

An existing and adequately functioning public health or hospital institute may similarly be given the task of policy development.

8.3 Implementation

The actual implementation of a national medical technology policy may be carried out using different approaches and combinations, which may be more or less effective according to local conditions.

8.3.1 Technical information and recommendations at national or regional levels

Some countries have developed a system of technical assessment of a limited range of medical equipment through specialized institutes forming part of a national network. The results are then collated and diffused to the interested institutions on a regular basis. This procedure is particularly useful in countries having national organized health services.

8.3.2 Market entry and issue of standards

This approach would require all medical equipment and devices to undergo a procedure of assessment in its widest sense, with approval by a national authority. Although it might delay or prevent the adoption of many innovations, it would not curb the use of technology once it was permitted to enter the market. It could be effective, however, in preventing the diffusion of useless or harmful technologies and would have the potential of providing a rich data base on risks and benefits. It would be difficult to apply to existing technologies.

8.3.3 Physician education

The current undergraduate and postgraduate training of physicians in most universities of the Region heavily emphasizes the use of the latest procedures and equipment. Even physicians being trained for primary care attend the same medical schools as future specialists, where "the practice of medicine" is epitomized by the best equipped, around-the-clock diagnostic and treatment facilities.

Teaching the utilization of medical technologies according to the real needs of patients and the community should be an essential part of all curricula and be incorporated in programmes destined for other health care personnel. General practitioners should be well informed about the values and limitations of all available technologies.

8.3.4 Consumer education

Under this approach, consumers would be educated about the costs of the health care they receive. If patients received copies of their bill, they would become more aware of the cost of the services and supplies provided to them.

The media could also be used more to publicize the need for second opinions, the existence of unnecessary operations, procedures and tests, and the limitations of certain medical interventions. If patients were enlightened about some of the uncertainties, costs and risks, some behavioural changes might take place. For example, with the development in recent years of extraordinary measures to prolong life for a limited time, patients have become aware of the "death with dignity" issue. They have begun to express concern about vegetating or being subjected to numerous and painful procedures that have little chance of significantly altering the outcome. Concepts such as "life-saving" and "life prolongation" could be explained to the general public.

8.3.5 Guidance of industry

Apart from designing, promoting and servicing medical equipment, industry should be encouraged to develop products according to the real needs of the health professions. When this guidance is lacking, new industrial developments may follow wrong lines and, thus, after expensive evolution, a project may not be accepted by testing authorities and/or consumers.

8.3.6 Manpower training policy

The trend toward medical specialization is linked directly with the availability and use of specific medical technologies. It follows that policies that influence the number and specialty distribution of physicians can be expected to have a direct impact on the use of medical technologies. This is particularly true of the high-capital (e.g. CT scanners) and high-labour (e.g. gastrointestinal endoscopy) technologies that tend to be restricted to specialists, and less true of the low-capital, high-volume technologies that apply to all categories of physician. While the specialist to generalist balance is a factor regulating high-cost technology use, the overall supply of physicians is an important determinant of the use of low-cost technologies. The need for a greater proportion of primary health care physicians, not only for overall health reasons but also to ensure appropriate use of technologies, is to be emphasized.

The regulation of numbers and types of physician is an important aspect of decisions that affect medical technology acquisition and use, but it must be remembered that, because of the prolonged time lag required for physician training, this strategy is effective only for a long-range solution.

8.3.7 Research policy

An important contribution may be made to cost control by appropriate channelling of projects for technology evaluation and cost-benefit assessment. There is evident need for research into the efficacy of existing medical practices involving the use of expensive equipment and the general tendency to equate technological sophistication with quality of care. Also, the information on efficacy produced by research should be used to make changes in medical education.

8.3.8 Process of technological change

Change due to new technologies is a dynamic process, marked by three identifiable but somewhat overlapping phases:

- identification of needs for new technologies within the health care system or development outside the health care system of technological prototypes for improvement of existing technologies;
- assessment;
- diffusion.

The first phase can be equated with biomedical research in its broadest context and takes place inside and outside health-related institutions. The second phase may occur as part of the first or may involve a significant time lag. Assessment in the clinical environment is likely to be concurrent with development activity to some extent. Diffusion represents the final phase prior to adoption of a technology for non-experimental use by individual or organizational decision makers.

8.3.9 Obstacles to technology development

In many situations, one or more of the following obstacles must be overcome to reach the assessment and diffusion phases:

- biomedical research funding policies which bias the kinds of clinically useful knowledge that develop;
- property rights' policies which provide inadequate incentives to developers of new technologies;
- small-sized and non-aggregated nature of potential markets;
- inadequate networks for communicating the results of clinically useful research to health care systems;
- regulatory processes required, in some of the more industrialized countries, before new technologies can reach markets.

8.3.10 Certificate of need system

Whenever a medical technology is required by an institution in certain countries, justification has to be given to a special authority which, after examination of the request, approves or rejects it. This authority may be located at national level in small countries or be combined with the national medical technology centre, but it should, whenever possible, be regionalized and combined with a regional instrument and equipment centre or committee. The responsibility could be even further decentralized, but then the local authority has to rely on regional or national centres, as it would not be rational to build up expertise and data at the peripheral level.

8.3.11 Reimbursement limitation

Hospitals

Applying a limit to reimbursement would force hospitals to exercise caution in expanding the technologies they use, the equipment they purchase and the personnel they hire. As they would not be paid for every new service they provide, more cost-conscious decisions would be made on how to allocate their potential revenues.

Ideally, in the future, prospective reimbursement rates could be established that reflected an efficient level of operation for each hospital and included an increase factor for the adoption of assessed and approved technology.

Physicians (and other health care workers)

If control of medical technology is to be based, at least in part, on changing the patterns of physicians' ordering and performing of technological services, the reimbursement mechanism that now favours the ordering of these types of service must be changed. More efforts should be spent in the area of adjusting physician reimbursement rates to counteract the built-in incentives to order unnecessary or inefficient technological services.

Limitation of reimbursement policies should be actively supported by information of consumers and the propagation of the cost-consciousness concept.

8.3.12 Centralized and regionalized capital expenditure limitation

This approach is intended to limit the growth of the cost of medical care through regulation of expenditure for new services, equipment or facilities. This type of regulation is based on the concept that duplication of services should be discouraged and planning for new services should be rationalized. A limitation on the supply of services would force the health care system to determine which patients most need to use the resources.

Capital regulation has not been especially effective in the past as it is generally done at central level. It may be effective in the future if it can lead the health care system to adopt a rationing mechanism, but this in turn will raise the social issues of access and equity.

The answer has recently been sought in many countries, and a functional regionalization of services has been proposed. The primary objective of regionalization is to coordinate available resources so that they can be used more efficiently and without unnecessary duplication to make the services of the Region's health establishments available to all upon demand. Functional regionalization of health services also permits establishment of effective linkage between the institutional and ambulatory health systems, thus rationalizing technological support.

In the same vein, administrative regionalization of services (in both the health care and other fields) will bring the services closer to the community and permit a high degree of self-sufficiency in specific sectors - to the extent that appropriate resources and a potential for improvement of the resources are available in the Region. When used as an instrument for health services coordination, administrative regionalization implies distributing work and responsibility among agencies in a mutually supportive manner for the purpose of maximizing the productivity of equipment and installed capacity.

9. Conclusions and recommendations

The three models of medical technologies assessment programmes described above exemplify how systems have evolved to meet problems in three different health care systems. The common purpose of all schemes is to develop some external control of technological development to ensure, above all else, the safety of equipment and to monitor its quality and efficacy. The way in which such controls operate in the health care field clearly depends very largely on the political and social environment of the countries concerned, but the need for some control is perceived by all.

It is clear that there would be considerable difficulty in developing a common system to meet the needs of all countries or even those countries within the European Region with developed health care systems. However, countries have much to learn from each other, and some aspects, particularly basic performance reliability and safety data, seem fundamental to virtually all assessments. As work is conducted at present, it is evident that a good deal of wasteful duplication of effort is occurring internationally.

The lack of reliable data or methodology for certain aspects of assessment, particularly that which could usefully influence different health care systems, is evident.

But for decision makers, there are other problems. Indeed, there is a need to establish who are the decision makers in any particular health care framework. They could be politicians, physicians, the general public or more usually a combination of all three, the relative importance of each depending on the local situation. There are thus educational problems for all those concerned with assessments and decision making, including the mass communication media, which are playing an increasingly important part in influencing public opinion and decision making.

In tackling these problems, the Consultation endorsed the priorities for future work in the field of evaluation suggested by the International Workshop on Evaluation of Medical Technology, held in Stockholm on 18-19 September 1979. These were:

- establishment of an organizational basis (expert groups, consensus groups, institutions) for systematic efforts in technology assessment;
- identification of technology in need of assessment, and compilation of information on numerous specific cases;
- harnessing of a variety of skills for a multidisciplinary approach to the complex problems of technology assessment;
- inclusion of the decision makers, the public and the press among the target groups for creating awareness of the issues in evaluation of medical technologies;
- assurance of international cooperation for exchange of experience and information, as a basis for collaborative efforts and as a means of avoiding duplication of work;
- in the long run, creation of the conceptual framework and the pedagogical basis for education in medical technologies assessment and decision making for health professionals.

Annex

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1974.12.16

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