
2. Information for Assessment

Knowledge is of two kinds. We **know a subject ourselves, or we know** where we can find information upon it.

—*Samuel Johnson*

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Information for Assessment

INTRODUCTION

A primary consideration in developing a strategy for assessing medical technologies are the needs of assessors for various types of information. This chapter is an introduction to the information needed for assessing health effects, performance standards, economic effects, and social effects of medical technologies, (Subsequent chapters will describe and critique the methods for obtaining and synthesizing this information). The second section of this chapter also provides an overview of existing sources of statistical data for assessment, both public and private. The third section describes existing biomedical literature sources, including bibliographic data bases. And the final section discusses libraries, clearinghouses, and similar organizations which can provide in-

formation that is useful for technology assessment. To supplement the material in this chapter, a compendium of statistical data sources and a compendium of bibliographic data bases are included as appendix A and B.

The discussion of the sources of information for medical technology assessment in this chapter is not an exhaustive one. Because of the complexity and diversity of medical technologies, information from disciplines such as engineering, social behavior, and genetics is often needed to perform a technology assessment. The focus in this chapter is on the significant sources of information that is directly related to health.

INFORMATION NEEDED FOR ASSESSMENT

Health Effects

The information needed for a complete assessment of a technology's health effects falls into three broad categories: efficacy, effectiveness, and safety. Efficacy refers to the probability of (usually health) benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use (266). *Effectiveness* is similarly defined, except that it refers to the probability of benefits under average conditions of use (266). *Safety* is a judgment of the acceptability of risk (i.e., the probability and severity of an adverse effect) associated with the use of a technology.

Information regarding the efficacy of a technology is needed to establish, within some defined estimate of probability, whether the use of a particular medical technology under "ideal" conditions can cause changes in patient outcome. Because information concerning the efficacy of medical technologies (under ideal conditions of use)

often cannot be generalized to wide populations receiving medical care in diverse settings, information on the effectiveness of such technologies (under average conditions of use) is also needed.

Most medical technologies have an element of risk associated with their use. Thus, any assessment policy needs mechanisms to determine the probable risk, or, conversely, safety, of a technology under various conditions of use, and then to weigh the risk with the expected benefit. Weighing risks with benefits is necessary, because the concept of risk is a relative one—i. e., a low risk is unacceptable if there is no expected benefit, but a high risk may be quite tolerable if the expected benefit is very high.

Performance Standards

Strictly speaking, only an improvement in patient outcome can be considered evidence of a technology's efficacy or effectiveness. However, some technologies' ultimate effect on health may

be so far removed from the technology's use that only some intermediate outcome can reasonably be assessed (270). For these technologies, information is needed concerning standards of performance.

Such information is especially needed in the case of medical devices, many of which perform some particular mechanical, electrical, or chemical function ultimately intended to be related to a change in health status.

In an earlier report, OTA classified relevant outcomes of diagnostic technologies to be: 1) technical capability, 2) diagnostic accuracy, 3) diagnostic impact, 4) therapeutic impact, and 5) patient outcome (266). Since diagnostic technologies are directly associated with intermediate outcomes and are often far removed from actual health outcomes, performance standards may be the most meaningful, as well as most easily obtained, measures of assessment.

Economic Effects

Good economic data are essential to a system of medical technology assessment. This is especially true today, when one of the driving forces behind technology assessment is concern for the high

costs associated with the adoption and use of technology. For the purpose of assessing medical technologies, information is needed on the direct costs associated with medical care usage: the cost of the physician, the hospital, and medical supplies. Also important to consider are indirect costs: the costs associated with the value of time lost while seeking and receiving medical care and, especially, in being sick. Indirect costs are often overlooked in assessments; when included, they are often measured in terms of lost (or gained) wages.

Social Effects

The importance of addressing social and ethical concerns in the assessment of medical technologies has been noted in a previous OTA report (270) and will be discussed at greater length in chapter 4. Even though such concerns cannot ordinarily be valued, they are often essential to the measure of worth of a medical technology. The distribution of costs and benefits, respect for the autonomy of individuals, and a myriad of other social and ethical issues result from the introduction, extension, or modification of medical technologies (19). These issues are important to consider in assessments.

SOURCES OF DATA

All medical technology assessments require data. The chapters that follow discuss a variety of methods of assessment which can be used to systematically generate data about specific medical technologies and to produce information that is useful for setting policy. In addition, as described below, there are numerous systems which produce health-related data routinely.

The health statistics system of the United States is largely decentralized. Responsibility and authority for health statistical activities are divided among Federal, State, local, and independent agencies and organizations.

The compendium of statistical data sources in appendix A lists current public and private sources of data on the health of the population, the availability and use of health resources, and health care

expenditures (especially as they relate to the assessment of medical technologies). Information for that compendium was obtained from a diverse group of individuals, governmental agencies, and nongovernmental organizations through data files, published reports, and personal interviews. Since each sponsoring agency or organization collects data using its own methods and procedures, the health data described in the compendium vary considerably with respect to source, method of collection, definitions, and reference period (93,282).

The largest single participant in the U.S. health statistical system is the Federal Government. The only Federal agency established specifically to collect and disseminate data on the health of the American people is the National Center for Health

Statistics (NCHS). Since 1960, NCHS has played a major role in the development of national health statistics policies and programs. The NCHS Division of Vital Statistics collects natality, mortality, marriage, and divorce statistics from the individual States and registration areas. In addition, NCHS conducts several general purpose surveys that provide statistics about the health status of the U.S. population. NCHS also has the primary administrative responsibility for the Cooperative Health Statistics System, a joint Federal, State, and local program for the collection of health data.¹

An OTA study on Federal health data collection systems in 1979 found that the system for collecting, storing, processing, and disseminating health care information had been affected by the rapid growth of the Federal role in health care (282). At the time of that study, the Public Health Service alone administered 153 individual data projects; the Health Care Financing Administration operated at least 13 large statistical projects; and several other agencies and departments outside the Department of Health and Human Services (DHHS)* also conducted major health statistical activities. OTA concluded that these numerous data bases were uncoordinated and in many cases duplicative (282).

Four types of medical data sources are discussed further below: 1) data banks, 2) vital statistics, 3) insurance claims records, and 4) *surveys* of patterns of medical practice (197). Not every medical data system necessarily fits exclusively into one or another of these categories, but this breakdown of categories is useful for evaluating general strengths and weaknesses of different existing collections of data.

Data Banks

A potential source of information about patients, their characteristics, and their responses to the use of different biomedical technologies dur-

ing their care are medical data banks. * Medical data banks, which are often computer based, are usually created by establishing a common terminology or vocabulary to describe a patient's clinical history and then entering observations on patients as events occur; sometimes, a data base management system is used to ensure accuracy, security, and easy entry and retrieval of observations. By extension, a medical data bank network contains the clinical history of large numbers of patients (from multiple centers) described in a uniform manner (218).

A medical data bank that contains extensive, comprehensive, reliable, longitudinal data on a number of patients can provide two important functions in assessing medical technologies. First, it can serve as an instrument for collecting the baseline and followup data on patients who have been subjected to a treatment. Second, the patients on whom this data has been collected can function as their own historical control group, which allows the investigation of the health effects associated with the treatment (93). Data banks can also be used to provide physician practice profiles and to assess the relative values of diagnostic and therapeutic choices.

Medical data bank demonstration programs have been funded by at least two Federal agencies: the National Institutes of Health (NIH) and the National Center for Health Services Research (NCHSR). NCHSR has supported a chronic coronary artery disease data bank program at Duke University and a rheumatic disease data bank program at Stanford.

Vital Statistics

Vital statistics such as those compiled by NCHS are of potential use in analyzing the safety and efficacy of medical technologies. When observational data are used to draw inferences concern-

¹ Additional information concerning NCHS data systems can be obtained from *Data Systems of the National Center for Health Statistics* (93).

● Then the Department of Health, Education, and Welfare (DHEW).

● Although the terms are sometimes used interchangeably, a medical data bank differs from a registry (e. g., that used for cancer tumors). In a registry, data typically are abstracted from a specific document (e.g., medical record or death certificate) using criteria that are applied retrospectively, rather than by adhering to a common terminology in the prospective collection of data (56,218). In practical terms, registries generally cover discrete political or geographic areas (267). In this chapter, registries are discussed under the heading "Surveys of Patterns of Medical Practice."

the safety and efficacy of medical technologies, however, there is a need to protect against bias in selecting the sample of records from which inferences will be made (197).

Vital statistics data can have an important function in the area of record linkage. The National Death Index (NDI) recently put into operation by NCHS is a case in point (267). Historically, because there was no integration of records for the country as a whole, no mechanism had existed at the national level to determine whether a person has died. The NDI is intended to serve that purpose.

The NDI is designed to provide medical and health researchers with probable fact of death, the death certificate number, and the location of the death certificate when supplied with a minimum set of identifiers (generally the person's name and social security number or date of birth). A researcher may then contact the registration area where the possible match has occurred to obtain the death certificate or the required information. The NDI will be of immediate use in ongoing long-term studies which include mortality. Beebe (24) has described this index as the most important recent advance in making vital statistics accessible to researchers (24). The National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program plans to use the NDI to determine deaths of all persons in the SEER registries. SEER often loses track of people who move out of SEER areas before they die. Use of NDI should reduce the number of people lost to followup by SEER and provide better information about survival.

Insurance Claims Records

Large data sets have been compiled by third-party payers in both the private and public sectors. Blue Cross/Blue Shield, for example, collects data on its subscribers—about one out of three Americans, or more than 80 million people—as well as on subscribers and participants in various other programs that it administers (including Medicare and Medicaid in some regions) (197).

On the Federal side, passage of the Medicare and Medicaid legislation in 1965 created the need to establish a national yet decentralized adminis-

trative mechanism to pay for services to beneficiaries of these programs and to gather statistics for managing the programs. Systems needed to pay those bills were designed to provide information (primarily determinations of patient eligibility, the completeness of the claim forms, the appropriateness of length of stay in hospitalizations, and information on charges) for use by fiscal intermediaries in making interim payments. Although none of the data are collected solely for statistical purposes, the resulting information is useful for that purpose (198).

Surveys of Patterns of Medical Practice

Disease-specific (or procedure-specific) registries, hospital discharge data systems, and Federal statistical surveys of selected medical practices are a fourth general source of data for evaluating medical technologies.

A recent and somewhat prominent example of a procedure-specific registry is the voluntary registry established by the National Heart, Lung, and Blood Institute for physicians using the new technique percutaneous transluminal coronary angioplasty (PTCA). (The PTCA registry is discussed further in app. E.) Because it has achieved fairly high physician participation, this registry permits the collection of data for evaluation of PTCA at an early stage of the technology's diffusion, and at a cost that may be less than that of a randomized clinical trial (197).

Several hospital discharge abstract systems emerged in the early 1950's to provide summary information abstracted from hospital medical records about patients and their episodes of illness in short-term general hospitals. Although they tended to be established by independent organizations, many were similar in their origins, system characteristics, available data items, and sponsorship (which was generally private, nongovernmental).

The earliest system, the Professional Activity Study, developed in 1953 with support from the W. K. Kellogg Foundation. This system is operated by the Commission on Professional and Hospital Activities (CPHA), a nonprofit corporation in Ann Arbor, Mich., sponsored by the American College of Physicians, the American College

of Surgeons, the American Hospital Association, and the Southwestern Michigan Hospital Council. The purpose of the Professional Activity Study is to link medical and surgical procedure rates with in-hospital mortality. The CPHA sample is a large one (approximately one-fourth of all hospitalized patients and one-third of the hospital discharges in the United States), and although not a random sample (it is based only on those hospitals that subscribe to their service), it has historically been representative of important hospital characteristics.

There are also an additional estimated 18 to 20 private, nonprofit hospital discharge abstract sys-

tems throughout the United States that process hospital utilization data for about half the hospitals in the country, representing over 20 million discharges yearly (198).

The Federal counterpart to these private, non-governmental systems is the National Hospital Discharge Survey initiated in 1964. Administered by NCHS, this survey collects information on the characteristics of patients, lengths of stay, diagnoses, surgical operations, and the patterns of use and care. Only short-stay hospitals with six or more beds and with an average length of stay for all patients of less than 30 days are included in the sample (267).

PUBLICATIONS AND BIBLIOGRAPHIC DATA BASES

Information concerning medical technologies is often found in primary publications such as journals, books, Government reports, technical publications, and patents. Because of a dramatic rise in the number of publications in the field of medical technology assessment (13), however, access to the primary literature is often confusing and difficult. As a result, secondary publications—e.g., catalogs, indexes, bibliographies, and abstracts—which facilitate access to primary literature sources are increasingly important in the information transfer cycle. Secondary publications can also provide readers with superficial information about subject matter. (A bibliography on computed tomography, for example, can allow a reader to crudely approximate the state of the art solely by scanning the listed titles.)

Secondary publications are now increasingly available in the form of bibliographic data bases that can be read by a computer. The information contained in many of the bibliographic data bases (i.e., references to literature) also can be obtained “on-line.” (A person at a computer terminal can carry on a dialog with a computer, directing it to locate, retrieve, and then display the information at the terminal or print the information on paper.) The growth of machine-readable bibliographic data bases in recent years has been extraordinary. In the United States alone, the number of data bases increased from 301 in 1976 to 528

in 1979, a 75-percent increase (394). Accompanying the growth in number of data bases has been a corresponding growth in use. The number of requests for information searches for individual data bases (on-line) grew from 700,000 in 1974 to an estimated 4 million in 1979 (395).

Medical technology assessment often may require information from many subject areas. Depending on the medical technology, the type of assessment, and a myriad of other factors, information may be sought in such diverse disciplines as biomedicine, law, finance, economics, and sociology. Such information is often obtained from computer-readable data bases. A common need in medical technology assessments is for information from the field of biomedicine. Information on biomedicine is found in numerous data bases. Worldwide, over 90 computerized data bases contain information on medicine alone (394). Although there is some overlap in the contents of many of the biomedical data bases, no one data base exactly duplicates another; each is unique in many aspects (e.g., contents, arrangement, and indexing philosophy). A descriptive list of biomedical-related bibliographic data bases of significance that are useful for medical technology assessment, along with the creator and vendor, appears in appendix B.

The major on-line service organizations, both public and private, that provide access to biomed-

ical data bases in the United States are the National Library of Medicine (NLM), which is a part of NIH, Bibliographic Retrieval Service, DIALOG Information Service, Inc., and System Development Corp.

NLM provides access domestically and internationally, both to data bases in the biomedical field that are created and maintained solely by NLM and to data bases that it sponsors or produces in collaboration with other Government entities and private organizations, by means of its computerized bibliographic retrieval and technical processing system MEDLARS (Medical Literature Analysis and Retrieval System).² Its major biomedical data base is MEDLINE (MEDLARS On-line), which contains 600,000 references to biomedical journal articles published in the current and 2 preceding years. Tapes of MEDLINE and other MEDLARS' data bases, including TOXLINE* and HEALTH,** can

²This system is the topic of an OTA technical memorandum entitled *MEDLARS and Health Information Policy* (276).

*Toxicology Information On-line. This is a collection of about 600,000 references from the last 6 years on published human and animal toxicity studies, effects of environmental chemicals and pollutants, and adverse drug reactions.

also be leased from the National Technical Information Service (NTIS) of the U.S. Department of Commerce.

Bibliographic Retrieval Service, DIALOG Information Service, and System Development Corp. are commercial firms that do not produce data bases, but enter into licensing agreements with the data base producers which permit these firms to mount producers' data tapes on their own computer facilities, adapt the tapes to their own software (i. e., computer instructions), and sell on-line access to subscribers. These commercial vendors typically sell access to a broader group of data bases than just biomedical bibliographic ones. The commercial vendors sell access to MEDLINE and other MEDLARS data bases, as well as to health-related data bases such as EXCERPTA MEDICA and BIOSIS PREVIEWS which are produced in the private sector. They also sell access to non-health-related data bases.

●*Health Planning and Administration. This data base contains about 200,000 references to literature on health planning, organization, financing, management, manpower, and related subjects.

LIBRARIES AND OTHER INFORMATION RESOURCE ORGANIZATIONS

The increase in the number and diversity of information products and services has been accompanied by an increase in the diversity of organizations that provide access to them.

Among the more important of these are health science libraries, which have for many years acquired, organized, and provided literature on biomedically related areas. As of 1979, over 2,700 public and private health science libraries were identified in the United States (74). The libraries were sponsored by medical schools, professional and vocational schools, business and industrial organizations, research organizations, societies and foundations, hospitals, area health education centers, health maintenance organizations, and health planning organizations (74).

In addition to having access to journals, books, and other print and nonprint materials, many health science libraries have access to biomedical

and other computerized data bases. For example, about 1,500 health science libraries have terminals connecting them directly to NLM's MEDLARS system for computerized searches. * In addition, many other health science libraries provide indirect access to MEDLARS by referring requests to facilities with terminals. Indeed, informal and formal networks and the use of telephones, computers, and interlibrary loans have broadened access to information resource organizations considerably.

Although there are other types of information resource organizations which have provided, and can provide, information that is relevant to med-

● The number and types of institutions which obtain access to the medical and other literature through the major commercial retrieval services (i.e., Bibliographic Retrieval Service, DIALOG Information Service, and System Development Corp.) are not known, because the information is proprietary.

ical technology assessments, it is difficult to get comprehensive information about them—and even their typology is elusive and fluctuating.

For example, the first conclusion of a 1980 National Science Foundation (NSF) study and survey is (138):

... that it is difficult to obtain comprehensive information on Federal S&T [science and technology] information centers. Even the National Referral Center at the Library of Congress is not provided accurate, timely, and complete information on federally supported information centers.

NSF restricted its definition of an information center in the 1980 survey to an organization whose primary function was:

... to store, retrieve and distribute scientific and technical information. Both textual and numeric data information of a primary (e.g., information analysis) nature were included. Organizations such as agency libraries, which were involved in serving parent organizations, were in general excluded.

NSF identified 55 “science and technology information centers” in DHHS (then DHEW), including NLM.

A more recent study prepared for DHHS identified and categorized 157 “human resource information organizations” (6). Forty-one had a health focus. Of the 157 organizations, 98 were funded by Federal agencies, 43 by private organizations, and the others by academic institutions or State and local governments. The majority of federally sponsored organizations were funded by DHHS, but others were supported by the Departments of Education, Transportation, Housing and Urban Development, Energy, Labor, Justice, Commerce, Agriculture, and the Community Services Administration. Of the 157 organizations, 72 were classified as “clearinghouses,” 76 were classified as “other types of information resource organizations,” and 9 could not be classified because of incomplete information. (The other types of information resource organizations **included** special libraries, document depositories, information analysis centers, information referral centers, resource centers and networks, and technical assistance centers.)

Clearinghouses, which were the focus of the study, were distinguished on the basis of particular activities and functions. Through a variety of user services, these organizations perform three important tasks: the collection, the analysis, and the dissemination of information. They identify, select, acquire, process, and sort documents and other materials, and provide “locator tools” (e.g., indexes) to this collection. They also synthesize and digest this information to guide users to the specific data in the collection that best serve their needs. A wide range of clearinghouse services, from bulletins and announcements to bibliographies and handbooks, can lead users to the information they seek. Some clearinghouses tend to collect unpublished Government reports, projects, descriptions, speeches, and other types of “fugitive” literature that is hard to get elsewhere.

For example, the National Health Planning Information Center, a clearinghouse in the Bureau of Health Planning of the Health Resources Administration, was created to provide information for the analysis of issues and problems related to health planning and resources development. This center acquires, screens, and stores information on published journal articles, books, and other documents about health planning and resources development. Besides published reports, the center seeks unpublished reports, conference and proceedings papers, bibliographies, publication lists, and appropriate audiovisuals and microfilms. Its collection currently includes some 20,000 documents on a wide range of general subjects pertaining to health planning (e.g., health care technology and equipment impact, health care utilization). To facilitate the dissemination of information to health planners, the center issues selected publications in three series: *Health Planning Methods and Technology*, *Health Planning Information*, and the *Health Planning Bibliographies* (92,123,124). Finally, the center is now collaborating with NLM to include the center's data base in MEDLARS' HEALTH data base (276).

A second information clearinghouse is project Share, which was created by DHHS to provide a central, systematic source of information for improving the management of human services. Tar-

geted primarily at State and local officials, Project Share acquires, announces, and makes available documents relevant to the planning, management, and delivery of human services. Types of information collected and disseminated include published and unpublished papers, theses, research reports, bibliographies, technical reports, operating manuals, and conference proceedings. Besides providing a source of documentary and reference services, the clearinghouse analyzes and synthesizes reports and other documents describing human services program activities, conducts original research, and publishes state-of-the-art literature and state-of-knowledge reports (121).

The central repository for scientific and technical information generated by federally funded

research and demonstration projects is NTIS. The NTIS collection exceeds 1.2 million titles. Most are drawn from the Departments of Energy and Defense, and approximately 10 percent have come from DHHS—5,700 reports from DHHS in 1979. In addition, NTIS has working relationships for the computerized processing of documents with at least three entities within DHHS: the National Cancer Institute, Project Share Clearinghouse, and the Bureau of Health Planning within the Health Resources Administration. NTIS is categorized as a clearinghouse, but the size of its collection and its function as the permanent repository of Federal technical information documents set it apart from all other clearinghouses except NLM (84,85).

CONCLUSION

The information needs for the assessment of medical technologies are both broad and deep, requiring the involvement of diverse disciplines. As the discussion in this chapter indicates, there exist numerous resources that are useful for assessing medical technologies. An earlier OTA study noted that a primary weakness of health-related

data sources is the lack of coordination between them (282). This problem persists.

The next three chapters consider systematic methods for gathering and synthesizing information concerning the health, economic, and social effects of medical technologies.