A CONSUMER'S GUIDE TO EVALUATING MEDICAL TECHNOLOGY

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foreword by

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FOREWORD

A number of forces have converged to promote a greater role for lay people in decisions within the health care system. As chronic disease becomes predominant, the alert and intelligent patient is to some extent replacing the stereotype of the comatose, acutely ill person. In such a situation, the patient shares decision-making with the physician. At the same time, as people are better educated both generally and scientifically, they are more able to take control of their own health. The limitations of modern medicine have been more clearly recognized in the last decade. In the social climate set up by these changes, the movement of large amounts of public money and insurance company funds into the largely private system have caused citizens to demand more of a voice in decisions. As far as I know, these demands for involvement have not included interference in the relationship between the individual patient and the health care provider. But the demands have focused on what Jonas called the "building-blocks" of the system: the facilities, the number and types of people, the services provided, and the technology involved.[1]

A number of programs have given lay people access to power within the system, as described in the preface of this manual. Probably the most important of these is the health planning program that resulted from the passage of Public Law 93-641 in 1974. Under this law, health planning agencies are given real powers within the system, including the right to review and disapprove capital expenditures for beds and for expensive technologies in advance. Boards of the local health planning agencies, called Health Systems Agencies (HSA's), are required to have a majority of consumers, and consumers also sit on the State Health Planning Councils.

To be effective, the consumers on these boards must have access to information. Hospital administrators and physicians proposing an investment in a new facility or technology such as a coronary care unit or a CAT scanner will naturally present it in the most positive terms. These providers themselves are probably not well-trained to interpret the scientific literature on the value of the services proposed. But more important, providers believe that the services they provide are worthwhile, or they would not provide them. Indeed, providers have a great psychological need to believe in the services that they furnish. Their arguments are presented in terms of life and death of people, and are often couched in very technical ways. The board members must be able to look at these arguments critically and skeptically.

This manual is an important step in presenting information that can help consumers evaluate the arguments. The questions to be asked are relatively simple, but they are at the same time profound. How many people in this service area can be expected to be helped? What is the scientific evidence that this technology does what you say that it does? Is there a randomized controlled clinical trial or other good evaluative study demonstrating clearcut benefit without serious risks?

I have carefully reviewed this manual and I think that it does a fine job of presenting basic information on medical technology and how it can be evaluated. Much of this material is drawn from reports by the Office of Technology Assessment (OTA). While our job at OTA is to advise the Congress on issues concerning science and technology, we try to develop material that will have wide applicability. Our reports are written so they will be useful to a broader audience. It is gratifying to the OTA staff to see that our reports provided a basis for a manual written specifically to meet the needs of lay members of HSA boards and other similar groups.

The Consumer Commission on the Accreditation of Health Services is to be commended for producing such a fine product, and the National Science Foundation is also to be congratulated for supporting the development of the manual. It is likely that many lay people, and not just those on formally-constituted boards, will find it useful in evaluating their health care system.

David Banta, M.D.
Office of Technology Assessment
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August, 1979

1. Steven Jonas, "A Theoretical Approach to the Question of 'Community Control' of Health Services Facilities," *American Journal of Public Health* 61: 916-921, 1971.

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CHAPTER 1

DEFINING THE CONSUMER ROLE IN EVALUATING MEDICAL TECHNOLOGY

THE CONSUMER CONSTITUENCY

This manual was written for consumers (i.e., persons who are not providers of medical care) who, through membership on health facility or planning agency boards, are involved in making decisions about the acquisition and placement of medical technology. Often, consumers who have become involved in this process have little or no previous acquaintance with health care issues and take on their roles without being provided with orientation or training to identify and carry out their unique functions as public decision-makers. This manual is meant to supply some useful tools to health care consumers by 1) helping them clarify their functions and range of action as decision-makers, and 2) developing a *practical* approach to assessing the value and appropriate use of particular medical technologies in their communities and regions.

As a first step in participating effectively, consumers on boards of health facilities and agencies need to know the legal authority for their board's existence and its legally mandated functions and responsibilities.

Consumers should get answers to the following questions:

1) Who has the *legal and financial responsibility* for the health facility's or the Health Systems Agency's operations and existence? That is, who is the *governing* board?
2) What is the *legal basis* for this board's existence (such as charter, law, statute, regulation)?
3) What does the enabling legislation or statutory authority say is the purpose and function of the facility/agency? What does it say is the purpose and function of the board?
4) Does this board have *direct* legal and financial responsibility or are its responsibilities delegated to it by the responsible body? If delegated, exactly *what* are its responsibilities? To whom does it report? i.e., to whom is it accountable?

TYPES OF BOARDS

We expect that consumers who use this manual will be involved in one of three basic types of boards: 1) *governing boards* of health facilities, such as the boards of most Community Health Centers, 2) *non-governing boards* of health facilities, such as the Community "Advisory" Boards of the New York City Municipal Hospitals, or the Community Boards for Ambulatory Care in the New York State Ghetto Medicine Program, and 3) *Health Systems Agency boards* and their Sub-area Councils/District Boards, and the Statewide Health Coordinating Councils. Boards differ by type based primarily on their functions and responsibilities, which are determined by the law, statute or charter which established the health facility or agency. The three basic types are as follows:

CONSUMERS ON HEALTH FACILITY GOVERNING BOARDS

Health facility governing boards are essentially boards of directors having legal responsibility for the institution they direct, policymaking authority, control of the budget and the power to hire and fire chief administrative staff. Common examples of this kind of board are the governing boards of Community Health Centers (formerly called Neighborhood Health Centers). Community Health Centers and their governing boards were brought into existence by federal law, the Equal Opportunity Act of 1965.

About 125 of these centers were established across the country and funded by the federal government through the Office of Equal Opportunity (OEO). Patients at the centers paid whatever they could afford on a sliding fee schedule. Many of them paid nothing. OEO was later dismantled,

and, between 1970 and 1973, the centers came under the direct jurisdiction of the Department of Health, Education, and Welfare (DHEW). Financial support from the government was greatly diminished, and the centers were supposed to become financially independent, relying on Medicare and Medicaid reimbursement and increased patient fees. This is pretty much the situation today, except that the centers can apply for other federal funding such as Urban Initiative Grants. Their current legal status is derived from Public Law 94-63, Section 30, 1975.

The federal legislation says that the boards of these health centers must represent the individuals served by the center, that they must meet at least once a month, establish general policies for the center (including selection of services and the determination of hours that services are offered) and approve the annual budget and the selection of the center's director.

Since board members come from the community and use the center's services, they are usually familiar with the staff, services and many aspects of the day-to-day operations of the center. This familiarity and involvement with the facility enhances their ability to effectively participate on board activities.

Still, it can happen that board members may not be thoroughly knowledgeable about their responsibilities. In such cases, the board will be unable to function effectively, leaving control of the center to the director, who develops his or her own policies and procedures for financing, budgeting, personnel, administration, evaluation and planning for new programs and services. The board may then find itself in the position of merely approving policies set by the director. It takes a tremendous amount of time and effort to reverse this process.

One of the first things a board would be within its legal rights to do in this case would be to withhold its approval of any policies, procedures, plans, or programs developed by the administration which were either in violation of its directives or adopted without board approval. The board could even take drastic steps and terminate the employment of administrative personnel responsible for expending center resources on activities which were not approved by the board.

The composition, rights and responsibilities of a Community Health Center provide the board with an excellent opportunity to become knowledgeably involved in decisions to acquire medical technology at the center and in evaluating technology already in place. For example, most centers provide x-ray services. To keep abreast of the quality of these services, and to guard against dangers of over-using the technology, the board could ask the medical staff the specific medical reasons (called "protocol") for ordering x-rays; determine if there is a policy for obtaining x-rays from other facilities for patients who have been recently x-rayed elsewhere; determine when and by whom x-ray equipment has been inspected (obtain a copy of the inspection report) and so forth. The board could also ask about the quality of the x-rays produced, whether they are frequently retaken because the image is of poor quality, and how often this happens. If x-rays are being used as part of a screening program, the board can make sure it is the right technology for the job by asking what disease or condition is being screened for, its incidence in the community, or other relevant questions. Let us say, for example, that the center's x-ray services are being used to screen for tuberculosis. It would be appropriate to ask why a cheaper and safer skin test (such as the tine test) is not being used and to suggest the use of the x-ray be limited to following up on people whose tine tests are positive.

By actively questioning medical and administrative staff in this way, consumer board members can become familiar with the uses and limitations of technological services offered by the health center. If any new technology should come along which would improve the center's x-ray capabilities, the board would already be well informed of the center's current services and in a better position to assess the need for the new technology.

CONSUMERS ON NON-GOVERNING BOARDS OF HEALTH FACILITIES

Many consumers feel that it is useless to serve on a non-governing board, especially if it does not have final authority over budget, administration or policy. Others are discouraged by the label "consumer advisory board," which sometimes carries the impression that the board is not really part of the decision-making process, that it may recommend but that no one need seriously consider its recommendations. This notion has at times hampered consumers' ability to function effectively.

In fact, non-governing boards can have a crucial effect on the process by which policy is formulated and in determining what kinds of programs are eventually implemented. For instance, a well designed plan and program for a walk-in clinic, which has been developed and supported by a community advisory board and facility staff, will not only be a better program for the involvement of consumer board members, but will often have a better chance of being approved by whatever board or agency does have final authority.

Nevertheless, to work effectively, a non-governing board should have its relationship to the regulatory or governing authority formally spelled out in a letter of intent or in a written motion passed by that authority. The statement should specify the delegated responsibilities of the non-governing board and should serve as the statement of purpose in the by-laws or constitution. In order for such delegations of responsibility to be effective, it is essential that the governing authority make clear what it expects the non-governing board to do, and that a mechanism be established for accountability and reporting back to the "higher" body.

While non-governing boards exist around the country in a variety of forms, only two general kinds will be discussed here. The first is the non-governing board which has been delegated certain responsibilities by the *governing authority.* The Community Advisory Boards of the municipal hospitals in New York City are examples of boards which have these kinds of delegated powers. The second type is the board of a facility which has been delegated certain powers by a *regulatory agency,* rather than by the governing authority. The Community Boards for Ambulatory Care in the New York State Ambulatory Care Program (formerly called the "Ghetto Medicine Program") are examples of boards which have been created in this way.

Non-governing boards across the country will have many different forms and different responsibilities, but no matter where they are located, they will have in common the fact that their responsibilities are delegated to them by the governing authority or regulatory agency. Following are actual examples of each of the two types of non-governing boards; each is described and then discussed in terms of how it might best function within its particular mandate.

Example 1. A board with authority delegated by a governing authority.

The Community Advisory Boards (CABs) of the New York City municipal hospitals were brought into existence and have their legal basis in the state law (Chapter 1016, Laws of 1969) which set up the city's Health and Hospitals Corporation (HHC). The HHC is a public benefit corporation which manages the city's municipal hospitals, which themselves exist by virtue of the City Charter. The HHC has its own board of directors responsible for managing the municipal system, and the state legislation gives the HHC board very broad powers and responsibilities. Beside the central HHC board, there is a CAB at each of the city's 17 municipal hospitals and at each freestanding Neighborhood Family Care Center.

Some years back, the HHC governing board delegated to the Community Advisory Boards responsibilities in the areas of budgeting, planning, and evaluation of the quality and acceptability

of patient care. In addition to delegating the above-named responsibilities to the CABs, the HHC also specified that CABs were to be included as participants in a number of its central board functions and procedures. Nevertheless, there have been times when the central board has not included the CABs as required. As a result of one instance of this kind, a CAB brought suit against the HHC because, contrary to established procedure, the HHC had bypassed the CAB in appointing an acting Executive Director to the CAB's facility. The judge ruled that the HHC had to abide by its own procedures for involving the CABs, and that these procedures had the force of the state law requiring that the HHC establish the CABs and specify CAB functions. This ruling created tremendous potential for CAB influence in the areas of their delegated responsibilities. In fact, CABs can have an empact very similar to the HHC governing board even though they do not have policymaking authority.

Example 2. A Board with responsibility delegated by a regulatory authority.

New York State's "Ghetto Medicine" or Ambulatory Care Program was created by state law in 1968 (Chapter 967, Laws of 1968). The New York State Health Department, in promulgating the regulations for this legislation, required the creation of the Community Boards for Ambulatory Care (CBACs). Originally the program was supposed to set up freestanding primary care clinics under local Health Department auspices, and a CBAC was required for each clinic. However, in New York City, the program came to be almost entirely located in the outpatient and emergency departments of voluntary hospitals, under contract with the New York City Health Department. The CBACs were still required and, under the regulations, were to function as arms of the health department. The health department, a regulatory agency, made hospitals responsible for delivering high quality primary care to the indigent at an affordable price; the CBACs were responsible for monitoring the facility's compliance with the terms of its contract with the state.

For a board to function effectively in this kind of arrangement, it must know the exact nature of its responsibilities, from whom the responsibilities have been delegated, to whom the board reports and how often. (In the case of CBACs, the boards at first reported to the City Health Department and later to the State Health Department.) One of the dangers in its role not being well defined is that a CBAC may develop its major relationship with the hospital rather than with the State Health Department and might even find itself siding with the hospital against the Health Department when the Health Department tries to enforce the terms of the contract.

This kind of non-governing board, with its responsibilities delegated from a regulatory agency, has exciting potential. Regulatory agencies can increase their effectiveness and focus their impact by requiring non-governing boards for facilities as conditions of the facilities' receiving funds or being eligible to treat patients who are paid for by governmental reimbursement. In this way, facilities which are resistant both to consumer involvement and regulatory oversight can be convinced to begin to involve communities in decision-making on health policy and delivery, including the appropriate use and acquisition of medical technology.

CONSUMERS ON HEALTH SYSTEMS AGENCY BOARDS, SUB-AREA COUNCILS (DISTRICT BOARDS) AND STATEWIDE HEALTH COORDINATING COUNCILS

Health Systems Agencies (HSAs) are regional health planning agencies which are part of a state and national health planning system created by the federal government through the National Health Planning and Resources Development Act of 1974 (Public Law 93-641). Each HSA has as its primary responsibility "the provision of effective health planning for its health service area and the

promotion of the development within the area of health services, manpower and facilities which meet identified needs, reduce documented inefficiencies, and implement the plans of the agency." This kind of regional planning (sometimes called "regionalization") aims to eliminate expensive duplication of services, to appropriately place technology so it will be available to those who need it, to contain and monitor costs and—overall—to improve the health of the region's population by providing a coordinated system of high quality health services.

HSA boards—which by law are required to have a majority of consumer members—are governing boards. They are responsible for the internal affairs of the agency (including staffing and budgeting) as well as development of procedures for review and approval/disapproval of certain federally funded projects, recommendations to the State Health Planning and Development Agency in regard to proposals for new institutional health services, and periodic review of all institutional health services in the area. HSA boards are also responsible for the development of a five-year Health Systems Plan (HSP) for the region, for Annual Implementation Plans (AIPs), for approving grants and contracts awarded to carry out the HSP and for issuing an annual report of HSA activities.

The HSA may establish sub-area councils (sometimes known as district boards), but it doesn't have to do this. The legislation calls sub-area councils "advisory" bodies and says that their purpose is to "advise the governing body on the performance of its functions." Thus, the governing board may delegate certain responsibilities to sub-area councils in order to be advised of whatever it wishes to be advised about. Sub-area council tasks may include the reviewing of applications by health institutions for new services, or review of drafts of the HSP and AIP and other documents produced by the agency.

The HSA board in pursuing the agency's goals of health planning and development for the region, can and should gather and analyze data on the health status and health status determinants of the region's population; the type and number of health care resources; usage of those resources by the population; the organization of resources into a delivery system; the effect of the offered services on the population's health; and environmental and occupational factors affecting immediate and long term health conditions.

In regard to medical technology in particular, the HSA board can have a significant impact on the way major technologies are adopted and absorbed into the region's health system. Because the HSA is required to review all proposals for new institutional services involving capital expenditures of more than $100,000, the HSA board is in a position to ensure that all projects for major institution-based technology are compatible with health needs and priorities of the region as set out in the HSP.

CHAPTER 2

ISSUES IN EVALUATING MEDICAL TECHNOLOGY

MEDICAL TECHNOLOGY DEFINED

The Office of Technology Assessment (OTA) of the U.S. Congress, defines *medical technology* as "the drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided." OTA further defines terms used in the above definition as follows: "A *drug* is any chemical or biological substance that may be applied to ingested by, or injected into humans in order to prevent, treat or diagnose disease or other medical conditions. A *device* is any physical item, excluding drugs, used in medical care (including instruments, apparatus, machines, implants, and reagents). A *procedure* is a medical technology involving any combination of drugs, devices and provider skills and abilities. Appendectomy, for example, may involve at least drugs (for anesthesia), monitoring devices, surgical devices, and physicians', nurses', and support staffs' skilled actions."

This definition of medical technology tells us that medical technology is a set of tools, an extension of human minds and hands, developed to help us achieve certain goals. The goals of medical technology in general are the same as the goals of the medical care system—to prevent unnecessary and untimely death, to improve health, and to alleviate the pain, discomfort and disability of medical conditions which can't be cured.

Drugs, devices, medical and surgical procedures (i.e., medical technology) are the end result of a sophisticated process which has two phases: 1) the *development of a systemized body of knowledge* derived from observation, study and experimentation carried on to determine the nature of a medical problem and 2) the *practical application* of this knowledge to the medical problem. For example, the treatment of cancer with radiotherapy was developed as a result of having a body of knowledge about the characteristics of cancer and how its growth can be inhibited. Technology is not necessarily expensive, complicated or of use for only rare or difficult to treat diseases. Many of our most effective technologies like pencillin or streptomycin, the tine test for tuberculosis, the chest x-ray and the blood pressure cuff are inexpensive.

STAGES IN THE DEVELOPMENT AND DIFFUSION OF MEDICAL TECHNOLOGY

According to the OTA, "The development, diffusion, and use of medical technologies is a process that has been described as including at least seven steps:

1. Discovery, through research, of new knowledge, and relation of this knowledge to the existing knowledge base;
2. Translation of new knowledge, through applied research, into new technology, and development of a strategy for moving the technology into the health care system;
3. Evaluation of the safety and efficacy of new technology through such means as controlled clinical trials;
4. Development and operation of demonstration and control programs to demonstrate feasibility for widespread use;
5. Diffusion of the new technology, beginning with the trials and demonstrations and continuing through a process of increasing acceptance into medical practice;
6. Education of the professional and lay communities in use of the new technology; and
7. Skillful and balanced application of the new developments to the population."

SOME PROBLEMS IN EVALUATING MEDICAL TECHNOLOGY

Many technologies have problems of safety and efficacy which must be addressed. Methods for estimating safety and efficacy vary from the practical experience of physicians to the conducting of complex, controlled testing procedures. Currently, most judgments about safety and efficacy are based on one or more of the following: 1) informal consensus among those in the medical community who have experience with the technology; 2) formal study and recommendations by a group of experts in the field; 3)pre-clinical trials, including animal testing and tests for chemical purity; 4) controlled clinical trials; and 5) statistical studies of the impact of the technology on specific populations.

Other problems such as whether the cost of a technology is justified, how much medical need is sufficient to acquire it, and what constitutes appropriate utilization are not problems of medical technology as such, but are social problems to be solved by the community on the basis of its own needs and values. For example, there is much discussion of the inappropriate or unnecessary use of the C-T Scanner. This is not a problem with the C-T Scanner, which is an effective device, but a problem with people's decisions about how the scanner is to be used. To prevent abuse, it may not be necessary to stop using the technology, but rather to set up professional protocols for using it and to establish review procedures to assure that all protocols are followed. Likewise, the "expensiveness" of the C-T Scanner (or any other technology) is a social as well as an economic question, relative to how much it will be used and the degree of its benefits to health or medical care. In Chapter Three of this manual there will be a discussion of the criteria by which a community, through facility and Health Systems Agency boards, can decide upon the acquisition and placement of medical technology. The criteria, however, will only indicate the questions which should be asked as part of this decision-making process. You will have to decide for yourself if the answers to your questions indicate that the technology is compatible with your own needs and values.

The issue of social values raises a basic question which bothers many people on facility and Health Systems Agency boards. Is medical technology really preventing unnecessary and untimely death? The U.S. spends more on health care than any other nation, but still has poor mortality data and health status indicators in comparison to many other industrialized countries. Our current medical technology has not had a great impact on the death rate from the nation's major killers—heart disease, stroke or cancer—even though a great deal of money is spent seeking cures for these diseases.

Some experts in prevention say that medical treatment is not the solution to our most serious medical problems today. They say that what is needed is a change in our environment, in the work place and in our life style. It is necessary to remove toxic substances from the environment and to reduce personal intake of alcohol, cigarettes and foods containing saturated fats, so that the major diseases, which are treated with so little effect, will be prevented from occurring. These major changes in our personal and public environment are not likely to happen until the public forces important policy changes, including such steps as establishing stricter controls over carcinogens in food, workplace and environment; providing financial support for sports and exercise; launching a broad campaign to improve people's dietary habits; and taking measures to discourage the production and/or consumption of tobacco and alcohol.

However, prevention is not a substitute for the medical care system or medical technology. We must still screen, diagnose and provide treatment for the medical problems that do exist, and we would have to continue doing so even if a full scale program for prevention were launched tomorrow.

In actual practice, decision-makers are rarely in a position to make a direct trade-off between a proposed new treatment technology and a needed prevention program. An HSA, for example, has the power to turn down a hospital's application for cancer treatment technology, but it cannot transform the unspent money and resources into a SmokeEnders program or a city ordinance against air pollution. Ultimately, we need both a healthful environment and life style and a medical system which can bring the best technology to bear on existing medical problems.

CATEGORIES OF MEDICAL TECHNOLOGY

There are three types of medical technology: preventive, diagnostic and treatment. These three categories and their sub-types follow:

Preventive

Primary preventive technologies are those that protect people from the development of disease or ill health. Immunizations are an example of primary prevention.

Secondary preventive technologies are those that detect disease processes before they become evident or serious. In some conditions, such as hypertension, the disorder can be detected even though the person feels perfectly well. In other situations, minor symptoms like a low fever or a cough may already be present. All *screening* procedures are examples of secondary preventive technologies.

Diagnostic

Diagnostic technologies are those which help determine what disease processes are occurring in a patient. The C-T Scanner, which can detect tumors or hemorrhages, is an example of a diagnostic technology.

Treatment

Curative technologies are those which can completely restore the person to his or her former state of health. Penicilin for "strep" throat, or the surgical repair of a hernia fall into this category.

Rehabilitative technologies are those which help a person to partially recover a former state of health: for example, whirlpool treatment for damaged muscles.

Maintenance technologies are those used either to stabilize a person's condition or to prevent it from becoming worse. Examples: daily injections of insulin to control diabetes; hemodialysis to prevent death from kidney failure.

LEVELS OF CARE: PRIMARY, SECONDARY AND TERTIARY SERVICES

Generally, different kinds of medical care (and technology) are available to patients at different points in the health system. Medical care services are often divided into three categories, or levels: primary, secondary and tertiary. Although these categories are not always hard and fast, health planners distinguish among primary, secondary and tertiary services as follows:

Primary care is the basic medical care for routine problems. It generally takes place at the point where the patient first contacts the health system—in doctors' offices, clinics, hospital outpatient departments, child health stations and free standing ambulatory care centers. Primary care is usually provided by general medical practitioners, family care practitioners, internists, pediatricians, gynecologists and various kinds of physicians' assistants.

Secondary care is provided by specialists who generally do not have first contact with the patient. Ophthalmologists, radiologists, surgeons and orthopedists are examples of secondary care physicians. Most radiological procedures and surgery are usually classified as secondary services. A great deal of secondary care takes place in hospitals, and other sites including specialists' of-

fices, specialty clinics and diagnostic centers. Community hospitals are often called secondary care facilities, since the bulk of the inpatient care they provide falls into this category.

Tertiary care is the care provided by highly specialized providers, such as heart surgeons, neurosurgeons and pediatric endocrinologists. Examples of tertiary care services are open heart surgery, plastic surgery, cardiac catheterization, hemodialysis, and high risk newborn intensive care. The population needs comparatively less tertiary care than it does primary and secondary care services. There are very few hospitals that provide only tertiary care. Examples of these are the Chester-Crozier Burn Hospital in Pennsylvania and the Memorial Sloan Kettering Cancer Hospital in New York City. Medical centers and teaching hospitals will tend to have a higher concentration of tertiary care services than community hospitals, which will frequently provide only one or two highly specialized services.

APPROPRIATE PLACEMENT OF MEDICAL TECHNOLOGY: SOME ISSUES

Members of facility and HSA boards need to consider whether the kind of technology under consideration would be appropriately placed in the facility which wishes to acquire it. Basic questions to ask are: *What kind of technology is being considered? In what kind of facility is it to be placed?*

Sometimes there will be questions about placing a "tertiary" care technology in a community (secondary) hospital. Tertiary care technology is usually expensive, often requiring additional staff with special training. Sometimes expensive renovations are necessary to bring the hospital's plant into compliance with standards governing the use of the technology. A burn care unit, for instance, must be completely sterile and have precise temperature and humidity control. Since all hospital costs are folded into the daily rate paid by reimbursing agencies, the addition of a burn care unit, or other tertiary care technology, will raise the cost of care for all of the hospital's patients, whether or not they are receiving tertiary care. How much of the costs of a tertiary care technology can be absorbed by the rest of a community hospital's services and how much of this additional expense ought to be paid for by community hospital patients are questions that need to be answered according to the values of the community and particular local circumstances.

Appropriate placement of technology affects safety and quality of services as well as costs. If the medical staff of a community hospital do not have the special qualifications or training required for delivery of the tertiary care service, or if the service will not be delivered often enough to maintain skills, quality of care may suffer. On the other hand, there are times when a tertiary care technology would be appropriately placed in a community hospital where it would be a natural extension of existing services. A neonatal intensive care unit might be well placed in a community hospital, if the hospital were known for providing extensive, high quality pediatric and maternity services to the region. Likewise, a community hospital with a major cancer treatment program might be the logical place for a linear accelerator. In both cases, the answer would depend in part on whether the tertiary care technology is available elsewhere in the region.

HSA boards may be also asked to review applications for technology, which is very sophisticated and expensive, but absolutely basic to the ordinary operation of an effective hospital. A radiologic/fluoroscopic room is almost as expensive as a C-T scanner, but it does all the radiologic diagnostic work that is needed to provide secondary care, and primary care too.

Some technology, while expensive in itself, does not require very much in the way of additional highly trained staff, or plant renovation. Kidney dialysis is an example.

In order to determine whether certain technology should go into a given facility, you will want to look not only at the technology itself, but also at the *related kinds of services* offered by the facil-

ity; the *kinds of staff* and their *qualifications;* any *evaluations* or inspections or site visits that have been done which will tell you something about the *qualification of the staff and the facility and quality of the services* already provided; the *financial strength* of the facility; and its track record in making care *accessible* to those patients without insurance or money to pay for the full cost of the services.

THE GOVERNMENT'S ROLE

The federal government is involved in some way at most stages of the process of the development of medical technology, beginning with basic and applied research, and extending through clinical trials, evaluation of safety and efficacy, development of criteria for safe use of the technology in medical practice, distribution of technology and payment for technological services.

Some of the most important activities undertaken by the federal government in relation to medical technology are: *regulation* through the Food and Drug Administration (FDA) of the Department of Health, Education and Welfare (DHEW); *research* through the National Institutes of Health (NIH); *evaluation* of the effects of technology, especially through the new National Council for Health Care Technology and the Congressional Office of Technology Assessment; *overseeing* the acquisition and placement of medical technologies through the Health Systems Agencies and DHEW; and *paying* for medical technology through Medicare, Medicaid and Title V. The Office of Health Practice Assessment (part of DHEW) collects available data on safety and efficacy of technology and makes recommendations to DHEW's Health Care Financing Administration (HCFA) regarding coverage of technological services under Medicare. HCFA makes final decisions regarding reimbursement of technologies. Professional Standards Review Organizations (PSRO) are part of HCFA, and their mission is to assure that any rendered services are medically necessary, consistent with professionally recognized standards and delivered at the appropriate level of care.

The Food and Drug Administration is one of the most important regulatory agencies charged with protection of the health of the public. Up until 1970, the FDA was responsible for assuring the safety of all food, and the safety and efficacy of all drugs and veterinary medicine. Since then, FDA has also become responsible for a broad range of medical technology, including x-ray equipment and other radiation-emitting devices, blood banks, vaccines and allergenics, organ transplants and other biological products.

The statutory authority for the activities of the FDA is derived from: the Food, Drug and Cosmetic Act of 1938, the Drug amendments of 1962, the Medical Device Amendments of 1976 and the 1968 Radiation Control for Health and Safety Act.

The National Institutes of Health (NIH) are comprised of eleven separate institutes which make up the principal biomedical research agency within the federal government. NIH was established immediately after World War II, for the purpose of consolidating the government's medical research activities in one agency, and to support and encourage medical research and development outside of government. NIH awards grants and contracts to academic and research institutions to conduct studies. NIH describes its goals as 1) advancing knowledge and understanding of the normal and pathological processes of the human body, and 2) developing ways in which the providers of medical care can safely and effectively intervene to prevent, treat or cure diseases and disabilities.

The statutory authority for NIH activity is Section 301 of the Public Health Service Act.

The *Health Systems Agencies* are regional health planning bodies which are the local units of the federal and state health planning system. HSAs are funded by DHEW and are responsible to DHEW in their operations and activities. They are charged with developing health plans for their regions and with reviewing the merits of all proposals by health institutions to make expenditures of more than $100,000 for acquisition of medical equipment or construction and renovation of facilities.

The statutory authority for the HSAs is the National Health Planning and Resource Development Act of 1974.

CHAPTER 3

ASKING QUESTIONS AND MAKING JUDGMENTS: SIX ESSENTIAL CONSIDERATIONS

This chapter presents questions for consumers to ask when confronted with decisions regarding the acquisition and distribution of medical technology. The questions have been organized into six categories, representing the essential considerations for evaluating a technology and for planning how it should be absorbed into the health system. The list of questions presented here by no means exhausts the possibilities for inquiry, but is intended to be a basic approach which can be applied to many decision-making situations.

Briefly, the six areas of consideration are as follows:

Need. What medical problem does the technology treat, diagnose or prevent? How serious and how widespread is the problem? Who will benefit from the adoption of the technology?

Safety. What is the probability of risk associated with the use of the technology? How does it compare in safety to other technologies or non-technological alternatives?

Effectiveness. Does the technology do what it's supposed to do? How reliable is it?

Cost. How much does it cost? Who will bear the expense?

Regional Impact. How will the addition of a technology affect the delivery of other health services in the region or area?

Consistency with the Health Systems Plan (HSP). Is introducing a new technology into the region compatible with the regional goals and priorities spelled out in the five-year HSP developed by the Health Systems Agency? Is it consistent with the Annual Implementation Plan (AIP) stating the yearly objectives for the region's health delivery system?

By posing questions and demanding answers in these six areas, the consumer decision-maker should be able to draw out enough facts on which to make a judgment about the adoption or purchase of a particular medical technology. Basic questions to be asked in each area are described below:

WHAT TO ASK ABOUT NEED

Question 1.

What is the medical problem being addressed by the technology?

As a basis for all further questioning, the consumer should have a good understanding of the nature of the medical or health problem which the technology is meant to prevent, diagnose or treat. The party who is arguing for the adoption of the technology should be required to present a thorough explanation of the medical problem in layperson's language. Independent sources of information on the subject should also be consulted.

Question 2.

How many people can be expected to benefit if the proposed technology is adopted?

To establish the relative need for the technology in the community and its appropriate placement in the region, it is necessary to determine the scope of the medical problem and to identify the population who will benefit—actually and potentially—from the technology.

Find out the incidence (rate of occurrence) or prevalence (number of cases) of the medical problem and whether it is widespread or limited to a specific group in the population (e.g., elderly, newborn, women, Blacks).

Since there can be a difference between potential and actual benefit from the technology, it should be known how and to whom the facility wishing to adopt the technology makes its services available. Is the facility intending to acquire the technology for use within its present patient population? Will it seek to serve others in the community who might benefit? Will the technology be available to all? Will ability to pay affect access? Will the placement of the technology in a particular facility promote or impede access by those needing the service?

Question 3.

How does the technology deal with the medical problem?

Does the technology in question prevent, diagnose or treat the medical problem? At what stage of illness does it intervene?

Question 4.

If the technology is used to diagnose or screen for a medical problem, is there treatment available for the conditions which are identified? If a treatment technology, does its use result in full or partial recovery? Does it stabilize or rehabilitate the patient?

Many people have questioned the wisdom of adopting diagnostic technologies which detect conditions for which there is no cure or for which treatment is not easily available. In considering such technologies, social and ethical as well as scientific factors must be taken into account. Improved ability to diagnose a disease, even if a cure is not immediately available, increases the general body of knowledge about that disease, and thus increases the probability of eventual cure, control or prevention. Psychologically and socially, it may be important to correctly diagnose an "untreatable" disease, if only so that patients and their families will be able to prepare for a death. The medical care system has been slow to recognize that there is much that can be done for a patient which patients and their families consider important, even if death is inevitable. In other words, medical technology may be able to offer benefits besides those of absolute recovery, prevention or stabilization.

Likewise, many have questioned the use of so-called "halfway technologies" which, with a great deal of expense and sometimes a great deal of discomfort, bring only a very limited reprieve for a patient. The "need" for chemotherapy or radiotherapy for certain cancers has been questioned in this way. Again, complex scientific, psychological and social judgments must be made, since with clinical use, such technologies may be refined and improved in the future, and since it is difficult, if not impossible, to say that an extra day, month or year of life is not worth any expense or difficulty.

Sometimes, conditions which are identified in a screening program are treatable, but in actual practice treatment services are not available because they are too far away, too expensive or not well publicized. If treatment is not available for these reasons, you will probably want to question whether there are plans to coordinate treatment services in the region with diagnostic or screening programs which have been proposed. If not, you will want to weigh in this liability with any benefits the diagnostic or screening program may bring.

Question 5.

What technology, if any, is currently being used for this medical problem?

It is important to know if the proposed technology will deal with the medical problem in an entirely new way or by a method similar or identical to technologies currently in use. Find out whether—in terms of medical needs—new equipment or procedures have distinct advantages over technology which is already in place.

WHAT TO ASK ABOUT SAFETY

Question 1.

What is the probability that a person will be harmed by being subjected to the medical technology?

Almost all technology has a side effect or a possible risk of harm. Over time, through testing and/or use, the side effects become known, and the probability of harm, or the risk, to the user can be determined. For example, one well known study found that users of birth control pills are four or five times more likely to develop blood clots than non-users.

Question 2.

How severe is the harm which may result from using the technology?

The harm risked may range from discomfort to disability, to death. Drugs and radiotherapy treatments for Hodgkin's disease, for instance, can cause other forms of cancer, as well as severe infections and bone marrow conditions. However, these same treatments have contributed to the increased survival rate for Hodgkin's disease victims. In the early 1940's, the chances of a person with Hodgkin's surviving three years were only 35 percent. In 1973 the five-year survival rate reached 87 percent.

You will also be interested in the amount of time over which side effects can occur and whether or not the harm is reversible. For example, a number of children of women who took the drug diethylstilbestrol (DES) during pregnancy to prevent miscarriage, developed cancers of their own reproductive systems. In this case, side effects of the technology emerged years later in the next generation. Likewise, cancers and genetic damage from radiation emitting technology may not surface for many years.

Hypertension and some other side effects of birth control pills may disappear as soon as treatment is stopped, but a stroke caused by birth control pills may cause irreversible or fatal damage.

In the final analysis regarding safety, you will have to balance three things—probability, severity and benefit. This concept is sometimes called the "risk benefit ratio."

The drug lithium carbonate for instance, is uniquely effective in treating people who have manic depressive symptoms. However, recent studies indicate that this drug carries a significant risk of liver damage to long-term users. Thus, benefits can be high and risks severe, with the final judgment being highly complex and subjective.

Question 3.

How does the technology compare with other technologies currently in use in terms of benefits and probability and severity of risk?

If the probability of harm is greater with the new technology, you will want to know why it is being proposed. As illustrated by the examples in Question 2, the answer may be that the benefits are so great that, for many people, they will override the risk.

At best, a technology will increase benefits and decrease risks. For diagnosing brain abnormalities, for instance, the adoption of C-T scanning technology brought the benefit of superior visualization of the brain with equal or less physical risk compared to previous x-ray techniques (arteriogram and pneumoencephalogram).

Question 4.

What standards are there for safe use of the technology? How frequently should the technology be used in order to maintain skills of the technical team (doctors, nurses, technologists and other health workers) who are performing the procedure or operating the equipment? Will the technology be used often enough in the proposed setting to assure that it will be skillfully and safely operated?

Technical procedures must be performed regularly to maintain skills. In some cases, there are published, quantified standards for how often complex procedures—such as open heart surgery—ought to be performed. To determine whether a technology will be safely used in your facility, you must find out how often it will be employed and how this figure compares with quantified standards, if they exist. In some cases, standards are published by professional associations (such as the American College of Surgeons) and the federal government (the National Health Planning Guidelines); in other cases, you may seek independent opinions from watchdog groups (such as the Public Citizen Health Research Group in Washington, D.C.) and experts in the field.

ASKING QUESTIONS AND MAKING JUDGEMENTS: SIX ESSENTIAL CONSIDERATIONS

WHAT TO ASK ABOUT *NEED*

1. What is the medical problem being addressed by the technology?
2. How many people can be expected to benefit if the proposed technology is adopted?
3. How does the technology deal with the medical problem?
4. If the technology is used to diagnose or screen for a medical problem, is there treatment available for the conditions which are identified? If a treatment technology, does its use result in full or partial recovery? Does it stabilize or rehabilitate the patient?
5. What technology, if any, is currently being used for this medical problem?

WHAT TO ASK ABOUT *SAFETY*

1. What is the probability that a person will be harmed by being subjected to the medical technology?
2. How severe is the harm which may result from using the technology?
3. How does the technology compare with other technologies currently in use in terms of benefits and probability and severity of risks?
4. What standards are there for safe use of the technology? How frequently should the technology be used in order to maintain skills of the technical team (doctors, nurses, technologists and other health workers) who are performing the procedure or operating the equipment? Will the technology be used often enough in the proposed setting to assure that it will be skillfully and safely operated?

WHAT TO ASK ABOUT *EFFICACY* AND *EFFECTIVENESS*

1. What is the medical technology supposed to do? What result is supposed to come from its application?
2. What are the optimal circumstances under which the technology is designed to work?
3. Under what circumstances will the technology be expected to work in your region?
4. How is the effectiveness of the technology evaluated?

WHAT TO ASK ABOUT *COST*

1. How much does it cost to purchase or lease the technology and to operate and maintain it?
2. How does the cost of the proposed technology compare with that of current techniques?
3. Will the proposed technology be able to pay for itself during its life span?
4. What impact will the proposed technology have on the reimbursement rate?

WHAT TO ASK ABOUT *REGIONAL IMPACT*

1. Is the proposed medical technology a part of an integrated regional system to provide a specific service or group of services to the region's population?
2. Is there an adequate, alternate way of providing a needed technological service without adding a new program or piece of equipment?
3. Will the use of the proposed technology change the characteristics of the region's population in a way which will affect the need for health services?
4. Will use of the proposed technology lead to a change in the management of the medical problem and consequently change the demands on other health services?

WHAT TO ASK ABOUT THE *HSP*

1. Does the proposed technology promote or conflict with an HSP goal?
2. Is the acquisition of the proposed technology consistent with the goal of planning on a regional basis for the distribution of certain medical technologies?

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;K ABOUT EFFICACY AND EFFECTIVENESS

efficacy" is usually used to indicate how well something works under *ideal* circum-
"effectiveness" refers to how well something works under *normal or usual circum-*
ifference between the two words might be summed up as being the difference
/ell something is supposed to work and how it actually does perform.

dical technology supposed to do? What result is supposed to come from its applica-

e the efficacy or effectiveness of a technology, you must know what it is supposed
he medical problem. Drugs used to treat hypertension are supposed to lower the
of persons following the prescribed regimen. Appendectomy, surgical removal of an
dix, is supposed to reduce the risk of death due to the spread of infection from the
; organ.

ptimal circumstances under which the technology is designed to work?

litions are necessary for efficacious use of the technology? Considerations might in-
affing levels, and the environmental temperature and pressure, as well as procedural
such as minimum weekly, monthly, or annual usage, and plans concerning what to
ment is being serviced.

cumstances will the technology be expected to work in your region?

realities, how effective can you expect the technology to be? It is important to find
ual conditions differ from the ideal ones and to get an estimate of how these dif-
ffect the technology's ability to do what is supposed to do. For instance, a computer
/ and/or stable temperature for optimal operation. However, it may happen that in the
:h the technology is proposed, the temperatures cannot be regulated. How will this
puter's accuracy and reliability?

ctiveness of the technology evaluated?

e evidence that the technology performs well? If new, has the technology been sub-
mental or clinical trials? If the technology is already in use, has it been connected to
)idity (sickness) or mortality (death) rates? Effectiveness can also be measured by
hich the technology improves people's ability to function and care for themselves.
cemaker, for instance, not only dramatically reduces the mortality rate from heart
)les people with this condition to live normal lives. The technology's effectiveness
)asured in terms of its ability to perform its functions more cheaply, quickly, accu-
)ss discomfort to patients than other similar methods.

COST

WHAT TO ASK ABOUT COST

Question 1.

How much does it cost to purchase or lease the technology and to operate and maintain it?

The costs of a new technology can be broken down into three parts: the cost of purchasing or leasing it, the cost of operating it, including the cost of building or acquiring the appropriate physical space and hiring and educating skilled technical staff; and the maintenance or service costs. Some technologies such as computers, require special physical environments, highly trained and expensive operating staff, and maintenance experts. All these should be considered when estimating the cost of a technology.

When speaking of costs the terms "capital expenses" and "operating expenses" are often used. Capital expenses are all those costs incurred in purchasing, building, replacing or remodelling a facility and the equipment it contains. Operating expenses are those relating to maintaining the facility or equipment at the standards with which it complied when first constructed or acquired. For example, the cost of heating fuel and air conditioning systems are operating expenses. Operating expenses also include staff costs and the cost of servicing the facility debt.

Question 2.

How does the cost of the proposed technology compare with that of current techniques?

Besides comparing the direct costs of new technology with that of the equipment now being used, it should be taken into account whether new equipment or methods will replace or be used in addition to technology which is already in place. In addition, there may be other indirect factors affecting the total costs of adopting the new technology.

The C-T (computerized tomographic) scanner which first appeared in 1973 revolutionized neuroradiology because of its ability to provide clear images of the soft tissues of the brain. In so doing, it has replaced the great majority, but not all, of the pneumoencephalograms (x-ray procedures involving the draining of the spinal fluid and the injection of air into the space surrounding the brain) and arteriograms (x-rays of arteries requiring the injection of a contrast dye) which were being performed to diagnose brain dysfunctions.

C-T scanning equipment is extremely expensive to purchase and maintain, but unlike arteriography and pneumoencephalography, the new process does not require that the patient be hospitalized. Thus, the saving of hospitalization charges must be taken into account when reckoning the total cost of adopting C-T scanning rather than its alternatives.

Question 3.

Will the proposed technology be able to pay for itself during its life span?

There are two factors to be considered when determining whether or not a technology will pay for itself before it is replaced. The first factor is its physical life span or the estimated amount of time over which the technology can be expected to function effectively. Every technology has a limited life span—after a specified period of time, drugs lose their potency; the estimated life span of a C-T scanner is five years.

The second factor to be considered is how fast the technology will become obsolete due to innovations in the field. Especially when a technology is very new, better ways of doing the same thing often follow each other in rapid succession. This happened with C-T Scanners where, long

before the physical life span of the first models had been reached, new models were already on the market. When this happens the costs of the obsolescent technology may not be recovered until the period of rapid innovation runs its course. In the interim, the cost per unit of service may be increased so that innovations can be purchased as they are developed. The physical life span and an estimate of its potential rate of obsolescence must be taken into account when determining whether or not the proposed technology will pay for itself.

Question 4

What impact will the proposed technology have on the reimbursement rate?

The reimbursement rate is the rate at which a health care provider is paid by government programs such as Medicaid and Medicare or other third party payers—such as Blue Cross—and by individuals. In considering costs it is important to know how the reimbursement rate of your facility will be affected by the purchase, operation and maintenance of the proposed technology. Simply put, the question is: By how many dollars will the daily reimbursement rate be increased?

WHAT TO ASK ABOUT REGIONAL IMPACT

Question 1.

Is the proposed medical technology a part of an integrated regional system to provide a specific service or group of services to the region's population?

Basically, the answer to this question should tell you if the proposed technology will be accessible to those people who need and can benefit from it.

When the technology is new or used for tertiary care and when it is the only service of its kind in a given area, it is important that it be accessible to all patients and providers in the area who need it. To achieve this, formal working relationships must be established with health facilities, other providers, voluntary agencies and emergency and transport services.

For example, a hospital proposing a neonatal intensive care unit will need to establish relationships with ob-gyn (obstetrics and gynecology) outpatient services, hospitals with maternity services, and emergency vehicles including the police department, to arrange for the identification and transfer of high-risk pregnant women and newborns requiring intensive care.

Question 2.

Is there an adequate, alternate way of providing a needed technological service without adding a new program or piece of equipment?

Are there services already existing in the region which could handle an increased patient load? If such services exist, what can be done to arrange for patients to use this facility? (The answer to this question will probably lead to a discussion of how facilities can share services and to consideration of technologies other than the one being proposed.) If these services do not exist, is there a facility in another region which could handle the increased patient load? And, is this medical problem one which usually does not require emergency, and therefore quickly accessible care? Sending patients to a facility not in the immediate vicinity may mean an investment in communications and transportation mechanisms. However, in comparison to duplicating the technology this is often a cheaper and more efficient way to provide needed services for some kinds of medical problems.

If going out of the region is not possible or advisable, and the needed service is not in the region, then you have another good reason to consider the acquisition of the proposed technology in your facility and/or region.

Question 3.

Will the use of the proposed technology change the characteristics of the region's population in a way which will affect the need for health services?

The answer to this question is important when estimating what affect the proposed technology will have on the health needs of the region's population. For example, since the use of birth control methods have become widespread the birth rate has fallen sharply. With fewer children being born, the need for obstetric, neonatal, and pediatric services has also decreased.

Question 4.

Will use of the proposed technology lead to a change in the management of the medical problem and consequently change the demands on other health services?

How the new technology may affect the management of the medical problem is important information for patients (Will I be able to stay at home whereas I used to go to the hospital? Will treatment sessions now take place more or less frequently?), for facilities (Will we need fewer or more inpatient beds? Outpatient services? Will there be less of a demand for maintenance and rehabilitation services because illnesses have been prevented or detected at earlier stages?) and for the region (Will there be more people at home needing nursing or homemaker services? Will demand on tertiary care services be greater or smaller?).

WHAT TO ASK ABOUT THE HEALTH SYSTEMS PLAN (HSP)

Question 1.

Does the proposed technology promote or conflict with an HSP goal?

Consumers must ask how the proposed technology relates to the high priority goals of the region. For example, a major HSP goal might be to reduce deaths due to accidents. In such a community, setting up a head trauma treatment center which used a C-T scanner would promote this goal. Accident victims with head injuries could have the effects of their injuries quickly and effectively diagnosed. Required treatment could be begun early and some deaths avoided.

Another high priority goal might be to reduce the infant mortality rate. In this case a hospital proposal to eliminate its obstetrical beds, and consequently to eliminate its obstetrical outpatient department might conflict with this goal. Closing the outpatient department might decrease access to prenatal care and thus increase the risk of death for newborns.

Question 2.

Is the acquisition of the proposed technology consistent with the goal of planning on a regional basis for the distribution of certain medical technologies?

The National Health Planning Guidelines require that certain medical technologies (such as C-T scanners, radiation therapy units, hemodialysis centers, and cardiac cathetrization units) be distributed on a regional basis according to specific standards. In addition, the HSP may itself set limits on the acquisition of technology or standards for its distribution and use. All proposals for new equipment and/or services must be checked against relevant regional standards and, when indicated, adequate plans should be developed for sharing the technology on a regional basis.

CHAPTER 4

SAMPLE QUESTIONS AND ANSWERS

Following are examples of the kinds of information you should expect to get by asking the questions presented in the last chapter. Three sample sets of questions and answers are presented, representing one preventive technology (chicken pox vaccine), one diagnostic technology (C-T scanning) and one treatment technology (hemodialysis).

PREVENTIVE TECHNOLOGY: CHICKEN POX VACCINE

NEED

1. What medical problem does the technology address?

The medical problem addressed by the technology is chicken pox, an infectious disease caused by a virus, Varicella Zoster (VZ). Chicken pox causes skin eruptions and mild constitutional symptoms such as fever.

2. How widespread is the problem? What special population does it affect?

Chicken pox primarily affects young children and is the second most frequently reported disease (after gonorrhea) in the United States. Recent national statistics show a 30 percent decline in the incidence of chicken pox from a high of 97 cases per 100,000 population in 1972 to a low of 72 cases per 100,000 in 1975.

Although the symptoms of chicken pox are usually mild, there were 106 reported deaths (1.3 per 1,000 cases) from the disease in 1974; most of these deaths occurred in children who were at high risk because they were already weakened by illnesses such as leukemia.

3. How does the technology deal with the medical problem?

The vaccine will prevent chicken pox by stimulating the body's own immune system to fight the invading virus.

4. If the technology is used to diagnose or screen for a medical problem, is there treatment available for the conditions which are identified? If a treatment technology, does it use result in full or partial recovery? Does it stabilize or rehabilitate the patient?

Since the chicken pox vaccine is a preventive technology, this question is not applicable.

5. What other medical technologies are currently used for this medical problem?

At the present time there is no alternate method of preventing chicken pox, although it has been suggested that gamma globulin containing antibodies from previously infected individuals might be used as "passive immunization" for high-risk groups such as leukemia patients. ("Passive immunization" means that antibodies are derived from another source, rather than being produced in the body of the patient by a vaccine or a case of the illness.)

SAFETY

1. What is the probability of a person's being harmed by a chicken pox vaccination?

The probability of harm is unknown and not easily established. However, experts say that certain high risk groups—such as leukemia patients—may have adverse reactions to being vaccinated.

2. How severe is the harm which might result?

It has been suggested that chicken pox immunization might have three long-term harmful effects: a) immunization might cause an increase in the number of adults suffering from zoster

(shingles). Shingles is also caused by the VZ virus and tends to occur years later in adults who had chicken pox in childhood; b) immunization might delay chicken pox until adulthood when it is more severe, while a mild childhood case of chicken pox gives lifelong immunity; c) the VZ virus has been shown to cause cancer in animals, and this finding raises the possibility that chicken pox immunization might cause cancer in humans.

All three of these possible side effects of chicken pox immunization are quite serious, do not appear to be reversible if they do occur, and take many years to show themselves. Shingles, for instance, may not appear until ten to thirty years after the original infection by VZ virus; adults could get chicken pox any time during their lives once the vaccine no longer protected them; and it is unknown how long it might take for a cancer to develop as a result of immunization.

3. In terms of safety and risk, how does the technology compare with other technologies currently in use?

Chicken pox is not now preventable through the use of an alternate technology. Therefore, threats posed by the disease itself must be compared with the risks of immunization.

4. What standards exist for safe use of the technology?

There are not quantified standards for use of this technology. No special skills are required beyond those already possessed by qualified health workers.

EFFICACY AND EFFECTIVENESS

1. What is the technology supposed to do? What result is expected from its application?

The vaccine stimulates the body's immune system and prepares it to attack the invading chicken pox virus. Overall, a chicken pox immunization program is supposed to prevent people from suffering the symptoms of that illness and to prevent any deaths which it might cause.

2. What are the optimal circumstances under which the technology is designed to work?

As with other vaccines, the only requirements are safe storage, trained staff and sterile equipment. Additionally, to be effective on a population-wide level, the technology must be made available to most of the target population.

3. Under what conditions will the technology be expected to work in your region?

The answer depends upon your facility or region. Does the facility proposing to administer an immunization program have the required personnel? equipment? storage capability?

4. How is the effectiveness of the technology evaluated or measured?

Preliminary evidence from a controlled clinical trial in Japan has shown the vaccine to be very effective. In a study in which 45 children were exposed to chicken pox, all of those who were vaccinated prior to exposure did not contract the disease, while all those not vaccinated developed it. Blood tests of the vaccinated children also showed evidence of immunity.

COST

1. How much does it cost to purchase or lease the technology? To operate or maintain it?

Although no vaccine for chicken pox is currently mass produced, its cost might be expected to be comparable to those of other vaccines for childhood diseases. Labor costs of an immunization program would be minimal if the vaccine could be administered by health personnel currently employed in health centers, hospitals, schools, or private practice.

2. How does the cost of the technology compare with that of current techniques?

Since there is no current technology to prevent chicken pox, the cost of a mass immunization program could only be contrasted to the cost of current practice in dealing with the disease. Doctor visits and drugs are the costs presently incurred by the consumer/patient suffering from chicken pox. With an immunization program, costs would rise for government and be transferred from the individual patient to all taxpayers.

3. Will the proposed technology pay for itself during its life span?

The physical life span (shelf life) of the chicken pox vaccine currently under study is unknown. If several vaccines were developed, it might happen that each improved variety would rapidly replace its predecessor, raising questions about the expense of stockpiling this very new technology too rapidly.

4. What impact will the technology have on the reimbursement rate for health facilities?

Since government usually bears the costs of purchasing and distributing a vaccine, the remaining expenses reflected in the facility's reimbursement rate would be the costs of storing and giving the vaccine. One would expect adoption of chicken pox vaccine to have very little effect on a facility's reimbursement rate.

REGIONAL IMPACT

1. Is the proposed technology part of an integrated regional system?

If a mass immunization campaign were approved, it would be a part of a nationally coordinated program to vaccinate the entire young population of the country, probably involving schools, public health clinics, hospitals and other facilities and individual doctors. Part of this program should be the identification of those children who have a high risk of suffering adverse side effects from the vaccine.

2. Is there another way of providing the needed technology?

In the case of chicken pox immunization, where young children are involved, a judgment must be made as to what combination of hospitals, schools, clinics, community health centers and individual practitiioners would be most appropriate and efficient in carrying out a mass immunization program.

3. Will the proposed technology alter the demographic characteristics of the region's population?

This technology should have little effect on the demographic features of the population.

4. Will the use of the proposed technology lead to a change in the management of the medical problem and consequently change the demand for other health services?

By reducing the incidence of chicken pox, an immunization program may somewhat lessen the demand for doctor visits and would certainly lessen the need for home care. However, these changes would probably have no measurable impact on the health delivery system. As the probability and extent of harmful side effects are unknown, it is impossible to speculate on whether needed treatment for side effects would alter demand for health services.

CONSISTENCY WITH HSP

1. Does the proposed technology promote or conflict with HSP goals?

HSAs have given little attention to preventing chicken pox, since treatment for this usually

mild disease generally takes place at home rather than in health care facilities and since, until recently, no vaccine had been developed. In spite of the low priority given prevention of chicken pox by most HSAs, the distribution of an approved vaccine might be compatible with the HSP's stress on prevention—but only if benefits were determined to outweigh risks.

2. Is the acquisition of the technology consistent with the goal of planning on a regional basis for distribution of certain medical technologies?

The question is not applicable to an immunization program.

DIAGNOSTIC TECHNOLOGY: COMPUTED TOMOGRAPHIC (C-T) SCANNER

NEED

1. What is the medical problem addressed by the technology?

The C-T scanner is used to identify and help diagnose internal, soft-tissue abnormalities and disorders due to tumors, hemorrhages, accidental damage and so forth. Initially, the C-T scanner was used to visualize the interior of the brain. More recently, so-called "whole body" scanners have come into use, but body scanning is not yet as advanced as brain scanning.

2. How widespread are the problems the technology addresses? What groups are affected?

C-T scanning of the brain can identify (and rule out) a great many disorders, including many kinds of brain damage, masses and lesions. It is estimated that 3.5 million brain x-ray procedures are done annually in the United States (including C-T scans) to detect such conditions.

When considering the acquisition of a C-T scanner locally, it must be determined how many similar procedures are done locally and for what medical problems. An area might, for instance, be considering the establishment of a treatment center for accidental trauma, with a C-T scanner as a central piece of diagnostic equipment. In such a case, data should be presented on how many cases of head trauma are currently being diagnosed in the region, and how many of these cases would be picked up by the proposed center. It should be shown that the facility setting up the center will draw enough such cases from its own patient population and from the rest of the region to justify the purchase of a scanner.

3. How does the technology deal with the medical problem?

A C-T scanner combines x-ray and computer technology to produce three-dimensional pictures on a television-like screen. In its ability to present clear images of internal soft tissues, it clarifies the nature of many medical problems with more accuracy than conventional x-ray.

4. If the technology is used for screening or diagnosis is there treatment available for the conditions which are identified?

C-T scanners are used to diagnose a range of medical problems, some of which can be treated with great success and some of which can be dealt with only minimally. Treatment (e.g. neurosurgery, radiotherapy, chemotherapy, etc.) for some conditions may be very expensive and not available locally or accessible financially.

5. What technology is currently used for these medical problems?

Other than C-T scanners, there are four procedures used to diagnose brain abnormalities. Two of these procedures, arteriography (also known as angiography) and pneumoencephalography, are physically uncomfortable and are considered to carry a serious degree of risk to the patient. Echo-

encephalography and nuclear brain scans are considered to be less risky, but also less accurate that the other two methods.

SAFETY

1. What is the probability that a person will be harmed in being subjected to the technology?

C-T scanning, like all other x-ray procedures, exposes the patient to the risks of harm from low level radiation. However, C-T scanning procedures expose patients to equal or lower doses of radiation than do pneumoencephalograms and arteriograms.

In some cases a contrast dye is injected into the patient's system to further clarify the C-T scan image. A small number of people may have a serious allergic reaction to the dye.

2. How severe is the harm which can result from use of the technology?

Currently, there is controversy in the scientific community over the effects of exposure to low doses of radiation. Some feel that there is no safe "threshhold." Large doses of radiation (much greater than the dose received during a single C-T scan procedure) can cause serious disorders such as birth defects and cancers. As with other x-ray technologies, too frequent use of the C-T scan on particular patients may cause serious harm. Because a C-T scan is easy and painless to perform, there is a possibility that it will be overused, resulting in higher total dosage to some patients.

Allergic reactions to contrast dyes vary in severity, but can be fatal. Some precautions can be taken against the possibility of severe allergic reactions by pre-testing patients for sensitivity and pre-treating those who are allergic with antihistamines or steroids.

3. In terms of safety and risk, how does the technology compare with other technologies?

C-T scanning is distinctly less risky than pheumoencephalography and arteriography, both in terms of radiation exposure and in the riskiness of the procedure itself. Both pneumoencephalography and arteriography are "invasive" procedures, i.e., they require entering the body surgically and/or with chemicals. In the former procedure, a dye is injected into an artery, and in the latter, the spinal fluid is removed and air injected into the spinal column. Both procedures require hospitalization, pneumoencephalography sometimes requiring up to ten days of inpatient care. C-T scans can be done on an outpatient basis, and contrast dyes may or may not be used to clarify the x-ray image. (Often, contrast dye is used for further clarification when a follow-up scan is prescribed.) Since a C-T scan also exposes the patient to comparable or less radiation than its alternatives, it is generally regarded as the safer choice of technology.

4. How frequently should the technology be used in order to maintain skills?

There are no governmental guidelines directly relating minimum use of C-T scanners to maintenance of skills. However, for economic reasons, the National Guidelines for Health Planning recommend that scanners should not be purchased unless they will be used for at least 2500 procedures annually.

EFFICACY AND EFFECTIVENESS

1. What is the technology supposed to do? What result is supposed to come from its application?

C-T scanners should facilitate more accurate and rapid disgnoses of brain (and other) dysfunctions.

2. What are the optimal circumstances under which the technology is designed to work?

The effectiveness of C-T scanners depends upon the qualifications and experience of those who operate them and interpret their findings (chiefly radiologists, neurologists, neurosurgeons) and upon the housing and care of the equipment.

3. Under what conditions will the technology be expected to function in your region?

The answer to this question will depend upon conditions in a particular facility and region. Are staff sufficiently trained for effective operation of the scanner? Will the scanner be used frequently? Is there an adequately controlled environment to house the scanning unit? What is the track record of the particular model to be acquired?

4. How is the effectiveness of the technology measured?

In terms of its effectiveness, there is general agreement in the medical community about the superiority of the C-T scanner in comparison to existing technologies for head x-ray. It is more difficult to measure or estimate how treatment outcomes will be changed because C-T scanning is used in diagnosis. Because the C-T scanner can detect internal brain abnormalities, we might expect to see an increase in demand for brain surgery or a long-term improvement in mortality rates from a number of brain abnormalities. Ultimately, the long term effects will depend on changes in treatment choices which are the result of the faster and more accurate diagnoses which the C-T scanners offer.

COST

1. How much does it cost to purchase, lease, operate and maintain the technology?

C-T scanners range in cost from about $300,000 to $700,000. However less expensive models (costing about $100,000) and more sophisticated ones (nearly $1 million) are under development. It is estimated that the usual cost of operating a scanner is about $400,000 per year.

2. How does the cost of a proposed new technology compare with that of current techniques?

In terms of its present purchase price, C-T scanning equipment is extremely expensive, and although it replaces most arteriography and pneumoencephalography, a hospital must still maintain its radiologic/fluoroscopic equipment. Therefore the cost of a C-T scanner will usually be an additional expense for a hospital or health center. However, since C-T scanning does not require that a patient be hospitalized, on the whole, it can be comparatively less expensive for the consumer and third-party insurers than the other procedures.

3. Will the proposed technology be able to pay for itself during its life span?

C-T scanners can easily pay for themselves (and even bring hospitals a profit) depending on three factors: (a) the willingness of insurers to reimburse the facility at the present average fees; (b) the scanner's being used frequently enough; and (c) the scanner's not being replaced by a newer model before it is paid for. Since C-T scanners are in a period of rapid innovation and older models are becoming rapidly obsolete, many scanners are replaced before the end of their expected five-year life span and before they have paid for themselves. It is also possible that the more advanced scanners will have higher maintenance costs.

4. What effect will the technology have on the reimbursement rate?

The introduction of C-T scanner services will require equipment, space and personnel. These additional operating costs for a facility will usually show themselves in an increase in the hosptal's per diem charge to patients and insurers. The total amount will vary from hospital to hospital.

REGIONAL IMPACT

1 and 2. Is the proposed technology part of an integrated, regional system? Is there an adequate alternative to providing the service without adding a new program or piece of equipment?

Because of high cost, rapid proliferation, and concern about their misuse, the spread of C-T scanners is being limited by HSAs, and institutions are often being required to share scanners for teaching, research and clinical diagnosis. The National Health Planning Guidelines established minimum usage requirements for C-T scanners. Therefore, any proposal for a new scanner must be looked at in terms of other resources already in the community. The Guidelines require that the new scanners should not be acquired until those already in place are operating at 4,000 procedures per year. If new scanners are adopted, proposals should include well defined plans to share this resource with other institutions and to make the service widely available.

3. Will the use of the proposed technology change the characteristics of the region's population in a way which will affect the need for health services?

The use of C-T scanners should not significantly alter the features of the population.

4. Will the use of the proposed technology lead to a change in the management of medical problems and consequently change the demand for other health services?

The use of C-T scanners may affect the demand for health services in two ways: (a) Since the scan itself is often done on an outpatient basis (whereas other techniques require hospitalization), its use may decrease the demand for inpatient beds; and (b) better diagnoses may shift the demand for particular treatments.

CONSISTENCY WITH HSP

1 and 2. Does the proposed technology promote or conflict with an HSP goal? Is the acquisition of the proposed technology consistent with the goal of planning on a regional basis for the distribution of certain medical technologies?

In general, HSAs have as a goal upgrading the efficiency and quality of health services by planning on a regional basis for high cost technologies such as C-T scanners. Depending upon the needs of a particular region, as spelled out in its HSP, an individual facility's acquisition of an additional C-T scanner may promote or conflict with these goals.

TREATMENT TECHNOLOGY: HEMODIALYSIS (ALSO CALLED RENAL DIALYSIS OR "ARTIFICIAL KIDNEYS")

NEED

1. What is the medical problem being addressed by the technology?

Dialysis machines, or "artificial kidneys", are used to treat kidney failure. In acute cases—when the kidney temporarily does not function because of injury, infection or presence of a poison—artificial kidney treatment (dialysis) is needed temporarily while the kidneys recover. In chronic renal failure, the kidneys have been permanently damaged and dialysis is needed either on a permanent basis or until a kidney transplant can be performed.

2. How many people can be expected to benefit if the proposed technology is adopted?

In the United States in 1977, there were about 51,000 people receiving dialysis treatment, and about 3,200 kidney transplants were performed. It is projected that by 1984 there will be 80,000 to 108,000 people needing renal dialysis. The number of people needing dialysis should be projected for each region when considering the adoption of dialysis technologies in particular facilities.

3. How does the technology deal with the medical problem?

Kidney failure leads to death unless remedied, and dialysis machines are used to stabilize the condition of people in kidney failure. The dialysis machine substitutes for the healthy kidneys' function by filtering or "washing" the blood mechanically. The blood of a person who is on the dialysis machine is conducted through an artery into the machine, where it is cleansed, and then returned back to the body via a vein. Patients in chronic kidney failure usually require two to three treatments a week, each lasting four to eight hours.

4. If the technology is used to screen for a medical problem, is there treatment available for the condition identified? If a treatment technology, does its use result in full or partial recovery? Does it stabilize or rehabilitate the patient?

Kidney dialysis can stabilize a patient for whom kidney failure would inevitably mean death. The procedure can maintain the patient for years if necessary, or for shorter periods while damaged kidneys recover functioning.

5. What other technology, if any, is being used for the same medical problem?

Kidney transplant is the only way, besides dialysis, in which kidney failure can be treated. Surgical transplant requires an organ donor, either someone recently deceased or someone with two healthy kidneys who is willing to donate one of them. However, with transplants, demand exceeds supply. At any given time in the United States, thousands of people are waiting for transplants.

SAFETY

1. What is the probability that a person will be harmed by being subjected to the technology?

Almost all persons receiving dialysis experience some negative physical and emotional side effects. In addition, all dialysis patients must have blood "shunt" tubes implanted in a vein and artery. This procedure, with its own risks and discomforts, must be repeated about every six months.

2. How severe is the harm resulting from use of the technology?

Dialysis patients may suffer from nausea and cramps, anemia and fatigue. Some of these problems are not direct side effects of the technical procedure but can be attributed to the inability of dialysis to totally remove all toxic residues from the blood. Similarly, dialysis patients may suffer from depression and other emotional and social difficulties as a result of being dependent on artificial kidneys. Many of these effects are reversible if the patient is able to go off dialysis. Many patients, however, can only leave dialysis treatment if kidney transplant is an available option.

3. In respect to safety, how does the technology compare with other technologies used for the same problem?

Kidney transplant and hemodialysis are the only alternative treatments for kidney failure. Without either procedure, the condition is inevitably fatal. Kidney transplant entails the risks of ma-

jor surgery, but if successful—80 percent of the time if the donor is a living relative and about 50 percent of the time otherwise—the side effects should be minimal. However, it should be noted that most transplants last only two years, when patients must either have a second transplant or return to dialysis. While dialysis has the above noted harmful side effects, some patients have been sustained for as much as eleven years by the dialysis procedure.

4. How frequently should the technology be used in order to maintain skills of the technical team? Will the technology be used often enough in the proposed setting to insure that it will be skillfully operated?

No extraordinary skills are required beyond those possessed by health workers trained in dialysis procedures. With the assistance of a trained attendant, many dialysis patients and their families have learned to use dialysis machinery at home.

EFFICACY AND EFFECTIVENESS

1. What is the medical technology supposed to do? What result is supposed to come from its application?

The main objective of hemodialysis is to prevent death from kidney failure. To do this, the artificial kidney machine must effectively cleanse the blood of toxic residues.

2. What are the optimal circumstances under which the technology is designed to work?

Hemodialysis requires no special physical environment. Although dialysis can be done either at home or in a hospital, and government is encouraging home dialysis, so far most patients have opted for in-hospital treatment. Home dialysis requires an attendant to monitor the procedure.

3. Under what circumstances will the technology be expected to work in your region?

The answer to this question would depend upon the specific proposals to provide dialysis to the region. The federally organized End Stage Renal Disease Network is composed of selected health facilities designated to provide dialysis services in each region. Each center is required to have a trained staff performing a minimum number of procedures.

4. How is the effectiveness of the technology evaluated?

The effectiveness of hemodialysis can be measured in terms of the mortality rate of those with diseased or impaired kidneys. While data are not available for the period prior to the introduction of the technology in the 1960's, since that time there has been a definite increase in the life span of those treated with hemodialysis. Now, 37 percent of dialysis patients survive at least ten years, 60 percent survive five years and a small percentage are able to work full- or part-time.

COST

1. How much does it cost to purchase, lease, operate and maintain the technology?

The average annual cost per patient in 1978 for dialysis conducted in a health facility was $24,500. Home dialysis costs about $15,000 per year after the first year. End-stage renal disease patients are covered for about 80 percent of dialysis charges under the Medicare legislation; and in 1977 the Social Security Administration paid about $700 million for the care of about 40,000 patients. Patients themselves pay about 20 percent of costs, or about $3,000 each per year, plus expenses for medications and supplies are not covered by Medicare.

2. How does the cost of the technology compare with other techniques?

The only other technological alternative to dialysis, a kidney transplant operation, costs about $25,000.

3. Will the proposed technology pay for itself over its life span?

The expected life span of dialysis equipment is not known. However, under current insurance systems, in which Medicare pays for 80 percent of the dialysis charges, with private insurance often covering the remainder, many profit-making dialysis centers have sprung up in recent years.

4. What effect will the adoption of the technology have on hospital reimbursement rates?

The high cost of equipping, operating and maintaining dialysis services has a substantial effect on a hospital's total expenditures and those costs are clearly reflected in its daily reimbursement rate.

REGIONAL IMPACT

1 and 2. Is the proposed technology part of an integrated, regional plan to deliver services? Is there an adequate way of providing the service without unnecessarily duplicating programs or equipment?

Renal dialysis centers are being established as the need for them arises. They are subject to regional health planning requirements and federal Medicare regulations. The ESRD (End Stage Renal Disease) Network coordinates the centers. Any proposals concerning the establishment of such centers should be checked for compliance with both Medicare regulations and planning guidelines.

3. Will the use of the proposed technology alter the characteristics of the region's population in a way that will alter the need for health services?

Renal dialysis, although forestalling death from kidney failure, should not change a region's overall demography significantly.

4. Will the use of the technology lead to a change in the management of the medical problem and change the demand for other health services?

As a result of the development of dialysis, management of kidney disease has undergone tremendous changes. Kidney patients are living longer, and some are able to hold jobs. Portable dialysis equipment has created a need for trained attendants to assist those treated at home, and if more and more patients elect home treatment, demand on hospital facilities will lessen.

CONSISTENCY WITH HSP

1. Does the proposed technology promote or conflict with an HSP goal?

Most HSAs have given a high priority to dialysis services and have taken inventories of the number of such services available in their region. One of the problems with expansion of dialysis services is the conflict between reimbursement incentives and HSP priorities. Medicare is more generous in paying for in-hospital dialysis treatment than it is for home dialysis. This represents a problem for many HSAs which are stressing out-of-hospital services and the more efficient use of scarce resources (home dialysis costs about $10,000 less annually than facility care).

2. Is the acquisition of the technology consistent with planning for regional distribution of technology?

On the other hand, the development and location of these dialysis centers is consistent with the concept of sharing services on a regional basis wherever possible.

APPENDICES

SOURCES
USED FOR
THIS STUDY

GLOSSARY

SOURCES USED FOR THIS STUDY

While many sources were used in the development of this manual, the principal sources of technical information are listed below.

1. University of Southern California, Center for Health Services Research. *Health Technology: Issues and Activities.* American Hospital Association, 840 North Lake Shore Drive, Chicago, Il. 60611. 1977.
2. Marshall J. Orloff, "Contributions of Research in Surgical Technology to Health Care" in *Technology and the Quality of Health Care,* ed. by Richard H. Egdahl and Paul M. Gertman. Aspen Systems Corporation. Germantown, Maryland. 1978.
3. Alexandra Alcott, *Analysis of New Health Technologies: A Guidebook for Health Planning Agencies.* Health Resources Administration Contract HRA 830-75-0063. Hyattsville, Maryland. December 1977. Under contract with Arthur D. Little, Inc. Cambridge, Mass. 02140.
4. *Development of Medical Technology: Opportunities for Assessment.* Office of Technology Assessment. U.S. Congress. August, 1976.
5. *Assessing the Efficacy and Safety of Medical Technologies.* Office of Technology Assessment. U.S. Congress. September, 1978.

GLOSSARY

Acceptability (of health services). An overall appraisal of health care services, based on factors including cost, quality, convenience, outcome and consumer perception of provider attitudes.

Accessibility (of health services). Ability to obtain medical care. The ability to gain access to services can be affected by geographic, financial, social, psychological, linguistic and ethnic factors.

Acute care. Care (usually provided in a hospital) of fairly short duration, given during a single episode of illness or injury.

Ambulatory care. All types of health services provided on an outpatient (walk-in) basis. Ambulatory care usually implies that the patient has come to a location other than the home to receive services and has departed the same day.

Amniocentesis. A procedure which tests for possible genetic defects in the unborn child. The uterus is tapped to extract a sample of the amniotic fluid. The cells in this fluid are then analyzed to determine or rule out the possibility of certain conditions such as Down's syndrome or Tay Sachs disease.

Annual Implementation Plan (AIP). The plan which HSAs must prepare annually, stating the year's workload and short term objectives for their health planning area.

Antibiotic. A drug, derived from a mold or bacterial substance, which inhibits bacterial infections.

Antihistamine. A medication used to counteract allergic symptoms.

Appendectomy. Surgical removal of the appendix.

Arteriography. The x-ray of an artery, a procedure requiring injection of a contrast medium (also called angiography).

Artificial kidney. See hemodialysis.

Availability (of health services). The extent to which the supply of health care services meets the demand or need for them. A health care service is "available" if a person can obtain it, from appropriate personnel, at the time and place it is needed.

Biomedical research. Research concerned with human and animal biology as it relates to prevention, diagnosis and treatment of disease.

Capital expense. The costs incurred in purchasing, building, replacing or remodeling a facility and the equipment it contains.

Carcinogen. Any substance that stimulates the development of cancer.

Cardiac catheterization. A method of diagnosing heart abnormalities which involves injecting a dye into the heart by means of a catheter, or tube.

Certificate of Need (C/N or CON). A certificate issued by a governmental body (usually the state or the HSA) approving an institution's plan to construct or modify a facility, to change an existing

service or to create a new service. This program to control capital expenditures according to public need is also administered under Section 1122 of the Social Security Act.

Chemotherapy. Treatment of a disease with chemical substances or drugs; especially the use of chemicals or hormones to destroy cancer cells.

Clinical trials or testing. An experimental research method in which human or animal subjects are used to test the safety or efficacy of medical technologies. In accordance to predetermined rules, subjects are assigned to one group, the *experimental* group, which receives the technology or dosage, or to the *control* group which receives some other technology, dosage or a placebo.

Computerized Arrhythmia Monitoring Systems. Procedure for monitoring and analyzing EKG's of cardiac patients in intensive care or coronary care units.

Constitutional symptoms. General bodily symptoms, such as fever.

Continuous Blood Flow Analyzer. Laboratory equipment capable of doing multiple diagnostic tests on a single sample of blood or other body fluid.

Contrast dye. A radio-opaque dye injected into the body to sharpen the picture of body tissues in x-ray images.

Coronary artery surgery. Surgery to relieve blockages of the arteries of the heart.

C-T scanner. (Computed tomography scanner). A computerized x-ray technology which can create three-dimensional images of internal structures. Unlike conventional x-ray technology, C-T scanners can accurately picture soft tissue structures.

Degenerative disease. A disease causing deterioration of tissue, with eventual loss of function.

Demand (for health services). The amount of health services which consumers actively seek out. (Compare *need.*)

DES (Diethylstilbestrol). A synthetic compound which acts like the female hormone estrogen. It was at one time prescribed to prevent miscarriage.

Dysfunction. Upset function; malfunction; difficult or abnormal function.

Echoencephalography. Technique which uses ultrasound (high frequency sound waves) to diagnose brain disorders.

Effectiveness. How well something works under *usual* (as opposed to *ideal*) conditions.

Efficacy. How well something works under *ideal* conditions of use.

Electrocardiogram (EKG or ECG). A recording of the electrical currents crossing the heart muscle before each heart beat. Used as a diagnostic tool in various heart dysfunctions.

Electroencephalogram (EEG). A recording of the electrical impulses of the brain (brain waves) used in the diagnosis of tumors, lesions, epilepsy and other causes of brain dysfunction.

Epidemiology. Study of the nature, cause, control, incidence and distribution of diseases and disabilities in human populations.

Fetal monitor. An electronic device used to detect distress in the unborn child. Usually used to monitor the fetal heart beat during labor.

Gamma globulin. A substance, derived from human blood plasma, which contains antibodies to infectious diseases. Injections of gamma globulin are sometimes prescribed for children who have been exposed to measles or other infections in order to make the course of the disease milder.

"Halfway technology". A phrase coined by medical scientist/author Lewis Thomas in his book, *The Lives of a Cell.* The term refers to complex (and often extremely expensive) technologies which "compensate for the incapacitating effects" of disease and which postpone death, but which are not medical "breakthroughs" or "triumphs" because they fail to strike at the underlying mechanisms of the disease or condition they treat. Examples are: artificial organs and transplants; irradiation and chemotherapy for intractable cancers; and so forth.

Health status. The state of health of a specified individual, group or population, including physical, environmental and work-related conditions.

Health status indicators. Objective indicators or measures of an individual's or group's health. For instance, the *infant mortality rate, longevity,* or *incidence* of certain diseases in the population are regarded as indicators of health status.

Health Systems Agency (HSA). The agency responsible for health planning and resources development in each of the federally designated health services regions in the United States. HSA's have their functions and organizational alternatives spelled out in Public Law 93-641.

Health Systems Plan (HSP). A long range (usually five years) health plan prepared by an HSA which details regional health goals in accordance with local need and nationally defined priorities and guidelines.

Heart block. A disorder in the transmission of the heart beat from one part of the heart (the atrium) to another (the ventricle).

Hemodialysis. (Also called renal dialysis, kidney dialysis). A process in which a machine (sometimes called artificial kidney) is used to cleanse the blood of wastes and toxins in patients whose kidneys cannot perform this function.

Hodgkin's disease. A malignant disease of the lymph system.

Hypertension. High blood pressure.

Hysterectomy. Surgical removal of the uterus.

Immunization. The process by which resistance to disease is produced; vaccination. *Active immunization.* Immunity acquired by stimulating the antibodies in the subject's own system. *Passive immunization.* Immunity acquired by the transfer to the subject of antibodies produced in another person or animal.

Incidence. The number of cases of a disease or other event, happening over a specified period of time, in a particular population.

Invasive procedure. Any medical technique which, in order to be performed, requires entering the body by some substance or instrument.

Lesion. An abnormal change in tissue, usually confined to a small area.

Linear accelerator. A device that produces high energy x-rays for use in radiation therapy.

Lithium carbonate (also called *Lithium*). A drug used in treatment of certain manic-depressive states.

Mammography. X-rays of the breast to determine the presence or absence of a tumor.

Manic depression. A term used to describe an emotional state or mental disorder marked by severe changes in mood.

Mastectomy. Surgical removal of the breast. *Radical mastectomy.* Removal of breast, armpit lymph nodes and underlying muscle tissue on the affected side. *Modified radical mastectomy.* Removal of breast and lymph modes on the affected side.

Morbidity. The extent of illness, injury or disability in a population—usually expressed in terms of *incidence* (number of new cases in a given period of time) or *prevalence* (number of existing cases in a given population).

Mortality. Death. The mortality rate is the relation of the number of deaths to the population in which they occur. Usually expressed as the total number of deaths in a given population per year.

Multiphasic health testing (or screening). A battery of tests to screen for a number of diseases in a healthy population.

Myocardial Infarction (MI). Heart attack caused by formation of a blood clot on the heart, causing damage to heart tissues.

Need (for health services). The condition of lacking some service essential to diagnosing, preventing or treating diseases or disabilities. Need is distinguished from *demand,* which is the expression of desire for a service whether or not it is needed. Likewise, need for a service may exist in a community without the active expression of demand.

Neonatal intensive care. Specialized care concentrated in a special area of a hospital set aside for seriously ill newborn infants needing constant nursing care and observation.

Oncology. Study of abnormal cellular growth of neoplasms (benign or malignant tumors).

Oncologist. Physician specializing in oncology.

Open heart surgery. Heart surgery performed when the chest has been opened and during which the blood is re-circulated and oxygenated by mechanical means (through a heart-lung bypass machine).

Operating expense. Costs related to maintaining the facility or equipment at their original standards of operation.

Otitis media. Infection of the middle ear.

Pacemaker. An electrical device which stimulates the natural pacemaking mechanism of the heart, stimulating normal heartbeats. This device is implanted in the chest and connected to the heart.

Pap smear. The microscopic examination of a cellular specimen from the cervix to detect the presence of cancer, to evaluate endocrine status and to discover other conditions. Most commonly known as a screening method for cervical cancer. Named for its developer, Dr. George N. Papanicolaou.

Pneumoencephalogram. An x-ray picture of the skull, taken after the injection of air into the space surrounding the brain.

Pre-clinical trials. Tests done prior to human use of medical technologies. There are two general kinds of pre-clinical trials: 1) chemical analysis for the purity, quantity, and quality of the active agents in drugs; and 2) tests using animals to estimate the potential benefit and harm of the technology to humans.

Prevalence.. The number of cases of a disease present at a particular time in a specified population. Prevalence is related to incidence. The prevalence of a disease equals its incidence times the average duration of a case.

Primary care. Basic health care sought by the patient for the simpler illnesses or disorders, at the point where the health system is first contacted. Primary care usually takes place in doctor's offices, health centers and outpatient clinics.

Primary Prevention. A health program or technique which will prevent a disease or condition from occurring. Example: vaccination against smallpox.

Protocols. Instructions, criteria and formal procedures for the use of a particular technique or technology.

Radiotherapy (Radiation therapy). Medical treatment of a disease which involves the use of electromagnetic radiation, radium, cobalt or other radioactive materials.

Reimbursement rate. The rate at which institutional health providers are paid for their services—often a daily rate based on an average of the total costs of operating the institution.

Renal dialysis. See hemodialysis.

Risk. The degree of probability that use of a certain technology or treatment will result in a physical and/or mental harm.

Risk-benefit ratio. In general, the comparison of any chance of harm resulting from a technology or procedure with its potential benefit.

Screening. The identification of unrecognized disease or defect by tests or examinations which can quickly separate seemingly well persons who have a disease from those who do not.

Secondary care. Services provided by the practitioners or institutions which do not generally have the first contact with patients, but who are involved in a case through referral from the primary source of care.

Secondary prevention. Detection of disease before it has manifested itself in a serious or acute manner. Example: Using the Pap smear to detect the earliest warning signs of cervical cancer.

Shingles (herpes zoster). Viral infection characterized by skin eruptions along the path of a nerve.

Statewide Health Coordinating Council (SHCC). A state council selected by the governor consisting of providers and consumers of health care, with a consumer majority, which supervises the work of the SHPDA, reviews the budgets of the HSA's, prepares a state health plan from HSA plans and reviews applications for HSA planning and resource development assistance.

State Health Planning and Development Agency (SHPDA). A state agency responsible for the state's health planning and development functions, having the tasks of: 1) preparing a state health plan (SHP) and medical facilities plan; 2) acting as the review agency for purposes of section 1122 of the Social Security Act; and 3) administering a certificate of need program.

Steroids. Drugs of hormonal origin, especially those derived from pituitary and adrenal glands. Often used to counteract allergic reactions. Cortisone is a steroid.

Streptomycin. An antibiotic used to combat many infections, but best known for its effectiveness against tuberculosis.

Technology (medical). The drugs, devices and surgical procedures used in medical care and the supportive systems within which such care is provided.

Tertiary care. A level of care which refers to complex diagnostic and therapeutic services which require the highly specialized personnel and equipment usually found in major medical centers.

Thermography. A procedure which detects diseases in tissue beneath the skin by measuring the amount of heat coming through the skin.

Third-party payer. Any organization which pays for or insures the health or medical expenses for beneficiaries or recipients. Blue Cross, Blue Shield, commercial insurance companies, Medicare and Medicaid are third-party payers.

Tine test. A skin test used to diagnose tuberculosis in which doses of tuberculin are injected into the skin by means of a tine (a slender, pronged instrument which pierces the skin).

Ultrasound. Diagnostic technique which enables the visualization of deep structures in the body by measuring the transmission or reflection of high frequency waves similar to sound waves.

Vaccine. Any preparation intended to immunize individuals against a disease.