Policy Implications of the Computed Tomography (CT) Scanner

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FOREWORD

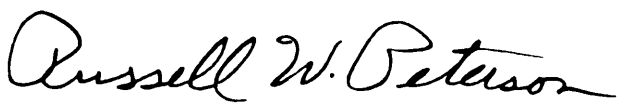
This study, Policy Implications of the Computed Tomography (CT) Scanner, was requested by the Senate Committee on Finance and the Senate Committee on Human Resources. It examines the CT scanner, an expensive, new diagnostic device that combines X-ray and computer equipment. The CT scanner has been rapidly and enthusiastically accepted by the medical community in this country since its introduction in 1973. It is a medical technology whose development and use illustrate many important issues of health policy.

The Senate Committee on Finance requested the Office of Technology Assessment (OTA) to consider such aspects of the CT scanner as "its usefulness, its costs, its effect on medical care delivery patterns, and ways to improve planning affecting such devices. "

The Senate Committee on Human Resources requested OTA "to examine current Federal policies and current medical practices to determine whether a reasonable amount of justification should be provided before costly new medical technologies and procedures are put into general use. " The Committee specifically asked that issues of efficacy and safety be addressed: "Before new drugs can be used, proof of efficacy and safety must be provided. However, no such legal requirement applies to other new technologies. "

The study was conducted by staff of the OTA Health Program with the assistance of the OTA Health Program Advisory Committee. The resulting report is a synthesis and does not necessarily reflect the position of any individual.

In accordance with its mandate to provide unbiased information to Congress, OTA has attempted in this report to present information accurately and to analyze that information objectively. The report contains no recommendations, but instead identifies a range of alternative policies for consideration by Congress. The views expressed in this report are not necessarily those of the OTA Board, the OTA Advisory Council, or their individual members.



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1.

SUMMARY

1

SUMMARY

The computed tomography (CT) scanner* is a revolutionary diagnostic device that combines X-ray equipment with a computer and a cathode ray tube (television-like device) to produce images of cross sections of the human body. The first machines were "head scanners," designed to produce images of abnormalities within the skull, such as brain tumors (figure 1). More recently, "body scanners" have been marketed, which scan the rest of the body as well as the head (figure 2).

CT scanning has been rapidly and enthusiastically accepted by the medical community. Developed in Britain in the late 1960's, the CT scanner was quickly hailed as the greatest advance in radiology since the discovery of X-rays. Head scanning has become a standard part of the practice of neurology and neuroradiology, and physicians believe that the potential of body scanning is great. Less than 4 years after the introduction of CT scanning into the United States, at least 400 scanners had been installed at a cost of about half-a-million dollars each. In 1976, about $300 million to $400 million were spent on CT scanning, and that figure was only partially offset by reductions in other diagnostic procedures.

The rapid spread of CT scanners, the frequency of their use, and the expenditures associated with them have combined to focus attention on the role of diagnostic medical technologies in the increase of medical care expenditures during recent years.** This concern over expenditures has caused decisionmakers to examine policies regarding the use of diagnostic technologies.

Physicians generally make a diagnosis by taking a medical history, conducting a physical examination, and, as appropriate, ordering diagnostic tests. During the physical examination, the physician may utilize instruments such as the stethoscope and blood pressure cuff. And for some years, diagnostic tests involving X-ray and clinical laboratory procedures have been available.

During the past three decades, a virtual explosion has occurred in the development and use of diagnostic technologies. A wide array of new devices has been developed, greatly extending the ability to diagnose medical problems. The list of technologies now

*In this report, the term computed tomography (CT) scanner refers to a transmission scanner. Other terms used for this device are CAT scanner (computerized axial tomography), CTT scanner (computerized transverse or transaxial tomography), and EMI scanner (for the company, EMI, Ltd., which developed the first scanner). Emission computed tomography scanners have also been developed.

**It should be noted that the contribution of the CT scanner to the overall problem of rising health care costs is relatively small.

Figure 1.—Computed Tomography (CT) Head Scanner



Photo *Courtesy* **of** *Clinical* **Center, National Institutes of Health**

includes such items as automated clinical laboratory equipment, electronic fetal monitoring, amniocentesis, electrocardiography (EKG), electroencephalograph (EEG), fiberoptic endoscopy of the upper and lower gastrointestinal tracts, ultrasound, mammography, and, of course, computed tomography. Each year the list grows longer. Diagnoses of some medical problems can be definitive and conclusive rather than ambiguous and inconclusive as they were just a few years ago. These technologies can sometimes guide physicians to appropriate treatments, preventing death and disability and relieving pain and suffering.

The incentives for physicians to make greater use of diagnostic tests are very powerful. Both patients and physicians desire accurate and precise diagnoses. During their medical education, physicians are taught to use diagnostic tests extensively so that medical problems will not be overlooked. The recent increase in malpractice litigation has also made physicians more cautious about diagnosing accurately and avoiding errors. Other incentives arise from fee-for-service payment, which provides fees for each

Figure 2.—Computed Tomography (CT) Body Scanner



Photo Courtesy of *Clinical Center, Nafional Institutes of Health*

additional diagnostic test performed. Moreover, reimbursement by third parties insulates patients from a considerable part of the expenditures and provides payment at rates largely determined by physicians and hospitals.

Both the availability of a wide variety of diagnostic tests and the strong incentives to use them have enormously increased their utilization during the past few years. In fact, there appears to be virtually no upper limit on the number and kind of diagnostic tests that a cautious and caring physician can order. Frequently, additional tests may provide little new information. And while sometimes new technologies actually replace older ones, they usually are just added on.

The increase in diagnostic testing has made a sizable contribution to the increase in total medical care costs during the past 10 years. New technologies require specialized personnel, supplies, or facilities, each contributing to total operating costs. Some technologies, such as the CT scanner, are depreciated over a short period of time. When fees

for tests exceed costs, creating wide profit margins, an additional incentive for proliferation of equipment exists. Other technologies such as clinical laboratory tests have both low unit costs and fees, but are produced in large numbers and result in high aggregate expenditures.

In recent years, concern about the rapid increase in costs of medical care has led the Federal Government, some State governments, and some private insurance companies to develop policies setting limits on the use of medical technologies. Policymakers have proceeded cautiously, not wanting to sacrifice quality of medical care in an attempt to lower costs. The CT scanner provides an instructive case study of policies regarding diffusion and use of medical technologies. The evaluation of such policies does not necessarily entail passing judgment on the rate at which CT scanners were adopted or on their value for patient care. It does, however, reveal certain shortcomings that apply not only to CT scanners, but to many other medical technologies as well.

FINDINGS

Efficacy and Safety of CT Scanners

- Well-designed studies of efficacy of CT scanners were not conducted before widespread diffusion occurred. * Information is still incomplete on benefits, individuals and populations who can benefit, diseases that can be diagnosed, and appropriate conditions of use. However, the efficacy of CT scanning has been more thoroughly studied than that of most other medical devices at a similar stage of diffusion.
- Those studies that had been done by mid-1977 showed that CT head scanners perform reliably and provide accurate diagnoses of nearly all abnormalities in or near the brain for 80 to 100 percent of patients. Greater than 90 percent accuracy was found for nearly two-thirds of patient groups studied. Although the information for body scanning was more limited than for head scanning, studies showed approximately **80** to 100 percent accuracy in diagnosing abnormalities of the abdomen.
- CT scanning is replacing other diagnostic procedures. In particular, the use of CT head scanning has reduced the use of pneumoencephalography, and in some settings cerebral arteriography and radionuclide brain scans as well. However, many more CT scans were being performed than would be necessitated by simple replacement of other diagnostic procedures. CT head scanning has produced a considerable net increase in the total number of procedures performed.
- Little information was available about the impact of CT scanning on either the planning of therapy or patient health.
- Contrast enhancement, which is frequently used with CT scanning, adds to the cost and risk of scanning. Lesions within the skull are often seen better after contrast injection. However, only a small number of lesions not visible on regular CT

*The National Institutes of Health initiated a trial in 1973. However, diffusion of scanners occurred at the same time that data were being accumulated.

head scans are made visible by contrast enhancement. Contrast enhancement in CT body scanning has been studied very little.

- CT scanning appears to be a relatively safe technology. It does expose patients to significant doses of ionizing radiation, and an additional small risk also arises if contrast material is injected. The risk from CT head scanning appears to be lower than that of the diagnostic procedures it is replacing, and the-pain and discomfort are definitely lower in many cases.

Number and Distribution of CT Scanners

- As of May 1977, 401 CT scanners were known to be in use in the United States. Nearly three-fifths of these machines were head scanners; the rest were full-body scanners. Most new purchases were of body scanners. *
- Of the CT scanners known to be installed in May 1977, 325 or 81 percent were in hospitals. The remaining 76 scanners were located in private offices and clinics.
- Data on the ownership of CT scanners were incomplete. The scanners known to be in private offices and clinics were either privately owned or leased. Of those located in hospitals, less was known about ownership. One survey reported that at least 10 percent of operational CT scanners identified in June 1977 were owned or leased by physicians but located in hospitals.**
- Most hospitals with CT scanners in May 1977 were not-for-profit community hospitals with general medical services. Six Federal hospitals also had CT scanners.
- Compared to all community hospitals, those with CT scanners in May 1977 were among the largest: 5 percent of all community hospitals have 500 beds or more, but 44 percent of all community hospitals with a CT scanner had 500 beds or more.
- Of the Nation's 113 accredited medical schools, 89 or 79 percent had a major affiliation with a hospital that had a scanner in May 1977.
- Of the companies producing machines for sale in the United States in May 1977, three—EMI, Pfizer, and Ohio Nuclear—had manufactured 99 percent of the CT scanners known to be in use.
- The rate of installation of CT scanners in the United States has increased steadily over time. Complete data exist for three time periods:

  —From June 1973 to October 1974, less thans scanners per month were installed;
  —From October 1974 through June 1975, less than 10 per month were installed; and
  —From July 1975 through September 1976, an average of 19 scanners per month were installed.

*Manufacturers reported 921 scanners operational at the end of **1977, 85** percent in hospitals.
**This survey found *637* operational scanners. See chapter *4.*

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- Installation rates might have been higher from 1973 to 1976 if manufacturers had been able to produce more machines. For example, in 1975, twice as many scanners were ordered as shipped. EMI's 1976 year-end backlog of unfilled orders exceeded 250 machines.
- In response to the demand for CT scanners through 1976, the two largest manufacturers, EMI and Ohio Nuclear, prepared to increase their production; EMI increased its plant capacity as well. In 1977, at least six other companies were planning to enter the market.
- Data from the end of 1977 indicated a national ratio of about 4 scanners per million population. The District of Columbia had the highest ratio of scanners to population, and South Carolina the lowest. All States had at least one scanner installed or approved.
- Differences in the number of CT scanners among States cannot be explained by the existence of certificate-of-need laws or section 1122 agreements or by the distribution of physicians.
- Future trends in the rates of orders and installation are not yet clear. New orders for scanners declined in the first half of 1977. One report predicted 200 new orders for 1977 compared to more than 400 in 1976. Orders during 1975 and 1976 may have been abnormally high in anticipation of Federal and State regulations on purchases. Therefore, the experience of 1977 may have represented a period of adjustment to a more stable growth rate for sales.

Uses of CT scanners

- CT head scanners can be used to scan only the head. CT body scanners are used for scanning primarily the head. When scanning the body, body scanners are used mostly for suspected abdominal problems, such as pancreatic tumors, abscesses, or jaundice.
- Although uses of CT head scanning have varied from institution to institution, the most common diagnoses made were mass lesions (mostly tumors), cerebrovascular disease (including stroke, hemorrhage, and aneurysm), and diseases with enlargements of the ventricular space of the brain (hydrocephalus and cerebral atrophy).
- One study of several institutions found **so** percent of head scans were negative, with some institutions running as high as 80 to 90 percent negative. A higher percentage of negative scans indicates use of CT scanning as a primary diagnostic or screening tool. Studies have found that CT head scanning is often performed because of headache. In the absence of other findings from the physical examination, these scans find few abnormalities.
- Frequently, patients are scanned, have contrast injected in their bloodstreams and then are scanned again. Overall, more than 50 percent of patients were scanned after injection of contrast material. This figure has been increasing over the past several years.
- At least 89 percent of all CT scanners were in hospitals or radiological offices in May 1977. In these settings radiologists typically perform CT scans at the request

of referring clinicians. Self-referral, where the physician who orders a scan also receives payment for it, characterized at most 11 percent of all CT scanners.

- CT scanning can be used for inpatients or outpatients. The American Hospital Association found in a survey of 41 hospitals that an average of 51 percent of scans were performed on inpatients, with a range of 23 to 90 percent. The waiting time for scans was 1.6 days for inpatients in 1976, compared to 11.5 days for outpatients. Waiting time apparently dropped during 1977.

Reimbursement for CT Scanning

- In 1976, the *price* of a typical EMI head scanner was $410,000 and an EMI body scanner $475,000. EMI price increases reported in 1974 and 1976 were less than increases in the Wholesale Price Index.
- The price of a CT scanner is not fixed. After soliciting bids, the Veterans Administration ordered CT body scanners for $375,000 each that usually sold for $475,000, *illustrating* that price can be reduced by bidding. Recently, several companies have begun to market head scanners for around $100,000.
- Estimates of total annual expenses of operating a CT scanner in **1975** and **1976** ranged from $259,000 to $379,000. These expenses can be divided into technical expenses, $59 to $130 per exam, and professional expenses, $20 to $43 per exam. In **1976,** a CT scanner averaged about 3,000 examinations per year. The estimated average cost of a CT examination was lower when a scanner was operated for two shifts daily. CT scanners were typically depreciated over 5 years, although the standard method of depreciating equipment uses 8 years.
- Average fees reported for CT head examinations ranged from $240 to $260 including professional and technical components. These averages took into account the use of contrast for head examinations. The average total fee was $228 for a basic CT body scan without contrast material and $278 for a CT body examination with and without contrast. Evidence suggests that fees have increased over time.
- Estimated annual *profits* (revenue minus expenses) from operating a CT scanner in 1976 ranged from $51,000 to $291,000. For a scanner priced at $450,000, annual profits represented 11 to 65 percent of the original purchase price.
- Estimated expenditures related to CT scanning are increased by expenditures for patients who were hospitalized while waiting for scans, but decreased by reductions in other tests and associated hospital days brought about by CT scanning. Calculated in this way, estimated net expenditures ranged from $180 million to $388 million for 1976.

POLICY PROBLEMS IDENTIFIED

This study of CT scanners highlights a number of policy problems in medical care that relate to new and old, expensive and inexpensive technologies alike. As is typical for medical technologies, well-designed, prospective studies of the efficacy of CT scanners

were not conducted prior to diffusion. No formal process, public or private, has existed to ensure that studies on efficacy of most technologies are conducted and that data are collected and analyzed. Information about efficacy is not disseminated to the many organizations and agencies to whom it is essential, such as planning agencies, Professional Standards Review Organizations (PSROs), third-party payers, and the practicing community. Instead, physicians gather information as best they can from practices, colleagues, publications, and manufacturers. Clinical experience, rather than scientifically developed information about efficacy, then becomes the guide for further use. Planning agencies, PSROs, and third-party payers have inadequate information for determining need for additional machines, appropriate standards of use, and appropriate services for reimbursement, respectively. Further, various Federal programs do not use a common definition of efficacy, making their decisions more difficult to defend or to enforce.

The intent of laws requiring review of capital expenditures is not reflected in practice. The laws do not relate "need" to indications for use, so an important basis for evaluating need may not be used. Planners are not required to consider whether existing equipment is operating near capacity when determining need for additional equipment. Nor is it mandatory to consider the implications of additional equipment on national medical expenditures. Furthermore, certificate-of-need provisions of the National Planning and Resources Development Act (P. L. **93-641)** and section **1122** of the Social Security Act exempt from review purchases of CT scanners by private physicians, including those scanners purchased by private physicians and placed in hospitals. These provisions and potential profits from scanning encourage acquisitions of CT scanners by private physicians.

Use of diagnostic technologies is not based on efficacy. PSRO standards are established by practicing physicians and based on accepted patterns of use rather than scientifically developed information about efficacy. No PSRO standards are known to have been developed for CT scanning. In any case, PSRO standards apply only to expenditures covered by Federal financing programs, less than one-third of all personal medical expenditures.

In some instances third-party payers have made reimbursement for CT scanning dependent on planning agency approval and on prior determination of efficacy. These policies have the potential to affect expenditures. However, as a result of gaps in State certificate-of-need laws and section 1122, many services are not covered by these planning policies. Even when such policies apply, their effect has been diluted by poorly defined standards and inadequate information on efficacy.

By its reimbursement methods, the Federal Government in effect has assumed an open-ended commitment to finance services. Reimbursement mechanisms exert little pressure to perform services such as CT scans efficiently; indeed, they have the opposite effect. Furthermore, in the context of prevailing financing methods, there is little incentive to choose among alternative technologies. Present methods promote the additional use of technologies, even if the results are duplicative.

POLICY ALTERNATIVES

The policy alternatives in chapter 7 are grouped into three sections, each representing an area of governmental policy that affects the use of technologies such as CT **scan-**ning. Section 1 containing alternatives 1 and 2 considers the development of information

on efficacy and safety; Section 2 with alternatives 3, 4, and 5 concerns changes in regulatory policies; and Section 3 including alternatives 6 and 7 addresses alternative financing methods. These alternatives are not mutually exclusive; several mechanisms may be needed to deal with the problems identified in current policy.

Alternative 1: Establish a formal process to identify medical technologies that should be assessed for efficacy and safety; conduct the necessary evaluations; synthesize the results from the evaluations and from relevant clinical experience; and disseminate the resulting information to appropriate parties.

Alternative 2: As part of alternative 1, establish a formal process for making official judgments about the efficacy and safety of medical technologies.

Alternative 3: Authorize a Federal regulatory agency, such as the Food and Drug Administration, to restrict the use of medical technologies to the conditions of use specified in the FDA-approved labeling.

Alternative 4: Link Medicare reimbursement to the information and judgments about a technology's efficacy and safety that would result from alternatives 1 and 2.

Alternative 5: Expand regulation of capital expenditures to cover purchases of medical equipment regardless of setting or ownership.

Alternative **6:** For services paid by Medicare and Medicaid, establish rates of payment that are based on efficiency.

Alternative 7: Fundamentally restructure the payment system to encourage providers to perform and use medical services efficiently.

SCOPE OF THE STUDY

The purpose of this study was to examine policies concerning the development and use of medical technologies such as the CT scanner. The study did not attempt to evaluate CT scanners per se or to make judgments about CT scanning. The study was limited to policies, both public and private. It attempted to determine the effects of policies on development, diffusion, use, and reimbursement concerning CT scanners. It identified problems being experienced in implementing those policies.

Public and private policies include incentives and sanctions that influence behavior. The assumption was made that individuals and organizations act in their own best interests within the framework provided by those policies. The study particularly attempted to identify those aspects of policies that influence behavior contradictory to the intent of the policies.

The study attempted neither to identify individuals or organizations in conflict with policies nor to investigate fraud and abuse. The study focused on problems of policy, not ethics.

Nor did the study attempt to evaluate the efficacy and safety of CT scanners. Although the report discusses many other studies of safety and efficacy of CT scanners, its purpose is to inform Congress of the kinds of studies being conducted, their methods and timing, and the information being obtained.

The study did not attempt to evaluate organizations responsible for implementing various policies, such as Health Systems Agencies or Professional Standards Review Organizations. The report does discuss some of the problems that these organizations are experiencing as a result of current policies. Only policies and actions related to planning, regulation, and use of expensive medical technologies are discussed in relation to these organizations.

Although deficiencies in reimbursement policies both governmental and nongovernmental, have been shown to exist, this study was limited to those policies only as they apply to medical technologies, such as CT scanners. No attempt was made to examine the entire reimbursement system to identify all problems.

ORGANIZATION OF THE REPORT

The report is organized according to the policies examined in the study—efficacy and safety, regulation of diffusion and distribution, regulation of use, and reimbursement. Each of these chapters presents information about CT scanning and then discusses the information in relation to policy, identifying shortcomings when they exist.

Chapter 2 is a background chapter that describes the principles and operation of CT scanners as well as their development and improvement.

Chapter **3** discusses the efficacy and safety of CT scanning. It considers the concept of efficacy and then explains the difficulty of defining efficacy for diagnostic technologies. Studies of the efficacy of both body and head scanning are reviewed, a discussion that includes the impact of CT scanning on other neurodiagnostic procedures. Data on the safety of CT scanners are examined. Federal policies concerning efficacy and safety are discussed, and important gaps in policy are identified.

Chapter 4 examines the rate at which CT scanners were installed, the number of scanners, and their geographical and institutional distribution. It describes policies designed to control the rate and distribution of expensive technologies such as CT scanners. The intent of these policies is compared to actual practice, leading to identification of their shortcomings.

Chapter 5 reports patterns of use of CT scanners, including the medical problems for which CT scanning has been used and the institutional setting for CT scanning. The importance of indications for use, as determined by studies of efficacy, is analyzed both for the practicing community and for the federally mandated program for quality assurance.

Chapter **6** reviews available data on the expenses, charges, and profits of CT scanning. Estimates of gross and net national expenditures are calculated. Public and private reimbursement policies and their shortcomings are examined in light of the data on CT scanning.

Chapter 7 presents policy alternatives for consideration by Congress. These alternatives address problems identified in current Federal policies concerning information on efficacy and safety, regulatory policies, and financing methods.

BACKGROUND

2.

BACKGROUND

PRINCIPLES OF CT SCANNING

CT scanning builds on the principles of conventional X-ray films: structures are differentiated by their ability to absorb energy from X-rays. The denser* a structure is, the more energy it will absorb. Thus, less energy will reach the film or other receptor, and the image of that structure will be lighter. Bone or metal, which are dense, appear white on the X-ray film; air or gas, which are much less dense, appear black. Structures with intermediate densities appear as shades of gray.

CT scanners use these principles in a new way **(184,236,237,245,331,408).** Each CT scanner has four basic elements (figure 3):

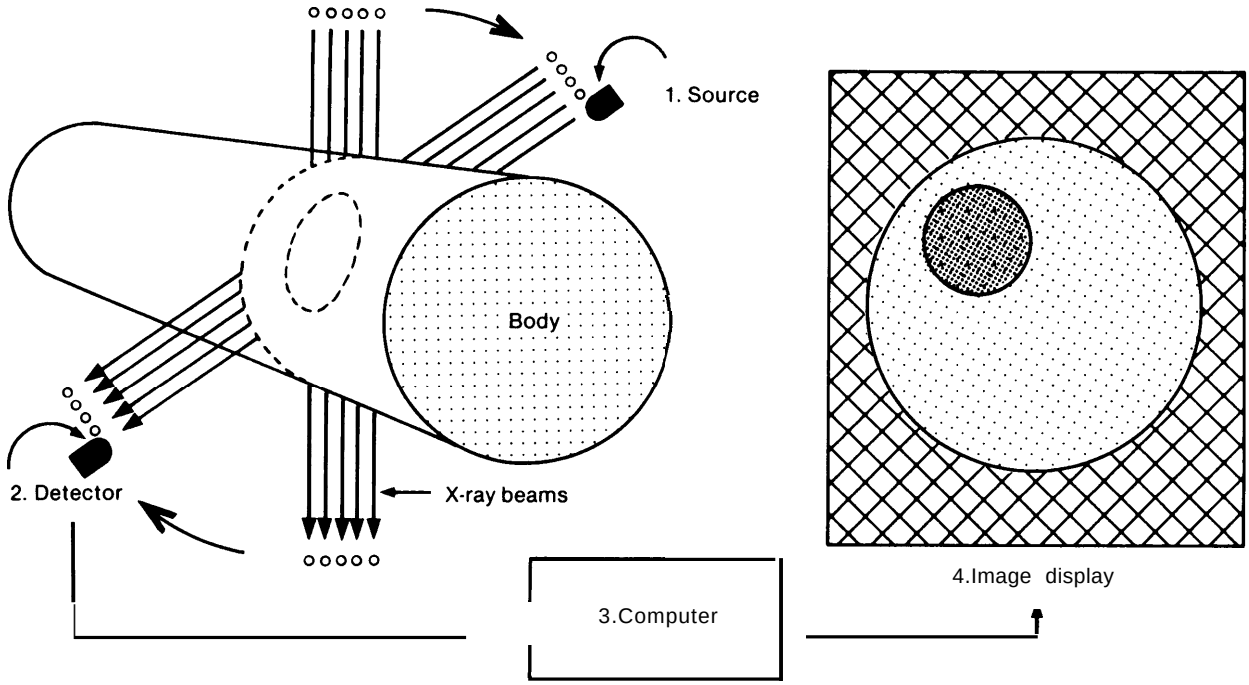
- A source, or X-ray tube, which emits a beam of X-rays.
- A detector, which collects energy from the X-ray beam after it has passed through the body. It then determines how much energy is still present in the beam.
- A computer, which collects, stores, and processes information from the detector.
- An imaging device (a cathode-ray tube**), which has a television-like screen on which the reconstruction produced by the computer can be displayed.

Except in the more recent models of CT scanners, the source and detector are mounted on a gantry (frame) as a single unit, attached to a table for the patient. When activated, the gantry moves around the patient's head or body in many small steps. At each position, the source emits a beam of X-rays which passes through the patient and is collected by the detector. The energy reading at each position and the beam's geometrical coordinates are stored by the computer. Depending on the model, *30,000* to *300,000* readings per scan are taken and stored. Each reading indicates how much energy was lost by the beam of the X-rays through the body. The computer then uses the complete set of readings to determine the density of the material or tissue through which X-rays passed (195,196). An image of a thin cross section (or slice) through the body is then displayed on the screen of the cathode-ray tube. Sample images are shown in figures 4 and 5:

* Technically, radiation absorption is a complex function associated with the energy spectrum and the atomic number as well as density.

** The picture tube of a television set is a cathode-ray tube.

Figure 3.—Schematic Illustration of CT Scanner



The source and detector are mounted on a single frame and move around the body together in a large number of small steps. X-rays emitted by the source pass through the body and are collected by the detector. Information from the detector is fed into a computer, which reconstructs and displays an image of a cross section of the body.

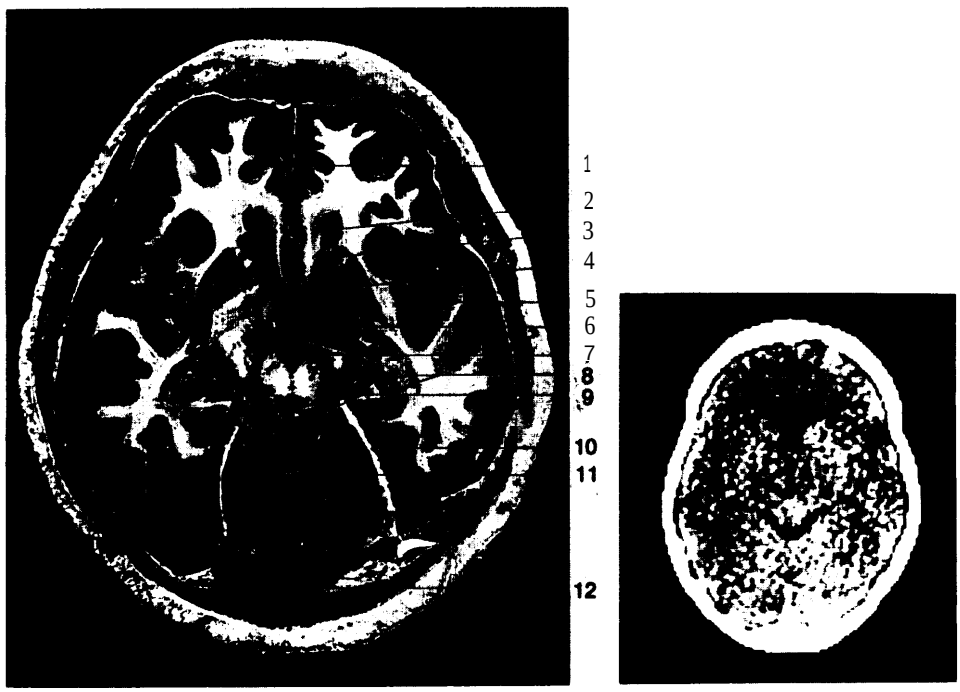
Source. Off Ice of Technology Assessment

CT scanning overcomes two shortcomings of conventional X-rays. First, in conventional X-rays, various organs overlap on the film and obscure each other. By rotating the beam and producing cross-sectional images, the CT scanner eliminates this problem. Second, conventional X-rays do not always differentiate between adjacent structures of similar density. A radiologist may be unable to distinguish among the shades of gray on the film. By using many exposures from different angles to produce one image, CT scanning can make slight differences in density apparent (441). CT scanning resolves (distinguishes) densities that are one-tenth as great as can be seen with conventional methods. These two advantages make CT scanning especially useful for visualizing soft, low-density tissues as in the brain. The brain's tissue is not "washed out" by the overlapping image of the skull, and subtle differences of density within the brain can be detected.

OPERATION OF THE CT SCANNER

A typical CT installation fills two rooms (figure **6).** The scanning unit, consisting of the gantry, source, detector, and patient table, is in one room. The computer, display equipment, and control unit are in the other. During a CT examination, the patient is positioned on the table, and the scanner is activated. The patient must

Figure 4.–Normal Brain Cross Section (left), CT Scan (right)



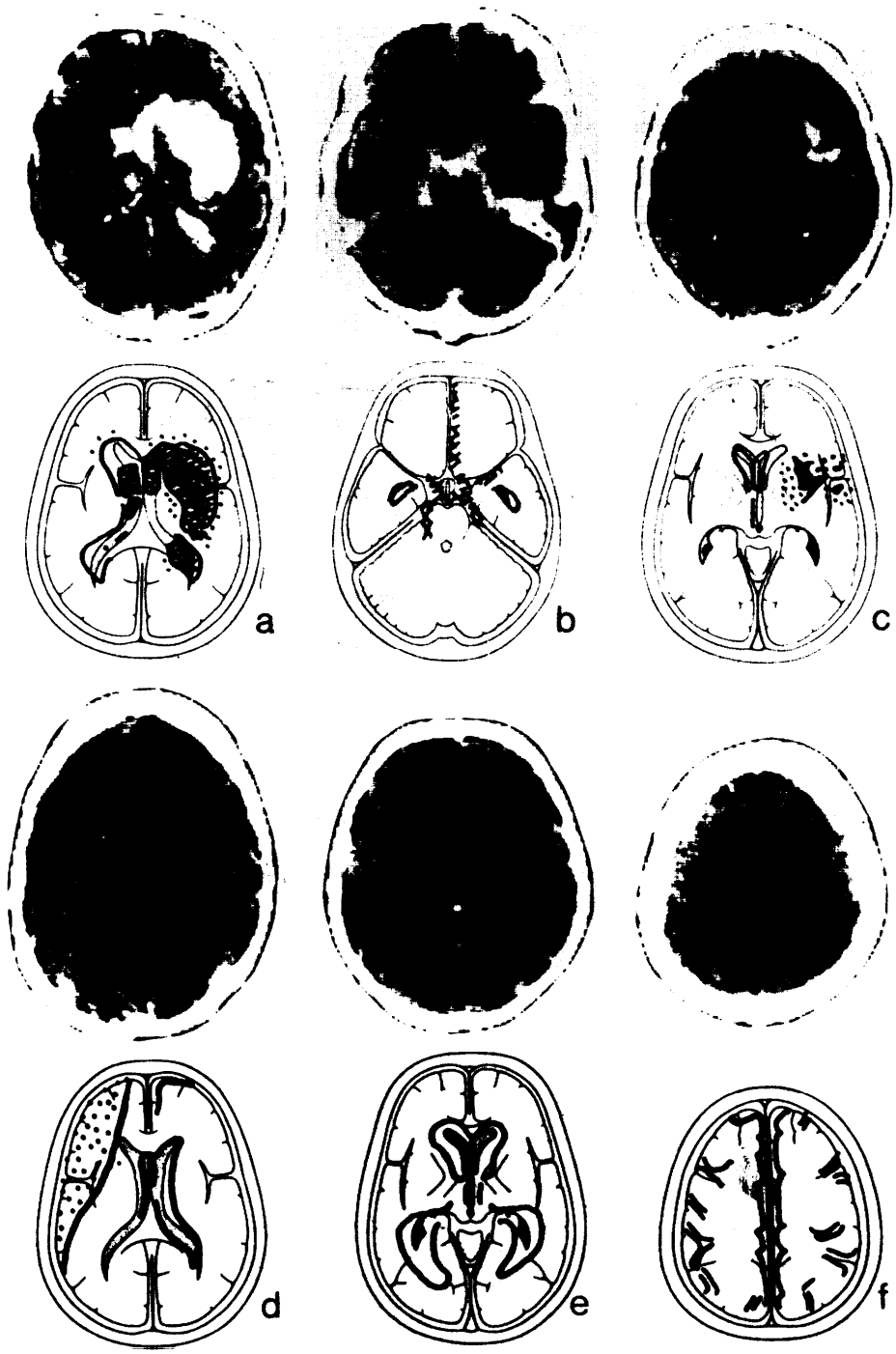
1 = Falx cerebri
2 = Cornu anterius ventriculi lateral is (tip)
3 = N. caudatus, caput
4 = Putamen
5 = Insula and lateral cistern
6 = Ventriculus tertius
7 = Corpus mamillare and fossa interpeduncularis
8 = Hippocampus and cornu inferius
9 = Aquaeductus cerebri and quadrigeminal cistern
10= Tentorium cerebelli (cut)
11 = Vermis superior cerebelli
12= Eminentia cruciata

Source. Reproduced with permission from Cranial *Computerized Tomography* **©, Springer-Verlag, Berlin Heidelberg New York, 1976, p 39**

remain still while the gantry is moving. Motion is not a problem for most patients, but sedation, anesthesia (3), or immobilization devices **(387)** are sometimes required for children, patients in severe pain, or agitated patients. In early machines, each scan took about 5 minutes, but the newest models take only 5 seconds (see below). After the gantry has completed its rotation around the head or body, the computer may require u p to *2½* additional minutes to process the information and to display the image. It appears on the screen of the cathode ray tube for immediate inspection, and it can be photographed for later examination. The computer can also make permanent records on tape, paper, or magnetic discs.

Because each CT cross section is quite narrow (usually about) centimeter) the procedure is often repeated at several places to cover the area of interest. A complete

Figure 5.—Examples of Graphically Reported CT Findings



(a) Basal Ganglia Hematoma With Ventricular Perforation. (b) Subarachnoid Hemorrhage. (c) Olgodendroglioma. (d) Chronic Subdural Hematoma. (e) Occlusive Hydrocephalus. (f) Cortical Atrophy.

Source: Reproduced with permission from *Cranial Computerized Tomography* ©, Springer-Verlag, Berlin. Heidelberg. New York, 1976, p. 77.

Figure 6.—Typical Computed Tomography Installation Involving Divided Rooms

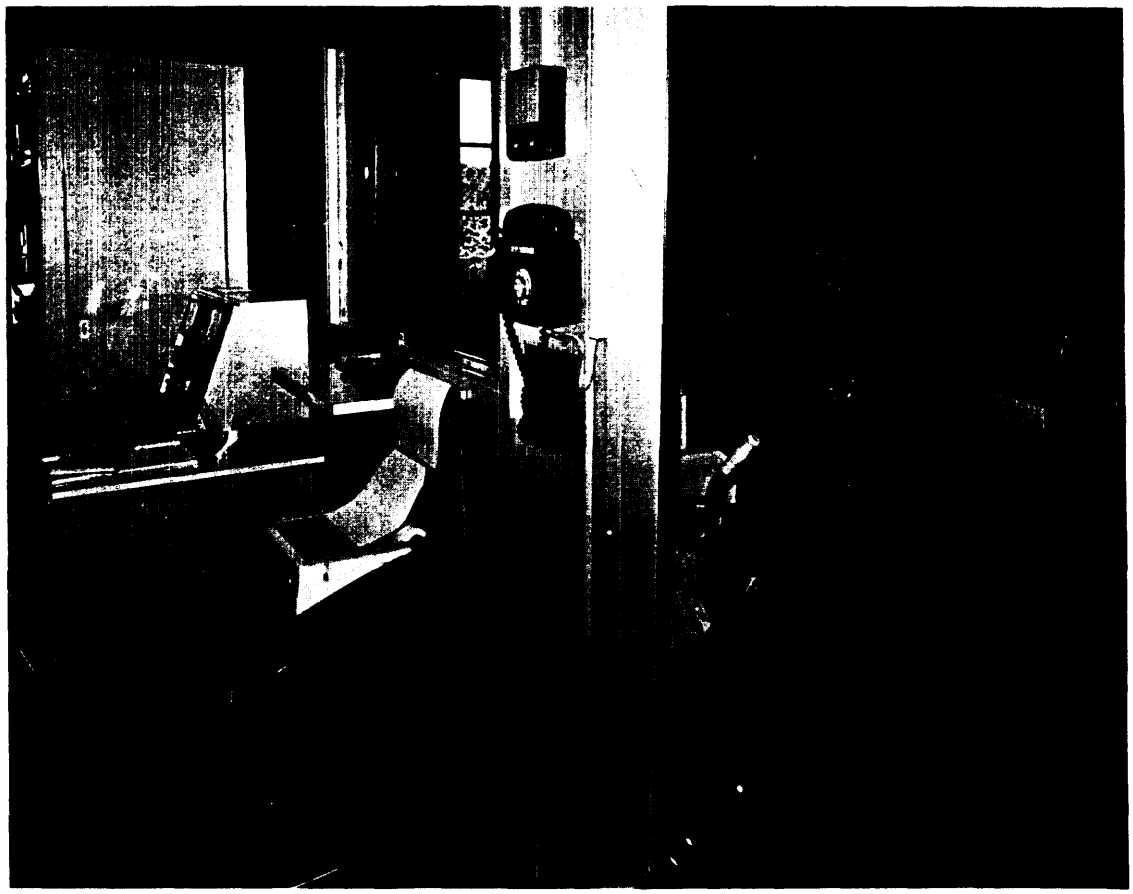


Photo: Courtesy of Clinical Center, National Institutes of Health

CT study usually includes images of at least six to eight sections. Most head scanners produce images of two adjacent sections during each traverse; thus, three or four scans are usually required. Most body scanners produce only a single section per traverse, so more scans may be necessary. In addition, a patient is often scanned, injected with contrast material, and then scanned again to get additional information. Thus, a full CT examination may take at least one-half hour to complete. In many hospitals, a radiologist is present during the examination. In some institutions, however, radiological technicians perform the examination, and a radiologist or other physician interprets the images later **(239).** This approach can be less costly than having a radiologist present; but if the scan is of poor technical quality or if the radiologist decides that additional sections are needed, the patient may need to return for another examination **(14,15,50,125,161,382,383,388,389,397,4 60).**

DEVELOPMENT OF THE CT SCANNER

The first CT scanner was developed in 1967 by Hounsfield, an engineer working at EM I Ltd., in Britain. Earlier, in the United States, Oldendorf (395) and Cormack

(117), had independently constructed tomographic devices that used some of the principles found later in the CT scanner. Both Oldendorf and Cormack realized the diagnostic potential of their devices. Oldendorf, a neurologist, could interest neither physicians nor corporations in developing his ideas **(379,396).** Cormack, a physicist, published his results in a journal of applied physics, but the article apparently went unnoticed by the medical community. Hounsfield, researching pattern recognition devices, developed a theoretical basis for CT scanning in **1967 and** built a device to test his ideas. Using inanimate objects first and diseased brain tissue later, he showed that his machine could produce images of sections difficult to visualize with conventional radiological techniques **(17,37,60).**

The British Department of Health was interested in Hounsfield's work, and in **1970** it supported the construction of a CT unit that could be used to examine patients (60). A prototype was installed at Atkinson Morley's Hospital in London in October 1971. Ambrose, a physician at that hospital, was soon successful in using the EMI scanner to image lesions of the brain, including tumors (22). The EMI scanner was shown publicly at professional meetings in **1972.** In June 1973, the Mayo Clinic installed the first commercial unit in the United States (47).

The early success of the EMI scanner encouraged a number of corporations to develop CT scanners. Ledley, at Georgetown University Medical School, developed a scanner that could image sections of the head and the entire body. Marketed as the ACTA scanner, it was operational by February 1974 **(315,316,317).** Soon thereafter, Ohio-Nuclear and Siemens also began to market scanners (Delta and Siretom scanners, respectively). By the end of 1975, some **20** corporations had developed or were developing CT scanners **(37,79,161,290,402,583).**

During the past 3 years, CT technology has not only extended scanning from the head to the entire body, but also has continually decreased the time required to complete a scan. Because motion by the patient during the scan can destroy the image, decreased scanning time is important. The first scanners—EMI, ACTA, Delta, and Siretom—required about 5 minutes to complete one scan. They used a single source and detector per section and are referred to as first generation CT scanners **(79,290).**

The next generation was equipped with a single source producing either a fan beam or multiple pencil beams and with multiple detectors. Such scanners gathered more information at each position of the gantry's traverse than did first generation scanners. The gantry moved in larger steps, and scanning time was reduced to between 20 seconds and 2 minutes per scan. Third generation scanners, which are now being marketed, reduce scanning time still further. Rather than thin beams of X-rays, they use a fan-shaped beam aimed at a bank of up to several hundred detectors. The gantry rotates, but unlike first and second generation scanners, no lateral motion is required. A scan can be completed in only 5 seconds. Some of the principal features of first, second, and third generation CT scanners are compared in table 1 and figures 7 and **8.**

Increasing the speed of CT scanning is desirable to minimize problems associated with patient motion and to permit imaging of motile organs such as the heart. But scanning speed must be balanced against the other variables of radiation dose and image quality (resolution). An ideal CT scanner would be one that produced high quality images using small amounts of radiation (thus causing little risk to the patient) in a short time period. A limiting factor in decreasing scanning time has been movement of the source and detector on the gantry, a mechanical motion requiring

Table I—Characteristics of CT Scanners

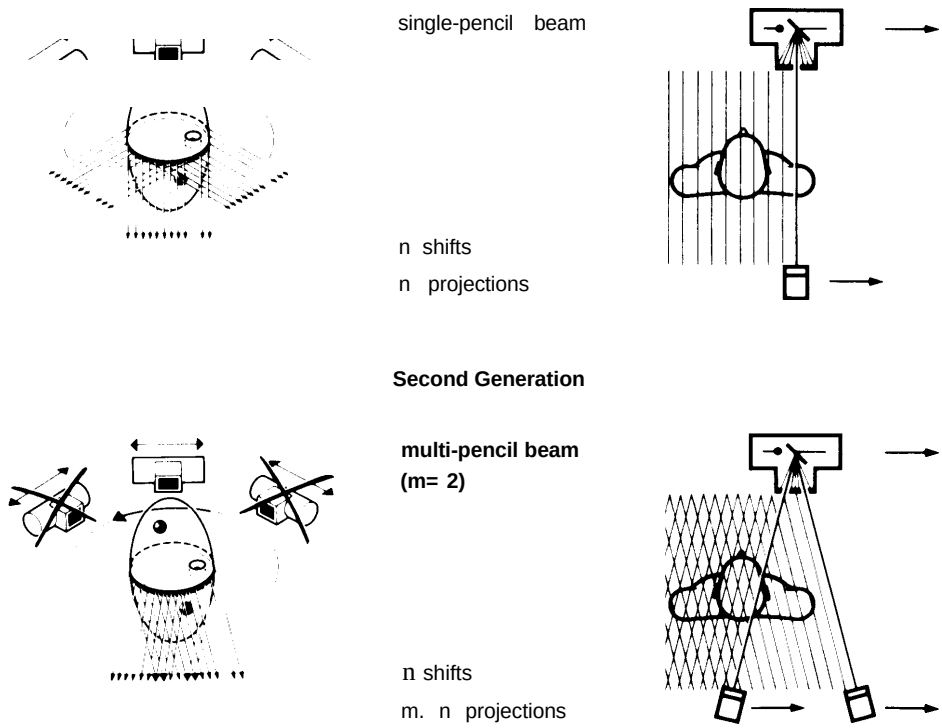
GENERATION [a]	I	II	III
Time to Produce One Section	4-6 min.	20 sec. -2 min.	under 20 sec.
X-ray Source	single pencil beam	2 or more pencil beams or single fan beam	single fan beam
Detectors	1	2 or more (up to 60)	hundreds - contiguous
Motion of Gantry	Source and detector move together in small lateral and small rotational steps	Sources and detectors move together in larger lateral and rotational steps than Generation 1	Rotational motion only. In most models, source and detectors move together, but in some, only source moves
Operational Commercial Models	EM I Brain Scanner (H) Pfizer ACTA 0100 (B)[c] Siemens Siretom (H) General Electric - Neuroscan CT/N (H)	EM I CT 1010 (H) EM I CT 5005 (B) Ohio-Nuclear DELTA (H and B) Syntex System 60 (H) Syntex System 90 (B)	Artronix Neuroscanner 1100 or 1110 (H) General Electric CT/T (B) Varian (B) American Science & Engineering (B) Searle Pho/Trax (B)
Models not yet installed [b]		Phillips Tomascan (B)	Artronix Whole-Body scanner 1120 (B)

a Nomenclature of Brownell (79).
[b] As of June 1, 1978.
c H = Head, B = Body.

several seconds. In order to overcome this problem, the latest models of CT scanners will employ a large number of sources and detectors, all of which can operate at the same time. This approach will not only overcome problems of motion, thus increasing image quality, but will make it theoretically possible to reduce radiation dose to very low levels.

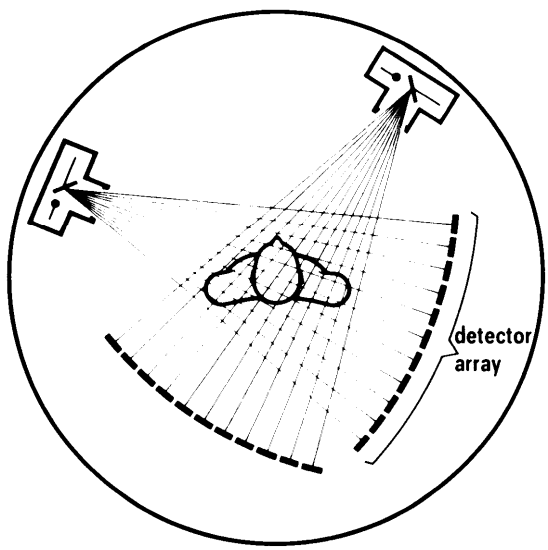
Improvements in technical capabilities may soon introduce new uses for CT scanners. New computer programs can produce images in a variety of planes or even in three dimensions from information now used to image cross sections, although at the cost of a higher radiation dose **(46,189,190,444).** Other programing changes can permit statistical analysis of data from scans to reveal differences in density or shape

Figure 7.—Configuration of First and Second Generation CT Scanners With Parallel Beam Data Acquisition



Source: Reproduced with permission from *Crania/ Computerized Tomography* c , Springer-Verlag, Berlin. Heidelberg, New York, 1976, p. 22.

Figure 8.—Third Generation CT Scanner Configuration With Fan-Beam Data Acquisition



Source: Reproduced with permission from *Cranial Computerized Tomography S,* Springer-Verlag, Berlin. Heidelberg. New York, 1976, p, 23.

undetected by visual inspection **(64,436).** The computer can also subtract normal from contrast-enhanced scans to reveal areas that have accumulated contrast material (64,415). This capability might be particularly useful if contrast agents for specific organs can be developed. Even without great reductions in scanning time, early evidence indicates that exposures can be synchronized with rhythmic motions so that organs that are now difficult to image, such as the heart, can be scanned **(2,486).**

Physicians also anticipate increased use of CT scanning in conjunction with other techniques. For example, biopsy needles may be more accurately positioned with CT scanning than with present methods **(11,272,324).** Also, CT units have been linked with cobalt or other radiation sources to form an integrated system for radiation therapy (96,244,272). Use of a calibrated head-holding device (a stereotaxic apparatus) permits more accurate radiosurgery on lesions discovered by CT scanning **(63).** Finally, periodic CT scans of some patients are being ordered to monitor responses of tumors to chemotherapy or radiation therapy **(272).**

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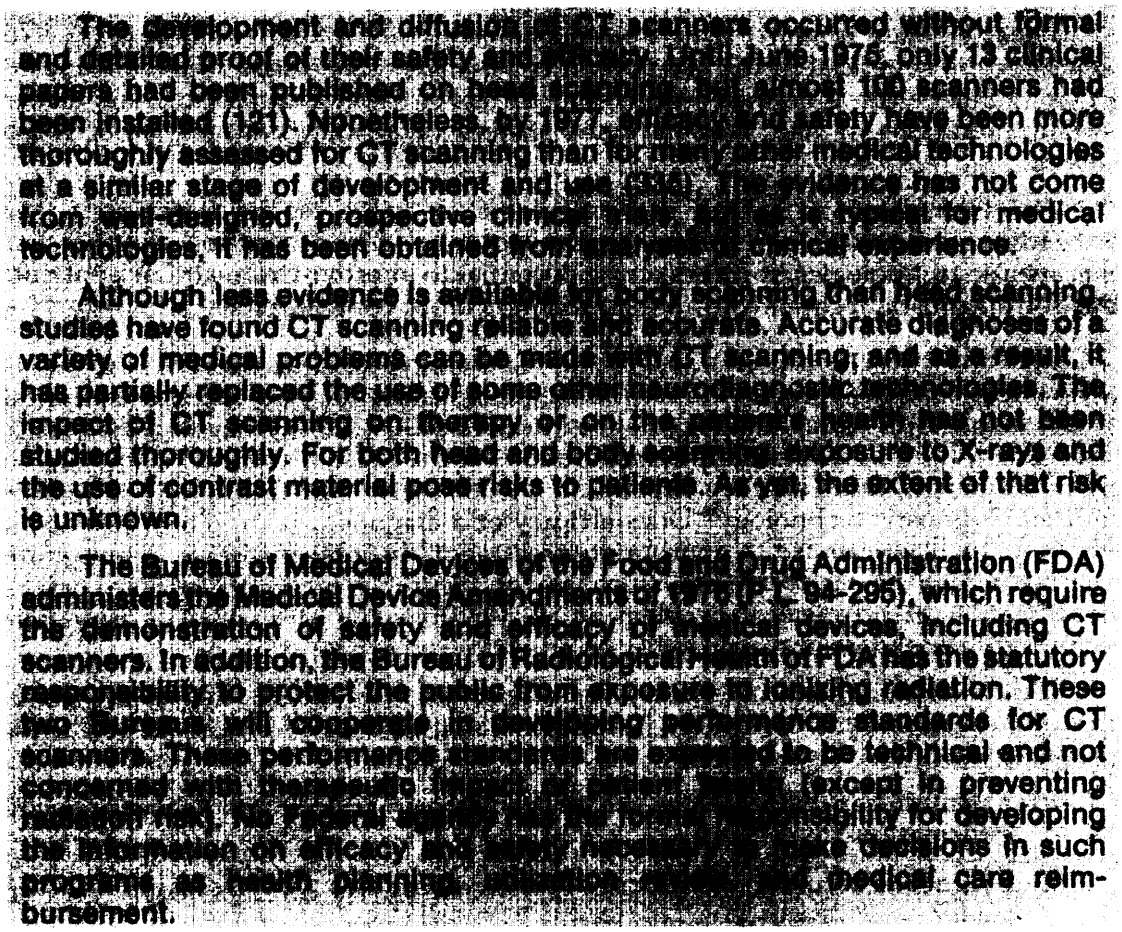
EFFICACY AND SAFETY

3 •

EFFICACY AND SAFETY



The development and diffusion of CT scanners occurred without formal and detailed proof of their safety and efficacy. Until June 1975, only 13 clinical papers had been published on head scanning, but almost 100 scanners had been installed (121). Nonetheless, by 1977, efficacy and safety have been more thoroughly assessed for CT scanning than for many other medical technologies at a similar stage of development and use (336). The evidence has not come from well-designed, prospective clinical trials, but as is typical for medical technologies, it has been obtained from analyses of clinical experience.

Although less evidence is available for body scanning than head scanning, studies have found CT scanning reliable and accurate. Accurate diagnoses of a variety of medical problems can be made with CT scanning; and as a result, it has partially replaced the use of some other neurodiagnostic technologies. The impact of CT scanning on therapy or on the patient's health has not been studied thoroughly. For both head and body scanning, exposure to X-rays and the use of contrast material pose risks to patients. As yet, the extent of that risk is unknown.

The Bureau of Medical Devices of the Food and Drug Administration (FDA) administers the Medical Device Amendments of 1976 (P.L. 94-295), which require the demonstration of safety and efficacy of medical devices, including CT scanners. In addition, the Bureau of Radiological Health of FDA has the statutory responsibility to protect the public from exposure to ionizing radiation. These two Bureaus will cooperate in developing performance standards for CT scanners. These performance standards are expected to be technical and not concerned with therapeutic impact or patient health (except in preventing radiation risk). No Federal agency has the formal responsibility for developing the information on efficacy and safety necessary to make decisions in such programs as health planning, education, [illegible] and medical care reimbursement.

THE ISSUE OF EFFICACY

Efficacy is defined as the potential benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. Efficacy is an abstract concept projecting the results that a technology might achieve. According to this definition, the efficacy of a medical technology can be determined only by examining information about four aspects of that technology:

(I) the benefit individuals receive and the probability of benefit,

(2) the population benefiting from the technology,

(3) the medical problem affected, and

(4) the conditions of use under which the technology is found to be beneficial. Technologies may be beneficial only when used in a certain manner. For example, dosages can affect the outcome of using drugs, and skill of the surgeon is important in surgery. For diagnostic technologies, conditions of use include findings from the history and physical examination indicating that use of the technology is appropriate.

Thus, efficacy is more than a simple consideration of potential benefits. No technology is beneficial in the absolute; it is beneficial only when used in an appropriate manner—for a defined population, for given medical problems, and under certain conditions of use. Well-designed studies of efficacy consider all of these factors.

The term *benefit* refers to the usefulness or value of the technology. For preventive technologies, it refers to the potential for preventing disease. For therapeutic technologies, it refers to the potential to improve the health of a patient. But for diagnostic technologies, the situation is more complicated.

Defining the efficacy of a diagnostic technology, such as the CT scanner, is particularly complex because the technology itself cannot directly affect the physical health of patients. Questions arise about how to judge the efficacy of a diagnostic technology. Is efficacy limited to considerations of the capability of the technology to aid in diagnosis? Does efficacy depend on the ability of that technology to replace another diagnostic technology? Does efficacy of a diagnostic technology depend on whether the diagnosis led to appropriate treatment? In some instances, appropriate treatment may be no treatment, such as for incurable medical problems or the identification of no medical problem at all. Or does the efficacy of a diagnostic technology depend on the availability of an efficacious therapy?

Several formulations of efficacy for diagnostic technologies have been developed. Fineberg and his coworkers have formulated efficacy of diagnostic technologies in terms of five levels **(167):**

(1) Technical capability—Does the device perform reliably and deliver accurate information ?

(2) Diagnostic accuracy—Does use of the device permit accurate diagnoses to be made?

(3) Diagnostic impact—Does use of the device replace other diagnostic procedures, including exploratory surgery and biopsy?

(4) Therapeutic impact—Do results obtained from the device affect planning and delivery of therapy?

(5) Patient outcome-Does use of the device contribute to improved health of the patient?

In a study sponsored by the American College of Radiology, an alternative approach to the assessment of efficacy of diagnostic technologies has been proposed:

Efficacy-l, the information content of the procedure; Efficacy-z, the use of the diagnostic information in prescribing treatment or in gathering more information; and Efficacy-3, the expected value of diagnostic information to the health of the patient **(335, 336).**

Assessment of the efficacy of diagnostic technologies is often limited to levels 1 and 2 of the Fineberg formulation as they are the easiest to perform. Levels 3 and 4 are more difficult to assess, but feasible. These four levels are primarily concerned with medical care processes. Patient outcome (level 5) is much more difficult and time-consuming to determine since followup of patients over time is required (33.5). Present policy and current practice have emphasized assessment of the accuracy of diagnosis, with little concern for effect upon therapy or outcome. Thus, few diagnostic technologies have been evaluated from these points of view.

EVIDENCE OF EFFICACY OF CT SCANNERS*

Efficacy cannot be measured directly, although evidence about it can be obtained from controlled clinical trials or from clinical experience. Such evidence allows judgments to be made about efficacy, judgments that may change as additional evidence accumulates. Efficacy has been more thoroughly assessed for CT scanners than for many other medical technologies at a similar stage of development and use. The available evidence has not come from well-designed, prospective clinical trials, but as is typical for medical technologies, it has been obtained from analyses of clinical experience. The results of these clinical studies are presented without necessarily endorsing the manner in which they were obtained.

Head Scanning

Technical Capability

Engineers and medical personnel find that head scanners perform reliably and deliver accurate information (44,125,129,338,382,386,405,406). Most of the technical problems and malfunctions that plagued early CT scanners have been eliminated (129,405,406). New installations often experience considerable "down-time," but most malfunctions can be corrected by hospital staff. Protocols and equipment for evaluating both the technical capabilities and performance of CT scanners have been designed **(25,191,338).**

While CT scanners usually function well and produce reliable images, their technical capabilities do have limitations. Objects are not always resolved if smaller than about 1 centimeter in diameter, or if their density differs only slightly from that of surrounding tissue (16,129,247,40.5,406). Because of the arrangement of sources and detectors in some machines, parts of sections being scanned may not be imaged at all or may be dually imaged (193). As a result of limitations in the imaging procedures, artifactual lines or patterns appear near areas of very high density or

* Conclusions in this section are based on a literature review carried out during May 1977. According to recent reviews, however, the conclusions remain valid. The interested reader should refer to Abrams, H, and McNeil, B. "Medical Implications of Computed Tomography ('CT Scanning')" *New Eng. J. Med.* 298:255 and **310,** 1978.

contrast, such as implanted ventricular shunts or surgical clips, or the skull **(108,129,191,386,405,406). Any** motion of the patient during scanning may also cause artifacts **(15,16,225,236,386,405,406),** but this problem is more serious for body than for head scanning.

Diagnostic Capability

(1) Diagnostic Accuracy. CT scanning has been used in diagnosing nearly all neurological disorders associated with an abnormality in or near the brain **(15-23, 39-41, 44-53, 55-58, 62, 74-76, 83, 87-88, 90, 92-94, 97-101, 103, 108, 124-130, 138-143, 154-156, 160, 162, 170-171, 173, 183, 192, 202-204, 210-212, 223-225, 230-231, 239, 248-249, 251-252, 255, 267-269, 271, 274, 276, 278-279, 284-289, 291-294, 308, 310, 312, 314, 318, 320, 326-330, 333-334, 343, 347, 353-354, 356-361, 368-372, 385-386, 388, 393-394, 397, 400, 405-407, 410-412, 420, 426-429, 432, 439, 441-442, 447,451, 458-460, 472, 478, 482, 488-489, 492, 516-518, 520, 522, 536-537, 539-543).** CT head scanning can reveal lesions in the brain itself, in the meninges (lining that surrounds the brain), and in the orbit (bony socket of the eye).

In a head scan, lesions are detected by abnormalities in the density or shape of the brain (125,236,237,386). A decrease in density (that is, a decreased ability of some part of the brain to absorb energy from X-rays) may indicate edema, an infarct, or a fluid-filled cyst. An increase in density suggests a tumor, hemorrhage, fibrosis, calcification or hemorrhagic infarct. An asymmetric image suggests mass lesions such as tumors. Large changes in shape, such as enlarged ventricles and dilated subarachnoid spaces, are suggestive of hydrocephalus or atrophy (see figure 5).

Many reports have attempted to assess the diagnostic accuracy of CT head scanning. Some results of these studies are summarized in table 2. In most of the studies, accurate diagnoses were obtained for 80 to 100 percent of the patients; greater than 90-percent accuracy was reported for about two-thirds of the patient groups.

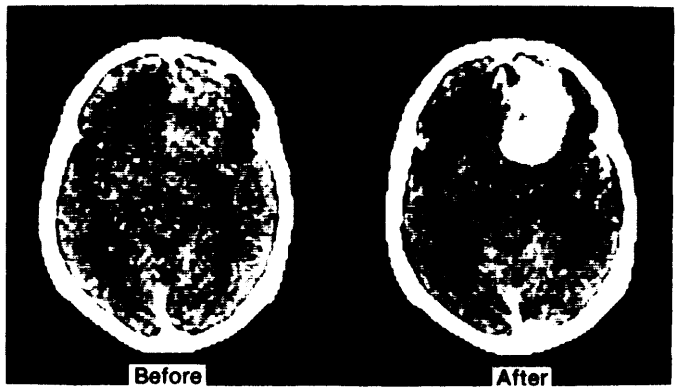
(2) *Contrast Enhancement and Diagnostic Capacity.* **In** about **60** percent of CT head examinations, and in more than 50 percent of all CT examinations, patients have contrast material injected into their bloodstreams. This percentage has increased over time **(240,241).** These patients are usually scanned both before and after the injection. The use of contrast material is often time consuming, adds sizably to the cost and price of CT scanning (see chapter 6), and exposes the patient to some risk. Although radiologists believe that these drawbacks are outweighed by the additional diagnostic information obtained, the empirical evidence is less convincing. Many lesions can be seen better on contrast-enhanced than on unenhanced scans, and information is gained about the nature of the lesion **(21,119,135,303,386)** (figure 9). On the other hand, in two large studies of the efficacy of contrast enhancement, injection of contrast material revealed lesions invisible on unenhanced scans in only 2 to **5** percent of all patients **(44,119).**

(3) *The Validity and Reliability of CT Diagnostic Capacity.* The studies summarized in table 2 and a variety of less systematic case reports lead to the conclusion that CT scanning permits more accurate diagnosis of some types of lesions than others. Tumors in or near the brain can be diagnosed and localized quite accurately, as can a variety of cerebrovascular lesions. On the other hand, hairline fractures, small tumors, and some new infarcts are difficult to image with CT scanning. Early

Table 2.—Diagnostic Accuracy of Head Scanning: Summary of Published Studies

Diagnostic Category	Numberof Patients	Percent Accurate Diagnosis	Reference
Unclassified Neurological Disorders	800	97	44
Unclassified Neurological Disorders	53	92	228
Unclassified Neurological Disorders	450	98	487
Unclassified Neurological Disorders	75	88	344
Unclassified Neurological Disorders	641	92	90
Unclassified Neurological Disorders	109	87	4
Unclassified Neurological Disorders	79	86	244
Cerebrovascular Lesions			
hemorrhage	17	88	24
hemorrhage	13	100	90
hemorrhage	15	81	437
hemorrhage	21	100	264
nontraumatic hemorrhage	18	100	463
nontraumatic hemorrhage	100	90	213
nontraumatic hemorrhage	46	90	419
acute cerebrovascular disease	60	85	375
cerebrovascular disease	51	75	266
cerebrovascular disease	89	72	95
subdural hematoma	35	100	368
angioma	14	86	368
angioma	41	80	260
infarct	52	52	90
infarct	84	75	118
infarct ....00...	58	98	264
infarct	100	93	476
infarct (middle cerebral artery)	174	86	89
Tumor			
intracranial tumors 00	106	94	164
intracranial tumors 0	24	100	95
intracranial tumors 0	209	97	259
intracranial tumors	174	95	368
intracranial tumors 0	88	95	375
intracranial tumors	633	96	20
intracranial tumors (children)	45	89	57
intracranial tumors	114	85	90
intracranial tumors .. ..O..	35	97	4
meningioma	71	96	93
orbital lesions -mostly tumor	25	84	486
juxtasellar lesions-mostly tumor	20	100	368
pituitary adenoma	12	100	91
Atrophy	20	90	401
Abcess	22	100	356
Abcess	10	100	346
Abcess	8	88	305
Abcess	26	92	92

Figure 9.—Malignant Lymphoma in Right Frontal Region Before and After Enhancement



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observations indicated that aneurysms, subdural hematomas, and small masses very near bone (such as tumors in the posterior fossa) were difficult to image **(15,16,108,129,202,405).** Other physicians, however, have reported considerable success in imaging such lesions (231,370,405,429,439).

Accuracy of CT scanning has been assessed by comparing diagnoses made through its use with those made by methods of presumably assured validity. Autopsy or surgery, which provide opportunities for rigorous confirmation, have been used in some studies. Many studies, however, rely on less exacting confirmation, such as other diagnostic tests or the subsequent course of the disease.

In a study by Messina (355, cited in 382), for example, autopsies confirmed, to some extent, diagnoses made by CT scanning in 88 percent of the patients. Only 55 percent of the diagnoses were confirmed completely, however. Partial agreement between CT scanning and autopsy results was observed in the remaining 33 percent. Many patients had multiple lesions, and when each lesion was considered separately, the accuracy of CT scanning was even lower. Only one-third of all lesions seen on autopsy were imaged by CT scanning; another third were so small that they could not possibly have been resolved; the final third, although large enough to resolve, were not seen in the CT images. It should be noted that these lesions would probably not be visualized by any other existing diagnostic technique.

Other diagnostic procedures may be more accurate than CT scanning for some diseases. A complete study of this possibility would test each procedure on each disease condition to compare true negatives, true positives, false negatives, and false positives. Such information is not yet available because few such studies have been undertaken.

Many studies include reports of early experience with CT scanners. Radiologists point out that many diagnostic failures were the result of inexperience or early equipment deficiencies. Thus the accuracy of CT scanning may be underestimated in early studies.

Several of the studies compare the simple accuracy of CT scanning and other diagnostic procedures. In general, CT scanning has been found to be more accurate

for neurological lesions than radionuclide brain scans or conventional skull X-ray films. It has been found to be at least as accurate as the risky and uncomfortable procedures of arteriography and pneumoencephalography (see below).

Diagnostic Impact

The most common neurodiagnostic procedures used before the development of CT scanning were cerebral arteriography, pneumoencephalography, radionuclide brain scanning, and skull X-ray. Others included echoencephalography, and electroencephalograph (see table 3).

(1) Arteriography or Cerebral Angiography. During arteriography, contrast material is injected into the patient's bloodstream while conventional X-ray images the blood vessels in the skull. Radiologists can recognize malformations of the blood vessels and/or infer damage to the brain itself from distortions in the vascular pattern. Arteriography requires 2 to 4 days of hospitalization (36) and exposes the patient to more radiation than a set of CT scans (443,564). Comparisons of the two procedures have found CT scanning to be at least as accurate as arteriography in revealing and pinpointing neurological lesions (21,39,45,48,62,101,180,294,388,439).

After the introduction of CT scanning in several institutions, the number of arteriograms performed decreased by 15 to 34 percent **(46,157,296,382,443).** While a 15 to 20 percent decrease is the most frequently quoted range (36,46,48, 262,264,296,382,582), a O to 5 percent increase has also been recorded (45,80). However, arteriograms were increasing in number in the late 1960's and early 1970's, and CT scanning may have halted this upward trend (45). CT scanning is most often used as an alternative to arteriography in emergency situations and on new admissions **(261,** 350,382,405,439). However, arteriography is still considered to be superior to CT scanning for delineating the vascular structure of the brain (38,45,264,41 2) and will continue to be used in some situations (264).

(2) *Pneumonencephalography.* In this procedure air is injected into the spinal canal where it moves upward into the ventricles of the brain and shows up on conventional X-ray films. Distortions in the ventricular space indicate space-filling lesions in the brain. Some risks of morbidity and a rare fatality are associated with this procedure, especially for certain groups of patients, such as the elderly. In addition, pneumoencephalography requires 4 to 10 days of hospitalization (36,264) and may expose the patient to more radiation than CT scanning (564). Clinical studies have shown that CT scanning and pneumoencephalography frequently provide diagnostic information of approximately equal accuracy (21,44,48,180,181 ,439).

The use of pneumoencephalography decreased by 20 to 75 percent in several institutions upon the introduction of CT scanning (36,45,50,82,138,140,157, 262,296,382,538,545,582). Because of its costliness in terms of resources and risks to patients' health, however, pneumoencephalography has never been a frequently used procedure. In fact, its use started to decline even before CT scanning was an available alternative (264,382). Although indispensable for identifying certain classes of tumors (62), use of pneumoencephalography continues to decline. It will probably become more restricted to neurological referral centers where medical personnel with the proper expertise are available (264).

(3) *Radionuclide Brain Scanning (RNS).* Radioisotopic material is injected into the bloodstream, and the head is scanned by a camera that can detect and record the

Table 3.—Comparison of CT Head Scanning With Other Neurodiagnostic Procedures[a]

Procedure	Diagnostic Accuracy[b]	Approximate Annual Numbers of Procedures in United States, 1976	Safety Compared to CT Scanning	Usable On Outpatients	Estimated Effect of CT Scanning on Utilization
CT Scanning	High-generally 80-900/o	855,400-987,000		Yes	
Arteriography	Similar to CT	1 00,000-350,000'	Riskier	No	-20% to 0[d]
Pneumoencephalography	Similar to CT	25,000-50,000'	Riskier	No	-40% to -750/0'
Radionuclide scanning	Inferior to CT	2,000,000	Similar	Yes	-90% to +15%
Skull X-ray	Used for purposes different from CT; inferior when compared	4,000,000'	Similar	Yes	Little or no effect

[a] Estimates of Office of Technology Assessment unless noted.

[b] Numbers given in this column are not strictly comparable. Arteriography is often used after diagnosis of a brain tumor, for example, to demonstrate its extent and vascularity. Arteriography and pneumoencephalog raphy are seldom used with stroke. Nonetheless, based on published studies, the comparisons are basically valid.

[c] Low figure is from reference 425. High figure is from reference 265.

[d] Reference 47 reported -20 percent and reference 82 reported + 0.05 percent.

[e] Figures are for 1973 and 1975. In 1976, CT head scanning had a great impact on the number of pneumoencephalograms performed, and estimates for 1976 are not available. Low figure is for 1975 (425). High figure is a national projection of a 1973 survey in southeastern Pennsylvania (582).

[f] Reference 47 reported -40 percent and reference 296 reported -75 percent.

[g] Reference 296 reported +15 percent and reference 383 reported -90 percent.

[h] Figure is for 1970 (504). The number of diagnostic X-rays rose approximately 4 percent a year from 1964 to 1970, so the number is probably larger now.

radioactivity. Areas with abnormal concentrations of radioactivity are presumed to be diseased. RNS is not considered to be a dangerous diagnostic procedure and is performed on outpatients. CT scanning has been shown to be superior to RNS in several studies of diagnostic accuracy of specific conditions (4,21,39,44,48,103,140, 180,293,295,380,382,388,393,439). Other investigators, however, have found that the two procedures produce anatomical information of approximately equivalent accuracy. RNS also gives information on the functioning of the brain and its blood supply (62,98,360).

Although a large study is underway (425) that attempts to determine the comparability of the two procedures, the change in the use of RNS after the introduction of CT scanning has varied substantially from one institution to another. The highest range shows a decline in the use of RNS by **50 to 90** percent **(46,50,382,545,582). At the other** extreme, the change in the use of RNS has ranged from a 15-percent increase to a 35-percent decrease (82,157,264,295). While some radiologists have stated a preference for CT scanning over RNS (48,140,141,380), others believe that, since the two procedures may yield different types of information, they should be used in a complementary fashion (62,76,360,382,412).

(4) *Echoencephalography.* This procedure applies ultrasound technology to neurological diagnosis. Ultrasound waves are directed at the head, and their reflections are detected and analyzed to find distortions in the shape of the brain. Echoencephalography is a safe and noninvasive procedure that can be performed on outpatients.

The accuracy of CT scanning and that of echoencephalography have not been compared systematically. The two procedures are not designed to yield exactly the same information. However, the Mayo Clinic, the only institution in this country to publish observed changes in the use of echoencephalography after the introduction of CT scanning, reported a decrease of 40 to 50 percent (50).

(5) *Skull Films or Skull Series,* A skull series involves a set of four or five conventional X-ray films taken according to a standardized protocol. CT scanning provides more accurate diagnostic information than a skull series for certain conditions (180,343,439). Skull films, however, are often used to detect abnormalities of the bone, such as fractures, which are difficult to image with CT. Also, skull films are accepted as a standard screening procedure for patients with general neurological symptoms. Medicolegal factors reinforce this use (61). CT scanning has had a small impact on the use of skull films because skull X-rays are usually performed prior to CT head scanning. Some radiologists have suggested that this practice is unnecessary (270).

(6) *Electroencephalography (EEG).* Electroencephalograph records the electrical activity of the brain through leads taped or pasted to the scalp. A noninvasive and safe procedure, it is widely used in diagnosing epilepsy. Because EEG provides different diagnostic information from CT scanning, its use has been little affected by CT scanning **(39,30,296).**

(7) *Exploratory Surgery.* One study examined the actual impact of CT scanning on neurosurgical procedures following head trauma. Before CT scanning, exploratory surgery often followed head injuries to ensure that life-threatening damage had not occurred and to correct such damage if found. A London hospital found a sharp reduction in the need for such surgery following introduction of CT scanning (21). In the year before introduction of the CT scanner, 33 percent of patients had such

surgery; in the year following introduction of the CT scanner, only 2 percent had such surgery. However, no attempt was made to ensure that the two groups of patients were comparable.

Therapeutic Impact

To date, only one study has attempted to assess the impact of CT head scanning on the planning of therapy. The study covered 194 patients; physicians were interviewed before and after their patients were scanned. Treatment plans were altered for 19 percent of the patients. This figure dropped to 15 percent when counting only those for whom improvement in outcome was possible (i. e., those who did not die soon). Changes included ordering new treatment, abandoning previous therapy plans and increased precision of already planned therapy, such as surgery or radiotherapy (167).

The only known study to examine the actual impact on neurosurgical procedures is summarized in the section above under exploratory surgery (21). A similar study examined groups of patients with stroke before and after introduction of CT scanning. No differences in therapy were found (313).

Patient Outcome

Better diagnosis does not necessarily lead to improved treatment and improved health. An extensive study of radionuclide scanning, for example, indicated that its application has little or no effect on patient outcome in cases of neurological abnormality **(185).** Nuclide scans are often used to diagnose diseases for which no definitive therapy is available; the same situation also applies to CT scanning, as discussed in chapter 5. In the one study of outcome, patients with head trauma who entered a hospital before installation of a CT scanner were compared with those admitted afterwards (21). No difference in mortality between the two groups was observed. However, as noted above, no attempt was made to ensure that the two groups of patients were comparable. More complete studies, or studies using less drastic indicators of health (such as morbidity or decreased worry, instead of mortality), have not yet been reported. However, simply reducing the use of dangerous diagnostic and therapeutic procedures can help improve the outcomes of patients.

Body Scanning

Technical Capability

The technical capabilities and limitations of body scanners are generally similar to those of head scanners (see below), Changes in density or shape are used to indicate abnormalities in both body and head scans, The major difference is that patient motion poses particular problems for body scanning. The normal, rhythmic motions of breathing, heartbeat, and intestinal contraction can all cause artifacts and may result in images of unacceptable technical quality (9,10). For this reason, the heart and intestine cannot be satisfactorily imaged (157). Whether new, faster machines will be able to overcome problems of motion is not yet fully known.

Diagnostic Accuracy

Reports on the diagnostic accuracy of body scanning have recently been published; their results are summarized in table 4. Evidence has been reported that CT scanning can image tumors in the liver, pancreas, kidney, pelvic, and retroperitoneal space that are invisible on conventional X-ray films (6,8,9,95,159,217,465,474,477,526). CT scanning can also differentiate obstructive from nonobstructive jaundice, a distinction that has important implications for therapy planning **(6,7,8,159),** and it can reveal abscesses **(215)** and aortic aneurysms **(38).** Although preliminary and limited in scope, these studies indicate that CT scanning can accurately diagnose mass lesions and other conditions in several organs of the abdomen. Diagnostic accuracy in other areas of the body such as the lung and heart has not been demonstrated.

Table 4.—Diagnostic Accuracy of Body Scanning: Summary of Initial Results

Area Scanned (lesions detected)	Number of Patients	Percent Accurate Diagnoses	Reference
Abdominal abscess	22	90	215
Aorta (aneurysms)	32	100	38
Bile duct (dilation, obstruction)	8	88	8
Bile duct (dilation, obstruction)	17	100	474
Extraperitoneum (mostly tumors)	13	100	474
Kidney (cyst and tumor)	18	94	474
Liver (mostly tumors)	31	94	474
Liver (mostly tumors and cirrhosis)	61	74	8
Pancreas (mostly tumors)	37	83	474
Pancreas (tumors)	25	92	216
Pancreas (tumors)	26	84	321
Pelvis (mostly tumors)	14	100	474
Spinal cord (syringomyelia)	9	78	134

Diagnostic Impact

Little information is available on the impact of CT body scanning on other diagnostic procedures. Preliminary results from a study conducted at the Massachusetts General Hospital indicate that when used in "high payoff areas" of the body, such as the liver, pancreas, and kidneys, body scanning can have considerable impact on diagnostic methods used. In 94 patients, **27** percent were spared surgery by the findings of CT scanners (533). No other studies of diagnostic impact are yet available. With the large number of organ systems that can be evaluated and the large number of alternative diagnostic tests that can be used, it will be some time before this area is understood.

Therapeutic Impact

Radiologists have suggested several ways in which information obtained from body scanning might be useful in the planning and delivery of therapy (157,

158,316,317,465,493). In patients with jaundice, for example, CT scanning may reveal whether the bile ducts are obstructed. If so, surgery may be needed; unobstructed ducts suggest a diagnosis of hepatitis, which can be treated nonsurgically. In cases of suspected tumor, CT scanning may reveal spread of the tumor, and thus differentiate patients who might benefit from surgery from those for whom it would be futile.

As mentioned above, one study found surgery was averted for 27 percent of patients. That study also found that treatment plans were changed for about 19 percent of patients scanned (533).

Patient Outcome

No analyses of available data examine the impact of body scans on improved health of patients. But simply averting dangerous therapeutic or exploratory procedures such as surgery can be expected to improve patient outcome.

SAFETY OF CT SCANNERS

The potential benefits of CT scanning must be weighed against its risks. Safety, like efficacy, can be assessed by well-designed clinical trials or by studies of clinical experience. Determinations of safety of a medical technology examine the four factors specified above for efficacy: potential risk, population at risk, medical problem, and conditions of use for minimum risk,

Like other radiological devices, CT scanners emit X-rays, a form of potentially dangerous ionizing radiation that can cause cancer, leukemia, and genetic changes. Early reports indicated that the EMI head scanner exposed a patient to about 1 to **2.5** roentgens (R), * less than other neurodiagnostic techniques using X-ray (see table 5) (189,190,338,397,564). Recent articles, however, indicate a higher radiation exposure (521). Horsley and Peters examined the question of scattered radiation from adjacent scans and found that with 3 scans, the peak exposure with the EMI head scanner is 4 to 5 roentgens (240). Newer systems used in certain areas of the body produce a higher exposure. The Bureau of Radiological Health of FDA has stated that machines in use give a patient a dose of radiation as high as 30 rads (503). A recently published article reported a dose as high as 31 rads from use of the Ohio Nuclear prototype head scanner and **16** rads from the Ohio Nuclear production model head scanner when used at slow speed **(521).** If scans were performed and then repeated after contrast injection, these figures could double. The number of sections scanned is proportional to dose and is variable depending on physician judgment. Furthermore, higher radiation makes the image clearer, and on many machines a radiologist can increase the radiation dose by a simple adjustment of a switch. For example, at normal speed the dose to the back of the head from six "scan pairs" with an Ohio Nuclear head scanner is 7.7 rads, which increases to 15 rads with scanning at slow speed (521).

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* A roentgen (R) is a quantity of radiation measured in air. A rad is the unit for absorbed dose of radiation. A rem is the quantity of ionizing radiation such that the energy imparted to a biological system has the same biological effectiveness as an absorbed dose of 1 rad of X-radiation. As the terms are used in this paragraph, the amounts are essentially equal.

Table 5.—Radiation Exposures From Use of Some Common Neurodiagnostic Procedures[a]

	No. of Roentgens
CT Head Scan (EMI) (3 slices)	1-4.5 R
Skull Series (4 films)	1.2 R
Pneumoencephalogram (8 films)	2.8 R
Cerebral Angiogram (24 films)	10.7 R

[a] Radiation exposure from CT scan derived from references 190,240,338, and 397, Other radiation exposures are based on the 1970 National X-ray Exposure Study (503). Numbers of films are for typical community hospitals, Institutions that specialize in neurodiagnosis or that see more complicated problems often do two or three times the number of films shown (135).

A specific risk cannot be attributed to these amounts of radiation because systematic information on the effect of life-long, low-dose irradiation is simply not available (373). The National Research Council estimated the risk as follows: "If such rates (taken from studies of people with known exposure to radiation) . . . are assumed to apply generally, then exposure of the U.S. population of about **200** million persons to an additional 0.1 rem during one year . . . could be expected ultimately to cause 1,350 to 3,300 deaths *annually,* provided that the effect of a given increment of dose did not persist beyond 25 years after exposure" (373). This kind of reasoning has led to rather low limits of allowable exposure to radiation (260,375). A prominent textbook sums up this way: "It is therefore prudent to adopt the working principle that radiation exposure be kept to the lowest practical amount" (42).

Reaction to contrast material is another risk. In practice, mortality from such injections ranges from 1 death in 13,000 examinations to 1 death in 50,000 examinations. This rate may be compared to a rate of approximately 1 in 1,500 cases in angiographic examinations (5).

Another risk stems from general anesthesia. Although CT scanning usually can be performed with the patient awake, some children and confused, uncooperative patients often must be sedated or anesthetized to ensure an adequate scan (3,300). Such anesthesia carries some risk (166).

FEDERAL POLICIES CONCERNING EFFICACY AND SAFETY

Developing information on efficacy and safety involves identifying technologies to be studied; conducting the appropriate evaluations; and synthesizing the results of those evaluations, clinical experience, and other relevant information. Synthesis may be of many types. Examples of synthesis include informal collection and interpretation of existing information, analyses of gaps in current information, and policy judgments based on clinical knowledge but often extrapolating from that knowledge. The judgments or other synthesized information may then be disseminated to the organizations and individuals in need of it.

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Food and Drug Administration (FDA)

Medical Devices Legislation

The Food and Drug Administration requires studies to be conducted by private industry prior to marketing certain medical devices and also synthesizes the results of such studies. The safety of medical devices first became subject to Federal regulation in 1938. However, it was not until **1976** that the Medical Device Amendments gave FDA the authority to require that manufacturers prove the safety *and* effectiveness* of medical devices prior to marketing.

The Amendments require FDA to classify all existing medical devices into one of three categories: Class I—General controls: medical devices for which general controls are sufficient to provide that the device is safe and effective or that the device is not used in the support or sustaining of human life, or for a use that is of substantial importance in preventing impairment of human health and does not present a potential unreasonable risk of illness or injury; Class II—Performance standards: devices for which Class I controls are not adequate and for which sufficient information exists to set performance standards that will ensure safety and effectiveness; and Class III—Premarket approval: devices for which Class I and Class II controls are not adequate to ensure that the device is safe and effective, and which are used in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health, and which present potential unreasonable risk of illness or injury. New devices, or devices introduced into use after May **28, 1976,** that are not of the same type and are not substantially equivalent to those on the market on May **28, 1976,** will automatically be placed in premarket approval category (Class III) and cannot be commercially marketed until either an application is approved or the device is reclassified into performance standards (Class II) or general controls (Class 1) categories.

According to the law, the safety and effectiveness of Class III devices are to be determined:

(a) with respect to the persons for whose use the device is represented or intended,

(b) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(c) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

The law continues

> the effectiveness of a device is to be determined, in accordance with regulations promulgated by the Secretary (of HEW), on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

The Bureau of Medical Devices has begun implementing the Amendments by

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* The language of the Act uses the term "effectiveness" instead of "efficacy."

appointing advisory panels to make recommendations as to which class each device belongs. The Neurology Panel and the Radiology Panel have recommended classifying existing CT scanners as Class II, but in September 1977, classification was not completed. Such a classification means that the CT scanner will be subject to performance standards of a technical nature, a point further discussed below. (Such panels are made up largely of the professionals who use the device in question, in this case radiologists, and who may have some vested interest.) New CT scanners that FDA determines to be similar to existing ones will be placed in the same class (i. e., Class 11). Any development that represents a radical departure in nature or operation from existing models could be placed in Class 111 requiring premarket approval.

Radiation Protection

The Food and Drug Administration also has statutory responsibility for protecting the public from radiation exposure from electronic devices such as X-ray machines. Its Bureau of Radiological Health develops and enforces standards to ensure minimal radiation exposure from X-ray devices. CT scanners have been subject to general radiation safety standards since the first one was installed. In 1974, specific guidelines were developed for their regulation.

Because the Bureau of Radiological Health has had experience with the CT scanner already, it will have the responsibility for developing performance standards for both safety and efficacy. * The Bureau of Radiological Health and the Bureau of Medical Devices have developed an inter-Bureau agreement to ensure cooperation in this effort. The Bureau of Radiological Health established a CT task force in 1970 that is presently considering the necessity for performance standards concerning efficacy.

The National Institutes of Health (NIH)

NIH supports basic and applied research and technology development. Initial human trials and then larger clinical trials are often stages in the research and development process. A little more than 5 percent of the NIH budget is allocated to clinical trials. The results of these investigations sometimes provide information about the safety and efficacy of technologies. However, NIH has no statutory mandate to conduct studies related to efficacy and safety.

NIH is using CT scanning in its intramural program and supporting extramural research studies involving its use. Extramurally, about 100 NIH-funded projects involve CT scanning, with the largest single group in cancer research. Several of these studies will provide more definitive information than is now available on the diagnostic accuracy of CT scanning. These studies are not, however, designed to examine efficacy in terms of its effect on therapy decisions or on the health of patients.

NIH has established a mechanism to develop and disseminate information on efficacy and has titled this mechanism “evolution of a consensus. ” During 1976, NIH applied this new process using outside experts to the problem of hypertension and its treatment. In September 1977, the second consensus process considered screening

* The legislation uses the term “effectiveness,” but the Bureau of Medical Devices considers efficacy and effectiveness to be synonymous,

for breast cancer. This mechanism may be a way of developing recommendations on efficacy for the use of other Federal programs, the public, and medical practitioners.

SHORTCOMINGS OF EFFICACY AND SAFETY POLICIES

Shortcomings in Federal policies related to efficacy and safety information occur in several areas: definition of efficacy, determination of efficacy and safety, dissemination of information, and use of the information. Use of information on efficacy and safety will be addressed in subsequent chapters.

A definition of efficacy and a discussion of some of the difficulties in applying any definition to diagnostic technologies were presented earlier in this chapter. Only FDA has been given a statutory definition of efficacy. In the FDA statutes, however, the term "effectiveness" is used rather than efficacy. According to the Food, Drug, and Cosmetic Act a medical device or drug is to be considered effective if it "will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling." This effect is largely determined by the manufacturer and is not necessarily a demonstrable impact on health outcome. This statutory language results in the FDA's evaluating the efficacy of diagnostic technologies on grounds other than patient outcome. Whether patient outcome should be the standard of efficacy for diagnostic technologies is controversial. However, the lack of any generally accepted measure of "benefit" for such technologies can lead to difficulties in assessing their efficacy,

Not only is FDA the only agency that has a statutory definition, no common definition has been developed for use by all Federal programs. Some Federal agencies develop information on efficacy and safety, others disseminate the information, and still others use it to regulate various aspects of medical practice. Personnel in these programs use the term "efficacy" in various ways, to mean different things. Lack of a policy on the definition of efficacy can lead to confusion and difficulty in cooperation and communication. Judgments by one agency of the efficacy of a technology may be of little use to other agencies because different criteria are used to determine efficacy by the various agencies.

No Federal policy sets out clear responsibilities for evaluating the efficacy and safety of all classes of medical technologies—drugs, devices, and procedures. Evaluating efficacy and safety involves identifying the technologies to be studied, conducting the appropriate clinical trials, and synthesizing the results of those trials with information from clinical experience. Such synthesis can include a formal or official judgment of the efficacy and safety of a particular technology. Information on efficacy is seldom collected, organized, and made available in such a way that it can be helpful either to policy makers or medical practitioners. Presently, evaluations of efficacy for devices and drugs are performed almost exclusively by the industry that produces them, although FDA examines the design and the results of these studies for validity.

No formal mechanism exists for determining which technologies warrant eval-

uation. In particular, when the private sector has not conducted adequate studies on efficacy, no mechanism exists to identify the inadequacies and to ensure that proper studies are funded. Thus, pre-clinical and clinical studies and clinical experience are not always evaluated, and no policy exists for developing tentative positions pending availability of definitive information. Further, lack of a formal system to identify technologies to be studied often results in the needs of users of efficacy and safety information being excluded from the decision to study.

There is no formal policy, nor has any Federal agency been assigned a clear mandate, for the conduct of evaluations of efficacy and safety. More than a dozen Federal agencies conduct clinical trials, but none of the agencies do so as a result of an explicit statutory mandate. Only NIH and to a lesser extent the Veterans Administration support a substantial number of trials. In fiscal year 1975, NIH spent about $100 million dollars on approximately 750 trials. This expenditure represented about 5 percent of NIH's budget. Trials of drugs and biologics predominated; trials of devices and procedures represented only a small proportion of the total. Existing technologies received far less attention than did new or emerging ones. No clear Federal policies for identification of technologies warranting study and for conducting the appropriate evaluations exist. And no agency has been assigned the responsibility for carrying out these functions. It is also clear that the clinical trials currently conducted are not fully satisfying the needs of health planners, third-party payers, Professional Standards Review Organizations, and the practicing medical community.

Determining which technologies to study is only one contributor to the situation. Current trials often do not develop information related to each of the four factors specified by the definitions given above for efficacy and safety. Questions have also been raised about the efficacy and safety of many more technologies than can be studied with the available resources. And once the trials have been conducted, no formal mechanism exists to collect and synthesize the results of the trials, along with relevant clinical information. No agency has the responsibility (or resources) to make formal judgments of the efficacy and safety of technologies, except FDA in the case of new drugs and devices. * Medical and surgical procedures receive no systematic scrutiny.

Once information is developed, no consistent policy or agency focus exists for disseminating it to the organizations and individuals in need of it. NIH and FDA both have major activities related to dissemination, but their efforts are hampered by a number of factors. For example, FDA disseminates information related to its evaluations of the efficacy and safety of drugs and devices, but the usefulness of that data is diminished by definition-related problems. Also, NIH has been given only moderate funding for the task, and historically lacks ties to the practicing medical community and to other Federal programs, such as Medicare.

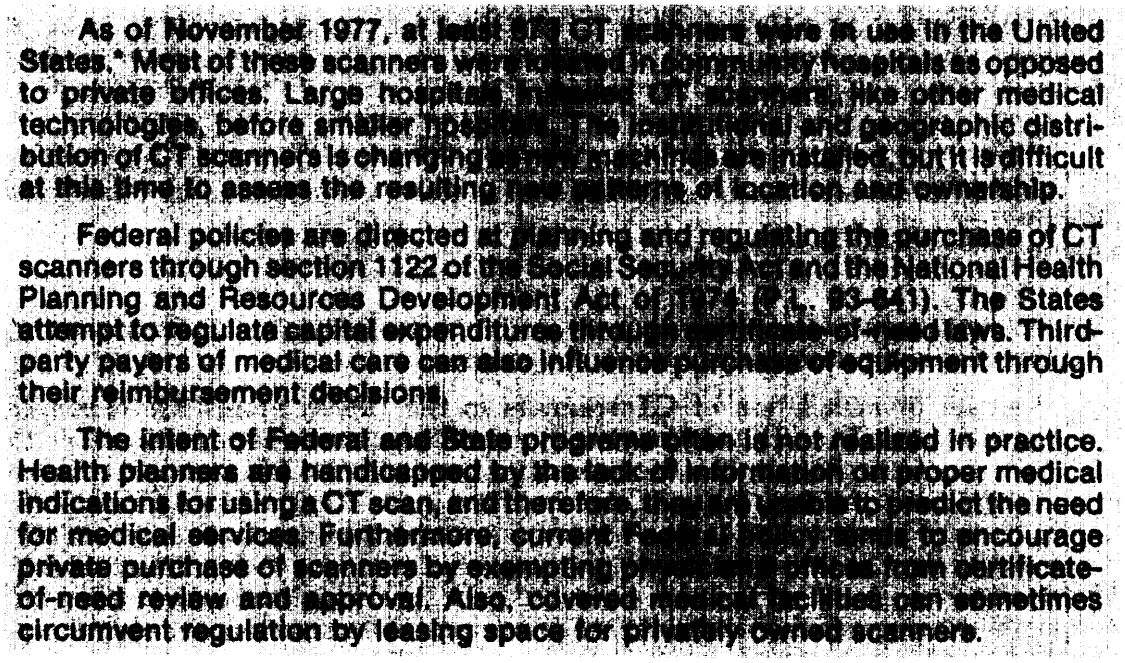
There are shortcomings in Federal policy at each of the stages in defining and evaluating efficacy and safety and in disseminating the resultant information. Moreover, the underlying problem is the absence of a consistent and explicit policy that views these stages as part of a continuous process. Evaluation depends on definition; dissemination depends on evaluation. Failure to recognize these dependencies can lead to fragmented policies relating to each of the parts.

*The FDA process is impacted by the definitional shortcomings mentioned here and from lack of funds to carry out efficacy and safety tests independent of the sponsoring industries.

4.

NUMBER AND DISTRIBUTION

NUMBER AND DISTRIBUTION



EXPERIENCE WITH CT SCANNING

Number of CT Scanners

As of May 1977, 401 machines were known to be in use in the United States.** Nearly three-fifths were head scanners; the rest were full-body scanners. However, body scanners account for most new purchases **(29).** By **1978,** more than half of the operational scanners were body scanners.

EMI, Pfizer, and Ohio Nuclear manufactured 95 percent of the machines used in the United States in May 1977 (table 6). The first CT scanners, and most of the scanners used then, were sold by EMI. At that time, six companies were producing machines for sale in the United States, and at least six more were developing

*A survey by J. Lloyd Johnson Associates reported **560** operational **scanners** by April 1977, and **637** by June 1977 **(263).** Fineberg, **et al. reported 567 operational scanners** by April 1977 (168).

**institutions with CT scanners are listed in appendix I.

Table 6.—Type and Manufacturer of CT Scanners in Use May 1977[a]

Manufacturer	Type of CT Scanner					
	Total		Head		Body	
	No.	Percent	No.	Percent	No.	Percent
EM I Ltd.	232	58	211	92	21	12
Ohio Nuclear (Delta)	109	27	0	0	109	64
Pfizer (Acta)	40	10	—	—	40	23
General Electric	8	2	7	3	1	1
Syntex	9	2	9	4	0	0
Artronix	3	1	3	1	0	0
Total	401	100	230	100	171	100

[a]Since May 1977, informal reports indicate that American Science and Engineering has installed several machines.

Source: Off ice of Technology Assessment.

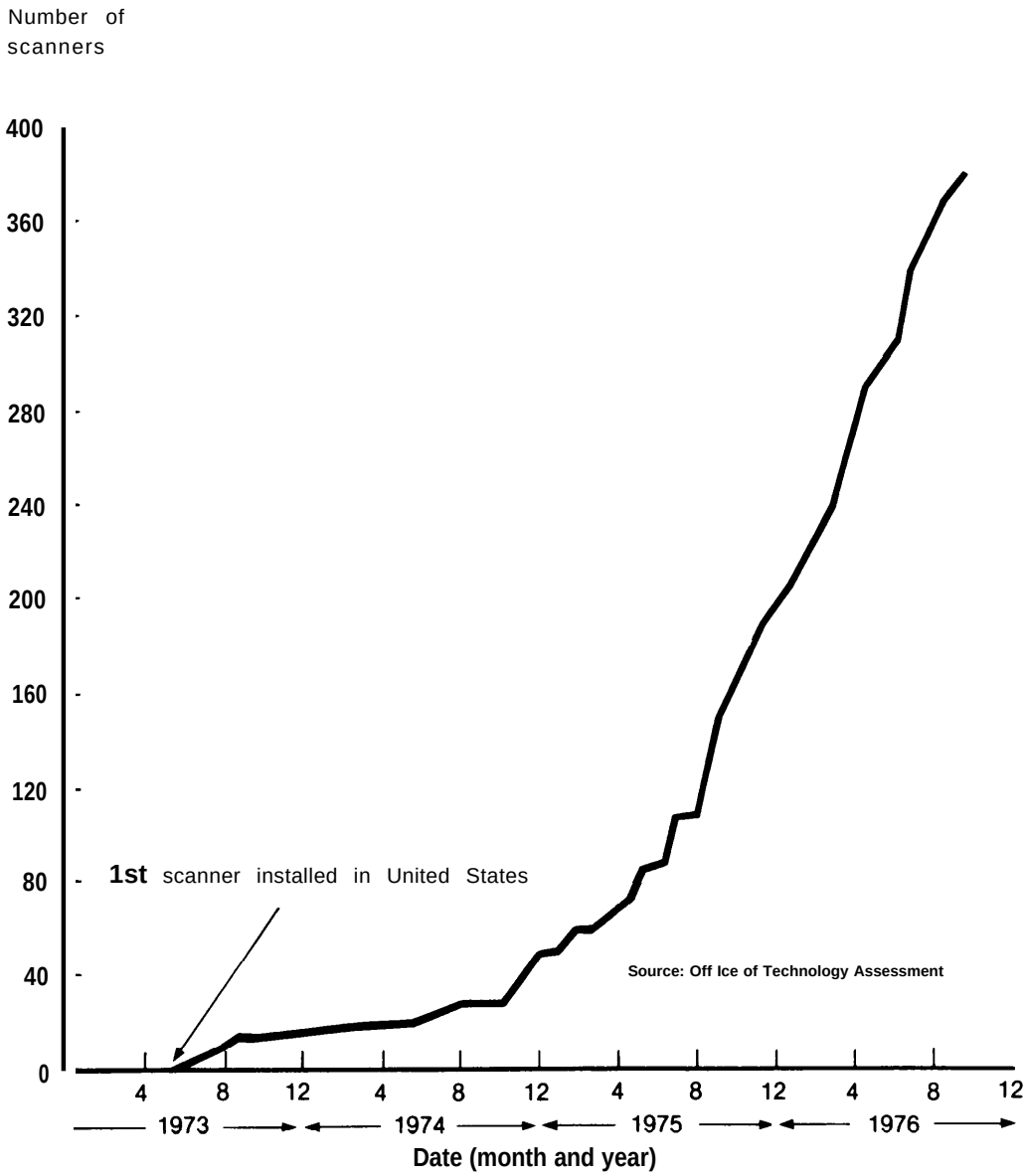
scanners for future sales or were about to enter the market (147,377). By May 1978, 11 companies had commerial machines in operation.

The rate of installation of CT scanners in the United States has increased steadily over time. The diffusion curve in figure 10 falls into three periods, each with a higher rate of installation than the preceding one (table 7). The first period began in June 1973, with the installation of the first head scanner at the Mayo Clinic. From that date until October 1974, the rate of installation was less than 5 per month. Between October 1974 and June 1975, the rate increased to just below 10 per month. The third and most recent period for which the data are complete began in July 1975 and extended through September **1976; an average** of 19 scanners per month was installed during that period. Incomplete data for 1977 show an even more rapid installation rate for that period.

The most recent rate might have been higher if manufacturers had been able to produce more machines. For example, in 1975, twice as many scanners were ordered as were shipped (402). EMI's **1976** year-end backlog of unfilled orders exceeded **250** machines (362). In response to the demand throughout 1976, EMI and Ohio Nuclear prepared to increase their 1977 production schedules of CT scanners (29). EMI is also increasing its production capacity.

The rate of installation will probably continue at more than 19 per month in the immediate future. Nationally, 330 scanners were either ordered from manufacturers or approved by planning agencies, and 200 applications for scanners were awaiting approval by State agencies as of August **1976 (266).** Longer term rates of orders and installations are not yet clear. The number of new orders in the first half of 1977 fell from the high of **1976. One estimate predicted 200** new orders in 1977 compared to more than **400** in **1976 (263).** In fact, orders during **1975 and 1976** may have been abnormally high in anticipation of State and Federal regulations on purchases. Experience during 1977 may represent a temporary adjustment to a more stable growth rate for sales.

Figure 10.—Cumulative Number of CT Scanners in the United States by Date of installation



Geographic Distribution of CT Scanners

The distribution of CT scanners by State and region of the country as of August 1976 is shown in table **8.** At that time, 44 States and the District of Columbia each had at least one scanner. Vermont, Delaware, Montana, Wyoming, and Alaska, which are 5 of the smallest States by population, as well as West Virginia, had no scanner. California had 60 scanners, the largest number of any State. The Los Angeles area alone had 29 scanners. Florida had the second highest number of machines, **27,** followed by Texas with 19, and Ohio with **16.**

Table 7.—Coordinates of Diffusion Curve

Date of Installation (Month and Year)	Number of CT Scanners (Cumulative)
1973	
6 June	1
8 August	2
9 September	5
10 October	6
1974	
1 January	9
2 February	12
4 April	13
5 May	15
6 June	18
7July	21
8August	23
9 September	26
IO October	31
11 November	39
12 December	45
1975	
1 January	47
2 February	55
3March	60
4April	67
5May	83
6June	92
7July	109
8August	123
9 September	142
IO October	167
11 November	183
12 December	196
1976	
1 January	216
2 February	236
3March	258
4April	285
5May	304
6June	327
7July	343
8August	363
9 September	379

Source: Office of Technology Assessment.

Table 8.—Distribution of CT Scanners by State, Region, and Population[a]

Region or State	Number of CT Scanners		CT Scanners per Million Population[b]	
	Installed	Installed plus Committed[c]	Installed	Installed plus Committed[c]
New England	17	24	1.4	2.0
Maine	1	3	1.0	2.8
New Hampshire	1	1	1.2	1.2
Vermont	0	1	0	2.1
Massachusetts	11	12	1.9	2.1
Rhode Island	1	1	1.1	1.1
Connecticut	3	6	1.0	1.9
Middle Atlantic	35	79	.9	2.1
New York	17	41	.9	2.3
New Jersey	2	12	.3	1.6
Pennsylvania	16	26	1.4	2.2
East North Central	50	134	1.2	3.3
Ohio	16	36	1.5	3.4
Indiana	4	15	.8	2.8
Illinois	15	49	1.3	4.4
Michigan	7	17	.8	1.9
Wisconsin	8	17	1.7	3.7
West North Central	30	48	1.8	2.9
Minnesota	9	10	2.3	2.5
Iowa	1	7	.4	2.4
Missouri	13	17	2.7	3.6
North Dakota	1	2	1.6	3.1
South Dakota	1	2	1.5	2.9
Nebraska	1	5	.6	3.2
Kansas	4	5	1.7	2.2
South Atlantic	49	99	1.4	3.0
Delaware	0	2	0	3.4
Maryland[d]	3	4	.7	1.0
District of Columbia	2	10	2.9	14.2
Virginia	5	14	1.0	2.8
West Virginia	0	5	0	2.7
North Carolina	4	4	.7	1.0
South Carolina	2	5	.7	1.8
Georgia	6	17	1.2	3.4
Florida	27	38	3.2	4.5
East South Central	18	36	1.3	2.6
Kentucky	3	5	.9	1.5
Tennessee	7	17	1.7	4.0
Alabama	6	11	1.6	3.0
Mississippi	2	3	.9	1.3

Table 8.—Cent.

Region or State	Number of CT Scanners		CT Scanners per Million Population	
	Installed	Installed plus Committed	Installed	Installed plus Committed
West South Central	30	59	1.4	2.8
Arkansas	3	5	1.4	2.4
Louisiana	5	11	1.3	2.9
Oklahoma	3	7	1.1	2.5
Texas	19	36	1.5	2.9
Mountain	19	39	1.9	4.0
Montana	0	2	0	2.7
Idaho	3	4	3.6	4.8
Wyoming	0	0	0	0
Colorado	4	12	1.6	4.6
New Mexico	2	2	1.7	1.7
Arizona	5	8	2.2	3.5
Utah	3	4	2.4	3.3
Nevada	2	7	3.3	11.5
Pacific	69	134	2.4	4.7
Washington	5	6	1.4	1.7
Oregon	3	6	1.3	2.6
California	60	119	2.8	5.5
Alaska	0	(e)	0	(e)
Hawaii	1	3	1.1	3.4
Total	321	652	1.5	3.0

[a] Statistics are current as of August 1976, andare fairly complete through May 1976. But therewere873 CT **scanners knownto be installed by November 1977.**
[b] **Population data were provisional asof July 1, 1976.**
[c] **Committed refers to CT scanners already ordered and approved by** local Health Systems Agencies.
[d] Four CT scanners at the National institutes of Health are excluded from Maryland, but included in Total.
[e] Not available.
Sources: 495; Office of Technology Assessment.

Throughout 1976, the national average was about 1.5* CT scanners per million population. States with the highest ratios of scanners per million population included Idaho (3.6), Nevada (3.3), Florida (3.2), the District of Columbia (2.9), California(2.8) and Missouri (2.7).

By November 1977, at least 873 scanners were operational, and every State had at least one. The national ratio was approximately 4 scanners per million population. The District of Columbia had the highest ratio of scanners to population (16.8), and States with high scanner to population ratios included Nevada (13,5), Florida (9.6), Alaska (8.5), California (8.4), and North Dakota (7.9). States with the lowest

*Only crude ratios are shown.

concentration of scanners included South Carolina (2.1), Rhode Island (2.2), New Hampshire (2.4), New Jersey (2.5), and Massachusetts (2.6). *

By the end of 1977, the CT scanner manufacturers reported 921 operational scanners, 85 percent of which were in hospitals.**

Institutional Distribution of CT Scanners

Table 9 shows that 76 scanners, or 19 percent of the 401 machines identified in May 1977, were owned by physicians in private offices and clinics. At least 33 scanners, or 43 percent of those 76 were in radiological offices.

Hospitals accounted for **325** scanners, or 81 percent, of the machines identified. The overwhelming majority of these institutions are nonprofit community hospitals

Table 9.—Distribution of CT Scanners by Type of Facility [a]

Type of Facility	Percent of All Facilities	Number of Facilities with CT Scanners	Percent with CT Scanners	Number of CT Scanners
Community Hospitals (by number of beds)	**100**	**302**	**5.1**	**323**
0-99	50	**6**	0.2	**6**
100-199	23	**10**	0.7	**10**
200-299	12	**43**	6.5	**43**
300-399	6	**53**	14.0	**53**
400-499	4	**58**	25.2	**60**
500-599	5'	**43**	44.0'	**48**
600-699		**30**		**32**
700-799		**13**		**13**
800-899		**14**		**16**
900-999		**10**		**12**
1,000-1,099		**7**		**8**
1,100-1,199		**6**		**7**
1,200-1,299		1		**4**
1,300 and over		**5**		**5**
Other Short-term Hospitals	100	**3'**	0.5	**6**
All Hospitals (total)	**100**	305	**4.7**	**323**
Offices		76		**78**
Total		381		**401**

[a] **Includes scanners known to reinstalled by May 1977.**
[b] **Percentages** apply to **all hospitals with** 500 beds **and over. Hospitals with** 1,000 **beds and over** account for 0.5 **percent of all beds, and68 percent of these hospitals havea CT scanner,**
[c] **Includes three Federal hospitals: Veterans Administration, Boston, Mass., 291 beds, 1 scanner; Veterans** Administration, Indianapolis, Ind., **725 beds, 1 scanner; and National Institutes of Health,** Clinical **Center, Bethesda, Md , 511 beds, 4 scanners.**

Sources: 30,32, 33. Office of Technology Assessment.

*** Data** from the Center for the Analysis of Health practices, Harvard School of Public Health.
** Information furnished by the National Electrical Manufacturers Association.

with general medical and surgical services. Six Federal hospitals and 50 non-Federal governmental hospitals were identified as owning CT scanners. Table 9 also compares the size of hospitals with scanners to the size of all community hospitals. Forty-four percent of all community hospitals with 500 beds or more had a CT scanner; 5 percent of all community hospitals are in this bed size category.

The diffusion of CT scanners by size of hospital has followed a pattern similar to the diffusion of other expensive technologies. For example, the largest hospitals were also the first to adopt cobalt therapy, electroencephalographs, and intensive care facilities **(448).** While small hospitals might eventually obtain an expensive medical technology, frequently they are not able to meet operating expenses due to a low patient load. The same reason may explain why smaller hospitals have not purchased scanners at the same rate as larger hospitals.

Like other large hospitals, those affiliated with medical schools have been among the first to acquire equipment requiring large initial expenditures, as borne out with CT scanners. Eighty-nine of the Nation's 113 accredited medical schools, or 79 percent, had a major affiliation with a hospital that had a scanner by May 1977 (24). This high percentage is consistent with a suggestion from the Department of Health, Education, and Welfare (HEW) that Health Systems Agencies give priority to placement of scanners in medical school teaching centers and hospitals with large neurological and neurosurgical caseloads **(500). ***

The greater the number of physicians in an area, the greater seems to be the purchase by hospitals of technologies with high fixed costs **(123).** However, a test of this hypothesis showed little correlation between physician to population ratios and CT scanners to population ratios.**

Little can be inferred from the data about the pattern of ownership of scanners. The scanners known to be in private offices and clinics are owned privately or by the facilities. Of the scanners located in hospitals, less is known about ownership. One report indicated that at least **61,** or 10 percent, of the **637** CT scanners identified in June 1977, were owned or leased by physicians (usually radiologists), but located in hospitals **(263).**

GOVERNMENTAL AND NONGOVERNMENTAL POLICIES

An objective of the Congress in enacting health planning legislation was to achieve equal access to quality medical care at a reasonable cost (505). Under the provisions of the National Health Planning and Resources Development Act of 1974 and other health laws, this objective applies to CT scanners. In addition, some policies adopted by the private sector complement those of the public sector.

Section 1122 of the Social Security Act

In **1972,** P.L. 92-603, section 221, added section 1122 to the Social Security Act. This section introduced an important concept that has influenced subsequent health

● HEW's reason for issuing this advice has not been made explicit.

Kendall's coefficient of τ = **.04. Possible values of τ are -1 (inverse relationship), O (no relationship), and +1 (identity). It would be useful to retest the hypothesis with a different statistical technique; a different geographical division, for example, by Standard Metropolitan Statistical Area; and ratios of medical specialists to population in lieu of all physicians.

legislation: that financing of medical care should be closely related to health planning.

Section 1122 provides that "health care facilities" may not be reimbursed for any depreciation, interest or return on equity relating to capital expenditures that the Secretary of HEW finds to be inconsistent with a State health plan. Those funds available from Medicare, Medicaid, and Maternal and Child Health Programs (titles XVIII, XIX, and V, respectively, of the Social Security Act) may be withheld under the provisions of section **1122. By statute, capital** expenditures that exceed $100,000 are subject to review. Currently, 37 States have contracts with HEW to conduct reviews of capital expenditures under section 1122 (table 10). Section 1122 also covers increases and decreases in numbers of beds, services offered in medical care facilities, the introduction of new services, and the cessation of existing ones that involve capital expenditures.

Federal regulations implementing section 1122 were amended in January 1977 to define medical care facilities subject to review as hospitals; psychiatric hospitals; tuberculosis hospitals; skilled nursing facilities; kidney disease treatment centers, including free-standing hemodialysis units; intermediate care facilities; and ambulatory surgical facilities. Health maintenance organizations are also included, but offices of private physicians are explicitly exempted **(234).**

Since operating expenses and physician services are not subject to regulation, only a small percentage of a provider's total income is at risk under section 1122. (For CT scanners, operating expenses account for **50 to 75** percent of the machine's technical expenses.) Even without strong penalties, compliance with the law is widespread. One explanation suggests that compliance is due to the threat of stiffer sanctions and to the tradition, among medical care providers, of voluntarily abiding by public regulation **(323).** A more critical interpretation cites the high rate of approvals of capital expenditures under section 1122 as evidence that it rarely threatens providers' investment plans **(85).**

State Certificate-of-Need Laws

Expenditures for the construction and expansion of medical facilities are also regulated through State certificate-of-need laws, In the 35 States that have enacted such laws since 1965, new construction and equipment purchases, additions to existing physical plant, expansion of the number of beds, or changes in services may occur only with prior State review and approval.

The type of facilities covered by certificate-of-need laws varies from State to State. Most States cover hospitals and nursing care facilities. Less than half cover outpatient facilities not associated with hospitals, such as surgical centers and health maintenance organizations. Like section 1122, most certificate-of-need laws exempt private physicians' offices from review. However, coverage of medical care facilities under section 1122 is usually more comprehensive than it is under current certificate-of-need laws.

Providers of medical services are subject to stringent sanctions if they do not comply with certificate-of-need rulings. The designated agencies can deny operating licenses, obtain court injunctions, and levy fines. State certificate-of-need laws differ in the minimum expenditure on physical plant or equipment that is subject to review. Furthermore, some States require a review whenever any facility, equipment, or service change is proposed, regardless of capital expenditures.

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Table 10.—States With Certificate-of-Need Legislation, Section 1122 Agreements, or CT Planning Criteria[a]

State	Certificate-of-Need Legislation	Section 1122 Agreement	CT Planning Criteria[b]
Alabama	Yes	Yes	Statewide
Alaska	No	Yes	No
Arizona	Yes	No	Statewide
Arkansas	Yes	Yes	Statewide
California	Yes	No	Statewide
Colorado	Yes	Yes	Statewide
Connecticut	Yes	No	Statewide
Delaware	No	Yes	No
District of Columbia	No	No	No
Florida	Yes	Yes	Regional only
Georgia	Yes	Yes	No
Hawaii	Yes	No	No
Idaho	No	Yes	Statewide
Illinois	Yes	No	Statewide
Indiana	No	Yes	Statewide
Iowa	Yes	Yes	Statewide
Kansas	Yes	No	No
Kentucky	Yes	Yes	Statewide
Louisiana	No	Yes	No
Maine	No	Yes	Statewide
Maryland	Yes	Yes	Statewide
Massachusetts	Yes	No	Statewide
Michigan	Yes	Yes	Statewide
Minnesota	Yes	Yes	Regional only
Mississippi	No	Yes	No
Missouri	No	No	Statewide
Montana	Yes	Yes	No
Nebraska	No	Yes	Statewide
Nevada	Yes	Yes	No
New Hampshire	No	Yes	No
New Jersey	Yes	Yes	Statewide
New Mexico	No	Yes	No
New York	Yes	Yes	Statewide
North Carolina	No	Yes	No
North Dakota	Yes	Yes	Statewide
Ohio	Yes	Yes	Statewide
Oklahoma	Yes	Yes	Regional only
Oregon	Yes	Yes	Regional only
Pennsylvania	No	Yes	Regional only
Rhode Island	Yes	No	Statewide

Table 10.—Cont.

State	Certificate-of-Need Legislation	Section 1122 Agreement	CT Planning Criteria
South Carolina	Yes	Yes	No
South Dakota	Yes	No	No
Tennessee	Yes	No	Statewide
Texas	Yes	No	Statewide
Utah	No	Yes	Statewide
Vermont	No	Yes	No
Virginia	Yes[c]	No	No
Washington	Yes	Yes	Statewide
West Virginia	Yes	Yes	No
Wisconsin	Yes[c]	Yes	Statewide
Wyoming	Yes	Yes	Statewide

[a] Data concerning certificate-of-need laws and section 1122 agreements are current as of July 1977. Data concerning CT planning criteria are current as of August 1976.
[b] Includes formal guidelines, regulations, and staff papers used in reviewing applications.
[c] Review and approval authority may extend to physicians' offices.

All certificate-of-need laws review the impact of a proposed change in existing facilities, equipment, or services on the basis of the population's need for medical services. Therefore, the critical component in the review process is how to determine need for the medical services and how to relate it to the number and distribution of facilities and equipment. The certificate-of-need form of regulation will continue to be associated with health planning since it figures prominently in the National Health Planning and Resources Development Act, P.L. **93-641.**

The National Health Planning and Resources Development Act of 1974, P.L. 93-641

P.L. 93-641 revised existing health programs and added new ones in order to unify the Federal Government's role in health planning, program development, regulation, and financing (505). The provisions of the Act which have particular relevance to CT scanners are those that authorize development of the National Guidelines for Health Planning and those that establish Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs). The National Guidelines are intended to clarify and coordinate national health policy, thereby assisting in area plan development. The responsibility for areawide planning and development is given to the HSAs. Statewide planning and administration of regulatory programs are the responsibility of. the SHPDAs. The major programs administered by the State agencies include certificate-of-need and reviews of existing institutional health services and facilities. Reviews under section 1122 of the Social Security Act are also conducted by SHPDAs.

The certificate-of-need provisions of P.L. **93-641** are to be implemented according to uniform minimum requirements and standards. The kinds of facilities to be covered have been specified and correspond to those covered under section 1122 of the Social Security Act. Minimum capital expenditures subject to review have been set at $150,000. Criteria for review of proposed services have also been specified

according to section 1532(c). HSAs and SHPDAs are required to consider at least the following criteria:

(1) The relationship of the health services being reviewed to the applicable HSP and AIP. *

(2) The relationship of services reviewed to the long-range development plan (if any) of the person providing or proposing such services.

(3) The need that the population served or to be served by such services has for such services.

(4) The availability of alternatives, less costly, or more effective methods of providing such services.

(5) The relationship of services reviewed to the existing health care system of the area in which such services are provided or proposed to be provided.

(6) In the case of health services proposed to be provided, the availability of resources . . . for the provision of such services and the availability of alternative uses of such resources for the provision of other health services.

(7) The special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas. . . .

(8) The special needs and circumstances of health maintenance organizations for which assistance may be provided under title XIII.

(9) In the case of a construction project—
(A) the costs and methods of the proposed construction, and
(B) the probable impact of the construction project reviewed on the costs of providing health services by the person proposing such construction project.

Because of their prices, CT scanners purchased or leased by covered facilities are subject to review by an HSA and approval by an SHPDA. These agencies will be assisted in their reviews of scanners by the National Guidelines. Seen as a short-term way to moderate escalating medical care costs, the National Guidelines set limits on supplies of CT scanners and eight other facilities and services. Health systems plans and, in turn, State health plans and medical facilities plans are to be consistent with the National Guidelines by March 28, 1979. The standards of the National Guidelines will be reflected in the States' criteria for review of certificate-of-need applications since certificate-of-need criteria are also required to be consistent with health systems plans.

Lastly, the SHPDAs are required to review existing medical services and make public findings of their appropriateness. Unlike the other two programs, no mechanism has been provided to translate these findings into recommendations for action. Nonetheless, inclusion of the reviews in the law may presage more comprehensive regulation.

*HSP refers to health systems plan and AIP refers to annual implementation plan.

Non-Governmental Policy

Increasingly, third-party payers link their reimbursement policies to the planning policies of the Federal and State governments. In 1976, 16 of 46 Blue Shield Plans limited payment for CT scans to institutions whose scanners had been approved by a planning agency. Eighteen had no such policy, and 12 had the matter under study (374). Similarly, most Blue Cross Plans link reimbursement to approval by planning agencies. Forty-two of 59 plans reporting in 1976, or 71 percent, had conformance clauses in their contracts or operated in States with certificate-of-need laws. These clauses made reimbursement for services contingent upon approval of equipment by planning agencies. * Unlike Blue Cross and Blue Shield, commercial insurance companies have shown little interest in coordinating reimbursement practices with the planning policies of the Government. There are indications that this pattern is changing. In response to a request from a commercial insurance company, the Connecticut Insurance Department in August 1976, authorized a rider denying payment for procedures performed in facilities or on equipment not approved by a designated State agency. The rider further provided that when State approval is not required, CT scanning will be reimbursed only if performed in a hospital (233).

FEDERAL POLICIES IN PRACTICE

Federal law ties planning for medical care services to the population's health "needs. " In the absence of readily available, valid, or reliable measures of the need for CT scanning, State and local planners have adopted substitute indicators of need. For a variety of reasons, to be explained in the concluding section, it cannot be shown that planning in practice has guided the diffusion of CT scanners in a manner consistent with the intent of the law.

Often, planners have used a fixed ratio of scanners per population to indicate the number of scanners needed, and therefore approved for installation within an area. This ideal or "target" ratio is derived in several ways (250). Three commonly used approaches are: (1) to specify by a "rule of thumb" the population served; (2) to specify the population by the incidence and prevalence of specific diseases; and (3) to determine the number of scanners needed by the number of diagnostic procedures that could be replaced by CT scanning.

In the first approach, much discretion is used to choose an optimal ratio of scanners to population. As a result, planning targets vary among planning areas, Indiana allowed one scanner in each service area with more than 100,000 population (554), while Alabama suggested that a service area should have at least 500,000 population (544). Massachusetts' (564) and New Jersey's (572, 573) guidelines stated that each health service area should have one scanner, while in Ohio, (581) the guidelines suggested one for every major medical center.

Instead of directly specifying the number of machines required, the second and third approaches estimate the number of scans required by the population and then

*Conformance clauses notwithstanding, some Blue Cross plans are contractually obliged to reimburse hospitals for CT scanning services rendered in private offices (70).

translate this number into a specific number of machines. Arriving at a number of scanners in this way depends on how the operating capacity of the machine is computed. The variables which determine the operating capacity of a CT scanner together with actual data from operating machines are presented in appendix II.

The second approach calculates the incidence and prevalence of diseases for which CT scanning is used and estimates the number of scans needed. Kentucky, for example, used data on risks, prevalence, and incidence of cancer and certain neurological diseases. The State estimated that **46,000** persons per year needed CT scans (558). However, identifying diseases suitable for CT scanning assumes knowledge of appropriate medical indications for use. As seen, information about the efficacy of scanning is still being accumulated.

Estimates of the replacement of other diagnostic procedures by CT scanning are being derived from both clinical and experimental data as discussed in the previous chapter. Some of these data have been incorporated into planning criteria by various States. For example, the South Central Pennsylvania Health Planning Council **(583)** used the formula (.90A + .20B + .75C) K = the number of CT scans needed; where A, B, and C are the number of brain scans, cerebral arteriograms, and pneumoencephalograms (respectively) that are performed yearly. * However, applying rates of use of alternative procedures as a guideline for CT scanning incorporates utilization patterns which were also developed without first evaluating their efficacy.

While an average of the results that different calculations yield might appear to reconcile different assumptions, it often does not in practice. A staff paper from the Massachusetts Department of Public Health (564) applied formulas from 11 different sources and found estimates of "need" ranging from 5 to **52** scanners for the State. The range is so wide that an average of the estimates is not representative of any set of assumptions.

Ideally, once the number of scanners needed by a population has been estimated, that number becomes the upper limit in approving purchases of additional scanners. The issue of the distribution of scanners is important in this phase of the planning process. Because of the large number of proposed purchases by mid-1975, many States and localities developed criteria for the placement of machines (table 11).

Many of these criteria reflect current medical practices. There is a preference for placing CT scanners in medical centers, usually university-affiliated ones with an active radiological-neurological service. Presumably, the motivation is to place scanners close to the more seriously ill patients and to large population centers, thereby maximizing potential use. However, concern for sharing services and proximity to ambulatory patients is also evident.

Most agencies do not specify the relative importance of various criteria. Among agencies that do assign priorities to certain criteria over others, there is little agreement among rankings. Available information has been widely circulated. Guidelines developed by the Comprehensive Health Planning Council of Philadelphia published early in 1974 **(582),** for example, have had a noticeable influence on guidelines of other States (appendix 111).

The standards for CT scanners in the National Guidelines are more specific than the criteria used by most planning agencies. The intention is that as the health

● K is an adjustment factor added to account for referrals and other unique circumstances.

systems plans become consistent with these standards, so too will the ranking of criteria for review of scanners. The three standards are:

1. A Computed Tomographic Scanner (head and body) should operate at a minimum of 2,500 medically necessary patient procedures per year, for the second year of its operation and thereafter.

Table II.—Criteria Used by Health Planning Agencies in Reviewing Applications for CT Head Scanners[a] August 1976

Type of Criteria	Number of Agencies Using Criteria
Active neurosurgical service	**29**
Requirement for full-time neurosurgeon	**12**
Specification of number of procedures	**18**
Requirement for an "active service"	**9**
Active neurological service	**29**
Requirement for full-time neurologist	**12**
Specification of number of beds or admissions	**13**
Requirement for an "active service"	**12**
Active radiology service	30
Requirement for full-time radiologist	4
Requirement for radiologist with training in neuroradiology	21
Radiologist merely mentioned	7
Requirements concerning other personnel (technicians, engineers, etc.)	12
Specified number of certain neurodiagnostic procedures	20
Utilization beyond an 8-hour day	20
Commitment to more than 8 hours	18
Commitment to 24 hours availability	5
Regionalization and geographic proximity	29
Proximity	15
Availability to ambulatory patients	11
Formal referral arrangements	14
Letters of endorsement from providers and/or consumers	11
University medical centers favored	5
Low priority for noninstitutional (physician offices) scanners	8
Requirement for scanning those unable to pay	11
General quality of care	18
Peer review	5
Availability of emergency services	6
Neuropathologist	3
Research and education capability	10

Table 11.—Cont.

Type of Criteria	Number of Agencies Using Criteria
Financial data	30
Statement of expected charge	15
Statement of projected volume	21
Statement of financial feasibility	14
Financial reporting after operational	18
General reporting	20
Long-range plan and evaluation	12
Consideration of alternatives	5
Training plan for staff	4
General reporting required after operational	16

[a] Arequestmade to all States to submit criteria used by the State or local agencies to review head and body scanners. Criteria submitted by Statesfor reviewof body scanners were similar to that for head scanners, with the exception of the neurological criteria.

Sources: 544-546,550,552-553,555-561 ,563-566,568-57O,573-577,579,58l-584,585-586,589-59O.

2. There should be no additional scanners approved unless each existing scanner in the health service area is performing at a rate greater than 2,500 medically necessary patient procedures per year.

3. There should be no additional scanners approved unless the operators of the proposed equipment will set in place date collection and utilization review systems. ”

SHORTCOMINGS OF PLANNING POLICIES

The impact of health planning on the number and distribution of CT scanners is difficult to determine in the absence of efficacy criteria. For example, even with regulation, the rate of diffusion of CT scanners has accelerated since their introduction in 1973. What production schedules might have existed in the absence of regulation are, of course, not known. But there is no basis for judging whether current levels of production are too high or too low.

The National Health Planning Act may not have been in effect long enough to affect the pattern of installation of CT scanners. However, State certificate-of-need laws and section 1122 agreements have been in effect longer. Taken together, these planning laws do not explain the differences in the number of CT scanners among States.

Throughout the entire country, only the District of Columbia lacked guidelines or legislation that applied to scanners in June **1976** (table 10). During the reference period, Missouri had statewide planning criteria for CT scanners. Of the other 10 areas with the highest concentration of scanners, Nevada, Colorado, and Florida had both certificate-of-need laws and section 1122 agreements. The remainder of this group of States had either a certificate-of-need law or a section 1122 agreement that covered CT scanners.

Among the 10 States with the lowest ratios of scanners to population in June **1976,** Mississippi, New Hampshire, New Mexico, and North Carolina did not have a certificate-of-need law. Neither did Wyoming, the only State without a scanner.

Nonetheless, all of these States had **section 1122** agreements.

This simple correlation may be misleading however, since at least 4 of the **30** States with certificate-of-need laws as of June 1976 did not cover CT scanners. Georgia and Illinois did not cover purchases of equipment; Ohio's law, which had not been implemented, did not specify coverage; and California's initial law covered only hospital beds (497).

In addition, the rate of State approvals of capital expenditures under section 1122 has been over 90 percent (85). Without further information, the effectiveness of planning cannot be judged by the extent to which it either prevents or encourages resource development.

Thus, the first shortcoming of public policy is that concepts essential for implementing plans and regulations are not defined. In particular, planners are seriously handicapped by the lack of appropriate medical indications for use of CT scanners, matters that hinge on efficacy. A population's need for CT scanning services cannot be adequately estimated without this information.

The best indications for use of particular neurodiagnostic procedures consider specific disease categories **(62,23).** However, defining acceptable medical practice for use of CT scans is in the early stages. Thus, diagnostic protocols have not yet been widely accepted for use of CT scanners. Without a protocol, the frequency with which physicians use CT scans as a complementary or as a substitute procedure is unknown (564,264).

In lieu of appropriate medical indications, present rates of use of CT scanners are incorporated into planning targets. Since the CT scanner is still a new technology, current experience with it is not likely to be representative of long-term experience. For example, familiarity gained over time with the technology can increase its use by physicians. Improvements in design for handling patients, which raise the potential productivity of the machine, could also increase average future use. On the other hand, obsolescence may decrease future rates of use. To date, no suitable planning indicators for CT scanners are available. In light of this finding, adherence to rigid planning targets may be unsound.*

The second shortcoming of Federal health planning policy is that regulations do not apply uniformly to all purchases of CT scanners. Offices of private physicians, whether for individual or group practice, are exempt from the certificate-of-need provisions of P.L. **93-641 and** from those of section 1122. These exemptions encourage the location and ownership of scanners in private practices, despite any efforts of planning agencies to the contrary.** In Ohio and Florida, for example, physicians have leased space from hospitals in order to install privately purchased machines. In these States, such arrangements are not subject to review by planning agencies. When a hospital in Miami was denied permission to purchase a scanner, a physician on the hospital staff purchased a machine, installed it in an adjoining office building, and made it available to the patients in the hospital **(256).*****

*There are indications that the Department of Health, Education, and Welfare supports more flexibility in the planning process. The Department endorses periodic review and revision of the standards proposed in the National Guidelines as experience with their use accumulates.

**Besides the laws' exemptions of private medical practices, the investment tax credit gives providers an incentive to install scanners outside of hospitals, The credit lowers the effective cost of a CT scanner to physicians in private offices as opposed to nonprofit hospitals.

***Final regulations of the National Health Planning Act prohibit leasing arrangements that have the intent of circumventing review. Intent, however, is difficult to prove under the law.

Current State certificate-of-need laws also usually exempt from review expenditures for facilities, equipment, or services by private physicians. Only seven States—Colorado, Connecticut, Hawaii, Iowa, Minnesota, Virginia, and Wisconsin—review acquisitions by private physicians. Massachusetts, New York, and Vermont are considering extending their laws, An expansion by the States of the minimum type of facilities covered under the provisions of P.L. 93-641 would not conflict with the law (498). These initiatives are often supported by a variety of organizations, including Blue Cross (71) and the Institute of Medicine **(258).**

PATTERNS OF USE

5.

PATTERNS OF USE

Ideally, patients are scanned when it can be reasonably expected that useful information about their condition will be found. Indications for use of a diagnostic technology such as CT scanning include consideration of the potential benefits, the population who will benefit, the medical problem affected, and appropriate conditions of use. However, insufficient studies have been conducted to determine the proper indications for use of CT scanners.

CT head scanners are usually used to diagnose mass lesions, cerebrovascular disease, and diseases with enlargement of the ventricles of the brain. Head scans also are commonly used for patients with symptoms such as headache and for victims of head trauma. Depending on the institution, studies have shown that results of 34 to 90 percent of all head scans are negative.

CT body scanners are used primarily for head scanning, although scanning for suspected abdominal problems is becoming more common. Patterns of use for body scanners are not yet as well established as those for head scanning because body scanners are at an earlier stage of development and often are not eligible for third-party payment. The complexity of medical diagnosis, the vast array of potential uses in the body from the neck down, and the capability of present CT scanners have also hindered the development of patterns of use of body scanning.

CT scanners are used for both inpatients and outpatients. Thus, they have the potential to avert hospital admissions and reduce the length of stay in hospitals. No data, however, show that this potential is being realized. Depending on the institution, from 20 to 90 percent of scans are performed on inpatients. The waiting period for a scan is generally longer for outpatients than for inpatients. Some inpatients may be scanned more quickly to expedite definitive treatment or discharge from the hospital. Other patients may be hospitalized to gain earlier access to CT scanners.

Current Federal policy does not link formally developed information on efficacy with the development of appropriate standards of use for CT scanners. The Professional Standards Review Organizations (PSROs) do review medical services for appropriateness, but no standards have been developed for CT scanners. The lack of information on appropriate indications of use hampers any effort to develop such standards.

EXPERIENCE WITH CT SCANNING

Patterns of Use

Head Scanning

The use of CT head scanners has varied considerably from institution to institution (47, 84, 108, 167, 205, 219, 249, 264, 265, 388, 405, 540). Many diseases and medical conditions can be diagnosed by CT scanning (table 12). The most common diagnoses have been mass lesions (mostly tumors, but some cysts as well), cerebrovascular disease (including stroke, hemorrhage, and aneurysm), and diseases with enlargements of the ventricular space of the brain (hydrocephalus and cerebral atrophy). Institutions reported that from 7 to **30** percent of patients scanned had brain tumors, **6** to **29** percent atrophy or hydrocephalus, **8** to 17 percent infarction (stroke), and 2 to 11 percent hemorrhage or aneurysm. The remaining CT examinations were either normal or revealed other neurological disorders. Reporting institutions found that from 11 to 44 percent of scans were normal (table 13). A recent study of nine hospitals reported that 53 percent of head scans and 36 percent of body scans were normal (149).

One study of several institutions found that about **50** percent of head scans were normal, with some institutions running as high as **80 to 90** percent normal. Two institutions surveyed had data on the percent of normal scans over time. One reported an increase of normal scans from **25** percent to 40 percent and the other from 34 percent to 46 percent (265). A high percentage of normal findings might indicate that CT scanning is being used more frequently as a primary diagnostic or screening tool than earlier. CT scanning is also used increasingly to plan therapy or to monitor changes in a patient's condition. For example, patients receiving radiation therapy for brain tumor are often monitored to observe the effects of therapy (90,407).

Body Scanning

As noted above, body scanners are often used primarily for scanning the head. In 1977, about **60** percent of examinations on body scanners were head scans **(158).** However, institutions that have both head and body scanners use their body scanners primarily to examine parts of the body other than the head. Mayo Clinic, for example, reported 76 percent of the examinations by its body scanners were body scans (465), and the Mallinckrodt Institute in St. Louis reported 95-percent (474) body scans on its body scanner. In institutions with both a head and body scanner, **65** percent of examinations on body scanners were body scans in a 1977 survey **(158).**

Most scans of the body relate to suspected abdominal problems, such as pancreatic tumors, abscesses, or jaundice (149). Scans are used less often for the thorax or extremities (table 12). However, these patterns of use are in flux. They can be expected to change rather dramatically as more becomes known about the usefulness of body scanning. For example, a study reported use of CT scanning as an adjunct of draining abdominal abscesses by needle, thereby avoiding surgery **(215).** According to a 1977 survey, 29 percent of scans on body scanners were of the abdomen, 6 percent of the pelvis, 5 percent of the chest, and 1 percent of the extremities (158).

Table 12.—Some Diseases That Can Be Diagnosed by CT Scanning[a]

HEAD SCANNING (Refs. 15,18,21,23,39,50,99, 124,125,162,211 ,223,224,229, 267,268,291 ,343,386,405,406, 410,41 1,459,472,478,537,539, 540)	BODY SCANNING (Refs. 6,7,8,9,38,95,157,209, 21 7,218,222,306,316,31 7,366, 452,461 ,465,474,477,493,526)
Mass lesions	**Tumors or cysts in:**
acoustic neuroma	adrenal
astrocytoma	bladder
epidermoid tumors	bone
glioblastoma	kidney
meningioma	larynx
metastatic neoplasms	liver
oligodendroglioma	lung
pituitary adenoma	lymph nodes
teratoma	mediastinum
cysts	pancreas
	parathyroid
Atrophy	pelvis
Cerebral abscess	pharynx
Hydrocephalus	retroperitoneum
Porencephaly	thyroid
Trauma	ureter
Tuberous sclerosis	
Multiple sclerosis	**Aortic aneurysm**
	Obstructive jaundice
Cerebrovascular disease	**Syringomyelia**
aneurysm	**Abdominal abscess**
arteriovenous malformation	
infarction (stroke)	**Traumatic damage to organs**
intracerebral hemorrhage	
subarachnoid hemorrhage	
Diseases of the eye	
tumors of eye and optic nerve	
exophthalmos	
Congenital abnormalities	

[a]This table lists only some of the diseases for which CT scanning has been applied and includes only selected references; it is not comprehensive.

Contrast Enhancement

The use of contrast enhancement varies from institution to institution (44, 45, 47, 48, 118, 119, 159, 264, 265, 303, 382), but has generally been increasing over the past few years **(45, 382).** Overall, more than 50 percent of patients are scanned after the injection of contrast material (29, 159). Initially, contrast enhancement was used less frequently for body scanning than for head scanning (149). But by 1977, a survey showed that 68 percent of head scans on body scanners were enhanced, while

Table 13.—Major Diagnostic Uses of Head Scanning

Tumor	Atrophy or Hydrocephalus[a]	Infarction	Hemorrhage or Aneurysm	Other Neurological Disorders	Normal	(Reference)
18	29	17	3	1	32	(82)
25	22	8	3	5	37	(47)
19	20	13	8	29	11	(388)
7	25	11	2	11	44	(108)
30	6	8	11	18	27	(405)
12	20	—13—		12	43	(264)

Each horizontal line shows the types of diagnoses made on the basis of CT scanning at one institution or group of Institutions. Numbers indicate the *percentage* of patients scanned who fell into a particular diagnostic category.

[a] Diseases which entail enlargements of the ventricular space

65 percent of abdominal scans were enhanced and 60 percent of scans of the pelvis were enhanced. Scans of the chest and extremities were enhanced less frequently (158).

Research Use

A few scanners are used solely for research; the National Institutes of Health has several CT scanners for use in the medical care of patients who are research subjects. Other scanners are scheduled for some research time, usually 5 to 10 percent of the total time available. Some uses combine service with research studies of accuracy or efficacy.

Although clinical researchers have concentrated so far on evaluating diagnostic usefulness, CT scanning is also a potentially valuable tool for biomedical research. Investigators have used CT scanning to study the anatomy and physiology of the normal brain (213, 220, 309, 414) and to seek correlations between brain anatomy and behavioral (170, 171,252,372, 441), biochemical (122, 453), or neurological (254, 442, 468) abnormalities. Experimental uses of body scanning are also increasing (145, 313, 461), such as evaluating damage to the heart **(200).**

Indications for Use of CT Scanning

The critical question of the appropriate indications for use of CT scanners has not been effectively addressed. Ideally, patients are scanned when it can be reasonably expected that useful information about their condition will be found. Indications for use must be specified through consideration of the benefits from CT scanning, the population who will benefit, the medical problem affected, and appropriate conditions of use.

Development of indications for use depends on information about efficacy. If arriving at a diagnosis is the goal, CT scanning may be used to diagnose all the conditions listed in table 12. If improved patient outcome were the goal, however, the indications for use would be different.

However the goal is defined, little is known about appropriate indications for use of CT scanners. Few institutions have reported indications used for head scanning. In two large neurological referral centers, CT head scans were ordered for patients because of suspected mass lesions in **30** percent of scans, vascular abnormalities (such as stroke) in 10 percent, trauma in **5** percent, suspected optic lesions in 5 percent, suspected hydrocephalus or shunts in 5 percent, and symptoms such as headache, confusion, seizure, or dementia in **23 to 30** percent. Indications for other patients were not given **(265).** A survey of nine hospitals in **1977** found the following indications for performing head scans (149):

Headaches	17.1 percent
Motor disturbances	14.2 percent
Tumors	9.5 percent
Cerebral vascular accident (stroke)	5.5 percent
Mental symptoms	5.4 percent
Trauma	4.2 percent
Other	44.1 percent
Total	100.0 percent

The same survey reported that suspected abnormalities of the pancreas, liver, abdomen, kidney, and pelvis, plus a variety of carcinomas, accounted for more than 64 percent of CT body scans (149).

Alderson and his coworkers reviewed the experience of one institution. They found that of 490 patients scanned, 195 had an abnormal neurological examination (38 of whom were diagnosed as having strokes), and 295 patients had a normal neurological examination. Of those with normal neurological examinations, 67 had headache only, 54 had seizures, 60 had mental deterioration, and the remaining 114 had miscellaneous complaints (4).

A CT head scan is commonly given to patients whose only symptom is headache. Two studies have examined the results of such scans. Alderson and his coworkers found that of **67** otherwise normal patients with headache, only 3 had abnormal scans, and that these were of little clinical importance (4). Carrera and his coworkers reviewed the experience of 53 patients whose chief complaint was headache but who had no other neurological findings. They found no abnormal CT examinations **(92).**

Another common use is for patients with head trauma. French and Dublin reported on 1,000 consecutive patients who were scanned for head injuries. Twenty-seven percent of the patients were alert and had normal neurological examinations; only 13 percent of those with normal neurological examinations had abnormal scans, and none of them required surgery (173).

Alderson analyzed the results of 295 patients with complaints but no focal findings* on neurological examination; 205 scans (0o percent) were normal. If "brain softening" is excluded, only 15 (5 percent) had an abnormality. A symptom that often indicated abnormalities was the acute onset of seizures. In 28 such patients, 4 had lesions, 2 of them tumors (4).

*Focal findings are those indicating an abnormality in a specific part of the brain.

Similar experience has not yet been reported for body scanning, so it will not be further discussed in this section.

Potential Levels of Use for CT Scanners

The five levels of efficacy suggested by Fineberg et al. (167) (chapter 3) indicate the impacts that different policies might have on the use of CT scanners. The maximum number of "appropriate" scans may vary greatly depending on the definition of efficacy. If efficacy is defined as the therapeutic impact of a diagnostic technology, data on such effects of CT scanning are currently too limited for full evaluation. One could identify possible therapies for a particular diagnosis and change in use of such therapies due to CT scanning. For example, the major available therapy for intracranial lesions is neurosurgery. In 1975, 89,000 intracranial procedures were performed in the United States (511). This figure represents a possible level of use based on the fourth level of the Fineberg definition of efficacy, therapeutic impact. Surgery canceled as a result of demonstrated spread of cancer could also be considered. Other diagnoses of potentially treatable conditions could be added to this figure.

If diagnostic reliability alone were used as the criterion on which to determine need, then the potential number of scans would be much greater. For example, in 1974, there were approximately 600,000 hospitalizations for stroke in the United States (513). Each person with a stroke serious enough to require hospitalization could be scanned one or more times. But it is unclear what this information would add to the patient's well-being, because generally, strokes can be well diagnosed clinically, and little effective therapy can be performed (314). One important use is to ensure that the stroke is not hemorrhagic if anti-coagulation is planned or contemplated.

Many patients present symptoms such as headache that could indicate a serious neurological disorder. J. Lloyd Johnson Associates estimated the number of scans required to diagnose intracranial disease *and* to examine patients with symptoms possibly indicating such a disease (table 14). Patients with serious disease would certainly be a minority of the total number of cases with symptoms (524). For example, about 12 million people with headaches visit physicians' offices each year (512)—J. Lloyd Johnson Associates estimates that 750,000 of these patients appear to be serious enough to be scanned (265). (Since the major concern in such headache is primary brain cancer, this figure may be compared to the yearly incidence of such cancer, which is about 6,000. See table 14.)

Using this reasoning, Johnson Associates estimated a level of use of about 4 million head scans annually (265). This estimate is partially based on the common medical assertion that it is valuable to scan worried patients likely to be normal to reassure them that no lesion is present; and it is valuable to scan patients likely to have untreatable disease to give them realistic prognoses, Scanning the brain of patients with lung cancer, breast cancer, and so forth could not only give such information, but might also obviate painful and expensive therapy if the cancer were found to have spread to the brain (a common condition in its final stages). Because of this philosophy and of the lack of data on using CT scanning to plan therapy, indications for appropriate use of scanning are difficult to define.

Similar rough estimates could be made for body scanning, but data on the efficacy of body scanning are even more limited than for head scanning. J. Lloyd Johnson

Table 14.—Estimated Types of Patients Diagnosed or Referred Annually Who Are Potential Cases for CT Head Scanning

	Number of Cases	Totals
Diseases of the Central Nervous System		
Subarachnoid Hemorrhage	15,000	
Cerebral Hemorrhage	555,000	
Cerebral Embolism	220,000	
Stroke	80,000	
Intracranial Abscess	6,000	
Head Injuries	250,000	
Unspecified Neurological Signs	700,000	
Other Diseases of the Brain	324,000	2,150,000
Malignant Neoplasms of the		
Brain	6,000	
Lung	80,000	
Breast	290,000	
Prostate	150,000	526,000
Functional and Other Symptoms		
Headache	750,000	
Convulsions	400,000	
Vertigo	100,000	1,250,000
Total		3,926,000

Source: Adapted from table B.1, reference 265.

Associates used assumptions similar to those for head scanning and projected a national level of use of about 2.7 million body scans annually (265).*

Thus, planning on the basis of expected patterns of use requires explicit consideration of the efficacy of a technology. The goal of using a diagnostic technology such as the CT scanner must be defined. Different goals yield very different levels of use. Depending on the goal, existing knowledge would justify either a very small or a large number of scanners. In fact, using the J. Lloyd Johnson Associates estimates, more than 2,200 CT scanners would be called for,' a number that could cost more than $1 billion to purchase the machines, and $l billion to $2 billion per year in payments for scans.

Institutional Setting of CT Scanning

Most CT scanners in hospitals are operated by the department of radiology, although they may be owned by that department, by the radiologists, or by the hospital One reason for operation by the radiology department is that the Joint Commission on Accreditation of Hospitals (JCAH) required that an authenticated report by a radiologist be included in every interpretation of a radiological procedure, including CT scanning. In 1976, however, this requirement was changed to allow

*6.7 million examinations divided by 3,000 scans per scanner.

any qualified physician to interpret special diagnostic procedures, including CT scans. Neither policy has applied to nonhospital scanners, some of which are under the control of neurologists and/or neurosurgeons. *

Regardless of the kind of institution or specialist owning or operating a CT scanner, a patient cannot be scanned except by a physician's order. In hospitals, clinical physicians refer patients to the department of radiology for a CT scan. A 1975 survey reported the source of referrals for head scans as follows (80):

Neurology	37%
Neurosurgery	26%
Other hospital staff	14%
Outside physicians	28%

Similar results were reported in a 1977 survey of nine hospitals (149):

Surgery	27%
Internal medicine	25%
Neurology	24%
Family/General practice	14%
Other	15%

This later survey reported on sources of referrals for body scans (149).

Internal medicine	391%0
Surgery	19%
Family/General practice	15%
Other	27%

Inpatient-Outpatient Use of CT Scanning

CT scanning can be performed on inpatients or outpatients, depending on the patient's condition and the physician's desire. Unlike arteriograms and pneumoencephalograms, the procedure does not require admission to a hospital. Although CT scanning can avert hospital admissions and reduce lengths of stay, available information indicates that that potential has not been fully realized.

Most institutions perform scans on both inpatients and outpatients. The fraction of those scanned who are inpatients varies from 20 to 90 percent (264) Massachusetts General Hospital performs 90 percent of its scans on inpatients, but Mayo Clinic conducts 80 percent of its scans on outpatients (582). In a 1975 survey of 10 institutions, Buenger and Huckman (82) found an average of 46-percent inpatient scans, with a wide range. The American Hospital Association **(29)** surveyed 41 hospitals in 1976 and found 51-percent inpatient scans, with a range from 23 to 90 percent. A recent survey of nine hospitals reported that 52 percent of head scans and 60 percent of body scans were performed on inpatients (149)

Outpatients have confronted much longer waiting periods for scans: an average of **11.5** days compared to **1.6** days for inpatients **(159).** A survey in 1976 reported

*Partly because they cannot profit from self-referral, radiologists consider CT scanners most appropriate in their custody. Neurologists and neurosurgeons believe that they should reinvolved in the control of head scanning because they have more training and experience in interpreting brain anatomy than radiologists.

that delays for inpatients had increased in 21 percent of the institutions and had decreased in 9 percent. Delays for outpatients had increased in 35 percent and had decreased in 6 percent. Waiting periods tended to decrease after installation of a new machine in the same region (159). By 1977, a survey of body scanners found a scheduling delay of **0.9** days for inpatients and **3.4** days for outpatients **(158).**

Self-Referral for CT Scanning

Self-referral occurs when a physician both refers a patient for a test or procedure and receives payment for performing the test. At least **89** percent of all CT scanners are in hospitals or in radiological offices where one physician orders, and another performs scans. Thus, self-referral is associated with 11 percent of existing scanners, at most. *

FEDERAL POLICIES CONCERNING USE

The Professional Standards Review Organizations (PSRO) program is one of the principal expressions of Federal policy concerning the use of medical services, including CT scanning. The PSRO program, established in 1972 by P.L. 92-603, is administered by the Health Standards and Quality Bureau (HSQB, formerly the Bureau of Quality Assurance) of the Health Care Financing Administration. The purposes of the program are to help improve the quality and control the costs of medical services reimbursed through Federal payment programs. The program operates by setting standards and criteria for the desired level and quality of medical services and by evaluating against these standards the services actually provided. This process is designed to ensure that payment will be made only when services are medically necessary (235).

The PSRO program is based on the concept that medical professionals are the most appropriate individuals to evaluate the quality of medical services and that effective peer review at the local level is the soundest method for ensuring the appropriate use of medical care resources and facilities. The PSRO program is made up of separate and independent organizations covering **203** geographic areas. Each PSRO must be substantially representative of all practicing physicians in an area. The PSRO program is new and is not yet fully implemented. Of the 203 PSRO areas in March 1977, only 120 PSRO agencies had been funded; 100 were in "conditional status; 20 were in "planning' 'status. By September 30, 1977, 120 were in "conditional" status and 60 in "planning" status.

PSROs usually review only services reimbursed through Federal payment programs, Medicare and Medicaid,** whose coverage policies and eligibility

*As noted in chapter **4**, **20** percent of all scanners are located in private offices of all kinds, including at least 8 percent that are clearly radiological practices.

● *Although the law mandates review of publicly funded services only, some PSROs have begun to review privately funded services also. PSROs also have authority over other health programs authorized by the Social Security Act, including Maternal and Child Health programs. Because of the small size of such programs, they will not be referred to further.

requirements are set nationally, and PSROs must function within those limits. A service may be ruled ineligible for coverage either nationally or locally, with national decisions taking precedence. As will be described in chapter 6, CT body scanning is not yet a covered service under the Medicare program. Therefore, PSROs neither are permitted to find body scanning to be "medically necessary," nor would develop standards for its use. Questions about coverage can be answered locally or referred to the national level for resolution. If a PSRO disagrees with coverage policies or eligibility requirements, it may ask for reconsideration of such policy. Although no such question has yet come to the national level, this mechanism does have promise as a method of obtaining reactions from the local level and from medical practitioners to the national Medicare program.

Each State with three or more PSROs has a statewide Professional Standards Review Council. Among other duties, these Councils have the responsibility to disseminate information and data among the PSROs within the State. At the national level, a National Professional Standards Review Council is established by law. This Council has several functions, including one to "provide for the development and distribution, among Statewide Professional Standards Review Councils and Professional Standards Review Organizations of information and data which will assist such review councils and organizations in carrying out their duties and functions." Such information is specified as including regional norms and standards. Local PSROs are not required to accept model standards issued by the National Council. However, the National Council has authority to disapprove local standards that deviate from model standards if the Council determines that the differences are not medically justified. The National PSRO Council has provided general guidance and sample criteria sets developed by several organizations, including the American Medical Association, under contract with the Department of Health, Education, and Welfare (HEW). The purpose of these contracts has been mainly to develop criteria on medical necessity for hospitalization for different disease categories. HSQB hopes that both technical assistance and norms and standards will have an important educational effect, as well as affecting practice directly through reimbursement policy.

Each PSRO is initially limited to reviewing hospital inpatient services. After a PSRO has demonstrated its effectiveness, the Secretary of HEW may grant permission for it to review outpatient services also, although none have yet begun to carry out such reviews. PSROs review the medical care provided by utilization review of medical care for individuals and by medical care evaluation (MCE) studies. Utilization review can be either admission review, to determine the necessity for admission, or concurrent stay review, to determine the length of time a patient should be hospitalized. * In most instances, hospital committees are delegated by PSROs to perform these reviews, but PSROs must monitor the review process. Medical Care Evaluation studies are retrospective reviews of the medical care that was provided to certain groups of patients (e. g, by diagnosis), of the use of specific medical technologies, or of any category of medical or administrative services provided.** As

*Under proposed regulations, concurrent review may be applied prior to major diagnostic or therapeutic procedures if medically unnecessary or inappropriate utilization of a procedure is documented (242). This provision could apply to CT scanning in the future.

**Through the use of medical information systems, the quality of medical care can be monitored during the process of medical care rather than afterward. For a discussion of this subject, see OTA report, *Policy Implications of Medical Information Systems.*

specified in the statute, PSROs review services to determine whether:

(A) such services and items are or were medically necessary;
(B) the quality of such services meets professionally recognized standards of health care; and
(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type.

The law requires that PSROs use norms, criteria, and standards in evaluating medical services. This approach allows nonphysicians to perform many of the reviews and also enhances the objectivity of the review process. Standards are developed by a consensus of physicians, based on typical patterns of practice in the area and on such regional or national information as may be available and considered applicable by the PSRO. No PSROs had developed standards for CT scanning by September 1977.

In its early stages, the PSRO program has concentrated on determining the need for hospitalization. Now PSROs are beginning to move beyond the question of necessity for hospitalization to review of surgical procedures and review of ancillary services, including such radiological services as CT scanning. HSQB which administers the PSRO program, hopes to provide sample criteria in these areas.

PSRO decisions on medical care utilization and quality can be enforced in several ways. Reimbursement for services provided can be withheld by Medicare and Medicaid (Medicaid regulations are established in each State and vary somewhat). For serious and repeated violations of PSRO standards, a physician's right to be reimbursed through Medicare and Medicaid can be suspended or revoked.

SHORTCOMINGS OF UTILIZATION POLICIES

Potential uses of CT scanning are virtually unlimited. The entire body of every patient could be scanned to provide physicians and patients the most complete and accurate anatomical information possible. Further, each patient could then be scanned periodically to monitor the effect of treatment and rate of recovery. CT scanning could even be used routinely as a screening tool. Such uses would require a large number of scanners operating at full capacity and would result in a substantial increase in national medical expenditures. Such extensive use would obviously represent an extreme approach. Optimal use of CT scanners would probably be at some level below this extreme. A principle issue, then, is how to ensure appropriate use. How can limits on use be established without sacrificing quality of care?

Historically, individual physicians have made decisions about appropriate use of a technology for each patient. Such decisions were based on clinical experience, advice from colleagues, information obtained from medical journals and manufacturers, judgment, and experience. As more physicians used a technology, usual and customary patterns of use developed. No formal process has existed for developing scientific information about the efficacy of medical technologies or for using that information as the basis for decisions about appropriate use.

The PSRO legislation established a framework by which appropriate use of medical technologies could be evaluated by physicians acting in organized groups rather than as individuals. Their decisions, however, are still based largely on traditional sources of information, so that customary practice patterns, whether appropriate or not, become accepted as standard. For CT scanners, as well as other medical technologies, little is known about the four factors defining efficacy: benefits received and probability of benefit, population benefiting, medical problem affected, and appropriate conditions of use. Evaluating the overall efficacy of diagnostic technologies such as CT scanning does pose special problems. Nevertheless, the lack of scientifically derived information on indications for use hampers the development of appropriate standards. Provided with such information, PSROs could become a mechanism for evaluating medical care. In its absence, PSROs are developing local standards for medical services based primarily on prevailing patterns of medical practice.

The Health Standards and Quality Bureau (HSQB) does not have the authority to impose national standards for use. It does have the authority, but not the mandate, to collect the results of studies concerning efficacy and safety and to provide them to PSROs as model or recommended norms, criteria, and standards. Experience with the PSRO program seems to indicate that local PSROs have generally been willing to adopt, with minor modification, the model standards and criteria developed nationally. Although limited information on efficacy and safety of CT scanners exists, HSQB has furnished none to PSROs.

REIMBURSEMENT

REIMBURSEMENT

Estimates of total annual expenses for performing 3,000 examinations on a CT scanner in 1975 and 1976 ranged from $259,000 to $379,000. These expenses can be divided into professional expenses, $20 to $43 per exam, and technical expenses, $50 to $130 per exam. The price of the machine, the largest technical expense, has increased since the introduction of CT scanners, but less than inflation in most cases. Because CT scanning is a new and rapidly changing technology, expenses could continue to change.

Fees for head scans averaged $240 to $280 in 1976. Charges have exceeded annual expenses by 39 to 330 percent, and estimated annual profits per scanner have ranged from $51,000 to $283,000. Estimates of total expenditures on CT examinations alone ranged from $189 million to $206 million in 1976. Expenditures for those patients who were hospitalized while waiting for CT scans increased estimated total expenditures. But calculation of net expenditures on CT scanning must consider reductions in other tests and associated hospital days brought about by CT scanning.

Under Medicare and some individual Blue Cross and Blue Shield plans, reimbursement for CT head and body scanning is conditional upon a determination of efficacy. Increasingly, third-party payers are making reimbursement for medical services conditional on an evaluation of their efficacy. However, CT scanning illustrates the perverse incentives of current reimbursement methods that encourage increased provision of services and fail to encourage cost-consciousness and efficiency by providers. Both private insurance companies and public programs most frequently reimburse costs or charges retrospectively, and they also pay on a fee-for-service basis. Hospitals and physicians do not operate within a budget that leads them to constrain expenditures for services or to use less costly alternatives.

EXPERIENCE WITH CT SCANNING

Expenses of Operating a CT Scanner

The figures in table 15 suggest, rather than describe, actual annual expenses of operating a CT scanner. (See appendix IV for more detail.) Although some of the studies were based on actual experience, all but one are estimates. The report of actual expenses documents the experience of one hospital **(81). As** described more fully below, the estimates depend heavily on judgments about accounting techniques, staff time, and the like that vary widely among the different sources.

Table 15.—Estimated Annual Expenses of Operating a CT Scanner[a]

Category	Range (Thousands of Dollars)
Technical expenses	**$177-337**
Equipment[b]	**76-117**
Interest	**0-28**
Maintenance on scanner	**3-40**
Other maintenance and remodeling	**0-13**
Nonphysician staff	**36-75**
Supplies	**15-38**
Indirect expenses	**2-112**
Other	**0-1o**
Professional expenses[c]	**60-130**
Total expenses[d]	**$259-379**
(Number of examinations per year.	*2,600.3,828)*
	Dollars
Average technical cost per exam	**$59-130**
Average professional cost per exam	**20-43**
Average total cost per exam[d]	**86-173**

[a] Estimates except forthereport ofone hospital's experience from reference 81. These reportsare based on experience during 1975 and 1976 when most CT scanners were head scanners, and most scanning was of thehead.

[b] **Straight-line, 5-year depreciation except for rental estimate of $76,000 in reference 81. Depreciation was based on purchase prices of $400,000 to $585,000.**

[c] **Based** on 1 radiologist except for the highest estimate using 1.3 radiologists (577). These figures represent the cost to the institution ofobtaining physician services, not revenue from physicians' charges.

[d] Half of the sources, including the two with the highest estimates of technical expenses, made no estimate of professional **expenses. Adding the highest estimates of technical and professional expenses would result in average total cost of $173. The highest total estimate made was $126 per exam.**

Source: Appendix IV.

Most estimates for the annual expenses of operating a CT scanner have been based on a rate of about 3,000 examinations per year (81,159,425,554,577,584). In effect, this rate assumes the machine is operating for one shift per day. These estimates are based on 1975 and 1976 figures when most scanners were head scanners.

Estimates of total annual expenses range from $259,000 to $379,000, or from $86 to $126 per examination (table 15 and appendix IV). Those making estimates distinguish between technical and professional expenses. However, the study with the highest estimate of technical expenses, $130 per examination, made no additional estimate of professional expenses (159). Adding the highest estimates of technical and professional expenses would produce $173, a more realistic figure for the highest estimate of total expense per examination.

Professional expenses ranged from $20 to $43 per examination. These figures represent the cost to the institution of obtaining physician services, not the revenue generated from fees charged. All estimates except one are based on the services of one radiologist. No specific information indicates what method is the most common one of paying physicians responsible for CT scanning. Possible variations include fee-for-service, a percentage of net or gross revenue the institution receives from scanning, and departmental or staff salary (577). The highest figure reported for the annual expenses of a physician, **$130,000, was** based on an annual salary slightly higher than the others. This high figure also included fringe benefits and assumed the services of the equivalent of 1.3 radiologists (577).

Total annual technical expenses ranged from **$177,000 to $337,000,** or from $59 to $130 per examination. Most CT scanners are depreciated using the straight-line method* over 5 years, although standard procedure f or depreciating equipment uses 8 years (577). The length of time chosen relates to the rapidly changing technology of CT scanning, that is, the issue of obsolescence.** An institution can reduce the risk of obsolescence by leasing a machine or updating older models. At least *26* percent of **96 institutions** surveyed in **1976** leased machines (159), and the annual rental charge has been estimated at **$76,000 (81).** This estimate suggests that rental is less expensive for providers than purchase and depreciation. Manufacturers also market kits to update older machines. The estimate of Evens and Jest, for example, includes **$25,000** for the purchase of new equipment in addition to depreciation (159). In **1976,** EMI charged $100,000 **to** update its original head scanner **(265).**

Different ways of accounting for interest on loans explain one discrepancy among estimates in table 15. Health planning agencies in Indiana, which made the highest estimate for equipment, included interest on a loan to purchase the machine (554). No other estimate mentioned interest. Such interest represents a cost to an institution and should have been included in other estimates involving purchase of a machine.

Estimates for other technical expenses also vary. An institution has several choices for maintenance of a machine: a service contract with the manufacturer, maintenance by its own staff, or some combination of the two. Installation of a scanner may require remodeling of a building. The time over which remodeling expenses and general building depreciation are spread may vary, reaching 20 years in some cases (577).

The technical expenses noted above are, by and large, fixed costs; that is, their amount does not vary with the rate of the machine's output.*** Other expenses increase with the number of patients examined during the year. Some basic staff is necessary for operation of the machine. Increases in staff, however, are necessary, for example when a second shift is added. Opinions differ about the number of staff needed to operate the machine, even at roughly the same level of output. But most include the full-time equivalents of one or two X-ray technicians, one or two aides, and one other person for about 3,000 annual examinations. The quantity and cost of supplies such as film, X-ray tubes, and contrast material clearly vary with the rate of output .

*The straight-line method of depreciation divides the total dollar amount to be depreciated into equal annual parts. In contrast, the accelerated method depreciates a higher percentage of the total amount at the beginning and gradually diminishes percentages over the course of the depreciation cycle.

**Of course depreciation, an allowance for the equipment's wearing out, differs conceptually from obsolescence.

***Maintenance may in fact increase after some level of output, but estimates treat it as a fixed cost.

All estimates of expenses are divided into direct and indirect costs. Indirect costs attempt to measure that portion of an institution's general expenses attributable to the CT unit, including such items as administration, billing, collection, hospital or university overhead, and messenger service (159). Estimates of indirect costs vary widely, from 50 percent of direct costs by Evens and Jest, to 15 percent of direct costs by the Health Planning Council of Rhode Island, to $2,000 per year by the Genessee Health Planning Council (159,577,584).

Because CT scanning is a new technology, changes in expenses over time are important. The price of a CT scanner is the largest single item in technical expenses. EMI manufactured 58 percent of all machines and **92** percent of all head scanners known to be installed by May 1977. During the three years from 1973 to **1976, the average** price of an EMI head scanner rose at an annual rate of 17, 12, and 3 percent respectively **(148)** (table **16).** The rate of price increase not only slowed, but in 1974 and **1976** fell below the increase in the Wholesale Price Index. More recently, some models of CT scanners have been priced under **$100,000.**

Table 16.—Prices of EMI Scanners, 1973-77a

Type of Scanner	1973	1974	1975	1976	1977b
Head Scanner	$310,000	$360,000	$400,000	$410,000	—
Change in Price . . .	·	17%	1 20/0	30%	
Body Scanner	—	—	—	$475,000	$530,000
Change in Price . . .	—	—	—	—	120/0
Change in Wholesale Price Index		190/0	90/0	50/0	

[a] Prices of the most commonly purchased configuration of CT scanning equipment, i.e., the modal value, prices are in current dollars.
[b] Estimated.

Sources: 148,501.

Diverse factors are at work here making future price projections difficult. According to the theory of a learning curve **(238),** the very process of production over time increases experience and leads to lower average costs. Insofar as economies of scale exist in the industry, average costs could also decrease as companies increase their levels of production. The entry of new firms into the industry is another potential force for lower prices over time, provided price competition exists. In **1976,** six firms in the United States were in active production, and six were in the developmental stage. Other foreign manufacturers, such as the Japanese, may begin marketing machines in the United States at lower prices, adding to the competition and potentially driving prices down (491).

At the same time, other factors are likely to produce increases or restrict decreases in prices. The market for CT scanners is by no means a perfectly competitive one with free entry of firms. Thus, competition cannot be expected to drive the price of machines down to the point at which it equals marginal cost. * In addition, price comparisons over time are not completely valid in this market because the technology

*Marginal cost is the cost of producing an additional scanner.

of scanning is undergoing great change. Third-generation machines already being marketed have features that increase the potential rate of examinations and the clarity of the scan. Finally, because inflation occurred throughout the economy during the **1970's,** prices of CT scanners must be measured against general inflation, which may increase manufacturing expenses and ultimately prices of scanners.

The Veterans Administration (VA) found that it could purchase scanners at a lower price by requiring bids from manufacturers. In 1977, the VA solicited bids from all known manufacturers for three body scanners that fit the VA's specifications. The company whose bid was accepted offered a scanner that usually sells for $450,000 for $375,000. A further indication of savings was the wide spread between the lowest and highest bids, $1 million for the three scanners (515).

Expenses of CT Examinations at Different Rates of Output

Within the ranges of operation reported, the average cost of a CT examination decreases as a scanner is used to produce more examinations per year. All of the expenses in table 15 have been calculated at the rate of about *3,000* examinations per year. Table 17 illustrates the differences in average costs per examination that result from higher and lower rates of operation. These estimates, made in 1975 and **1976,** were based primarily on CT head scanning.

Table 17.—Estimated Average Cost of a CT Examination at Different Rates of Output

Cost Per Examination (Dollars)	Annual Number of CT Examinations Per Scanner												
	Rhode Island, 1975			Indiana, 1976				Evens and Jest, 1976				Genessee, 1975[a]	
	1,000	2,000	3,000	1,500	2,500	4,500	7,500	2,080	2,600	3,120	4,160	3,000	5,500
Average Technical cost	175	91	62	140	97	60	46	157	130	112	89	59	42
Average Professional cost	72	36	24	—	—	—	—	—	—	—	—	43	36
Average Total Cost	247	126	86	–	–	–	–	–	–	–	–	102	78

[a] Straight-line 4-year depreciation has been changed to 5-year here

Sources: 159,554,577,584.

An annual rate of 3,000 examinations has been considered average for a machine operated on one shift daily. However, according to the estimates of the Genessee Region Health Planning Council, the average total cost of an examination would be 24 percent lower, **$78** instead of $102, with two shifts (577). All of the other sources in table 17 also estimated lower average costs with increased operation of a CT scanner.

In **1976, average use of a head** scanner varied with the length of time it had been operational. Scanners in operation for less than 1 year averaged 11 examinations per day, and those in operation from 1 to 2 years averaged 13 examinations per day. Although a machine's output apparently increases over time, these rates of operation represent about 3,000 examinations a year, approximately one shift daily (265). The

experience with CT scanners therefore conforms to the observation that hospital equipment is typically used at only 50 to 70 percent of capacity (123).

These observations suggest that, other things being equal, a given number of CT examinations could be performed at lower cost on a smaller number of scanners operating more intensively, rather than on a larger number operating less intensively. Of course, cost, quality, and access must all be considered when deciding the number of CT scanners that are appropriate for sparsely populated areas. Operating a CT scanner more than one shift daily would also require adjustments in the work schedules of radiologists and technicians. It is interesting to note, however, that one estimate by radiologists calculated that certain CT head scanners can perform 6,600 annual examinations per machine if used 12 hours a day and 5% days a week (519).

Little information is available about differences in rates of use and costs of scanning between hospital and office settings. One survey distinguished between hospital and office scanners, but made no mention of variations in diagnoses and other characteristics of patients that could have greatly influenced utilization and costs. Although machines in hospitals operated an average of 1 hour a day longer, they performed 5 percent fewer examinations than the office-based machines (159). Hospitals took longer than offices to perform fewer examinations. This lower rate might not have resulted from the setting itself: patients in hospitals are often more seriously ill and could have taken longer to scan for reasons associated with their illnesses.

Fees Charged for CT Scanning

Several categories of fees are charged for CT scanning. Providers differentiate between scans with and without contrast material and between technical and professional services. About 59 percent of institutions surveyed in 1976 levied separate technical and professional charges (265).

According to a survey of CT head scanning, over 10 percent of the institutions charged a standard fee whether an examination used contrast material, no contrast material, or a combination of the two (265). The other 90 percent levied an additional charge for the use of contrast material. Experience indicates that about 60 percent of CT examinations involved scans with contrast material, either alone or in addition to scans without contrast material. About **60** percent of the institutions charged more for a contrasted scan when performed without an uncontrasted scan, than for an uncontrasted scan alone.

In **1976,** fees for CT head scans covered a wide range. Surveys reported averages of **$240, $244, and $260** for both technical and professional charges **(29,159,265) (table 18). The lowest total** charges were found at the Cleveland Clinic: **$100** for a scan without contrast material, $135 for a scan with contrast, and $175 for scans with and without contrast **(102).** The highest total charge reported was $325 without contrast and $476 with and without contrast (265).

Average fees for body scans were slightly more than for head scans. The average charge for a basic body scan was *$228,* and the average charge for an examination with and without contrast material was $278 (265). A survey of CT body scanners in 1977 reported higher average total charges: **$273** for a head scan and **$286** for a body scan (158).

Table 18.—Fees Charged for CT Examinations, 1976 (dollars)

Type of Examination and Source	Total Charge		Technical Component	Professional Component
	Average	Range	Average	Average
Head Scans				
Basic scan				
40 sites	205	150-350	155	50
48 sites	220	—	157	63
96 sites	224	175-325	—	—
Scans with contrast				
40 sites	—	—	—	—
48 sites	—	—	—	—
96 sites	243	200-330	—	—
Scans with and without contrast				
40 sites	257	150-440	202	55
48 sites	260	156-410	186	74
96 sites	292	200-476	—	—
Average charge for CT examination				
40 sites	240	—	—	—
48 sites	244	—	—	—
96 sites	260	—	—	—
Body Scans				
Basic scan				
15 sites	228	200-335	—	—
Scans with and without contrast				
3 sites	278	—	—	—

Sources: 29,159,265.

Charges for specific kinds of scans have shown no variation between hospitals and offices. The average charge per examination did vary, however, from $171 in hospitals to $203 in offices (159).

Some evidence suggests that charges have increased over time. Sixteen sites surveyed in 1975 and again in 1976 had increased their charges for uncontrasted scans an average of 8 percent, from $200 to $216. Fees charged for examinations with and without contrast material had risen an average of 12 percent, from $245 to $274. Likewise, some increase had occurred in the percentage of scans with contrast material. In 1975, 35 to 40 percent of patients had scans with contrast material; in 1976 at least half of the same sites reported increased use of contrast material (265).*

*As noted earlier, in 1976 about 60 percent of CT examinations used contrast material

In another 1976 survey, no definite pattern emerged from historical charges reported by five institutions that acquired CT head scanners in 1973 and 1974. Two of the institutions, Massachusetts General Hospital and Cleveland Clinic, have lowered their rates; two others, George Washington University Hospital and the Mayo Clinic, have raised theirs; and one, Mallinckrodt Institute, reported no change (102,186,341,345,349).

Less weight should be given to changes in rates reported in the latter survey because it had a smaller sample of institutions, 5 compared to 16. Furthermore, many of the five are large teaching hospitals, which are perhaps atypical of providers in general. However, increases in charges reported in the first survey also should be interpreted cautiously. The institutional composition of the 16 sites is unknown, and they represented only 9 percent of all scanners installed by the end of 1975.

Annual Profits From Operating a CT Scanner

Average charges for CT examinations have exceeded estimated expenses by 39 to 229 percent. Average total fees reported by different sources range from $240 to $260, and the extremes of estimated technical and professional expenses range from $79 to $173 (table 19). In general, providers initially set fees for CT scanning to cover expenses projected on the basis of about 2,000 examinations yearly for each scanner. But in practice, the use turned out to be much higher, about 3,000 examinations yearly (564). Because the cost of a CT examination decreases with greater use of a scanner, the average cost of an examination was lower than expected, and the gap between charges and costs was greater than expected.

Looking only at the difference between charges and costs would overstate profits (revenue minus cost) from operating a CT scanner. Providers do not receive 100 percent of charges for all examinations. Some examinations are paid on the basis of costs. Parties who provide services directly (the Department of Defense and Veterans Administration) or who reimburse on the basis of costs (Medicare, Medicaid, and some Blue Cross plans) account annually for about 30 percent of all personal medical expenditures. Furthermore, about 45 percent of annual expenditures for hospital services are based on costs or direct provision of services (364,365), and 81 percent of all installed CT scanners documented in May 1977 were located in hospitals. *

The percentage of CT examinations reimbursed on the basis of cost is not clear. Part of the expenditure for a CT examination performed in a hospital is for physician services, typically a charge rather than a cost. Such a charge may be 50 percent or more of estimated technical costs (tables 15 and 17 and appendix IV). Available information also indicates that scanners in ambulatory settings (private offices and hospital outpatient departments) may be used more intensively and hence may account for a higher percentage of examinations than their number would indicate (159). Insufficient data prevent calculation of profits separately for hospital and ambulatory settings.

*Expenditures based on costs included those for hospital services by Medicare and Medicaid, half of the benefit expenditures of Blue Cross, and health service expenditures by the Department of Defense and Veterans Administration. Expenditures based on charges included those for physician services by Medicare and Medicaid, the other half of the benefit expenditures of Blue Cross, all the benefit expenditures of Blue Shield and commercial insurance companies, and out-of-pocket expenditures of patients.

To calculate revenue and profit of a scanner, it is necessary to estimate how much revenue is based on costs and how much on charges. For the portion of a scanner's annual revenue based on costs, the estimates of profit in table 20 use 30 percent, the

Table 19.—Reported Charges and Estimated Expenses of a CT Head Examination[a]

	Range (Dollars)
Average total charge	$240-260
Average total expense[b]	79-173
Average technical charge	174-200
Average technical expense	59-130
Average professional charge	53-70
Average professional expense	20-43
(Annual number of examinations	*2,600-3,000)*

[a]Levels of charges take into account relative use of contrasted and uncontrasted scans. Data are for 1975 and 1976.

[b]Average total expense differs from that drawn from the literature. Half of the sources in table 15 gaveno estimates for professional expenses. Here the extremes of technical and professional expenses were added to produce a more realistic range, especially for the high estimate.

Sources: Table 18 and appendix IV.

Table 20.—Estimated Average Annual Profits From a CT Head Scanner, 1976

[dollars]

	Low	High
Average charge per examination	$240	$260
Average revenue[a]	222	210
(Number of examinations	2,600	3,000)
Total gross revenue	577,200	630,000
Less bad debts	-57,720	-63,000
Total net revenue	$519,480	$567,000
Average total cost per examination	$180[b]	$92'
(Number of examinations	2,600	3,000)
Total costs	468,000	276,000
Average profit	51,480	291,000
(Percent of original purchase price	11	65)

[a]Average revenue= .3 x average cost + .7 x average charge. Based on nonphysician expenditures byMedicare and Medicaid, personal health expenditures by Defense Department and Veterans Administration, and half of benefit expenditures by Blue Cross.

[b]Based on estimate in reference 159 for technical cost and in reference 577 for physician cost. The latter estimates were prorated toa rate of2,600 annual examinations, $50 per examination.

[c]Based on estimatesin reference 577, with physician cost prorated to one radiologist, $33per examination.

Sources: 29,159,265,425, 554,577,584.

approximate percentage of overall personal medical expenditures reimbursed on a cost basis. The difficulty in approximating cost reimbursement underscores the rough nature of the estimating procedure. The cost statistics are themselves estimates, which vary widely among sources. Third parties define costs in different ways. In addition, methods for cost reimbursement are not limited to paying costs, but may include paying costs plus or minus some percentage.

In table 20, estimated annual profits from operating a CT scanner in 1976 range from $51,000 to $291,000. The high boundary was constructed from high charges and low costs, and the low boundary from low charges and high costs. Bad debts were estimated at 10 percent of gross revenue, an average of estimates in the literature. It is interesting to note that a profit results even with low charges and high costs. For a scanner priced at $450,000, estimated annual profits range from 11 to 65 percent of the original purchase price.

The estimates of profits in table 20 are approximations of average profits. Any one institution might have charges and costs outside the high and low boundaries. As noted previously, institutions have reported total fees as high as $476 with and without contrast material (29,265) and as low as $100 without contrast (102).

Evidence presented above indicates that fees have tended to increase over time (265) despite the gap between charges and costs and the resulting profits from operating a CT scanner. The gap between charges and costs does not deter use of scanners because use depends on decisions of physicians who order, but do not pay for, scans. When paying charges, third-party payers do not look at profit margins, and individual consumers are unable to affect providers' prices. In general, there is little stimulus from competition and free entry for fees to approach costs. However, there may be some competition among radiologists, especially in large urban areas with several CT scanners.

Although economic forces will not necessarily lead to lower profits over time, regulatory and political factors may have that effect. In some areas of the country, State rate review commissions are examining the gap between charges and costs. The Massachusetts Rate Setting Commission, fen- example, suggested that fees of physicians for CT scanning be reduced because annual use of scanners had increased (564). The Commission has, in fact, lowered allowable rates for scanning in some cases (346). Such instances, although rare, illustrate the potential effect of rate review on fees.

In addition, providers appear somewhat cautious about cost and price increases in an attempt to avoid formal regulation, especially after restrictions experienced under the Economic Stabilization Program (423). Massachusetts General Hospital and Cleveland Clinic have lowered their rates. They attributed their decisions to greater use of scanners and hence higher profits than originally expected (102,345). Cleveland Clinic also noted that it had paid off the original cost of a scanner installed in 1974 before reducing rates in 1975 (102).

Of course profits per se are not grounds for concern. A provider's profits from CT scanning may be counterbalanced by losses from other technologies. The level of profit is also likely to change over the history of a technology. At issue are net expenditures on CT scanning and, if net expenditures are positive, whether the extra benefits are worth the extra expenditures.

Gross and Net Expenditures

Estimated expenditures on CT examinations alone ranged from $189 million to **$206** million in 1976 (table 21). In addition, expenditures for patients who were hospitalized while waiting for CT scans brought estimated total expenditures to $278 million to $377 million. ' Expenditures associated with hospitalization thus accounted for about 30 to 45 percent of total expenditures.

Net expenditures on CT scanning are those that remain after subtracting from total expenditures the savings that resulted from the replacement of other diagnostic

*These estimates used the mix of costs and charges in table **20; 327** scanners, the number installed by June **1976; 46** to **51** percent of examinations performed on inpatients; and a wait of **1.6 to 2.2** days for inpatients to receive a scan. Excluded are standard diagnostic tests performed on all inpatients. Also, calculations assume the extra hospital stay occurred only because of the wait for a CT scan. To the extent that other required procedures are performed during the wait, expenditures for CT scanning are overestimated. To the extent unnecessary procedures are added during the wait, expenditures connected with CT scanning are underestimated.

Table 21.—Estimated Expenditures for **CT** Scanning, 1976
[thousands of dollars]

	Low	High
Based on costs and charges'		
Expenditures, all scanners	**$188,744**	**$206,010**
Hospital day expenses[b]	**81,459**	**143,286**
Inpatient physician charges[c]	**7,917**	**27,853**
Total expenditures on CT scanning	**$278,120**	**$377,149**
Based on charges only [d]		
Gross expenditures, CT examinations (Includes scans, hospital days, and inpatient physician visits)	**$293,425**	**$426,199**
Reduced expenditures (Includes reduced tests, hospital days, and inpatient physician visits)	**– 113,318**	**– 38,336**
Radionuclide brain scans	**-37,499**	**– 17,375**
Pneumoencephalograms	**-53,944**	**- 8,790**
Arteriograms	**-21,875**	**-12,171**
Net expenditures on CT scanning	**$180,107**	**$387,863**

[a] Based on **the mix of costs and charges of CT examinations from table 20 for 327 scanners, the number Installed by June 1976.**
[b] **Based on 274 hospital scanners, 46 to 51 percent of hospital examinations for inpatients, a wait of 1.6 to 2.2 days, and adjusted hospital day expenses of $155.36.**
[c] **Based on 1 to 2 physician visits per hospital day by an internist charging $15.10 for a followup hospital visit.**
[d] **Based on charges, not costs, of procedures, except for hospital day expenses. See appendix V for calculations.**

Sources: 29, 82, 159, 241, 507.

procedures by CT scanning. Estimated net expenditures on CT examinations ranged from $180 million to $388 million (table 21). Calculation of net expenditures was based on charges alone, rather than the mix of costs and charges used in table 20 and in the first part of table 21, because cost data for other procedures were not available. Substituting CT examinations for radionuclide brain scans, pneumoencephalograms, and arteriograms reduced average expenditures by an estimated $38 million to $113 million, or 9 to 39 percent. These estimates are rough, but the range includes the most likely figures. They make no allowance for reduced hospitalization independent of reductions in alternative procedures and do not differentiate between head and body scanners.

CT scanning has the potential to reduce expenditures further for other services and procedures. Patients receiving scans do not require hospitalization for the procedure itself, whereas arteriograms and pneumoencephalograms necessitate hospitalization. CT scanning subjects patients to less danger and discomfort. Furthermore, the marginal cost of a CT examination, which can be derived from the figures in table 17, falls below $50 with an annual utilization rate of 3,000 examinations or more. These data suggest a need for exploration into the costs and benefits of using CT scanning compared to alternative procedures.

Three studies* have attempted to evaluate the cost-effectiveness or cost-benefit of CT head scanning as compared to other neurodiagnostic tests (160,440,538). All concluded that CT scanning lowered diagnostic costs while permitting diagnoses of equivalent accuracy. They found a decrease in hospital use due to CT scanning for a specific diagnosis, procedure, or department. However, they did not report whether hospital use changed overall. One study (538), for example, estimated only potential savings from CT scanning and stressed the necessity of closing facilities, such as hospital wards, to achieve actual reductions in use and expenditures for medical care in general.

Two other surveys of actual hospital use reported that 46 to 51 percent of patients scanned were inpatients, with ranges from 11 to 90 percent (29,82). None of these studies indicated whether changes in patient mix occurred after a hospital acquired a CT scanner. This information is necessary for evaluating the effect of CT scanning because patient characteristics greatly affect use and expenditures. Trends that existed before the introduction of CT scanning are also important. As noted earlier, some authors have reported declines in pneumoencephalography prior to and independent of CT scanning (4,33).

A study sponsored by EMI in 1977 investigated the costs and benefits of CT body scanners and concluded that they could reduce the costs of making certain diagnoses if used at the optimal time so that prompt diagnosis and treatment resulted. Costs could be reduced by eliminating other tests, shortening hospital stays and obviating surgery. The study, then, described typical and optimal courses of diagnosis and estimated possible savings, but did not present any evidence that savings had in fact occurred (149).

*Another study being conducted by Arthur D. Little, Inc., for Ohio Nuclear concerns the actual cost savings from the use of CT head scanning in cranial diagnosis. Arthur D. Little is also investigating body scanning for Ohio Nuclear (480).

GOVERNMENTAL AND NONGOVERNMENTAL REIMBURSEMENT POLICIES

Third parties in the United States pay two-thirds of all personal medical care expenditures and nine-tenths of expenditures for hospital care **(364).** The percentage paid by third parties for CT scanning probably falls somewhere between these two extremes since scans can be performed on an inpatient or ambulatory basis. No available information refers specifically to CT scanning. The policies of Medicare and some private third parties that have withheld reimbursement for CT body scans may have resulted in a lower percentage of body scans paid by third parties.

For all personal medical expenditures, Government programs have accounted for the largest share of third-party payments, 40 percent, compared to 27 percent by private insurance companies. For hospital care, Government programs have paid an even larger share of expenditures, 55 percent, compared to 36 percent by private insurance. The largest Government effort is Medicare, the Federal program for the aged and disabled. It accounted for about $15 billion, or 15 percent of all personal medical expenditures in 1975. Medicaid, under which the Federal Government provides matching funds to States for medical care to welfare recipients and the medically indigent, spent $13 billion or 13 percent of all personal medical expenditures in 1975 (364,365). All payments under Medicare, Medicaid, and Maternal and Child Health programs must be compatible with section 1122 (see chapter 4) and section 1151 (PSRO program; see chapter 5) of the Social Security Act.

Linking Reimbursement With Efficacy

Historically, third-party payers have made few attempts to link reimbursement with a determination of the efficacy of a new technology. With CT scanning, however, Medicare and some individual Blue Cross and Blue Shield plans have made reimbursement for head and body scans conditional upon an appraisal of their efficacy. These programs have also begun to link reimbursement of other services to a determination of their efficacy, a development that appears to indicate a new direction in reimbursement policy.

The Public Health Service evaluates the efficacy of technologies for Medicare under section 1862(a)(l) of the Social Security Act. That section states that Medicare shall pay for services only if they are reasonable and necessary for the diagnosis or treatment of illness or injury or for improved functioning. The Social Security Act thus restricts consideration of benefits to diagnosis, treatment, and functioning and apparently restricts the definition of efficacy of diagnostic technologies to Fineberg's third level, diagnostic accuracy. To put into effect any other definition of efficacy would appear to necessitate a change in the law.

The Public Health Service provides advice on efficacy under an interagency agreement with the Medicare program. For drugs, Medicare limits its coverage to the indications for use that the Food and Drug Administration (FDA) approves for labeling. Until the reorganization of the Department of Health, Education, and Welfare (HEW) in 1977, advice about the efficacy of other medical technologies was provided by the Bureau of Quality Assurance (BQA) of the Health Services Admin-

istration. Although Medicare is exploring the possibility of relying on FDA for advice about medical devices, FDA's experience under the 1976 Medical Devices Amendments is not yet sufficiently advanced to provide a basis for Medicare coverage.

In recommending whether or not a service should be covered by Medicare, BQA considered four factors: safety, efficacy, acceptance by providers, and stage of development. BQA had no formal, systematic mechanism for making these decisions: it identified certain Federal agencies, representatives of professional associations, and others and asked for their judgments. Its decisions were not necessarily based on formal studies, although if available, such studies were sometimes used.

Thus, BQA was an important decisionmaking agency in determining Federal policy about use of a new medical technology, even though it gave advice only when asked by the Medicare program. Under the 1977 reorganization, BQA was made part of the new Health Care Financing Administration, and its name was changed to Health Standards and Quality Bureau. At the same time, the responsibility for making recommendations on efficacy was left in the Public Health Service. This activity was subsequently assigned to the Office of Health Practice Assessment in the Office of the Assistant Secretary for Health.

After receiving advice form the Public Health Service, Medicare conveys its decisions to the intermediaries and carriers, who are responsible for implementing them. Carriers and intermediaries notify physicians and hospitals of coverage policies and institute administrative mechanisms to monitor compliance. Because of the large volume of services involved, especially drugs, implementation depends ultimately on the good faith of providers and the possibility of a future audit.

In 1973, the Bureau of Health Insurance (BHI), which administers Medicare, refused to reimburse for CT scans on grounds that CT scanning had not been established as a reasonable and necessary procedure (496). Such a course of action is open to Medicare under section 1862 of the Social Security Act. At the same time, BHI sought the advice of BQA, which advised Medicare that it considered head scanning an efficacious procedure, BHI then authorized reimbursement by Medicare for head scans. Because the data examined by BQA had pertained only to EMI machines, only EMI scans were authorized for reimbursement, Although other manufacturers began marketing scanners in 1974, Medicare reimbursement for CT scans was formally limited to EMI machines until October **1976. At** that time, BHI changed its policy to authorize Medicare payment for scans performed on machines of several additional companies. Medicare coverage was later broadened to include head scans performed on both head and body scanners, but not body scans themselves. The issue of body scanning is still under consideration; coverage is expected for specified medical conditions.

At the Federal level, Medicaid does not consider efficacy in reimbursing for its share of expenditures. The States decide whether to pay for new procedures, and Federal administrators honor the States' decisions. No information has been compiled on the manner by which the 53 Medicaid regions make these determinations (510).

Blue Shield and Blue Cross plans contract directly with hospitals and physicians for payment of services to their beneficiaries. Provisions of contracts allow Blue Shield plans to exclude reimbursement for experimental procedures or to limit reimbursement to procedures considered part of accepted medical practice. The

national Blue Shield Association consulted with American College of Radiology (ACR) about the efficacy of CT head and body scanning. On the basis of that advice, the national Blue Shield organization advised individual Blue Shield plans to pay for CT head scanning only (374). Until 1977, the national Blue Shield advised against reimbursement for CT body scanning on the grounds that insufficient data supported its efficacy (91). In June 1976, only four of the 50 Blue Shield plans were reimbursing for CT body scans (374), In April 1977, ACR endorsed CT body scanning. Although Blue Shield is not bound by the decisions of ACR, in September 1977, Blue Shield's Board recommended that individual plans reimburse for body scanning. At the same time, the Board recommended that the plans establish local standards of appropriate medical indications for using body scans (174).

Under its Medical Necessity Program, Blue Shield has become more active in linking reimbursement with efficacy. In May 1977, the national Blue Shield Association announced that it would pay for **30** procedures only when physicians justified their medical necessity. The list included diagnostic and surgical procedures that were said to be outmoded, redundant in combination with others, unlikely to yield additional information through repetition, and of unproven value. Three societies of medical specialists helped to develop the program: the American Colleges of Physicians, Radiology, and Surgeons. Blue Shield planned to expand the list of procedures of undemonstrated effectiveness in the future (257, 35 I).

Individual Blue Cross plans, like those in Blue Shield, decide whether CT scanning is a reimbursable category. In November 1976, at least three Blue Cross plans were refusing to reimburse for body scanning because clinical evidence about its appropriate use was lacking. Individual Blue Cross plans vary greatly in the way they decide upon reimbursement for CT head and body scans. The Arizona Blue Cross-Blue Shield plan reimburses for CT scanning only for particular medical conditions. Some plans reimburse for CT scanning in general, and others base their decisions on the opinions of medical advisors (67).

Like Blue Shield, the National Blue Cross Association has also become more actively concerned with efficacy. In late **1976,** Blue Cross requested the Institute of Medicine to examine the policy implications of CT scanners. Linking reimbursement with efficacy, the Institute of Medicine recommended that third parties pay for CT head and body scanning when used appropriately. The report further recommended that usual standards of clinical practice be accepted as criteria of efficacy (258).

In their contracts with and payments to consumers, commercial insurance companies historically have not questioned appropriate use of particular technologies when used under a physician's direction. And individual patients who pay out-of-pocket for scans are inclined to accept physicians' judgments concerning the advisability of a procedure and to pay for charges as billed.

Third-Party Coverage

Third-party coverage affects total expenditures for CT scanning. Such coverage influences the setting in which CT scans are performed and the use of other procedures. If coverage extends to inpatient but not ambulatory diagnostic procedures, providers and patients are encouraged to favor hospitalization. Increased hospitalization would produce greater revenues for providers and lower out-of-pocket expenses for patients but higher per capita expenses. In contrast to ambulatory use, performing CT scanning on an inpatient basis increases total expenses and charges for a patient's medical care because of the costs of inpatient care and additional physician services. These related services taken together greatly raise total expenditures attributable to CT scanning. Running multiple diagnostic tests also results in greater expenditures for a patient work-up. Coverage that applies to diagnostic procedures as a category offers no incentive to substitute less costly procedures for expensive ones of equal value.

Third-party coverage typically does not encourage substitution of procedures on the basis of either lower costs or extent and accuracy of information. Incentives concerning hospitalization vary among third parties. Under Medicare, * a patient receiving a CT scan must pay a deductible for inpatient care (under Part A) or a deductible and coinsurance for ambulatory services (under Part B). For inpatients under Part A, Medicare pays 100 percent of the reasonable cost or charges of the CT scan itself and for ambulatory patients under Part B, 80 percent of costs or charges after the deductible. A patient who had no deductible for Part B accumulated for the year would probably be indifferent about the expense of being scanned as an outpatient or an inpatient. But a patient who had already met the deductible under Part B would pay less out-of-pocket for an outpatient scan. Section 1151 of the Social Security Act, which pertains to Professional Standards Review Organizations, restricts payment for inpatient services. Medicare and Medicaid are authorized to pay for services on an inpatient basis only if they cannot be provided effectively on an outpatient basis.

Although Medicaid covers the expenses of hospitals and staff physicians, the extent of coverage varies among States. For nonhospital physicians, Medicaid uses the reasonable and customary charge of physicians as an upper limit for the State's payment and often pays them much less than the upper limit.

Blue Cross plans typically cover inpatient diagnostic services and would therefore reimburse for CT scans on inpatients. Outpatient coverage would depend on a particular subscriber's policy. Most Blue Shield plans pay for the charges of physicians who are not on hospital salary and for some outpatient services. These plans would therefore pay the professional fees of nonhospital physicians for inpatient scans. Blue Shield plans, with appropriate coverage for diagnostic procedures, would pay professional fees of nonhospital physicians for outpatient scans in hospitals, and would pay both professional and technical fees for scans in physicians' offices (67).

Commercial insurance companies usually cover diagnostic services such as CT scans for inpatients, while coverage for outpatients is subject to more variation.

*Bills submitted for Medicare payment of inpatient services do not clearly identify the procedure. Consequently, it is difficult to distinguish a CT scan from another radiological procedure (106).

According to a small sample of companies, payment for CT scans ranged from 70 to 100 percent of total charges (29).

Retrospective Reimbursement

For the most part, third parties reimburse retrospectively, that is, they pay for costs after they have been incurred or charges after billing. Because of this policy, third parties often have an open-ended commitment to finance covered services that are provided.

Payments related to providers' *costs* are almost entirely based on those already incurred. Such payments include those by Medicare and Medicaid for institutional services (Parts A and B), about half of the benefit expenditures of Blue Cross, and medical services expenditures of other governmental agencies, such as the Department of Defense and Veterans Administration, that provide medical services directly to patients. Cost-based reimbursement for CT scans by Medicare, Medicaid, and Blue Cross would apply to costs incurred by hospitals in the course of performing the procedure. Both Medicare and Medicaid pay that portion of costs attributable to their own patients, but may use different definitions of costs. Cost-related formulas used by Blue Cross plans may have several bases, such as reasonable costs, costs plus a certain percentage, or costs minus a certain percentage.

Payments based on charges billed by providers include those of Medicare and Medicaid for physician services and certain noninstitutional ambulatory services, the other half of the benefit expenditures of Blue Cross, most of the expenditures of Blue Shield, payments by commercial insurance companies, and out-of-pocket payments by patients. Charge-based reimbursement could apply to CT scans in both hospitals and physicians' offices.

Several third parties use some variation of the "usual, customary, and reasonable" approach when paying charges. In some cases, limits apply to the charge for a service, but additional numbers and kinds of services may be performed. Medicare (under part B) pays "reasonable" charges for physicians' services. In establishing what is reasonable, Medicare compares the physician's customary charges with charges prevailing in the area for the specific service. Payment is then limited to the 75th percentile of the customary charges in the area (259). Under "assignment," physicians agree to accept as total payment for a service the limit determined by Medicare. The proportion of claims for which providers accepted assignment had fallen to 52 percent by 1975 (197). If a physician does not accept assignment, the patient is liable for any difference between the physician's charge and Medicare's limit. Medicaid uses "usual and customary" charges in an area as the ceiling for payments to physicians. Medicaid typically pays a smaller proportion of usual and customary charges than Medicare, and only a small fraction of physicians accept assignment under Medicaid (54).

For about half of its business, Blue Shield uses fee schedules or pays usual, customary, and reasonable charges up to a certain percentile. The rest consists chiefly of indemnity payments (374). Commercial insurance companies usually pay either indemnity payments or physicians' charges subject to coverage of specific policies.

Patients who pay out-of-pocket are liable for whatever providers bill for their services.

Recent activities by Blue Cross and Blue Shield indicate that they plan to take a much more active role in controlling expenditures. Blue Cross plans in May 1977 unanimously approved a program that requires each plan to put into effect certain measures to control costs. Each plan must keep data on and try to affect key statistics on use and expenditures. Programmatic requirements include multilevel claims review, educational programs for subscribers, investigation of fraud and abuse, and participation in health planning. Requirements also call for each plan to explore alternative payment systems by such methods as demonstration projects or comparison of costs under alternative payment methods. The national Blue Cross Association will monitor the effort and provide technical assistance as needed. The measures adopted were developed as part of a joint effort with the Blue Shield Association. Blue Shield plans have adopted similar standards aimed at cost control **(68, 35 I).**

Fee-for-Service Payment

Under the fee-for-service method of payment, providers receive more revenue from a service with a higher fee. Thus, relative charges can affect use and total expenditures. When the fee is higher for contrasted scans, providers have an incentive to perform more of those scans. In 1976, 90 percent of the institutions with scanners charged extra for scans with contrast material **(265).** One study examined relative fees and use of contrasted scans. But that study failed to give any information about other relevant factors, such as patient characteristics, that might have prompted use of contrast material independently of fee structure (159). Therefore, no conclusions may be drawn.

No third-party reimbursement policy considers relative prices of CT scans and other neurodiagnostic procedures. Therefore, third parties give providers and patients no incentive to prefer less costly substitutes.

Prospective Reimbursement

Prospective reimbursement on the basis of costs or charges exists, but mostly on a small and experimental scale. Prospective reimbursement refers to payment according to rates set prior to the time during which they apply; the unit of payment (case, physician visit, hospital day, plan member, institutional budget) may vary. In **1976,35** Blue Cross plans were engaged in prospective reimbursement, in some cases as an option for hospitals or as part of an experiment.

Some States have attempted to review the appropriateness of rates prospectively. The jurisdiction of State rate review bodies has usually been limited to hospitals. The potential and actual authority connected with rate review varies greatly among States. Of course, State laws do not apply to Medicare payments by the Federal Government. Laws in Massachusetts, Washington, and Maryland cover rates paid by other

purchasers of services, including self-payers (individual patients who pay out-of-pocket). * New York and New Jersey set rates for Blue Cross and Medicaid, but not for Medicare and self-payers. Indiana and Rhode Island have voluntary systems (344). As mentioned previously, the Massachusetts Commission has recently lowered some of its approved rates for CT scanning.

Medicare prospectively sets limits on its payment of routine operating costs to hospitals. Under a provision of section 1861 of the Social Security Act added in 1972, Medicare determines in advance limits that will apply, usually for the coming year. Limits vary according to bed size, SMSA or non-SMSA area, and per capita income of the area. Only about 750 hospitals have in fact had their payments limited under this provision. It is notable that only operating costs are restricted. Since other costs, such as costs of ancillary services, are not restricted, hospitals could channel costs into those categories (352, 508).

The Health Care Financing Administration in HEW is funding demonstration projects involving prospective reimbursement under the Social Security Act. A project in the State of Washington, for example, is comparing the results under prospective reimbursement of total budgets for hospitals, prospective reimbursement by hospital departments, and continuation of present retrospective reimbursement. The Maryland Health Services Cost Review Commission has a contract to review budgets and rate structures using a public utility approach. In the area of Rochester, N. Y., 23 hospitals together plan to stay within a total community budget rather than focusing on costs or charges of a single hospital. Other demonstration projects are taking place in Massachusetts, western Pennsylvania, Connecticut, New Jersey, and California (514).

The objective of section 1526 of the National Health Planning and Resources Development Act of 1974 is to evaluate the feasibility of rate regulation by State planning agencies. This section authorizes the Federal Government to award demonstration grants to a maximum of six State agencies. Provisions of the Act and proposed regulations go beyond the mechanics of rate review to the implications of reimbursement methods. For example, proposed regulations for awarding grants consider the extent to which a State agency offers positive and negative incentives for efficient and appropriate use of services (514).

In September 1977, final approval of the regulations was imminent. However, grants can be made only to fully designated State agencies, and no State agencies have been fully designated. Some State agencies will pass from conditional to fully designated status in mid-1978. Only then may they apply for these demonstration grants. Awards of grants and implementation of the program stretch further into the future (506).

*Connecticut's law technically applies only to commercial insurance companies and self-payers. To the extent that a hospital's costs are equal to or greater than charges, some cost-based payers pay the lesser of costs or charges, Connecticut rate review affects such cost payers as well (IIS). Under an experimental program in Maryland, Medicare is following decisions of the State cost review commission **(54).**

SHORTCOMINGS OF REIMBURSEMENT POLICIES

Because third parties, the Federal Government in particular, account for such a large portion of personal medical care expenditures, they have the potential to restrain expenditures on medical care and to channel funds into efficacious services. The data for CT scanning indicate that, although third parties have increasingly been taking an active role, they have not fully realized this potential.

Public and private third parties reimburse for services that have already been provided. Review processes question whether claims may be reimbursed in light of limits on services covered and expenses allowed, rather than whether production is efficient. Third parties then act as intermediaries in passing on any increased expenditures resulting from higher use or costs. Private companies raise health insurance premiums for subscribers, and governments increase taxes or decrease expenditures for other sectors of the economy.

In some cases, Federal and private programs have tried to link reimbursement of CT scans with efficacy and are exploring similar requirements for other procedures. But their efforts have been handicapped by inadequate procedures of evaluation and insufficient data. The Bureau of Quality Assurance did not consider itself well qualified to advise Medicare about new technologies (502), The Bureau had no formal mechanism for arriving at decisions about CT scanning. A small staff of one or two people, little money, and no formal procedure are problems that will continue under the new Office of Health Practice Assessment. Third parties interested in efficacy and appropriate utilization have often relied on medical advisors. But the medical profession itself has had insufficient information on appropriate indications for CT head scanning, as chapters 3 and 5 have discussed.

Apart from the issue of efficacy, this study of CT scanning illustrates the perverse incentives of reimbursement policies for medical care delivery in general. These policies have not been structured to encourage efficiency or to heighten concern about increased expenditures on CT scans or other medical services. Retrospective reimbursement, by costs or charges, existing third-party coverage, and fee-for-service payment all stimulate providers to increase services and result in higher expenditures. Payment methods generally fail to encourage efficiency or cost-consciousness by providers.

The experience of Kaiser-Permanente in Northern California is noteworthy as a contrast. Kaiser-Permanente receives a predetermined cavitation (per patient) payment that remains fixed regardless of the number of services provided. In Kaiser-Permanence's budget during **1976,** CT scans added to expenses, but not to revenue. Kaiser did not own a CT scanner, but ordered about 2,500 annual examinations from outside providers, at the rate of **1,900 examinations** per million population for its 1.3 million members. Under the assumption that 3,000 annual examinations have been the equivalent of one scanner, Kaiser-Permanente has been using the equivalent of **0.65** scanner per million population. That rate is roughly **23** percent of the California rate of 2.8 scanners per million population, and 50 percent of the national rate of 1.5 scanners per million population. Kaiser-Permanente's rate of 1,900 examinations per million population compares to 8,400 estimated examinations per million in California. Standardization for age would raise Kaiser's relative rates: the Kaiser-Permanente membership has fewer persons **65 years and over than** California's population (4.9 percent compared to 7.8 percent). Kaiser also expects an increase in use after installation of its own scanner (283) because it will then internalize expenses

instead of paying charges to outside providers. Even with these qualifications, utilization under the Kaiser-Permanente system has been dramatically lower than that for the State or the country.

In contrast to Kaiser-Permanente's method of payment, retrospective reimbursement of services by costs or charges gives providers an incentive to order additional tests to gain revenue. It also provides no incentive for physicians and hospitals to try to lower costs of performing a CT examination by, for example, using a scanner more intensively. Existing reimbursement mechanisms contain no incentives for a CT examination to be performed when possible on an ambulatory basis. In fact, coverage, billing methods, and reimbursement policies often encourage the provision of scans on an inpatient basis, the more costly manner. In the absence of a budget or fixed payment, providers have no need to consider total costs when choosing which neurodiagnostic procedure to order for patients. Undercurrent policies, providers are reimbursed for many tests performed, even if some provide the same or little additional information. No mechanism stimulates providers to make trade-offs between increased information and increased costs.

7.

POLICY ALTERNATIVES

7.

POLICY ALTERNATIVES

The computed tomography (CT) scanner is a new diagnostic device that represents an important advance in medical detection. Studies show that CT scanners perform reliably and provide accurate diagnoses of abnormalities in the head and abdomen. As a relatively safe and painless procedure, CT scanning can replace several less safe and more painful technologies, such as pneumoencephalography. CT scanning has been readily accepted by the medical profession, and its use is expanding rapidly. To the extent that a fundamental problem with CT scanning exists, it lies not in the existence of the technology, but in its appropriate use.

Although this study focuses on CT scanners, its findings are applicable to the general problem of appropriate use of diagnostic medical technologies. Appropriate use includes considerations of safety, efficacy, and cost. Overuse of a technology may lead to both excessive expenditures and unwarranted risk to patients; underuse may result in delayed detection or prolongation of medical problems. In either case the study demonstrates basic policy problems related to the appropriate use of medical technologies.

Use of a diagnostic medical technology such as a CT scanner depends on many factors: some increase and others restrict use. A principal and obvious factor is the desire of physicians to provide good care for their patients. Attempts to identify medical problems and to refine diagnoses lead physicians to use the technologies available to them. Medical education also predisposes physicians to liberal use of diagnostic technologies by emphasizing thoroughness rather than discrimination and concern for costs. The current medical malpractice situation further encourages the use of diagnostic tests to avoid error. In some instances patients themselves request that physicians perform diagnostic tests. Although these are important issues, this report has not addressed medical education, malpractice, and patient demand. Rather it concentrated on available information, governmental regulation, and financing.

After their formal training, physicians continue to receive information about medical technologies from scientific meetings, professional publications, colleagues, manufacturers' representatives, and their own clinical experience. Two Federal agencies, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), develop and disseminate such information. By law, manufacturers of drugs and medical devices must submit to FDA data that supports claims made in labeling. NIH conducts evaluations of certain medical technologies and makes the results available to the public. However, as illustrated by this study, no single Federal or private policy establishes a formal, systematic process to develop needed information about medical technologies. Nor is there a clearly defined mechanism for disseminating what is known to all appropriate parties.

Without such information, physicians appear to test new technologies using a variety of methods to develop a sense of their worth empirically. Unfortunately, these methods are often not designed to yield statistically reliable information. This informal experimentation can both retard the early application of valuable technologies and advance the use of questionable ones. Without valid information obtained from well-designed studies, physicians face a very difficult task in deciding on the appropriate use of new technologies.

Prevailing methods of financing medical care provide incentives for additional use of technologies, regardless of their marginal value. Health insurance programs have continued previously existing fee-for-service payment of physicians; performance of additional tests thereby generates additional revenue for the physicians. Hospitals are reimbursed on the basis of their costs or charges. These methods at the least facilitate and at the most stimulate providers to prescribe additional use. Under such a system, providers have little incentive to weigh the benefits and costs of additional tests.

The regulatory framework created by FDA, the Professional Standards Review Organizations (PSROs), and capital expenditure laws also affects the use of medical technologies, in a restrictive sense. FDA requires proof of safety and effectiveness before drugs and devices may be marketed. The PSRO program was designed to establish norms and standards for hospital utilization and medical care provided under Medicare and Medicaid. And review of proposed capital expenditures is aimed at avoiding unnecessary duplication of facilities and promoting their efficient use. Unlike many of the other factors affecting technologies, these programs may restrict their use. The PSRO program and capital expenditure review were created in part to counter incentives for greater use, especially from financing methods.

The following sections present alternatives that might improve the use of medical technologies such as CT scanners. The alternatives are presented in three sections, each addressing a specific category of governmental policy: Section 1 focuses on developing and disseminating information on efficacy and safety; Section 2 on regulatory policies; and Section 3 on financing. The alternatives in each of these sections illustrate, but do not exhaust, possible options. Nor are they necessarily mutally exclusive. Each alternative should be measured against the continuance of current policies and their consequences as well as against the consequences of the alternative itself. These alternatives represent broad guidelines for policy. As such, they do not consider in depth the more technical aspects of implementation, such as the mechanisms for evaluating efficacy, specific criteria for utilization review, methods of cost accounting, or details of ratesetting.

1. INFORMATION ON EFFICACY AND SAFETY

Many decisions concerning the use of a medical technology depend—directly or indirectly—on an assessment of its efficacy and safety. Much of the available information on efficacy and safety is not derived from well-designed controlled clinical trials, epidemiological studies, or analyses of clinical experience. Instead, informal judgments evolve, judgments based primarily on the experience and perceptions of individual physicians. Judgments of this type, when they do not accurately reflect the efficacy and safety of a technology, may contribute substantially to inappropriate use.

The development of information on efficacy and safety involves identifying the technologies to be studied, conducting the appropriate evaluations, and synthesizing the results of those evaluations and relevant clinical experience. The synthesized information may then be disseminated to the individuals and organizations most in need of guidance. Although simple to delineate on paper, this process of synthesis and dissemination can be complex and difficult to implement.

This section presents two policy options designed to address the needs of medical care decisionmakers for efficacy and safety information. The first concerns the development and dissemination of the information. The second requires the type of synthesis that analyzes information to produce formal policy judgments about a technology's efficacy and safety. This section and the alternatives presented in it are concerned only with developing and disseminating information.

Together, the two alternatives, if adopted, would increase the amount of information available to physicians in their use of medical technologies. It would also be helpful to planners, regulators, and public policy decisionmakers. As explained in alternative 3 of the following section, FDA already requires the development of information and makes certain policy judgments about the safety and efficacy of medical technologies. The alternatives in this section would substantially enlarge these existing processes.

As discussed in chapter 3, information about efficacy is used or could be used by many Federal programs, as well as by providers of medical care. Decisions and policies based on efficacy may now be inconsistent as each user defines efficacy in its own way. As described in chapter 3, only FDA has a formal definition of efficacy at present, and that definition mereIy ensures that the evidence substantiates the claims of the manufacturers. But FDA's decisions on efficacy and safety are of limited value to health planning agencies, PSROs, and reimbursement programs.

A general definition of efficacy could be developed for all types of medical technologies—preventive, therapeutic, and diagnostic. No medical technology is beneficial in all circumstances and some technologies can be extremely beneficial only if used in very limited situations. Therefore, the efficacy of a particular technology must be related to a defined population, a given medical problem, and particular conditions of use. A complete specification of efficacy encompasses all three of these factors. *

> Alternative 1: Establish a formal process to identify medical technologies that should be assessed for efficacy and safety; conduct the necessary evaluations; synthesize the results from the evaluations and from relevant clinical experience; and disseminate the resulting information to appropriate parties.

Except for new drugs and, potentially, new medical devices, the Federal Government's identification of technologies warranting study occurs in an ad hoc manner. Often, decisions to evaluate a technology depend on the curiosity of investigators or Federal program administrators. Few efforts have been made to coordinate the selection of technologies to be studied with the informational needs of relevant governmental agencies and private groups.

*Efficacy is defined as the potential benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. These ideal conditions may be approached in research settings, but are unlikely in average practice. Efficacy, then, represents an outer limit to benefit.

No existing Federal procedure systematically identifies those technologies that are most in need of investigation. Indeed, no formal set of criteria has been developed for establishing such priorities. The private sector identifies medical technologies to be assessed for efficacy and safety through an even more informal process. As described in chapter 6, however, some efforts have been initiated by organizations such as the Federal Health Care Financing Administration and private Blue Cross-Blue Shield to identify and develop information on possibly inefficacious or unsafe technologies.

Various Federal agencies currently have responsibility for conducting or funding studies on efficacy and safety, although in each case their mandate is limited and often ambiguous. The NIH effort is by far the largest; that agency spent approximately $100 million on more than 750 studies during fiscal year 1975. The emphasis at NIH is on new technologies, rather than on those already diffused;* thus, existing technologies receive relatively little scrutiny. Similarly, drugs and biologics receive more attention than devices or medical and surgical procedures.

No Federal policy focuses responsibility for the dissemination of efficacy and safety information. Although NIH and FDA both disseminate substantial amounts of information, their efforts are hampered by various factors. For example, NIH historically lacks working relationships with many of the parties in need of the information. Although FDA obtains information on efficacy of drugs and devices from manufacturers, most of that information is considered to be proprietary and is not released in that form by FDA to the public or to providers. In addition, the information disseminated is often not in a form readily usable by parties in need.

This study of the CT scanner illustrates some of the consequences of using the present informal assessment process. Although the CT scanner has been the subject of much publicity since its introduction, few well-designed evaluations of its efficacy and safety have been conducted. Despite this dearth of information, CT scanning has been more fully evaluated than many other diagnostic technologies.

Instead of continuing the present informal assessment system, the process could be made explicit and formal as indicated by this alternative. The process could be applied to both existing and new medical technologies. With the implementation of an explicit, formal system, criteria could be developed for screening the thousands of existing and future medical technologies to establish priorities for investigation. These criteria could take into account factors now excluded or only minimally included in the process of assigning research priorities. Such factors as needs of health planning agencies and third-party payers and the level of expenditures for the technology could be included in the criteria to be established.

Also, under this alternative, an agency or agencies would be given explicit responsibility for conducting studies of efficacy and safety or ensuring that they are conducted, for synthesizing the results of those trials and other available information, and for disseminating the synthesized information to appropriate parties. (Two bills before Congress, H.R.12584 and S.2466, would create an office within the Department of Health, Education, and Welfare (HEW) to evaluate medical technologies.) The direct anticipated result of this alternative is the production of science-based information for use by medical professionals, policymakers, Government agencies, and the public.

*Diffusion of a technology refers to the process of adoption from development until general acceptance.

This alternative is not designed to change the current processes of introducing and using medical technologies except to increase the amount of validated information available. The present process allows a broad and varied experimentation process to occur with new medical technologies. Through its processes of careful human experimentation, the present system also permits technologies to be used early in their development. Controlled clinical trials, epidemiological studies, and other forms of technology evaluation are often lengthy activities. Thus, the development of information on efficacy and safety can be a time-consuming process. Under this alternative, diffusion and use of a medical technology would not necessarily be postponed until the conclusion of the evaluation process.

Implementation of this alternative could be costly. Controlled clinical trials are expensive: an average trial funded by NIH costs more than $100,000 per year, and those for surgical procedures or expensive technologies may be several times higher. Formalizing activities under this alternative is likely to increase substantially the number of trials because the screening and synthesizing processes would identify problems with technologies and gaps in efficacy and safety information. A large number of medical technologies might warrant careful examination, requiring complete reviews of available information and attention to clinical experience. The process outlined would make cooperative trials (such as many of those of the National Cancer Institute) more feasible, a development that could reduce the magnitude of the increase in the trials.

A distinction can be made between changing the total use of medical technologies and reducing inappropriate use (e.g., of technologies that are underused or overused). This alternative makes the latter possible, though it does not ensure it. Reduction in the use of certain technologies, following evaluation, might be offset by increased use of other technologies, some of which may themselves be unevaluated. The relative magnitude of these three factors—reducing use of overutilized technologies, increasing use of underutilized ones, and the unpredictable shifting of utilization patterns from one technology to another—will in part determine the effect of this alternative on total use of medical technologies and on expenditures for medical care.

Alternative 2: As part of alternative 1, establish a formal process for making official judgments about the efficacy and safety of medical technologies.

Under current law, FDA must determine the efficacy and safety of a drug or device before it can be marketed. No Federal organization is responsible for officially determining the efficacy and safety of medical and surgical procedures. At least two components of the U.S. Public Health Service (NIH and the Office of Health Practice Assessment) are attempting to develop formal systems to synthesize information and arrive at decisions on particular medical technologies.

The synthesis process of alternative 1 could take many forms. It could collect and analyze existing information, or it could attempt to identify gaps in existing knowledge as a guide for further research. Under this second alternative, synthesis would involve collecting and analyzing available information in order to produce official policy judgments about the efficacy and safety of the technologies under examination.

This alternative would establish a process whereby relevant information on a medical technology is critically evaluated. The evaluation would result in a judgment, or policy decision, as to a technology's efficacy and safety. This alternative would be integrated with alternative 1. The judgments could contain detailed information on a wide

range of indications for appropriate use of the technology. Thus, they could be broader than FDA's current determinations for marketing approval.

Providing official judgments to relevant individuals and organizations would add to the information available to them for making decisions. However, those individuals and groups would still make the final decisions. The judgments about efficacy and safety might be issued as guidelines or as recommendations. They would not be binding. This second alternative would only produce information; it would not be a regulatory process.

Such official information might reduce the errors in judgment that such individuals and organizations make. However, mistakes made by the group developing the judgments, while perhaps fewer in number, would have broader ramifications because of their official nature. Since mistakes are inevitable and judgments of efficacy and safety can change as additional information becomes available, this alternative would require a substantial degree of flexibility in operation. The process outlined in this alternative and alternative 1 could be used initially for a small number of technologies to test its feasibility. An evaluation of CT body scanning, for example, could produce judgments about the types of benefits likely to result for certain kinds of patients and specific medical conditions.

This second alternative would almost certainly have an effect on the current medical malpractice situation. The existence of official, though voluntary, statements as to the efficacy and safety of a technology might become the standard for judging whether a provider properly used that technology.

The major controversy surrounding this alternative would be determining the process that would be used to make such scientific judgments. Because such judgments could be used to decide whether a technology is to be reimbursed and where it can be useful, this alternative could become the focus of considerable political and economic pressure. Care would have to be taken to see that the process is both timely and scientifically appropriate.

2. GOVERNMENTAL REGULATORY POLICIES

In an attempt to offset powerful incentives encouraging the use of medical technologies, Congress has established three regulatory programs: the FDA, the PSRO program, and capital expenditures review. FDA regulates the marketing of drugs and devices. Marketing requires prior FDA approval that the technology is safe and effective, and advertising is limited to the approved conditions. FDA does not have authority to restrict subsequent use by physicians or patients. PSROs evaluate appropriateness of care given to Medicare and Medicaid patients. PSROs may establish standards for the use of specific medical technologies, such as CT scanners, although few such standards have yet been developed.

State certificate-of-need laws require prior approval for capital expenditures greater than a certain amount, usually $100,000 to $150,000. Federal and most State laws cover hospitals, but exclude private physicians' offices. In general, capital expenditure laws do not regulate use of facilities or equipment once they are in place. The Social Security Act also restricts payment under Medicare to services that are reasonable and necessary for diagnosis, treatment, or improved functioning.

Inadequate information about efficacy and safety handicaps the effectiveness of these three programs. FDA obtains information about efficacy and safety from manufacturers, but that information is limited to certain uses of the drug or device. PSROs, reimbursement agencies, and State and local planning agencies need information about the appropriate use of a technology—the population benefiting, the medical problems affected, and the conditions of use under which the technology is safe and effective. Further information is required concerning the substitution of a new technology for existing ones. Both the PSRO and the health planning programs are new and not yet fully implemented. In addition, lack of universal coverage facilitates circumvention of these programs.

This section includes alternatives concerning the use of medical technologies, capital expenditure review, and Medicare reimbursement. Alternatives 1 and 2 from Section 1 would facilitate alternative 3 and would be necessary for alternative 4. Alternative 3 would restrict the use of medical technologies to those indications approved by FDA for marketing purposes. Alternative 4 would link Medicare reimbursement to the information and judgments of alternatives 1 and 2. And alternative 5 would expand the regulation of capital expenditures to include all purchases of medical equipment regardless of setting or ownership.

Alternative 3: Authorize a Federal regulatory agency, such as FDA, to restrict the use of medical technologies to the conditions of use specified in the FDA-approved labeling.

When FDA approves a drug or device for marketing, it also approves the specific wording of the product's labeling, i.e., the written information used by the manufacturer to describe the product. Labeling (which includes package inserts) lists medical conditions (and possibly populations) for which the drug or device is deemed to be safe and effective and warns about possible side effects.

These "indications for use" are usually not exhaustive. A manufacturer that has conducted premarketing clinical tests to evaluate safety and effectiveness for defined medical conditions and population groups could then seek marketing approval only for those conditions. Thus, the FDA marketing approval process might consider only a portion of the possible indications or contraindications for a new drug or device.

Use of drugs and devices by physicians and patients, however, is not restricted to the approved conditions. Although the manufacturer provides only the approved information to physicians and other providers, this information is in effect merely advice. Nothing in the law prevents the use of drugs or devices for conditions other than those specified. (A bill before Congress, S.2755, would restrict distribution of drugs to particular providers.)

Uses of a technology for conditions other than those approved by FDA are not necessarily inefficacious. Conceivably, some potentially efficacious uses are not evaluated prior to initial marketing approval by FDA. However, the absence of a particular use from the list of approved uses implies that sufficient information is not available to determine the technology's efficacy for that use.

Examples can be cited of beneficial uses that were neither anticipated nor evaluated by the manufacturer but were later adopted by practitioners. Use of the drug propranolol for treating hypertension (high blood pressure) is such an example. Other unevaluated uses, however, have been shown to be medically unjustified when investigated after the

drug or device was marketed. For example, chloramphenicol has often been used for upper respiratory infections when equally effective and less toxic drugs were available. The balance between positive and negative effects of unapproved uses of drugs and devices is difficult to determine. One factor is clear—unapproved uses usually have not been verified by the rigorous clinical research that is necessary to gain FDA approval.

Allowing physicians to use technologies for unapproved uses has resulted in a *de facto* research or experimentation process. Formal clinical investigations of a new use must proceed under an FDA-monitored Investigational New Drug (IND) process for drugs and under a similar process for devices. Unapproved use by physicians and patients could be considered an unofficial clinical investigation. This result can be either beneficial if a new efficacious use is found or harmful if the use is unsafe or ineffective. Also, aside from the technical questions of efficacy and safety, moral or human rights questions may be raised by this unapproved application.

This third alternative would make FDA decisions binding on physicians. Drugs and devices could be used legally only in accordance with the indications for use specified by FDA's marketing approval. Other uses would be allowed only as part of an approved IND or an investigational process for devices. The investigational process for unapproved uses, the mechanics of which could be similar to the current process, could replace the present practice of unapproved use. A scientific process evaluated by FDA or another agency charged with the task could add validated indications or contraindications to the approved labeling for a drug or device. This alternative is based on marketing approval, which is now limited to drugs and devices; it would not cover medical and surgical procedures.

The indications for use comprise one aspect of efficacy and safety, as noted above. Therefore, this third alternative would be most effective if generally accepted and comprehensive definitions of efficacy and safety were developed. In addition, a publication listing the FDA-approved indications for use of all covered technologies might be necessary to inform physicians who rely on these technologies.

The principal intention of this alternative is to improve the quality of medical care by ensuring more appropriate use of medical technologies. Fewer patients would then be subjected to unapproved and unscientific uses of technologies. Instead, medical technologies would be more likely to be used in accordance with valid scientific information.

A probable consequence of implementing this alternative would be an increase in premarketing clinical investigation to determine appropriate indications for use. The number of such investigations would depend on the proportion of potential uses that had already been investigated.

This alternative could affect the timing of using a technology for a new indication. Use of the technology for the new indication would not be permitted until the experimentation process had been completed (although some use would obviously occur as part of the experimentation process itself). However, once a use had been demonstrated to be efficacious and safe, the manufacturer would be allowed to advertise that use. This advertising promotion might result in diffusion of the new use to a larger number of individuals in a shorter period of time than occurs under the present system. However, if no firm or other organization decided to conduct investigations and seek approval for a particular condition of use, that potential use might go undetected.

The financial costs of this third alternative are not predictable. Additional clinical

trials would increase the costs of bringing a technology to market. The net cost to manufacturers is not clear. They would bear the costs of extra clinical trials, but might receive revenue from additional sales if a new use gained approval. A system of financing additional evaluations of efficacy and safety could be developed, possibly through a combination of manufacturers, patients, and third-party payers. Expenditures for the use of many technologies might fall if third-party payers and patients did not have to pay for unapproved uses. But expenditures on new uses might rise.

Adoption of this alternative would require a system for ensuring compliance. One can imagine very elaborate enforcement measures requiring additional paperwork and specialized personnel that are not readily available. A more simple approach would rely on the good faith of providers. A provider found to be noncompliant would be penalized, but compliance would otherwise be assumed.

The practicality of this third alternative is questionable. Although laws and regulations can mandate this alternative, their enforcement could be cumbersome and expensive. Monitoring, let alone altering, physicians' use of medical devices and drugs is difficult. In addition, the cost of enforcement might exceed the benefits. At a minimum, however, enactment of this alternative might increase providers' awareness of their legal liability in using technologies for unapproved uses and might lead them to operate within the approved investigational process. In fact, approved uses might serve as a basis for liability.

Alternative 4: Link Medicare reimbursement to the information and judgments about a technology's efficacy and safety that would result from alternatives 1 and 2.

Medicare administrators have interpreted the provision of the Social Security Act limiting payment to reasonable and necessary services as allowing Medicare to withhold payment for experimental procedures whose efficacy has not been determined. It was under this provision that Medicare withheld payment first for CT head scanning and then for CT body scanning pending evaluation of efficacy. Historically, Medicare has denied reimbursement for outmoded procedures rejected by the medical community. But Medicare's action on CT scanning used efficacy and safety criteria to make a more controversial decision. And overall Medicare policy supports strengthening the dependence of reimbursement on efficacy and safety. It is Medicare's policy to restrict reimbursement for drugs to conditions of use approved by FDA. FDA's evaluation of devices under the Medical Device Amendments of 1976 does not yet provide a sufficient basis for Medicare action. For advice on procedures and devices, Medicare continues to rely mainly on the Office of Health Practice Assessment of the Public Health Service.

Although Medicare policy links reimbursement to efficacy and safety, major problems remain. As discussed in Section 1, information on the efficacy and safety of devices and procedures is insufficient for reimbursement purposes. These deficiencies range from inadequate clinical data through incomplete syntheses of existing information to the processes used in making judgments. The task of evaluation is much beyond the present capability of the Office of Health Practice Assessment. Besides an inadequate information base, the office has a small staff and no formal process for evaluating technologies. FDA labeling provides more available and useful information on drugs.

This fourth alternative suggests linking Medicare's reimburesement for use of a technology to the information provided by alternative 1 and to the judgments about efficacy

and safety reached under alternative 2. Medicare would not only refuse payment for a technology considered inefficacious or unsafe, but would also limit payment to conditions for which the technology was deemed efficacious and safe. The Office of Health Practice Assessment could continue to advise Medicare. It could secure the relevant evaluations, digest them for Medicare purposes, and point out areas needing further information. Alternatively, Medicare could deal directly with any new office established.

Theoretically, the same procedure could apply to reimbursement under Medicaid, but such a step might require amending the Social Security Act. Although Medicare officials have already decided that the program has administrative authority to deny reimbursement for new technologies, Medicaid administrators are less certain of Medicaid's legal authority at the Federal level. States have the authority to deny Medicaid reimbursement and have exercised that authority.

As a probable consequence of this fourth alternative, judgments about efficacy and safety would affect the use of medical technologies. To the extent that payment by Medicare is important to hospitals, physicians, and patients, all three groups would have an incentive to follow the judgments made. As a result, this alternative could help prevent inappropriate and harmful technologies from being introduced, diffused and used, and could reduce expenditures on them for Medicare patients. At the same time, however, this alternative is less intrusive than directly prohibiting the use of a technology. Providers might use unapproved technologies, but would then simply forego Medicare reimbursement.

Substantial changes in the medical care system could flow from this alternative. The traditional process of third-party payment by Government would change. Government has traditionally left decisions of appropriate technologies and conditions of use to practicing physicians. To the extent that Government reimbursement exerts leverage on providers, this alternative would restrict the use of technologies.

Implementing decisions at the local level to deny reimbursement would pose difficult technical problems. Medicare already transmits to its carriers and intermediaries instructions on particular technologies and conditions of use for which reimbursement should be denied. These Medicare agents in turn have the responsibility of informing providers and enforcing the restrictions. Because of the magnitude of services involved, implementation depends primarily on the good faith of providers and secondarily on selected audits.

Billing practices, for example, make monitoring the use of specific technologies difficult. CT scans may be reported under the general category of radiological procedures. The present level of detail rarely indicates specific drugs or their conditions of use. In theory, Government agents adjust cost reimbursement for institutions to exclude costs of disallowed technologies, such as CT body scans. If implementation of this alternative made these adjustments too intricate and lengthy, the Government might choose to drop cost reimbursement and switch to payment by service, even in institutional settings.

This alternative could substantially lengthen the time required to introduce an innovation into medical practice. As discussed in Section 1, the mere existence of information and judgments might influence the use of technologies. By denying Government reimbursement for unapproved uses of technologies, this alternative would give substance to those judgments. Providers would be reluctant to adopt procedures for which they and their patients could not receive payment. And the longer time required to introduce an innovation would apply to both efficacious and inefficacious technologies.

Linking Medicare reimbursement to more systematic evaluations of efficacy and safety could occur only as a gradual process and over a long period of time. Clinical studies, syntheses, and judgments are all lengthy undertakings. A practical approach would be an incremental process of making reimbursement contingent on comprehensive evaluations as they become available. Or in the case of new technologies, the Government could mitigate the problem of delay by screening and permitting reimbursement for those with the potential to save patients for whom no efficacious technology exists. A new surgical procedure, for example, might be reimbursed for patients suffering from an otherwise fatal condition.

While a new technology is undergoing evaluation, Medicare could pay for it only in designated locations. The choice of centers would have to take into account access for patients throughout the country. These centers could provide data for evaluating the technology; their participation in controlled clinical trials could be a condition of their designation. These trials could generate data for analyzing efficacy and safety without widespread dissemination of the technology .This alternative might reduce innovation because it would make the process of innovation riskier for developers of new technologies. If other third-party payers followed Medicare's lead and if this policy affected use and sales of a technology, innovation could become more risky.

Another consequence of this fourth alternative is that reimbursement would be withheld for patients covered by governmental programs, but not for other patients. Medicare and Medicaid cover certain subgroups of the population because they have greater medical need or less ability to pay. Restricting reimbursement for these patients would probably result in their receiving different services from other patients because many Medicare and Medicaid patients would be unable to pay for their own medical services. Such a consequence could protect these patients from harmful and inefficacious services as well as prevent their receipt of efficacious and safe services. Other third parties such as Blue Shield are starting to make payment contingent on efficacy. To the extent that other insurers followed the same course, Medicare and Medicaid patients might not be restricted more than other patients with insurance.

The Department of Health, Education, and Welfare is already linking reimbursement and efficacy through administrative action, as discussed in chapter 6. HEW's decisions, then, may make congressional action superfluous.

Alternative 5: Expand regulation of capital expenditures to cover purchases of medical equipment regardless of setting or ownership.

Under the provisions of the National Health Planning and Resources Development Act (P. L. 93-641), capital expenditures over $150,000 are subject to certificate-of-need review only if made by specific medical care facilities. These facilities include hospitals and certain categories of ambulatory care facilities, but exclude private physicians' offices. Similarly, section 1122 of the Social Security Act applies to capital expenditures over $100,000 only if made by the same types of facilities. Therefore, unless State certificate-of-need laws authorize such regulation, purchases of equipment by physicians in private offices are not subject to review by planning agencies. At the end of 1977, the laws of only seven States covered physicians' offices.

These State laws encourage circumvention of the regulatory process by treating the same kinds of equipment differently, depending on ownership or setting. Physicians and other individuals may lease or purchase capital equipment, such as a CT scanner, place it

near a facility that is regulated, and be exempt from review. To the extent that the National Guidelines issued under P.L. 93-641 increase the stringency of criteria for regulated providers, the Guidelines will further induce placement of equipment in unregulated settings.

Incomplete coverage of capital expenditures may foil the plans developed by local agencies. A planning agency may decide that a certain number of CT scanners is appropriate for its area and approve that number of applications from regulated providers. Purchase of scanners by other unregulated providers would counteract the local plan, but would lie outside the planning agency's jurisdiction.

This fifth alternative suggests amending current laws to cover capital expenditures over a certain amount, regardless of the ownership or setting where the equipment is operated. A planning agency would then have more complete control over the number and distribution of such equipment in its area. By expanding the regulation of capital expenditures to cover providers such as physicians' offices that are now exempt, the alternative would remove the present incentive for providers to place equipment in unregulated settings. This alternative would not give preference to one setting or form of ownership over another. Planning agencies could still set priorities among applications and exercise discretion over the placement of equipment. (Two bills, S. 2410 and S. 2551, that would so amend P.L. 93-641 are now before Congress.) The Social Security Act and the National Health Planning and Resources Development Act differ in the amount of the expenditure that triggers coverage. Legislation could make these amounts uniform, but that is an issue separate from this alternative.

Broadening the planning provisions under this fifth alternative would necessitate arrangements for physicians to have access to available equipment. Since laws now generally apply to hospitals, any new problems of access would be limited to ambulatory patients; these patients could be transported between facilities. Many planners already include sharing of services in their criteria (see chapter 4). Ensuring access to equipment for physicians might require changes in the legal liability that a medical practice bears. A practice, which is now responsible for its own staff physicians, might otherwise become responsible for the actions of other physicians who are using the facility's equipment.

Implementation of this fifth alternative would increase the workload of the regulatory process. The total number of purchasers of equipment covered by the law would increase substantially, with a probable rise in the number of certificate-of-need applications. Administrative costs of capital expenditure regulation would increase accordingly. To the extent that newly regulated purchasers of medical equipment required additional personnel time to apply for certificates of need, their costs would also rise. One should note that regulated providers already bear the cost of applications.

An increase in the level of regulatory activity could also slow the diffusion of new medical equipment. The implications for quality of care are unclear, since delay would affect efficacious and inefficacious technologies alike. Likewise, the effect on expenditures for a given technology is difficult to determine. The certificate-of-need process may deter some potential purchasers. Later purchasers of new products may benefit from lower prices as a result of competition or decreased manufacturing costs. Or they may face higher prices due to inflation, increased demand, or product development.

A related issue is the effect of this fifth alternative or any such regulation on total capital expenditures. Practical limitations of time and money require a minimum expenditure threshold for certificate-of-need review. But it has already been observed that

regulated providers such as hospitals shift their capital expenditures to less regulated technologies. Such substitution is sometimes possible within the same category of equipment; some models of CT scanners sell for less than $100,000. This situation is part of the larger context wherein a new technology is not necessarily substituted for another. Rather the new are typically added to the store of existing technologies. This alternative, then, will not in itself limit either total capital expenditures on medical equipment or expenditures on the use of that equipment.

3. FINANCING METHODS

The financing of medical care influences use of and expenditures for technologies through incentives to providers and patients and through restrictions on coverage and payment. The Federal financing programs, Medicare and Medicaid, have largely continued the reimbursement methods that prevailed in the private insurance field (see chapter 6). Payment by these programs to hospitals on the basis of costs incurred, and to physicians on the basis of charges, has resulted in an open-ended commitment by these Federal programs to finance the use of covered services.

In the course of financing medical care, public and private third-party payers have restricted the extent of coverage and payment. They have, in effect, defined the product for which they will pay. Medicare and certain private third parties in some cases have limited coverage to efficacious technologies. On that ground, Medicare refused payment for CT body scans. (Setting maximum rates of payment for certain services is more widespread. Medicaid, for example, has placed ceilings on its reimbursement for drugs, and most third parties place some limits on their payment of physicians' charges.) Ironically, Federal financing—like health insurance in general—has encouraged the use of services such as CT scans, but not efficient methods in their performance or their substitution for other services. No restrictive mechanism such as a finite budget induces providers to make tradeoffs between increased information or benefit and increased costs from using technologies. On the contrary, financing methods reward with higher revenue those providers who perform additional services, regardless of their marginal value or efficient performance. As a result, providers have little incentive to choose among alternative procedures or to perform services efficiently. Prevailing third-party payment thus insulates providers as well as patients from the financial consequences of using technologies.

Contained in this section are two alternatives to address problems with current financing methods. Under the first, Medicare and Medicaid would continue to use **costs or** charges as the basis for reimbursement, but would base their rates on efficient methods of performing services. The second alternative would fundamentally change the payment method in order to create incentives for providers to become cost-conscious in using and producing medical services. Although the alternatives in this section are mutally exclusive, either could be combined with alternatives from the previous sections on information and regulation.

Alternative 6: For services paid by Medicare and Medicaid, establish rates of payment that are based on efficiency.

The Department of Health, Education, and Welfare has set limits on routine hospital operating costs and charges of drugs payable under Medicare and Medicaid, respective-

ly. However, reimbursement limits on routine hospital costs are only very generally related to efficiency of operation. And with routine costs of a hospital day limited, hospitals have a strong incentive to allocate costs as much as possible to ancillary services, which are often not limited.

These policies give providers who receive cost reimbursement little incentive to be cost-conscious in their services and production methods. As a result, governmental payments probably exceed those that would result from limits based on a tighter definition of efficiency.

Similarly, reimbursement to physicians is based not on standards of efficient operation, but on charges prevailing in a given area. Nor does governmental policy coordinate payments to hospitals and physicians' offices to ensure comparable payment for comparable services. Medicare, for example, could pay different amounts for the technical component of an ambulatory CT scan depending on the setting where it occurred. And the charge for that service in a physician's office is typically higher than its cost in a hospital.

Under this sixth alternative, rates of payment would be based on the basic costs necessary to operate a facility or piece of equipment at an efficient level. Soliciting bids from manufacturers might be required to lower purchase prices of equipment. To make payments consistent for comparable services that are based on charges in one setting and on costs in another, fee schedules would be developed for services paid by charges. Fees paid to physicians would also be based on costs using efficient methods of operation. To that basic amount would be added a predetermined profit margin to arrive at the allowable fee. This alternative could apply to all payers or all third-party payers, not just Medicare and Medicaid. In that case, the alternative would entail the establishment of national ratesetting for medical services.

Under this alternative, Medicare and Medicaid would not pay for inefficient methods of operation or for high profits. Rates could be reviewed to enable Medicare and Medicaid to take advantage of changes that had resulted in lowered costs, such as reductions in prices of equipment or improvements in methods of operation. Of course, changes in these factors could lead to increases in rates as well as decreases.

Under the assumption that Medicare and Medicaid payments exert a degree of leverage over providers, these federally set rates could encourage the performance of services in ways considered desirable by the Government. The relative rate structure for different settings, different tests, and different types of physician specialists could provide incentives favoring one over another. For example, the Government could establish rates for CT examinations and alternative diagnostic procedures, such as arteriograms, that would encourage the relative level of use of each test that was considered desirable. If all physicians were considered equally capable of reading CT scans, all could be reimbursed at the same rate. If some were considered capable and others not, reimbursement could be limited to those considered capable.

Considerable technical expertise would be needed to set, monitor, and review rates under this sixth alternative. For both hospitals' and physicians' rates, the Government would require experts with detailed knowledge of such factors as budgets, methods of performing services, and types of equipment. Also, to set fees and monitor costs, hospitals and physicians would have to adopt uniform methods of recording and reporting their costs. (P. L. 93-641 mandated the development of uniform accounting and reporting, and P.L. 95-142 required uniform reporting for institutions.) If payment under

Medicare and Medicaid were based on the efficiency of services provided, hospitals would have to apportion costs to specific services, not to departments or functions as is currently done.

Whether the ratesetting described here would result in lower net expenditures on medical services is not clear. Rates would probably be lower for Medicare payments, but total expenditures would not necessarily rise more slowly or decline absolutely. Other governments, such as those of the Canadian provinces, have found that rates of use and therefore total expenditures have risen when rates of payment were held fixed. The costs of hiring the new technical experts required would also add to government expenditures. Despite the time and expense involved, this alternative would not necessarily lower payments under Medicaid. Since 1972 when the law was amended, Medicare's definition of reasonable costs for hospitals has been a maximum limit for Medicaid payment; many States pay less. Medicaid's limits for physicians' services are also typically below those of Medicare.

Certain adverse consequences might result if Medicare rates paid to physicians were reduced below their current levels. For example, fewer physicians might be inclined to accept assignment for Medicare patients (acceptance of Medicare rates as full payment); the rate of assignment is already falling. In such circumstances, Medicare patients with some financial means could pay the difference between physicians' charges and Medicare's allowable fee. But patients with less ability to pay might have to rely on physicians with lower charges.

Overall, ratesetting entails detailed consideration of each service, the method of performing that service, and the profit margin. This course of action would be time-consuming and expensive for providers and governmental agencies alike. Implementing this sixth alternative might result in the Government's questioning in detail how medical services are provided. Furthermore, ratesetting would not affect the incentives of present reimbursement methods that encourage additional medical services, such as diagnostic tests, regardless of their marginal value.

Alternative 7: Fundamentally restructure the payment system to encourage providers to perform and use medical services efficiently.

Present retrospective payment of costs and charges and fee-for-service payment contain perverse incentives, as discussed in alternative 6. These payment methods, used by public and private third parties and by self-payers, reward physicians and hospitals with higher revenue when they provide additional services. This result occurs regardless of whether the services substantially improve patient care or whether they are produced efficiently. Medicare, for example, pays for a CT head examination regardless of any other neurodiagnostic tests that have been performed and the information that may have been gained from them.

This study has identified the incentives of the present reimbursement system, but has not systematically analyzed possible changes in that system. This alternative, then, suggests a general restructuring of payment methods, but does not propose a definite substitute. The altered payment system would contain incentives for physicians and hospitals to provide appropriate care and to do so efficiently, instead of present incentives that confict with these goals. Rather than control rates of payment for each service as in alternative 6, this alternative would indirectly or directly fix the total revenue of a provider in advance of the delivery of medical care. Payment by cavitation (per person) would do so

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indirectly, while review of providers' budgets would fix that revenue directly.

The consequences of a restructured payment system would depend on the specific plan put into effect. Nevertheless, certain generalizations are possible. Limiting total revenue would both enable and force providers to make choices among alternative services and among alternative methods of performing those services. Within the predetermined revenue, a provider could choose which services to perform and how to perform them. With total revenue limited, for example, a hospital's administrator and physicians would decide whether to operate a CT scanner, how many scans to perform annually, which patients to scan, and how to combine CT scans with other diagnostic procedures.

Furthermore, physicians and hospital administrators rather than Government would make the decisions. The Government would set the cavitation payment or budget limit, but would not become involved with production methods, use, or payment for particular services. Providers could consider the cost implications of their actions, choose services to provide, and determine how to perform those services. The factors that physicians and hospitals weigh when making decisions would undoubtedly undergo great change. Additional services would no longer automatically increase their revenues and might even decrease their incomes by increasing their costs.

This seventh alternative could pertain either to Federal financing programs alone or to all payers of medical care. However, if only Medicare and Medicaid limited their payments, a provider could increase costs and charges and generate additional revenue from other third parties and self-payers. The alternative could also cover either hospitals or physicians. But some services that are performed in both hospitals and physicians' offices, such as ambulatory CT scans, are often substitutes for each other. If revenue were limited only for hospitals, one would expect payments to rise for nonhospital providers whose revenues were not limited. Although this alternative would clearly be most effective if applicable to all payers and providers, such an approach would represent a major policy decision. Private payers could, of course, follow any Federal lead. This alternative would also be compatible with national health insurance, for the Federal Government would then be the major payer of health care.

Calculating cavitation levels or revenue limits would require the responsible Government office to have much technical expertise. Experts would have to identify variables that cause costs to differ among providers or consumers and adjust payment levels accordingly. (Such efforts have not proved very successful in the past.) Governmental experts would also have to review rates periodically. The ways in which rates changed would greatly influence total medical expenditures. For example, a system of basing the rate of change on an indicator within the medical care system could simply accept and transmit increases with a lag of 1 year. Rate changes could be based on broader economic indicators, such as the GNP deflator, which would not necessarily be self-generating. But broader indicators might be insensitive to changes specific to the medical care sector.

Although the changed payment system would create an environment with different incentives, this seventh alternative would not necessitate substantial changes in the way providers are organized. Providers could continue to deliver medical care under current practice arrangements. Compared to the current situation, the new environment would enhance the competitive position and perhaps stimulate the growth of Health Maintenance Organizations (HMOS) and other providers currently paid by cavitation. Such groups now compete for physicians, supplies, and enrollees with providers who gain more revenue from the provision of additional services. If cavitation payment or budget

limits applied to all providers, all would have similar incentives and be subject to similar restrictions under the payment method. But the relative position of providers now paid by cavitation would be improved if others faced some limit on their total revenue.

The presence of different incentives would affect the kind of medical care delivered and expenditures on that care only over a long period of time. Similarly, any effect on the nature of medical care delivery and the strength of HMOs would occur over several years.

Changing payment to providers as described in this seventh alternative would be compatible with regulatory programs of certificate-of-need and utilization review, and might make these programs even more valuable than at present. Under this alternative, providers would have an incentive to underserve patients in order to stay within their budgets. Minimum standards of appropriate use might have increased importance in this new context. Utilization review under the PSRO program currently applies only to Medicare and Medicaid patients, as described in chapter 5. To prevent providers from economizing on services to non-Medicare and non-Medicaid patients, PSRO review could be broadened to cover all patients. Such an expansion of the PSRO program would represent a major policy decision and would substantially increase PSRO regulatory activities and administrative costs. Utilization review might also guard against the tendency of providers to consider costs exclusive of benefits in order to meet their budgets. Standards of appropriate use would thereby function as a counterweight to the possibility of increased cost-consciousness by providers.

APPENDIXES

Appendix I

LOCATION OF CT SCANNERS INSTALLED IN THE UNITED STATES, MAY 1977

State/City	Name of Facility	Type of Facility
Alabama		
Birmingham	Baptist Medical Center-Montclair	H
Birmingham	Baptist Medical Center (Princeton)	H
Birmingham	University of Alabama Hospitals	H
Huntsville	Neuro-Radionics	P
Mobile	Mobile Infirmary	H
Mobile	Mobile General Hospital	H
Montgomery	Montgomery Baptist Hospital	H
Montgomery	Jackson Hospital	H
Alaska		
(Not available)		
Arizona		
Phoenix	Computed Neurological Scanning Center	P
Phoenix	Dr. Allen Yudail	P
Phoenix	Drs. Tobias & Waldman	P
Phoenix	Good Samaritan Hospital	H
Phoenix	St. Joseph's Hospital & Medical Center	H
Scottsdale	Scottsdale Memorial Hospital	H
Tucson	Tucson Medical Center	H
Arkansas		
Ft. Smith	Sparks Regional Medical Center	H
Little Rock	Baptist Medical Center	H
Little Rock	Radiology Association	P
California		
Arcadia	Arcadia Radiology Medical Group	P
Bakersfield	Kern Radiology & Nuclear Medical Group	P
Bakersfield	Mercy Hospital	H
Berkeley	Alta Bates Hospital	H
Burbank	St. Joseph Medical Center	H
Carmichael	Mercy - San Juan Hospital	H
Culver City	David M. Brotman Memorial Hospital	H
Eureka	Carlos Sullivan Eureka General Hospital	H
Fountain Valley	Fountain Valley Community Hospital	H
Fresno	St. Agnes Hospital & Medical Center	H
Fullerton	St. Jude Hospital - Rehabilitation Center	H

Key: Hospitals are denoted by H; clinics and private offices are denoted by P. For institutions with more than one CT scanner, the number is indicated in parentheses.

Appendix I—Cont.

State/City	Name of Facility	Type of Facility
Gardena	Computerized Axial Tomography	P
Glendale	Glendale Adventist Hospital	H
Inglewood	Daniel Freeman Memorial Hospital	H
Laguna Hills	Saddleback Community Hospital	H
LaJolla	Hospital of Scripps Clinic	H
LaJolla	Scripps Memorial Hospital	H
LaMesa	Grossmont Hospital	H
Loma Linda	Loma Linda University Medical Center	H
Long Beach	Bauer Hospital - St, Mary Medical Center	H
Long Beach	Long Beach Community Hospital	H
Los Alamitos	CT Systems	P
Los Angeles	Children's Hospital of Los Angeles	H
Los Angeles	Hospital of the Good Samaritan	H (2)
Los Angeles	St. Vincent's Medical Center	H
Los Angeles	University of California Department of Radiological Sciences	H (2)
Los Angeles	White Memorial Medical Center	H
Los Angeles	Los Angeles New Hospital	H
Lynwood	St. Francis Hospital of Lynwood	H
Modesto	Doctors Hospital	H
Newport Beach	Hoag Memorial Presbyterian Hospital	H
Oakland	Brain Scan Laboratory Center - Samuel Merritt Hospital	H
Orange	St. Joseph Hospital	H
Palo Alto	Children's Hospital at Stanford - Stanford University Hospital	H
Palo Alto	Palo Alto Clinic	P
Palo Alto	VA Hospital	H
Pasadena	Huntington Memorial Hospital	H
Riverside	K.W. Zimmerman	P
Sacramento	Sacramento Medical Center (University of California - Davis)	H
Sacramento	Sutter General Hospital	H
San Bernardino	St. Bernadine Hospital	H
San Diego	Alvarado Community Hospital	H
San Diego	Mercy Hospital & Medical Center	H
San Diego	University of California Medical Center	H
San Francisco	Mt. Zion Hospital & Medical Center	H
San Francisco	Ralph K. Davis Medical Center	H
San Francisco	University of California Hospitals & Clinics - San Francisco	H (3)
San Francisco	Presbyterian Hospital of the Pacific Medical Center	H
San Francisco	St. Francis Memorial Hospital	H
San Jose	San Jose Hospital & Health Center	H
San Jose	Santa Clara Valley Medical Center	H
San Leandro	Doctors Hospital of San Leandro	H

Appendix I—Cont.

State/City	Name of Facility	Type of Facility
San Luis Obispo	Sierra Vista Hospital	H
Santa Barbara	Santa Barbara Cottage Hospital	H
Santa Cruz	Dominican Santa Cruz Hospital	H
Santa Monica	St. John's Hospital & Health Center	H
Santa Monica	Santa Monica Radiologic Association	P
Santa Rosa	Santa Rosa Radiology	P
Stockton	St. Joseph's Hospital	H
Tarzana	Medical Center of Tarzana Hospital	H
Torrance	Little Company of Mary Hospital	H
Van Nuys	Valley Presbyterian Hospital - Olmstead Memorial	H
Ventura	Community Memorial Hospital of San Buenaventura	H
Walnut Creen	Neuroscan	P
West Covina	Computed Neurodiagnostic Center	P
West Covina	Queen of the Valley Hospital	H
Colorado		
Colorado Springs	Colorado Springs Neurological Association	P
Denver	Denver General-Hospital	H
Denver	Presbyterian Medical Center	H
Englewood	Swedish Medical Center	H
Pueblo	Parkview Episcopal Hospital	H
Pueblo	Drs. Chepousky, Reilly and Husan	P
Connecticut		
Hartford	Hartford Hospital	H
New Haven	Yale New Haven Hospital	H (2)
Delaware		
Wilmington	Radiologic Associates	P
District of Columbia		
	George Washington University Hospital	H
	Georgetown University Hospital	H
	Howard University	H
Florida		
Clearwater	Clinical Neurological Specialties, Inc.	P
Ft. Lauderdale	Broward General Medical Center	H
Ft. Lauderdale	EM I Scan Center	P
Ft. Lauderdale	Holy Cross Hospital	H
Ft. Lauderdale	North Beach Medical Center	H

Key: Hospitals are denoted by H; clinics and private offices are denoted by P. For institutions with more than one CT scanner, the number is indicated in parentheses.

Appendix I—Cont.

State/City	Name of Facility	Type of Facility	
Ft. Meyers	Medical Computer Scan Service	P	
Gainesville	North Florida Regional Hospital	H	
Gainesville	Shands Teaching Hospital (University of Florida)	H	
Hollywood	Memorial Hospital	H	
Jacksonville	St. Lukes Hospital	H	
Jacksonville	St. Vincent's Medical Center	H	
Lakeland	Lakeland General Hospital	H	
Lauderdale Lakes	Florida Medical Center	H	
Melbourne	Melbourne Necrologic	P	
Miami	Baptist Hospital of Miami	H	
Miami	Brain Tomography Lab	P	
Miami	Delta Scan Corporation	P	
Miami	Dr. Donald Q. Vining	P	
Miami	Drs. Lombardo, Shafey, et al.	P	
Miami	Jackson Memorial Hospital	H	
Miami Beach	Mt. Sinai Hospital	H	
Orlando	Florida Hospital	H	
Pensacola	Baptist Hospital	H	
Pensacola	West Florida Hospital	H	
Pensacola	Sacred Heart Hospital	H	
Sarasota	Memorial Hospital	H	
South Miami	South Miami Hospital	H	
St. Petersburg	Bayfront Medical Center	H	
St. Petersburg	St. Anthony's Hospital	H	
Tallahassee	Tallahassee Neurological Foundation	H	
Tampa	St. Joseph's Hospital	H	
Tampa	Tampa General Hospital	H	
Tampa	University Community Hospital	H	
Georgia			
Atlanta	Grady Memorial Hospital	H	
Atlanta	Computerized Tomography Center	P	
Atlanta	Emory University Hospital	H	
Augusta	University Hospital	H	(2)
Decatur	DeKalb General Hospital	H	
Decatur	Computerized Cranial Services	P	
East Point	Atlanta Scan Lab	P	
Macon	R-N Partnership-Medical Center of Central Georgia	H	
Savannah	Memorial Medical Center	H	
Savannah	Delta Medical Associates	P	
Hawaii			
Honolulu	The Queens Medical Center	H	

Appendix I—Cont.

State/City	Name of Facility	Type of Facility
Idaho		
Boise	Boise Clinic	P
Boise	St. Alphonsus Hospital	H
Idaho Falls	Community Hospital of Idaho Falls	H
Illinois		
Chicago	Dr. Val Vasson	P
Chicago	Michael Reese Hospital & Medical Center	H
Chicago	Northwestern Memorial Hospital	H
Chicago	Rush Presbyterian - St. Lukes Medical Center	H (3)
Chicago	University of Chicago Hospitals and Clinics	H
LaGrange	Community Memorial General Hospital	H
Maywood	Foster G. McGaw Hospital - Loyola University	H
Morton Grove	Diagnostic Scanning Laboratory	P
Peoria	St. Francis Hospital	H
Pales Heights	Neurological institute	P
Rockford	Rockford Memorial Hospital	H
Rockford	St. Anthony's Hospital	H
Springfield	Memorial Medical Center	H (2)
Urbana	Carle Foundation Hospital	H
Indiana		
Evansville	Tri-State Cranial Laboratory	P
Fort Wayne	Parkview Memorial Hospital	H
Indianapolis	Methodist Hospital	H
Indianapolis	VA Hospital of Indianapolis	H
Iowa		
Iowa City	University of Iowa Hospital & Clinic	H
Kansas		
Kansas City	University of Kansas Medical Center	H
Topeka	Stormont-Vail Hospital	H
Wichita	St. Francis Hospital	H
Wichita	Wesley Medical Center	H
Kentucky		
Lexington	Good Samaritan Hospital	H
Lexington	St. Joseph's Hospital	H

Key: Hospitals are denoted by H; clinics and private offices are denoted by P. For institutions with more than one CT scanner, the number is indicated in parentheses.

Appendix I—Cont.

State/City	Name of Facility	Type of Facility	
Lexington	University Hospital	H	
Louisville	Kentucky Baptist Hospital	H	
Louisiana			
Bossier City	Northwest Louisiana Diagnostic Center	P	
Lafayette	Our Lady of Lourdes Hospital	H	
New Orleans	Ochsner Foundation Hospital	H	
New Orleans	Tulane Medical Center	H	
New Orleans	Southern Baptist Hospital	H	
Shreveport	Willis-Knighton Memorial Hospital	H	
Maine			
Bangor	Eastern Maine Medical Center	H	
Portland	Maine Medical Center	H	
Maryland			
Annapolis	Anne Arundel Hospital	H	
Baltimore	Johns Hopkins Hospital	H	
Baltimore	University of Maryland Hospital	H	
Bethesda	National Institutes of Health	H	(4)
Chevy Chase	The Neurology Center	P	(2)
Lanham	Doctor's Hospital	H	
Massachusetts			
Boston	Boston City Hospital	H	
Boston	Boston VA Hospital	H	
Boston	Dana Cancer Research Center/Sidney Farber	H	
Boston	Lahey Clinic Foundation	P	
Boston	Massachusetts General Hospital	H	
Boston	New England Medical Center (Tufts)	H	
Brookline	Drs. Sabin & Mark	P	
Dorchester	The Carney Hospital	H	
Lowell	St. John's Hospital	H	
Springfield	Medical Center of W. Massachusetts	H	
Woburn	CAT Scan Lab	P	
Michigan			
Ann Arbor	University of Michigan Hospital	H	
Battle Creek	Community Hospital Association	H	
Birmingham	M.C.T. Associates	P	
Detroit	Harper Hospital (United Hospital of Detroit)	H	
Detroit	Henry Ford Hospital	H	
Flint	Scanner Diagnostic Associates	P	
Flint	Flint Osteopathic Hospital	H	
Grand Rapids	Kent Radiologic Institute	P	
Royal Oak	William Beaumont Hospital	H	
Southfield	Southfield Radiology	P	

Appendix I—Cont.

State/City	Name of Facility	Type of Facility
Minnesota		
Minneapolis	Abbott-Northwestern Hospital Corporation	H
Minneapolis	Methodist Hospital	H
Minneapolis	Metropolitan Medical Center	H
Minneapolis	North Memorial Medical Center	H
Minneapolis	University of Minnesota Hospital	H
Rochester	Mayo Foundation	P (2)
Rochester	St. Mary's Hospital of Rochester	H
St. Paul	St. Paul Radiology Group	P
Mississippi		
Jackson	Mississippi Baptist Hospital	H
Jackson	University of Mississippi Medical Center	H
Missouri		
Columbia	Boone County Hospital	H
Columbia	University Medical Center	H
Creve Coeur	Neurological Scanning Center	P
Kansas City	Menorah Medical Center	H
Kansas City	St. Mary's Hospital	H
Kansas City	St. Luke's Hospital	H
Springfield	L.E. Cox Medical Center	H
St. Louis	DePaul Hospital	H
St. Louis	St. Luke's Hospital East	H
St. Louis	St. Luke's Hospital West	H
St. Louis	University Clinic	H (2)
St. Louis	Washington University	H (4)
Montana		
Billings	Eastern Radiological Association	P
Nebraska		
Omaha	Bishop Clarkson Memorial Hospital	H
Nevada		
Las Vegas	Desert Springs Hospital	H
Las Vegas	Sunrise Hospital	H
Reno	Washoe Medical Center	H
Reno	Computerized Diagnostic Lab	P
New Hampshire		
Hanover	Mary Hitchcock Memorial Hospital	H

Key: Hospitals are denoted by H; clinics and private offices are denoted by P. For institutions with more than one CT scanner, the number is indicated in parentheses.

Appendix I—Cont.

State/City	Name of Facility	Type of Facility	
New Jersey			
East Orange	Computerized Axial Tomography of Essex	P	
Fairlawn	Bergen Passiac Tomography Center	P	
Summit	Overlook Hospital	H	
New Mexico			
Albuquerque	Bernalillo County Medical Center (University of New Mexico)	H	
Albuquerque	X-ray Associates (Scanner Partnership)	P	
New York			
Albany	Albany Medical Center	H	
Bayside	Dr. Rabiner	P	
Brooklyn	Nuclear Diagnostic Laboratory	P	
Buffalo	E.J. Meyer Memorial Hospital	H	
Buffalo	Buffalo General Hospital	H	
Buffalo	Children's Hospital	H	
Buffalo	Millard Fillmore Hospital	H	(2)
East Meadow	Nassau County Medical Center	H	
Flushing	Drs. Soffin and Karlin	P	
Johnson City	Charles S. Wilson Memorial Hospital	H	
Manhasset	North Shore University Hospital	H	
Mineola	Nassau Computed Tomography Center	P	
New York	Columbia Presbyterian Medical Center	H	
New York	Drs. Kaplan & Rabner	P	
New York	Memorial Sloan Kettering	H	
New York	Montefiore Hospital	H	
New York	Mount Sinai Hospital	H	
New York	New York Hospital	H	
New York	New York University Medical Center	H	
New York	St. Vincent's Hospital	H	
New York	St. Luke's Hospital	H	
Plainview	Computerized Radiological Services	P	
Rochester	Strong Memorial Hospital	H	
Rochester	Westfall Park Medical Center	P	
Syracuse	Crouse Irving Medical Center	H	
Syracuse	Upstate Medical Center	H	
North Carolina			
Chapel Hill	North Carolina Medical Center Memorial Hospital	H	
Charlotte	Charlotte Memorial Hospital and Medical Center	H	
Durham	Duke University	H	
Greensboro	Piedmont Neuro-Diagnostic Lab	P	
Raleigh	Wake County Medical Center	H	
Winston-Salem	North Carolina Baptist Hospital	H	

Appendix I—Cont.

State/City	Name of Facility	Type of Facility
North Dakota		
Fargo	Neuropsychiatric Institute Hospital	H
Ohio		
Akron	Akron City Hospital	H
Akron	Neuro-Radiology, Inc.	P
Beachwood	Drs. Sachs & Ross & Associates	P
Cincinnati	Cincinnati General Hospital (University of Cincinnati)	H
Cleveland	Cleveland Clinic	H (3)
Cleveland	Drs. Hill & Thomas	P
Columbus	Ohio State University Hospitals	H
Columbus	Riverside Methodist	H
Dayton	Kettering Medical Center	H
Euclid	Euclid Clinic Foundation	P
Lorain	Lorain Community Hospital	H
Toledo	St. Vincent Hospital Medical Center	H
Toledo	The Toledo Hospital	H
Youngstown	Computer Cerebral Scanning, Inc.	P
Zanesville	Bethesda Hospital	H
Oklahoma		
Oklahoma City	Baptist Medical Center	H
Oklahoma City	St. Anthony's Hospital	H
Tulsa	St. Francis Hospital	H
Tulsa	St. John's Hospital & School of Nursing	H
Oregon		
Eugene	Sacred Heart General	H
Medford	Rogue Valley Memorial Hospital	H
Portland	Good Samaritan Hospital & Medical Center	H (2)
Pennsylvania		
Allentown	Allentown and Sacred Heart Hospital Center	H
Danville	Geisinger Medical Center	H
Greensburg	Westmoreland Hospital Association	H
Hershey	Milton Hershey Medical Center	H
Philadelphia	Albert Einstein Medical Center	H
Philadelphia	Episcopal Hospital	H
Philadelphia	Hahnemann Hospital	H
Philadelphia	Hospital of the University of Pennsylvania	H
Philadelphia	Pennsylvania Hospital	H
Philadelphia	Temple University Hospital	H
Philadelphia	Thomas Jefferson University Hospital	H

Key: Hospitals are denoted by H; clinics and private offices are denoted by P. For institutions with more than one CT scanner, the number is indicated in parentheses.

Appendix I—Cont.

State/City	Name of Facility	Type of Facility	
Pittsburgh	Allegheny General Hospital	H	
Pittsburgh	Children's Hospital	H	
Pittsburgh	Montefiore Hospital	H	
Pittsburgh	St. Francis General Hospital	H	
Pittsburgh	Western Pennsylvania Hospital	H	
Reading	Reading Hospital	H	
Scranton	Community Medical Center	H	
Rhode Island			
Providence	Drs. F. Conklin and Khodarahmi	P	
Providence	Rhode Island Hospital	H	
South Carolina			
Charleston	Medical University Hospital of the Medical University of South Carolina	H	
Columbia	Richland Memorial Hospital	H	
Greenville	Greenville General Hospital	H	
South Dakota			
Sioux Falls	McKennan Hospital	H	
Tennessee			
Chattanooga	Baroness Erlanger Hospital	H	
Knoxville	East Tennessee Baptist Hospital	H	
Knoxville	Ft. Sanders Presbyterian Hospital	H	
Knoxville	St. Mary's Memorial Hospital	H	
Knoxville	University of Tennessee	H	
Memphis	City of Memphis Hospital	H	
Memphis	Baptist Memorial Hospital	H	
Memphis	Methodist Hospital	H	
Nashville	Vanderbilt University Hospital	H	
Texas			
Amarillo	Northwest Texas Hospital	H	
Austin	Brackenridge Hospital	H	
Austin	Austin Neuro-Diagnostic	P	
Corpus Christi	Memorial Medical Center	H	
Dallas	Baylor University Medical Center	H	(2)
Dallas	St. Paul Hospital	H	
El Paso	Providence Memorial Hospital	H	
El Paso	Sierra Medical Center	H	
El Paso	C-T Diagnostic Center	P	
Fort h Worth	Harris Hospital	H	
Forth Worth	St. Joseph Hospital	H	
Galveston	University of Texas Medical Branch Hospital	H	
Harlingen	Delta Medical Electronics	P	
Houston	St. Joseph's Hospital	H	

Appendix I—Cont.

State/City	Name of Facility	Type of Facility
Houston	St. Luke's Episcopal Hospital	H
Houston	The Methodist Hospital	H (2)
Lubbock	Methodist Hospital	H
San Antonio	Santa Rosa Medical Center	H
San Antonio	Southeast Baptist Hospital (Baptist Memorial Hospital System)	H
San Antonio	SW Texas Methodist Hospital	H
Temple	Scott & White Memorial Hospital	H
Waco	Hillcrest Baptist Hospital	H
Utah		
Salt Lake City	Latter Day Saints Hospital	H
Salt Lake City	St. Mark's Hospital	H
Salt Lake City	University of Utah Hospital	H
Salt Lake City	Western Neurological Association	P
Vermont		
Burlington	University of Vermont Medical Center Hospital	H
Virginia		
Norfolk	Norfolk General Hospital	H
Richmond	Medical College of Virginia and Virginia Commonwealth University	H
Richmond	St. Lukes Hospital	H
Roanoke	Roanoke Memorial Hospital	H
Vienna	Drs. Kirschner, Buckley, Chung, and Mero	P
Winchester	Winchester Memorial Hospital	H
Washington		
Seattle	Providence Medical Center	H
Seattle	Swedish Hospital & Medical Center	H
Seattle	Virginia Mason Hospital	H
Spokane	Sacred Heart Medical Center	H
Tacoma	Tacoma General Hospital	H
West Virginia		
Charleston	Charleston Area Medical Center	H
Wisconsin		
Lacrosse	Gunderson Clinic	P
Madison	Madison General Hospital	H
Madison	University of Wisconsin Hospital	H

Key: Hospitals are denoted by H; clinics and private offices are denoted by P. For institutions with more than one CT scanner, the number is indicated in parentheses.

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Appendix I—Cont.

State/City	Name of Facility	Type of Facility
Marshfield	Marshfield Clinic	P
Milwaukee	Columbia Hospital	H
Milwaukee	Lutheran Hospital of Milwaukee	H
Milwaukee	Milwaukee County Medical Complex	H
Milwaukee	St. Lukes Hospital	H
Milwaukee	Neurodiagnostic Associates Neuro-Center	P
Wyoming		
(None)		

Key: Hospitals are denoted by H; clinics and private offices are denoted by P. For institutions with more than one CT scanner, the number is indicated in parentheses.

Source: Data collected by OTA Health Program. See "Method of the Study," appendix VIII.

Appendix II

THEORETICAL CAPACITY AND ACTUAL OUTPUT OF A CT SCANNER

The theoretical capacity of a CT scanner is the number of scans that it can produce per time period and is a function of several variables. The most important variables are scanning speed (determined by machine design), hours of operation per day, and time spent per patient examination. Because all of these factors, except scanning speed, may vary during use, estimated theoretical capacity may differ from actual output. In particular, the number of hours per week considered full utilization has ranged from 40 or 50 to **80** hours.

Early calculations of capacity were based on the fact that head scans were scheduled at hour intervals. The Colorado Radiological Society made the lowest known estimate of operational capacity on this basis, **1,800 examinations** per year **(109).** This figure assumes 1 hour per scan, **40** hours per week, and allows for holidays and "downtime." Different manufacturers estimated different numbers of scans possible per 8-hour day in 1975 and 1976, with ranges from 10 to almost 30 per 8-hour day, or 2,600 to 7,800 examinations per year (assuming 260 days of operation per year). The Philadelphia Comprehensive Health Planning Agency estimated an operational capacity of 4000 examinations per year (assuming 16 patients per day) (582). Thus, theoretical capacity, assuming an hour per head scan, could range from below 2,000 examinations per year with a 40-hour week to about 4,000 examinations per year with an 80-hour week. One hour per head scan continues to be valid, as indicated by Evens and Jest **(158), which** found that head scans done on body scanners take an average of 32 minutes without contrast material and 53 minutes with contrast (presumably a noncontrasted scan followed by a contrasted scan).

Few data on actual operation levels of CT head scanners have been collected, and most surveys have been limited to older and slower machines. The following yearly numbers of examinations per machine (uncorrected for case mix) have been reported for **1975** and **1976:** Evens and Jest, **3,276 (29);** Buenger and Huckman, 3,260 (264); Genessee Valley Health Planning Council, 3,000 (577); Health Planning Council of Rhode Island, 3,000 (584); Tri-State Area Health Planning Council, Inc., **2,900 (556);** and Podell, **3,100 (425).** Most machines in these surveys were available more than **8** hours **a day, 5 to 5.4 days a week (29, 159, 440).**

These results do not translate directly to CT body scanners. In 1977, Evens and Jest (158) found that an abdominal scan takes 50 minutes without contrast material and 77 minutes with contrast, and a pelvic scan takes 44 minutes without contrast material and 62 with contrast. Thus, if a body scanner performed only body scans and used contrast material on all examinations, and if one assumes that all scans were of the abdomen, the average time per scan would be 77 minutes. Operating **50** hours a week and 50 weeks a year, such a body scanner could perform about 2,000

contrasted abdominal scans per year. To achieve 2,500 scans would require operation for about 64 hours per week.

If a body scanner were used as the Evens and Jest survey of 1977 (158) indicates, performing 59 percent of its scans of the head and 41 percent of the rest of the body (mostly the abdomen), a scanner's theoretical capacity would be higher. The body scanners in the Evens and Jest survey operated an average of **46** hours per week **(52** hours minus **6** hours "downtime"). Contrasted head scans required 53 minutes per scan and contrasted abdominal scans 77 minutes. If all scans were contrasted and the machine was operational 50 weeks a year, the theoretical capacity would be about 2,200 examinations per year. Since 68 percent of head scans and **65** percent of abdominal scans were contrasted, the capacity of a body scanner, operating the stated number of hours, would be higher, about 2,500 examinations per year. These calculations may underestimate the **capacity of a body scanner-,** since they use the average time of abdominal examinations for the 41 percent of examinations other than the head. Abdominal examinations accounted for an average of only **29** percent of all examinations, but required the longest time per examination (158).

These theoretical calculations may be compared to actual experience. In a 1975 survey, Buenger (80) found that institutions performed scans an average of 12.5 hours per day. The American Hospital Association reported similar figures in its **1976** survey of 41 hospitals (29). In a 1976 survey Evens and Jest **(159)** found the average operating time of **98 machines was 11.8** hours per day, and **90 of the 98** scanners were available 24 hours a day for emergencies. These machines were primarily head scanners. In 1977, the Evens and Jest survey of body scanners found that the usual body scanner operated **5.2** days per week and 10 hours **a day (158).** However, only **32 patients** per week were examined on those body scanners. That number may be compared to the earlier Evens and Jest survey of primarily head scanners which found **58 patients** a week being examined (159).

Although downtime can reduce the level of output, it has not seriously limited CT scanners. Downtime is reported to average 2.4 to 7.0 hours a week and is expected to decrease as staff gain experience with CT scanners **(82, 159).**

The National Guidelines for Health Planning are based on a theoretical capacity of 2,500 examinations per year, regardless of type of examination (582). It appears from the 1977 Evens and Jest survey that many body scanners in this country will not reach the standard (158). One purpose of the Guidelines is to assure full utilization of existing scanners before allowing additional scanners in a particular area. The Guidelines do not take into account some of the complexities described above, but do allow adjustment of the standards by HSAs and State health planning agencies to allow for such factors.

Appendix III

INTERIM PLANNING GUIDELINES FOR COMPUTERIZED TRANSAXIAL TOMOGRAPHY (CTT) (Published by the Regional Comprehensive Health Planning Council, Inc., Philadelphia, Sept. 25, 1974)

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GUIDELINES FOR PLANNING

The CTT scanner represents a major technological advancement in the field of medicine. This instrument will create dramatic changes in the utilization of certain traditional studies used to diagnose diseases of the brain, and its potential for scanning other parts of the body are enormous. There is no doubt that a CTT scanner makes possible faster and more accurate test results, however, the equipment is complicated, expensive, and in limited supply. Therefore, its benefits to the community can best be realized through development of this vital new diagnostic service on a regionalized basis with cooperative arrangements among several institutions to support maximum utilization.

I. It is recommended that a hospital considering acquisition of this type of equipment have the following service capabilities:

A. The hospital must have an active neurosurgical service. This requires that the hospital has a geographically full-time* board certified neurosurgeon, and at least 50 intracranial procedures should be performed annually.

B. The hospital must have an active neurological service. This requires that the hospital has a geographically full-time* board certified neurologist.

C. The institution must have on staff a qualified neuroradiologist. It is recommended that the definition adopted by the American Society of Neuroradiology be used as a guide in determining the radiologist's qualifications:

1. At least 50 percent of the radiologist's time must be spent in the field of neuroradiology.

2. The radiologist must have trained for 2 years in neuroradiology; or

The radiologist must have trained 1 year in neuroradiology and have 2 years experience devoting at least 50 percent of time in neuroradiology; or

The radiologist must have 4 years of experience devoting at least 50 percent of time in neuroradiology.

II. In addition the following "primary" and "secondary" criteria are recommended:

A. Primary Criteria (in order of priority)

1. Number of brain scans and skull X-rays performed annually (at least 1,000 radioisotope brain scans must be done currently).

2. Number of cerebral arteriograms/angiograms and pneumoencephalograms performed annually.

3. Size of the inpatient neurological and neurosurgical services (average daily census and annual admissions for each service).

*This requires that the physician's private office be located at or near the hospital and that his full-time commitment is to that hospital.

B. Secondary ***Criteria*** (no priority)

I. Ability to offer patient utilization beyond an 8-hour day.

2. Geographic proximity to neighboring hospitals.

3. Research capability.

III. The CTT scanner utilization level should be a minimum of eight patients per day.

IV. An applicant requesting Council support must submit financial data stating charges, sources of income, and expenses connected with the project's operation.

V. Further, an applicant must submit letters of agreement to utilize the scanner services from area hospitals. These letters are to be signed by the hospital administrator or director and written on the hospital's stationery.

Appendix IV

ESTIMATES OF ANNUAL EXPENSES OF OPERATING ACT SCANNER

Category	Health Planning Council, R.I. 1975 (532)	Genessee Region Health Planning Council, N.Y. 1975 (524)	Buenger and Bass[a] 1976 (76)	Indiana 1976 (501)	Podell 1975 (387)	Evens and Jest 1976 (144)
			Thousands of Dollars			
Direct expenses						
Equipment	84[b]	90[c]	76[d]	117[b]	80[b]	102[b,e]
Interest	—	—	—	28	—	—
Maintenance of scanner	17	23	3	20	40	25
Other maintenance and remodeling	—	1	1	13	·	10
Miscellaneous	1	2	3	10	—	·
Nonphysician staff	36	40	59	58	75	49
Supplies	15	20	25	37	24	38
Indirect expenses	34[f]	2	85	7	100	112[g]
Technical expenses	187	177	252	290	319	337
Professional expenses[h]	72	130	—	—	60	—
Total expenses	259	307	—	—	379	—
(Patients examined per year	3,000	3,000	3,828	2,900	3,000	2,600)
			Dollars			
Average technical cost per exam	62	59	66	100	106	130
Average professional cost per exam	24	43	—	—	20	—
Average total cost per exam	86	102	—	—	126	—

[a] Actual experience of one hospital.
[b] Straight-line, 5-year depreciation.
[c] Straight-line, 4-year depreciation has been changed to 5-year here.
[d] Rental charge.
[e] Includes new equipment of $25,000 per year to update the scanner.
[f] Indirect costs estimated as 15 percent of direct costs.
[g] Indirect costs estimated as 50 percent of direct costs.
[h] Based on 1 radiologist except for reference 577 which used 1.3 radiologist.

Appendix V

CALCULATION OF NET EXPENDITURES FOR CT SCANNING', 1976

	Low	High
Average charge, CT examination	$ 240	$ 260
Total examinations[c]	850,200	981,000
Charges for all CT examinations	204,048,000	255,060,000
Hospital day expenses[d]	81,459,287	143,286,042
Inpatient physician charges[e]	7,917,322	27,852,976
Total gross CT expenditures	293,424,609	426,199,018
Reduced radionuclide brain scans[f]	139,000	139,000
Charges[g]	24,603,000	17,375,000
Hospital day expenses[h]	10,797,520	0
Inpatient physician charges[e]	2,098,900	0
Reduced expenditures	37,499,420	17,375,000
Reduced pneumoencephalograms	35,750	16,250
Charges[J]	7,507,500	3,250,000
Hospital day expenses[k]	38,878,840	5,049,200
Inpatient physician charges[e]	7,557,550	490,750
Reduced expenditures	53,943,890	8,789,950
Reduced arteriograms'	22,500	22,500
Charges"	5,175,000	4,500,000
Hospital day expenses[n]	13,982,400	6,991,200
Inpatient physician charges[e]	2,718,000	679,500
Reduced expenditures	21,875,400	12,170,700
Total reduced expenditures	113,318,710	38,335,650
Net expenditures on CT Scanning	$180,105,899	$387,863,368

[a] Basedon charges, not costs, of procedures, except for hospital day expenses.

[b] Sources: 29, 265.

[c] Based on327 machines as of June 1976 (274 machines in hospitals) and output of 2,600-3,000 annual examinations per machine (159,425,577,584).

[d] Based on 46-51 percent of hospital examinations on inpatients, an inpatient wait of 1.6-2.2 days, and adjusted hospital expensesof $155.36 per day (29,82,159,241).

[e] Based on 1 to2 physician visits per hospital day byan Internist charging $15,10 for a follow-up hospital visit (507),

[f] Estimated 35 percent decline in 1.1 million scans in 1973 (265).

[g] From $125 to$177 per nuclide scan (296,375).

[h] From O to 1 day stay for 50 percent of patients.

[I] Estimated decline of 65 percent. Estimates of the absolute number of pneumoencephalograms before CT scanning range from 55,0000r5 percent ofradionuclide brain scans in 1973 t025,000 (265,425,582).

[J] From $200to $210 per pneumoencephalogram (296,375).

[k] From 2 to 7 days stay and all patients as inpatients.

[l] Estimated decline of 20 percent (265).

[m] From $200 to$230 per arteriogram (296,375).

[n] From 2t04days stay and all patientsas inpatients.

Appendix VI

FEDERAL DEPARTMENTS AND AGENCIES WITH DIRECT INVOLVEMENT IN CT SCANNING

Various aspects of CT scanning come under the jurisdiction of different Federal departments and agencies. Many of these agencies are part of the Department of Health, Education, and Welfare, but other agencies and departments also are involved. Federal programs and their involvement with CT scanning are listed in table 22 and described below.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE (HEW)

Public Health Service (PHS)

Office of Health Practice Assessment (OHPA)

As described in chapter **6,** the Public Health Service, as part of an interagency agreement, gives advice to the Medicare program on its reimbursement when requested to do so. That function is currently carried out by the Office of Health Practice Assessment in the Office of the Assistant Secretary for Health.

Food and Drug Administration (FDA)

The Bureae of Radiological Health (BRH) has jurisdiction over the performance of CT scanners under the Radiation Control for Health and Safety Act of 1968. CT scanners must meet the diagnostic X-ray machine standards for safe performance which became effective August 1, 1974. Owners of CT scanners must report to BRH when a new machine is installed or an existing machine modified. BRH develops tests to measure radiation output from CT scanners and patient dose levels. BRH has contracted with George Washington University Medical Center to develop radiation dose data using an EMI head scanner,

The Bureau of Medical Devices ***(BMD)*** has regulatory control over these medical devices, as described in chapter 3 of this report. Two of its classification panels have Jurisdiction over CT scanners: the Radiology Panel and the Neurology Panel.

The Bureau of Drugs has no direct involvement with scanners, but does regulate drugs (contrast materials) used in conjunction with CT scanning. At least one such new drug application has been submitted.

Table 22.—Federal Departments and Agencies With Direct Involvement in CT Scanning

- **Department of Health, Education, and Welfare**
  - **Public Health Service**
    - **Office of Health Practice Assessment**
    - **Food and Drug Administration**
      - **Bureau of Radiological Health**
      - **Bureau of Medical Devices**
      - **Bureau of Drugs**
    - **National Institutes of Health**
    - **Health Resources Administration**
      - **Bureau of Health Planning and Resources Development**
      - **National Council on Health Planning and Development**
    - **Health Services Administration**
  - **The Health Care Financing Administration**
- **Department of Labor**
- **Department of Defense**
- **Veterans Administration**
- **Department of Energy**
- **National Aeronautics and Space Administration**
- **Environmental Protection Agency**
- **Department of Commerce**
  - **Domestic and International Business Administration**
  - **National Bureau of Standards**
- **The National Council on Radiation Protection and Measurements**
- **The National Science Foundation**

National Institutes of Health (NIH)

As noted in appendix I, NIH has four operational CT scanners. These machines are used both for NIH patients and for clinically oriented research. Extramurally, NIH is supporting about 100 research projects using CT scanning. The largest number of these are funded by the National Cancer Institute (NCI). NCI is itself funding a large collaborative clinical trial of the efficacy of CT scanning. The National Institute of Neurological and Communicative Disorders and Stroke held an International Symposium on Computerized Axial Tomography on October **12-15, 1976.**

Health Resources Administration (HRA)

The Bureau of Health Planning and Resources Development (BHPRD) carries out the provisions of P.L. 93-641, the National Health Planning and Resources Devel-

opment Act. Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (S HPDAs) are responsible for local and State health planning activities respectively.

The responsibilities of HSAs include: developing the health systems and annual implementation plans (corresponding to short- and long-term plans, respectively); providing technical and financial assistance for developing health resources; reviewing proposed Federal grants for health projects; assisting the State level review of new health services and proposed facilities; reviewing the appropriateness of existing facilities and services; and making their findings available to the State agency. The functions of the SHPDAs include preparing a State health plan, administering the certificate-of-need program and reviews under section 1122 (if the State had entered into an appropriate contract with HEW), reviewing existing institutional health services and facilities, and publishing findings on their appropriateness.

The Bureau of Health Planning and Resources Development (BHPRD) is responsible for providing technical assistance and policy guidance (through the issuance of regulations) to these agencies. Technical assistance takes two forms: one is general guidance on the implementation of P.L. **93-641; the other** is the development of recommended criteria and standards for reviewing and ruling on applications for capital expenditures or services, P.L. **93-641** established **10** Centers for Health Planning to provide technical assistance in the form of training of HSA and SHPDA board members and staff, and direct consultations with HSAs and SHPDAs for specific projects.

National Council on Health Planning and Development. Under the National Health Planning and Resources Development Act of 1974, HEW is required to establish a National Council on Health Planning and Development composed of 15 members. Six of the 12 are at-large members, and 6 are representatives of HSAs and SHPDAs. The Council met for the first time on December 10,1976. The functions of the Council are to advise, consult with and make recommendations to the Secretary of HEW with respect to the development of national guidelines, the implementation and administration of P.L. **93-641,** and the evaluation of new medical technology for the organization, delivery, and equitable distribution of medical services.

Health Services Administration (HSA)

HSA provides CT scanning when necessary through its direct service programs, including Public Health Service Hospitals and the Indian Health Service.

The Health Care Financing Administration (HCFA)

HCFA administers the Medicare program, which funds medical services mainly for the elderly. Medicare presently reimburses for CT head scanning and has been requested to reimburse for CT body scanning; that request is still under considerate ion. HCFA does not make decisions regarding direct coverage of CT scanning by the Medicaid program, but does provide matching funds to the State programs that might include reimbursement for CT scanning. X-ray services are mandated under the Medicaid program, and the required State plan might or might not include CT scanning. In addition, Medicaid reimbursement is on a “cost-related” basis: if purchase

of a CT scanner increases a hospital's costs; inpatient charges may be increased for all patients, and Medicaid payments increase.

HCFA also administers the Professional Standards Review Organizations (PSRO) program, a peer review program concerned with quality of care and with utilization of services and facilities. HCFA is developing guidelines for the relationship between PSROs and State planning agencies and Health Systems Agencies. HCFA encourages PSROs to provide technical assistance to such programs about the distribution and use of CT scanners, and such assistance already has been given in a few local areas. HCFA is not presently developing any materials relating to appropriate use of CT scanners for PSRO programs.

HCFA also staffs the National PSRO Council, which has the following functions:

(1) to advise the Secretary of HEW on the administration of the law;

(2) to provide for the development and distribution, among Statewide Professional Standards Review Councils and PSROs, of information and data which will assist such councils and organizations in carrying out their duties and functions; such information includes regional norms of medical care;

(3) to review the operations of statewide councils and PSROs to determine their effective and comparable performance; and

(4) to make or arrange for studies and investigations designed to lead to recommendations to the Secretary of HEW and to the Congress on how to improve the program.

The PSRO Council also must approve local norms and standards of care. Thus, the PSRO Council may disapprove such norms and standards if they are not adequate.

DEPARTMENT OF LABOR

The Occupational Safety and Health Administration (OSHA) has responsibility for ensuring the safety of the workplace. Thus, it has jurisdiction over medical settings where employees may be exposed to X-rays. General guidelines, dating back several years, set standards for allowable radiation exposure, and employers must ensure that this dose is not exceeded.

THE DEPARTMENT OF DEFENSE (DOD)

The Department of Defense operates hospitals and clinics to provide medical care for active duty and retired members of the Army, Navy, Air Force, and Marines. Acquisition of an expensive technology such as a CT scanner must be approved by the Department of Defense Health Council, which includes the Surgeons General of the Army, Navy, and Air Force, and the Assistant Secretary of Defense for Health

Affairs. Because local levels are expected to coordinate their requests with civilian facilities, local HSAs are also usually consulted.

Military hospitals and clinics have been using the CT scanning facilities of civilian institutions for some time and paying fees out of operating budgets. A decision has been made to purchase six scanners, two for each of the uniformed services. One of these was operational as of July 1, 1977. DOD also funds health research but is not supporting research related to CT scanning.

THE VETERANS ADMINISTRATION (VA)

The Veterans Administration operates a system of medical care facilities, including 171 hospitals. Care is planned centrally, but such planning responds to local level requests. The Radiology Service of the VA makes all decisions concerning CT scanning, with the assistance of an advisory committee including the directors of Medicine, Surgery, Neurosurgery, and Neurology, VA's policy is to purchase a CT scanner only after the local Health Systems Agency (HSA) has certified it as needed, although such HSA review is not required by law.

Six VA hospitals had operational CT scanners by July 1977; five were being installed, and three more scanners were on order. In addition, local VA hospitals pay for scanning by civilian institutions out of operating budgets. VA also funds health research. A research project in Boston will link four satellite hospitals to the area VA hospital's CT equipment to evaluate sharing of such equipment, permitting a radiologist in the central hospital to read the scans.

DEPARTMENT OF ENERGY (DOE)

As the primary agency in energy research, development, and demonstration, DOE encourages peaceful uses of atomic energy, including radioisotopes and radiation. For this reason, ERDA (now DOE) funded a project at the University of California at Los Angeles to conduct research on the CT scanner—focused both on instrument development and imaging techniques.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

NASA has a medical science program which supports research in medical applications. The program is presently supporting two projects related to CT imaging of the heart. Other projects to improve the technology of radiology are also being supported, especially to achieve higher sensitivity of X-rays with lower radiation doses,

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THE ENVIRONMENTAL PROTECTION AGENCY (EPA)

EPA has broad responsibilities for protecting public health from radiation hazards. These responsibilities include the development of national guidelines in radiation protection. EPA also carries out research on environmental hazards.

Under Federal Radiation Council authority, which was transferred to this agency in 1970, EPA has been studying the hazards of exposure to ionizing radiation, including radiation from medical and dental X-rays. EPA presently has an Interagency Working Group on Medical Radiation, which is developing broad guidelines on diagnostic radiology for Federal medical care facilities. The Working Group is developing recommendations on the qualifications of medical personnel who prescribe and operate X-ray equipment, the description of adequate X-ray equipment, and the principles which minimize patient exposure without sacrificing diagnostic quality. The guidelines being developed are expected to cover routine radiographic procedures, but have not yet considered the CT scanner. The Public Health Service of HEW, although furnishing technical assistance, has declined a request from EPA to participate in the Interagency Working Group.

DEPARTMENT OF COMMERCE

Domestic and International Business Administration

Nonprofit institutions, including nonprofit hospitals, are permitted to import scientific instruments duty-free. The Department determines whether a piece of equipment qualifies as a scientific instrument, and it has classified scanners made by EMI, Ltd. as scientific instruments.

National Bureau of Standards (NBS)

In order to set standards for a variety of technologies, NBS develops measuring instruments of many types. To evaluate structural materials with nondestructive methods, NBS has developed ultrasonic imaging devices. NBS and NIH will cooperate on comparing ultrasonic devices with CT scanners. NBS may attempt to develop CT scanning devices that use ultrasound instead of X-ray.

THE NATIONAL COUNCIL OF RADIATION PROTECTION AND MEASUREMENTS

This Council is a nonprofit corporation chartered by Congress and made up of nationally recognized scientists. The Council collects, analyzes, and disseminates information and recommendations about radiation protection and measurement. Council recommendations provide the scientific basis for radiation control, and they

are used by Federal Government organizations such as the Nuclear Regulatory Commission, the Public Health Service, and the Environmental Protection Agency. The Council has not produced any reports specifically related to CT scanning, but does have general reports concerning equipment design and use, protection of patients, and similar topics that bear upon CT scanners.

THE NATIONAL SCIENCE FOUNDATION (NSF)

NSF supports medical research under several different programs. Presently, it is supporting three projects related to CT scanning, two to improve imaging by CT scanners, and one to attempt imaging by ultrasound.

Appendix VII

INTERNATIONAL VIGNETTES

CT scanners have been installed and used in other countries at lower rates than in the United States. Although medical systems and policies in these countries are different from those in the United States, the primary factor limiting use of CT scanners appears to be financial.

BRITAIN

The British National Health Service plans medical services within an annual budget approved by the British Parliament. Because the budget is fixed, there is considerable competition for funds among various activities within the Health Service. In addition, Britain's financial problems have heightened pressures on the Health Service. Therefore, new technologies are examined with some care before widespread diffusion occurs, especially if the technology is as expensive as a CT scanner.

The British Department of Health and Social Security (DHSS) supported the development of the prototype EM I head scanner that was installed in 1971. Because initial clinical tests were promising, two more first-production head scanners were purchased with DHSS Research and Development funds (494). Evaluations continued to be promising, so three more scanners were purchased. In **1976,** the Department was informed of the evaluations conducted with common protocols, and a national policy was adopted to locate one head scanner in each Regional Health Authority area. Consequently, each major neurological/neurosurgical unit serving a million people or more will have a head scanner. In October **1976, 18** head scanners were operational in Britain (England, WaIes, and Scotland), with another 14 on order, to serve a population of about **58** million. By mid-1977, about 30 brain scanners were operational.

In June 1975, the first body scanner was installed for evaluation purposes at a Medical Research Council center (494). Promising initial results led to the purchase of two more units, with five more on order in October **1976.** According to a DHSS report, "The whole body scanner has not yet been established so definitively. Nevertheless its promise in the diagnosis and monitoring of therapy of malignant disease along with the signposts of its potential value in the investigation of other lesions merits support for more widespread evaluation in a number of centres of excellence" (494). However, subsequent diffusion of body scanners was not so rational. By April 1977, 11 EMI whole body scanners were installed or on order in the United Kingdom, and only three of those were official health service acquisitions, The other eight were donated by philanthropists or charities, or purchased with endowment funds. *

* This information was furnished by Barbar Stocking, Nuffield provincial Hospitals Trust, London.

As indicated, the head scanner has undergone rather extensive evalution. Use of head scanners in Britain and the United States appears to be quite similar. Evaluations indicate that installing an EMI scanner into an existing neurological/neurosurgical unit leads to increased costs. DHSS recognizes that the benefit to patients is not easily calculated, but assumes that as a more effective diagnostic tool, the CT head scanner "must represent a significant advance in an area of medicine which is associated with a high rate of death, disability, and long-term morbidity" (494).

Planning for body scanning has proceeded differently. Full evaluations have not been done, and scanners have been purchased with private funds. Thus, the goals of proper evaluation and geographic access to body scanners have been problematic in Britain.

CANADA

Under the national health insurance program in Canada, each province establishes minimum benefits and standards and receives about 50 percent of its funding out of Federal tax revenues. During the past 2 years, rising costs of medical care have considerably restricted the funds available for new technology. The Federal Government has recently negotiated a new basis for its participation in provincial programs, which probably will continue the financial restrictions.

In February **1976,** eight CT scanners were operational in Canada, seven of which were head scanners (399). Two more head scanners and five more body scanners were on order. The Canadian Ministry of Health reports that all of these units were installed as of December **1976, and that no others** have been ordered because of financial restrictions. Thus, nine head scanners and six body scanners, all located in hospitals, were serving the Canadian population of **23** million, that is, one scanner per **1.5** million population,

The Ministry of Health of the province of Ontario, with a population of about **8** million, evaluated the CT scanner in February **1976,** noting that Ontario had four operational scanners and three more on order (401). A Task Force on the Placement of Instruments for Computerized Axial Tomography of the Ontario Ministry of Health analyzed patterns of use of existing machines (401). Its recommendations included the following:

(1) All CT scanners acquired should have combined head and body scanning capability;

(2) The number of CT scanners should be increased to 1 per **500,000 population;**

(3) CT scanners should be installed only within University Hospitals or University Affiliated Hospitals.

Reported uses and rate of use of CT scanners in Ontario are quite similar to those in the United States. Toronto General Hospital, in 1975, calculated its cost per procedure to be approximately $86 (Canadian), including **$20 (Canadian)** for depreciation over a 5-year period (399). In November 1976, a representative of Toronto General Hospital indicated that the cost had risen to about $95 (Canadian) per scan.

Other Canadian hospitals are depreciating their CT equipment over a 10-year period. In Ontario, funds for CT scanning are provided within the budget for a department of radiology, and there is usually no financial incentive for the hospital or the radiologists to perform scans.

In December 1976, three CT scanners were operational in the Province of Quebec, which has a population of about 6 million. Three more scanners were on order. A document prepared for the Provincial government stated that existing scanners had been installed to evaluate their use and impact (401). The document suggested that widespread diffusion in Quebec should depend upon demonstrated diagnostic advantages leading to a measurable reduction in mortality and morbidity or contribution to a proportional reduction in the cost of other diagnostic techniques.

SWEDEN

All of Sweden's 8.2 million citizens are insured for medical benefits, including physician care, hospitalization, and partial reimbursement for prescription drugs and dental care. The organization of medical care is highly decentralized, with hospital care almost entirely provided by county and municipal hospitals. The Central Government makes relatively little financial contribution to either capital funding or daily operation of these hospitals.

In July 1976, Sweden had two operational CT scanners, and three more were on order, to be operational before January 1977 **(280). One hospital** with a CT head scanner, Karolinska Institute in Stockholm, reported a decline in number of pneumoencephalograms, from **900 to** about **200** during **1968-1974 (280).** However, because the CT scanner was not installed until 1973, its specific impact was not clear. Karolinska Institute also reported a modest decline in number of cerebral angiograms since **1972,** but the impact of the head scanner was uncertain. The other hospital, Emea General Hospital, has had its head scanner only since 1975, but reported a considerable reduction in both pneumoencephalograms and cerebral angiograms (280).

Sweden performed a total of ***2,400*** pneumoencephalograms and ***11,700*** cerebral angiograms in 1975 at some 80 radiology departments (280). The total number of pneumoencephalograms has been dramatically reduced in Sweden, but most of the reduction preceded installation of any CT scanner (see table **23).**

Swedish planners examined the use of the two operational scanners and concluded that improved diagnoses and potential financial savings justify a modest expansion in the use of CT scanners **(280).** They noted that, in addition to the cost of the replaced diagnostic procedures, the indirect costs of neurodiagnostic procedures are large. Patients must remain in bed for about 3 days after a pneumoencephalogram, and they must be hospitalized for about a week for a complete neuroradiological examination. Therefore, the planners argued that CT scanning of outpatients is cost-effective.

Table 23.—Numbers of Cerebral Angiographic and Pneumoencephalographic Examinations in Various Swedish Hospital Categories

	Pneumoencephalographic Examinations				Cerebral Angiographic Examinations			
	1972	1973	1974	1975	1972	1973	1974	1975
Regional hospitals	—	1,900	1,800	1,700	—	6,600	6,700	6,900
County hospitals .	—	1,000	700	550	—	3,500	3,400	3,300
Local hospitals . . .	—	400	250	150	—	1,500	1,500	1,500
Total	3,850	3,300	2,750	2,400	11,700	11,600	11,600	11,700

Source: 280.

Appendix VIII

METHOD OF THE STUDY

GENERAL DATA COLLECTION

Information for this study was obtained in a number of ways:

- *Medical literature.* Journals of radiology, neurology, and health planning were searched for relevant articles. Computerized literature searches, using the MEDLINE-MEDLARS system of the National Library of Medicine, were conducted periodically to ensure complete, up-to-date information. All literature on CT scanning listed in MEDLINE through May 1977 was reviewed.
- *State planning agencies and health departments.* Documents on CT scanning prepared by State and local health planning agencies were obtained from a variety of sources. In addition, each State health planning agency was contacted by telephone and asked to send to OTA information, policy statements, and guidelines on CT scanning.
- *Federal agencies.* Federal agencies with involvement in CT scanning were contacted. Information was summarized and returned to the agencies for verification, correction, and additions.
- *Consultants.* J. Lloyd Johnson Associates, Chicago, had collected information about CT scanners on order and CT scanners approved by planning agencies but not yet ordered. OTA contracted with Johnson Associates for a summary of that data.

DOCUMENTATION OF LOCATION OF CT SCANNERS

No public program has compiled a list of CT scanners by type, location, date of installation, and type of facility served. The list in appendix I was compiled from a variety of sources, including the following:

(1) The Food and Drug Administration, which requires reporting of installation of CT scanners by date and type of machine. This information was helpful, although incomplete.

(2) The Commerce Department, which maintains a list of nonprofit institutions seeking duty-free import of CT scanners. (At present, this policy applies only to medical institutions purchasing scanners from EMI Ltd.)

(3) The General Electric Company, which surveyed existing machines in certain parts of the country and furnished this information to OTA.

(4) Pfizer, which furnished a list of locations and dates of installation of its machines.

(5) J. Lloyd Johnson Associates, which had compiled a list of operational machines for its study. The list was shared with OTA staff, allowing cross-checking with other lists.

(6) Staff papers from planning agencies in several States, which listed installed and ordered machines.

(7) Scientific literature, especially from university medical centers, which often mentioned machine type and date of installation.

When any question arose, facilities were contacted individually by telephone for clarification.

REVIEW PROCESS

In response to a request by the staff of the Senate Committee on Finance, OTA staff first prepared a brief memorandum on CT scanners. It summarized the initial data collected and highlighted some of the issues to be studied. About 200 copies of the memorandum were circulated for review to individuals and groups inside and outside of government. A first draft report was later written and circulated for review to the Health Advisory Committee, the Technology Assessment Advisory Council, and about 100 interested individuals and groups. Many helpful suggestions were received, including additional research possibilities. As a result of these reviews, considerable new research was carried out. Another draft report was then prepared and reviewed by many of the same individuals and groups and also by additional reviewers. The final report was written in accordance with the comments received.

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