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SUMMARY

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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.