1.

Introduction

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This paper is an update of the OTA report *Policy Implications of the Computed Tomography (CT) Scanner*, published in August of 1978 (129). The CT scanner remains an instructive case study of Government involvement in the policy areas of evaluation, regulation of diffusion and use, and financing of medical technologies.

After 7 years' use in the United States, the CT scanner has established itself as a revolutionary diagnostic device (69,81,137). It has given physicians a diagnostic capability that they previously lacked. The development of this and other diagnostic technologies has made possible the definitive and conclusive diagnosis of some conditions. These technologies can sometimes guide physicians to appropriate treatments, preventing deaths and disability and relieving pain and suffering. These basic activities are unquestionably valuable. There seems to be little doubt that CT scanning has been a remarkably useful addition to the array of medical technology. During the past few years, however, both the availability of a wide variety of new diagnostic tests and the strong incentives to use them have enormously increased the use of these tests. 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. Likewise, hospitals desire to acquire new technologies such as the CT scanner for a variety of reasons, not least of which is to make their program more effective in relieving human suffering and sometimes saving lives. In the case of the CT scanner, radiologists felt (and continue to feel) that the improvement in imaging, and thus in diagnosis, was so evident as to allow reasonable clinicians to accept the new instrument readily. For the radiologist, CT scanning was easier, safer, and in many cases more reliable than the X-ray procedures in use,

However, the CT scanner appeared in the United States at a time when the benefits, risks, and costs of medical technology were of increasing concern. Because of this concern, CT scanning has been evaluated more than is usual. Thus, the CT scanner itself is not the problem. The problem is much broader and concerns appropriate use of medical technology in society. Perhaps a detailed examination of some aspects of policy toward CT scanning can indicate how far we are from having effective policies to promote the efficient expenditure of our health care dollar (142). In particular, OTA is concerned about regulatory approaches being considered to control CT scanners and other technologies in the absence of definitive scientific information that will allow wise decisionmaking by Federal officials or insurance companies.

The purpose of the original OTA study on the CT scanner (129) was twofold. First, it was to examine the usefulness and costs of CT scanning, the effect of CT scanners on medical care delivery patterns, and ways to improve planning affecting such devices. In the background was a concern about the implications of costly new technologies such as CT scanners. The second purpose was to examine policies toward CT scanners. The 1978 study examined emerging and existing policies concerning the development, evaluation, diffusion, use, and financing of the CT scanner. It attempted to determine the effects, both real and potential, of those policies, and to identify problems experienced in implementing them.

Like the original report, this update (covering the period since August of 1978) documents the changes in the number, distribution, and diffusion of CT scanners. It also summarizes changes in Federal policies, agencies, and programs during that time that affect research, development, and diffusion of CT scanners, and the evaluation and financing of CT scanning. Wherever

possible, it focuses on the relationship between changes in policy and in the numbers and distribution. Although the 1980 CT scanner is quite different from the 1973 edition, most of the discussion treats all scanners as if they are the same (see app. B). Nevertheless, the continued development of technological improvements in CT scanners and the concomitant documentation of new uses for scanners, has posed a serious problem for policymaking.

The dramatically rapid rate of diffusion of scanners during 1975 and 1976 set the stage for OTA's original study. An equally dramatic drop in this rate during 1978, 1979, and 1980 provides the backdrop for this update. During 1977, the rate of installation of scanners was about 40 per month. (ch. 2 compares this rate of diffusion with that of other technologies.) In 1978, the rate fell by half to about 20 per month. Whereas about 480 scanners were installed in 1977, only 270 units were installed in "1978. These turnabout trends in the installation of scanners are also reflected in the manufacture of CT scanners. The consolidation of production evident in 1978 is in sharp contrast to the expansion that had occurred steadily since the mid-1970's (see ch. 2).

This diffusion pattern has occurred during a period of change in Federal policies toward medical technology. With recent changes in Federal law, the Federal Government is involved in every stage of research, development, diffusion, and use of CT scanning (see table 1). The Government has invested in R&D on CT scanning. But the Government also regulates CT scanners through the Food and Drug Administration, which approves medical devices for marketing. Since 1974, a nationwide network of

Table 1 .—Medical Technology Development and Use: Formal Programs of the Department of Health and Human Services

Policy area	Stage of development	Function	Agency or program
R&D	1. Research and development		
	a. Basic research	• Support and planning of research	NIH, other small
	b. Applied research	Support and planning of research	NIH, other agencies and programs
Evaluation. .	2. Demonstration of safety, efficacy, and cost effectiveness		
	a. Clinical trials	• Test safety • Test efficacy • Protect human subjects	NIH, other small
	b. Assure efficacy and safety of drugs and devices	• Control of testing procedures . Postmarketing surveillance	FDA
	c. Provide economic analyses	• Cost-benefit analysis • Cost-effectiveness analysis	NIH (limited) NCHCT, NCHSR
	d. Evaluate social, ethical, and political impacts	• Technology assessment	
Regulation .	3. Diffusion	• Premarket approval of drugs and devices	FDA
		• Encourage distribution by information dissemination	NIH (limited)
		Control distribution through CON, review of purchase	HRA
Financing . .	4. Widespread use	• Assure appropriate use	PSRO certification programs
		• Monitor practice	PSROs (limited)
		. Reimbursement	Medicare (elderly)
		• Define benefits package	Medicaid (poor)
		• Set reimbursement levels	

CON = certificate of need.
FDA = Food and Drug Administration
HRA = Health Resources Administration.
NCHCT = National Center for Health Care Technology.
NCHSR = National Center for Health Services Research.
NIH = National Institutes of Health
PSRO = Professional Standards Review Organization.

SOURCE: H. D Banta, "Public Policy and Medical Technology: Critical Issues Reconsidered," presented at the conference "Policylnnovation and the Service Sector," Berlin, West Germany, June 13-16, 1978.

health planning agencies has had approval power over capital investments such as that required to purchase a CT scanner. The medicare and medicaid programs pay for CT scanning. And the Professional Standards Review Organization program has had the authority since 1972 to review medical services provided under the medicare and medicaid program for medical appropriateness. The impact of these policies and programs is explored in succeeding chapters.