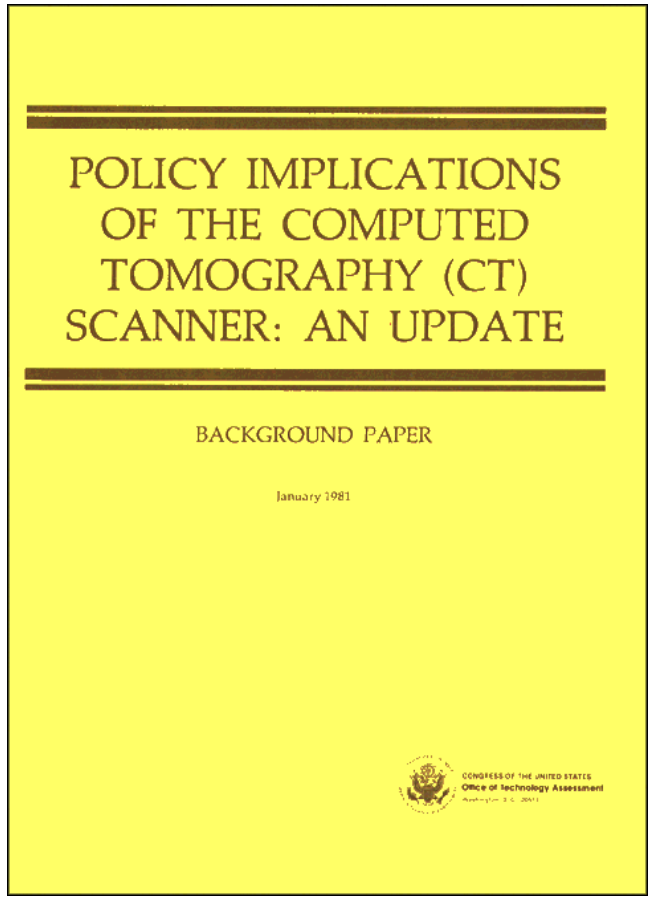
Policy Implications of the Computed Tomography (CT) Scanner: An Update

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Foreword

In August 1978, OTA published a report called *Policy Implications of the Computed Tomography (CT) Scanner*. The report has generated much interest in both the CT scanner itself and Federal policies aimed at rationalizing its diffusion and use. During the summer of 1979, OTA staff reviewed the status of policies concerning the scanner and found that they were very much in the process of change. A number of staff of congressional committees (especially the Senate Committee on Finance, which had requested the original study) expressed interest in an update of material in the original report. In addition, OTA continued to be consulted by outside organizations and groups, including Federal and State government agencies, on implications of CT scanners, For these reasons, OTA decided to update the 1978 report.

This paper does not repeat material in the original report. For the most part, it is assumed that the reader is familiar with the 1978 report. Thus, basic descriptions of the scanner and of certain Federal laws and policies are found in the earlier report.

As part of this paper, OTA has updated its list of operational CT scanners. The OTA list apparently continues to be the most complete and reliable inventory of scanners. An analysis of data from the list is presented in chapter 2.

This paper considers the CT scanner in the context of the entire field of what has come to be called "diagnostic imaging" (making pictures of the inside of the human body for the purposes of diagnosis). A number of new applications of existing technologies as well as several new technologies have developed. The field of diagnostic imaging is developing rapidly, and presents a significant challenge to policy makers. Can the relative advantages of the different technologies be demonstrated? Can Federal policies rationalize the use of the many technologies? Or will the new technologies merely be added on to the existing methods, driving up costs and contributing only a small marginal benefit to people's health?

Since this is a background paper, no policy options are presented. The purpose of this paper is to summarize the most important development concerning CT scanners that have occurred over the past 21/2 years. However, since the policy options of the 1978 report seem generally valid, they are reprinted in appendix A.

Drafts of the final paper were reviewed by the Health Program Advisory Committee chaired by Dr. Sidney Lee and by a number of other individuals and groups representing manufacturers, radiologists, and Federal agencies (see app. I). We are grateful for their assistance.



JOHN H. GIBBONS
Director

Health Program Advisory Committee

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General Director
Beth Israel Hospital

Frederick C. Robbins
President
institute of Medicine

Kerr L. White
Rockefeller Foundation

Computed Tomography Scanner Project Staff

Joyce C. Lashof, *Assistant Director-, OTA*
Health and Life Sciences Division

H. David Banta, *Health Program Manager*

Karen Kohlhof, Co-Project *Director*
H. David Banta, *Co-Project Director*

Chester Strobel, Research *Associate*
John Bell, Computer *Prograrner*
Kerry Britten Kemp, * *Editor- and Writer*
Virginia Cwalina, *Administrative Assistant*
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Publishing Staff

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Patricia A. Dyson*

● Contract personnel

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1.

Introduction

Introduction

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.

2 .
Number and Distribution of CT Scanners

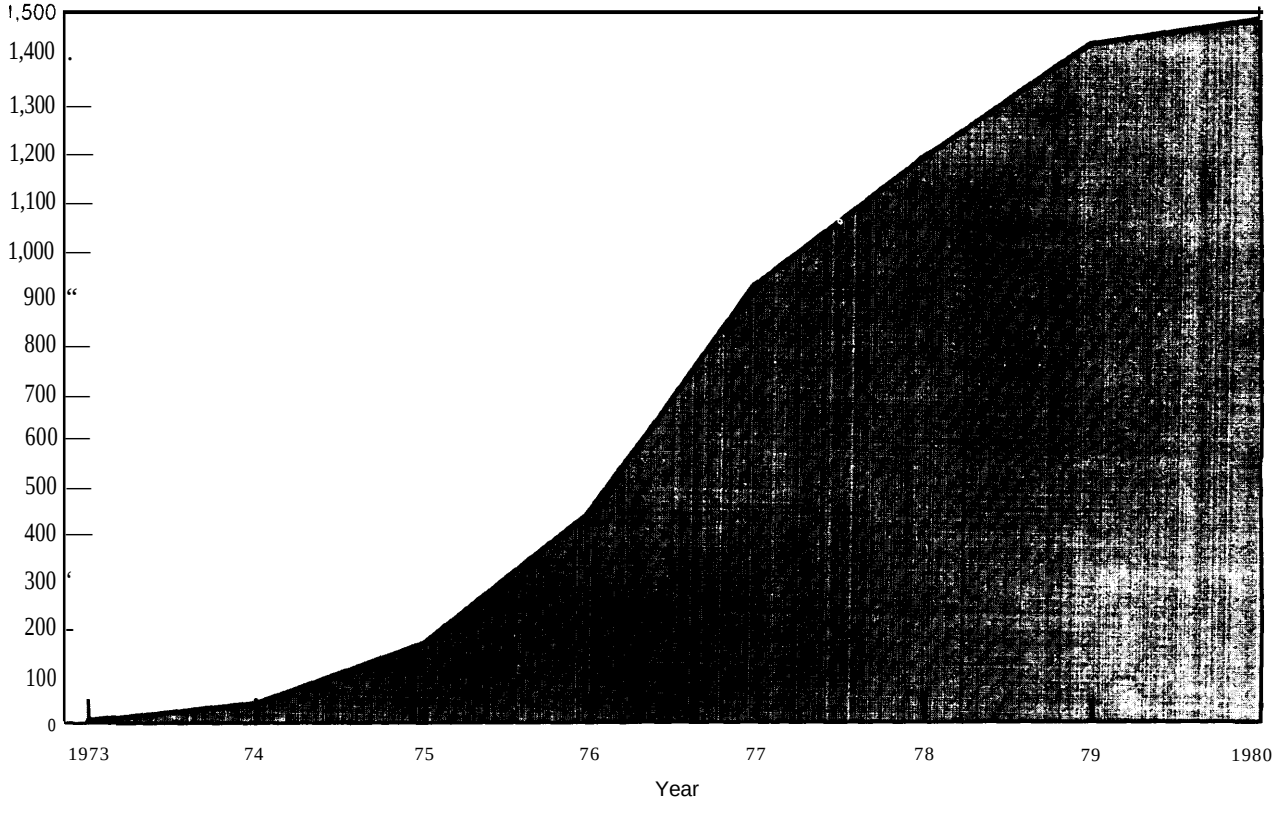
2.

Number and Distribution of CT Scanners

By May 1, 1980, there were 1,471 operational scanners in the United States. This number of operational scanners has been rapidly attained (see figure 1). ' At the end of 1974, only 45 scanners were in operation. Two years later, at the end of 1976, the number of operational scanners had increased to 475. Diffusion was even more rapid in 1977, when about 40 scanners were installed per month. During 1978, however, the rate of installation of scanners fell by nearly half, In 1979 and the first 4 months of 1980, the rate fell a little more, to about 17 scanners per month.

'Based on data collected through April **1980.**

Figure 1.—Cumulative Number of CT Scanners Installed (1973-80)



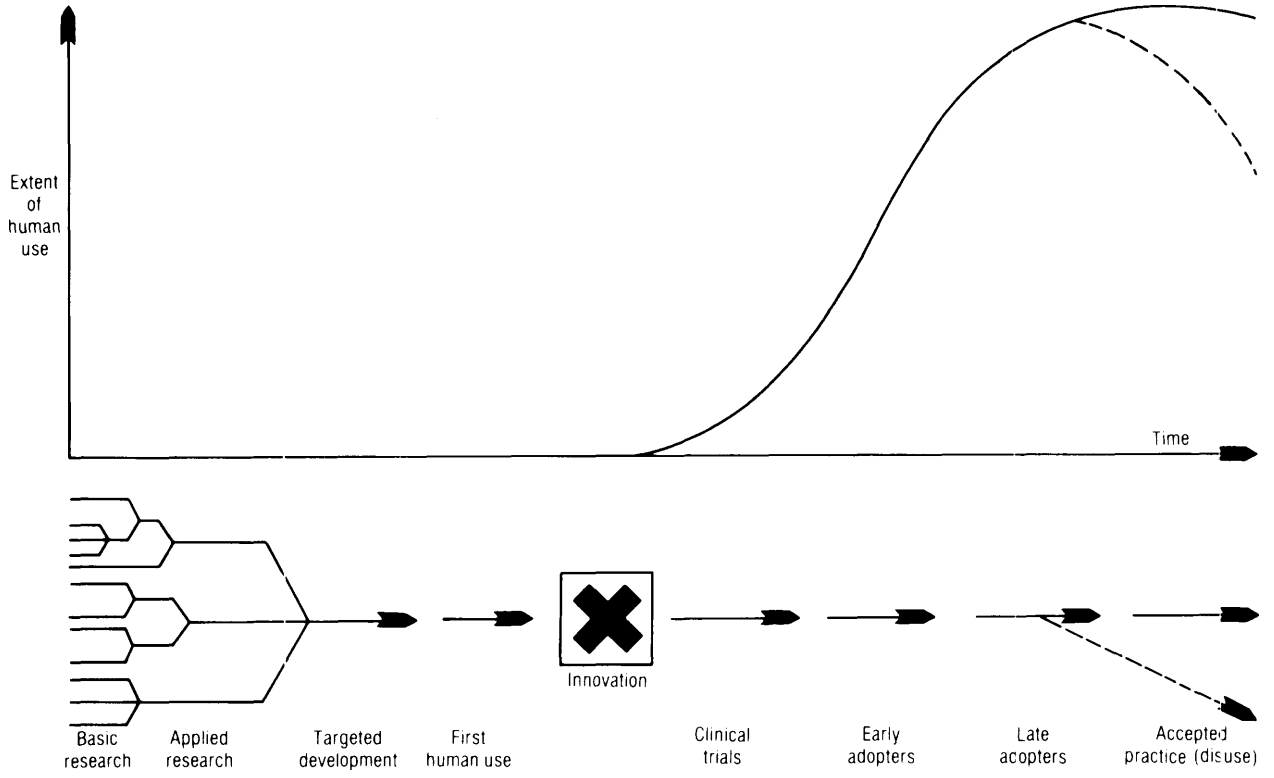
SOURCE Off Ice of Technology Assessment

DIFFUSION OF' MEDICAL TECHNOLOGY– SOME GENERAL CONSIDERATIONS

The process by which a technology enters and becomes part of the health care system is known as diffusion. The diffusion of a technology follows the stage of R&D and may or may not occur following careful clinical trials to demonstrate efficacy and safety. Descriptive research has shown that the diffusion process for any technology usually follows an S-shaped or sigmoid curve, relating the percentage of potential adopters to actual adopters (see figure 2). Generally, there is an early phase of diffusion that is somewhat slower. This has been interpreted as indicating caution on the part of users (145), although it could also indicate problems of communication of information about the innovation (126). As experience indicates that the technology does indeed have some benefit, acceptance increases. Finally, when most potential adopters have accepted the innovation, diffusion slows and the curve flattens. Although most of the work demonstrating the S-shaped diffusion curve is outside the health care area, this curve has been documented for such medical technologies as intensive care units (1.46), cardiac pacemakers (126), respiratory therapy (146), diagnostic radioisotope facilities (1.46), and electroencephalographs (146).

The diffusion of medical technologies does not always follow the sigmoid curve. One major departure from this model occurs when diffusion reaches a high rate almost immediately

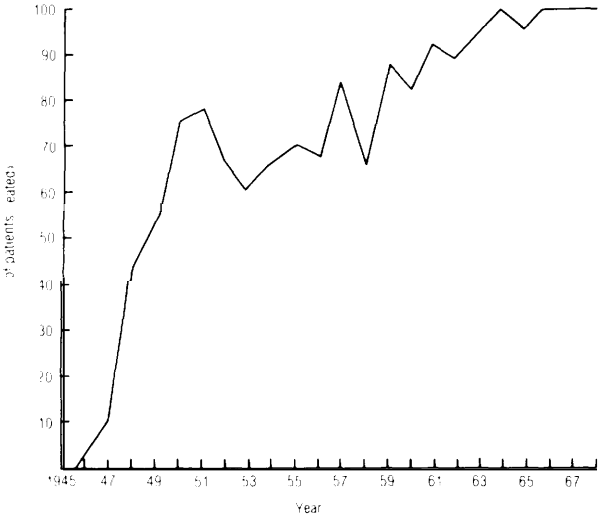
Figure 2.—A Scheme for Development and Diffusion of Medical Technologies



SOURCE Off Ice of Techology Assessment, U S Congress, *Development o/ Medical Technology Opportunities for Assessment* (Washington, D C Government Printing Off Ice, August 1976)

after the technology becomes available (see figure 3). This pattern has been referred to as the "desperation-reaction model" (182). A first phase of rapid diffusion seems to occur because of the provider's sense of responsibility to help the patient and their mutual desperation. Later, results of clinical tests and experience begin to influence the physician's behavior. If results of tests are positive, diffusion may continue rapidly. If the evidence is not clear cut, there may be caution and slow diffusion. If the evidence seems negative, use of the technology gradually declines.

Figure 3.— Diffusion of Chemotherapy for Leukemia



SOURCE K Warner, "A 'Desperation-Reaction' Model of Medical Diffusion," *Health Service* Research 10369, 1975. Redrawn by the Off Ice of Technology Assessment

Whatever its initial pattern of diffusion, a technology may eventually be partially or completely abandoned. The rate of tonsillectomy (surgical removal of the tonsils), for example, is presently declining (119). Such a decrease in use can result from additional knowledge or the introduction of a more effective technology. The introduction of polio vaccine, for example, almost overnight entirely supplanted the costly halfway technology of rehabilitation centers (176).

Little work has been done on the diffusion of specific medical technologies, but some comparisons can be made. Intensive care is an expensive technology that had its most rapid spread in U.S. hospitals from 1960 to 1968. The most rapid diffusion rate was slightly over 200 per year, or less than 20 per month (146). Another technology, nuclear medicine, spread at the rate of almost 200 facilities per year during the period 1969 to 1972 (141), As noted above, the diffusion of CT scanners was considerably more rapid than the diffusion of either of these two technologies. The more rapid diffusion of CT scanners could be due in part to the change in reimbursement policies since the 1960's.

Technologies have been observed to diffuse most rapidly among large hospitals **(146).** Early diffusion to hospitals affiliated with medical schools was observed for intensive care (146) and nuclear medicine (141). Cromwell, et al. (39), however, found that when size and long-term debt were held constant, medical school affiliation had little effect *on* equipment expenditures. These investigators also showed that technologies diffuse more rapidly as the percentage of hospital resources from third parties increases. As seen below, except for its rapidity, the diffusion of CT scanners generally follows the pattern predicted by previous research.

The sections that follow give detailed information on the diffusion and present distribution of CT scanners.

DISTRIBUTION OF OPERATIONAL SCANNERS[2]

Geographic Distribution

Table 2 summarizes information on the location of scanners by State. All States have at least one scanner. There are no scanners in American Samoa, Guam, the Trust Territory of the Mariana Islands, or the Virgin Islands. The national average is now about 6.7 scanners per million population. Washington, D. C., has the highest ratio, with 16.7 scanners per million population. States with high scanner-to-population ratios include Nevada (12.8), Florida (10.9), California (10.5), Missouri (9.4), North Dakota (9.1), Arizona (9.0), Nebraska (8.3), and New Mexico (8.0). States with the lowest scanner-to-population ratios include South Carolina (2.4), Rhode Island (3.3), Idaho (3.3), Delaware (3.4), Michigan (3.6), New Jersey (3,7), Kentucky (3.7), and Montana (3.8). Puerto Rico has only about 1.6 scanners per million population. Table 3 shows that a ranking of States according to scanner-per-population ratios changed little with the addition of new scanners between February 1979 and May 1980.

[2]Numbers in this paper may differ from those in the 1978 OTA report on CT scanners because they include additional scanners identified, replacements, and so on.

Table 2.— Distribution of CT Scanners by Region and State (May 1980)

Region and State	Number of CT scanners		Number of CT scanners per million population[a]		
	Hospital	Office	Hospital	Office	Total
New England	48	9			
Maine	5	0	4.6	—	4.6
New Hampshire	3	1	3.4	1.3	4.7
Vermont	1	1	2.3	2.3	4.6
Massachusetts	25	5	4.3	0.9	5.2
Rhode Island	2	1	2.2	1.1	3.3
Connecticut	12	1	3.9	0.3	4.2
Middle Atlantic	147	56			
New York	61	42	3.5	2.4	5.9
New Jersey	20[b]	7	2.7	1.0	3.7
Pennsylvania	66[b]	7	5.6	0.6	6.2
East North Central	190	41			
Ohio	50	12	4.7	1.1	5.8
Indiana	24	6	4.4	1.1	5.5
Illinois	69[c]	11	6.1	1.0	7.1
Michigan	27	6	2.9	0.7	3.6
Wisconsin	20	6	4.2	1.3	5.5
West North Central	107	15			
Minnesota	17	6	4.2	1.5	5.7
Iowa	13	4	4.5	1.4	5.9
Missouri	44	2	9.0	0.4	9.4
North Dakota	5	1	7.6	1.5	9.1
South Dakota	3	0	4.4	—	4.4
Nebraska	11	2	7.0	1.3	8.3
Kansas	14	0	5.9	—	5.9
South Atlantic	205	51			
Delaware	1	1	1.7	1.7	3.4
Maryland	21[d]	6	5.1	1.4	6.5
District of Columbia	10	1	15.2	1.5	16.7
Virginia	27	4	5.2	0.8	6.0
West Virginia	9	1	4.8	0.5	5.3
North Carolina	28	4	5.0	0.7	5.7
South Carolina	7	0	2.4	—	2.4
Georgia	32	7	6.2	1.4	7.6
Florida	70[c]	27	7.9	3.0	10.9

Table 2.—Distribution of CT Scanners by Region and State (May 1980)–continued

Region and State	Number of CT scanners		Number of CT scanners per million population[a]		
	Hospital	Office	Hospital	Office	Total
East South Central ...,	67	6			
Kentucky, ..., ..., ..., ...,	11	2	3.1	0.6	3.7
Tennessee. ..., ..., ...	24	3	5.5	0.7	6.2
Alabama ., ..., ..., ...,	22	0	5.8	—	5.8
Mississippi ., ., ..., ..., ..., . . .	10	1	4.1	—	4.1
West South Central	126	1			
Arkansas	9	1	4.1	0.5	4.6
Louisiana	25[b]	3	6.2	0.7	6.9
Oklahoma	15	0	5.2	·	5.2
Texas	77	25	5.8	1.9	7,7
Mountain	62	14			
Montana	3	0	3.8	—	3.8
Idaho	3	0	3.3	—	3.3
Wyoming. . ., ...,	2	0	4,4	—	4,4
Colorado	17	3	6.1	1.1	7,2
New Mexico	5	5	4.0	4.0	8.0
Arizona	18[c]	4	7.3	1.6	9.0
Utah.	6	1	4.4	0.7	5.1
Nevada.	8	1	11.4	1,4	12.8
Pacific. . . . ., ...,	239	54			
Washington. . . . .,	19	11	4.8	2.8	7.6
Oregon.	16	0	6.3	—	6.3
California. . . ., ...	196[e]	43	8.6	1,9	10.5
Alaska . . . ., ..., .	3	0	7.4	—	7.4
Hawaii ., ..., ..., ..., ...	5	0	5.5	—	5.5
Puerto Rico.	2	3	0.6	1.0	1.6
Subtotal	1', 193	2 7 8	5.4	1.3	6 . 7
Total scanners in the United States ..., ...	1,471			6.7	

[a]Population data were obtained from the U S Bureau of the Census
[b]Including 1 mobile scanner
[c]Including 2 mobile scanners
[d]Including 3 scanners at the National Institutes of Health If they are removed from the totals, Maryland has 58 scanners per million population
[e]Including 8 mobile scanners

The ratio of scanners per million population is often used as a standard by which to compare scanner availability in the United States to scanner availability in other countries. Table 4 gives the number of CT scanners in the United States and in a number of other industrialized countries early in 1979. It seems apparent from these data, and from other sources, that the United States at present has the greatest number of CT scanners of any country in the world. This information is not easy to interpret, however, because the appropriate number of scanners is not known. One also needs to consider that the United States has, in addition to scanners, the greatest amount of other diagnostic technologies such as conventional X-ray **(120)** and a large number of surgeons per capita in comparison to such countries as Canada and the United Kingdom (28,178).

Within the United States, the ratio of scanners per million population is often used as an indicator of relative geographic maldistribution from State to State, as the discussion above illustrates. The ratio is inadequate as an indicator of relative access, however, because it does not incorporate the geographic dimension of access. The ranking of States by number of square miles is shown in the last column of table 3. It is striking that the 10 States with the highest scanner-to-population ratios are all relatively large States characterized by relatively low population densities. Several of these States are further characterized as mostly rural, so their population may be expected to be dispersed over the State.

The point to be made is that both population and geography are essential factors to consider

Table 3.—Ranking of States by CT Scanners per Million Population as of February 1979 and May 1980

States (ranked by May 1980 ratio of scanners/ million population)	May 1980 ratio of scanners/million population	February 1979 ratio of scanners/million population	State ranking based on 1979 ratio of scanners/ million population	State ranking based on size in square miles
1. Nevada	12.8	12.8	1	7
2. Florida	10.9	10.3	2	22
3. California	10.5	9.8	3	3
4. Missouri	9.4	8.3	4	19
5. North Dakota	9.1	7.7	7	17
6. Arizona	9.0	7.8	6	6
7. Nebraska	8.3	8.3	5	15
8. New Mexico	8.0	4.2	37	5
9. Texas	7.7	6.3	12	2
10. Georgia	7.6	7.5	8	21
11. South Carolina	7.6	2.1	50	40
12. Washington	7.6	6.3	13	20
13. Alaska	7.4	7.4	9	1
14. Colorado	7.2	7.2	10	8
15. Illinois	7.1	6.0	14	24
16. Louisiana	6.9	5.6	18	31
17. Maryland	6.5	6.3	11	41
18. Oregon	6.3	5.2	20	10
19. Pennsylvania	6.2	4.5	30	33
20. Tennessee	6.2	6.0	16	34
21. Virginia	6.2	4.5	31	36
22. Iowa	5.9	4.2	36	25
23. Kansas	5.9	4.7	26	14
24. New York	5.9	4.8	25	30
25. Alabama	5.8	4.9	23	29
26. Ohio	5.8	4.4	32	35
27. Minnesota	5.7	6.0	15	12
28. North Carolina	5.7	4.9	24	28
29. Hawaii	5.5	4.5	29	47
30. Indiana	5.5	5.3	19	38
31. Wisconsin	5.5	5.2	21	36
32. Massachusetts	5.4	3.6	41	45
33. West Virginia	5.3	4.3	34	42
34. Oklahoma	5.2	4.6	28	18
35. Utah	5.1	5.1	22	11
36. New Hampshire	4.7	4.7	27	44
37. Arkansas	4.6	4.2	35	27
38. Maine	4.6	3.6	40	39
39. Vermont	4.6	4.2	38	43
40. South Dakota	4.4	4.4	33	16
41. Wyoming	4.4	2.5	48	9
42. Connecticut	4.2	3.6	39	48
43. Mississippi	4.1	3.3	44	32
44. Kentucky	3.7	3.2	45	37
45. New Jersey	3.7	2.6	47	46
46. Michigan	3.6	3.4	43	23
47. Delaware	3.4	3.4	42	49
48. Idaho	3.3	5.8	17	13
49. Rhode Island	3.3	2.2	49	50
50. Montana	3.0	3.0	46	4

SOURCE. Office of Technology Assessment.

in determining access, This is of particular importance when making comparisons of access between States or countries. An intuitive appreciation of the relationship between population and geography is illustrated by comparing the availability of CT scanners in the largest State, Alaska, and the smallest, Rhode Island. 130th States have three scanners, but Alaska has 7.4 scanners per million population while Rhode Island has only 2.2. Few would infer from this in-

Table 4.— Distribution of Installed CT Scanners in 10 Countries (1978 and 1979)

Country[a]	March 1978 Number of scanners Head	Body	Total	Scanners per million population	1979 Number of scanners Head	Body	Total	Scanners per million population
United States	3 3 7	668	1,005	4.6	400	854	1,254	5.7 (Feb.)
Japan	180	112	292	2.6	304	212	516	4.6 (Apr.)
West Germany	51	42	93	1.5	u	u	160	2.6 (July)
Australia	u	u	u	u	7	21	28	1.9 (Jan.)
Canada	u	u	u	u	9	29	38	1.7 (May)
Sweden	8	5	13	1.6	8	6	14	1.7 (Feb.)
Netherlands[b]	u	u	u	u	u	u	20	1.4 (Jan.)
United Kingdom	36	16	52	0.9	39	18	57	1.0 (Jan.)
France[c]	10	2	12	0.2	20	10	30	0.6 (Jan.)
Iceland	0	0	0	0.0	0	0	0	0.0 (Jan.)

Key to symbols U = Unknown
aRanked by scanners per million population in 1979
bThe Netherlands has planned to Install 30 head scanners and 8 body scanners
cIn France an additional 21 scanners were authorized in July 1979

SOURCE Reprinted from reference 128 Data sources can be found there

formation, however, that Alaskans have better access to scanners (according to geographic availability) than Rhode Islanders. On the other hand, the population of Rhode Island is almost twice that of Alaska. Consequently, its greater population density implies that access may be greater in the geographic sense, but less in terms of the greater population served.

OTA suggests consideration, therefore, of an alternative index of scanner availability that would incorporate the geographic dimension of access. The index is based on the index used to compare physician availability for any designated unit of analysis (124). The unit of analysis that would be most appropriate in this case would be individual health services areas. [3] First, a ratio of the number of scanners in a health service area to the number of scanners in the entire United States would be computed. Next, a ratio of the population density (persons per square mile) of the health services area to the population density of the United States would be determined. The availability index of the geographic unit of analysis would be the weighted average of the ratio between the first ratio and the second. This index would have the advantage of incorporating the relative impacts of geographic effects and population effects on access. The calculation of such an index would not give a clear indication of what appropriate access should be, since the only point of reference would be the national average. Although this index would not be the ideal indicator, given the data currently available, it would be an improved indicator to use in discussions of comparative accessibility.

In terms of health service areas, the distribution of scanners has improved. In 1979, there were 16 health service areas with no CT scanners, but now there are only 3. Table 5 shows the number and type of CT scanner (head or body) by health service area of May 1980. Although health service areas are smaller units than States, and therefore give a better sense of geographic distribution, some encompass the entire State. However, the ratio of scanners to population still varies greatly from one health service area to another.

Institutional Distribution

In May 1980, 18.9 percent of the 1,471 operational scanners were in private offices and clinics: This is *very close* to the figure of 19 percent observed in the May 1977 data presented in the original OTA CT report (129). Table 2 shows the number of scanners in noninstitutional settings by State. More importantly, table 2 also shows the ratio of private office scanners to population. States with high ratios include New Mexico, with 4.0 scanners per million per-

[3] Health service areas are the geopolitical areas served by corresponding health systems agencies (HSAS).

Table 5.— Number of CT Head and Body Scanners by Health Service Areas (May 1980)

State	Health service area (by number)														
	1	2	3	4	5	6	7	8	9	10	11	12	13-	14	Total
Alabama	2B	1B	6B 2H	2B	4B 1H	2B 2H	* —								5H
Alaska		2B	1B												3B —
Arizona	9B 3H	3B 3H	 1H	* —	2B 1H										14B 8H
Arkansas	3B	 1H	3B 1H	1B 1H											7B 3H
California	4B 3H	6B 4H	3B 2H	17B 5H	14B 7H	3B 2H	6B 7H	5B 2H	4B 5H	3B 3H	47B 40H	9B 2H	12B 5H	12B 7H	145B 94H
Colorado	11B 4H	3B 1H	 1H												14B 6H
Connecticut	3B 1H	3B	1B	1B 1H	3B										11B 2H
Delaware	1B 1H														1B 1H
District of Columbia	8B 3H														8B 3H
Florida	3B 3H	4B 1H	5B 2H	14B 7H	5B 2H	9B 3H	7B 2H	7B 3H	14B 6H						68B 29H
Georgia	* 1H	2B 1H	13B 4H	4B* 1H	4B* 2H	3B 1H	2B 1H								28B 11H
Hawaii	3B 2H														3B 2H
Idaho	2B 1H														2B 1H
Illinois	3B 1H	2B 1H	3B 1H	2B 3H	2B	17B 8H	15B 8H	5B 2H	1B 1H	1B*	3B* 1H				54B 26H
Indiana	7B 3H	10B 3H	6B 1H												23B 7H
Iowa	11B 3H	2B*	*												13B 4H
Kansas	1B	1B 2H	3B 1H	5B* 1H											10B 4H
Kentucky	5B 2H	6B	* —												11B 2H
Louisiana	11B 4H	5B 1H	6B 1H												22B 6H
Maine	3B 2H														3B 2H
Maryland	2B	8B 2H	3B	8B 3H	1B										22B 5H
Massachusetts	2B	2B	2B 1H	9B 10H	1B	1B 2H									17B 13H
Michigan	14B 5H	2B	2B 1H	2B	1B 2H	1B 1H	1B	1B							24B 9H
Minnesota	* —	2B*	* —	1B	13B 3H		2B 2H								18B 5H
Mississippi	8B 3H														8B 3H
Missouri	11B*	3B 1H	17B* 8H	3B 1H	2B										36B 10H
Montana	2B 1H														2B 1H
Nebraska	1B 1H	2B	7B* 2H	* —											10B 3H
Nevada	3B	3B 3H													6B 3H
New Hampshire	3B 1H														3B 1H
New Jersey	4B 2H	5B 2H	3B 1H	5B 1H	2B 2H										19B 8H

Table 5.—Number of CT Head and Body Scanners by Health Service Areas (May 1980)–continued

State	Health service area (by number)														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total
New Mexico	5B 5H	* —													5B 5H
New York	7B 6H	7B 1H	4B 3H	1B* 1H	1B 3H	7B 3H	34B 11H	10B 4H							71B 32H
North Carolina	2B	3B 4H	5B 3H	6B 2H	2B 1H	3B 1H									21B 11H
North Dakota	3B 1H	1B*	* 1H												4B 2H
Ohio	4B* 4H	3B 2H	2B	4B 1H	7B 4H	3B	3B	4B 1H	12B 3H	4B 1H					46B 16H
Oklahoma	13B 2H														13B 2H
Oregon	9B	3B 2H	1B 1H												13B 3H
Pennsylvania	19B 7H	2B 1H	1B 1H	7B 1H	1B 1H	16B 8H	2B 2H	1B*	3B						52B 21H
Rhode Island	2B 1H														2B 1H
South Carolina	2B 1H	1B	1H	2B —	*										5B 2H
South Dakota	3B														3B —
Tennessee	3B* 1H	5B 1H	2B* 2H	4B 1H	1B	4B 3H									19B 8H
Texas	1B 1H	2B 2H	2B 4H	1B	12B 9H	4B 3H	3B	2B 2H	7B 5H	1B 2H	22B 15H	2B			59B 43H
Utah	7B	*													7B —
Vermont	2B														2B —
Virginia	1B 4H	3B 2H	4B 1H	5B 3H	5B 3H	* —									18B 13H
Washington	8B 10H	3B	3B 1H	5B											19B 11H
West Virginia	7B 3H														7B 3H
Wisconsin	2B 2H	7B 5H	2B 1H	2B	2B	2B 1H	* —								17B 9H
Wyoming	2B														2B —
Puerto Rico	4B 1H														4B 1H

Key to symbols: H = head scanner; B = body scanner.
*Interstate health service areas:
Alabama 7 and Georgia 5.
Arizona 4, and New Mexico 2, and Utah 2.
Georgia 1 and Tennessee 3.
Georgia 4 and South Carolina 5.
Illinois 10 and Iowa 3.
Illinois 11 and Missouri 3.
Iowa 1 and Nebraska 4.
Iowa 2 and Nebraska 3.
Kansas 4 and Missouri 1.
Kentucky 3 and Ohio 1.
Minnesota 1 and North Dakota 2.
Minnesota 2 and Wisconsin 7.
New York 4 and Pennsylvania 8.
Tennessee 1 and Virginia 6.

SOURCE Office of Technology Assessment

sons, Florida (3.0), Washington (2.8), New York (2.4), and Vermont (2.3). A number of States have no private office scanners.

The proportion of scanners located in private offices versus hospitals raises concern over the issue of access. Data on the hospitals by type and size do little to assuage this concern. Tables 6 and 7 present data on the distribution of CT scanners by type of facility and for short-term, general community hospitals, by size of hospital. Of a total of 5,881 short-term general hospitals (12), 1,01.5 or 17.3 percent have CT scanners. As shown in table 7, 361 hospitals, or 35.6

Table 6.—Distribution of CT Scanners by Type of Facility (May 1980)

Type of facility	Facilities with CT scanners: Number	Facilities with CT scanners: Percentage of total	CT scanners: Number	CT scanners: Percentage of total
All hospitals	1,041	78.7%	1,175	79.9%
Community hospitals[a]	(1,015)	(76.7)	(1,147)	(77.9)
Other short-term hospitals[b]	(26)	(1.9)	(28)	(1.9)
Mobile scanners	18	1.4	18	1.2
Office and clinics	264	19.9	278	18.9
Total	1,323	100.0%	1,471	100.0%

[a]Includes proprietary, public, and voluntary community hospitals
[b]Includes 17 VA hospitals and 8 armed forces hospitals

SOURCE: Office of Technology Assessment and American Hospital Association

Table 7.—Distribution of CT Scanners in Community Hospitals[a] by Hospital Size (May 1980)

Size of hospital	All hospitals: Number	All hospitals: Percentage of total	Hospitals with CT scanners: Number	Hospitals with CT scanners: Percentage of total	Number of CT scanners
O- 99 beds	2,833	48.2%	14	0.5%	14
100-199 beds	1,401	23.8	129	9.2	133
200-299 beds	713	12.1	218	30.6	225
300-399 beds	380	6.5	220	57.9	228
400-499 beds	243	4.1	170	70.0	187
500 and over	311	5.3	264	84.9	360
Total	5,881	100.0%	1,015	17.3%	1,147

[a]Includes proprietary, public, and voluntary hospitals Does not Include federally supported hospitals

SOURCE Office of Technology Assessment and American Hospital Association

percent of the total community hospitals having CT scanners, are less than 300 beds in size.

Of the total short-term general hospitals, 1,832 are supported by State and local governments, and only 161, or 8.8 percent, have CT scanners. When size is taken into consideration, this point becomes even more striking. A short-term general hospital with 500 beds or more is almost certain to have an active emergency room, a neurosurgery service, and other specialized and acute care services that virtually require a CT scanner for the provision of appropriate care. But of the 47 local-government-supported community hospitals of at least 500 beds, only 32 have CT scanners. New York City alone has six such hospitals with no CT scanner. These include Bellevue Hospital (1,258 beds),[4] Harlem Hospital Center (884 beds), Metropolitan Hospital (754 beds), and the City Hospital of Elmhurst (816 beds). Other important public hospitals in the United States without CT scanners include Cook County Hospital in Chicago (1,326 beds), D.C. General Hospital in Washington, D. C. (600 beds), and San Juan Municipal Hospital in San Juan, Puerto Rico (687 beds). Not only are the patients of these hospitals poor, but they are often members of minority groups.

The problems related to the distribution of CT scanners in hospitals are not confined to those in urban ghettos. The Department of Defense and the Veterans Administration (VA) operate large hospital systems. Although these hospitals do not run the busy emergency rooms of the urban public hospitals, they do serve large populations. Only 17 of 171 VA hospitals and 8 of 135 armed forces hospitals currently have CT scanners. There are 44 VA hospitals across the country with 500 beds or more that have no CT scanner. (The average bed size of this group of VA hospitals is over 800 beds.)

[4]Money is currently budgeted for a scanner for Bellevue Hospital.

There is 1 armed forces hospital of over 500 beds with no scanner. (See app. C for more details on the VA and armed forces' policies toward CT scanners.)

As shown in table 7, 84.9 percent of short-term general hospitals of over 500 beds now have at least 1 CT scanner; 264 such hospitals have 360 scanners. Thus, there is a fair proportion of community hospitals with more than one scanner. This category is comprised of several types of hospitals including voluntary, public, and proprietary. Most of the community hospitals with CT scanners are voluntary. The category of public hospitals includes hospitals supported at the level of hospital district, city, county, and State governments, but excludes federally supported hospitals. Of the State-supported hospitals with over 500 beds that have CT scanners, all but one are affiliated with the State university. This reflects the concentration of diffusion of CT scanners in hospitals affiliated with virtually all medical schools in the country. However, not all university teaching hospitals are large, and some major ones lack a CT scanner (e.g., Beth Israel in Boston).

The plight of local-government-operated hospitals has already been discussed above. The case of proprietary hospitals also illustrates inequity in distribution of CT scanners. There are a total of 81 such institutions with CT scanners. In general, proprietary hospitals tend to be smaller, in terms of bed size, than other community hospitals. Of the 80 proprietary hospitals with scanners, 40 have less than 200 beds.

In total, there are 97 hospitals of all types with 500 beds or more which are still without a CT scanner. The 44 VA hospitals constitute almost half of these, or 45.4 percent. The 15 large, publicly supported urban hospitals and 1 military hospital discussed above comprise another 16.5 percent, and the remaining 36 hospitals, or 40.3 percent, are "private" community hospitals, including voluntary and proprietary hospitals.[5] There are, then, 51 community hospitals of 500 beds or more without scanners, which account for the 16.5 percent of all hospitals of that type and size that are still without CT scanners.[b]

Based on these data, a seemingly clear case of maldistribution of scanners within the category of hospital settings emerges. It is not clear, however, which type and size of hospital may derive the greatest benefit from having a CT scanner. Modest evidence from a new study suggests that scanners may have a greater diagnostic and therapeutic impact in *a* public university-affiliated hospital than in a private medical center with a similar affiliation (14). Yet it is these hospitals for whom the economic and technical support a scanner requires may be less feasible.

The capital expenditures and technical support required may prohibit the hospital of less than 200 or 300 beds from installing a scanner. Table 7, showing the proportion of community hospitals by bed size and the proportion of each of these groups that has a CT scanner, would lend support to this hypothesis.

This analysis of type of setting, and type and size of hospital, suggests another issue besides that of institutional distribution of scanners: The commercial market for CT scanners, at least in voluntary community hospitals of appreciable size (500 beds), may be approaching saturation. Such a conclusion, however, is subject to the qualification of type and generation of scanner being considered. Thus far, in discussing the diffusion and distribution of scanners, the technical capabilities (beyond those indicated by dedicated head v. total body CT units) of scanners have not been explicitly considered. Clearly, any statements regarding saturation of the market are a function of the fact that these facilities merely have a CT scanner—not that they have the CT scanner of a type that they might need or desire. One outcome of the "rush" for scanners in 1975 was that a great many hospitals purchased scanners representing the state of the art of CT technology at that time—typically an early head scanner. Since that time, improvements in scanning speed and

[5]The discrepancy of two hospitals from the data in table 6 is due to the fact that two large hospital systems were counted as one hospital each in the American Hospital Association data, In OTA's analysis, the scanners were listed under individual hospitals.

[b]There is also one Public Health Service hospital not included in these figures that has 500 beds but lacks a CT scanner.

image resolution, as well as the potential to reduce radiation exposure to patients, have occurred in successive models of scanners, creating a concomitant demand for these new state-of-the-art CT scanners,

In considering the question of whether health planning policies have influenced diffusion, either in terms of the aggregate number of **scanners**, the rate of purchase, and/or market saturation (as qualified above), the concomitant effects of the distribution and technical capability of existing operational scanners have been ignored. The focus on whether these policies have been effective in either limiting diffusion or promoting market saturation reflects concern for only one of the two objectives of the health planning laws—the containment of costs. But if, in the attempt to control diffusion, the law and related regulation can be shown to have effected an inequitable distribution of medical technology that is inadequate for the needs of various health care providers, then they have failed to assure the second objective—namely, ensuring access to and quality of care. Perhaps more important is the issue of whether existing health planning policies will be able to redress distributional inequities and resolve problems related to appropriate technology in the future (see ch. 3).

TRENDS IN THE TYPE AND MANUFACTURE OF SCANNERS

The CT scanner market has undergone dramatic changes since EMI, Ltd., developed the first commercial head scanner in the early 1970's. By May 1980, there was a striking change in type of scanner being sold (see table 8). Only slightly more than half of the EMI scanners are now head scanners, compared to 92 percent of the EMI scanners installed as of May 1977, Body scanners have increased their domination of the market, and by May 1980, almost 69 percent of operational scanners were body scanners. During the 24 months from January 1978 through December 1979, however, Ohio-Nuclear installed 83 head scanners.[7]

Since the sale of the first scanner in this country by EMI in 1972, the CT market has undergone "see-saw" changes in both the number of companies manufacturing CT equipment and in

[7]Comparison with FDA data on scanners reported installed indicates that a good portion of these were the new lower priced scanners.

Table 8.—Manufacturers of CT Head and Body Scanners in Use (May 1980)

	Head scanners		Body scanners		Total scanners	
Manufacturer	Number	Percentage of total	Number	Percentage of total	Number	Percentage of total
EMI, Ltd.	284	61.60/0	267	26,40/.	551	37.5%
Ohio-Nuclear	109	23.6	309	30.6	418	28.4
General Electric	16	3.5	221	21.8	237	16.1
Pfizer	—	—	107	10.6	107	7.3
Artronix	28	6.1	4	0.4	32	2.2
Syntex	11	2.4	17	1.7	28	1.9
Picker	—	—	22	2.2	22	1.5
Elscint	—	—	13	1.3	13	0.9
Varian	—	—	16	1.6	16	1.1
AS&E	–	—	11	1.1	11	0.7
Philips	—	—	10	1.0	10	0.7
Omni	9	1.9	—	—	9	0.6
Other[a]	3	0.6	14	1.4	17	1.2
Total	460	100.0%	1,011	100.0%	1,471	100.0%

[a]Three Companies—Neuroscan, Siemens, and CGR

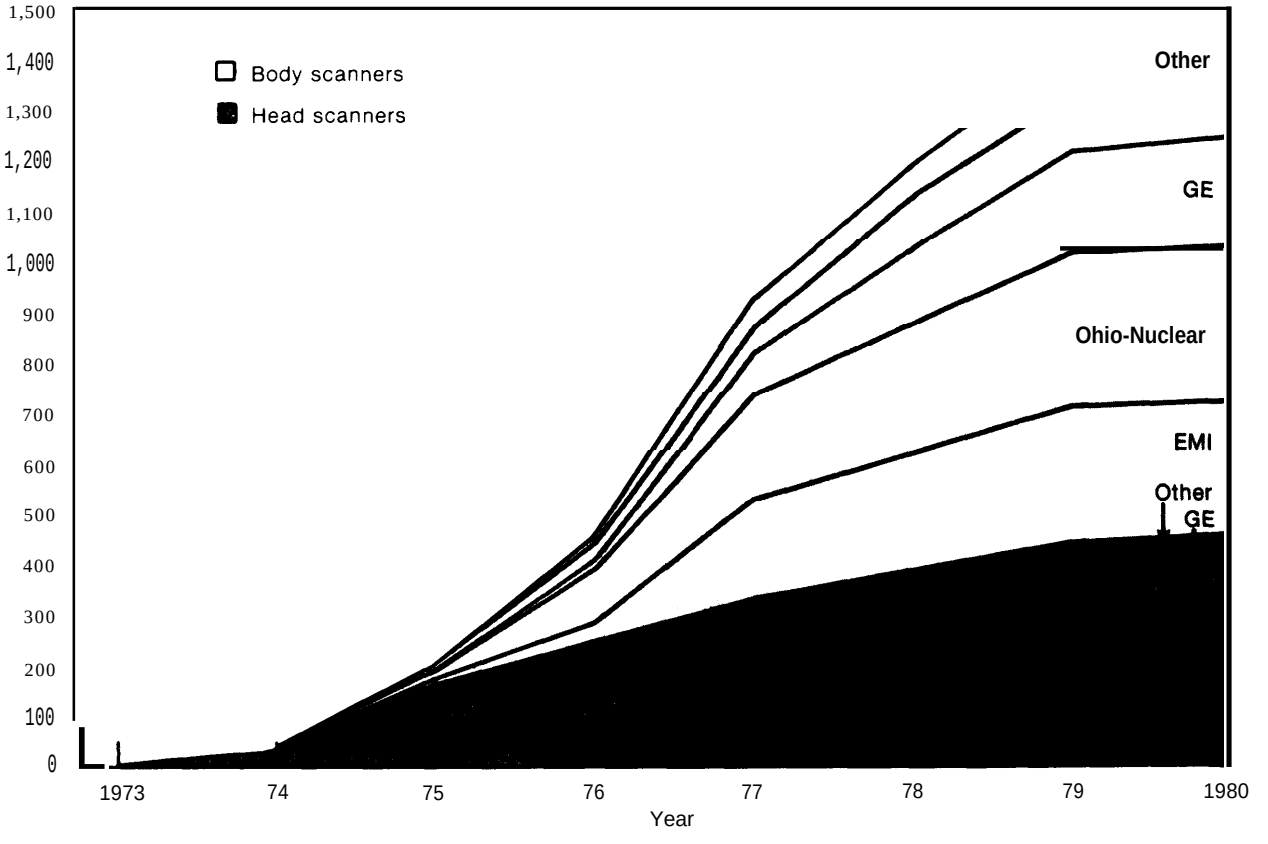
SOURCE Off Ice of Technology Assessment

their respective shares of the CT market. EMI dominated the American (and world) market through mid-1975 (see figure 4). Although six other companies were marketing CT scanners in the United States by May of 1977, EMI still had sold almost 60 percent of all operational scanners at that time.

However, the rapidly increasing number of new companies entering the market, as well as the new generations of scanners they introduced to the commercial marketplace, brought about some abrupt changes in the share of the market controlled by early manufacturers. By March 1978, there were 15 companies worldwide that had CT scanners in operation: Only 4 of these (EMI, Pfizer, General Electric (GE), and Siemens) had ever manufactured a rotate and translate, dual-detection scanner; 7 more of these (Philips, Elscint, Picker, Ohio-Nuclear, Syntex, Hitachi, and CGR) had entered the market with a rotate and translate, multiple detection scanner; and 4 more (Varian, Artronix, Searle, and American Science and Engineering (AS&E)) had entered with a rotate-only scanner (see table B-3 in app. B) (65,120).

The most dramatic change in the U.S. market share occurred in 1977 with the sharp increase in the number of scanners installed by GE. This is primarily attributable, not to expansionary market trends, but to GE's introduction of its new rotate-only scanner (which had been pioneered by that company) to the commercial market. Both GE and Ohio-Nuclear expanded their share of the market during 1978, so that by 1979, EMI's share had fallen to 40 percent of operational scanners. By 1980, EMI's share had

Figure 4.—Cumulative Number of CT Scanners Installed, by Manufacturer



SOURCE *Off Ice of* Technology Assessment

been further reduced to about 37 percent. Figure 4 shows the changing relative market shares of manufacturers, as measured by the proportion of operational scanners in the United States, over the past several years.

Another indicator of changing market shares is worldwide sales of scanners. According to one source, estimated 1979 sales yield a ranking of manufacturers **as** follows: GE ($100 million), Siemens ($50 million), Johnson & Johnson (Ohio-Nuclear) ($45 million), both Picker and Pfizer ($30 million), EMI ($15 million), Elscint ($l4 million), Philips ($10 million), and both Toshiba and Hitachi ($5 million)[8] (48). Naturally, different companies tend to be more successful in certain countries, usually their own or contiguous countries. For example, Siemens, a West German company, tends to dominate the market in West Germany. Despite an early lead by EMI, the Japanese companies are gaining dominance in Japan. Siemens dominates in Belgium, with CGR, a French company, having major success as well. Other countries have a larger spread of manufacturers, although EMI tends to have larger percentages because of its early domination of the market. GE is apparently the only U.S. company that has had significant success outside of the United States (33).

The precipitous decline in both the number of scanners sold and in scanner sales in 1977 and 1978 marked the beginning of the end of previous expansionary market trends. As the first, and for many years dominant, manufacturer of CT scanners, EMI aptly illustrates the various aspects of the troubled CT market over the past few years, Following a $29.1 million profit for the fiscal year of 1977 (115), the medical electronics division of EMI, including the CT scanner business, incurred major losses in both fiscal years 1978 (– $28.7 million) and in 1979 (– $27.8 million) (172). In early 1979, it was reported that EMI had begun to seek a merger of its medical division with a U.S. company in order to cushion these losses (31). In December 1979, EMI was acquired by Thorn Electrical Industries, Ltd., of Great Britain, but in April 1980, Thorn attempted to sell its newly acquired EMI scanner interests with a sale to GE (26,165). GE sought an advisory opinion from the U.S. Department of Justice, however, and was informed that such a takeover would probably be found to violate antitrust law. The upshot was that GE only acquired EMI's non-U. S. operations, leaving EMI's U.S. operation in limbo. In 1977 and 1978, EMI initiated litigation against Technicare of Ohio-Nuclear (45), Pfizer (113), and GE (@I). The suits filed by EMI against these companies sought damages for alleged infringements of its many patent rights on the CT scanner.[9] Part of GE's agreement in purchasing EMI was the settlement of this patent litigation (26).

Further signs of the troubled CT scanner market are evident in the trend toward market consolidation as measured by the number of other companies that have merged, are seeking to sell, or have already sold their scanner interests. The depressed state of the CT scanner market in 1978 is reflected by the fact that by the end of that year, at least two companies (Searle and Syntex) went out of the CT scanner business (26,43); another (AS&E) sold its rights to market and produce the scanner it had pioneered (to Pfizer) (42); and one of the leading manufacturers of body scanners at that time (Ohio-Nuclear) was acquired by the single newcomer to the CT scanner market (Johnson & Johnson) in 1978, (44). In 1979, Varian also put its CT scanner division on the market, with the intent of eliminating the divison if it could not find a buyer (114). By October 1979, Neuroscan was no longer making scanners, and Artronix had notified the Food and Drug Administration (FDA) that it would cease to market scanners (90).

Thus since the beginning of 1978, eight companies, EMI, Searle, Syntex, AS&E, Ohio-Nuclear of Technicare, Varian, Neuroscan, and Artronix, have left the CT market (in some fashion), and only one, Johnson & Johnson, has entered it. As of September 1979, there were 10 companies which still had CT scanners certified as meeting FDA performance standards marketed in the United States (90): These included

[8] Data collected by U.S. manufacturers indicate that the estimate for the Japanese companies is much too low.

[9] In a separate agreement with EMI, Johnson & Johnson agreed to pay EMI $15 million to drop suit against Technicare of Ohio-Nuclear (44).

GE (United States), Siemens (West Germany), Johnson & Johnson (formerly Ohio-Nuclear, United States), Picker (United States), Pfizer (United States), EMI (Great Britain), Elscint (Israel), Philips (Netherlands), CGR (France), and Omni Medical (United States).

With the apparent exit of EMI in late 1979, nine companies remain. Counting the three Japanese companies (Shimadzu, Toshiba, and Hitachi), there are now 12 companies worldwide still manufacturing CT scanners. It is believed that the remaining market for scanners will not support all of these companies, however, and further consolidation is predicted for the future (26).

Manufacturers have cited Federal interventions as the culprit behind the millions of dollars lost on the CT scanner market over the last few years. Specifically, this calamitous turn of events has been blamed on the implementation of the health planning laws enacted in 1974 and on the consequent certificate-of-need (CON) regulations imposed through local health systems agencies (HSAs) since 1976 (26,65). However, it is also true that the expansionary trends exhibited in the mid-1970's could not continue forever: The number of scanners that could ultimately be sold was not limitless, and that number could have been reached by far fewer manufacturers than the number of manufacturers that rushed to share in profits such as those EMI was realizing in 1975[10], In addition, companies like EMI in 1976 which in 1976 faced a backlog of 250 unfilled orders, had geared up production capacities to meet the wildly escalating demand for scanners. Thus, it appears that there may have been substantial overestimation of the potential market for scanners on the part of manufacturers.

In the wake of this controversy, there have also been modifications in marketing strategies, some of which appear to be in response to the CON review process and specific regulations. The advent of the new low-priced scanners, in particular, has drawn the attention of policymakers. At least three companies have models of a head scanner having a list price of less than $200,2000 (49). Four of these models sell for less than $l50,000, the threshold figure at which CON approval is required for purchase. One company has a body scanner whose purchase price is less than $100,000, plus maintenance costs (49). The interim regulations issued in April 1979 by the Bureau of Health Planning (BHP), however, have countered this particular strategy as a means of skirting the purview of CON review (see ch. 3).

According to FDA data on scanners reported as installed between June 1978 and June 1979, there were 39 scanners listed that sold for less than $200,000 (95). Ohio-Nuclear has been particularly active in selling these scanners, having sold 16 of the model 150 Delta-Scan head scanner that costs approximately $145,000 and 6 of the model 110 Delta-Scan that is priced at $96,500 (49). Omni Medical has also been active in the promotion and sale of these scanners and has reportedly concentrated its production in a low-cost (sub-$l50,000) highly reliable cranial CT scanner (40). The technical capabilities of these scanners are more limited than those of the more expensive and technically sophisticated models, and this reduces their appeal to many potential buyers. Still, these new lower priced scanners avail themselves to a new market of small hospitals and private offices (49).

Another strategy of some manufacturers has been to upgrade and refurbish older scanners; this includes modifying head scanners to body units. Several of the "new" cheaper scanners are actually older scanners that have been bought back, or traded in on more advanced newer equipment, and then refurbished by the manufacturers (90). EMI and Pfizer have both been engaged in programs of updating older models to the latest specifications. Generally, refurbishing can be done for less than $100,000. The change in definition from CT scanning equipment to CT scanning services (again by virtue of the April 1979 interim regulations issued by

[10]A. U.S. market estimate in 1975 prepared by Kidder, Peabody, and Co., predicted that a total of 1,425 CT units would be in place by the end of 1980. In fact, this number was probably attained by the end of 1979 (according to manufacturers' sales data). In reporting the above projection, however, it is interesting to note that the author, critical of the imposition of health planning measures in 1976, noted: "The growth curve was well on the way to reaching that level (1425) until it encountered the Federal and State CON laws that were imposed" (65).

BHP), however, means that changes such as upgrading a head to a body machine are subject to CON review (see ch. 3).

Another strategy manufacturers have used to diversify their CT markets has been to install scanners in a mobile environment. At least two companies are now selling various models of their scanners installed in special vehicles. According to OTA's data, the number of mobile scanners as of February 1979 had doubled, going from 7 to 14 in less than a year; by May of 1980, the number had increased further to 18. For a while, the market potential for mobile units appeared substantial, since these scanners were not subject to CON review. It was also expected that medicare would soon begin to pay for scans done on mobile scanners. In anticipation of that announcement by medicare, however, mobile scanners were placed within the purview of CON review (once again, under the interim regulations issued by BHP in April 1979) (see ch. 3). Furthermore, when the announcement did come from medicare, the regulations for reimbursement stipulated that reimbursement would be made only for scans done on CON-approved mobile scanners (85). Nonetheless, the number of mobile scanners seems certain to increase. One company is now servicing the needs of 44 hospitals in southern California for CT scanners (166), and that company reports to OTA that it expects to expand its present stock of 21 operational scanners (as of October 1980) by 1 to 1 1/2 per month. This development is clearly to the advantage of the smaller hospitals that cannot support a scanner on their own, and it may well be an efficient way to provide access to CT scanning services (70). So far, however, Federal policy with respect to mobile scanners has been conservative, and sharing has not been encouraged.

It would seem fair to conclude that manufacturers have attempted to place the blame for the changes that have occurred in the CT scanner market over the past 2 years on cost-conscious Federal policies. Although it is unlikely that these policies are solely to blame for the rather abrupt turn of market events, it is clear that the trend in Federal policies toward the CT scanner market over the past 2 years has been one of increased restraint in a kind of "cat and mouse" game with the manufacturers in the name of cost containment. It would seem that Federal policymakers and manufacturers alike could benefit from taking a broader, more comprehensive view of the forces shaping these events, and developing a more balanced appreciation of the two objectives of ensuring access and quality care and containing costs. One of the forces, research and development of existing and emerging diagnostic imaging modalities with which CT is competing (or will eventually compete) for a place in medical practice, is discussed in appendix B. Federal policies toward CT scanners and changes in those policies since 1978 are summarized in the next chapter,

3.

Changes in Federal Policies Toward CT Scanners

3.

Changes in Federal Policies Toward CT Scanners

This update of information presented in OTA's 1978 report on the computed tomography (CT) scanner (129) focuses on four areas of Government policy: 1) research and development, 2) evaluation, 3) regulation, and 4) financing. Generally, the policies in these four areas address issues characterizing the stages of research, development, and demonstration of efficacy and safety, diffusion, and widespread use of medical technology, respectively. These functions are performed largely by agencies and programs within the Department of Health and Human Services (DHHS), as shown in table 1 in chapter 1.[12] The changes that have occurred in these functions, programs, and agencies since 1978 are discussed below.

[1] Following the creation of a separate Department of Education, the name of what was formerly the Department of Health, Education, and Welfare (DHEW) was changed Effective May 4, 1980, the new name is the Department of Health and Human Services (DHHS).

'OTA's original report (129) describes the involvement of nine other agencies or departments outside DHEW that were involved in some way with CT scanning. Most were concerned with safety and radiation exposure. Two of these, the Veterans Administration and the Department of Defense, purchase scanners and provide services. An update of activities and policies of these two agencies is presented in app. C of this update.

RESEARCH AND DEVELOPMENT

As previously stated, biomedical R&D has been generously supported by Federal funds. Nevertheless, Federal investment in the development of CT scanning was small. Because CT "is well beyond the initial stage of development, Federal support has now largely ended. The last major CT project funded by the National Institutes of Health (NIH) ended in April 1978 (22). It supported the development of a more technically advanced, ultrafast prototype scanner. Basic R&D agendas at present reflect the pursuit of alternative imaging techniques that promise even greater technical capabilities than CT. Such new technologies may eventually become alternatives to, and may even surpass the capabilities of, CT scanning (122).

At this time, there are a number of new imaging techniques evolving that have present and greater future clinical applications. These include ultrasound tomography, scintigraphy, dynamic and spatial reconstructive CT, and electronic recording. In addition, there are two new techniques that will require considerable capital investment: positron emission transaxial tomography scanning and nuclear magnetic resonance scanning. The latter two applications are described in some detail in appendix B.

EVALUATION

The available efficacy information on CT scanning in 1978, OTA found, was inadequate for the purposes of planning agencies and other organizations in need of such information (129). Planning agencies, Professional Standards Review Organizations (PSROs), and third-party payers did not have the information they required to determine the need for scanners, appropriate standards of use, and appropriate indications for reimbursement, respectively. The

1978 report on the CT scanner (129) stated: "The development and diffusion of CT scanners occurred without formal and detailed proof of their safety and efficacy . . . 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. The evidence has not come from well-designed, prospective clinical trials, but as typical for medical technologies, it has been obtained from analyses of clinical experience. " This summary statement is still generally valid. The Federal Government must take a large share of the blame for this situation. Federal investment in clinical trials of efficacy and safety has been small (125).

As defined in the original CT report, efficacy is more than a simple consideration of benefits. No technology is beneficial in the absolute. It is beneficial only when used in an appropriate manner—for a defined population, for a given medical problem, under certain conditions of use, and for a specified outcome(s) (125). Determining efficacy thus becomes a matter of determining indications for use, stated in terms of all four of these criteria. The task is a formidable one.

For a diagnostic technology such as CT, evaluating these benefits can become very complicated, depending on the type of impact specified (125). For example, should a diagnostic device be evaluated for its impact on diagnosis, on treatment, or on patient outcome (13,61)? Most of the available evaluations of CT scanning are limited to evaluations at the levels of technical capability and diagnostic accuracy. Few address diagnostic and therapeutic impacts. Fewer still are available that attempt to determine efficacy in terms of patient outcome (102,181,185,186). The focus of research is often on the methods for going about the task of evaluation (27,173,185). There has been little Federal initiative to undertake or support such evaluation of efficacy of CT scanning (60,181). Little information that indicates in a definitive way either appropriate uses or the benefits of use beyond diagnostic accuracy has been forthcoming (32).

Available information regarding the efficacy of CT scanning is much more conclusive for head than for body scanning (92,93), and it is generally acknowledged that efficacy is much better established for the former (3). As yet, there are insufficient numbers of adequate studies or patterns of use available to ascertain in full the proper indications for CT body scanning (167). However, it should be noted that body scanners are able to perform head scans whose quality is at least as good as that of head scanners. To the extent that a body scanner is used to scan heads, its usefulness may be said to be more firmly established.

There have been numerous evaluations enunciating the comparative benefits of CT and other diagnostic modalities for specific clinical indications in the case of head scanning (19) and for certain anatomical regions in the case of body scanning. CT of the head has been found to perform favorably in comparison with several neurodiagnostic procedures and to have partially supplanted the use of some of these (4). Body scanning capabilities have most often been compared to ultrasonography, but have not always been found to be decisively superior (1,2). To a large extent, the inconclusive efficacy status of body scanning is a function of the many more possible clinical indications and organs to which computed body tomography may be applied, as well as the large number of alternative imaging and other diagnostic technologies with which it must be compared (167). In addition, any physician or institution has a limited number of patients with a specific condition, and outcome data are generally lacking in all medical care (125).

To complicate matters further, a more imporant question now emerging is when to use CT scanning vis-a-vis other modalities rather than whether or not to use it at all. Evaluations of efficacy that compare the benefits of applying one technology to those of another for a given problem can provide information that will enable efficient, as well as efficacious, application for these technologies (184). To this end, the objective of comparative evaluation should be not only to determine whether one modality can supplant or replace another, but also to determine whether, when, and how the modalities

might be used in a complementary way to achieve even greater benefit and efficiency.

Even if there were available efficacy information for CT scanning that was complete according to the criteria of application, benefit, relativity, and complementarily, the question would remain as to whether planners, PSROs, and third-party payers would then have the information they need to make decisions required of them. The decisions made by planning agencies and PSROs should be in keeping with their triple mandate to contain the cost of medical care while simultaneously assuring quality and access. For third-party payers, the availability of even the best efficacy information may address only the problem of reimbursement for inefficacious procedures and technologies. The important policy question is whether it is possible to encourage a choice between competing alternatives or develop methods to assure complementary uses of them based on diagnostic superiority.

An idea gaining prominence is that the needs of decisionmakers in these agencies and programs can be met by information from economic evaluations, perhaps in the form of cost-benefit analyses (CBAs) or cost-effectiveness analyses (CEAs). The momentum in the research community toward these formal analytic techniques is based on the premise that the techniques of CEA/CBA can contribute to achieving cost-containment objectives—an assumption that may be untenable. Countering this optimism is a growing body of skepticism regarding the potential use and usefulness of these economic analyses (127). Nevertheless, the new National Center for Health Care Technology (NCHCT) (see below) has a specific mandate to develop such information.

Review of the cost impact literature of CT scanning reveals a myriad of approaches to economic evaluation (20,50,51,54,55,89,187), few of which offer real assistance to planners, utilization review groups, or third-party payers faced with resource allocation decisions (180). To date, the bulk of most economic evaluations of CT have been analyses of costs of CT scanning only or of the impact of CT on diagnostic costs (180). Still, CT scanning is probably the medical technology which has been most often subjected to economic evaluation, and specifically, to so- called CEA/CBA.

The difficulties in applying CEA/CBA to medical technologies in general are well documented (127). But applications to diagnostic technologies present even more difficult problems (183). In the application of CEA/CBA to any technology, there are tremendous problems in estimating both costs and benefits (or effects). The ability to conduct the CEA/CBA is dependent on (among other things) the availability not only of good cost estimates, but also of valid efficacy studies which are the basis for quantitative estimates of benefits (183). This methodological role underscores the need to develop scientifically based efficacy information. Lack of such information greatly exacerbates the methodological difficulties of any analyses attempting to rationally compare costs and outcomes. The inclusion of CEA in the mandate of the new NCHCT is appropriate, but high expectations regarding its contribution to policy objectives may not be, owing both to a continued lack of adequate efficacy and effectiveness information and to the other unanswered questions concerning the methodological validity of the analyses themselves and their usefulness in decisionmaking.

Despite these complications, well-designed studies are possible. The relative paucity of scientifically derived efficacy information persists, and repercussions continue to be felt by the affected agencies and organizations. Some changes along the lines of proposals contained in OTA's 1978 report regarding efficacy have been made. The most promising of these is the legislation authorizing NCHCT. Newly mandated by the Health Services Research, Health Statistics, and Health Care Technology Act of 1978,[3] this fledgling organization has now been in operation a little less than 2 years. The effects of this organization lie in the future, however, because staff and resources so far have been limited.

The mandate of NCHCT is a broad one, relating in some fashion to most technology-

[3] *Health Services Research, Health Statistics, and Health Care Technology Act of* **1978** (Public Law 95-623).

related issues and activities within DHHS. As of October 1979, CT scanners were 1 of 16 technologies on the NCHCT list of priorities for assessment. One of NCHCT's most important authorities, however, is its responsibility to recommend to the Health Care Financing Administration (HCFA) what technologies should or should not be reimbursed by the Federal Government. This determination is to be made primarily on the basis of available information regarding the safety and efficacy of the technology. This formal link between safety and efficacy information and reimbursement decisions realizes one of the proposed options presented in OTA's original CT report (129) (see app. A). In this advisory capacity, NCHCT formally assumes the function previously served by the now defunct Office of Health Practice Assessment (OHPA) in the Office of the Assistant Secretary for Health (OASH). To date, the limited staff and resources of the Center have been primarily devoted to answering inquiries from HCFA regarding these reimbursement decisions (177). However, NCHCT has a specific mandate to develop information on efficacy, safety, and cost effectiveness.

A second development relating to evaluation efforts at a Federal level is the series of consensus development conferences being sponsored by the Office for Medical Applications of Research of NIH. These meetings convene over a particular technology or disease category and attempt to reach a consensus judgment regarding efficacy and appropriate conditions of use. These conferences provide a forum for bringing together representatives of the academic and practicing medical communities. The outcome represents a consensus falling on a middle ground between analyses of clinical practice and scientifically derived evidence from clinical trials of efficacy and safety. The first of these conferences was held in September 1977. Altogether, 12 were held in 1977 and 1978, and 28 had been held by October 1980 (58). Both CT head and body scanning are on the conference agenda. The first consensus conference on CT will focus on CT scanning of the central nervous system and is scheduled to be held in 1981.

The consensus development conference planned for CT scanning will be jointly sponsored by NCHCT and NIH. The Center's responsibility will be to provide cost-effectiveness information, while the responsibility of NIH will be to provide the medical and technical evidence. The conference on CT scanning will be one of the first that will include cost-effectiveness information (131). What sort of cost information NCHCT will supply, however, remains to be seen.

Because scientific evidence, clinical experience, and expert opinion regarding the use of CT are fragmented, and because practitioners and policy makers have had an immediate need for efficacy information, various scientific organizations, professional medical societies, and peer review groups have reviewed and weighed the available evidence (see app. D). Several have reached a consensus and issued formal policy statements on appropriate applications of CT in medical practice. For example, in 1977, the Institute of Medicine (IOM) published a list of indications for appropriate use of CT scanning of the head and body as part of a policy statement (116). In July 1979, part of this list was updated and augmented by the Society for Computed Body Tomography (SCBT), which published a list of indications for extracranial (other than brain) applications of CT (164). In September 1979, the American College of Radiology (ACR), the professional organization of radiologists, issued a formal policy statement on CT scanning which concluded that the diagnostic efficacy of CT is no longer in question and cited six roles for CT scanning in medical practice (10,11). These roles were offered as a general guide for use of CT, while the specific clinical areas and indications for CT scanning were left to be determined locally by hospital medical staffs or other recognized peer review groups. Also the Radiological Society of North America held a convention in November 1979, at which papers documenting new uses of CT in clinical practice or reviewing evidence of established clinical uses were presented and discussed (134). These mechanisms are critically important to the practicing medical community

in establishing the role and application of CT scanning in medical practice.

It is critical to develop some form of information that addresses the issue of resource allocation underlying all policymaking. From the planner's perspective of allocating resources, the important question is not simply whether the procedure or the technology producing it is justified on the basis of its having some efficacy, or even whether its introduction and use might raise or lower total health care costs: It is how the diagnostic capability should be used in the practice of medicine (180), Only by being able to identify which patients should receive a procedure during their treatment is one able to know whether there is too little or too much CT capacity to meet the needs of any community. This requires balancing benefits and risks (125). Similarly, evaluations of CT, whether economic or some other type, should be able to address the incentives toward excessive use that characterize current reimbursement policy. Present methods of reimbursement decisionmaking promote the use of additional technologies and procedures—not tradeoffs between them (184). Evaluations that could identify when, if at all, CT should be used in the diagnostic evaluation, treatment, or monitoring of a given patient could provide the necessary information to enable reimbursement policy to encourage the most efficient—as well as the most efficacious—use of technologies in patient care.

REGULATION OF EFFICACY AND SAFETY

Somewhere between the policy areas of evaluation and regulation lie the medical devices program and the radiation safety program administered by the Food and Drug Administration (FDA). At the time of OTA's original CT report (129), FDA regulated CT scanners to ensure minimum radiation exposure with an equipment standard and it was beginning to implement the enabling Medical Devices Amendments of 1976.[4] Under the Medical Devices Amendments, CT will be categorized as a class 11 device, which means that CT scanners will be required to meet specified technical performance standards. These standards have been developed by the Bureau of Radiological Health (BRH) within FDA. By virtue of an interbureau agreement with the Bureau of Medical Devices, BRH assumed the lead role in FDA for all radiological devices as of April 1979 (18,189). Safety of radiological devices is also regulated by FDA through BRH, as described in OTA's 1978 report (129). CT scanners became subject to the 1974 performance standard that applied to diagnostic X-ray equipment. Since 1976, BRH has been in the process of developing amendments to the general X-ray performance standards to include criteria specific to CT scanners. In March 1978 and October 1978, draft amendments were sent out for comment. The final analysis of comments has been completed, and final rules are expected to be published in 1981.

These amendments to the X-ray standard will be the first performance standards written specifically for CT scanners. The amendments primarily address radiation safety of CT systems and require information on the imaging performance and radiation dose to be provided to purchasers (86). Image information from a given CT system is proportional to the radiation dose. With a particular CT system, slower scan time results in both a higher radiation exposure, as well as a better image. In addition, it is generally true that increased radiation provides more image information.

The amount of radiation to which the patient is exposed is partially dependent on how the clinician using the scanner specifies certain variables such as scan time. Usually this is determined by the clinician's preference. There is sometimes a tendency to opt for more image information at the expense of a higher dose of radiation (129). Another problem found was that because of the complexity of CT equipment, there is potential (through suboptimal

[4] *Medical Devices Amendments of 1976* (Public Law 95-292).

performance) for obtaining a poor quality image even at a higher close of radiation (86).

The proposed amendments require information concerning the absorbed dose delivered by CT systems to a standard phantom (a test object) and the imaging performance corresponding to this dose, within the normal range of system operating conditions. This information will help to estimate the relationship between dose and imaging performance. However, the clinician will continue to be expected to exercise professional judgment in selecting conditions of operation of CT scanners.

It is difficult to summarize available information on radiation dose from CT scanning. Maximum doses from a number of systems and under a number of conditions of operation were recently examined and were found to range from less than 0.5 rad to almost 10 rad for a single scan (158). As noted by the investigators, however, "All of the systems are capable of alternate conditions of operation which will result in different doses than those reported here, many of them significantly larger. "

The language of the Medical Devices Amendments of 1976 specifies assurance of effectiveness, but this is apparently used as a synonym for efficacy. FDA approaches efficacy from a rather technical standpoint. It interprets its charge as one of assuring that the products sold in the marketplace are safe and technically capable of their professed abilities. It does not interpret or perceive its purpose as being one of determining how, and under what conditions, those products are to be applied by practitioners. FDA has supported research related to efficacy and safety of CT scanners. A survey of the system performance of CT scanning in selected U.S. hospitals has produced data for developing dosimetry standards and technical specifications of scanner performance (157,1.59). FDA has also awarded a contract that will evaluate utilization of CT head and body scanners. Survey items on its impact on diagnosis and therapy relating to management and patient outcome have been included to examine clinician perspective and motivation (30).

DIFFUSION AND UTILIZATION

Diffusion

This area of policy has been the site of the greatest controversy over CT scanning during the last several years. Contention has surrounded the health planning law, [5] certificate-of-need (CON) review mandated in that law, and the National Guidelines for Health Planning. [b] Although it is difficult to say which, if any, of these have had an impact on the rate of diffusion of scanners, and/or the current aggregate supply of CT scanners, the most heated debate has focused on the standards pertaining to CT that are set in the national guidelines.[7]

The National Guidelines for Health Planning have been controversial since their inception, following the enactment of the Health Planning and Resources Development Act of 1974 (117). The guidelines established standards for 11 technologies which were to be used by local health systems agencies (HSAs) and State health planning agencies in reviewing and approving applications for capital expenditures by hospitals of greater than $150,000. Published in September of 1977,[9] the first public request for comment elicited more than 50,000 responses, most of which protested the proposed standards. Several months of deliberations ensued. A revised set of guidelines was issued in January of

[5] *Health Planning and Resources Development Act* of *1974* (Public Law 93-641).

'National Guidelines for Health Planning, *Federal Register,* Mar. 28, 1978, p. 13040.

'As noted in OTA's 1978 report (129), section 1122 of the Social Security Act gave many States the authority to review capital expenditures over $100,000. This mechanism was available beginning in **1972** and was used by a number of States early in CT scanner diffusion. However, 1122 reviews are being replaced by the CON process. Now 36 States have CON laws.

"The use of this term is not intended to be negative. The impact of the discussions and documents described below to promote learning and mutual understanding of the issues on the part of all parties must be recognized and valued.

"National Guidelines for Health Planning, Advance Notice of Proposed Rulemaking, *Federal Register,* Sept. **23, 1977,** vol. **42,** p. **48502.**

1978, and a set of standards for nine technologies became official in March 1978. [11]

The three standards set forth in the section of the National Guidelines for Health Planning pertaining to CT scanners (see app. E) are as follows:

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.
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 data collection and utilization review systems.

The current round of debate was instigated by a request for comment and recommendations concerning the existing guidelines for CT scanners. In issuing the final rules, DHHS had made it clear that the newly established standards would continue to be open to discussion and suggestions for change. In keeping with its commitment, on March 23, 1979, almost 1 year after the guidelines had become effective, the Department issued a public call for comment on the standards for CT scanners.[12] The notice was prompted by recognition of the fact that because CT scanning is a rapidly changing field, new developments, experience, and data may have emerged since publication of the original standards just a year earlier that might provide a basis for altering that standard.

Comments and suggestions received in response to the notice have been considerable and reflect the divergent opinions of various interest groups. Among the suggestions have been increasing or lowering the number of patient procedures required; developing a population-based standard for determining need; use of a weighting formula; further specification of circumstances for adjustments; no change in the existing standard; elimination of the quantitative target; and elimination of the standard from the national guidelines (72,98,99,100,108, 109,135,168).

The request for comment renewed a vigorous and intense debate over the CT standards (52,112). Responses focused on the question of whether there is sufficient evidence to suggest the need for changing the single quantitative standard of 2,500 patient procedures per scanner per year. In general, the response from providers and private associations (including manufacturers) has been that the target levels are unrealistically high. In support of this position, new evidence from a national survey of CT capacity sponsored by the National Electrical Manufacturers' Association (NEMA) was presented which found that 61 percent of the 441 installations surveyed could not meet the existing standards (82). The response from planning agencies, on the other hand, has been the opposite, i.e., that the target levels may be too low, but in any case are not unreasonable (97). The experiences of HSAs that had established standards higher than the 2,500 scans per year *were* brought to bear on their case.

Several months of deliberations ensued over a wide range of options for change suggested in public comments (36). On September 13, 1979, DHHS proposed changes that would provide increased flexibility in the standard to take into account the proportion of head and body scans and double studies[13] performed, and would ensure that access to necessary CT services is maintained (139). Commitment to further study of alternative weighting approaches was also recommended. However, no change in the quantitative target of 2,500 procedures was recommended at that time.

Considerable support for the incorporation of a weighting scheme in the guidelines had been

[10] National Guidelines for Health Planning, Proposed Rulemaking, *Federal Register*, Jan. 20, 1978, vol. 43, p. 3056.

[11] See footnote **6,** p. **32.**

[12] Notice of Request for Comment on the CT Scanner Guidelines of the National Health Planning Guidelines, Federal *Register* Mar. **23, 1979,** vol. **44,** p. **17760.**

[13] The term "double study" refers to a series of two CT examinations consisting of an unenhanced study, followed by an enhanced study. An enhanced study is one in which (one of several) contrast agents is administered to the patient prior to the examination, the objective being to obtain a clearer image of an abnormality. The improvement in diagnostic information resulting from this procedure has been debated (129).

expressed in the comments; no fewer than 33 different weighting formulas and sliding scales had been suggested (8). The HECT formula (Head Equivalent Computed Tomography Unit), based on results of the capacity survey and proposed by NEMA, received the most vigorous and consistent promotion (35,171). While the concept of a weighting approach found widespread support, the lack of consensus on the specifics argued that mandating the use of any one approach would be premature. As a next step, DHHS initiated efforts to evaluate alternative weighting approaches in selected areas (111).

With respect to the addition of provisions for increased flexibility, the reaction to the proposed changes was generally supportive both from planners, and from providers and private associations. However, while planners concurred with the need for further study of weighting approaches, NEMA and ACR protested this recommendation, arguing that there was already sufficient evidence on which to base a weighting system. The recommendations for increased flexibility prepared by the Health Resources Administration (HRA) and approved by the Subcommittee on National Guidelines, Goals, Standards, and Priorities of the National Council for Health Planning were sent to health planning agencies by DHHS, In November 1980, HRA was in the process of preparing revised standards that would incorporate a weighting formula. Such a standard must be published for comment in the Federal Register first, but it could be functioning by some time in 1981.

Other developments regarding the Federal regulation of diffusion of CT scanners took place on April 25, 1979. '4 On that date, BHP of HRA issued interim regulations regarding reviews of proposed capital expenditures for CT services under the capital expenditure review program of section 1122 of the Social Security Act[15] and under the provisions of the CON review program of the Health Planning and Resources Development Act (see app. I). Expansion of the 1122 review authorities was brought about by concern on behalf of DHHS over the appearance of head scanners in 1978 that were being sold at prices well below the threshold figure for review of $100,000 (74). The regulations were changed to cover any CT scanner under a "change in service" review trigger. The other target of amendments to both CON and 1122 regulations was the growing market for mobile scanners: According to OTA data, the number of mobile scanners doubled (from 7 to 14) during 1978. The potential market for mobile scanners appeared to be great because CON regulations did not yet cover mobile units. Further, the anticipated change in medicare reimbursement policy to cover scans performed on mobile units was expected to make the purchase of the units even more attractive and to increase sales significantly. Consequently, it was felt that mobile scanners should be subject to the review process (74).

There was limited public reaction to the April 25th issuance, but as was the case during the controversy over the guidelines discussed above, there was protest from individual providers, provider associations, and manufacturers of CT equipment, and support from many local and State health planning agencies (74). Objections to the additional restrictions on the purchase of CT equipment focused on the belief that the regulations were yet another example of overregulation of the CT scanner as the "scapegoat' -unfairly singled out when other hospital equipment more costly than CT scanners was not subject to review.

The changes in the regulation of capital expenditures under 1122 also specified the review of proposed changes in CT "services" (in contrast to CT equipment), the implication being that replacing a dedicated head scanner with a body scanner and/or upgrading existing equipment is now subject to review. Under CON, such changes have always been regarded as new services and have therefore been subject to review. One outcome of the "rush" for scanners in 1975 was that scanners purchased at that time have since been outmoded by total body scan-

[4]Inclusion of Computed Tomographic Scanning Services, Interim Regulations, *Federal Register*, Apr. 25, 1979, vol. 44, p. 24428.

[15]*Social Security Amendments of 1972* (Public Law 92-603), sec. 221, Limitation on Federal Participation for Capital Expenditures, 1972.

ners with markedly improved scan time and image resolution. The updating and replacement of CT units within these health facilities has become an issue of great concern for providers as new generations of scanners have become available.

Taken together, the new rules promulgated might be interpreted as concrete evidence of the increasing emphasis placed by DHHS on the objective of cost containment—possibly at the expense of access and quality of care concerns.

The final change occurring in 1979 with the potential for affecting the diffusion and, more importantly, the distribution of CT scanners was the enactment of new amendments to the Health Planning and Resources Development Act of 1974. Those amendments were signed into law in September 1979.[16] Under the provisions of the 1974 law, all major capita I expenditures by physicians for out-of-hospital settings were exempt from CON review (37). OTA, in its CT report of 1978 (129), cited this exemption as one of the greatest weaknesses in the original planning legislation. At that time, OTA proposed expanding regulations to cover all purchases of major medical equipment regardless of setting or ownership (see app. A).

The 1979 amendments only partially address this weakness. The health planning law now requires State review and approval of equipment outside hospitals, regardless of ownership or physical location, if the equipment is to be used to provide services for hospital inpatients. This amendment represents a compromise resolution from the 1978 Senate bill, which had required certification for all major medical equipment purchases irrespective of ownership or setting. It is aimed at the loophole in the previous law whereby physicians could make a private purchase of a scanner for a hospital that might either have applied and failed to win approval or wished to avoid the CON process entirely, and then could locate that scanner in the hospital setting.

While the above amendment extended CON review beyond purchases by health facilities (i. e., hospitals), another amendment to the law resulted in the exemption of certain health maintenance organizations from the CON review and approval process.

Finally, the new law includes a preemption provision barring States from passing CON laws that are more stringent than the Federal statute after September 30, 1982. At last report, seven States had broader certification requirements than Federal law stipulates (130).

Overall, the new health planning law added limited new regulatory authority, and it postponed the date (January 1980, set in the 1974 law) for a pending cutoff of certain Federal funds to States that had not yet enacted mandated CON programs by that date (71). Currently, only 36 States have enacted CON laws (73,161).

The major gap in the health planning law remains, and what was intended to partially close an existing loophole in the law affecting the diffusion of scanners may have a perverse effect on the distribution of scanners. Under the old law, CT scanners owned by physicians but operated in hospitals may have skirted CON review, but they were at least more accessible to the community in these settings than in private offices. Hospitals have always had a more difficult time purchasing scanners than private physicians have. The new amendments, leaving them with one less option, however, place hospitals at an even greater disadvantage.

Thus, the price exacted by curtailing the diffusion of scanners (i.e., the aggregate number of scanners) may possibly be increased institutional maldistribution of scanners: The law now favors not only private purchase, but private location of scanners as well. This is another example of the preeminence of the cost-containment objective—possibly at the expense of access and quality of care concerns—found in Federal policies toward the diffusion of CT scanners. It is little wonder that the debate over the guidelines is long and loud and hotly argued by those parties that are subject to them.

To summarize, the emphasis on cost-containment objectives may be to omit other important considerations such as access, medical effec-

[16] *Health Planning and Resources Development Act Amendments of 1979* (Public Law 96-79).

tiveness, equity of distribution, and safety, as well as other (besides capital) costs. This is not to suggest that the emphasis on cost containment in the case of CT is unwarranted or that it necessarily should be lessened, but is to suggest that these other considerations should not be sacrificed (either unwittingly or intentionally) in restricting the deployment of scanners in the name of cost containment. Such policies may strike particularly at the poor and underprivileged (14). The tradeoffs between containing costs on the one hand and assuring access and quality on the other should be made explicit, and a better balance struck between them. In keeping with the statutory mandate of the health planning program, it is critical to recognize a much broader set of indicators than cost moderation in estimating the impact of planning and regulatory activities on the deployment of CT scanners.

Utilization

The history of coverage of CT scanning by publicly funded third-party payers has been one of increasing expansion, but it also is the first instance of a policy decision by HCFA to withhold reimbursement payments for a particular new procedure pending evidence of efficacy (184).[17] Eligibility for reimbursement of CT scans through the medicare program administered by HCFA has always been restricted by the type and manufacturers of scanners used, and to a set of conditions deemed appropriate for use. Scans of the head, when performed on an EMI, Ltd., head scanner, have been reimbursed since September 1976 (103, 129).

Scans of the body, however, have been reimbursed only since August 1978 (103). Under the "reasonable and necessary" clause of the Social Security Act authorizing medicare payments (118), HCFA already had a mechanism for denying payment for clearly antiquated procedures. Based on a broad consensus that the procedures were not useful, rather long lists of such procedures were sent to medicare intermediaries. Using this same clause, medicare denied payment for body scans for almost 2 years, pending study and recommendation by the now defunct OHPA in OASH for reimbursement of certain indicated body scans (184). In January 1978, OHPA made its determination (107). Eight months later, medicare began reimbursing for certain body scans in addition to head scans, based on detailed medical indications for scanning.

Until April 1979, reimbursement for both head and body scans was limited to scanners installed in a fixed location. But again, based on the findings of a 15-month study carried out by OHPA, that Office recommended in June 1978 that scans done on mobile scanners also be reimbursed (105). Fourteen months later, coverage was extended to scans done on mobile units (104).

Increasingly, the areas of reimbursement policy and planning are being tied together. For example, medicare instructed its intermediaries in 1979 to pay for scans from mobile scanners only if they have been approved by CON review (104). The regulations discussed above regarding reviews of proposed capital expenditures under section 1122 of the Social Security Act also state that denial of reimbursement under the medicare, medicaid, and maternal and child health programs may be the penalty for capital expenditures that fail to conform with the review plans, standards, and criteria.

Other, more subtle disincentives concern levels of payment. In August 1978, HCFA instructed its carriers by letter (intermediary letter No. 78-38) that services on CON-approved scanners would be reimbursed at cost, while services on scanners without approval (e. g., those in private physicians' offices or those located in hospitals but owned by physicians)

[17] Private third-party payers have exhibited similar kinds of policy decisions with respect to CT that have also been precedents. Blue Cross and Blue Shield, for example, has kept a list of procedures and services (such as gastric freezing) that are widely agreed to have no medical benefit, and for which they do not reimburse. Blue Cross and Blue Shield also withheld payments for CT scans for some time, and it was that insurance company who requested the study on CT scanning that resulted in the first published concensus on indications for CT scanning (116). The influence of the private sector on the acceptance of CT scanning in medical practice is, therefore, recognized as being significant but is not the focus of this discussion. The potential for leverage on diffusion and practice patterns through private sector health insurers warrants further investigation

would be subject to ceilings. Mobile scanners not owned by hospitals would also be subject to ceilings. These changes were in part an attempt to counter reimbursement incentives toward the purchase and use of scanners outside the planning review and approval process (106). However, in March 1980, in a case in South Carolina (Starns v. Harris), a U.S. District judge enjoined HCFA from continuing the policy based on its having been promulgated without due process. Rather than appeal, HCFA announced its intention to reissue the policy and make it applicable to other expensive technologies as well.[18] The proposed rule should be published in the Federal Register within a year.

Besides being linked to planning policies, reimbursement policy is also being increasingly tied to evaluation policies. HCFA now has access to an institutionalized resource in the newly mandated NCHCT and its functions to which it may direct reimbursement inquiries regarding efficacy of medical technologies and their applications (133). OTA's 1978 report (129) previously proposed that rates of reimbursement be based on efficient use of technologies and that the payment system be fundamentally restructured to encourage providers to perform and use services efficiently (see app. A). To the extent that NCHCT can develop cost-effectiveness information, HCFA will be better able to translate it into a structure that might promote cost-effective physician behavior. Whether the information will be developed and, if so, whether it can be translated into effect through reimbursement policies remains to be seen. A recent OTA assessment (127) examined some of the difficulties of applying cost-effectiveness techniques in reimbursement. In addition, there is a possible ethical question involved in withholding a service or procedure on the basis of the question, is it worth its cost? rather than on the question, does it confer a health benefit? The use of such a criterion in providing services for only that part of the population receiving publicly financed health care has obvious ethical ramifications that might cast doubt on the desirability of reimbursement policy based on it.

Finally, one of the major expressions of Federal policy toward the use of medical services, including CT scanning, is the PSRO program established by law in 1972.[19] PSROs are separate and independent organizations covering almost 200 areas of the country. Each PSRO must be substantially representative of all practicing physicians in an area. 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.

OTA's 1978 report on CT scanners (129) described the PSRO program in detail, and that material is not repeated here. The only major change that has occurred since 1978 that could affect CT scanning is that the national PSRO program distributed draft screening criteria for body and head CT scans on February 22, 1979 (160). These criteria, which were developed by the American Association of Professional Standards Review Organizations, reflect the lack of well-validated information on efficacy and appropriate use of CT scans (see app. D). The body criteria are taken virtually word for word from the IOM report of April 1977 (116). In July 1979, SCBT published a list of indications intended to "clarify, update, and augment the indications published in the April 1977 policy statement of the Institute of Medicine" (164). Thus, by the time the PSRO draft guidelines were beginning to be applied, the body criteria were out of date, according to the most expert group dealing with the subject. (The National Professional Standards Review Council, recognizing this problem, suggested to potential users that the criteria should be reevaluated at least every 6 months and updated if necessary.) This is not to judge the validity of the recommendations themselves, since they were based largely on clinical experience, and not on well-designed studies.

By October 4, 1979, eight PSROs had completed medical care evaluation studies on CT scanning (188). Four others were carrying out or

"Medicare Program; Reasonable Charge Limitations, *Federal Register*, May 29, 1980, vol. 45, p. 36100.

'* *Social Security Amendments of 1972* (Public Law 92-603), sec. 301.

planning CT scan review at that time. On May 28, 1980, OTA staff visited one of the PSROs that was studying CT head scanning. The draft review criteria had been used by that PSRO to produce a list of 21 criteria justifying CT head scans, arrayed in order of importance (see app. D, exhibit 4). The first eight criteria related to evaluation of suspected or previously known diagnoses, the next eight related to abnormal physical findings, and the next five related to symptoms noted on a medical record when no suspected diagnosis was listed. Only 8 of 427 scans the PSRO reviewed did not meet these criteria. Of these 427, however, 58.3 percent yielded negative results. The PSRO concluded that CT head scans were used judiciously in that region.

There are numerous reasons that this PSRO's conclusion cannot be supported. One is that the indications written in medical records as indications for procedures are known to lack validity. Secondly, the indications are broad and general enough so that almost any patient would qualify (one of the criteria is simply "headache"). But perhaps most important is that the criteria have not been firmly connected to evidence of efficacy. The truth is that it is not known in that PSRO area, or in any other, whether the CT head scans are done judiciously. What can be observed is that PSROs deal primarily with extreme cases, and thus cannot be expected to have a great impact on the utilization of any procedure that is accepted by the medical community. In the absence of scientific efficacy information, existing practice may become the standard of practice-whether or not it is "appropriate." Established patterns have the habit of lingering in medical practice even after such time as efficacy information becomes available (60).

An interesting pilot project is attempting to use evidence of efficacy of an X-ray procedure, pelvimetry, to significantly reduce the use of X-rays. FDA's BRH developed a consensus policy statement concerning the lack of efficacy of X-ray pelvimetry. The statement was endorsed by ACR and the American College of Obstetrics and Gynecology. In the study project, PSROs intend to change the practice norm by moving to eliminate these X-ray procedures for purposes where they are proved not to be efficacious. This project demonstrates the promise of PSROs, and with the development of better information on efficacy, can perhaps become the norm rather than the exception.

In summary, utilization policies toward CT scanning are still very much in the process of change. HCFA perceives that it has a role in controlling technologies such as CT scanners and will undoubtedly make further changes in its payment and review policies. Further regulation through these mechanisms seems inevitable. In October 1980, HCFA had drafted proposed regulations (not yet available) that will define "reasonable and necessary," the criteria specified for payment for services in the medicare law, [20] According to HCFA staff, the definition will include costs and broader social implications in addition to efficacy and safety.

[20] *Social Security Amendments of 1972* (Public Law 92-603), sec. 1862(a)(1).

4
Summary and Conclusion;

4. Summary and Conclusions

The computed tomography (CT) scanner remains an instructive case study which illuminates both the process of innovation and Federal policies toward medical technologies. Although the CT scanner is not in itself a major health policy issue, it can be used to understand problems in Federal policies.

The trends in diffusion of CT scanners have been the cause of much controversy. Federal policies have been cautiously developed to curtail the rapid diffusion of medical technologies such as the CT scanner. Critics have leveled a general charge that Government interference is inhibiting the process of innovation— one of the critical signs of a robust, dynamic economy. But it is difficult to ascertain whether the existence of the Health Planning and Resources Development Act itself, the process of review by health systems agencies (HSAs) and approval by State health planning and development agencies (SHPDAs) of applications for large capital expenditures by hospitals under certificate-of-need (CON) provisions of that Act or section 1122 of the Social Security Act, or the standards for CT scanning set in the National Guidelines for Health Planning to assist HSAs and SHPDAs in these functions have influenced the CT scanner diffusion rate. Although one would expect the diffusion and distribution of scanners to be related to Federal policies addressing them, there is really no good evidence available to indicate whether and to what extent any or all of these factors have influenced the diffusion of CT scanners.

Opposition to Federal policies concerning CT scanners has focused on the National Guidelines for Health Planning. For over a year now, the debate between manufacturers, providers, planners, and Federal authorities has honed in on the specific standards set in those guidelines. Although the guidelines have the potential to restrict diffusion and affect the distribution of scanners, diffusion slowed before development of the guidelines (see figure 1 in ch. 2). The standards set in the guidelines became effective only in March 1978. It should also be noted that the standards are advisory rather than mandatory. Scanners installed during 1979 were probably ordered months earlier. The rigor with which the guidelines are applied by HSAs in reviewing CON applications and the extent to which SHPDAs adhere to them in deliberating approval of CON applications are unknown. All these factors make the impact of the guidelines uncertain, It may be that the opposition to the guidelines themselves and the debate over the specific standards for CT scanners in them are based largely on the potential impact that the guidelines may have in the future, rather than on any effect that has been witnessed in the recent past. In addition, the role of the Federal Government in regulating diffusion of medical technology is being questioned.

The impact of CON regulations on the diffusion and distribution of scanners is, in general, currently unknown. (One study that is investigating the correlation between the implementation of State CON laws and the diffusion rate of CT scanners on a State-by-State basis is underway (21).) The manufacturers of CT scanners believe that the guidelines and CON regulations have had an impact. While requests for CT scanners are approved far more often than they are disapproved (74), the effect of the health planning process of discouraging applications must be considered as well. It may well be that the extremely high number of scanners sold in 1975 was induced by the anticipation of the impeding sanctions embodied in the upcoming health planning regulations (15). It also seems likely that a number of scanners were purchased for physicians' offices because of delays in obtaining permission for hospital scanners (15). Thus, the health planning program has partial responsibility for the existing maldistribution of CT scanners (see ch. 2). With the large number of older scanners in place, the health planning process may impede appropriate replacement and upgrading as well.

This discussion suggests a partial alternative explanation regarding the slowdown of the diffusion rate that would be the logical outcome of the intense market activity of 1975. That is that the market for CT scanners may be beginning to reach its limits. It is supported by close inspection of the data on distribution and diffusion of CT scanners to May 1980, when there were 1,471 operating scanners. Analysis of the institutional placement of scanners indicates that more than 80 percent of all large hospitals, or those over 500 beds, now have operational scanners. Even in early 1979, 62 percent of hospitals over 300 beds and 46 percent of those over 200 beds had scanners, A July 1979 presentation by the Technology Marketing Group, Ltd. (66), showed that of 2,250 hospitals with over 100 beds that did not have a scanner, only 23 percent were considering purchase of a scanner, while only 22 percent of the 624 hospitals with scanners were considering purchase of an additional one.

That the slowdown is more a natural phenomenon than a result of Government policy may be supported from a theoretical point of view as well as an empirical one. The cumulative diffusion curve of the installation of CT scanners in the United States is a textbook illustration of **a** theoretical innovation diffusion process (see ch. 2). The logistic curve is a model of that process that holds true of innovations such as automobiles, televisions, and automatic washing machines. Following the introduction of an innovation to the market, a certain percentage of interested parties will purchase it. Through time, this percentage will accumulate until virtually all of those who are expected to purchase will have done so. As more parties of this target group make their purchase, a smaller percentage are left to make theirs, so that over time the rate of diffusion must slow down and eventually level off. This phenomenon may just be manifesting itself in the 1978, 1979, and early 1980 data on CT scanner installations.

In addition to the question of whether or not Federal policies embodied in health planning programs have had an impact on the number of scanners, the question of whether they have had an impact on the distribution of scanners also remains at issue. Questions persist about the effectiveness of health planning laws with respect to the optimal location of scanners. Provisions of the health planning laws do not require CON approval of large expenditures made by private physicians. Currently, about 19 percent of the total number of scanners in this country are located in nonhospital settings. In particular, large urban hospitals typically serving a predominantly indigent clientele and large Veterans Administration hospitals lack scanners. Geographic maldistribution is also evident. Some urban areas have exceptionally high scanner-to-population ratios (the District of Columbia, for example, has 15.9 scanners per million population, and the Los Angeles area has 14.0 scanners per million); but some rural areas have no accessible CT scanner. Health planners have limited tools to assure placement in appropriate sites—their powers are largely negative. This may be the greatest problem with the health planning program.

Although Federal health planning programs may aim to curtail the diffusion of CT scanners, the stance assumed by the Federal Government in its policies toward other stages of development and use of scanners has tended to foster diffusion and widespread use. As noted earlier, Federal policies address all of the four stages in the development and use of medical technologies: R&D, demonstration of efficacy and safety, diffusion, and widespread utilization. In particular, the Federal Government has traditionally been a generous supporter of biomedical R&D. The real boon to diffusion and use of CT, however, has been in the Federal policy area of financing. Through its reimbursement policies, the Federal Government continues to assume an almost open-ended commitment to pay for CT scans. This posture has doubtless played an important role in the rapid acceptance of CT scanners and scanning in medical practice, thereby influencing the rate of diffusion and the aggreate supply of scanners.

Thus, a number of factors have affected CT scanner diffusion, not least of which is the revolutionary nature of the technology itself and its potential for improving diagnosis. The relative

impact of each of these factors will probably never be fully understood.

Although some changes have been made in policies regarding CT scanners since 1978, the underlying programs remain little changed, and the problems identified in OTA's 1978 report (129) remain largely unaddressed. For this reason, the policy alternatives of the 1978 report are reprinted in appendix A. They still seem to have relevance to those interested in improving Federal policies toward medical technologies.

Appendixes

Appendix A.— Policy Alternatives

(Reprinted From *Policy Implications of the Computed Tomography (CT) Scanner,* Office of Technology Assessment, August 1978)

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 HeaIth (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 avoidin$_g$ 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 mutually 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 The information 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 merely 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.

[1]Efficacy is defined as the potential ber efit to Individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. These idealconditions may be approa(hed in research settings, but are unlikely m average practice. Efficacy, then, represents an outer limitto 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, how**ever, 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; [2]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 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 (DHEW) to evaluate medical technologies,) The direct anticipated result of this alternative is the production of science-based information for use by medical professionals, policy makers, Government agencies, and the public.

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 under-

[2]Diffusion of a technology refers to the process of adoption from development until general acceptance

used 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 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 evaluted 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 addition 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 reimbursement 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 marry 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.** DHEW'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 (Public Law 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 Public Law 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 Public Law 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,

The broadening of 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 ch. 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 ch. 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 are 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 mutually 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, respectively. 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. (Public Law 93-641 mandated the development of uniform accounting and reporting, and Public Law 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 conflict 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 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 sub-

ject 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 service to nonmedicare and nonmedicaid 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.

Appendix B.— Research and Development of CT and Other Diagnostic Imaging Technologies

The computed tomography (CT) scanner was developed with little involvement of U.S. Government research agencies. Nonetheless, Federal support for R&D of the CT scanner has been substantial in the past. It is clear that this support has decreased significantly and steadily in the past few years (23,110). Meanwhile, private industry has assumed an increasing share of further basic R&D of CT scanners.

The National Institutes of Health (NIH) has been the major source of Federal funding for R&D of CT. Of the Institutes, the National Cancer Institute (NCI) has been the most active, supporting an estimated total of over $4 million in CT-related research projects *over* the past several years. The last major project funded by NIH (NCI) concerned with developing technological improvements in CT scanners, however, terminated in April **1978:** This extramurally supported research yielded the fixed-detector geometry type scanner developed by the American Science and Engineering Co. (AS&E) (1 10).

Currently, most CT-related research funded by NIH is concerned with new and improved uses of CT scanners and/or applications of CT scanning. The funding levels of current projects, however, are much more modest than those of earlier projects concerned with basic R&D of CT itself. More importantly, NIH resources currently being allocated to CT pale in comparison to NIH moneys being allocated to the R&D of other imaging technologies.

For example, NIH is currently supporting basic R&D of the dynamic spatial reconstructor (DSR) imaging system; positron emission transaxial tomography (PETT); and zeugmatography, or the application of principles of nuclear magnetic resonance (NMR) to imaging techniques, In addition, ultrasound (which much preceded CT historically) continues to be researched at NIH for improvements in the technology itself, as well as for new and improved applications.

Theoretically, the imaging capabilities of some of these new technologies exceed those of CT. Some of these technologies may also be safer than CT, because they do not use ionizing radiation. Given these advantages, the development of these technologies and their eventual emergence into clinical use could play a decisive role in the future of CT scanning. One trait that the new technologies (in particular) have in common with CT that might dampen this potential effect, however, is their costliness. In some cases, their estimated cost not only rivals, but exceeds, that of the most advanced CT equipment currently available.

Consequently, these emerging technologies will soon face many of the Federal policies established in the wake of the introduction, diffusion, and widespread use of CT scanners. Just how these expensive —but nonetheless, miraculous—technologies will fare when they encounter Federal policies toward the evaluation, diffusion, and reimbursement of new high-cost technologies will be interesting indeed. The field of diagnostic imaging is already a large and expensive one, as shown in tables B-1 and B-2.

Table B-1–Overview of Diagnostic Imaging in the United States (1977 and 1980)

	Number of hospitals with capability	Number of procedures (millions)		Costs (millions)	
		1977	1980	1977	1980
Diagnostic X-ray	7,000[a]	158[b]	171[b]	$5,300[b]	$7,600[c]
CT scanning	1,OOOC	1-1.4[c]	3.4[c]	$300[d]	$875[cd]
Nuclear medicine	3,300[e]	8.2[f]	11.1[b]	$800[f]	$1,250[b]
Ultrasound	All	Approximately 4[g]		na	$360[g]

[a]This is the approximate number of hospitals in the United States It is assumed that all have such equipment
[b]Estimates of Bureau of Radiological Health 186) The diagnostic X-ray figures Include dental X-ray
[c]OTA estimates
[d]This figure is partially offset by reductions in other diagnostic procedures Estimates are presented in OTA's 1978 CT report 11291
[e]American Hospital Association *Hospital Statistics 1978 Edition* (Chicago, Ill 1978)
[f]L Russell Technology *in Hospitals* (1461 Russell s 1975 estimates are extrapolated to 1977
[g]No reliable figures are available The State of New York survey of Rochester N Y if projected nationally, would Indicate 76 million procedures in hospitals alone (29) Sources in the Bureau of Radiological Health cite Informal estimates of 1 4 million procedures in 1979 excluding obstetrical use (a large component), but also indicate that that estimate seems too low Ultrasound use is growing rapidly The Stanford Research Institute estimates 12 million to 14 million procedures in 1979 growing to over 125 million in 199011 63)

NOTE Estimates are approximate for illustration only The Bureau of Radiological Health is presently beginning a survey of 125 hospitals to determine the rates of use of diagnostic X ray, ultrasound, and nuclear medicine This study will give much more conclusive figures than those shown above

Table B-2.-Sales of Diagnostic Imaging Equipment in the United States, by Year (1977-83)

	Sales (millions of dollars)						
	1974	1975	1976	1977	1981	1982	1983
Diagnostic X-ray	$265[a]	$300[b]	$230[b]	$280[b]	$375[b]		—
CT scanning	—	100[b]	12ob	160[b]	2 0	0[b]	
Nuclear medicine	40 [c] —		—	100[d]	—	$127[d]	—
Ultrasound	65a	—	—	160[e]	—	269[f]	$490[e]

NOTE The validity of the sales figures is not known They are undoubtedly rough They are included here as general indicators only The Stanford Research Institute estimates expenditures for diagnostic imaging equipment, supplies, accessories, and maintenance of $2 billion in 1978, rising to almost $65 billion in 1990 (163)

SOURCES
[a] *Electrical News* Mar 29, 1976, p 59
[b] *Electronic*, Jan 5, 1978, P 148
[c] *Predi* 88, May 1531973, P 24
[d] *Electric Business*, May 1979, P 66
[e] *I* E/cc *Eng*, November 1979, P 14
[f] *Inst* Tech April 1978, p. 18

Basic and Applied Research on CT

Current CT Scanners

Since the publication of the 1978 OTA report on CT scanners (129), the technical capabilities of CT scanners have increased as new models have been developed. This increase has expanded the potential usefulness of these scanners. The new scanners offer technically improved image resolution, largely by virtue of reduced scanning times and the consequent minimization of problems associated with patient motion. The scan times of the most recent CT scanners are less than 5 seconds for a single cross-section image. The most recent scanners are capable of achieving image resolution of as little as 0.61 mm (see table B-3).

The scanners listed in table B-3 were developed privately with the exception of the AS&E scanner. AS&E received considerable Federal support from NCI of NIH ending in April 1978 (22). AS&E, however, only sold a few of the new scanners. In January 1978, Pfizer, Inc., made an agreement with AS&E to purchase the rights to market and produce the scanner. Using the AS&E gantry, Pfizer made certain technical modifications (primarily in the electronic computer of the scanner) and now markets a hybrid of the AS&E scanner known as the 0450 Pfizer/AS&E scanner. The scanner has a price tag of approximately **$650,000** to **$700,000.** According to the Food and Drug Administration (FDA), 13 of these scanners were reported to be sold in the United States between June 1978 and 1979 (95).

'The term 'generation" is often applied to describe the type of scanner The first scanners to be developed all used a similar approach, and have often been labeled ' first generation ,' The primary meaning of the phrase was to indicate that that type of scanner was the first to be developed, However, there is an inevitable impression conveyed that the 'second generation" is superior to the ' first generation. ' For this reason, OTA, in consultation with the manufacturers, has accepted labels that are more descriptive and not as misleading. In particular, this was done because what has been called the 'fourth generation' " scanner is not superior to the "third generation" scanner according to both the National Electrical Manufacturers Association and the Bureau of Radiological Health of the Food and Drug Administration. The columns in table B-3 are in order of development, with those scanners sometimes called "third generation' and "fourth generation" together in the column labeled "rotate-only.

The Dynamic Spatial Reconstructor

Development of the DSR imaging system at the Mayo Clinic is currently receiving substantial NIH support (23). The DSR system adds the critical dimension to computerized tomography that is necessary for accurate imaging of moving organ systems (such as the heart and lung) and for studies of three-dimensional anatomy and circulatory dynamics in all regions of the body (88). These capabilities are dependent on the development of high-speed electronic data processing and digital computing techniques which is an integral part of the R&D of the DSR system (23).

Developers of the DSR system do not believe that it represents an extension of previous CT scanning principles and logic. They are reluctant to call it an advanced CT scanner (67). The DSR system does use X-ray (as does CT): But whereas CT is capable of producing only a 2-mm thick cross-section at a scan time of just a few seconds, the DSR when completed will be able to scan up to 240 1-mm thick cross-sections in 11 msec, repeat the complete scan procedure at intervals of 1/60th of a second, and reconstruct the entire three-dimensional volume of a whole organ, as well as dynamic changes in shape and dimension of moving structures (88). The principle components of the system are shown in the illustration below (see figure B-l). The DSR is described as follows (88):

> . . . A set of 28 rotating-anode X-ray sources, independently controlled, is arranged around a semicircle whose radius is 143 cm. Abutting this arrangement is another semicircle that contains 28 independently controlled image intensifiers and image isocon cam-

Table B-3.—Typesand Models of CT Scanners(1980)

	Rotate and translate, dual detector	Rotate and translate, multiple detector	Rotate only
	4-6 min scan time	20 see-2 min scan time	Under 5 sec scan time
	Single pencil beam X-ray source	2 or more pencil beams or single fan beam X-ray source	Single fan beam X-ray source
	2 detectors	3-60 detectors	Hundreds of contiguous detectors
Motion of gantry:	Source and detectors traverse gantry in parallel, gantry rotates through small angle, process repeats,	Sources and detectors traverse gantry in parallel, taking more readings and rotating through larger angle than dual detector.	Rotation motion only. In some models, source and detectors move together; in other models only source moves.
Scanners no longer available commercially in the United States as new equipment	EM I Mark I General Electric Neuroscan CT/N Pflzer0100 Siemens Siretom	Elscint 850 EM I CT 1010 EM I CT 5005 EM I CT 7020 Ohio-Nuclear 25 Ohio-Nuclear 50 Ohio-Nuclear 50FS Picker TR-120 Philips Tomoscan 200 Syntex System 60 Syntex System 90 Toshiba TCT-10A	AS&E 500 Artronix 1100 Artronix 1120 EM I 6000 EM I 7070 Searle Pho/Trax 4000 Siemens Somatom I Varian V-360
Current models		CGR ND 8000 Elscint 905 Hitachi CT-W Ohio-Nuclear 100 Omni Medical 4001 Pfizer 0200FS Toshiba TCT-30	General Electric CT/T 7800 General Electric CT/T 8000 General Electric CT/T 8800 Ohio-Nuclear 2005 Ohio-Nuclear 2010 Ohio-Nuclear 2020 Omni Medical Pfizer 0450 Philips Tomoscan 300 Picker Synerview 300 Picker Synerview 600 Siemens Somatom II Toshiba TCT-60A
Scanners-announced but not yet available commercially			CGR CR 10000 Philips Tomoscan 310

SOURCE National Electrical Manufacturers Association 1980

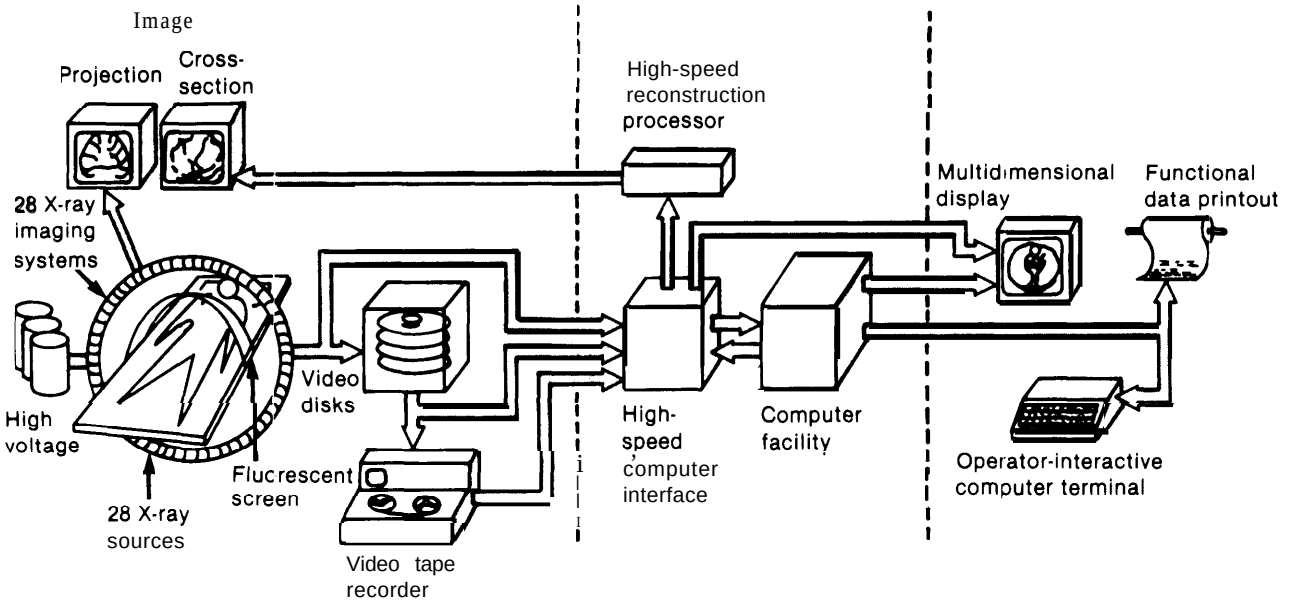
eras. These two semicircles make up one circle of equipment. Inside the circle is a 30 cm-wide flourescent screen, bent to form a semicircle with a 58-cm radius. The 28 image intensifiers and image cameras produce 28 images on the flourescent screen .

, . . The entire assembly—X-ray sources, flourescent screen, and video camera chains—is mounted on a cylindrical gantry, which is rotated at 90 degrees per second about a horizontal axis. Each X-ray source is pulsed on sequentially to irradiate the patient for 350 seconds. Simultaneously, the image intensifier and video camera for each X-ray source are activated to record the image on the flourescent screen. The heavy reliance on image intensification lowers, in effect, the X-ray dosage to levels no greater than those now employed for X-ray for X-ray procedures in general medical practice .

The DSR system, somewhat reduced for funding reasons, is currently being tested on animals on a limited basis. Researchers estimate it will be at least 2 to 3 years before it will be used to scan the first patient. At this time, it is being developed for medical research purposes, and not wit h an eye towards mass clinical application (67). The system will cost about $5 million, and might cost $3 million in mass production (34). The ultimate use of the multimillion dollar DSR system in the practice of medicine is viewed as a tertiary, or even a Quarternary tool, with perhaps 5 to 10 serving the entire country (67,83).

NIH has been the primary supporter of R&D of the DSR imaging system. The National Heart, Lung, and Blood Institute (NHLBI) has been the major source of

Figure B-1 .—Principal Components of the DSR Imaging System



SOURCE :IEEE *Spectrum,* January 1979, p 77

funding for this project since one of the major objectives is to permit accurate measurement of the structure and function of the diseased and normal heart (144). NHLBI support totals about $2 *million over* the past few years for development of the imaging device itself. Development of the high-speed computer system necessary to the device has been supported by the Division of Research and Resources (DRR) of NIH, which has spent about $1 million during fiscal years 1978 and 1979 (23).

Research on Applications of CT

It is difficult to compile an inclusive listing of projects related to the applications and uses of CT scanning at NIH. First, since such projects are organized by disease and organs as the Institutes are, identification of CT-related research is difficult. Secondly, even when such projects can be identified, it is difficult to determine the proportion of moneys that should be apportioned to research on CT. Without a formal survey of the Institutes, therefore, precise estimates of such projects and their funding levels are unavailable. Consequently, the projects discussed below are meant only to indicate the kinds of ongoing research being supported by NIH, Similarly, the accompanying dollar figures are provided as a rough estimate of current Federal investments in this type of CT-related research project.

Formerly the major NIH backer of research (on CT scanning, NCI spent only approximately **$75,000** in fiscal year 1979 on research for scanner development (11), In addition, however, NCI spent approximately $400,000 in that year for CT-related studies with such objectives as developing better contrast agents and new algorithms for diagnostic use to reduce radiation exposure (110). Also, in that year, NHLBI supported some extramural research grants involving the use of CT scanners in diagnostic methods for particular cardiac diseases (110), DRR, a major funding source of the DSR imaging system discussed **above,** also supported about 15 projects involving the use of CT scanners through its biomedical research support program: These few projects, however, are very modest totaling approximately $65,000 in fiscal year 1979. In addition to this research, about 3,000 patients per year are scanned in the NIH Clinical Center. Most of these represent patients who are on protocols requiring a CT scan (110).

The major project at NIH related to the application of CT is funded by the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS). In fiscal year 1979, the Institute funded a $500,000 project investigating the use of CT scanning

in the diagnosis of head trauma (110). The Institute also had supported about $50,000 in intramural research projects related to the use of computed head tomography for diagnosis of diseases particularly relevant to it, such as brain tumor (110).

In conclusion, although there are still many initiatives at NIH related to applied, as opposed to basic, research on CT scanners and scanning, the cumulative resources devoted to these activities do not begin to approach the levels of funding for the ongoing development of the DSR system, for example. At this time, the Federal Government is not a significant contributor to R&D of CT scanners and scanning: Its time has come and gone. Instead, Federal support of biomedical R&D is concentrated on new imaging technologies.

Emerging Imaging Technologies

There are a number of new technologies and technological applications in the imaging field that hold great promise for medical research and eventual clinical application. These will not be covered in detail. However, there are two new technologies that are particularly exciting and at the same time raise many of the same policy issues characteristics of CT scanners. These are PETT and zeugmatography, or the application of principles of NMR to imaging techniques. Various Institutes at NIH are supporting R&D of both of these imaging techniques, and there is considerable private (worldwide) R&D investment being made in them as well.

There are now only a few PETT and NMR scanners throughout the world, and these so far have been limited to experimental clinical use (with human patients). However, the unique capabilities and attributes of these two imaging techniques have generated a great deal of excitement in the medical research community, and the possibilities for clinical application have sparked even greater enthusiasm for these technologies. Speculation regarding their role in clinical practice, associated operational costs, and commercial viability has already captured the attention of the media **(83,96).** One reason for excitement is that these two technologies may provide the means to image tissue function, whereas present CT and ultrasound techniques provide the means to image tissue structure.

The excitement, enthusiasm, and speculation surrounding these technologies has also drawn the attention of the Office of Health Regulation of the Health Care Financing Administration (HCFA), and the National Center for Health Care Technology (NCHCT) of DHHS (143). For example, NCHCT is preparing an overview paper on NMR that reviews the efficacy, diffusion, and utilization questions surrounding the introduction of new medical devices (73). It appears that PETT and NMR have already been flagged by these two Federal agencies, and that if and when they are ready to be introduced into medical practice, these technologies will undoubtedly be subjected to Federal policies toward the evaluation, diffusion, use, and reimbursement of high-cost medical technologies—many of which were formulated around the CT scanner. [2]

Positron Emission Transaxial Tomography

PETT is the latest of several radionuclide imaging systems belonging to the family of nuclear medicine techniques. Although ionizing radiation is used in PETT, the technology differs significantly from CT in principle and in capability. A PETT scanner may be briefly described as ". . . a large, computer-controlled tomography unit that maps the distribution of positron-emitting pharmaceuticals in order to construct detailed images of organ metabolism, physiology, and function" (96).

In the PETT scanning procedure, radioactive isotopes of elements such as oxygen, carbon, fluorine, and nitrogen are administered to the patient, usually by injection, but also sometimes by inhalation. This is in contrast to the manner in which CT scanners (and conventional X-ray techniques) expose the patient to ionizing radiation by means of an external X-ray tube. The radionuclides are administered as metabolically active compounds, such as glucose, or as naturally occurring compounds, such as carbon monoxide, which may be used as tracers. The images produced by PETT scanners are based largely on the detection of the distribution of the radioactivity through body tissue. Reconstructed images produced by PETT scanners, therefore, may reflect compartmentalized localization, flow, or biochemical and metabolic activity, whereas CT scanners basically detect and display anatomical structure, although the use of iodinated contrast media may give significant functional information. The difference in information presented in a comparable cross-section of the brain produced by these two technologies is illustrated by the fact that while CT scans of a cadaver and a live human would show a similar image, a PETT scan of a cadaver would show a relatively blank screen image in comparison to the scan of a live human, since due to lack of flow, the radioactive material would not have been *transported* (143).

[2]The memorandum from the Office of Health Regulation in HCFA suggests that local health systems agencies and State health planning and development agencies be alerted to the impending introduction of these two technologies as well (143)

Ter-Pogossian and his coworkers (175) have recently described PETT as follows:

> In this technique a chemical compound with the desired biological activity is labeled with a radioactive isotope that decays by emitting a positron, or positive electron. The emitted positron almost immediately combines with an electron, and the two are mutually annihilated with the emission of two gamma rays. The two gamma rays fly off in very nearly opposite directions, penetrate the surrounding tissue and are recorded outside the subject by a circular array of detectors. A mathematical algorithm applied by computer rapidly reconstructs the spatial distribution of the radioactivity within the subject for a selected plane and displays the resulting image on a cathode-ray screen . . . . With suitable interpretation PETT images can provide a noninvasive, regional assessment of many biochemical processes that are essential to the functioning of the organ that is being visualized.

NIH investment in the basic R&D of the use of positrons for imaging which led to PETT has been considerable, amounting to almost $9 million in grants to one research center alone over an 18-year period (143). Significant support of PETT continues and is projected for the next few years. For example, NINCDS initiated a series of new PETT projects in 1979. In the first year of support, the Institute spent $5.9 million in grants to establish five university-based neurology centers of research around the country and the construction of a positron emission tomography scanning instrument in each (151). Continued grant support for these centers is projected for the next 3 years. The Institute's interest in PETT stems from the expectation that PETT will enable physiological research of cerebral metabolism just as CT enabled research of cerebral vascular anatomy and flow (151). Thus, the purpose of research on PETT by the Institute has been to understand normal brain biochemistry and metabolic disorders and to study the effects of lack of oxygen, various pharmaceuticals, trauma, and varieties of stress on neural tissue (151).

There are probably more than 20 experimental positron emission scanning devices in the world at this time, half of which are located in the United States at 10 different locations: At least three more PETT devices are scheduled for installation (all at U.S. locations); these are also to be used for experimental purposes (143). [3] In addition to the investigation of brain functions PETT scanning is also being used for a variety of other research purposes, most of which are related to heart and lung functions (96). The strategy in research is to administer different positron-emitting chemicals which respond to different metabolic pathways in the target organ. By measuring the behavior of these chemicals at various times, information concerning the function of the organ can be obtained. For example, red cells "labeled" with the positron emitting carbon-n monoxide will show the blood distribution in the heart. Clearly, the number of positron-emitting radiopharmaceuticals and biological pathways that can be paired for study presents an almost infinite number of permutations. This potential suggests that PETT will play an important role in research in both organ physiciology, and in basic physiological research (96).

The estimated cost of a PETT scanner and its associated equipment (i. e., a cyclotron or linear accelerator for the preparation of positron-emitting isotopes, and the computer software and hardware systems necessary for imaging) is from $1.35 million (143) to $1.94 million (7).[4] Such a high cost suggests that the use of PETT scanners might be restricted to research purposes, since the cost would be prohibitive to all but the most major institutions. Nevertheless, the potential of PETT technology for clinical application and use has been recognized by manufacturers of medical equipment, and it is reported that at least a few have undertaken feasibility studies for marketing PETT scanners (143).

Nuclear Magnetic Resonance Tomography

Although the principles of NMR were discovered by atomic physicists at least 30 years ago, and have been incorporated in the techniques of NMR spectroscopy developed and used by chemists in analytical chemistry almost since that time, NMR tomography, or zeugmatography, has only been under development for the past several years (96). Since 1973, when Paul C. Lauterbur of State University of New York (SUNY) at Stony Brook first demonstrated a means for reconstructing an image in two (and even three) dimensions based on NMR signals, zeugmatography has been the most rapidly expanding application of NMR in medicine (76).[5] A variety of

[3] As of August 1980, PETT scanners are located at Washington University (2), Massachusetts General Hospital (2), UCLA, University of Miami's Brookhaven Laboratories, University of Pennsylvania, University of Chicago, Oak Ridge National Laboratory, Sloan Kettering Institute for Cancer Research, and the National Institutes of Health (7). The University of Michigan, Johns Hopkins University, and Houston are reported to have ordered PETT devices also (143).

[4] Almost half of the total estimate of $1.35 million is represented by the estimated cost of cyclotron at $600,000. The computer systems necessary for imaging represent another $250,000, and the PETT scanner itself, approximately $500,000 (143)

[5] Examples of ongoing research on NMR at various Institutes and divisions at NIH were presented at a science writers' seminar on NMR held on Apr 23, 1980. These included. studies of the structure and mobility of DNA and proteins by NMR techniques, NMR studies of sickle cell in the intact red blood cell, and NMR studies of the molecular structure of collagen. These Intramural projects were in addition to the presentation of the project involving production of two- and three-dimensional images by NMR tomographic methods and a discussion of their potential diagnostic applications by Dr. Hoult (122),

techniques have been developed by numerous researchers in Europe and the United States since the first experiment by Lauterbur. While it remains to be seen which method(s) will gain acceptance, the technology is ready to be clinically evaluated.

Since 1973, zeugmatography has made significant advances in the clarity of computer-generated images of the body (143). It is estimated that approximately 200 individuals have been subjects of NMR scans (79). Theoretically, the resolution potential of zeugmatography is much greater than X-ray, nuclear, or ultrasound imaging techniques (for reasons which will be shown below) (77). However, this potential is not the sole—or even the major—reason for the excitement surrounding NMR tomography. Rather, the excitement stems from the fact that NMR does not use ionizing radiation (either X-ray or gamma-ray), is not "stopped" by bone, and most importantly, can yield metabolic information with appropriate adjustments (77). The relatively greater potential capabilities of NMR tomography in comparison to other imaging technologies (including PETT) implies tremendous potential for application to a wide range of diagnostic and treatment monitoring functions. However, the effects of the magnetic fields used in NMR are unknown. Although NMR may be safer than X-ray, it is much too soon to know for certain.

Hounsfield, who was awarded the Nobel prize for his work in CT scanning, described the principles of NMR as follows (80):

> When hydrogen protons are placed in a magnetic field they will precess (or "wobble") around the field direction just as a spinning top precesses around its vertical gravitational field. This precession occurs at a definite frequency, known as the Larmor frequency, and is proportional to the magnetic field intensity.
>
> The usual NMR procedure for imaging is to apply a strong magnetic field along the body to be studied. After a short period of time, the nuclei will align with their magnetic moments along the field. A radio frequency tuned to the precession frequency of the hydrogen nucleus is then applied at right angles to the main field by means of a set of coils at the side of the body, This causes some of the hydrogen nuclei to precess—all keeping in step. After the radio receiver field has been switched off, the nuclei will continue to precess in phase, generating a similar radio frequency which can be picked up in receiver coils placed at the side of the body, these signals detect the water content of the body. It will take some time for the precession to die away, as the nuclei again realign themselves with the magnetic field. The measurement of this time is important as it gives us some information about the nature of the tissue under investigation.

This knowledge immediately suggests the comparison of recovery times of hydrogen atoms in healthy versus diseased tissue. In early 1971, Raymond Damadian at SUNY Downstate Medical Center in Brooklyn published research suggesting that the NMR signal from the water in tumor cells differed from that in normal cells, the signal from cancerous cells being much longer than that from normal cells (96). The possibilities of a noninvasive, highly *sensitive* diagnostic tool based on chemical information at a cellular level were obvious.

In 1973, these subtle differences in chemical information in human tissue were displayed in the first NMR tomographic pictures, published by Paul C. Lauterbur. Lauterbur realized that by changing the direction of the magnetic field (in which the patient, or portion of the patient is placed) gradient, and repeating the experiment at a variety of orientations (i.e., taking projections at many different angles, and then reconstructing them by computer), it was possible to picture the subject in two (and potentially) three dimensions (77).[6] Lauterbur named this technique "zeugmatography" (from the Greek "joining together") based on the underlying physics whereby the magnetic field gradient joins together frequency and spatial information (77). Although a variety of NMR tomographic techniques are currently being pursued, all are based on the phenomenon of resonance of hydrogen atoms in body tissue. The outcome is a reconstructed image of an organ or whole body cross-section which appears on a screen (143). Differences in body tissue are thus detected by their intrinsic chemical differences, rather than by their density or absorpability of X-rays as in CT scanning, or by tracing administered positron-emitting isotopes as in PETT scanning.

Perhaps the most exciting potential of NMR, however, is the potential for metabolic studies that will be realized over the longer term. The dimension of metabolic information is already represented in NMR images. Eventually, it may be possible to "zoom in" on part of an organ, such as the ventricle of the heart or hemisphere of the brain, to obtain metabolic information in that specific region (79). In these extended capabilities, one may envision the imaging of metabolic information that would be comparable to that currently obtainable only by biopsy. It is the combination of metabolic information (not intrinsically available in any other imaging technique) with the image that makes the NMR technique potentially so powerful.

Hoult (79) has described one potential application, a scan of a baby's head for hydrocephalus or intracranial bleeding. NMR could locate a particular artery, measure the blood flow in that artery, and

[6] The techniques of projection and reconstruction associated with tomography are similar to those first developed for the CT scanner (96).

then check that the oxygen uptake of a hemisphere is adequate. All of this would be done totally noninvasively, and perhaps without risk to the infant (77). In the Biomedical Engineering and Instrumentation Branch of the Division of Research Services at NIH, such an experiment is under way. The imaging system developed at NIH has been almost entirely built within the Branch (apart from the computer required). The crux of this particular NMR tomographic system is a novel magnet design that has two movable hemispherical windings which can generate powerful transverse magnetic field gradients (78). Construction of the magnet was near completion in May 1980. Initially the equipment will be used with phantoms and animals to obtain experience and verify safety. Imaging of human subjects is to begin in spring 1981 (approximately). Eventually, the NIH system will be used to scan premature neonates in a series of experiments. It is hoped that the NMR instrument will provide a major imaging facility at NIH for diagnosis and repeated observation of diseases to which NMR is particularly suited (77).

Besides these capabilities, the final and immediate advantage of NMR over other imaging techniques is that it may be safer because it does not use ionizing radiation (79). However, there are real and potential hazards from strong magnetic fields, especially with pulsed or alternating polarity fields, and resulting induction currents (101). Although some have proposed that NMR is particularly well suited for use with infants and fetuses of pregnant women, FDA spokesmen urge caution in applying it to infants or pregnant women (86).

Meanwhile, the expectations based on the capabilities and attributes of NMR have attracted the intense interest of researchers throughout the world. University and research centers developing NMR scanning techniques include Nottingham, London, and Oxford Universities in England, and SUNY at Stony Brook, SUNY at Downstate New York Medical Center, the University of California at Berkeley, the University of Illinois, and Johns Hopkins University in the United States (143).[7] Damadian, who is affiliated with Downstate has formed his own company, FONAR Corp. and plans to place an instrument in a diagnostic center in Cleveland, Ohio, for clinical evaluation (101).

In addition, there is substantial private investment currently being made in R&D that will translate the principles of NMR tomography into devices that may be commercially marketed. In the United States, Pfizer has a scanner at the University of California in San Francisco (143). Johnson & Johnson (Technicare), General Electric, and Intermagnetics are also reportedly involved in the commercial development of NMR scanners (79,101). In Europe, there are four companies known to be developing NMR scanners. These are: EMI, Ltd. (United Kingdom), Brouker West *Germany), Siemens* (West Germany), and Philips (Holland) (143). The intense involvement of these companies attests to their expectations regarding the potential marketability of NMR techniques. The estimated cost of an NMR for whole-body scanning is about **$500,000,** but with the addition of computer equipment necessary to provide the imaging capability of the scanner, total costs would approach $750,000 (101,143) .

Interestingly, EMI, Ltd. (now Thorn EMI), which pioneered the R&D of the CT scanner, is actively involved in NMR (80,101). Both EMI and Nottingham University have recently produced images of body sections using NMR. These models have been the basis for research by several of the U.S. manufacturers (143). In May 1980, EMI installed its prototype NMR scanner in Hammersmith General Hospital in London with the purpose of evaluating the device under conditions of hospital use (79). It is conjectured that EMI will begin manufacturing and marketing this device in the near future (143).

Ultrasonography

Ultrasonography is not a new technology: Its development preceded that of CT scanners by at least **20 years and** it has been used in the clinical practice of obstetrics since 1956 (59), Ultrasound has experienced a much slower developmental history than CT scanning, and it has been slower than CT to gain wider acceptance by practitioners and broader application in medical practices (153). However, there are now several indications that suggest that ultrasound is rapidly coming of age [8]

Recent improvements in ultrasound instrumentation have resulted in enhanced image quality and reliability, convenience of use, and quicker study times, all of which have heightened the appeal of ultrasound to practitioners. These emerging improvements in the technical performance of ultrasound imaging systems, however, are not the sole reason for its relatively newfound appeal. There is also increasing importance being placed on cost and safety —two attributes that have always made ultrasound appealing relative to CT scanners for some uses. Ultrasound

[7] Also in this country the Massachusetts Institute of Technology, Harvard University, and Bell Laboratories are developing NMR scanners They have not yet produced images that are comparable to those of the institutions listed in the text, however (143).

[8] Market trends indicate that ultrasound is currently the most rapidly growing market of imaging products (see table B-2)

equipment is much less expensive than any CT scanner (in terms of capital cost): The most technologically advanced, fully automated ultrasound imaging systems now commercially available still sell for about $150,000, a price that is about one-fifth that of some present generation CT scanners. [9] A real-time ultrasound scanner costs around $50,000 (174). In addition, ultrasound units are smaller than CT, require no elaborate installation, and are portable, allowing them to be used in areas such as the newborn nursery and the intensive care unit.

The second attribute of ultrasound that has always made it preferable to CT scanning (and other X-ray modalities) is that it is based on the physics of sound rather than radiation, and therefore does not impose the risks associated with ionizing radiation (136). The higher growth rates for ultrasound sales observed in 1979 data and projections through the coming decade suggest a market trend toward imaging devices that do not use X-ray (91). In part, this may reflect the heightened public awareness of the harmful effects of radiation **(91).** However, relative to CT, ultrasound has the limitation that it cannot penetrate bone and thus cannot be used to image the adult brain, and the limitation that it cannot penetrate gas, and hence cannot be used to image structures surrounded by gas- filled loops of bowel (136). It likewise has no role diagnosing disease in the lungs.

Although it is true that ultrasound is safer than CT because it does not use X-ray, more cautious observers point to the possibility that ultrasonics may involve other risks yet unknown **(86).** Until recently, ultrasound has been presumed to be harmless, and its supporters have insistently promoted it on this basis. Indeed, this assumption has been one of the primary reasons for its near-routine application in the practice of obstetrics. [10] Now, however, the possibility of risk entailed in using ultrasound is becoming the focus of considerable concern particularly because of its prevalent application in obstetrics (17). It is more realistic, and safer, to say that the risk associated with ultrasonic energy is unknown rather than nonexistent.

The principles of ultrasonics can be clarified by a discussion of one of the two types of ultrasound, pulse echo imaging (59). The key element of the ultrasound system is the transducer that changes voltage into high-frequency sound by means of a piezo-electric crystal: This crystal also has the capability of picking up reflected sound and changing it back into electricity. This electronic input is then converted into visual data. There are several formats for display, not all of which provide a two-dimensional image. The format most closely approximating the X-ray view supplied by CT scanner is that of the B-mode compound scanning method which provides a two-dimensional, cross-sectional view of a body tissue or structure (59). Its principal components include the transducer, transmitter and receiver, digital or analog processor, and display monitor. There may also be a television camera, video tape recorder, and record monitor so that image sequences of particular interest may be recorded for later analysis (88). An ultrasound imaging system is shown schematically in figure B-2.

One problem with ultrasound is that the quality and reliability of the images depends directly on the skill of the person operating the equipment. Recent refinement and automation have not yet solved that problem **(136).** In addition, some observers have attributed the rather long developmental path of ultrasound, as well as its consequent slow application and acceptance by practitioners in diagnostic capacities, to the fact that ultrasound has no "natural" constituency among the medical specialties (153). There is no medical specialty to which ultrasound is particularly germane (outside obstetrics), although it is now being applied in many: Cardiology is one specialty with rapidly expanding applications of ultrasound (150). Many other specialities including ophthalmology, pediatrics, and neurology, are now acquiring their own units, which helps explain the recent explosive growth (174).

Historically, ultrasound has received fairly large funding support from NIH. Table B-4 shows Federal investment in 1975—present levels are probably comparable. NCI has done some recent work: Two projects are currently in progress, each funded at about **$500,000** in fiscal year 1979 (153). NHLBI is also investigating the use of ultrasound diagnostic techniques in cardiology. The most active research unit for ultrasound applications at NIH is the Division of Radiology in the Clinical Center of NIH. Most of the work done in that division relates to clinical applications, but research has involved advances in instrumentation as well. New equipment is being developed in the field of real time scanning **(153).**

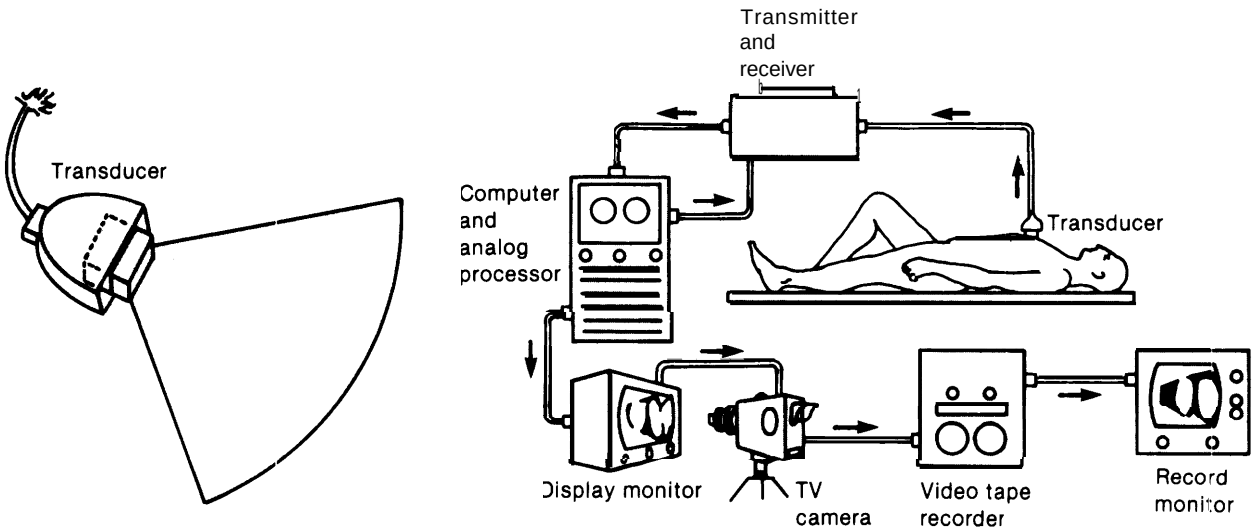
In spite of these past trends in development and adoption into wider use in medical practice, however, ultrasound is now being applied to a variety of medical problems outside its longstanding and now

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[9] This is the price of the Datason manufactured by General Electric and introduced in November 1979, which integrates the B-mode and real time scanning capabilities (123).

[10] The technology was first found to be very useful in obstetrics because of the fact that sound transmits very well through water, or fluid such as that found in the amniotic sac. Its safety was assumed and later accepted based on accumulating clinical experience. This application is based on the sonar principle. It displays images of sections of the human body so rapidly that internal movement may be detected. Its main use is recording the fetal heart rate during labor.

Figure B-2. -Principal Components of Real-Time B-Mode Ultrasound Imaging System



SOURCE:IEEE *Spectrum,* January 1977, p 80

Table B-4.—Federal Funding for R&Din Ultrasonic Imaging Diagnostic Instrumentation (1975)

National Bureau of Standards	$ 100,000
Department of Defense:	
Army	120,000
Navy	285,535
Energy Research and Development Administration	80,000
Department of Health, Education, and Welfare:	
Food and Drug Administration	841,459
Health Resources Administration	25,000
National Institutes of Health:	
National Cancer Institute	418,514
National Heart and Lung Institute	2,851,165
National Institute of General Medical Sciences	1,530,166
National Institute of Arthritis, Metabolic, and Digestive Diseases	118,964
National Eye Institute	439,297
National Institute of Neurological and Communicative Disorders and Stroke	379,905
Division of Research Resources	20,000
Division of Research Services	50,000
Social and Rehabilitation Service	24,851
National Aeronautics and Space Administration	360,000
National Science Foundation	818,850
Veterans Administration	20,500
Total	$8,484,206

[a]Does not include all Intramural programs, which are considerable

SOURCE: All lance for Engineering in Medicine and Biology, *Directory of Federal Programs in Medical Diagnostic Ultrasound* (Chevy Chase, Md , 1976).

near-routine use in the practice of obstetrics. Applacations of ultrasound have expanded to include studies of the brain, eyes, and various organs and structures of the abdomen (including the liver, gall bladder, spleen, pancreas, kidney, and adrenal glands), as well as fluid collections in the abdomen (147). With the emergence of these new applications, ultrasound has become the diagnostic imaging modality that is currently most often compared to CT scanning for studies of the abdomen.

Thus, ultrasound is being applied in diagnostic roles that compete with and/or complement those typically performed by CT scanners and/or other radiological diagnostic imaging modalities. Ultrasound has proved particularly popular in applications where the risks associated with ionizing radiation are especially high (as has always been the case with the use of ultrasound is obstetrics). The recently published results of a clinical trial testing the efficacy of using ultrasound for breast cancer screening for tumor,[11] for example, showed ultrasound to be able to accurately and reliably diagnose tumors of the breast when they are fairly large **(25).**

The successful application of ultrasound for breast cancer screening for tumor would be significant in that it would offer an alternative to X-ray mammography, a procedure for breast cancer screening that has been the focus of much controversy. Breast cancer screening was the topic of the first consensus development conference sponsored by NIH **(24).** Consideration of X-ray mammography, as used for screening rather than diagnosis, was an important part of that conference. The risks and potential benefits of X-ray mammography screening were such that the panel recommended routine screening for women age **50** and over, but that women between **40** and 49 years be routinely screened only if they have either a personal or family history of breast cancer, and that women under **40** years of age not be routinely screened unless they have a personal history of breast cancer **(24).**

Other potential applications of ultrasound may become increasingly important. One is carotid artery scanning to diagnose occlusion (blocking) of the artery (156). Another is the use of ultrasound to characterize tissue such as liver (155) and pancreas (154) to diagnose such diseases as pancretitis. In terms of its capability to diagnose some diseases, ultrasound is not superior to or even equal to CT: For other diseases, the two may be about equal. In those cases where the images produced by each modality can enable accurate and reliable diagnosis, and one modality involves irradiating the patient while the other does not, it stands to reason that the obvious choice would be to avoid imposing the risk associated with radiation.

It is important to stress, however, that ultrasound cannot be assumed to be harmless because no ionization occurs with the interaction of ultrasonic energy and human tissue. Rather, the associated risk is unknown and is cause for growing concern by more cautious observers **(148).** Proponents of ultrasound maintain that the risk is negligible, noting that no adverse effects attributed to ultrasound have been reported by either obstetricians or pediatricians **(59).** Proponents further substantiate this claim by pointing to the fact that the developing embryo or fetus is tremendously susceptible to traumatic influences and that such a fragile organism would be the first to manifest any ill effects. Critics argue that the absence of reported hazards does not constitute proof of safety (59). Although there have been no adequate human studies of the risk entailed in the use of obstetric practice to date, experimental laboratory studies with mice and primates have indicated a variety of problems as a direct result of using ultrasound at high levels (148).

The possibility of risk associated with intrauterine exposure to ultrasonic energy is particularly poignant given its prevalence of use in the United States (59). Virtually every large labor room in the country is equipped with ultrasound for the purposes of monitoring the fetus during labor; an application now regarded as routine practice. More recently, there has been a trend toward the routine use of ultrasound for monitoring the embryo and fetus in early stages of gestation as well (59). The current high use levels observed and expanding routine application of ultrasound may not be justified in terms of the benefits attained by the monitoring procedure **(17).**

Thus, at the same time that considerable concern is being expressed over the safety of ultrasound as applied in obstetrics, it is being more liberally applied: The controversy over risks and benefits has placed the technology at the center of a heated debate regarding its appropriate use in obstetrics. Certainly there is the potential for abuse in applying the technology. At the least, unnecessary use of ultrasound could result in unnecessary costs. But at the worst, it could result in unknown damage in a generation of children. The controversy points out, in the most dramatic way, a great need for basic information regarding the safety and efficacy of ultrasound.

The Future of CT Scanning

As recognized by the honor of the Nobel Prize bestowed on its originators in **1979,** the CT scanner undoubtedly remains a remarkable advance in diagnostic medicine. With CT technology now well beyond the phase of basic R&D to which Federal funding sources are primarily oriented, Federal funding has recently supported the R&D of new imaging technologies such as NMR, PETT, and ultrasound, the capa -

[11] These are the first clinical trials of this application of ultrasound. However this equipment was marketed commercially a few years ago, and there are already at least three commercial models presently available (153).

[12] There are nine human studies but all are methodologically flawed (153).

bilities of which may exceed those of current CT scanners.

This is not to suggest that the limits of the CT scanner, based on the principles of radiology and CT, have been fully realized. But continued refinements and improvements in CT technology are now more the concern of those private companies that currently have considerable vested interest in the future of CT scanning. Among the performance improvements that current CT technology may now be capable of supporting are subsecond, high-resolution, and/or three-dimensional reconstructions **(64).** Proponents of CT are confident regarding the continuing technical evolution of the technology through the remainder of this century (64).

Meanwhile, however, private, as well as Federal, investments in the R&D of new principles of imaging have resulted in the emerging technologies of NMR and PETT scanning. While the contribution of CT imaging to biomedical research and medicine was to provide studies of anatomical structure in a noninvasive, automated mcde, the techniques of PETT and NMR provide studies of physiology and function, and metabolism (respectively) in that same mode (151). In the case of NMR, these capabilities are particularly enticing since they are achieved via a technique that does not involve radiation exposure, either from X-ray or from the administration of radionuclides.

It is not only the new and emerging imaging techniques that are poised to present a challenge to CT scanners, but also other older techniques such as ultrasound. Continued research on ultrasound diagnostic imaging techniques has resulted in improvements in equipment and procedure that have brought about comparable diagnostic capabilities for certain conditions, as well as convenience of use for practitioners. At the same time, the appeal of diagnostic ultrasound has been enhanced as increasing emphasis has been placed on cost and safety of equipment and procedure. Diagnostic ultrasound, which is assumed to be not only safer than X-ray imaging techniques but also far less expensive even in its newest forms, can be expected to continue its competitive position in medical practice, and consequently in the commercial marketplace.

Several indicators already reflect the increasing preference and demand for less expensive, noninvasive, non-radiation-emitting modalities such as ultrasound. For example, an estimate of 1979 (worldwide) dollar volume sales in ultrasound imaging equipment indicates an increase of **40** percent over sales in 1978, while an increase of 10 percent over 1978 was estimated for CT scanner sales (48). Projections of annual growth rates from 1979 through 1982 show an extension of these trends: It is expected that sales of CT scanners will continue to increase at an annual rate of approximately 10 percent, but ultrasound is expected to show a 31-percent rate of increase per year (48). Increased utilization of ultrasound in medical practice may also be expected in the coming years based on such indicators as the papers presented at the annual meeting of the Radiological Society of North America in November 1979 (134). While the number of papers on applications of ultrasound increased from the previous year by about 15 percent, the number of papers on applications of CT decreased by about 10 percent (91). It is already predicted that the increased use of ultrasound in diagnostic capacities enabled by recent refinements in ultrasound technology will affect the future sales of CT scanners (91).

Eventually, the diagnostic imaging instrument market will be further altered by the introduction of new technologies. However, it also seems to be recognized that these new imaging techniques will be subjected to an increasingly critical and extended period of evaluation to establish efficacy, and also cost effectiveness (64). Further, primarily because of their costliness, they will come under particular scrutiny as their diffusion and widespread utilization in medical practice become imminent (143). If well-designed studies are not done of their clinical utility, two equally undesirable outcomes are possible: Rapid spread without demonstration of usefulness or concerted attempts by Government to restrict diffusion without a good basis on scientific studies on which to rely.

Expectations surrounding the introduction and use of new technologies have given rise to a certain skepticism regarding their becoming generally available (64). Some believe that the cautious environment into which expensive new diagnostic modalities such as NMR will be introduced will have a net effect of favoring continued evolutionary changes in diffused, accepted technologies and procedures— in this case CT scanners and scanning. The recent trends observed with respect to the development and use of ultrasound equipment and procedure are a pertinent example of this prediction. [13]

Ultimately, the way in which these new and improved diagnostic imaging modalities will compete with CT scanners in the marketplace will be determined by the way in which their capabilities are used

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"Although ultrasound is not nearly as capital intensive as either CT is, or NMR is expected to be, expenditures associated with its use now rival those associated with CT because of the prevalent and frequent application of ultrasound in its current capacities. And as the diagnostic applications of ultrasound expand, these expenditures can also be expected to rise, The issue of capital costs v. the cost associated with actual utilization (that ultrasound so aptly Illustrates) is an Important one.

to complement, supplement, or replace CT scanning in medical practice. Essentially, this is tantamount to saying that the clinical efficacy of CT scanning—as well as that of emerging and improved diagnostic imaging techniques—must be evaluated. The future of CT scanning lies in determining what the potential impact of CT scanning can be and under what conditions these benefits can be attained. For example, comparisons of CT and ultrasound for abdominal diagnoses show that CT is generally the better imaging technique for corpulent patients, ultrasound the better for thinner ones (153). Since ultrasound does not require the patient to be motionless, it is also better than CT for imaging very young, elderly, and agitated patients (153). To be sure, the principles underlying each technique, as well as the attributes of the associated procedure, will aid in determining the ultimate place that each will occupy in the practice of medicine.

Until very recently, CT has been used primarily as a supercapable X-ray machine. But new applications of CT need to be explored and refined if i t is to establish a legitimate position relative to other diagnostic technologies that are being, or soon will be, used in medical practice. Investigation of the use of CT in capabilities that lie beyond its traditional diagnostic role is especially important to extending and establishing the boundaries of its domain. Examples of such applications are the use of CT in the planning and delivery of radiation and chemotherapy treatment, and the monitoring of cancer patients under treatment (5,68, 75, 169). Another is its application in emergency medicine for head trauma (9 I). A final example is the use of CT as a guide in biopsying tumors, aspirating cysts, and draining abscesses of the brain.

Applications of CT outside conventional diagnostic roles will be important to establishing its clinical efficacy. The benefits accruing from the use of CT in therapeutic capacities (e. g., in conjunction with radiotherapy for cancer) are more readily discerned than those accruing from the use of CT in diagnostic capacities, partially because they have a more direct potential influence on health outcome (102,183,185, 186). These new applications could provide a broadened base for arguing the need for additional CT scanners. However, they have not yet been raised as a major issue in the current heated public debate surrounding the National Health Planning Guidelines. Presently, the evaluation of efficacy and cost effectiveness, the regulation of diffusion, and the financing of CT scanning are primarily based on the application of CT in its diagnostic capacities. New applications being made outside the diagnostic role in **which CT was born, however, will be a Critical** factor in determining its future.

Appendix C.—CT-Related Policies of the Department of Defense and the Veterans Administration

The Department of Defense

The Department of Defense (DOD) Health Council, including the Surgeons General of the Army, Navy, and Air Force, and the Assistant Secretary of Defense for Health Affairs, reviews all requests for capital expenditures exceeding $100,000. Acquisition of computed tomography (CT) scanners proceeds in the same way for each of the three armed services. The Commanding Officer of a hospital will make the initial request for a scanner to the Surgeon General's Office. Justification of the purchase request will state the need for the scanner in terms of expected patient load, the beneficiary population, and geographic access. Local health systems agencies (HSAs) are consulted, since military requests are to be coordinated with those of local civilian facilities. The Surgeon General will then bring the request and justification before the Health Council for authorization. Funding of authorized expenditures is a separate process, and money may not be appropriated for some time following authorization of purchase. The time from initial request to installation of a new scanner may be as long as 2 years.

At last report, a decision had been made to purchase six scanners, two for each of the armed services. As of May 1980, the Army has two operational scanners, and the Navy has four; the Air Force has two, and a third one is being installed. Since July 1, 1977, when only one scanner was operational, seven more have been added for a total of eight scanners for the entire DOD. All are total body scanners and are located in large medical and teaching facilities. Others have been approved and funded, but are not yet installed. Military hospitals and clinics without scanners continue to use CT scanning facilities of civilian institutions and pay for such scans out of operating budgets.

DOD is currently not supporting any major research related to CT scanning, although it does fund health research. The Air Force, however, is a partial supporter of the dynamic spatial reconstructor imaging system being developed at the Mayo Clinic. Its interest in that project does not lie with the diagnostic capabilities of the technology, but with the generic problem of high-speed processing of information for imaging that is inherent in it.

The Veterans Administration

There has been a major shift in Veterans Administration (VA) policy toward the purchase of CT scanners for the VA system of hospitals. The predominant means of obtaining scans for VA patients has been for VA hospitals without scanners to contract with local civilian institutions and to pay for such scans out of operating budgets, As of August 1978, a total of 14 scanners were either operational, being installed, or were ordered for the 171 VA hospitals. Currently, there are 17 operational scanners in the VA system (5 head and 12 body), another 6 total body scanners have been purchased, and there are 2 mobile scanners—for a total of 25 scanners in the VA system. As noted in chapter 2, a number of large VA hospitals do not have scanners.

The shift towards preference for purchasing CT scanners rather than contracting for services is justified in a 1978 VA report by the Special Central Office Advisory Group for Computerized Tomography Units (179). The study compared the cost of obtaining scans for its patients by these two methods and found that the cost of performing a CT examination on VA-owned and operated scanners was only about **60** percent of the cost of the same exam obtained under contract from a civilian institution. The convincing cost differential suggests that the VA cannot afford not to buy its own scanners. This evidence, in combination with VA's special characteristics of a fixed operating budget, and the legislative mandate it has to serve veterans, has led the VA to adopt a policy of purchasing CT equipment whenever possible,

The report suggests optimal guidelines for the purchase of CT scanners under this new policy. These guidelines state that at least 500 exams per year would be required to cost justify purchase of a dedicated head scanner costing $l50,000 or less; 1,500 exams per year would be necessary to justify a total body scanner costing $450,000 or less; and more than **1,500** exams per year would be required to justify one costing more than **$450,000.** At least 2,500 exams per year would be necessary to cost justify purchase of a second CT unit in a facility. Under no circumstances would purchase of a CT scanner be considered if a VA or other federally owned scanner is within **30** minutes from the facility in question.

It should be emphasized that these guidelines are only optimal. While more generous than the proposed National Health Planning Guidelines of 2,500 exams per year for both a first and a second scanner in a given facility, and the VA is legally exempt from that standard, they are attempting to conform as closely as possible. In practice, the VA is using a

guideline of about 2,000 exams per year as a threshold for considering a request for purchase of CT equipment. It is also continuing its policy of coordinating purchase decisions with existing local CT capacities by seeking local HSA certification of need, although this review is not required by law.

Decisionmaking on purchase and placement of CT scanners is done centrally, although it is responsive to local level requests. The VA Advisory Group on CT Units, including the directors of Medicine, Surgery, Neurosurgery, and Neurology, have developed a list of VA hospitals that are priority candidates for placement of additional CT scanners in the VA system. At this time, purchase of the total body scanners have been given precedence so that only the biggest, most well-equipped and staffed, and busiest hospitals are being considered for placement of these scanners. Being at the top of this list, however, does not ensure that the hospital will receive a scanner. Local available CT capacity may mediate this apparent necessity. Acting within the constraints of a fixed annual budget, the decisions of purchase and placement of CT units for the system must be based on the criterion of maximizing total VA scanning capacity, by whichever means it may be obtained.

Purchase of scanners by the VA is itself a unique process. Once a decision has been made to buy a unit for a particular facility, or facilities, the VA requests bids from manufacturers quoting prices of models that meet the particular specifications of the scanners required at each site. The VA accepts the lowest bid made by manufacturer for a machine that meets the necessary specifications. The large purchasing power of the VA allows them to purchase scanners in this way, typically resulting in a purchase price between $100,000 and $200,000 below the usual market price. Even so, the manufacturers bids seem very high in light of the fixed annual budget within which the VA must operate. Price tags quoted for total body scanners being considered for purchase by the VA at this time were between **$750,000** and **$900,000.** This may explain the fact that the Office of Management and Budget disapproved VA's plan to buy nine CT scanners with year-end money in September **1980. How**ever, information recently collected by the VA from a number of its large hospitals indicates that the costs of buying outside CT scans has increased since the 1978 report. It may cost as much as three times as much to obtain scans in this way.

Several alternatives are open to the VA as possible solutions to their apparent dilemma. One, the purchase of the new cheaper scanners, is not now being considered by the VA. Such scanners are not believed to be adequate to the task required in the large hospitals now being given priority for placement of CT units. Another avenue of approach recently used was the purchase of a refurbished EM I head scanner, originally costing $450,000, for **$160,000.** This scanner was purchased for the Palo Alto VA hospital which had been ranked number one on the priorities list for placement of a total body scanner. Because of the nearby scanning capacities of Stanford-University-owned body scanners, however, it had not been approved, A compromise solution was made whereby at least the head scans may be done in-house.

A final alternative that holds promise for the VA is the purchase and operation of mobile scanners. Financially, such units are advantageous for the VA because they can use their own physicians, technicians, attendants, and vehicles. A research project funded by the VA is just getting underway to investigate this possibility. The study will evaluate the sharing of VA-owned equipment with four satellite hospitals in the Boston area. A radiologist at the central VA hospital will read all scans performed by this unit.

Appendlix D.— Indications for CT Scans (Exhibits 1 -4)

Exhibit 1:

Draft *Screenin Criteria for Body and Head Computerized Axial Tomography (CT) Scans.* **Memorandum from Director, Office of Professional Standards Review Organizations, Health Standards and Quality Bureau, Health Care Financing Administration, DHEW, to Planning and Conditional PSROs, Statewide Councils and Regional PSRO) Officers, Feb. 22, 1979.**

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH CARE FINANCING ADMINISTRATION
HEALTH STANDARDS AND QUALITY BUREAU
OFFICE OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

TO : Planning and Conditional PSROs, Statewide Councils, Regional PSRO Project Officers

DATE: FEB 22 1979

GENERAL MEMORANDUM NO. 3.79

FROM : Director

SUBJECT: Draft Screening Criteria for Body and Head Computerized Axial Tomography (CT) Scans

Attached are sample screening criteria for body and head CT scans collected from several sources by the Ad Hoc Computerized Axial Tomography Criteria Commit tee of the American Association of Professional Standards Review Organizations (AAPSRO) . These critertia were accepted without change by the National Professional Standards Review Council (NPSRC) . PSROs may wish to adopt and adapt the criteria for local use. The criteria should be helpful to PSROs that now review CT scan procedures or plan to do so.

Due to rapid developments in the field, the AAPSRO Committee recommended that the criteria be evaluated in six months for necessary revisions. This recommendation was approved by the NPSRC. To assist AAPSRO in this effort, please address your comments to Lloyd Cloud, DDS, Chief, Allied Health Branch. The mailing address is Health Standards and Quality Bureau, Dogwood East Building, 1849 Gwynn Oak Avenue, Baltimore, Maryland 21207.

Dennis F. Siebert

Attachment

NOTE: The PSRO standards (exhibit 1) are virtually identical to the Institute of Medicine standards, so the latter are not reproduced here.

Criteria for CAT Head Scans

CAT scans of the head should be covered for the following signs, symptoms, and/or disease processes:

A. Symptoms - persistent symptoms after physical examination including neurological evaluation.

1. Headache of significant magnitude
2. Persistent vertigo
3. Persistent seizures, adult onset; in the absence of drug/alcohol withdrawal or recent head trauma
4. Acute or progressive focal necrologic findings, when systemetic or metabolic origin has been excluded, such as:
   a) apasia
   b) ataxia
   c) paresis or
   d) sensory deficit
5. Unexplained dementia; progressive organic mental deterioration unexplained by systemic disease (e.g. , memory loss)

B. Physical Findings

1. Papilledema, or other signs of increased intracranial pressure
2. Apraxia or aphasia
3. Visual field defects
4. Cerebella dysfunction signs
5. Hemiparesis
6. Exophthalmos after thyroid disease has been ruled out
7. Other focal neurological signs

C. Unresolved Medical Problems

1. Vascular
   Suspected Intracranial hemorrhage, such as:

   a) subarachnoid hemorrhage,
   b) subdural hematoma,
   c) bleeding arteriovenous malformation (AVM),
   d) bleeding aneurysm,
   e) complications of anticoagulation (e.g., Progressive headache in patient on Coumadin, Heparin ,
   f) intracerebellar or intracerebral hematoma

2. Traumatic

   Suspected lesion secondary to trauma (significant head injury) with progressive neurological findings.

3. Neoplastic

   Suspected neoplastic lesion, such as: a) primary brain or meningeal tumor or cranial nerve tumor or
   b) intracranial metastasis
   c) paranasal sinuses and nasopharynx

4. Congenital Lesions

   Congenital lesions, such as: a) hydrocephalus
   b) encephaloceles
) anomaly of brain

5. Calverial lesions (skull); lesions not fully defined by skull x-rays.

6. Detection of cerebral metastasis in proven lung cancer prior to thoracic surgery

7. Evaluation of effectiveness of treatment of documented cerebral lesion including:

   subdural hematoma
   neoplasm, after surgery, radiation, and/or chemotherapy
   hematoma, arteriovenous malformation or aneurysm
   hydrocephalus, after shunt
   management of brain abscess
   when signs and symptoms suggest progression, recurrence, or lack of response to therapy

The following problems are generally not considered to be appropriate situations for C.A.T. use and will be reviewed:

1. Vertigo as an isolated symptom.
2. Syncope as an isolated symptom.
3. Migraine headache, uncomplicated
4. Febrile seizures in children under six years of age.
5. Alcohol withdrawal, repeated, with seizures, upon initial evaluation.
6. T.I.A. on hospitalized patients unless cerebral arteriography and surgical re-vascularization.
7. Uncomplicated meningitis
8. A head injury followed by a transient loss of consciousness (concussion) admitted for hospital observation which in twenty-four hours resolves without persistent neurological signs.
9. Completed Stable Cerebral Infarction (Stroke).

At the present time, indications for contrast studies vary according to the diagnostic problem and the judgment of the radiologists and clinicians. Therefore, decisions concerning the use of contrast are not addressed in these screening guidelines.

Patients having more than three scans should be subject to peer review.

Criteria for Body CAT Scan

Neck -- CT scanning is not indicated at this time.

Chest --

- Pleura

  --Detection of pleural metastasis and other chest wall lesions.

- Lung

  --Detection of multiple tumor modules where one cr more have been found by conventional x-ray techniques.

  --Search for a primary tumor when a positive sputum for malignant cells has been obtained, but no evidence has been found through conventional x-ray techniques.

  --Determination of extent of spread to adjacent lobes in patients with impaired pulmonary function.

  --Differentiation of solid, cystic, fatty, inflammatory and vascular masses.

  --CT is not indicated for detection of pulmonary emboli at this time.

  (If there is clearcut evidence of bilateral tumor involvement, CT is not appropriate.)

- Mediastinum

  --Detection and evaluation of masses.

  --Differentiation of solid, cystic, fatty, inflammatory, and vascular masses.

  --Determination of extent of primary or secondary tumor.

- Heart

  --Studies of the heart are not indicated at this time

Great Vessels (including abdominal aorta)

-- CT scanning is not indicated in the aorta and great vessels except in the few post-operative patients in whom aortic graft abscesses are suspected.

Spine and Contents -

- Spinal Cord

--CT is not indicated for disease of the spinal cord at this time.

- Spinal Column

--Determination of content and extent of meningoceles and meningomyeloceles.

--Biopsies under CT guidance.

--Otherwise, CT scanning of the spinal column is indicated only where other procedures, including conventional tomography, radionuclide scanning, and myelography have failed to detect primary tumors, metastasis, and inflammatory diseases in the presence of persistent symptoms or *signs*.

Abdomen -

- Retroperitoneal Area

--Diagnosis and staging of nodal and extranodal extension of Iymphomas, determination of extent of retroperitoneal involvement with lymphomas, and extent of other types of retroperitoneal metastasis from various primary sites.

--Detection of primary malignancies such as those of mesenchymal, neural, lymphatic, embryonic rest origin, melanomas, and benign conditions such as cysts which may mimic malignancies. Trauma with suspected retroperitoneal hemorrhage.

Peritoneum -

--Detection and aspiration of abscesses and cysts.

Liver -

--Search for primary and secondary tumors and some life-threatening benign lesions such as liver cell adenomas and cavernous hemangiomas and abscesses.

--Determination of extent of tumor and differentiation of solid, cystic, inflammatory, vascular, and fatty lesions.

-- Biopsies under CT guidance.

Spleen -

--CT 'is not indicated at this time.

Pancreas

--Search for primary and secondary tumor. When principal diagnostic consideration is pancreatic tumor, CT should precede and when positive supplant such less sensitive studies as upper GI, barium enema, liver and spleen scans.

--Determination of extent of tumor.

--Differentiation of solid cystic, inflammatory, vascular, and fatty lesions.

--Biopsies under CT guidance.

Kidney -

CT scanning of the kidney is indicated only when preceded by a conventional IVP study, and then for:

--Search for primary and secondary tumor.

--Determination of extent of tumor.

--Differentiation of solid, cystic, inflammatory, vascular, or fatty lesions.

--Biopsies or aspiration under CT guidance.

Gall Bladder -

--CT is not indicated at this time.

Biliary Tree -

--Differentiation of obstructive from non-obstructive jaundice in those cases where cholecystogram and/or ultrasound fails to define cause.

Gastrointestinal Tract -
(Stomach, Small and Large Bowel)

--CT is not indicated at present. Except for determination of extent of tumor spread to other organs (see other indications).

Adrenal Glands -

--Search for primary and secondary tumor.

--Determination of extent of tumor.

--Differentiation of solid, cystic, inflammatory, vascular, or fatty lesions.

--Biopsies under CT guidance.

Pelvis -

- Uterus and Ovaries

--CT scan is appropriate for the staging and evaluation of extent of tumors.

Indication for CT is limited and cases should be subject to individual review. Pelvic exam and ultrasonography should define most masses.

- Bladder, Ureter, Prostate, Testicles

--CT scan is appropriate for the staging and evaluation of the extent of tumors.

CT adds little information and cases should be subject to individual review.

--Differentiation of solid, cystic, inflammatory vascular, or fatty tumors.

(For retroperitoneal primary and secondary, see retroperitoneal.)

Bones

--Evaluation of bone lesions.

--Biopsies under CT guidance.

Extremities -

--CT is indicated for determining the local extent of a tumor and presence of regional metastasis.

Therapy Planning & Follow-up -

--CT may be indicated for collection of information on cross-sectional anatomy and attenuation coefficients of bone

and soft tissue in tumor-bearing areas for planning surgery and radiation therapy.

--CT may be indicated in follow-up evaluation of effectiveness of radiotherapy, surgery, or chemotherapy in cancer patients at primary or metastatic tumor sites when part of an established and acceptable follow-up protocol or when signs and symptoms suggest progression, recurrence or failure or therapy.

Foreign Body -

Foreign body localization anywhere in the body when other conventional techniques have failed to resolve the problem (e.g., F.B. :orbit, globe of eye, intracranial or extremity).

Conditions for which CT scanning is more hazardous than or diagnostically inferior to other procedures were not included in the list of indications. For some indications listed, other tests may be more appropriate in particular patients. If other diagnostic tests have permitted a definitive diagnosis to be made, CT scanning is justified only for planning treatment.

Conversely, if a CT scan establishes a definitive diagnosis, additional diagnostic tests are unjustified. Sometimes, tests may complement each other either by providing difterent information or when one test succeeds after the first has failed to yield useful information. Recent studies comparing CT scanning with ultrasonic imaging of the abdomen suggests the two methods are complementary. (20)

Based on current evidence, CT is not superior in all applications. For dynamic studies of the circulatory and digestive systems and for high-resolution radiography in which structural details below a millimeter must be discerned, CT cannot compete with conventional radiographic techniques. In mammography, for example, xeroradiography provides definitive diagnostic information at a lower cost, although at a higher radiation level. Ultrasonic imaging is safer, and, therefore, diagnostically superior to CT scanning in obstetrics and gynecology. In cardiology, TM mode and real-time ultrasonic imaging provide more valuable data than do currently available CT scanners. CT scanning cannot replace those nuclear medical techniques that provide unique information about body functions and body chemistry, as in the case of thyroid scans.

Because CT scanning of the body is an efficacious diagnostic tool for the conditions listed above on the basis of current standards of evidence, the committee recommends that CT scanning of the body when used for appropriate indications be recognized as a covered service under third-party reimbursement plans until and unless a decision is made to require more demanding standards of evidence for these decisions. However,

experience with body scanning is evolving rapidly and the list of indicators for which coverage is warranted should be reviewed at least every six months. Therefore, the committee recommends that:

- CT scanning of both the head and body, when appropriately used for specified indications should be a covered diagnostic service under third-party reimbursement plans, accepting as criteria of efficacy the usual standards of clinical practice.

As with any radiologic procedure, the clinician must exercise caution in ordering number and extent of studies and repeat studies, since radiation dose varies widely with number of slices and area examined, and with the equipment used.

Exhibit 2:

New Indications for Computed Body Tomography. **Update to indications published in the April 1977 policy statement of the Institute of Medicine by the Society for Computed Body Tomography, July 1979. Published in the American Journal of Roentgenology, July 1979.**

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Special Report

New Indications for Computed Body Tomography

[redacted]

Society for Computed **Body Tomography**

The Society for Computed **Body Tomography has prepared the following** list **of indications for computed tomography in extracranial applications. These new guidelines are intended to clarify, update, and augment the indications published** in the April 1977 policy statement of the Institute of Medicine. They reflect the consensus opinion of members of the Society and include many new uses for which CT body scanning has been judged to be clinically indicated by the Society.

The Society met on three separate occasions as a group to formulate, debate, and, by general concensus, to select the following indications. During the Society's first annual meeting in the spring of 1978, members were divided into various subcommittees, each with a chairman and several subcommittee members to examine indications for computed tomography related to a particular organ system. During the ensuing months the chairman of each subcommittee, after discussion with members of the subcommittee, was able to compile a list of indications related to that organ system. Once completed, these were submitted to the president of the Society. They were reorganized, edited, and sent to all members of the Society for their comment and study.

At the scientific meeting of the Society in August 1978, the drafts of the subcommittees were presented to the Society members, where again indications were discussed and selections made by concensus. Between August 1978 and February 1979 additional details were added, and again recirculated to the members. They were again discussed at the annual meeting of the Society, February 1979. Final decisions were made and the document submitted for publication.

Prior to submission for publication, the American College of Radiology, the President of the National Blue Cross, the Secretary of the Department of Health, Education and Welfare, the Office of Technologic Assessment, the Bureau of Radiologic Health, and the Institute of Medicine were contacted and supplied with drafts for their suggestions and comment. In all, the manuscript has gone through six drafts, including preliminary study by the editorial staff of the *American Journal of Roentgenology*.

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Indications for Body CT

Neck

- Determinationsmatton of the extent of primary and secondary neoplasms of the neck.
- Evaluation of **bony abnormalities of the cervical spree** including neoplasms, fractures, dislocations, and congenital anomalies.
- **Localization of foreign bodies in the soft tissues, hypopharynx, or larynx and assessment of airway integrity after trauma.**
- **Evaluation of retropharyngeal abscesses**

Mediastinum

- **Evaluation of problems presented by chest radiograph**
  - **— Mass.**
    - **— Differentiation among cystic, fatty, or solid nature**
    - **— Localization relative to other mediastinal structures.**
  - **— Mediastinal widening.**
    - **— Assessment of whether cause is pathologic or anatomic variation**
    - **— Distinction of solid mass, vascular anomaly, or aneurysm, and physiologic fat deposition.**
  - **— Hilum**
    - **— Differentiation of enlarged pulmonary artery from solid mass when conventional tomography fails or is not capable of making this distinction**
  - **— Paraspinal line widening.**
    - **— Distinction among lymph node enlargement, vascular cause, or anatomic variant**
- **Search for occult thymic lesion**
  - **— Detection of thymoma or hyperplasia in selected** patients with myasthenia gravis when plain chest radiography is negative or suspicious

Lung

- **Search for pulmonary lesions**
  - **— Detection of occult pulmonary metastasis when**
    - **— Extensive surgery is planned for a known primary neoplasm with a high propensity for lung metastasis or for apparent solitary lung metastasis.**
  - **— Detection of primary tumor in patient with positive sputum cytology and negative chest radiography and fiberoptic bronchoscopy.**
  - **—— Assessment of lung and mediastinum for underlying pleural effusion and the postpneumonectomy fibrothorax for recurrent disease**
- **Search for diffuse or central calcifocation in a pulmonary** nodule **when conventional tomography is Indeterminate**
- **Determination of extent of intrathoracic spread in selected patients with bronchogenic carcinoma including mediastinal or pleural Invasion.**

Chest Wall

- **Determination of extent of neoplastic disease.**
  - **— Assess bone, muscle, and subcutaneous tissues**
  - **— Detection of intrusion into thoracic cavity or spinal canal**

Percutaneous Needle Biopsy

- Assist **biopsy of lesions when fluoroscopic guidance inadequate.**
  - **— Certain mediastinal masses.**
  - **— Mass low in costovertebral angle or obscured by overlying bone.**

Heart

- **Examinations of Intracardiac anatomy are not indicated at this time. Future advances in CT equipment may allow** more **clinically useful demonstration of cardiac anatomy and physiology.**
- **Distinction of cardiac (e. g., ventricular aneurysm) from pericardiac (e.g., mediastinal or pulmonary lesion) mass.**
- **Detection of aortacoronary vein graft occlusion is possible with Intravenous contrast medium bolus with third- and fourth-generation scanners.**

Major Blood Vessels

- **Evaluation and detection of thoracic aortic aneurysms**
- **Screening and measurement of abdominal aortic aneurysms** when ultrasound fails or is unavailable
- Detection of Intraluminal clots, chrome leakage, and rupture of thoracic and abdominal aneurysms.
- Evaluation of aortoprosthetic disruption
- Evaluation of suspected infection of synthetic grafts of the major vessels
- Detineation of relation of major vessels to retroperitoneal tumors, infections, or other abnormalities.
- Demonstration of invasion of vena cava by tumor

Spine

- Type I **examination. No contrast medium Type II examinatlon: Dilute metrizamide. Type III examination Concentrated metrizamide Installed originally for conventional myelography with subsequent CT, performed within 4 hours after metrizamide instillation.**

- Evaluation (type 1) of spinal stenosis to determine extent and specific causes of bony and soft tissue encroachment.
  - — Diffuse spinal stenosis, congenital or acquired.
  - — Localized spinal stenosis, associated with degenerative disease or malalignment.
  - — Posttraumatic stenosis: detection of fracture fragments or hematoma.
  - — Postspinal fusion stenosis: fusion bone overgrowth.
  - — Detection of midline or foraminal spurs not seen on plain films.
  - — Combined causes including degenerative, iatrogenic, traumatic, infection/tumor, as well as herniations of the nucleus pulposus.
- Evaluation (types I and II) of congenital dysraphic abnormalities (spina bifida, meningomyelocele, meningocele, diastematomyelia).
- Evaluation (type I or II) of spinal cord and/or nerve root masses, usually as secondary procedure to further determine nature and extent of lesion.
- Localization procedure (type O for CT-guided biopsy or aspiration.
- Evaluation (type 1) of nature and extent of boney or paraspinal tumors and inflammatory masses.
- Following nondiagnostic conventional myelography (type I or II procedure) using myelogram and/or clinical findings to specify CT level(s).
- Alternative procedure (type 1) in situations precluding standard myelography as primary examination (allergic history, mechanical difficulties, emotional factors).

Retroperitoneum

- Detection of primary malignancies such as those of mesenchymal, neural, lymphatic, and embryonic rest origin, melanomas and benign conditions, such as cysts that may mimic malignancies.
- Staging of nodal and extranodal extension of lymphomas and other types of retroperitoneal metastasis from various primary sites (e g., initial staging or detection of recurrent metastatic testicular tumor).
- Detection of retroperitoneal abscess or hemorrhage (hematoma); localization for needle aspiration.
- Further evaluation when other radiologic studies unexpectedly suggest abnormality, such as deviated ureter by normal retroperitoneal fat.
- Guidance for retroperitoneal biopsy

Peritoneum

- Detection and differential diagnosis of free or loculated intraperitoneal fluid collections and inflammatory processes.
- Detection of primary or secondary peritoneal masses (neoplasms and abscesses, etc.)
- Guidance for the aspiration of intraperitoneal fluid collections and peritoneal masses.

Liver

- Evaluation of space-occupying lemons.
  - — Primary and secondary malignant neoplasm and clinically significant benign lesions, such as adenomas, cavernous hemangiomas, and abscesses.
    - — Initial detection; whether liver is primary organ of interest or examined as part of CT evaluation of other suspected abdominal disease, such as pancreatic carcinoma, in which knowledge of associated hepatic lesions is of clinical importance.
    - — Confirmation of the presence or clarification of the nature of hepatic lesion(s) suspected or found on other imaging procedure. such as an inconclusive or nonspecific radionuclide scan.
    - — Differentiation of solid, cystic, inflammatory, and vascular lesions.
    - — Assessment of location, extent, and number of lesions, when such information is of clinical Importance.
    - — Guidance for hepatic biopsy and aspiration.
    - — Assessment of response to nonoperative therapy.
- Evaluation of trauma.
  - — Detection of hepatic laceration and intrahepatic and subcapsular hematoma, and determination of extent of injury in cases of blunt or penetrating trauma
- Evaluation of diffuse liver disease.
  - — CT currently of limited value, but may be useful in specific circumstances, such as detection of fatty infiltration of the liver and conditions of excessive iron deposition (hemochromatosis) and glycogen storage disease in children.

Spleen

- Detection and estimation of age of subcapsular hematoma.
- Detection of intrasplenic mass and differentiation of solid, cystic, and inflammatory lesions.

Pancreas

- Evaluation for possible mass lesion.
  - — Detection of primary tumor and its extent.
  - — Search for primary lesion in patient with distant metastasis.
  - — Evaluation of jaundiced patient.
  - — Evaluation of suspected pancreatitis.
  - — Evaluation of patient with possible upper abdominal masses.
  - — Serial assessment of regression or persistence of tumor during and after therapy.
- Differentiation of pancreatic from parapancreatic mass.
  - — Distinction among solid, cystic, vascular, inflammatory, calcified, and fatty lesions.
- Detection of complications of acute or subacute pancreatitis.

— Detection of pseudocysts, their number, size, and extent
— Serial assessment of pseudocyst following medical or surgical management.
— Detection of abscess: determination of size and extent.
. Guidance of percutaneous pancreatic biopsy and aspiration procedures.

Kidneys

. Evaluation of kidneys when excretory urography or angiography is contraindicated by risk of serious reaction to contrast medium.
. Evaluation of renal mass or suspected mass detected on another imaging procedure.
— Differentiation of an anatomic variant from a pathologic process,
— Differentiation of a benign fluid-filled cyst from a cyst and/or solid renal mass.
— Determination of the extent of renal neoplasm before and after treatment.
. Evaluation of selected patients, suspected clinically of renal neoplasm, when excretory urogram is negative.
. Evaluation of juxtarenal (para- or perirenal) lesions seen or suspected on excretory urography
— Differentiation of anatomic vanant from pathologic process.
— Determination of the cause, location, and extent of a lesion.
• Evaluation of urographic nonfunctioning kidney(s)
— Assessment of size, outline, and parenchymal thickness.
— Detection of obstruction, determination of site, cause, and extent of disease process
— Documentation of congenital absence.
— Detection of minimally calcified renal calculi not demonstrated by conventional techniques.
. Determination of cause of renal and perirenal calcification
• Assessment of extent of renal trauma.
. Guidance for antegrade nephrostomy, renal biopsy, or mass aspiration.

Gallbladder

• CT is not Indicated at this time unless oral and Intravenous cholecystography and ultrasonography are indeterminate or unobtainable

Biliary Tree

. Differentiation of obstructive from nonobstructive jaundice.
•Determination of site and etiology of obstruction
. Determination of etiology of obstruction

Gastrointestinal Tract

. CT is useful in the assessment of extent or recurrence of tumor or tumorlike condition into the mesentery or adjacent organs. CT is not currently indicated for the detection of mucosal lesions.

Adrenal Gland

. Evaluation of patients with biochemical evidence of adrenal hyperfunction
. Evaluation of patients with suspicion of adrenal mass found on conventional radiographic examination.
• Guidance for adrenal biopsy.

Uterus and Ovaries

• Evaluation of mass detected by clinical examination, after positive biopsy, after failure of ultrasound examination, or when strong clinical suspicion exists for a mass lesion.
• Evaluation of primary tumor and its extent of spread: and evaluation of secondary tumor.
. Differentiation of solid, cystic, inflammatory, vascular, or fany masses.
• Guidance for uterine and ovanan biopsy.

Bladder, Ureters, Prostate, and Seminal Vesicles

• Evaluation of primary and secondary tumor, including extent of tumor.
•Differentiation of solid, cystic, inflammatory, vascular, or fatty tumors.
. Detection of obstructing, minimally calcified ureteral calculi not detected by conventional studies
• Guidance for biopsy

Pelvic Bones

• Evaluation of bone lesions and accompanying soft tissue extent
. Guidance for biopsy.

Musculoskeletal System

• Evaluation of selected patients with known or suspected primary bone tumors.
• Evacuation of patients with suspected recurrence of bone tumors.
• Evaluation of patients with suspected but Indefinite signs of skeletal metastasis when Conventional studies fail to clarify.
• Evaluation of joint abnormalities difficult to detect by conventional methods.
• Evaluation of patients with soft tissue tumors, either

known or suspected to confirm presence and determine extent.
- Guidance for biopsy.

Therapy Planning and Followup

- Definition of cross-sectional anatomy and attenuation coefficients of bone and soft tissue in tumor-bearing areas for the purpose of planning radiation therapy.
- Provision of baseline prior to radiation therapy and chemotherapy from which effectiveness of these treatment modalities can be judged
- Conformance as part of an established and acceptable follow-up protocol.
- Evaluation of signs and symptoms suggesting progression, recurrence, or failure of therapy.

Foreign Body Localization

- In chest and abdomen when other traditional imaging techniques provide insufficient information.

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Members and Officers of the Society for Computed Body Tomography

Ralph J. Alfidi, M.D.
Case Western Reserve University School of Medicine

Ronald G. Evens, M.D.
Mallinckrodt Institute of Radiology

William Glenn, M.D.
Long Beach Memorial Hospital

John Haaga, M.D.
Cleveland Clinic

George S. Harell, M.D.
Stanford University Medical Center

Robert R. Hattery, M.D.
Mayo Clinic

Elias Kazam, M.D.
New York Hospital–Cornell Medical Center

Melvyn Korobkin, M.D.
Duke University School of Medicine

Stuart S. Sagel, M.D.
Mallinckrodt Institute of Radiology

W. Frederick Sample, M.D.
University of California Center for Health Sciences

Dieter Schellinger, M.D.
Georgetown University School of Medicine

Patrick F. Sheedy, II, M.D.
Mayo Clinic

Robert J. Stanley, M.D.
Mallinckrodt Institute of Radiology

David Stephens, M.D.
Mayo Clinic

Jack Wittenberg, M.D.
Massachusetts General Hospital

Exhibit 3:

New Policy CT *Approved.* Policy statement by the American College of Radiology, October 1980. **Published in the ACR Bulletin, October 1980.**

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New Policy on CT Approved

Computed tomography is a proven radiologic modality which provides **valuable clinical information in the early detection, differentiation and demarcation-of** disease.

Abundant documentation of its safety and diagnostic **efficacy has** been presented in the scientific literature, It has totally changed the practice of radiology and has become the primary diagnostic modality for a variety of presenting problems. it is even more widely accepted as a supplement to other imaging techniques. It is particularity helpful in solving problems where there is conflicting information from other radiologic or laboratory studies. It frequently replaces other examinations, many of which carry greater discomfort and expense.

APPROPRIATE SUPERVISION OF **CT** FACILITIES

1) Computed tomography is a form of medical imaging which, like other x-ray and radionuclide procedures, involves the exposure of patients to ionizing radiation. Its use should be limited to physicians with the necessary training in radiation protection to optimize examination safety. Radiation physics support and a trained technical staff must be provided.

a) Necessary training in radiation protection to optimize examination safety should include formal structured didactic **and practical** courses in radiation physics, monitoring and safety including **actual** experience in the use of radiation monitoring equipment and the design and use of **equipment** for radiation protection. Certification by the American Board of Radiology would be acceptable as verification of this level of competence for a physician,

b) Radiation physics support should include regular, periodic inspection, and performance and quality testing of both the scanning equipment and the protection devices. Access to the consultative services of a qualified radiation physicist should be readily available at all times

c) At least one registered radiologic technologist should be present at ail times during the actual operation of the scanning equipment for patient use. Trained technologists with prior experience in operation of the equipment must be available in sufficient numbers to allow patient access to the equipment over a broad range of time.

2) The different imaging procedures now available in diagnostic radiology, i.e., angiography, ultrasound, radionuclide imaging and computed tomography make selection and interpretation of appropriate studies for a specific patient more complex. A referring physician should consult with a radiologist with experience in imaging with ail available modalities concerning the procedures and sequence best suited to answer a specific clinical question.

Such experience in the selection, execution and interpretation of appropriate imaging procedures is usually obtained during radiological residency training or fellowships and supervised clinical experience following such radiological training. Any training program or experience should emphasize gross and cross-sectional anatomy, radiation absorption characteristics of the involved tissues and the pharmaco-physiology of contrast media in the organ systems of interest,

3) Each computed tomographic procedure must be individually designed for the problem presented by the patient. The radiologist should be directly involved in the performance of the procedure, determining its extent, administering and/or supervising the use of contrast media and modifying the study after immediate interpretation of the initial images obtained.

Direct involvement in the performance of scanning procedures requires:

a) Selection of the appropriate scanning sites, levels and sequences for each patient.

b) Determination of the need for contrast media (if any), the type and quantity of contrast, and the route and method of administration.

c) Administration or supervision of the administration of the contrast.

d) Recognition and proper treatment of any and all contrast reactions

Council OKs New CT Concept

e) Modification of the procedure after viewing the initial **scans** in order to optimally demonstrate the appropriate findings in each case.

ALL of the elements listed are equally necessary regardless of the anatomical area being examined.

APPROPRIATE UTILIZATION OF CT SCANNERS

The diagnostic efficacy of the CT is no longer in question. In general, guidelines for its utilization are based upon:

1) Determining the site, type and extent of disease.
2) Immediate diagnosis of trauma and other medical emergencies.
3) Problem solving in patients when conflicting information exists.
4) Radiation therapy planning and monitoring.
5) Follow-up of treatment **results.**
6) Guidance for **biopsy control.**

There are many specific clinical *areas* in which CT is recognized as **a** necessary and definitive diagnostic modality. However, specific indications for CT scanning should be determined locally by hospital medical staffs or other recognized peer review groups.

APPROPRIATE DISTRIBUTION OF COMPUTED TOMOGRAPHY SCANNERS

Adequate distribution of safe and reliable CT scanning service is necessary to assure accessibility to appropriate and equitable medical care for all patients. CT scanners should be located in facilities which permit their availability to patients of all physicians. No one set of criteria meets the dual requirements of medical need and economic justification. Determination of need for a CT scanner should be **made at** the local level.

In addition to demographic and geographic factors, special considerations should be given to the capabilities and demands of the medical community. Teaching and research centers, regional medical facilities, cancer treatment programs, neurological facilities and trauma centers all have a demonstrated need **for CT scanning capabilities.** The existence of any of these may produce numerical relationships between CT scanners and need indicators at a variance from community criteria based **upon population** or utilization projections.

The location of a CT unit in a physician's office should meet the same criteria as for institutions. Instances when a CT unit is located other than in an acute care hospital should be infrequent due to the interdependency of CT scanning and specialized medical services.

The economic justification of a CT scanner depends upon sufficient patient demand to allow reasonably full utilization of the unit. Capital costs are high and depreciation over five years is prevalent. Operating costs are substantial, particularly when CT scanners are operated and available outside of normal working hours. Provision must be made for updating and replacement of obsolescent equipment. Utilization goals should be directed toward optimal performance, allowing for maintenance, research and patient handling. They should not be set so high as to generate marginal patient referrals or to impose unrealistic working conditions for staff and supporting institutions.

SUMMARY

When appropriately located, properly utilized and correctly supervised, CT scanners can have a positive impact upon both the cost and the quality of medical care. Through reduction or elimination of hospital stays, replacement of other expensive and more hazardous diagnostic studies and avoidance of some operative procedures, CT scanning can contribute positively to cost containment. Earlier and more precise diagnoses will provide opportunities to modify therapeutic approaches which may be expected to improve the outcome and/or the quality of life. **Access to** this technology must therefore be assured to all patients who may be expected to benefit from CT scanning.

Exhibit 4:

Criteria for Clinically Indicated Head Scans. **Used by the Colonial Virginia Foundation for Medical Care, Virginia Beach, Va., in a concurrent review of CT of the head in PSRO Area V, Va., 1980.**

Criteria for Clinically Indicated Head Scans (16)

Criteria

1—Suspected Intracranial Hemorrhage
2—Suspected Lesion Sec. Head Trauma
3—Suspected Neoplastic Lesion
4—Congenital Lesions
5—Skull Lesions Undefined by X-Ray
6—Detection Cerebral Met. Before Tharacic Surgery
7— Eval. Treatment of Documented Cerebral Lesion
8—Delineation of Residual Structural Abnormality After Neur. Disease, Injury
9—Papilledema, Obtundation or Coma
10—Apraxia or Aphasia
11 —Visual Field Defect
12—Ataxia, Nystagmus, Dsmetria, Tremor or Incoordination
13— Hemiparesis or Hemiplegia
14—Exophtalmos After Thyroid Disease Ruled Out
15—inequality of Pupils, Ocular Palsies, Ocular Ptosis
16—Proptosis (suspected orbital tumor)
17— Headache
18—Persistent Vertigo Unresponsive to Outpatient Management
19—Seizures (grand mal or complete, focal or partial, with altered level of consciousness)
20—Acute Focal Neurological Symptoms
21 —Unexplained Dementia, Progressive Mental Deterioration
22— Does Not Meet Criteria

Appendix E.— National Guidelines for Health Planning: Standards for CT Scanners (Federal Register, March 28, 1978)

Section 5121.210 Computed Tomographic Scanners

(a) Standard. A computed tomographic (CT) 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.

(2) There should be no additional scanners approved unless each existing scanner in the health service area is peforming 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 data collection and utilization review systems.

(b) Discussion. Because CT scanners are expensive to purchase, maintain, and staff, every effort must be made to contain costs while providing an acceptable level of service. Intensive utilization of existing units, regardless of location, will prevent needless duplication and limit unnecessary health care costs.

Estimates and surveys for efficient utilization of CT scanners range from 1,800 to over 4,000 patient procedures a year. (One patient procedure includes, during a single visit, the initial scan plus any necessary additional scans of the same anatomic area of diagnostic interest.)

The Institute of Medicine, the Office of Technology Assessment, and others have carefully reviewed these data and the capabilities of various available units. The Department has reviewed these analyses as well as the extensive literature that has been developed on CT scanners.

In arriving at a standard for the use of these machines, the Department has considered a variety of factors, including the difference in time required for head scans and body scans, the need for multiple scans in some patient examinations, variations in patient mix, the special needs of children, time required for maintenance, and staffing requirements. Moreover, the Department considered the actual operating experience of hospitals and institutions reflected in reports on the use of CT scanners.

The standard set in the Department's guidelines is intended to assure effective utilization and reasonable cost for CT scanning. These machines are expensive, and therefore must be used at levels of high efficiency if excessive costs are to be limited.

The Department recognizes that the cost of some machines is declining, particularly those that perform only head scans which require less time. For machines that do predominantly head scans, the standard represents an efficient but more easily attainable level of utilization.

For scanners capable of performing both head and body scans, it is imperative that they be effectively used in order to spread the high capital expenditures over as much operating time as possible. As the Institute of Medicine report stated, "The high fixed cost of operating a scanner argue for as high a volume of use as the equipment allows without jeopardizing the quality of care. "

The Department believes that a .50- to 55-hour operating week is both consistent with the actual operating experience of many hospitals and a reasonable target. Based on reported experience for the time required for both head scans and body scans, the Department estimated that a patient mix of about *60*-percent head scans and about 40-percent body scans, making allowance for the other factors identified above, would allow a CT scanner to perform about *2,500* patient procedures per year if it is efficiently used about 50 to 55 hours per week. This estimate assumes a higher percent of body scans than is currently being performed. If fewer than 40-percent body scans are performed, then 2,500 patient procedures would involve less than 50 to 55 hours per week. Basing the standard on a higher percentage of body scans also takes account of current trends toward increased proportions of such scans.

The Department believes that sharing arrangements in the use of CT scanners is desirable, in line with the national health priorities of section 1502. Individual institutions or providers should not acquire new machines until existing capacity is being well utilized.

In planning for CT scanners, the health systems agency should take into consideration special circumstances such as: 1) an institution with more than one scanner where the combined average annual number of procedures is greater than *2,500* per scanner although the unit doing primarily body scans is operating at less than 2,500 patient procedures per year; 2) units which are, or will be, devoting a significant portion of time to fixed protocol institutionally approved research projects; and 3) units which are,

or will be, servicing predominantly seriously sick and pediatric patients.

A summary of the data collected on CT scanners should be submitted by the operators to the appropriate health systems agency to enable it to adequately plan the distribution and use of CT scanners in the area. The data to be collected should include information on utilization and a description of the operations of a utilization review program.

Appendix F.—Amendments to Regulations Governing Reviews of CT Scanners Under 1122 and CON Programs (April 25, 1979)

Review of Proposed Capital Expenditures for CT Scanners Under the Capital Expenditure Program of Section 1122 of the Social Security Act

42 CFR Part 100

Inclusion of Computed Tomographic Scanning Services.

Agency: Public Health Service, HEW.

Action: Interim regulations.

Summary: This notice sets forth interim rules regarding reviews of proposed capital expenditures for computed tomographic (CT) scanner "services" under the capital expenditure review program of section 1122 regulations with minor revisions, a policy notice on this matter which has already been issued by the Department. Interested persons are invited to submit written comments and suggestions concerning these interim rules.

Dates: These regulations are effective on April **25, 1979.** Comments must be received on or before June **25, 1979.**

Address: Interested persons may submit written comments on these interim regulations to the Acting Director, Bureau of Health Planning, Health Resources Administration, Center Building, Room 6-22, 3700 East-West Highway, Hyattsville, Md. 20782. The comments will be available for public inspection at the above address between the hours of 8:30 a.m. and 5:00 p.m., Monday through Friday.

For Further Information **Contact:** Colin C. Riorrie, Jr., Ph. D., Acting Director, Bureau of Health Planning, 3700 East-West Highway, Center Building, Room 6-22, Hyattsville, Md. 20782, 301 /436-6850.

Supplementary Information: Section 1122 of the Social Security Act (42 U.S. C. 1320a-1) provides for a program for reviews of certain proposed capital expenditures by designated planning agencies (DPAs) in participating States to determine their conformity with applicable health plans, standards, and criteria. Subject to certain procedural requirements, the Department will not provide reimbursements, under the medicare, medicaid, and maternal and child health programs for expenses related to capital expenditures found by DPAs to use out of conformity with these plans, standards, and criteria. Section 1122(g) of the Social Security Act defines a capital expenditure subject to review as one which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance, and which: 1) exceeds $100,000 or *2)* changes the bed capacity of the facility with respect to which the expenditure is made, or 3) substantially changes the services of the facility with respect to which the expenditure is made. The third of these categories is further defined in the regulations under section 1122 (42 CFR part 100) as including an expenditure "which results in the addition of a clinically related (i. e., diagnostic, curative, or rehabilitative) service not previously provided in the facility . . . (42 CFR 100. 103(a)(2)(iv)).

On February 3, 1978, the Department issued section 1122 Notice *78-05* to clarify the requirements of section 1122 with respect to CT scanner services. The purpose of these interim regulations is to incorporate that policy notice with minor revisions, into the section 1122 regulations, to the extent it is not already a part of these regulations.

The Department recognizes that the existing regulations do not explicitly include all aspects of the February 3 notice and accordingly amends the regulations so that they will, subject to the following revisions. First, because the Health Maintenance Organization (HMO) Amendments of 1978 (Public Law 95-559) deleted from section 1122 all references to HMOs, expenditures by or on behalf of an HMO are no longer subject to review, unless they are also on behalf of a health care facility which is subject to review. Thus, if an HMO proposes to purchase a CT scanner on behalf of a hospital, the proposed expenditure is subject to review. Second, the regulations specify that the proposed expenditure for a CT scanner by or on behalf of a health care facility is subject to review, whether it is for a fixed or a mobile CT scanner. Third, the purchase of an additional CT head scanner by or on behalf of facility which already has such a scanner is not subject to review if it costs less than $100,000 because this is a service which was "previously provided in the facility. " (See the present §100.103(a)(2)(iv).)

Accordingly, the regulations are amended as set forth below, so that the acquisition of a CT scanner costing $100,000 or less will be governed by the following principles:

A. The purchase of a CT scanner by or on behalf of a health care facility involving a capital expend-

iture less than $100,000 is subject to review if it results in the addition of a new diagnostic service.

B. Such a purchase involving a capital expenditure of less than $100,000 is considered to be the addition of a new diagnostic service unless the CT scanner is in addition to or replaces an existing scanner.

C. If a health care facility proposes to purchase a CT full-body scanner to replace an existing CT head scanner or to purchase equipment to upgrade an existing head scanner to a full-body scanner, this purchase is considered to result in a new diagnostic service for the facility and, therefore, is subject to section 1122 review.

D. If a health care facility proposes to offer the services of a mobile CT scanner, this is considered the addition of a new diagnostic service unless it is in addition to or replaces an existing fixed or mobile CT scanner of the same type (head or full-body scanner).

E. The lease (acquisition through a comparable arrangement) or the donation of a CT scanner by or on behalf of a health care facility is also subject to section 1122 review if its purchase, under the principles noted above, would have required review. (See 42 CFR 100.103 (b).)

F. Any capital costs associated with installing a CT scanner, as well as the costs of any renovations to accommodate its installation or use, are to be included in the estimated cost of the proposed capital expenditure under the section 1122 review program.

In relation to these regulations, attention is called to another interim regulation, also being issued in this edition of the Federal Register, which amends 42 CFR parts 122 and 123 to require review of fixed and mobile computed tomographic scanners in satisfactory certificate of need programs under title XV of the Public Health Service Act.

For the reasons set forth below, the Secretary has determined that public participation in rulemaking before issuance of these regulations and a delay in their effective date would be impracticable, unnecessary, and contrary to the public interest. First, this is in large part simply a clarification of the Departmen t's interpretation of the existing regulations. Second, given the recent proliferation of CT scanners, a delay in implementing these revisions and clarifications would likely result in the purchase or other acquisition of scanners which are not needed. Third, because these amended regulations complement amendments to regulations governing certificate-of-need reviews under title XV of the PHS Act and because those regulations are being issued on an interim basis to give those States needing revised legislative authority the maximum time possible to obtain it. Proper coordination of reviews requires that these regulations also be effective upon publication. As noted above, however, the public is invited to submit comments on these amended regulations during the next 60 days, and the Secretary will revise the regulations further as warranted by his evaluation of the comments received.

The Assistant Secretary for Health, with the approval of the Secretary of Health, Education, and Welfare, amends *42* CFR Part 100 as set forth below.

Dated: January 30, 1979.

Julius H. Richmond, Assistant Secretary for Health.

Approved: April **16, 1979.**

Joseph A. Califano, Jr., Secretary

Section 100.10 is amended by adding at its end the following sentences:

§100.103 Expenditures covered

(a) . . .

(2) . . .

(iv) . . . The addition of CT scanner services not previously provided in or through the facility is a substantial change of services within the meaning of this subparagraph, whether these services are provided through a fixed or mobile CT scanner. The addition of CT full-body scanner services is included in the previous sentence if it is added to or replaces existing CT head scanner services.

(Sec. 1122, Social Security Act, 86 Stat. 1386 (42 U.S. C. 1320a-1): sec. 1102, Social Security Act, 49 Stat. 647, as amended (42 U.S. C. 1302).)

(FR Doc. 79-12637 Filed 4-24-78, 8:45 a.m.) Billing Code 411 O-83-M.

Reviews of Proposed New Institutional Health Services by SHPDAs and HSAs Under State CON Programs

42 CFR Parts 122 and 123

Inclusion of Computed Tomographic Scanning Services.

Agency: Public Health Service, HEW.

Action: Interim regulations.

Summary: The Assistant Secretary for Health, with the approval of the Secretary of Health, Education, and Welfare, proposes to amend the regulations governing reviews of proposed new institutional health services by State health planning and development agencies (SHPDAs) and health systems agencies (HSAs). These regulations set forth requirements for satisfactory State certificate-of-need (CON) programs. The amendments would require review of radiological diagnostic health services which are proposed to be offered in, at, through, by, or on behalf of a health care facility or health maintenance organization, which are to be provided by fixed or

mobile CT scanning equipment whether or not an addition to or replacement of these services offered by fixed or mobile CT equipment. Interested parties are invited to submit written comments and suggestions concerning these proposed amendments.

Dates: These regulations are effective on April 25, 1979, subject to the discussion set forth under "Supplementary Information" below. Comments received on or before June 25, 1979, will be considered.

Address: Interested persons may submit written comments on the interim regulations to the Acting Director, Bureau of Health Planning, Health Resources Administration, Center Building, Room 6-22, 3700 East-West Highway, Hyattsville, Md. 20782. The comments will be available for public inspection at the above address between the hours of 8:30 a.m. and 5:00 p.m., Monday through Friday.

For Further Information Contact: Colin C. Rorrie, Jr., Ph. D., Acting Director, Bureau of Health Planning, 3700 East-West Highway, Center Building, Room 6-22, Hyattsville, Md. 20782, 301/436-6850.

Supplementary Information: Section 1523(a)(B) of the Public Health Service Act ("the Act") requires each fully designated SHPDA to "administer a State CON program which applies to new institutional health services propose to be offered or developed within the State and which is satisfactory to the Secretary" of Health, Education, and Welfare, Section 1523(a)(5) of the Act requires each SHPDA to make findings as to the need for proposed new institutional health services, after consideration of recoin-" mendations submitted by HSAs. Section 1513(f) requires HSAs to assist SHPDAs by reviewing and making recommendations concerning the need for proposed new institutional health services. Institutional health services are defined in section 1531(5) of the Act, and at §122.304 and §123.401 of title 42, Code of Federal Regulations. Sections 122.304 and 123.404 establish thresholds for review of institutional health services. The amendments add an additional threshold: radiological diagnostic health services provided by fixed or mobile CT scanning equipment.

The Secretary, wishing to contain the rising costs of health care, is concerned with the high cost of CT scanning, both as to the initial cost of the equipment and its subsequent operating expenses, These amendments require review of CT scanning services proposed to be performed in space leased or made available to any person by a health care facility or HMO. As to mobile scanners, although it is realized that there may be cost saving, since a number of institutions may share the same equipment, the offering by a health care facility or HMO of services of mobile scanners is also subjected to review by health planning agencies.

The Secretary notes that the amendments do not necessarily require changes in any State's statutes or regulations or in any lists of services which may be embodied therein. The amendments require simply that, for a State CON program to be satisfactory}', the proposed services be required to be reviewed, and those services not be offered or developed without a prior determination of need and issuance of CON.

In relation to these amendments, the Secretary calls attention to another interim regulation, also in this edition of the Federal Register, which amends the regulations for review of proposed capital expenditures under section 1122 of the Social Security Act to clarify the coverage of CT scanners under that program.

Effective date *provisions.* --For the reasons set forth below, the Secretary has determined that public participation in rulemaking before issuance of these regulations and a delay in their effective date would be impractical and contrary to the public interest. First, given the recent proliferation of CT scanners, a delay in implementing these regulations would likely result in the purchase or other acquisition of scanners which are not needed. This is especially true with regard to mobile CT scanners. Hospitals can now receive reimbursement through medicare for fixed scanners, but not for scans from mobile scanners. Medicare, however, will soon begin reimbursing hospitals for scans from mobile scanners as well. As a result, it is expected that sales of mobile scanners will increase significantly. Second, in order to give those States which need revised legislative authority to implement these amendments the maximum time possible to obtain it, these regulations should be effective immediately.

As noted above, however, the public is invited to submit comments on these amended regulations during the next 60 days, and the Secretary will revise the regulations further as warranted by his evaluation of the comments received.

As noted above, these regulations are effective upon publication in the Federal Register. However, because the question of when the Secretary will determine whether a State's CON program is satisfactory is not addressed in the regulations themselves, the Secretary has decided as follows.

Initially, the Secretary notes the relevant statutory provisions under section 1521(b)(2)(B) of the Act the term of a conditional designation agreement of SHPDA may not exceed 36 months. A fully designated SHPDA must, under section 1521(b)(3) be capable of performing all of the functions specified in section 1523, including CON reviews, during its first year of full designation, If, on September 30, 19&0, a designation agreement under section 1521 is not in ef-

feet in a State, the Secretary is prohibited by section 1521(d) from paying certain Federal funds for the development, expansion, or support of health resources in that State.

Accordingly, in determining whether a SHPDA is capable of administering a satisfactory CON program (which is a necessary element in establishing eligibility for full designation), the Secretary will require compliance with these revised regulations as follows:

(1) For States in which SHPDAs do not require additional legislative authority to implement the revisions to these regulations, the Secretary will require their implementation within 6 months after publication of this document in the Federal Register, and in accord with other SHPDA designation requirements.

(2) For those States in which the SHPDAs do require additional legislative authority to implement the revisions to these regulations, the Secretary will require their implementation within 6 months after the end of the earliest legislative session in which legislation to permit this implementation may be introduced and acted upon, and in accord with other SHPDA designation requirements.

After consulting with their legal counsel, SHPDAs should contact the appropriate DHEW Regional Office to determine into which of these categories they fall.

Accordingly, 42 CFR Part 122, subpart D, and 42 CFR part 12, subpart E, are amended in the manner set forth below.

Dated: April 13, 1979.

Julius B. Richmond, Assistant Secretary for Health.

Approved: April 16, 1979.

Joseph A. Califano, Jr., Secretary.

1. Section 122,304 of part 122 of title 42 is amended by adding to its a new paragraph (a)(5), to read as Follows:

$122.304 of part 122 of title 42 is amended by adding to it a new paragraph (a)(5), to read as follows:

(a) . . .

(5) Radiological diagnostic health services which are offered in, at, through, by or on behalf of a health care facility or HMO (including services offered in space leased or made available to any person by the health care facility or HMO), which are provided by fixed or mobile CT scanning equipment except where these services are an addition to or replacement of the same service offered in, at, through, by, or on behalf of the health care facility or HMO. For purposes of this subparagraph, a CT head scanner and a CT body scanner, do not provide the same service and a CT fixed scanner and a CT mobile scanner do not provide the same service.

2. Section 123.404 of part 123 of title 42 is amended by adding to it a new paragraph (a)(5), to read as follows:

§123.404. New institutional health services subject to review.

(a) . . .

(5) Radiological diagnostic health services which are offered in, at, through, by, or on behalf of a health care facility or HMO (including services offered in space leased or made available to any person by the health care facility or HMO), which are provided by fixed or mobile CT scanning equipment, except where these services are an addition to or replacement of the same service offered in, at, through, by, or on behalf of the health care facility or HMO. For purposes of this subparagraph, a CT head scanner and a CT body scanner do not provide the same service, and a CT fixed scanner and a CT mobile scanner do not provide the same service.

(Sec. 215 of the Public Health Service Act. 58 Stat. 690 (42 U.S. C. 216), sees. 1501-1536 of the Public Health Service Act, 85 Stat. 2225-57 (42 U.S. C. 300k-l-300n-5).)

(FR DOC. 79-12636 Filed 4-24-79, 8:45 a.m.) Billing Code 4110-83-M.

Appendix G.— Methods of Data Collection

The OTA list of computed tomography (CT) scanners from **1976** included *321* scanners, listed by location, type, and manufacturer of scanner, and date of installation. That list, as well as the 1977, 1978, and 1979 updated lists, were developed using multiple sources. First, the previous list was updated by checking against a listing from the Food and Drug Administration (FDA). In **1978,** the updated list was sent to all State planning agencies and selected urban health systems agencies (HSAs). Those sources contacted were asked to make corrections on the updated list. Because of the necessity of many telephone calls to HSAs in 1978, inquiry was made to all State health planning agencies and HSAs in 1979. The first letter was sent in February. Two followup letters were sent to nonresponders. When State information was incomplete and HSAs had not responded, they were contacted by telephone. The same procedure was followed in **1980, with** the first letter sent in May.

All States had information on the institutional location of CT scanners, but the information was often incomplete. Some States knew only the names of institutions that had had an application for a certificate-of-need approved. Others knew which institutions had operational scanners, but did not know how long they had been in operation or the manufacturer. When incomplete information on an operational scanner was received, and the HSA information was either incomplete or in conflict, the institution or physician was called. A special attempt was made to identify out-of-office scanners. Frequently, staff of HSAs were more aware of the locations of such scanners than were staff in State agencies.

Only scanners delivering clinical services to patients were included. Thus, scanners registered by a manufacturer, by a leasing company, or by a company providing mobile scanners were included only if the site of clinical services could be identified.

The main effort in this study has been to ascertain the geographic and institutional location of scanners. No attempt was made to ascertain the owner of an individual scanner. Some States collect information differentiating between scanners owned by radiologists but located in a hospital, and scanners owned by a hospital. It was assumed that the location—hospital or private office—was the important factor in terms of access to the entire community. Scanners owned by radiologists but located in hospitals were treated exactly as were scanners owned by hospitals. Even when a scanner was registered to an individual physician, if its address indicated location within a hospital, it was considered to be a hospital scanner. If the scanner was located in a private clinic or physician's office building close to the hospital, however, it was considered to be a private scanner.

Other data for this report were collected from published literature and extensive interviews. Many of the interviews are cited, as the information is not available in any other source. Many individuals and groups also furnished helpful written materials (see app. I).

Based on these materials, a draft of the policy information was developed and reviewed by the OTA Health Program Advisory Committee at its meeting of April *28, 1980.* A draft of the entire report was then developed and was sent to the committee and to more than 100 individuals and groups for review on August 1, 1980. Most comments were received by October 1, **1980.** The final report was then written based on the many excellent comments and suggest ions.

Appendix H.—Glossary of Acronyms and Terms

Glossary of Acronyms

AAPSRO — American Association of Professional Standards Review Organizations
ACR —American College of Radiology
AHPA —American Health Planning Association
AS&E — American Science & Engineering Co.
BHP – Bureau of Health Planning (HRA)
BMD — Bureau of Medical Devices (FDA)
BRH – Bureau of Radiological Health (FDA)
CBA — cost-benefit analysis
CEA — cost-effectiveness analysis
CFR — Code of Federal Regulations
CON — certificate of need
CT — computed tomography, computerized tomograph y
DHEW — Department of Health, Education, and Welfare
DHHS — Department of Health and Human Services (formerly DHEW)
DC – Division of Compliance (BRH)
DEP – Division of Electronic Products (BRH)
DOD — Department of Defense
DPA — Designated Planning Agency
DQA – Division of Quality Assurance (BRH)
DR — Division of Radiology (NIH)
DRR — Division of Research and Resources (NIH)
DSR — dynamic spatial reconstructor
FDA — Food and Drug Administration (PHS)
FR — Federal Register
GE — General Electric
HCFA — Health Care Financing Administration (DHHS)
HECT — head-equivalent computed tomography
HMO — health maintenance organization
HRA — Health Resources Administration (PHS)
HSA --- health systems agency
HSP — Health Systems Plan
IOM – Institute of Medicine (NAS)
MCE — Medical Care Evaluation (studies)
NAS — National Academy of Sciences
NCHCT — National Center for Health Care Technology (OASH)
NCHS — National Center for Health Statistics (OASH)
NCHSR — National Center for Health Services Research (OASH)
NCI — National Cancer Institute (NIH)
NEMA — National Electrical Manufacturers Association
NHLBI – National Heart, Lung, and Blood Institute (NIH)
NIH —National Institutes of Health
NINCDS — National Institute of Neurological and Communicative Disorders and Stroke
NMR — nuclear magnetic resonance
OASH — Office of the Assistant Secretary for Health (DHHS)
OHPA — Office of Health Practice Assessment (defunct)
OMAR — Office for Medical Applications of Research (NIH)
PETT —positron emission transaxial tomography
PHS – Public Health Service (DHHS)
PSRO — Professional Standards Review Organization
RSNA — Radiological Society of North America
SCBT — Society for Computed Body Tomography
SHPDA — State health planning and development agency
SUNY — State University of New York
USC —United States Code
VA — Veterans Administration

Glossary of Terms

Cost-benefit analysis (CBA): An analytical] technique that compares the costs of a project or technological application to the resultant benefits, with both costs and benefits expressed by the same measure. This measure is nearly always monetary.

Cost-effectiveness analysis (CEA): An analytical technique that compares the costs of a project or of alternative projects to the resultant benefits, with cost and benefits effectiveness not expressed by the same measure, Costs are usually expressed in dollars but benefits effectiveness are (ordinarily expressed in terms such as "ii\'es saved, " "disability avoided, " "quality adjusted life years saved (QALY), " or any other relevant objectives. Also, when benefits/effectiveness are difficult to express in a common metric, they may be presented as an "array. "

Device (medical): Any physical items, excluding drugs, used in medical care (including instruments, apparatus, machines, implants, and reagents).

Diffusion: The process by which a technology enters and becomes part of the health care system. It has two phases: adoption and use of the technology. Most studies of diffusion have only examined the adoption phase.

Effectiveness: Same as Efficacy (see below) except that it refers to". . . average conditions of use."

Efficacy: The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use.

Medical technology: The drugs, devices, and medical and surgical procedures used in medical care, and the organizational and support systems within which such care is provided.

Procedure: A medical technology involving any combination of drugs, devices, and provider skills and abilities. Appendectomy, for example, may involve at least drugs (for anesthesia), monitoring devices, surgical devices, and physicians', nurses', and support staffs' skilled actions.

Risk: A measure of the probability of an adverse or untoward outcome's occurring and the severity of the resultant harm to health of individuals in a defined population associated with use of a medical technology applied for a given medical problem under specified conditions of use.

Safety: A judgment of the acceptability of risk (see above) in a specified situation.

Appendix 1.—Acknowledgments

In addition to reviews by the members of the Health Program Advisory Committee, OTA received reviews of drafts or parts of drafts of this report from the following people and groups. These reviewers do not necessarily approve, "disapprove, or endorse the report.

Leonard J. Bisaccia, M.D.
Director
Radiology Service
Veterans Administration

Bruce G. Breamer
Government Affairs Manager
Technicare
Cleveland, Ohio

Russell A. Brown, M.D.
General Electric Co.
Milwaukee, Wis.

David O. Davis, M.D.
Professor and Chairman
Department of Radiology
The George Washington University Medical Center
washington, DC.

Michael Eliastam, hf. D., M.P.P.
Special Assistant to the Director
National Center for Health Care Technology
Department of Health and Human Services

Henry A. Foley, Ph.D.
Administrator
Health Resources Administration
Department of Health and Human Services

Jean R. Herdt, M.D.
Deputy Chief
Diagnostic Radiology Department
The Clinical Center
National Institutes of Health

Gordon C. Johnson, M.D., and staff
Bureau of Radiological Health
Food and Drug Administration

Otha W. Linton
Director of Governmental Relations
The American College of Radiology
Washington, D.C.

Joseph A. Marasco, Jr., M.D.
Director, Diagnostic Radiology
St. Francis General Hospital
Pittsburgh, Pa.

Barbara P. McCool, Ph.D.
Acting Director
National Center for Health Services Research
Department of Health and Human Services

Robert G. McCune
Division Staff Manager
Diagnostic Imaging and Therapy Systems Division
National Electrical Manufacturers Association
Washington, D.C.

David A. Pistenma, M.D.
Chief, Radiotherapy Development Branch
National Cancer Institute
National Institutes of Health

Dennis F. Siebert
Direct or
Office of Professional Standards Review
Organizations
Health Standards and Quality Bureau
Health Care Financing Administration
Department of Health and Human Services

Thomas H. Shawker, M.D.
Chief, Ultrasound Section
Diagnostic Radiology Department
The Clinical Center
National Institutes of Health

Michael Walker, M.D.
Director
Stroke and Trauma Program
National Institute of Neurological and
Communicative Disorders and Stroke
National Institutes of Health

Daniel Zwick
American Health Planning Association
Washington, D.C.

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