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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).