



Computed Tomographic Scanning: A Policy Statement (1977)

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INSTITUTE OF MEDICINE

A POLICY STATEMENT

Computed Tomographic Scanning

April 1977

NATIONAL ACADEMY OF SCIENCES
Washington, D.C.

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NOTICE

The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the Committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 Congressional charter responsibility to be an adviser to the Federal Government, and its own initiative in identifying issues of medical care, research, and education.

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INSTITUTE OF MEDICINE
OFFICE OF THE PRESIDENT

April 29, 1977

Mr. Walter J. McNerney
President
Blue Cross Association
840 North Lake Shore Drive
Chicago, Illinois 60611

Dear Mr. McNerney:

It is my pleasure to transmit to you the report on computed tomographic scanning, undertaken by the Institute of Medicine at the request of the Blue Cross Association.

In responding to your request for a rapid report on this important and complex subject, the Institute committee, chaired by Dr. Charles Sanders of the Massachusetts General Hospital, addressed the issues of efficacy, planning policy, utilization, costs and charges, and information and evaluation needs. As you requested, the report provides specific recommendations for action as well as a review of the current status of this significant new technology.

The swift spread of CT scanning as a diagnostic technique may well make it a watershed for policy decisions about appropriate distribution and use of costly medical technologies. We are pleased that your request afforded us the opportunity to address this important issue, and we trust that the Institute's report will

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help your association and its member plans develop reimbursement policies. We hope the report will also provide guidance for other agencies and institutions, public and private, which are attempting to develop plans for the effective and efficient use of CT scanning.

Sincerely,

A handwritten signature in cursive script that reads "David Hamburg". The signature is written in dark ink and is positioned above the typed name and title.

David A. Hamburg, M.D.
President

INSTITUTE OF MEDICINE

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INTRODUCTION

Computed tomographic (CT) scanning is a recently developed technique which combines radiographic and computer techniques to produce cross-sectional images of the head and body.[1] Whereas conventional x-ray films show internal structures superimposed upon each other and, therefore, are best suited to high contrast structures such as bone, the CT scanner can produce high quality images of soft tissue structures.

The technology of CT scanning was developed for clinical use in England in the early 1970s; the first units provided images only of the head. By 1974 scanners were available for producing transverse section images anywhere in the body.

The first two CT scanning units in the United States were installed in mid-1973. Slightly less than four years after that introduction, it was estimated that at least 760 CT scanners were in operation or had been ordered by American hospitals, clinics, and physicians, [2] posing a ratio of one machine for every 281,000 people in the nation.[3]

Such swift and widespread adoption of this new medical technology has attracted the attention of planners, insurers, and investigators of health services.[4] Their questions concern efficacy and expense. The long-term effects of CT scanning on medical care and its costs are not yet discernible, although there is little doubt that the technique represents a major improvement in diagnostic imaging. Head scanning became an accepted diagnostic tool before coordinated studies of its impact on diagnosis could be completed,[5] and there are as yet few reports to indicate what the information from CT scanning of the head has meant for patient treatment methods or outcomes.[6]

Now, as CT is extended to other areas of the body, the same concerns apply.

As for medical care expenditures, scanners range in price from \$300,000 to \$700,000 each, the newer systems being the more expensive.[7] Operating costs for a unit are estimated to range from \$259,000[8] to \$371,000[9] per year. The real costs of CT scanning will depend not only on the number of units purchased and the number of scans performed, but also on the extent to which CT scanning replaces other diagnostic procedures and reduces hospitalization. There is not enough evidence now to enable measurement of these effects.[10]

The rapid acceptance of CT scanning has also heightened concerns about other diagnostic technologies and even medical technology in general. Evidence is accumulating that the present organization of medical care and methods of financing and regulating that care in the United States have encouraged investment in beds and equipment beyond a socially efficient level.[11] Competition among hospitals for medical staff, prestige, or revenues is often cited as a reason for overinvestment in capital equipment.[12] The risk of losses from overinvestment has been reduced or eliminated by the retrospective, cost-based reimbursement systems that predominate today.[13] Regulation designed to control large capital expenditures may have had a perverse effect itself; state certificate of need (CON) laws requiring institutions to obtain approval for purchasing expensive equipment like the CT scanner may have stimulated hospitals to adopt new technologies quickly--before the planning agency has sufficient facts to approve or deny the purchase.[14] The fact that most CON laws do not cover capital expenditures in freestanding ambulatory care settings, combined with the high fees currently charged for CT scans, has further encouraged the purchase of CT equipment by private physicians.

Concurrent with the proliferation of equipment has been an increasing rate of use of diagnostic tests, including x-rays.[15] Such increases have been attributed to several factors. Changes in medical education have placed increasing emphasis on objective tests and precise measurement when less technologically advanced methods might still be adequate for diagnosis.[16] Fear of malpractice litigation encourages "defensive" medical practice, usually expressed as over-utilization of services,

particularly diagnostic tests.[17] The growing share of personal health care expenditures covered by third-party reimbursement has reduced the incentives to control use, because the physician's decision to use services is separated from the patient's immediate expenses.[18]

Concerns about the proliferation and overuse of new medical technologies have called attention to the fact that information about their efficacy is inadequate. Well designed studies of the efficacy of procedures are necessary to evaluate any technology, but the completion of such studies prior to the introduction of new technologies is very unusual. The application of new diagnostic or treatment techniques has typically been based on observational studies with inherent problems of observer bias, rather than on rigorous evidence that can only be gathered through well-designed clinical trials or the statistical analysis of large numbers of observations. Often an assessment of the broader implications of introducing new technologies is also needed.[19] At present, such studies are not required or coordinated by any organization, public or private, and no system exists to identify areas for evaluation of emerging technologies at an early stage. The Office of Technology Assessment of the United States Congress is developing guidelines for measuring the efficacy of medical technologies.[20]

Until better data are available, all attempts to recommend and implement policies on the use of new technologies must be viewed as tentative because of the inadequacies of our traditional approaches to acquisition and evaluation of clinical information. These inadequacies must permeate the committee's recommendations, or any recommendations based on current knowledge.

SCOPE OF THE INSTITUTE OF MEDICINE STUDY

The problem of CT scanning is important both in itself and as representative of other medical technologies.* The

*The Institute of Medicine is cooperating in a year-long, National Academy of Sciences study of the relation between technology and the efficiency and effectiveness of the health care system. That study, focusing on costly,

committee recognizes that the eventual solution to many of the policy problems created by CT scanning, as well as other medical care technologies, depend on availability of data that meets much higher standards of evidence than are presently required and on structural changes in the way that health services are delivered and financed. However, health planning agencies and third-party payers must make decisions now about reimbursement for CT scanning. In order to meet these immediate needs of planning agencies and third-party payers, and within the time constraints imposed by these needs, the committee has made recommendations on the assumption that certain aspects of the medical care system will remain constant. In particular, the committee has assumed that the general structure of the health care delivery and financing system remains as it is today; that no major changes occur in the medical compensation system; that present emphases in medical education remain the same; and that the health planning system as structured under the National Health Planning and Resources Development Act of 1974 remains in existence.

The inadequacies of existing data raised a more fundamental problem for the committee. Obviously, all recommendations concerning the distribution, use, and financing of CT scanning capabilities must be based on a prior finding of efficacy, defined in some manner. But many different standards of evidence can be used in establishing that efficacy. The standards which have guided most changes in clinical practice have been criticized as inadequate.* The committee recognizes that to require higher standards for CT scanning than for other diagnostic or treatment techniques is to advocate either a dual standard of evidence or a fundamental change in the standards by which the practice of clinical medicine is determined. The former course raises issues of fairness; the latter raises issues of practicality in the context of this report. Yet, the issue cannot be ignored. Therefore, in addition to calling for better clinical data (see the last section of

capital-intensive technologies, will explore the major obstacles to the appropriate use of such technology and will suggest policies to correct deficiencies.[21]

*A. L. Cochrane, Effectiveness and Efficiency: Random Reflections on Health Services (London: The Nuffield Provincial Trust, 1972).

this report for details), the committee has presented two approaches to the evidence about efficacy, one based on past and current standards in clinical medicine and the other based on a requirement for higher standards of evidence that meet more rigorous criteria of experimental design. These options are presented in the chapter on efficacy.

With these study constraints, the committee examined the following matters.

Efficacy At the current stage of technological development, for what uses is CT scanning safe and efficacious and, therefore, indicated?

Cost and Level of Reimbursement How should the level of reimbursement for the technical and professional components of CT services be determined?

Placement How should the need for and placement of CT scanners be determined?

Implementation What policy instruments--of reimbursement, planning, and quality control--are required to promote appropriate utilization, costs, and placement of CT scanners? How and by whom should these policies be implemented? How can flexibility to accommodate new developments be incorporated into these policies?

The Institute of Medicine convened a committee to review what is currently known about these matters and to develop a policy statement that would offer recommendations for immediate implementation by third-party payers and health planners. This study was sponsored by the Blue Cross Association, but the Institute of Medicine did not limit the study to policies affecting only Blue Cross. The committee considered short-run policy options open to both public and private organizations. It used several policy studies as background material for its deliberations, including the draft report on CT scanning of the Office of Technology Assessment[22] and a technical report by the American Hospital Association.[23] In addition, the committee invited speakers from several

organizations representing a wide variety of interests and perspectives to participate in a discussion of these issues (Appendix).

SUMMARY OF RECOMMENDATIONS

This committee urges careful consideration of two possible approaches to reimbursement and policy for CT scanning procedures.

The first option would require of CT scanning only the traditional and incomplete evidence of efficacy that builds up in the clinical research literature as experience accumulates.

The second option would require that the efficacy of CT scanning be established by clinical trials that meet high standards of experimental design and statistical significance. Policy recommendations arising from choice of the second option would include reimbursing only for CT scans conducted as part of a clinical trial designed to provide more definitive evidence of efficacy, and approving wider reimbursement only when that definitive evidence is available.

Although the committee does not endorse this second option as the preferred path for body scans in the immediate future, the final section of this report contains recommendations which would begin to correct existing deficiencies in information about the effects of CT scanning. A basic shift to new standards of evidence as the basis for decisions requires a careful analysis of its full implications for public and private policies concerning all medical care, including techniques for policy implementation. The scope and time constraints of this report precluded such a major re-examination of the base of evidence for all clinical practice, although the first steps in providing improved information are recommended at this time.

The following policy recommendations are founded on the first option, but also contain the initial steps to generate the improved information required by the second option.

Reimbursement for CT Scanning

- 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.
- Third-party payers should reimburse only for services provided by CT installations approved under a certificate of need program.
- Third-party payers should reimburse only for examinations approved under a utilization review program satisfactory to the payers.
- Third-party payers should continue to work toward elimination of differences in coverage for ancillary services between inpatients and outpatients.
- A uniform cost-based method for determining the technical component of charges for all CT scanning should be established to eliminate excessive surplus or profit. This method should include amortization of equipment and remodeling costs over a minimum of five years and should be based on a minimum annual volume of 2,500 patient examinations and on actual use above that volume.
- Professional fees for the interpretation of all CT scans should be at a rate which eliminates excessive profits. A rate of \$35 per patient examination is recommended at this time, unless special local conditions can justify a lower or higher rate. This charge may be subject to a modest adjustment for examinations involving the use of contrast material.

Planning for CT Scanning

- Congress should amend the National Health Planning and Resources Development Act of 1974 to include the review of proposals for large capital equipment expenditures in freestanding ambulatory care settings.

- Certificate-of-need laws in each state should require the review and approval of the acquisition of major capital equipment whether by an individual, group, or institution.
- Health systems plans and state health plans should include specific provisions for CT scanning services.
- CT scanners should be placed in freestanding ambulatory care settings only when placement in full-service hospitals is not practical.
- New units should not be approved until there is full and appropriate use of existing scanners.

Utilization of CT Services

- Each request for a CT examination should be reviewed by a physician with responsibility to control access to determine whether the scan is appropriate. No facility should be operated in such a way that scans are performed without such prior review.
- An advisory panel should be established by third-party payers to develop criteria for use of CT services.

Information Needs

- The federal government, perhaps in cooperation with national professional and third-party organizations, should develop and implement a comprehensive research protocol to provide definitive evaluation of CT scanning.
- The federal government should sponsor the development of a common data collection protocol to be followed by all providers of CT scanning services.
- Willingness to collect uniform data by owners of CT equipment should be a condition of CON approval and reimbursement by third-party payers.

- A procedure should be developed at the federal level to identify and evaluate costly technological innovations before their widespread introduction into the medical marketplace.

ASSESSMENT OF EFFICACY

Computed tomographic scanning should provide information that contributes to the formulation of a diagnosis. To examine the value of the information from the CT scan, the committee adopted a hierarchy of five levels of efficacy based largely on the work by Fineberg, Bauman, and Sosman.[24] In this, the determination of efficacy on any level is a necessary but not sufficient condition for a finding of efficacy at subsequent levels. The levels are:

1. Technical capability--accurate representation of the area scanned.
2. Diagnostic accuracy--provision of information that contributes to the formulation of a correct diagnosis.
3. Diagnostic impact--the extent to which CT scan information replaces other diagnostic procedures, including diagnostic imaging, surgical exploration, and biopsy.
4. Therapeutic impact--change in disease management that would not have taken place without the information from the scan.
5. Patient outcome--the effect of CT scan information on patient morbidity or mortality.

Diagnostic procedures should be evaluated not only on their own merits but also in comparison with competing procedures and combinations of procedures. It may be, for example, that efficacy is increased when CT

scanning is used in conjunction with other modalities such as diagnostic ultrasound, conventional x-ray, or radioisotope scans. The results of such comparative efficacy studies should be useful in defining diagnostic protocols.

Little is known about the efficacy of most diagnostic procedures above the level of diagnostic impact. Only the absolute and comparative efficacy of CT scanning at levels of technical capability and diagnostic impact can be assessed at this time. However, when unequivocal improvements in diagnostic impact occur, improvements at higher levels of efficacy can follow.

The efficacy of any diagnostic procedure must be evaluated against its costs and risk to the patient. The risk of ionizing radiation and the risks associated with other diagnostic imaging modalities, such as ultrasound, radioisotope scans, and conventional x-ray procedures are not fully known and should continue to be explored. The risks of CT scanning result from the possibility of allergic reactions to the contrast material injected intravenously in 40 to 60 percent of the scanning procedures[25] and from the effects of ionizing radiation. The committee finds that the risk associated with ionizing radiation in properly designed and calibrated scanners is equivalent to conventional x-ray procedures and substantially less than most invasive x-ray procedures. Exposure to x-rays should be kept to the minimum level that provides adequate information from the scan; manufacturers of CT equipment are urged to continue to incorporate this principle into machine design.

EVIDENCE FOR ESTABLISHING EFFICACY

As the committee indicated in its introductory remarks, a finding of efficacy at the level of diagnostic impact, or any of the higher levels of efficacy, depends upon the type of evidence that is found acceptable. The traditions of clinical medicine have accepted evidence based on observation and informed judgment. Agreement on that evidence by leaders in the field has usually been accepted as the guide to clinical practice and to reimbursement by third-party payers. Sometimes, a large-scale cooperative clinical trial is conducted after a technique has been introduced to general use, although ethical issues can

then be raised about the use of double-blind experimental designs. But well-designed clinical trials have not been a requirement for widespread utilization or reimbursement. Only in the case of drugs have we had a legal requirement for a finding of efficacy based on clinical trials.

An additional problem about evidence is raised by a technique like CT scanning that is evolving so rapidly and where the diagnostic accuracy for many applications, especially in the body, is so dependent upon the speed of the scan. The new generations of scanners have much more rapid scan times, now below five seconds in some cases, and the results from these rapid scanners show definite differences in findings in the body. The rapid changes in the capability of new equipment means that the usual lag before studies are published in the literature may make rapidly obsolete any judgments based on published studies. Since the lag in this field is only several months, however, a wait until studies are published seems reasonable before reaching conclusions about efficacy and reimbursement. This stance is consistent with the traditional principles of scientific evidence that call for evidence to be submitted to peer scrutiny with opportunities for reproduction of results or critiques of methodology.

In making specific recommendations about efficacy, the committee has based its judgments on the published literature. That literature shows the remarkable promise of CT scanning, both in its applications to the head and more recently, as scan times have been reduced, to a number of indications in the body. However, this evidence is not based on carefully designed, large-scale clinical trials. Therefore, the committee can reach two different sets of conclusions about efficacy at the level of diagnostic impact. The first would be based on existing standards of clinical evidence evaluated by the expert judgment of leaders in the field. Many significant advances in diagnosis and treatment have been introduced into practice on the basis of this type of evidence, and the results over time, when evaluated, have shown very positive value. The second type of evidence would require clinical trials meeting high standards of experimental design and statistical significance. The evidence for CT scanning, even in the head, does not yet meet this second standard.

The policy recommendations can be very different, depending on which standard of evidence is chosen. The first standard would call for a finding of diagnostic efficacy for CT scanning in the head and for a number of indications in the body. The second standard would find the results still inconclusive. The logical policy conclusion based on the first standard would be to recommend reimbursement for those uses found efficacious. The conclusion based on the second standard would be that the procedures are still experimental and should be supported only in settings that are part of a clinical trial leading to more definitive evidence. Only when that more definitive evidence is available would reimbursement in all approved treatment settings be available.

Because the focus of this study is on the near term, the committee has based the specific recommendations in this report on the first standard, which is the standard currently used in most decisions about the use of new techniques. The committee recognizes that recommendations based on the second standard would be substantially different. Because CT scans of the head are so widely used, the more rigorous evaluation of these applications must be considered retrospective, rather than prospective studies completed before a decision about reimbursement. However, CT scans of the body are such a recent use of this technology that delaying decisions about efficacy and reimbursement until prospective clinical trials are completed is still a feasible option. Implementing this option might call for the design of a cooperative large-scale clinical trial, with payment for CT scans of the body being limited to those institutions participating, or eligible to participate, in the trial, as determined by a national committee. The committee would also determine which indications were being examined in the trial. The trial design would involve not only absolute determinations of diagnostic efficacy but also comparative determinations involving other diagnostic techniques. Only when the trial was complete for a particular indication would a recommendation for general use in clinical practice be made and reimbursement provided for scans performed in other institutions. At that time, all other recommendations made by this committee concerning the location, financing, and evaluation of CT scanning would apply.

Although the committee does not endorse this second option as the preferred path for decisions about body scans in

the immediate future, the final section of this report contains recommendations which would begin to correct existing deficiencies in information about the effects of CT scanning. A basic shift to new standards of evidence as the basis for decisions requires a careful analysis of its full implications for public and private policies concerning all medical care, including techniques for implementation. The scope and time constraints of this report precluded such a major re-examination of the base of evidence for all clinical practice, although the first steps in providing improved information are recommended at this time in the final section.

EFFICACY OF CT HEAD SCANNING

Using current standards for evaluating clinical evidence, the committee finds CT scanning of the head to be efficacious at the level of diagnostic impact when used to diagnose and determine the effect of treatment on mass and structural lesions in or about the brain, including the meninges and orbit. CT scanning holds promise in demonstrating other lesions, including those resulting from demyelination and cerebritis. Indications for a scan should include sufficient clinical information for determining the area of the head to be scanned and whether contrast should be used. CT scanning of the head is not an appropriate diagnostic procedure in the absence of strong clinical indications and supporting signs and symptoms.

CT scanning of the head is usually efficacious in comparison with other diagnostic procedures.[26] Cerebral angiography, radionuclide scans, pneumoencephalography, echoencephalography, and skull x-rays will continue to have diagnostic utility, but CT is likely to replace them to some extent, to judge from comparisons of the information and risk associated with each method. The committee supports the decision of most third-party payers to reimburse for CT head scanning when competent judgment finds it clinically indicated.

EFFICACY OF BODY SCANNING

Although many possible uses of CT scanning in the body are presently under research, recent studies have presented substantial evidence meeting current standards that CT

scanning is diagnostically accurate in certain applications.[27] The committee has considered the most recent results obtained by clinical researchers and has applied its best judgment in evaluating these results. On this basis, the committee finds that CT scanning of the body is efficacious at the level of diagnostic impact when used for specific indications, limited largely but not entirely to diagnosis and managing treatment of cancers at certain sites. The areas of the body for which CT scanning is or is not indicated at this time are listed below.

Neck - CT scanning is not indicated at this time.

Chest -

● Pleura

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

● Lung

-- Detection of multiple tumor nodules where one or more have been found by conventional x-ray techniques. If there is clearcut evidence of bilateral involvement, CT is not appropriate.

-- 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 of tumor to adjacent lobes in patients with impaired pulmonary functions.

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

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

● 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 in the spinal cord at this time.

● Spinal Column

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

-- CT biopsies.

-- 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, metastases, and inflammatory diseases in the presence of persistent symptoms.

Abdomen -

● Retroperitoneal Area

-- Diagnosis and staging of nodal and extranodal extension of lymphomas, determination of extent of retroperitoneal involvement with lymphomas, and extent of other types of retroperitoneal metastases 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.

- 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.

 - CT biopsies.

- Spleen
 - CT is not indicated at this time.

- Pancreas
 - Search for primary and secondary tumor.

 - Determination of extent of tumor.

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

 - CT biopsies

- 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.

 - CT biopsies or aspiration.

- Gall Bladder
 - CT is not indicated at this time.

- Biliary Tree
 - Differentiation of obstructive from non-obstructive jaundice.

- Gastrointestinal Tract

- 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.

- CT biopsies.

Pelvis

- Uterus and Ovaries

- CT scanning is indicated after detection of a mass by clinical examination or after positive biopsy for:

- Evaluation of primary tumor and its extent of spread; and evaluation of secondary tumor.

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

- CT biopsies.

- Bladder, Ureters, and Prostate

- Evaluation of primary and secondary tumor, including extent of tumor.

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

- CT biopsies.

- Flat Bones

- Evaluation of bone lesions.

- CT biopsies.

Extremities -

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

Therapy Planning & Follow-up -

- CT is 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.

- 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 of therapy.

Foreign Body Localization in the Chest and Abdomen.

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 different 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.[28]

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.

The committee considers it essential, however, that controls be placed on the location and use of and charges for CT services. The controls are discussed in the succeeding chapters of this report.

HEALTH PLANNING POLICY FOR CT SCANNING

A fundamental problem with CT scanning and, indeed, with all diagnostic services is the seeming inability of the health care system to assure that only medically necessary and appropriate use occurs. The lack of control over use provides financial support for socially undesirable proliferation of facilities capable of rendering such services. In the absence of a complete restructuring of providers' economic incentives, two regulatory approaches to this dilemma are possible; control over the number and location of scanners; or control over the utilization of CT services. The first approach assumes that providers of health care can and will develop systems for appropriately rationing the use of such services. The committee believes that control over the placement of CT scanners is necessary but not sufficient; effective control over the utilization of CT services is also required. Providers of CT services cannot be expected to effectively ration access to CT scanning capability without such controls. This section discusses policy issues involving planning and regulation of CT scanner placement. The following chapter will consider policies for controlling the utilization of such services.

CERTIFICATE OF NEED

The major regulatory tools currently available to control the number and location of CT scanners are state certificate of need (CON) laws. CON legislation requires approval by a planning agency for major capital investments in health care resources. Twenty-nine states and the District of Columbia have CON requirements, and PL 93-641

mandates CON legislation in each state by 1980. However, laws in only three states require CON approval for capital investments made by private physicians. In the others physicians wishing to purchase CT equipment are legally exempt from review and approval, although administrative policy may encourage voluntary submission.

The Congressional Office of Technology Assessment reports that 15 percent of identified CT installations are owned by physicians and located in private offices or clinics; 6 percent are owned by physicians but located in hospitals.[29] There is every indication that a similar proportion of CT equipment will be owned by physicians in the future. Some physicians wishing to purchase CT equipment have voluntarily submitted applications for CON; others have been encouraged or required to apply for CON by legal, administrative, or reimbursement policies. However, some physicians appear to have deliberately circumvented the intent of CON requirements by purchasing CT equipment for use in private offices.

The exclusion of physicians' offices from planning agency review and approval under the CON program undermines the program as it applies to CT scanning. Although CON may not be an ideal mechanism for controlling the allocation of capital investment in medical care technologies, it is the only mechanism currently available. Planning agency decisions about the appropriate number and location of CT installations in a health service area will be ineffective as long as this loophole exists. Further, other prospective institutional purchasers may be denied CON approval because the quota for an area has been met or exceeded as a result of private ownership. The committee, therefore, recommends that:

- Certificate of need laws in each state should require the review and approval of the acquisition of major capital equipment whether by an individual, group, or institution.

Federal action is also recommended. There has been considerable debate since the passage of PL 93-641 about the congressional intent regarding noninstitutional providers of health care services. The administration has interpreted the law to exclude freestanding ambulatory care facilities. PL 93-641 expires in mid-1977, providing

a timely opportunity for Congress to clarify its position. Therefore, the committee recommends that:

- Congress should amend the National Health Planning and Resources Development Act of 1974 to include the review of proposals for large capital equipment expenditures in freestanding ambulatory care settings.

In making these recommendations, the committee is aware of the further burden that would be placed on health planning agencies which are considered by many to be developing and, therefore, fragile.[30] At the same time, the committee recognizes the importance of effective health planning and is anxious to assure that planning agencies have the power to develop and implement policies at the state and local level. To enhance the effectiveness of certificate of need programs, the committee recommends that:

- Third-party payers should reimburse only for services provided by CT installations approved under a certificate of need program.

In making this recommendation, the committee recognizes that some existing CT installations were not required to obtain a CON in the past. These installations should not be denied reimbursement for this reason.

In some states, CON laws do not exist or are ineffectively administered at present. Although the National Health Planning and Resources Development Act mandates the establishment of CON laws meeting certain specifications in all states, the network of capability to administer such laws has not been uniformly established. But the need for control over the placement of CT scanning capability is immediate. Consequently, third-party payers must evaluate the extent to which state legislation can be relied upon now to perform this function. Where such capability does not presently reside in existing agencies, third-party payers are urged to establish mechanisms to determine the eligibility of CT scanning installations for reimbursement using criteria consistent with sound health planning principles.

PLAN DEVELOPMENT

PL 93-641 requires that HSAs develop a health systems plan containing long-range goals and objectives. State Health Planning and Development Agencies also must assist the State Health Coordination Council in the Development of a state health plan. These plans play an essential role in describing the desired future state of the health care system in all health service areas. The committee recommends that:

- Health systems plans and state health plans should include specific provisions for CT scanning services.

If this recommendation is followed, the process of CON review and approval can then be used to implement these priorities.

In developing objectives for CT scanning services, health planning agencies should consider the desirable attributes of facilities which might offer CT services to area residents. These attributes should include:

Responsibility for training and medical education

Physicians in all specialities should be familiar with the appropriate use of CT services, and those specializing in diagnostic imaging should acquire expertise in the use and interpretation of CT scans. Technicians must also have the opportunity to be trained in CT.

A full range of diagnostic modalities CT Services, particularly body scanning, sometimes complement other diagnostic modalities such as ultrasound, radionuclide scanning, and conventional x-ray. CT is better placed in facilities which have the full range of these services so that inpatients need not be moved nor outpatients inconvenienced by the need to visit several facilities. Clustering complementary modalities also has the advantage that providers become conversant with each modality. The administrative burden is likely to be reduced since the patient receives services from one facility only. Since this policy would concentrate complex diagnostic services in fewer places, regional transportation systems become particularly important.

Capability of treating many of the conditions diagnosed by CT procedures CT scanning of both the head and body is capable of diagnosing many conditions which require highly complex treatment modalities. Therefore, CT equipment should be located in institutions which have the facilities for treating many of the conditions likely to be diagnosed by imaging with CT.

Services to both inpatients and outpatients CT equipment can be used most efficiently in facilities which have an outpatient department as well as inpatient beds. Such a policy suggests that most ambulatory care facilities and physicians' offices are less well suited for CT services.

Radiation physicist on staff or as a consultant A staff or consultant physicist with expertise in the technical aspects of CT scanning is desirable to assure the quality and safety of CT equipment. Consideration should also be given to facilities which include biomedical engineers and computer experts on their staffs.

Acceptance of referral from all area physicians Patients should not be denied access to CT services because of restrictive referral policies or on the basis of physician status. CT services should be considered a community resource.

Emergency facilities and services CT services may be indicated for certain emergency conditions. Priority should be assigned, therefore, to the installation of at least one CT unit in an appropriately defined geographic area to be available for use on a 24-hour, 7-day-a-week basis. The number of emergency cases in most communities, however, is unlikely to justify the cost of constant availability of more than one CT installation.

Because full-service hospitals have most of these attributes, the committee recommends that:

- CT scanners should be placed in freestanding ambulatory care settings only when placement in full-service hospitals is not practical.

ASSESSING THE NEED FOR CT SERVICES

Each health planning agency must determine the number of scanners which should be placed in its region if priorities for placement are to have any meaning. Yet, generally accepted methods for determining need have not been developed. Health planning agencies have used four general bases for calculating the need for scanners:

Population to be served Indiana suggests that there should be one scanner in each service area with more than 100,000 population.[31] Idaho guidelines state that a service area should have at least 250,000 population.[32]

Area to be served Massachusetts [33] and New Jersey[34] guidelines state that each HSA area should have one scanner, and Ohio suggests one for every major medical center area.[35]

Incidence of diseases among the population Kentucky has developed a complicated formula based on the incidence of cancer and the incidence and prevalence of neurological diseases.[36]

Number of other diagnostic procedures currently being performed The South Central Pennsylvania Health Planning Council uses a formula for determining the number of cranial CT scans based on the number of radionuclide scans, cerebral arteriograms, and pneumoencephalograms per year.[37]

Most agencies recognize that there are insufficient data available on which to base estimates of need and that the estimates adopted are crude. The uncertainty in these estimates is illustrated in a staff paper from the Massachusetts Department of Public Health which applied formulas from eleven different sources to data from Massachusetts and found estimates of "need" ranging from 5 to 52 scanners for the state.[38] The federal government has distributed two technical assistance memorandums which offer general guidance to health planning agencies, but they do not suggest a particular need assessment method.[39]

One suggested solution to the problem of inadequate information is to impose immediately a national moratorium on acquisition of all new scanners until firm guidelines can be developed based on studies of efficacy.[40] Such a

moratorium could be implemented either by health systems agencies if they have the power to conduct CON reviews for CT scanners in all settings, or by third-party payers if they have the authority to refuse payment for examinations performed on new scanning units. The committee believes, however, that such action is not warranted by the present situation. However, approvals in areas with existing CT units should be granted prudently. The committee recommends that:

- New units should not be approved until there is full and appropriate use of existing scanners.

If effective utilization review programs are established, congestion measured by long waiting lines for scans or near-capacity volumes of existing units will serve as good indicators of additional needs.

In the absence of effective controls on use, aggregate formulas for determining the number of scanners which should exist in an area must serve as a guide for health systems plans. The committee had neither sufficient time nor access to epidemiological data to evaluate alternative guidelines for the number of scanners which should exist in any defined region; moreover, these guidelines would soon become obsolete as new information on the efficacy of body scanning is generated. The problems facing health planning agencies in developing guidelines will not be solved until better information for policymaking is collected.

UTILIZATION REVIEW OF CT SERVICES

The tendency toward overuse of diagnostic tests in general and x-ray tests in particular has been discussed earlier in this report. CT scanning is no exception. Effective utilization review (UR) programs for CT examinations of the head and body as well as other diagnostic procedures are essential both to control costs and to assure adherence to standards of medical practice.

Formal programs of UR involving independent review of the use of CT services by parties outside of individual clinical decisions are necessary. Such UR programs can occur at various points in the process of delivering CT services. Prospective review involves an independent assessment of the appropriateness of or medical necessity for the procedure before its performance. Retrospective review involves a similar assessment sometime after the service has been rendered. Formal UR programs do not necessarily imply review of all CT examinations. A periodic analysis of patterns of care can isolate particular procedures, diagnoses, physicians, or institutions whose unusual features merit case-by-case review for some period of time.

Regardless of its configuration, a UR program must carry with it real sanctions and incentives to alter unsound patterns of use. Therefore, UR should be tied to payment for services. The committee recommends that:

- Third-party payers should reimburse only for examinations approved under a utilization review program satisfactory to the payers.

Third-party payers presently reimbursing for CT scans of the head or body should institute CT utilization review programs if they do not exist already. Third-party payers may wish to contract with qualified professional groups such as Professional Standards Review Organizations or foundations for medical care to conduct such programs.

The value of any UR program depends both upon its effectiveness in deterring inappropriate examinations and its cost. A program that works well in one environment may be ineffective or too costly in another. The committee considered various approaches to the review of CT scanning services. Prospective review of all or selected examinations by a physician with competence to judge the appropriateness of the use was suggested as the most effective control over unnecessary scans; however, the costs of such a program and the difficulty of finding competent reviewing physicians in some areas were considered by a majority of the committee to be major disadvantages. Retrospective utilization review programs as part of the claims review process were considered to be more feasible in most situations. However, many claim forms provide little information about the case. Claims review requires that all claims meet an initial set of screening criteria which identify cases for additional review. Often claim forms do not include information on ancillary services sufficient to identify cases of inappropriate use. The Medicare claim form for inpatient care, for example, does not require the identification of a CT scan independent of other x-ray procedures. Third-party payers and intermediaries should work to correct such deficiencies.

Any UR program must be based on criteria for appropriate use. Because the indications for CT body scanning are limited at present, this is a particularly appropriate time for third-party payers to develop such criteria. Third-party payers, perhaps in cooperation with each other, should establish an ongoing advisory group on CT scanning composed of radiologists, neurologists, neurosurgeons, oncologists, nuclear medicine specialists, ultrasonographers, clinical researchers, statisticians, computer experts, and consumer representatives. This body should develop criteria for use of CT scanning and should meet periodically to revise

those criteria as new information develops. Therefore, the committee recommends that:

- An advisory panel should be established by third-party payers to develop criteria for use of CT services.

The criteria for use developed by the advisory panel should address the following considerations:

- suspected diagnoses or therapeutic uses for which CT scanning is indicated;
- presenting signs and symptoms;
- place of CT scanning in the sequence of diagnostic procedures (including neurological consultations, where indicated and available).
- appropriateness of contrast-enhanced scans; and
- number of, and time elapsed between, repeat CT scans.

The advisory panel should also consider the need for information to develop profiles of use and to conduct studies of patterns of care. The panel should consider and recommend characteristics of CT facilities that can be used for these purposes, such as proportion of examinations that are contrast-enhanced, percent of examinations that are positive, and percent of scans used before or after other tests were conducted.

The committee recognizes that utilization review can be expensive and that it has met with mixed success.[41] In the absence of a complete restructuring of the economic incentives to which health care providers react, the committee believes UR is a necessary tool that should be initiated immediately to influence the use of CT services. UR should also be developed for other diagnostic services.

The imposition of formal utilization review programs does not relieve the referring physician and the CT provider from the responsibility of using the service

appropriately. Requests for CT scans should be required to contain the results of a clinical examination or assessment, to include suspected diagnoses and information sufficient for accurate localization of the scan and determination of the need for contrast enhancement. In the case of head scanning, this requirement ordinarily entails a neurological examination by the referring physician. Therefore, the committee recommends that:

- Each request for a CT examination should be reviewed by a physician with responsibility to control access to determine whether the scan is appropriate. No facility should be operated in such a way that scans are performed without such prior review.

COSTS AND CHARGES OF CT SERVICES

The variation in charges for CT services and the relation of costs to charges, in the light of actual costs, raises several questions for policymakers. It is apparent that there is a potential for individuals and organizations to charge significantly more than cost for both the technical and professional aspects of CT. Cross-subsidization and excessive profits can and have resulted from the installation of a CT unit.

CT charges include a professional component, which covers the physician's services, and a technical component, which covers all other expenses. In many cases, a single charge covers both components, as in hospitals where radiologists are salaried or when the scan is performed in the physician's office. To analyze the reasonableness of the total charge, however, it is necessary to review them separately.

TECHNICAL COSTS AND CHARGES

Charges for the technical component of CT examinations vary from \$100 to \$440, with an average of \$240;[42] the charge for a study with contrast media--used for image enhancement in 40 to 60 percent of scans[43]--averages \$67. About 10 percent of institutions charge a standard fee for CT scanning, regardless of whether the scan is unenhanced, enhanced, or both. The others make separate charges for enhanced and unenhanced scans and may have a third rate when both unenhanced and enhanced scans are ordered at the same time.

The real costs of providing scans vary in different settings because of differences in methods for allocating indirect costs. It is generally believed that overhead and administrative costs are lower in physicians' offices than in hospitals; but, unlike hospitals, physicians are rarely required to report costs or use cost-finding methods to establish or justify their charges. If charges for scans in physicians' offices mirror those in hospitals, then it is safe to say that when hospital charges are too high relative to costs, the same is true of physicians.

The reported costs of CT installations are summarized below:

- Annual operating costs range for \$259,000[44] to \$371,000.[45] One study reported an average of \$285,000.[46]
- Purchase price and installation range from \$300,000 to \$700,000.[47]
- Maintenance contracts average \$25,000 per year after a first year's warranty on most parts.[48]
- Updating costs per installation range from \$12,000 to \$220,00, with an average of almost \$74,000.[49]
- Remodeling costs average \$19,903, with a reported range of \$15,055 to \$34,000.[50]
- Technical staff costs approximate \$36,000 annually for two technicians and a secretary-receptionist.[51]
- Insurance costs average \$1,000 per year.[52]
- Contrast materials average \$7.70 per use.[53]
- The cost of other supplies has a mean value of \$10 per patient.[54]
- Overhead rates vary from 10 percent to 60 percent of direct costs.[55]

In reviewing the relation between technical costs and charges for CT services, the committee concluded that present charges do not represent the true resource costs

of CT scanning and do not promote efficient use of existing equipment. Charges are affected by the period of amortization, the volume of procedures, and methods for calculating indirect costs.

Amortization Period

CT scanning equipment for both the head and whole body has reached a state of development where present equipment will not become clinically obsolete before it wears out. Equipment may be made more efficient and convenient, but it is not expected that a major breakthrough in design will render present CT systems inadequate in terms of clinical information and diagnostic capability. In addition, it has been possible to update existing systems as new features are developed, although there is always an additional expense.

Amortization periods of five years or longer are considered to be realistic at this time. This finding should be re-examined at least once a year to take account of further experience with the life span of CT scanning equipment. The actual life span of CT equipment depends on the number of scans performed and will, therefore, vary with use.

Number of Procedures

The high fixed costs of operating a scanner argue for as high a volume of use as the equipment allows without jeopardizing the quality of care. Charges based on low volumes of examinations do not encourage efficient use of existing equipment.

The number of scans performed with a CT scanner depends largely on demand and the number of hours equipment is available for use. Each patient examination takes up to an hour. Estimates of full use vary from a low of 1,800 scans a year (based on one per hour, 40 hours a week, and excluding downtime[56], to approximately 4,000, based on 16 patients a day.[57] In their survey, Evens and Jost found an average of 228 patients per month;[58] the AHA reported a daily range of 6 to 25 with an average of 13 patients.[59]

The committee acknowledges that a few types of existing machines are slower than others and urges manufacturers to design CT equipment capable of handling more patients in less time. The committee also recognizes the limits

placed on some institutions by labor agreements which discourage or prohibit working hours beyond one shift.

The committee recommends a minimum volume of 2,500 patient examinations per year as a conservative basis on which to establish charges after a start-up period of up to one year. To avoid inappropriate use for the purpose of generating revenue, it is recommended that, above a minimum of 2,500 patient examinations, charges should be based on actual volume. The relatively low variable cost should lead to a decrease in charges at higher volumes. The period over which actual volume would be calculated should be determined by third-party payers. For example, it might be decided that volume over one six-month period should be used to calculate the charge made for CT examinations over the following six months.

Indirect Costs

Providers use different methods for allocating indirect (administrative and overhead) costs to various services and procedures for purposes of reimbursement. These variations can be used to justify large differences in scanning charges. One Blue Cross/Blue Shield plan estimated that indirect costs have ranged from 10 percent to 60 percent of direct costs.[60] This difference would justify a 45 percent difference in charges if direct costs were the same for all providers. The committee suggests that such differences in cost-finding methods be eliminated by third-party payers and that a uniform method for determining costs be adopted by third-party payers.

The committee, therefore, recommends the following:

- A uniform cost-based method for determining the technical component of charges for all CT scanning should be established to eliminate excessive surplus or profit. This method should include amortization of equipment and remodeling costs over a minimum of five years and should be based on a minimum annual volume of 2,500 patient examinations and on actual use above that volume.

For new installations a start-up period of up to one year should be granted. This recommendation applies to institutional and private settings. It implies that charges

for CT examinations would be the same for inpatients and outpatients and that the charge should be the same for enhanced or unenhanced examinations, singly and together.

The committee recognizes the biases in patterns of use that result from differences in coverage of benefits between inpatient and outpatient use of services. Therefore, the committee urges that:

- Third-party payers should continue to work toward elimination of differences in coverage for ancillary services between inpatients and outpatients.

PROFESSIONAL COSTS AND CHARGES

Fees charged by professionals for the supervision and interpretation of CT scanning examinations range from \$25 to \$75.[61] The average professional fee is estimated at \$55.[62] Using an estimate of one full-time-equivalent radiologist required for 2,500 scans per year, this would generate annual gross earnings of \$137,000. (Blue Cross/Blue Shield of Michigan has estimated that 3,000 examinations a year would require a half-time radiologist.[63]) Using this and other information, the committee finds the average charge for CT to be excessive even when bad debts and other costs are considered and recommends:

- Professional fees for the interpretation of all CT scans should be at a rate which eliminates excessive profits. A rate of \$35 per patient examination is recommended at this time, unless special local conditions can justify a lower or higher rate. This charge may be subject to a modest adjustment for examinations involving the use of contrast materials.

INFORMATION AND EVALUATION NEEDS

In addressing the many policy questions raised by the introduction of CT technology into the routine practice of medicine, the committee recognized the serious deficiencies in information available for sound planning and policymaking. Data are needed so that the usefulness of the technology can be determined and decisions on the number and location of CT units can be made. The committees' recommendations, or any recommendations affecting distribution and utilization of CT scanning, will remain deficient until better data, based on soundly conceived and executed clinical trials, are available.

The evaluation of CT scanning must consider not only its diagnostic efficacy relative to other procedures, but also the impact of CT scanning on therapy and on patient outcomes. Carefully controlled studies of CT procedures should produce information that can be used to develop indications for use and diagnostic protocols related to signs and symptoms.

Studies are being conducted at several institutions; these studies should be coordinated and, where necessary, expanded to include information on the impact of CT on the use of other health care services. At present, a comprehensive plan for the evaluation of CT scanning does not exist, and no agency, public or private, is developing one. Therefore, the committee recommends that:

- The federal government, perhaps in cooperation with national professional and third-party payer organizations, should develop and implement a comprehensive research protocol to provide definitive evaluation of CT scanning.

Information necessary for planning for CT services requires the development of a comprehensive data base from a wide range of CT facilities on the patterns of use of these services. Data of the following kinds are required:

- Presenting signs and symptoms of recipients of CT examinations
- Demographic characteristics of recipients of CT examinations.
- Rate of positive diagnoses of different disease conditions by CT.
- Place of CT examinations in sequence with other diagnostic procedures.
- Sensitivity and specificity of CT examinations performed in different parts of the body.

Uniform data collected from many facilities would make it possible to establish the approximate population base for which a scanner is needed. The committee recommends that:

- Willingness to collect uniform data by owners of CT equipment should be a condition of CON approval and reimbursement by third-party payers.

Common data collection formats should be developed at the federal level. The committee recommends that:

- The federal government should sponsor the development of a common data collection protocol to be followed by all providers of CT scanning services.

The history of CT scanning has shown that manufacturers of medical equipment and providers of medical care are willing to make major financial commitments before the efficacy of a technology is proven. The lack of a coordinated policy for collecting data to provide that information before major new technologies are diffused has exacerbated problems of control. The committee

recommends that:

- A procedure be developed at the federal level to identify and evaluate costly innovations before their widespread introduction into the medical marketplace.

If manufacturers and providers could expect early dissemination of the results of evaluations, they might alter their investment patterns accordingly. As long as providers bear no risk for poor investment decisions, as is the case now with cost-based reimbursement, they will continue to adopt new technologies prematurely.

APPENDIX

The individuals and organizations listed below were invited to make a presentation to the Committee on CT Scanning Policy at its meetings on December 21, 1976, and January 3, 1977.

Blue Cross and Blue Shield of Greater New York
(Steven Sieverts)

Blue Cross of Michigan, Detroit (Louis F. Hayes, M.D.)

Division of Health Policy and Planning, Madison, Wisconsin
(Steven Grode)

Health Research Group, Washington, D.C.
(Sidney M. Wolfe, M.D.)

Health Systems Agency of Northern Virginia, Falls Church
(George Parker)

National Electrical Manufacturers Association
(Gene E. Lewis)

Office of Technology Assessment, United States Congress,
Washington, D.C. (Carl A. Taylor)

Society of Nuclear Medicine, New York
(C. Douglas Maynard, M.D.)

Raymond Gize, M.D., Fort Wayne, Indiana

George L. Sheppard, M.D., Winchester, Virginia

The American Hospital Association was unable to send a representative to the meeting but presented written testimony. (Herbert K. Gatzke; written testimony)

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