5

Specific Medical Technologies; Linking Coverage Policy and Technology Assessment To Contain Costs

> Indeed, what is there that does not appear marvelous when it comes to our knowledge for the first time?
>
> *Pliny the Elder*

Contents

LIST OF TABLES

FIGURE

5

Specific Medical Technologies: Linking Coverage Policy and Technology Assessment To Contain Costs

INTRODUCTION

The introduction of a new technology sometimes has large and unanticipated impacts on Medicare expenditures (see ch. 3). The extent of impact depends on whether Medicare chooses to cover (i. e., pay for) the technology, and, if it chooses to cover it, to specify the conditions of its use. Coverage policy, i.e., policy that governs the eligibility of services (technologies) for payment, has been a significant factor in hospitals' decisions regarding the *purchase* of expensive, visible medical technology *(24,289).* The relationship between coverage policy and adoption of other kinds of medical technology or the *use* of any medical technology remains speculative.

Title XVIII of the Social Security Act specifies broad, general categories of medical and health services (e. g., hospital services and physicians' services) and some specific items (e. g., home dialysis supplies, pneumococcal vaccine) that the Medicare program will cover (see ch. 2). It also lists a number of specific services and items that the program will not cover. For the most part, however, decisions about which technologies Medicare will pay for are made at the national level by the Health Care Financing Administration (HCFA) or at the local level by Medicare contractors.

In the past few years, rapid technological development has led to an increasing need for decisions by Medicare and other third-party payers about the coverage of specific technologies. Many coverage decisions are based on an assessment of the health effects of the particular technology. For the most part, these assessments are not rigorous. Indeed, it is estimated that only 10 to 20 percent of technologies used in medical practice have been shown to be efficacious by controlled trials (341). Evaluation of the nonmedical effects, for example, economic and social effects, of specific technologies is usually not part of an assessment for coverage purposes.

This chapter discusses the possibility of refining Medicare's coverage policy, for example, by using appropriate technology assessments, as a means of influencing the diffusion of medical technology. Changes in Medicare's coverage policy for specific technologies may provide an incremental approach to controlling Medicare costs.

DEFINITIONS

Coverage is generally defined as "the guarantee against specific losses provided under the terms of an insurance policy. " The term is frequently used interchangeably with benefits or protection. Coverage also means "the extent of insurance offered by a policy" (33.5). Insurance plans (including Medicare) specify, to varying degrees of precision, the benefits they will pay for. Thus, coverage refers both to the broad categories of benefits specified in the law or in a plan as well as to the specific services actually provided and paid for. In the Medicare program, coverage is distinguished from payment or reimbursement: coverage refers to benefits available to eligible beneficiaries, and payment refers to the amount and methods of payment for covered services (434).

. . . [Technology assessment is simply a broader form of policy research than is commonly conducted. The goal of technology assessment, as of all policy research, is to provide decision-makers with information on policy alternatives, such as allocation of research and development funds, formulation of regulations, or development of legislation" (23). A comprehensive assessment examines the technical, economic, social, and legal consequences of technological applications. A less comprehensive assessment of a medical technology may focus only on the health effects of the technology. The typical meaning of the term "technology assessment" in health policy today is an evaluation of a technology's efficacy and safety and sometimes costs.

MEDICARE COVERAGE

The basis for decisions by HCFA or Medicare contractors regarding the coverage status of medical technologies not otherwise specifically mentioned in Title XVIII of the Social Security Act is Section 1862. Section 1862, among other things, prohibits payment by Medicare for any expenses incurred for items and services which are not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed-body member. . . ." The provision applies "notwithstanding any other provisions" of the title.

Coverage policy for specific technologies is expressed in the development, issuance, and implementation of coverage decisions. Such policy is made in light of Medicare's twin principles of not interfering with the practice of medicine and of assuring beneficiaries a free choice of providers. For the most part, questions regarding Medicare coverage status arise with respect to new technologies or new applications of covered technologies, although occasionally, the coverage status of covered, established technologies is reexamined. The focus of this chapter is on the Medicare coverage process for new technologies and new uses of covered technologies. [1]

There is a basic contradiction between Medicare's stated intention of not interfering with the practice of medicine and the delivery of health care and its coverage policy that judges technologies to be used in medical practice. A decentralized approach to the coverage process attempts to minimize the contradiction by accepting the premise that medical practice varies from one geographic area to another.

Some Medicare coverage decisions for specific technologies are made at the national level by HCFA's central office. Most of the decisions, however, are made by Medicare contractors who perform the Medicare program's claims processing and payment function under the policy and operational guidance of HCFA. Medicare contractors, called intermediaries and carriers, are either Blue Cross/Blue Shield plans or commercial insurers. On the U.S. mainland, ***84*** intermediaries administer Part A (institutional services) of the Medicare program, and 61 carriers administer Part B (physicians services) (see app. E).[2] HCFA'S 10 regional offices assist contractors with coverage decisions and transmit information between HCFA's central office and Medicare contractors.

Because of the general language of Section 1862 and the absence of regulations that implement the section, HCFA officials and Medicare contractors alike have had considerable latitude **in determining which technologies are to be covered for reimbursement.**

Medicare coverage policy is continuously evolving and is developed and implemented in a decentralized manner. National policy has developed largely as a result of questions from individual contractors about whether they should pay for specific technologies (366,435). HCFA informs contractors about the coverage status of

[1]The term "new technologies" henceforth refers to both new technologies and new uses of established technologies.

[2]There are two governmental bodies that perform similar functions: the Office of Direct Reimbursement and the Group Health Plan Operations Staff in the Bureau of Program Operations. HCFA is moving to contract out the intermediary functions of the Office of Direct Reimbursement to regional intermediaries.

some specific technologies through transmittal letters and a Medicare manual. However, HCFA's coverage instructions have no standing in law or regulation, so the contractors' compliance is essentially voluntary (366).

There is variation among Medicare contractors in a number of areas (54,143,353, and app. E):

- their identification of specific medical technologies that are not covered,
- their decisions about the coverage of specific technologies, and
- their implementation of national coverage decisions made by HCFA.

Because of the variation among contractors, some technologies may be covered and paid for in one geographic area and not in another. There is no national or local listing of procedures that are not covered (163).

Part of the variation stems from the absence of precise definition of "reasonable and necessary. " There are, however, specific criteria that are applied to a technology to determine if the technology meets the broad statutory language of "reasonable and necessary. " These criteria are found in program instructions prepared by HCFA and sent to the Medicare contractors. The technology must be (435):

- generally accepted as safe and effective,
- not experimental,
- medically necessary, and
- provided according to accepted standards of medical practice in an appropriate setting.

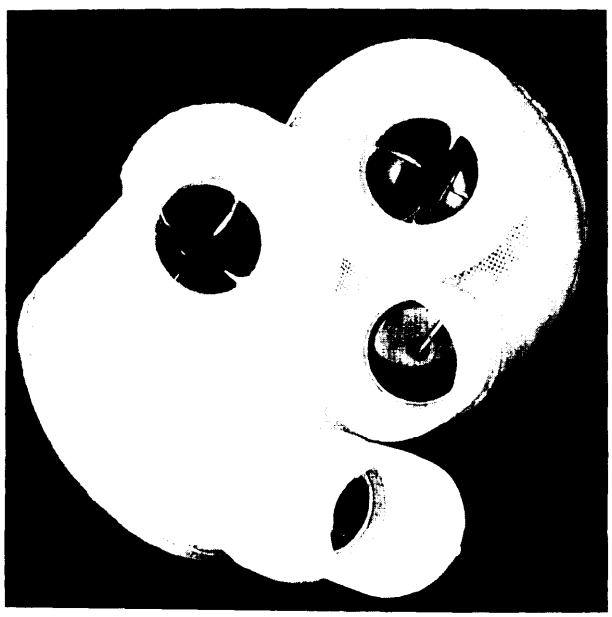


Photo credit The University of Utah Medical *Center*

The Jarvik 7 artificial heart is an example of an experimental technology that has not been approved for Medicare coverage

Of particular interest to cost-containment efforts is that Medicare's policy is to exclude the explicit consideration of cost information in making coverage decisions.[3] At one point, in the context of a proposed regulation to define the meaning of "reasonable and necessary" more clearly, HCFA debated establishing criteria and standards for taking nonmedical factors, including economic factors, into account in making coverage determinations (268). Active consideration ended with the change in administration in 1981.

Another important point is that Medicare has refrained from a policy of limiting coverage of particular technologies to restricted circumstances (e.g., to institutions offering specific services or having specialized equipment, or to physicians with specific skills). Although the notion of limiting coverage has gained importance with the increasing development of sophisticated technologies that require particular expertise, the dictum of refraining from interfering with medical practice appears to be foremost.[4]

On the other hand, Medicare does limit coverage of some technologies to appropriate medical conditions. Thus, for example, in August ***1981,*** HCFA announced the coverage of specific types of therapeutic apheresis for three conditions but

[3]A dramatic exception was heart transplantation A\ a result of the controversial nature of the technology, including economic, social, ethical, legal, and moral concerns, the evaluation andsubsequent coverage decision has been delayed for additional research evidence, Including cost-effectiveness data (107)

[4]There appears to be a lessening of adherence to the concept of not coven ng technologies for limited situations Al t houghno policy change has been announced, the coverage of apheresis, which became effective on Jan 31, 1983, is limited to the performance of apheresis only in the inpatient or outpatient hospital setting (74) Also, in July 1983, HCFA released coverage instructions to Medicare cent ractors that limits payment for a technology to its use in a specific setting and by specific providers. Closed loop bloodglucose control devices will be paid for only if used in a hospital inpatient setting under the direction of specially trained medical personnel for insulin dependent diabetes during crisis intervention (383)

denied coverage of apheresis for other indications. Three additional disease indications were added in 1983 (349).

The Coverage Process

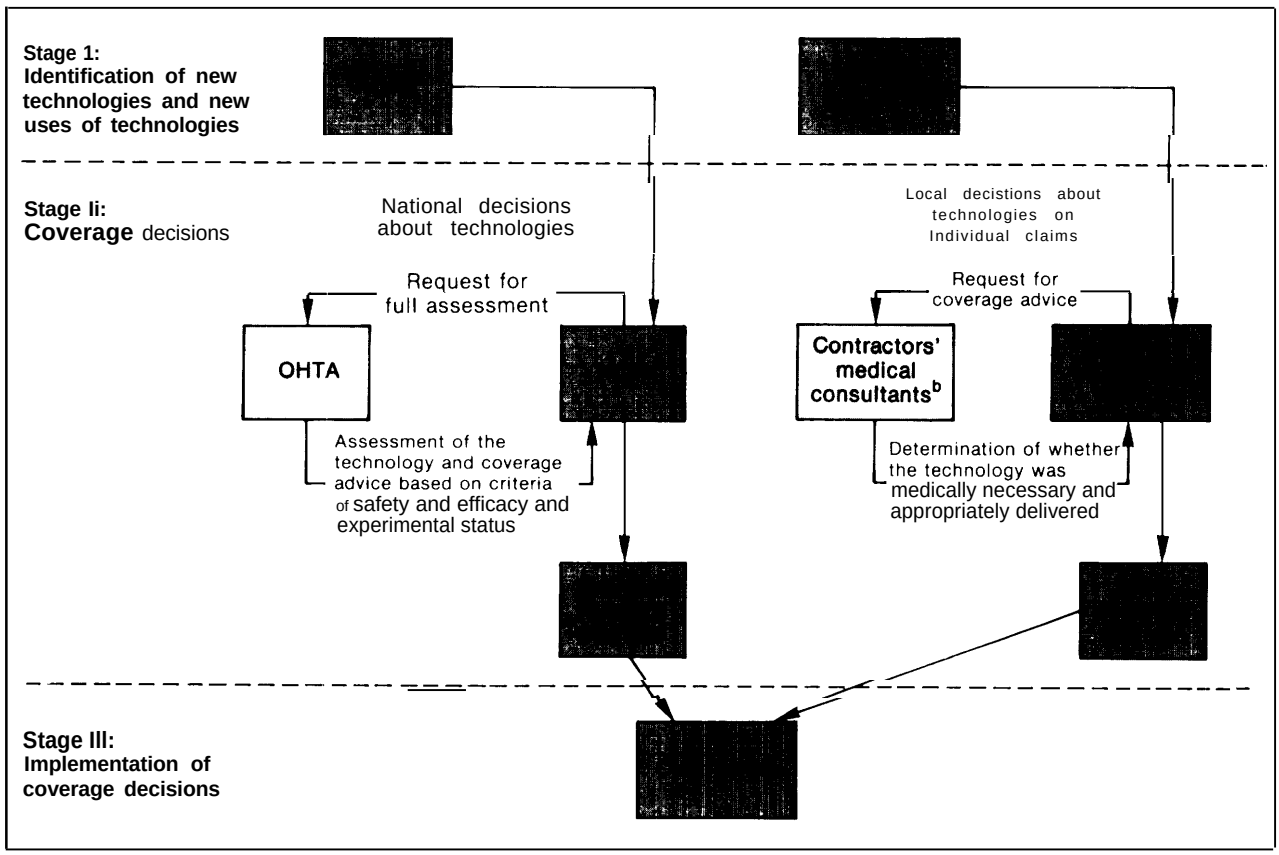
Medicare's coverage process is depicted in figure 2 and described in detail below. The coverage process is generally (except for details) the same at the national and contractor levels. First, a new technology or new use of a covered technology is identified. Second, a decision is made about covering the identified technology for Medicare payment. The third and final step of the process, implementing the coverage decision, is mainly the contractors' responsibility.

Identification of New Technologies and New **Uses of Technologies**

The identification of a new technology for a coverage determination may be done by a Medicare contractor, by one of HCFA's 10 regional offices, or by HCFA's central office. Medicare contractors use general guidelines distributed by HCFA. In the last few years, the guidelines have been made broader and more general. HCFA assumes that Medicare contractors are familiar with medical and hospital practices and thus relies on the contractors' knowledge and experience (173).

Medicare contractors use various methods for identifying new technologies, In the recent past, claims review appeared to be the primary method

Figure 2.—Model of Medicare's Coverage Process for Individual Medical Technologies



[a]Sources of coverage questions submitted to HCFA are identified in table 15.
[b]Sources of assistance for Medicare contractors' medical consultants in making coverage decisions are identified in table 14.

SOURCE: Office of Technology Assessment.

for identifying uncovered technologies. A 1983 survey of Medicare contractors, the results of which are presented in appendix E, however, found that most contractors learn about new technologies for which coverage questions might be raised through inquiries from providers and manufacturers prior to the submission of claims. Other important sources of information about new technologies are the drug and device approval lists from the Food and Drug Administration (FDA) and announcements from HCFA. Some contractors keep informed about new developments through the medical research literature, or contacts with medical specialists, or supplier demonstrations and mailings.

The claims form, despite the use of other tools, is still an essential, albeit imperfect, identification tool. The claims review process, described in appendix E, was established for paying bills, not for identifying technologies. Furthermore, under HCFA's current allowances for administrative costs, Medicare contractors are financially constrained to limit their review process.

The claims form for hospital services under Medicare's traditional cost-based hospital reimbursement method[s] is not designed to identify new technologies. This claims form groups services under broad headings, such as radiology and pathology, and provides little information about specific technologies (291). Furthermore, under cost-based reimbursement since 1981, HCFA has required intermediaries to examine only a 20-percent sample of inpatient hospital claims (384).

On the claims form for physician services, a Part B service, the physician is required to supply information about the use of specific surgical and medical technologies. New technologies are recognized by the absence of code numbers, by the presence of codes that are not recognized, or occasionally, by the excess charges for a type of service (54 and app. E). Because of the nature of the claims form and the fact that almost all the forms for physicians' services are reviewed, it is commonly assumed that carriers, the contractors who administer Part B of Medicare, are more likely to identify uncovered technologies from claims forms than are intermediaries. It should be noted, however, that carriers may overlook new technologies because of inefficiencies in the review process and a high number of coding errors. It is also possible for physicians and hospitals to code new procedures under codes for established procedures **(54).**

Some observers indicate that intermediaries, the contractors who administer Part A, can identify high-cost technologies. If a hospital or other inpatient facility exceeds a set level of expenditure for a particular type of service, the intermediary may examine the medical record and identify an uncovered technology. Intermediaries may compare annual Medicare cost reports (MCRs) from year to year to compare expenditures for groups of services. At times, hospitals have recorded a specific uncovered technology on the MCR, as well (17). On the whole, however, specific technologies are not identified on the MCR, which is reviewed for financial purposes and not technological use.

Most Medicare contractors in the 1983 survey presented in appendix E were reasonably well satisfied with existing methods for identifying new technologies and reported that this was not a serious problem for them. Some contractors mentioned a need for greater cooperation between national medical and insurance associations and governmental agencies in supplying information about new technologies to facilitate the identification process.

Coverage Decisions

Coverage decisions are made by Medicare contractors and by HCFA's central office. Local decisionmaking is informal and has no standing in law or regulation. National coverage decisions are made informally, as well, and the decisionmaking process has no regulatory status (114).

Medicare contractors, advised by their medical consultants, decide most of the coverage issues that are raised in their own geographic area. Indeed, less than 1 percent of the ***250*** million claims processed in fiscal year 1983 were sent to HCFA's central office for coverage decisions (88). Most

[s] The claims term and the claims review process under Medicare's DRG payment method are not sufficiently established for comment at this time. As noted in ch. 2, some hospitals and some hospital units will continue to be paid under Medicare's cost-bawd reimbursement method.

questions are not of national interest. Furthermore, the contractors view their function as paying claims as quickly as possible and are disturbed by the delays in referring questions centrally (366). Although a special office dealing with coverage issues, the Office of Coverage Policy in the Bureau of Eligibility, Reimbursement, and Coverage, was established in HCFA as a result of a 1979 memorandum, it does not appear that the pattern of decisionmaking has changed significantly (61),

When considering coverage questions, most medical consultants to contractors appear to rely on similar sources of reformation, including HCFA regional offices, colleagues in other insurance companies or Blue Ckoss/Blue Shield plans, and State or national medical or specialty societies (see table 14).

Most of the questions raised during claims review pertain to whether a particular technology was medically necessary in the case under review and whether the technology was furnished in an appropriate manner and setting, Sometimes, however, the broader issue of general coverage arises, i.e., whether the technology should be covered under any circumstance. National coverage questions are to be referred to HCFA's central office (435). Nonetheless, some contractors' medical consultants make decisions about national coverage issues.

Because of variation in the types of coverage questions that Medicare contractors consider and their decisions about any one question, the specific package of covered services varies from contractor to contractor. The 1983 survey of Medicare contractors found variation in coverage decisions made by medical consultants of Medicare contractors (see app. E).

In an attempt to modify differences and inconsistencies in Medicare benefits in its region, HCFA's Boston Regional Office issued a bulletin in 1978 to Medicare intermediaries and carriers describing a "general approach that should be taken with respect to determining coverage of new or unusual procedures which the Medicare Bureau either has not categorized as covered or uncovered, or on which [it has] not advised [them] that a national coverage policy decision is currently pending" (388). The bulletin emphasized the expeditious use of medical consultants and suggested the referral of general issues to HCFA's regional and central offices. Although the guidelines described in the bulletin are not enforceable, the Boston Regional Office believes that contractors in the Boston region have improved their coverage process and that the improvement has resulted in greater consistency in covered benefits in the area ***(73).***

HCFA's central office issued a similar directive to contractors nationwide in 1981 concerning its expectation that contractors refer coverage issues of national interest to the office (384). However, referral is not required by statute or regulation, and HCFA's request is not uniformly honored.

The current locus for coverage questions within HCFA is the Office of Coverage Policy. If medical advice is needed in order to arrive at a coverage decision, the question is presented to HCFA's Physician Panel, The panel may then request tech-

Table 14.—Sources of Information Used by Medical Consultants in Making Coverage Decisions

Source	Percent of consultants using source	
	Yes	No
Colleagues in another insurance company or Blue Cross/Blue Shield Association plan	78.6	21.4
HCFA regional office	87.5	12.5
University medical center	44.6	55.4
PSRO (PRO)	26.9	73.1
National insurance association	37.5	62.5
State or national medical or specialty association	75.0	25.0
Drug or device manufacturer	53.6	46.4
Other	51.0	49.0

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

nology evaluations from the Office of Health Technology Assessment (OHTA), ' which has taken over the coverage responsibilities of its predecessor, the National Center for Health Care Technology (NCHCT) (386).

After conducting an assessment on the safety, efficacy, and clinical effectiveness of a technology (399), OHTA may recommend to HCFA that a technology not be covered by Medicare or that it be covered with or without restrictions. The coverage decision is made by HCFA, which subsequently notifies its contractors and State Medicaid agencies. In almost all cases, HCFA accepts OHTA's recommendation.

In the late 1960's and throughout most of the 1970's, the vast majority of coverage questions received at HCFA'S central office were submitted by the regional offices (381). From 1978 to 1982, however, the proportion of questions submitted by the regional offices declined (see table 15). After 1979, other parties, particularly manufacturers, increased their participation in the coverage process. In 1978 and 1979, there were no direct inquiries from drug or device manufacturers, but during 1981, 25 percent of the coverage questions submitted to HCFA's central office were from producers of medical technologies (see table

'OHTA 15 located in the National Center for Health Services Research in the Public Health Service It should not be confused with the congressional Office of Technology Assessment (OTA).

Table 15.—Sources of Coverage Questions Submitted to HCFA's Central Office

	Inquiry source—by source, year, number, and percentage				
Source	1978	1979	1980	1981	1982 (through November)
HCFA regional office	19 (61.3%)	9 (32,1 %)	19 (59.4%)	11 (34.6%)	7 (24.1%)
Manufacturers			1 (3.1%)	13 (25.0%)	3 (10.3%)
Hospitals/clinics	1 (3.2%)	1 (3.6%)		1 (1.9%)	1 (3.4%)
Physicians	1 (3.2%)	4 (14.3%)		5 (9.6%)	3 (10.3%)
Medical schools		2 (7.1%)			1 (3.4%)
Legislatures	1 (3.2%)			1 (1.9%)	1 (3.4%)
Professional societies	2 (6.5%)	(17:9%)	2 (6.3%)	2 (3.8%)	
Blue Cross		(3,61/o)	2 (6.3%)	2 (3.8%)	1 (3.4%)
Blue Shield			2 (6.3%)		
Blue Cross/Blue Shield					1 (3.4%)
Private insurance			1 (3.1%)	2 (3.8%)	
Health Care Financing Administration		5' (17,9 %	1 (3.1%)	2 3.8%)	(24%)
Public Health Service			2 (6.3%)	2 (3.8%)	(6.9:/o)
Attorneys			1 (3.7%)		(3,41%)
Information not available	7 (22.6%)	1 (3.60/.)	1 (3.1%)	4 (7.7%)	(6:°/0)
Total	31 (100%)	28 (100%	32 (100%)	52 (98.2%)	29 (99.60/o)

[a]Four of these questions arose from the Blue Cross/Blue Shield Medical Necessity Project

Data sources Health Care Financing Administration internal data sheets and HCFA staff

SOURCE Off Ice of Technology Assessment

15). The now defunct NCHCT may have been partially responsible for the increase in manufacturers' questions, because it referred the manufacturers' inquiries it received to HCFA (258). HCFA files show that questions about coverage for a particular drug or device in some cases were submitted at approximately the same time by both the manufacturer and an interested provider.

The Health Industry Manufacturers Association (HIMA) has spent considerable effort in educating its members about health coverage and reimbursement (385). Such attempts may be a significant factor in stimulating manufacturers' interest in requesting coverage. For a few years, HIMA encouraged manufacturers to go directly to HCFAsS central office to obtain coverage for their products and service. In the past year or two, HIMA has suggested that its members contact contractors, particularly carriers, because of its perception that the time required for making and releasing coverage decisions and the number of denials at the national level has increased. The decline in direct inquiries for coverage to HCFA's central office—from *25* percent of the total number of inquiries in 1981 to 10.3 percent in 1982–may reflect the change in strategy.

Implementation of National Coverage Decisions

There is no formal mechanism for implementing Medicare coverage decisions made at the national level, For the most part, HCFA's function is limited to disseminating the decision to contractors and providers through various sources, including HCFA's regional offices, instruction manuals, and transmittal letters. Government involvement is largely confined to cases of fraud and abuse.

As noted earlier, Medicare contractors have no legal responsibility to adhere to the coverage decisions made by HCFA's central office, The manual instructions, including the coverage index appendix, and the letters to the contractors are usually considered interpretive rules and thus not legally enforceable (366),

Nonetheless, the contractors' claims review process is an unofficial and limited means of implementing national coverage decisions. Claims requesting payment for noncovered services and claims with incompatible diagnostic and procedure codes are usually referred to the contractors' nurse reviewers, and if necessary, to physician consultants (see app. E). However, no distinction can be made between those technologies that are not covered because a coverage question has not been raised and those technologies that are not covered because they have been denied coverage.

Until recently, little empirical evidence was available about the contractors' role in implementing national coverage decisions. A recent survey of the implementation of Medicare nursing home benefits by intermediaries found the use of skilled nursing facilities by Medicare beneficiaries to vary considerably from one State to another, a variation that reflected wide differences in the interpretation and administration of rules governing nursing home coverage (314), The researchers concluded that the wide variation was due to the complexity of Medicare coverage rules and to Medicare's decentralized administration,

The 1983 survey of Medicare contractors mentioned above (see app. E) came to somewhat similar conclusions. The survey found considerable variation in the implementation of HCFA transmittals among contractors. This variation was apparently not related to certain characteristics of the contractors, including insurance type (Blue Cross/Blue Shield or commercial), geographic location, or claims volume.

Part of the variation in implementation of coverage decisions appears to result from what is perceived as a lack of clarity in HCFA's coverage instructions. Fifty-five percent of the Medicare contractors surveyed in 1983 said they were always or almost always able to implement HCFA transmittals concerning the coverage status of particular technologies without obtaining further interpretation. However, 45 percent of the contractors reported that the transmittals sometimes, rarely, or never could be implemented without further interpretation (app. E).

Some contractors also indicated they were not given sufficient time for implementing national coverage decisions, sufficient information about technologies undergoing assessment, or revisions in coverage policy. As noted earlier, HCFA's current policy is based on the premise that contrac-

tors' have sufficient knowledge and expertise to allow for general coverage instructions. Nonetheless, some contractors are not content with the policy and said that the content of HCFA's instructions could be improved by including more specific criteria and by eliminating ambiguous terms, such as "chronic" and "necessary" (app. E).

The 1983 survey of Medicare contractors also examined decisionmaking by Medicare contractors regarding the coverage of specific technologies.[7] It found various degrees of variation among contractors in their coverage of technologies included in the survey (app. E).

The study technologies were categorized according to HCFA coverage status: 1) explicit coverage by HCFA, 2) HCFA coverage with qualifications, 3) no explicit HCFA policy, 4) implicit denial of coverage by HCFA, and 5) explicit denial of coverage by HCFA (see table 16). The variation in coverage was least in instances in which HCFA had explicitly approved coverage. Table 16 shows that some contractors covered technologies in this category with qualifications when

[7] The study was exploratory) and descriptive, with many methodological limitations (see app E) The questions about individual technologies were intended to ascertain what the contractor's policies generally were with respect to coverage The telephone interviewers researchers did not use the word 'implementation' and did not check on the degree to which contractors adhere to HCFA policy guidelines Indeed most coverage issuances allow for variation depending on further investigation of the claim and the circumstances of the individual patient. Variation among contractors was expected, because the coverage status of the technologies included in the survey are difficult to determine. Nonetheless, examining the contractors' coverage decisionmaking process at one point in time does give some indication of the contractors' compliance with national coverage decisionmaking.

Table 16.– Reported Coverage Decisions by Medicare Contractors

Technology/HCFA coverage policy	Decisions/policy of contractors: Covered	Not covered	Covered with qualifications	Refer for advice
HCFA explicitly covers:				
Lens implant	98.2%	—	—	1.8%
Pacemaker: chronic second degree AV block	70.9	—	20.0%	9.1
PTCA: single vessel procedure	61.1	3.7%	25.9	9.3
EEG monitoring: carotid endarterectomy	68.0	14.0	10.0	8.0
Apheresis: hyperglobulinemias (multiple myeloma)	81.1	5.7	7.5	5.7
HFCA covers with qualifications:				
Home blood glucose monitor	11.8	7.8	72.5	7.8
External osteogenic stimulator: long bone fracture	27.5	3.9	58.8	9.8
PUVA: psoriasis	38.5	5.8	50.0	5.8
Implantable chemotherapy infusion device: primary hepatic malignancy	51.9	21.2	11.5	15.4
Implantable chemotherapy infusion device: cancer metastatic to liver	38.5	26.9	15.4	19.2
External insulin infusion pump	10.6	46.8	27.7	14.9
No explicit** HCFA policy—contractor decides **(local option):				
Chelation therapy: rheumatoid arthritis	3.8	81.1	1.9	13.2
Streptokinase at cardiac catheterization: AM I	30.2	45.3	151	9.4
Chemonucleolysis: herniated disc	64.0	10,0	14,0	12.0
HCFA denies, but not explicitly:				
Biofeedback: intractable pain	9.3	55,6	31,5	3.7
PTCA: two or more coronary arteries	19,2	51.9	19.2	9.6
Apheresis: systemic lupus erythymatosis	18.0	60.0	14,0	8.0
HCFA explicitly denies:				
Chelation therapy: atheroscleros~s	—	87.0	3.7	9.3
Pacemaker: sinus bradycardia without symptoms	13.0	44,0	29.6	13.0
24-hour blood pressure monitoring: automatic (policy effective 7/83)	8.3	52.1	27.1	12.5
24-hour blood pressure monitoring: semiautomatic or patient activated	*4.2*	*77,1*	8.3	10.4
EEG monitoring: open heart surgery	15,4	71.2	9.6	3.8
Topical oxygen therapy: decubitus ulcers	7.8	86,3	5.9	—

SOURCE L K Dernlo G T Hammons, J M Kuder,et al Report of a Study on Declslonmak!ng by Medicare Contractors for Coverage of Medical Technol Ggles prepared for the Off Ice of Technology Assessment U S Congress Oct 28, 198.3

there were no qualifications imposed by HCFA, However, this practice reflects not a lack of compliance with HCFAss policy, but rather caution on the part of contractors to assure that HCFA's criteria were met.

From table 16, it would appear that there is significant variation among the technologies in the second category, i.e., those that HCFA covers with qualifications. However, most of the variation exists because of the three infusion device technologies included in the category. When the survey was conducted, policies concerning infusion devices were undergoing review, and there was considerable uncertainty among contractors as to the current coverage status of the devices. If one eliminates the infusion device therapies from the category, the variation decreases considerably (app. E),

Coverage decisions on technologies for which HCFA had explicitly denied coverage showed more variation than one might expect, That may be an artifact of the particular technologies included in the survey or may indicate a reluctance on the part of the contractors surveyed to flatly deny coverage without further investigation of the claim. Variation is, predictably, much greater for technologies for which contractors have made local coverage decisions and those for which HCFA intends to be denied but for which there is no explicitly stated policy (app. E).

In most instances, the majority of the contractors complied with HCFA'S directives. Yet compliance was sufficiently diverse among the contractors as to result in variation. In general, the variation can be attributed to differing impressions on the part of the contractors about the coverage status of the particular technology, which may result from unclear or complex HCFA coverage policy, a change in policy, or a policy in the formation stage; the inherent complexity of clinical medicine and the difficulty of precisely matching a claim for a specific patient with a general policy written to cover many patients; and limitations of the study –e.g., the findings reflect responses to a hypothetical situation at one point in time.

Coverage Policy Under Medicare's DRG Hospital Payment System

In October 1983, fo]lowing enactment of Public Law 98-21, Medicare began phasing in prospective hospital payment system using Diagnosis Related Groups (DRGs) as the case-mix measure.[8] Federal regulations (114) state:

> . . prospective payment legislation did not change Medicare coverage or eligibility rules currently in effect . . . as a result, national coverage rules continue to be applicable. These rules will continue to be applied by intermediaries with assistance from PROS [utilization and quality control peer review organizations] and PSROs [professional standards review organizations] where appropriate.

DRG payment is not applicable to psychiatric hospitals, rehabilitative hospitals, pediatric hospitals, long-term hospitals, psychiatric and rehabilitative units operating as distinct parts of acute care hospitals, and physician services-provided in or out of the hospital. Thus, Medicare coverage for these institutions and services remains unaffected by the change in payment method.

Although the regulations require that coverage rules remain, the structure of DRGs places little emphasis on individual technologies. Thus, under DRG payment for inpatient services, HCFA will rarely be able to discern the use of particular technologies. Multiple combinations of drugs, devices, and procedures are possible within almost all DRG categories; specific technologies are not easily evident from DRG classification, For the most part, only a few of the 470 DRGs mention particular technologies. With few exceptions, specific drugs and medical devices were not variables in the construction of DRGs as a patient classification system, Drugs are not specified in any of the 470 DRGs, and only one medical device, the pacemaker, is specified as or part of a DRG. Although the first major subdivision within most of the 23 major diagnostic categories (MDCS) of the classification system is "the presence or absence of an

[8] *See* chs. *2* and *6* for further discussion of the DRG hospital payment method,

operating room procedure" (389), the specific type or types of surgical procedures are not explicitly mentioned in most DRGs. Except for a few, such as heart transplantation surgery (DRG 103), coronary bypass (DRGs 106 and ***107),*** and perhaps arthroscopy (DRG 232), the DRGs that describe most surgical procedures, e.g., pelvic procedure (DRG 334), are so general that many different surgical techniques could be used to carry them out (32).

The inability to identify the use of particular technologies under Medicare's DRG hospital payment method does not differ markedly from the situation under Medicare's previous retrospective cost-based hospital payment method. As noted above, inpatient hospital claims forms and MCRs under cost-based reimbursement do not specify the use of individual technologies.

There are, however, several ways under DRG hospital payment to identify uncovered individual technologies that may raise hospitals' costs. For example, outlier cases, cases involving either an extremely long length of stay (LOS outlier) or extraordinarily high costs (cost outlier) when compared to most discharges in the same DRG, will be reviewed in their entirety for noncovered or medically unnecessary or inappropriate days or services (11 **4).** Outlier cases may occur precisely because new *and* costly technologies were used in the care of the patient. If a new technology is not covered, outlier payments will be denied.

New technologies will also be recognized during the process of adjusting DRG rates for all hospitals. **Indeed, updating DRG weights appears to offer the most significant opportunity for identifying new technologies for coverage purposes.** The decision to adjust DRG rates can therefore be considered a quasi-coverage decision itself.

Changes in DRG relative weights or prices will be made, in part, to reflect technological change. Because the DRG rate adjustment process includes identification of new technologies, it is reasonable that some of the techniques, including technology assessments, used in the process will be similar to those used for supporting coverage decisions. Indeed, the Prospective Payment Assessment Commission (ProPAC) has been given broad powers to assess medical technology and the appropriateness of medical practice patterns in developing its recommendations for DRG rates. ProPAC's role is only advisory; HCFA makes the decision concerning the appropriate payment rate for hospital services.

Thus, both the coverage process and the process of adjusting DRG rates share a similar "approval for payment" function. They differ in that a coverage determination focuses on specific technologies, while adjusting DRG payment rates focuses on the larger entity of a diagnostic group, which may include particular technologies. **A** more important difference is that the coverage process rarely considers **costs, while** the **DRG rate adjustment process must include cost as an integral issue. Nonetheless, the technology assessments performed for both processes** may be similar. The potential for duplication is not to be ignored. **The processes seem to be sufficiently similar to warrant coordinated Government effort.**

Whether technologies will be subject to a double review of safety and efficacy for payment purposes will depend on the approach chosen to update DRG rates. Irrespective of approach, it is reasonable to assume that hospitals' adoption of cost-raising technologies will be made evident to HCFA for DRG payment and for coverage determinations, However, some approaches to updating DRG rates, such as through outlier cases, would not surface cost-saving technologies. In addition, specific technologies will not be identified on the DRG hospital claims form, so the use by a hospital of a new, uncovered technology that lowers per case costs will not become known to HCFA through hospital claims review. HCFA intends to rely on physician claims and other sources for information to stimulate the initiation of a technology assessment solely for coverage purposes. As in the past, many technologies may go unnoted.

EVALUATING TECHNOLOGIES FOR COVERAGE DECISIONS

Current Activities[9]

Before arriving at coverage decisions, both Medicare contractors and HCFA's central office have medical technologies evaluated, The evaluations performed for contractors by medical consultants are usually informal and have limited influence on the diffusion of medical technologies. The evaluations performed for HCFA's central office affect the diffusion of technologies nationwide. The primary factors considered in such assessments are safety and effectiveness. **Because cost criteria are not included as factors in assessments for Medicare coverage decisions, expensive technologies are eligible for coverage without regard to cost effectiveness.**

At present, the body that is responsible for evaluating the medical and scientific aspects of medical practice for HCFA is NCHCT's successor, OHTA. OHTA responds to HCFA's simple inquiries about the regulatory and research standing of particular technologies by providing information obtained from the responsible Public Health Service (PHS) agency. It also conducts "full" assessments at the request of HCFA with the objective of providing HCFA with the most current and scientifically valid information on which to base coverage decisions.

The OHTA assessment process follows the process established by NCHCT. OHTA reviews the scientific literature and obtains opinions from experts in the public and private sector and then synthesizes the information it receives.

In conducting its evaluations, OHTA uses numerous sources for information. [10]If the evaluation concerns drugs or certain medical devices, prior evaluations by FDA provide some indications of safety and efficacy; for procedures, however, there is no comparable mechanism. For a drug to be covered under Medicare, FDA approval is required. The *use* of drugs, however, is not usually questioned by HCFA. Drugs are covered for payment when provided in an inpatient setting and their use is not monitored by HCFA; hardly any drugs are covered for payment when provided in an outpatient setting.

OHTA'S evaluations are confounded by definitional problems. The definitions of safety and effectiveness, for example, differ among Government agencies. Thus, FDA considers a medical device to be effective when, on the basis of well-controlled investigations or other valid scientific evidence, the device is shown to have the effect claimed by the manufacturers under the manufacturer's specified conditions of use (21 U.S.C. 260c(3)). On the other hand, HCFA judges the effectiveness of a medical device in terms of its ability to improve health. Thus, some devices **approved** by FDA for marketing purposes are not covered by HCFA for payment (435),

There are other definitional problems. Coverage decisions about technologies of national interest are based on criteria of "general acceptance" and "stage of development. " If a technology is generally accepted by the medical community as being safe and effective ("general acceptance") and is perceived to have moved beyond experimental status to clinical application (reasonable "stage of development"), then it is considered "reasonable and necessary. " However, the terms used in the criteria are not defined precisely.

Applying the criterion of "general acceptance" to a new technology is difficult, because a new technology has usually been used by only a small fraction of the medical community. In such cases, coverage decisions are based on scientific evidence and professional judgment of safety and effectiveness. Yet standards for adequate proof of safety and effectiveness have not been established **(435).**

The criterion of reasonable "stage of development" also creates problems in evaluating a new technology for coverage. Technologies do not progress neatly from research to development to clinical phases but more often are used simultaneously as research and investigational tools and in medical practice (359). The distinction between an experimental and emerging technology may be arbitrary. Some contend, for example, that Medicare reimbursement was approved for kidney

[9]See app. C for a detailed discussion of the Government and private sector assessment activities,

[10]For a discussion of OHTA's method of evaluating medical technology, see app. C.

transplantation when the survival rate was less than it is now for liver transplantation, which is not reimbursed (43).

Following its evaluation, OHTA sends its assessment and a recommendation based on the assessment to HCFA. The recommendation summarizes the evidence and PHS' conclusions about the safety and clinical effectiveness of the technology under review. The assessment is not made public routinely upon its completion; the recommendation is not released until HCFA has made its decision on the issue (58).

For the most part, OHTA has not explicitly considered cost and cost effectiveness in its evaluations, although the Memorandum of Understanding between HCFA and PHS does not preclude this possibility **(410).** ProPAC is given powers to assess the cost effectiveness as well as the safety and efficacy of new and existing medical and surgical procedures, but its primary responsibility is to recommend changes in DRG payment rates. Although ProPAC is specifically mandated to assess medical practice in making its recommendations, it is unknown at this time how extensive its assessment activities will be.

In addition to the Federal Government, the private sector is involved in assessing technologies. Insurers and other organizations use technology assessments for coverage and other determinations (e.g., payment, purchasing, and management decisions). Indeed, the present approach to medical technology assessment is characterized by multiple participants from the public and private sectors and by uncoordinated activities (359). The private and nonprofit sectors have increased their involvement in the past 2 years. However, many OF the assessments that are conducted are limited to specific organizational objectives and have limited value for national policy decisions. Safety and efficacy are usually used in technology assessments; economic, legal, social, and ethical criteria are sometimes used.

Analytic Methods of Comparing Costs and Benefits

Although evaluating the safety and efficacy of medical technology has protected patients from risky, unproven, and ineffective services ***(359),*** the need for evacuation of the economic effects of medical technology is becoming increasingly important as Medicare and health care costs in general continue to escalate.

In theory, the chance of containing Medicare costs through coverage policy would be increased by including not just safety and efficacy criteria but cost and cost-effectiveness criteria **in Medicare coverage decisions.** The general value of formal analytic techniques for comparing costs and benefits, referred to collectively as cost-effectiveness analysis /cost-benefit analysis (CEA/CBA),[11] in decisionmaking about the use of medical technology was addressed in OTA's 1980 report *The Implications of Cost-Effectiveness Analysis of Medical Technology (353).* That report also identified the methodological strengths and weaknesses of the techniques and the potential for initiating or expanding the use of CEA/CBA in reimbursement coverage programs.

CEA/CBA potentially can be more valuable for decisionmaking under a constrained budget, when tradeoffs have to made directly, than when constraints are nonexistent or very indirect (as in most current reimbursement programs). In neither case, however, would CEA/CBA necessarily function as an effective cost-constraining mechanism or tool. Under a budget system, the budget itself would be the constraining mechanism. Under a nonconstrained system, since no direct tradeoffs are required, no direct limit on expenditures is set. Nevertheless, CEA/CBA might change the mix of expenditures ***(353).*** Medicare's DRG hospital payment system, while not a fixed budget, provides more constraints than the previous cost-based reimbursement system.

CEA/CBA can be conducted from a variety of perspectives, including that of the individual, the family, the hospital, the insurer, or society. Many researchers agree that societal perspective is desirable for policy decisions. When private or program benefits or costs differ from social bene-

[11]The main difference between CEA and CBA is the method of valuation of desirable consequences of a decision. In CBA, benefits (e.g., health outcomes) as well as costs are valued in monetary terms. In CEA, benefits are measured in nonmonetary units, such as years of life saved, days of morbidity avoided, or quality-adjusted life-years (which combine mortality and morbidity measures). The reason for a nonmonetary measure of benefits is either the impossibility or undesirability of valuing them in monetary terms.

25-337 O - 84 - 7

fits and costs (and if a private or program perspective is appropriate for the analysis), the differences should be identified (353).

The inherent conceptual and methodological strengths and weaknesses of CEA/CBA are addressed at length in previous OTA reports (353, 359) and later publications (347,420). A methodological issue of particular importance to the Medicare program in performing CEA/CBAs is whether to include discounted future medical care costs (due to longer life spans for patients resulting from the use of a medical technology) as a direct cost of the technology. Extending the life span of patients who are 65 years and older increases the chance that they will become high-cost consumers of medical care. Elderly people are particularly prone to chronic diseases. [12] And, about 80 percent of health care resources in the United States are used for chronic disease ***(321).***

One can argue that future medical care expenditures should be included in an analysis of a technology's influence on medical care costs. Both public and private insurers are interested in how the use of a technology will affect their future expenditures. It is important to recognize, however, that reducing the measured benefits of a technology by the extra medical costs attributed to longer life biases the analysis against the technology. People consume medical care and other goods and services as long as they live. "To reduce benefits by a part or all of the value of this consumption may lead to the erroneous conclusion that prolongation of life is not worthwhile especially when consumption exceeds production" (417).

Another methodological issue that is of special interest to the Medicare program is whether the human capital approach should be used in valuing life in the analysis of a technology. The human capital approach values life in terms of earning potential; health outcomes are valued in terms of the economic productivity they permit (420). Because of its emphasis on economic productivity, the human capital approach values the lives of young people more than the lives of elderly people. The bias of the approach is most explicit in CBA. CEA, however, has built-in value judgments, i.e., once money is allocated to save lives, the value of life is implied. In CBA, the analyst must choose a value to complete the analysis; in CEA, the policymaker chooses the value, albeit indirectly (353).

It is important to bear in mind that CEA/CBA does not necessarily or easily take into account social values, moral judgments, legal implications or political realities. Thus, it does not easily or commonly address issues of equity and distribution.

The power of CEA/CBA is diluted in many instances not only by methodological problems but by a lack of efficacy data on which to base cost-effectiveness calculations. Some of the difficulties associated with these techniques will diminish with time, but others will not. An analysis rarely can account for the vast range of applications of a specific technology and the technology's unpredicted effects. The setting of care, volume of use, and the practice of medicine also influence the cost effectiveness of a technology.

Despite its limitations, CEA/CBA provides an analytical basis for integrating the economic aspects of a decision about medical technology with the health aspects. It can be very helpful in assisting the policy maker in structuring a problem and understanding its ramifications. As Fuchs says, "given the will and the mechanism . , . CEA/CBA offers the most rational human basis for effective, efficient allocation" (129).

Cost-Saving Technology

Definitional Complexities

The technical complexity of determining the cost effects of emerging and new technologies is compounded by the problem of defining a cost-saving or cost-raising technology. Differences in perspective impede arrival at a universal definition of a cost-saving or a cost-raising technology. The disparity in perspective may bring about conflict between parties because of the limited supply of resources for medical care. [13] If resources are

[12] About 1 out of 10 40- to 50-year-old people has a chronic disease; by age 65, approximately 2 people out of 10 have a chronic disease; after 75 years of age, the number increases to 4 out of 10; and by age 90, almost 9 of every 10 people have a chronic disease (164).

[13] "Costs of medical services are the economic resources (e.g., equipment, supplies, professional and nonprofessional labor, and the use of buildings) consumed in the provision of those services *(423).*

used by one party, they are not available for use by another.

The question is: From whose perspective should the cost effects of a technology be examined? Are the cost implications of a technology to be considered from the perspective of the individuals, the hospital, the insurer, one Government program, the entire Government, society as a whole, or others? Each party has its own *view* of the cost effects of a particular technology, because health expenditures affect each differently. A technology that is considered cost saving by one may be considered cost raising by another. An associated question is: Is a cost-saving technology one that saves costs in the present or in the future?

For purposes of this study, a cost-saving technology might best be defined as a technology that saves Medicare program costs. Yet this definition dces not distinguish between Medicare costs and societal costs—a distinction that may be required for policy decisions. Does the definition imply that the development, adoption and use of technologies that save Medicare program costs but raise societal costs should be encouraged or discouraged? One rationale for the Government's role in the health care system is "the promotion of the allocation of resources in the collective interest of the population of patients and potential patients" ***(423).*** Those who act on the belief that "Government agencies that plan and regulate the distribution of medical services may be viewed as agents for society" ***(423)*** would discourage technologies that decrease Medicare program costs but increase societal costs. Those who act on the belief that "Government agencies develop bureaucratic and organizational objectives that may not be consonant with the broader public interest" ***(423)*** would encourage technologies that decrease Medicare costs but increase societal costs.

Developing Criteria for Identifying Cost-Saving Technologies

Considering the difficulties in defining a cost-saving or cost-raising technology, it is not surprising that research on developing criteria to identify cost-saving technologies is in an early stage. One type of technology that can be identified as cost saving is a technology that substitutes exactly or very nearly for another and is also cheaper. The Shouldice method of hernia repair, for example, both substitutes for other methods of repairing hernia and is performed less expensively (166).

On the other hand, while it is generally accepted that the automated clinical chemical analyzer substitutes for previous nonautomated chemical tests, it is not clear whether the automated analyzer is producing more units of a formerly performed service or instead is producing a new type of laboratory analysis. Such distinctions, although often subtle and difficult to identify or measure, are crucial in analyzing the cost implications of technology.

Another problem in developing criteria is that the cost implications of a technology vary with the technology's stage of development: an assessment performed at one time may yield a different result when performed at another time. Technologies change over time. The dosages of a drug may be refined. New generations of devices replace old ones. Surgical procedures are modified. New, unanticipated uses, particularly for diagnostic technologies, are discovered. [14] Thus, the indications for using the technology change and its potential benefits and costs change over time.

Furthermore, the cost implications of a particular technology depend on the setting of care. For example, computerized energy management and bacterial susceptibility testing allegedly save hospital costs, but only if the size of the hospital and its volume are large enough to justify the investment (418), Thus, a technology that saves costs in one hospital may raise costs in another. Because of the variation among hospitals, reports about the cost-saving nature of one or another technology may be only partially accurate and have to be interpreted cautiously.

[14] For example, the computed tomography (CT) scanner, a high capital investment instrument, was thought in the 1970's to increase the per unit cost of services (3), The current notion is that the CT scanner in fact may lower the per unit cost of health services by substituting for expensive, invasive procedures *(420)* If used appropriately, the CT scanner has the potential for decreasing health care costs, but it may increase health care costs when used inappropriately (347).

Attempts have been made to categorize technologies in hopes that distinctions can be made among types of technologies on the basis of expected costs and benefits (283). If all technologies within a category had similar pressures on cost and delivered similar benefits, a coverage policy could be designed using a categorical approach (283). Technologies with a common medical purpose (e.g., therapy) have some characteristics in common, and CEAS are conducted with them in mind. For example, the analysis of a treatment technology considers the effect of the technology on morbidity, disability, and/or mortality. But, it is difficult to identify the cost implications of such characteristics. There are, as well, characteristics not held in common among all technologies in a medical purpose category that may affect costs. **A method that is sufficiently sensitive to predict the cost implications of a particular technology based on its medical purpose category has not yet been developed.**

DISCUSSION

In the past, coverage policy has had important potential, but limited opportunity, to contain Medicare program costs by influencing the diffusion of medical technology. The Medicare provision that a technology must be covered before it can be paid for, however, may have protected beneficiaries from the indiscriminate adoption and use of technology and possibly from some unsafe and ineffective medical technologies.

The deliberate use of Medicare coverage to influence the adoption and use of medical technology, however, has been limited by several factors. These include Section 1801 of the Social Security Act, which prohibits Federal interference in the practice of medicine and the manner in which services are provided; the imprecise phrase "reasonable and necessary" governing the introduction of technology into the Medicare program; the decentralized mechanism for promulgating and implementing Medicare coverage policy; and the wide discretion allowed individual contractors in making coverage decisions.

Inadequacies in the current Medicare coverage process contribute to the circumscribed role of coverage policy in the rational diffusion of appropriate technology (26). The current coverage process does not ensure identification of all important new technologies that are introduced into the Medicare program or those covered technologies whose safety and efficacy has not been proved. Indeed, the universe of new technologies that are introduced into the Medicare program through contractors' coverage decisions is not known. The possibility that some new technologies are not identified but are paid for cannot be ignored. Medicare contractors vary in whether they cover (and then pay for) some particular technologies and in the extent to which they refer technologies to HCFA'S central office for national coverage decisions. The absence of formal, legally binding requirements that contractors comply with national coverage decisions leads to the lack of uniform implementation of such decisions and a disparity in the coverage of technologies across the country.

Tightening the coverage process would no doubt save money for Medicare and would provide for a more rational diffusion of medical technology, It might also ensure equal access to the same technologies by Medicare beneficiaries. With respect to centralization, however, caution is necessary. A nationally controlled coverage process might not take into account the unique needs of all patients and could be administratively expensive. Thus, a decision to reduce variation in coverage policy and increase the explicitness and uniformity of Medicare benefits would require careful judgment and balance. Reconciling a more centralized coverage system with the independent practice of medicine could be a potential political problem.

The current process of evaluating medical technology at the national level may need modification in order to achieve the more rational diffusion of technology. Although the safety and effectiveness of technologies that are brought to the na-

tional level for coverage decisions are evaluated more rigorously there than at the contractor's level, the information available for an evaluation is often limited. The amount and type of data available vary for drugs, devices, and procedures. New drugs are subject to FDA's premarket approval requirements, and data on their safety and efficacy are usually available. For a drug to be considered for coverage, it must have FDA approval. (There is, however, no monitoring of drug use in hospitals.) Medical devices, depending on their classification, are subject to general controls, performance standards, or premarket approval requirements for safety and effectiveness by FDA. '5 However, few clinical trials have been performed on new medical devices submitted for coverage approval. Also, FDA's definition of effectiveness differs from that used for coverage. Analytic data on medical and surgical procedures, which are not subject to FDA regulatory requirements, are even less available than data on medical devices.

The guidelines used by OHTA to evaluate the safety, efficacy, and clinical effectiveness of medical technology stress the value of basing coverage judgments on information derived from controlled clinical trials or other well-designed clinical studies. Unfortunately, there is a dearth of such information—information from clinical trials of any type was available for only 2 of 12 full assessments published by OHTA in 1982 (352). Furthermore, even when such information is available, it often has limited value for coverage purposes. Very few clinical trials are designed to compare competing technologies. Most assess only one technology. Comparing the results of studies is often misleading because patient populations and study designs differ markedly. Few trials use individuals 65 years and older in the study population. Furthermore, few trials deal with questions about indications for use of a technology, and their results are not available soon enough to be included in a coverage decision. The lack of quantitative data is one force behind the statute (Public Law 98-21) that allows HCFA to fund controlled clinical trials of concern to the Medicare program.

Medicare may have further constrained the potential of coverage policy to influence the diffusion of technology by not limiting the coverage of certain technologies to specific providers and specific sites of care and by not explicitly considering costs in coverage decisions. In theory, one way to use coverage policy for containing program costs would be to include cost criteria in the assessment of medical technologies. But it appears that incorporating cost criteria into an assessment does not necessarily lead to the identification of cost-saving technology. Not only is a cost-effective technology not necessarily a cost-saving technology, but many experts contend that the definitional and methodological uncertainties of CEA/CBAs have not been sufficiently resolved for the use of these techniques as allocation tools. These techniques cannot provide decisions but can aid decisionmaking when used in conjunction with other kinds of information (353).

Finally, the relationship between coverage policy and DRG hospital payment needs further exploration. The importance of coverage policy will be only marginally diminished by DRG payment. Furthermore, the newly created ProPAC will assess DRG payment rates in association with the technologies that might be incorporated into those DRGs—an activity that represents the first explicit merging of costs and effectiveness in the Medicare program.

"For more information, see OTA s forthcoming report *Federal Policies and the Medical Devices Industry* (345).