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A PROCEDURE FOR DETERMINING THE GENERAL AVAILABILITY OF NEW OR IMPROVED DIAGNOSTIC TECHNIQUES FOR SOCIAL SECURITY DISABILITY EVALUATION

Report of a Study

Division of Health Promotion and Disease Prevention

Council on Health Care Technology

INSTITUTE OF MEDICINE (U.S.). Committee to Recommend a Process to Determine the General Availability of New or Improved Diagnostic Techniques for Disability Evaluation under Social Security

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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 competencies 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.

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This study was conducted under the auspices of the Council on Health Care Technology of the Institute of Medicine. The council exists to promote the development and application of technology assessment in medicine. This report draws upon an Institute of Medicine report, Assessing Medical Technology, that precedes the council and on the Medical Technology Assessment Directory, a recent publication of the council. The existence of the council and its programs greatly facilitated the conduct of this study.

PREFACE

In 1987, the Social Security Administration (SSA) requested the Institute of Medicine to convene a panel of experts to develop a process for determining the meaning of "generally available" as it applies to a listing of new or improved diagnostic techniques, specifying a means for assigning a date when a technique becomes "generally available," and recommending a mechanism for reviewing and updating the list.

The Institute convened an expert panel, chaired by Robert A. Derzon, whose members were drawn from the fields of medicine, law, medical insurance, technology assessment, economics, and social science to conduct this study. The panel met on November 19-20, 1987, reviewed a detailed set of background materials provided in advance by the SSA, heard representatives of the agency describe the benefit determination and termination processes, and discussed the major issues associated with the updating of a list of new or improved diagnostic techniques as to their general availability.

Based upon the discussion at that meeting, a preliminary report was prepared and circulated to the committee members in advance of a second and final meeting on January 25, 1988. At that time, the committee considered the major unresolved issues and agreed in principle on the conclusions and recommendations that it wished to make. Following the second meeting, a revised report was circulated to committee members and their comments were incorporated into this final report.

This report responds to the SSA's request for advice on a procedure that meets its adjudicatory needs for implementing a provision of the Social Security Amendments of 1984 related to the termination of disability benefits. In doing so, the report emphasizes the need for SSA to use as a

INTRODUCTION

The Social Security Administration (SSA), in the early 1980s, sought to terminate payments to a number of beneficiaries of its disability programs. Congress, reflecting strong adverse judicial and public reaction to this effort, enacted the Social Security Disability Benefits Reform Act of 1984 (P.L. 98-460) and required that the agency establish specific standards of review before terminating a person's benefits.

This study report responds to a request by the SSA for advice in implementing a part of the 1984 statute. Specifically, the SSA requested the assistance of the Institute of Medicine (IOM), in establishing a procedure for listing and updating new or improved diagnostic techniques that may be used in the termination of payments to beneficiaries of its disability programs. The SSA administers social security disability and supplemental security income programs under Titles II and XVI of the Social Security Act, both of which involve essentially identical disability criteria and procedures. Disability is defined by law and regulation as "the inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months."[1]

Eligibility Determination

The determination that a person is disabled involves both the development of medical evidence and an administrative decision that often has adjudicatory characteristics. The initial claim by an individual applicant for disability benefits begins with the development of medical evidence, usually by a treating physician, that shows whether or not the

individual has a specific impairment or combination of impairments and the level of severity of the condition(s). The medical evidence of impairment provides the clinical basis for the administrative determination about whether, and to what degree, the impairment affects the person's ability to work.

An application for disability benefits is filed in a SSA District Office, which helps applicants complete and document their applications, and checks nonmedical eligibility requirements. The District Office also ascertains whether the person is currently engaged in substantial gainful activity (SGA). If so, the person is found ineligible for disability benefits, which in such a case may be denied because the individual is working, notwithstanding the existence of impairments. Otherwise, the case is forwarded to the appropriate state disability agency, which actually makes disability determinations on behalf of the Secretary of Health and Human Services for residents of that state.

The state disability agency often develops further medical evidence, either from the individual's treating physician or from a consulting physician, who may undertake an independent examination of the claimant, paid for by the SSA.* The state agency evaluation first concentrates on medical factors to determine whether the person's impairment is so severe as to preclude SGA. If not, for most claimants, an assessment is made of their

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* Consulting examinations are obtained by the SSA when it wishes to augment the medical evidence in the file of a claimant or beneficiary. The SSA uses a number of physicians across the country on a contract basis. These contract physicians are often specialists in relevant areas of disability-related medicine such as orthopedics, pulmonary medicine, and cardiology. The agency pays for consulting examinations; it may also pay for the reasonable expenses incurred by a claimant or beneficiary, especially when substantial travel is involved.

residual functional capacity (RFC)--that is, what they can still do given the limitations imposed by their impairment. This RFC assessment is used to determine whether the claimants can still do their past work. If not, the RFC assessment, along with a person's age, education, and work experience is used to determine whether he or she can do some other type of work available in the national economy. The state agency makes a determination on each case and forwards it to the SSA for administrative processing.

The SSA administers the cases subsequent to state determinations and establishes from the state determination a date for subsequent review of the disability. SSA also routinely reviews a proportion of the state agency determinations before authorizing payment.

Benefit Continuation or Termination

The clinical and functional status of disability beneficiaries must be reviewed periodically to determine whether they remain eligible for benefits or whether their status has changed so that SSA must find them ineligible to continue to receive benefits. This process is known as the continuing disability review (CDR). It is in connection with this process, and especially with consulting examinations that may be required at this stage of reexamining the case, that the issue with which this report deals first comes into play.

The SSA is required by P.L. 98-460, the Social Security Disability Benefits Reform Act of 1984, to apply a specific standard of review before terminating the disability benefits of an individual.[2] That standard establishes the general criterion that benefits may be terminated only for those beneficiaries who have experienced medical improvement in their impairment and who are found able to perform substantial gainful activity.

However, in the case of the individual for whom the evidence does not meet the general criterion of substantial medical improvement to the extent of a consequent ability to engage in substantial gainful activity, his or her payments may be terminated on the basis of certain stipulated exceptions. There are two groups of exceptions. Group I exceptions are that (1) the beneficiary has benefited from advances in medical or vocational therapy; (2) the beneficiary has undergone vocational therapy; (3) new or improved diagnostic or evaluative techniques show that the person's impairment is not as disabling as determined in the original decision or in the most recent CDR decision; (4) the prior decision (original or CDR) was in error; and (5) the person is currently engaging in substantial gainful activity. Ability to engage in SGA must also be shown for exceptions 1 through 4 to apply.

Group II exceptions, carried over from previous statutory authority, also allow the agency to terminate benefits. These include fraud, failure to cooperate, unknown whereabouts, and failure to follow prescribed treatment. Current ability to engage in SGA does not have to be shown for this group of exceptions to apply.

THE CHARGE TO THE INSTITUTE OF MEDICINE

The third exception of Group I is the subject of this report. It holds that a disability beneficiary can lose benefits if "substantial evidence exists that, as determined on the basis of new or improved diagnostic techniques or evaluations, the individual's impairment or combination of

impairments is not as disabling as it was considered to be at the most recent decision . . . and that, therefore, the individual is able to engage in substantial gainful activity."

It should be noted that the SSA can use the third exception only if the new diagnostic technique became available after the date of the most recent decision, whether initial or CDR. This requirement imposes discipline on the SSA and ensures fairness in the agency's dealings with beneficiaries. (SSA can use such a diagnostic technique for the evaluation of medical improvement and the ability to engage in SGA for benefit termination, however, before the exceptions bases for termination are considered.)

Implementation of this exception requires that the SSA (1) establish a list of "generally available" new or improved diagnostic or evaluative techniques in general use since 1970,* and (2) develop a process for the future identification of new or improved technologies, including an indication of when they are considered "generally available."

The first of these requirements was met with the publication of a list in the Federal Register on May 29, 1986.[3] Regarding the second requirement, the SSA asked the IOM in 1987 to convene a panel of experts to develop a process for determining the meaning of "generally available" as it applies to new or improved diagnostic techniques or procedures, a means for assigning a date to when a technique becomes "generally available," and a mechanism for reviewing and updating the list.

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* The SSA chose 1970 because it expected few, if any, claims to involve evaluation for continuing disability eligibility for periods before that year.

THE LIST OF MAY 29, 1986

The SSA's initial list of "new or improved diagnostic techniques for determining impairment severity" included diagnostic techniques that were new or improved since 1970.[4] It described these techniques, indicated how they would be applied in determining disability, and listed a date when they had become "generally available."

The list was developed by the SSA relatively quickly after consulting its contract physicians engaged in the disability determination process nationwide, querying the Health Care Financing Administration for tests covered by Medicare, and reviewing the medical literature.

In the list, each diagnostic technique is dated by the year in which the SSA judged it had become "generally available." This date controls the agency's ability to employ the test as an exception for CDR purposes. If a new diagnostic technique has become "generally available" since the time of the most recent favorable medical decision, the SSA may potentially use it in the CDR as an exception to the general requirement of medical improvement. If the technique was "generally available" before the most recent favorable decision, however, but was not used for determination purposes in an individual's case at that time, the law bars the SSA from using it for applying the exception at any later time. The technique could, by law, be used in the overall agency evaluation of the claimant's impairment and the determination of whether medical improvement had occurred or not.

The Nature of the Items on the List

The SSA list of diagnostic and evaluative techniques and procedures is organized into body system categories: cardiovascular (12 diagnostic techniques), gastrointestinal (1 diagnostic technique), musculoskeletal (3 diagnostic techniques), ophthalmologic (2 diagnostic techniques), otolaryngologic (3 diagnostic techniques), miscellaneous tests applicable to several body systems (4 diagnostic techniques), and psychological tests (11 diagnostic techniques). The list is heavily weighted toward medical devices (equipment), but also includes psychological tests that are used for diagnostic purposes. This distinction between "hard" and "soft" diagnostic techniques runs throughout this report, with various implications that are spelled out at the appropriate juncture.

DIAGNOSTIC TECHNIQUES AND THE DETERMINATION OF DISABILITY

Diagnostic Techniques in Medicine

Diagnostic techniques in medicine are developed to characterize disease, illness, injury, or impairment. They emerge continuously as the result of interaction between scientific and technical advances, on the one hand, and clinical problems and opportunities on the other.

The evaluation of new diagnostic techniques has typically focused on the safety and validity of particular tests. Some attention has also been given to the outcome of testing as measured in clinical trials. The conceptual bases for the assessment of diagnostic techniques, however, have developed beyond the narrow questions of safety, technical capacity, and diagnostic accuracy in recent years to encompass the effect that diagnosis

has on therapeutic intervention and patient outcome.[5] A recent report from the IOM suggests that the evaluation of diagnostic tests should include an assessment of the diagnostic information they provide and the impact of the resulting information on patient outcome.[6] This report cites Fineberg et al.[7] regarding the elements of a comprehensive evaluation of diagnostic technologies:

1. Technical capacity--Does the device or procedure perform reliably and deliver accurate information?

2. Diagnostic accuracy--Does the test contribute to making an accurate diagnosis?

3. Diagnostic impact--Does the test result influence the pattern of subsequent diagnostic testing? Does it replace any other diagnostic test(s) or procedure(s)?

4. Therapeutic impact--Does the test result influence the selection and delivery of therapy? Is more appropriate therapy used after application of the diagnostic test than would be used if the test were not available?

5. Patient outcome--Does performance of the test contribute to the maintenance or improvement of the health of the patient?

The IOM report acknowledges that relatively few new diagnostic tests or procedures are evaluated thoroughly. Most evaluations are restricted to questions of technical capacity and diagnostic accuracy, sometimes addressing diagnostic impact. Therapeutic impact and patient outcome are seldom evaluated, nor are they always recognized as legitimate criteria for inclusion in the assessment of diagnostic techniques.

Nevertheless, the concept of a more comprehensive evaluation is gaining important followers. The American College of Physicians, in a project

supported by the Blue Cross and Blue Shield Association, published a manual in 1987 entitled Common Diagnostic Tests, which analyzed 16 routinely administered tests for their usefulness in affecting patient management and patient outcomes.[8] In addition, a recent, literature-based assessment of magnetic resonance imaging by the American College of Physicians explicitly examined the indications for magnetic resonance imaging in terms of the information provided for therapeutic intervention and patient outcome.[9]

The Central Problem of Disability Determination

Most diagnostic techniques used in the disability determination process were first developed for clinical medicine. Few were explicitly developed to relate the diagnosis of impairment to an individual's residual functional ability to work. Nevertheless, the central problem of disability determination and review lies in relating the medical diagnosis of impairment and its severity to a judgment that the individual's residual functional capacity to work is reduced to a degree that is or is not disabling.

The assessment of diagnostic techniques in medicine pertains to the problem facing the SSA. Should new diagnostic techniques be evaluated for their technical ability to diagnose impairments or for their utility in providing information about the relation between impairment and functional ability to work? In the judgment of the committee, new evaluative techniques should be assessed for their ability to fulfill both purposes.

The Rationale for the List

The criteria for listing new or improved diagnostic and evaluative techniques and procedures and for updating the list, in the committee's view, should be that items on the list improve SSA's ability to establish

the extent and severity of physical or mental impairments and make judgments about their expected duration. The improved ability to diagnose impairments in and of itself may be quite important, for example, for individuals with multiple sclerosis, but it may or may not increase the ability to make a disability determination in other cases.

On the other hand, the information derived from a new or improved diagnostic technique may warrant its listing even though the test yields little additional benefit in making disability determinations. For example, a new diagnostic technique may be listed because it provides comparable or better information than existing techniques, but does so in a way that benefits the patient (it may be less invasive than existing techniques) and, therefore, may be used more often.

In the main, however, the committee believes that the SSA should add new diagnostic techniques to its list because they are judged by experts to yield information that improves the determination of disability. As a corollary, the committee wishes to underscore a principle already recognized by SSA policies--that diagnostic tests that are invasive, painful, or substantially risky to the applicant should not be required, even if they might offer better information about impairment or functional capacity, and regardless of their general availability or acceptance in medical practice.

THE CONCEPT OF "GENERALLY AVAILABLE"

The term "generally available" was first used in the SSA's 1986 regulations. The legislative history of the 1984 statute does not refer to this concept. SSA introduced the term to establish a standard that would

assure a reasonable degree of national uniformity for relating new diagnostic techniques to the CDR process. The SSA defined it in its regulations in the following manner:

> By "generally available," we mean a technique is no longer experimental or available only at centers of medical learning and research. Rather, the technique (with appropriate equipment) has become "generally available" to the appropriate practitioners throughout the country and the technique results are accepted by the medical community.

The task confronting the IOM committee, therefore, was to develop the concept of "generally available in a manner consistent with the intent of the law, the rights of disability beneficiaries and claimants, and the agency's need to promulgate a list of new or improved diagnostic or evaluative techniques in light of the concept. The following discussion attempts to lay out the conceptual underpinnings of the term.

General Administrative Principle

The SSA is experienced in the administration of disability income programs. Its institutional competence, however, does not lie in the assessment of new medical diagnostic technology. Organizations that administer medical benefits programs, as a rule, have more competence in assessing new medical diagnostic technology.

Consequently, the committee concluded that the SSA, to the extent feasible, should seek justifiable ways to rely upon other agencies that have greater institutional responsibility for, experience with, and competence in reaching certain basic decisions. Therefore, it should not seek to duplicate the decision-making processes of medical benefits agencies like the Health Care Financing Administration in assessing medical diagnostic

techniques or in compiling and updating a list of new or improved diagnostic and evaluative techniques and procedures.

In particular, judgments about the basic criteria of safety, efficacy, and effectiveness of new diagnostic technologies should be based upon the work of other organizations to the extent feasible. What do these terms mean? For purposes of this study, the committee uses the following definitions:*

Safety: a judgment that the risks of a given diagnostic technique are sufficiently reasonable to warrant its use for the prescribed purpose of the test.**

Efficacy: a judgment about the benefit of a given procedure for a particular medical problem under ideal conditions of use.

Effectiveness: a judgment about the benefit of a procedure for a given particular problem under average or normal conditions of use.

Safety and Efficacy

Safety and efficacy should be regarded as basic criteria in the listing of new or improved diagnostic techniques and procedures by SSA. For those diagnostic techniques that are reviewed by the Food and Drug Administration (FDA) for safety and efficacy before they may be introduced into clinical practice, no consideration should be given by SSA to listing them until an affirmative FDA decision has been publicly announced. Also, the SSA should not consider for listing those diagnostic techniques that have been rejected

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* The committee drew upon Assessing Medical Technologies in this effort, modifying that volume's definitions as appropriate to suit the needs of SSA.

** The FDA determination of safety, which is more restrictive, involves a judgment that the benefit of a drug or medical device in a specified situation exceeds its risk sufficiently to warrant its use for that purpose.

by the FDA as unsafe or ineffective. The FDA defines efficacy narrowly, often restricting the meaning to what the manufacturer claims that the drug or device in question does under optimal conditions. Frequently, the manufacturer's claims do not extend beyond the "technical capacity" criterion discussed above.

Not all diagnostic techniques and procedures listed by the SSA for the diagnosis of impairment and determination of disability are reviewed by the FDA for safety and efficacy. In particular, psychological tests are not reviewed by the FDA. In those cases, when the SSA considers listing new diagnostic techniques in this category, it should make every effort to determine that the test is safe and efficacious. The SSA should seek to identify public and private agencies that do make such determinations and systematically take their judgments into account under these circumstances.

It should be noted that the above recommendation pertains to what the SSA decides to include in the list of diagnostic techniques. Regardless of formal definitions of safety and effectiveness, the agency may use any information introduced into a patient's record by a treating physician.

Effectiveness

No federal government agency makes determinations of medical effectiveness for diagnostic and therapeutic procedures in the way that the FDA determines safety and efficacy. The closest approximation to such judgments are the decisions by third-party payers to cover and reimburse for a given procedure. Traditionally, these decisions have been predicated on the contention that a procedure meets one of the two criteria of "no longer experimental" or "medically necessary." However, public and private coverage decision making is becoming more rigorous with respect to

assessments of effectiveness as a basis for favorable decisions.

National coverage determinations by the Health Care Financing Administration (HCFA) for Medicare should be reviewed by the SSA in deciding whether to consider a particular new diagnostic technique or procedure for inclusion on its list. The evidence supporting a Medicare coverage decision should be reviewed for its relevance to the SSA situation. It may also be appropriate for the SSA to ask HCFA to query Medicare carriers and intermediaries regarding their coverage of a particular diagnostic procedure, because many Medicare coverage decisions are made by these entities on a decentralized basis.

Medicare national coverage decisions should be given serious consideration by the SSA, because such decisions are likely to have been made after an effort to assess the medical evidence about effectiveness. Decisions by carriers and intermediaries should be scrutinized more closely because they may not be supported by the same degree of rigor. Favorable Medicare coverage decisions, then, should be seriously considered but not regarded as an automatic basis for the SSA's decision. The SSA may still wish to reserve for itself the determination of a test's utility for illuminating the assessment of functional ability to work as distinct from its use in diagnosing a particular chronic abnormality. On the other hand, an explicit judgment by HCFA that a technique remains experimental, and thus will not be covered by Medicare, should be a basis for SSA to refuse to consider such a technique as a candidate for the list.

Private third-party payers, both Blue Cross plans and commercial health insurers, as well as medical specialty societies, often approve a procedure for coverage before HCFA. Favorable coverage decisions on a diagnostic

procedure by Blue Cross and Blue Shield plans, or advice on coverage issues by the Blue Cross and Blue Shield Association, should be closely studied by the SSA. In particular, decisions of the major plans should be given consideration because the beneficiaries of such plans are more likely to represent the working age population of the country and be more similar to the disability beneficiary population of SSA than to the elderly patient population of Medicare.

Similarly, SSA should also consult with the Health Insurance Association of America, relative to commercial health insurers, and the Group Health Association of America (GHAA), for health maintenance organizations. The major health insurance companies, including Aetna, Prudential, Travelers, Metropolitan Life, Equitable, CIGNA, and several others, might be systematically surveyed. The major health maintenance organizations -- the Kaiser plans, Harvard Community Health Plan, Group Health Cooperative of Puget Sound, and others identified by the GHAA, might also be surveyed.

Accessibility

At the heart of the concept of "generally available" is the idea that new diagnostic or evaluative techniques should be accessible to beneficiaries under normal circumstances, including those when the SSA requests a consulting examination as part of the CDR. This idea raises the question of whether a geographic criterion should be stipulated in the definition of "generally available." It also suggests other factors that could affect the definition.

For the most part, new or improved diagnostic and evaluative techniques will be introduced mainly for use in the medical care system in the

diagnosis and treatment of acute illness. The primary clinical market for their use will seldom be the diagnosis of impairments or assessment of functional ability to work within the disability system. Such techniques will frequently diffuse widely in medicine well in advance of their use for diagnosis of impairments and determination of disability. In short, the candidates for the list of "new or improved" diagnostic techniques for the SSA disability system may become "generally available" in medicine--that is, accepted by the appropriate medical practitioners--long before they are suggested for inclusion on the disability list.

Many factors are involved in a determination of whether a technique is "generally available" for disability listing, including geographic distribution of population, location of diagnostic facilities relative to population, and availability of the technique in major medical centers and to the appropriate physicians. Because no single, a priori criterion for interpretation of the term "generally available" exists, the SSA will probably be unable to make consistent applications of the rule. In arriving at its determinations, therefore, the SSA should strike a reasonable balance among these various factors as they affect particular situations.

For example, there have been efforts within the medical care establishment from time to time to constrain the diffusion of new technologies. The rationale for such efforts usually is to dampen the cost impacts of an expensive new procedure or to limit its use to qualified centers or professionals. The effort to limit diffusion began in the late 1970s as health planning agencies sought, unsuccessfully in the main, to restrict the diffusion of CT scanners. More recently, some states have attempted to constrain the number of magnetic resonance imaging sites to

some relationship to population. In other words, constraints on the diffusion of new diagnostic technology imposed by federal, state and private agencies may limit the availability of a given technique to academic medical centers. In such cases, the SSA should adopt a more flexible interpretation of "generally available" than it would otherwise.

It can be expected that third-party payers will make further efforts to introduce "selective coverage,"* especially when they confront expensive medical technologies whose application may affect only a small number of prospective patients. In cases in which selective or limited coverage of diagnostic technologies is established by the medical care system, the SSA should acknowledge this in making a determination of "generally available." The selective or provisional limitation to academic medical centers of a diagnostic technique by other health institutions should not be presumptive grounds for SSA to declare that a procedure is not "generally available." On the other hand, a procedure with such limited availability should be put on the list only if it provides significant information about functional capacity that is otherwise unavailable from existing diagnostic techniques.

UPDATING THE LIST

The committee discussed the various factors that should be taken into account by the SSA in updating the list for the next and subsequent occasions of its publication. First, the SSA should update the list of new or improved diagnostic techniques that are "generally available" on an

* Selective coverage limits reimbursement for a procedure on the basis of its being performed by centers meeting specified criteria or by professionals having specified training and experience.

annual basis. An annual announcement of SSA additions and deletions to the list would reduce the need to arbitrarily assign a date to when procedures become "generally available." Under this recommended procedure, the date is determined by the regular agency determination. This implies a process involving standing committees that meet annually, a matter discussed below.

Second, the listing of new or improved diagnostic techniques and procedures should focus mainly on those techniques that generate information about impairments and improve the agency's ability to make determinations about an individual's functional ability to work. Consideration should be given to those techniques that provide only increased diagnostic information but these should not be the primary concern of the SSA.

Third, if ethical considerations limit the use of particular diagnostic procedures by the SSA in consulting examinations, the considerations should be stated in general terms in the introduction to the list and in specific terms for particular techniques or procedures. These limitations apply only to information generated by the SSA in ordering consulting examinations, not to the use by the agency of evidence provided by the treating physician.

Fourth, if a diagnostic technique is not used in the initial review of a disability applicant or in the first CDR of that applicant after the technique is listed, it may not be used to show exception to the standard for benefits termination. (SSA can, however, use such a diagnostic technique to evaluate medical improvement and the ability to engage in SGA for purposes of considering benefit termination before the exceptions bases for termination are considered.) Consequently, once the agency lists a diagnostic technique or procedure, it should encourage its subsequent use in both initial reviews and CDRs. If the technique generates information that

tells the agency about an individual's functional ability to work, SSA may wish to encourage its use in ordering consulting examinations.

Fifth, in compiling a list of new or improved diagnostic techniques and procedures for updating the list, the SSA should canvass broadly for candidates and should consult widely with appropriate organizations. Most of these techniques will be identified by individuals and organizations in the medical care system. The SSA should then narrow the number of candidate techniques for inclusion on the list to those that relate to the determination of functional ability to work.

The IOM's recently published Medical Technology Assessment Directory will facilitate the identification of the appropriate organizations.[10] Regarding cardiovascular diagnostic procedures, for example, SSA should consult, among others, the American College of Cardiology-American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Procedures, the American College of Physicians Clinical Efficacy Assessment Project, and the Blue Cross and Blue Shield Association Technology Evaluation and Coverage Program. For gastrointestinal diagnostic procedures, the SSA should consult, among others, the American College of Gastroenterology, the American Gastroenterological Association's Patient Care Committee, the American Society for Gastrointestinal Endoscopy's Committee on Technology Assessment, the American College of Physicians, and the Blue Cross and Blue Shield Association. In general, among other organizations, the SSA should consult the American Academy of Physical Medicine and Rehabilitation. Many other organizations appropriate for consultative purposes can be identified in the directory.

The Medical Technology Assessment Directory applies to medical

technology defined as equipment or procedure. Psychological diagnostic procedures are not included. For assessment purposes, the SSA should consult, among others, the American Psychological Association and the American Psychiatric Association. For some diagnostic techniques, the SSA should consult the American Academy of Neurology.

Sixth, in compiling information about candidate technologies for inclusion on the list, the SSA should consult widely with appropriate organizations, in addition to calling upon expert committees. It should routinely ask specific organizations for their documented views about new or improved diagnostic techniques. Over time, such a process would sensitize these agencies, many of which are likely to be part of the medical care system, to the particular problems of diagnosing impairments and determining disability. Assistance in the identification of data sources can be obtained from the Medical Technology Assessment Directory.

Seventh, SSA should consider the establishment of standing advisory committees to help it update the list. A framework for such an approach has been established in the advisory committees convened to update the list of impairments used by the SSA, although these particular committees are one-time-only bodies and not continuing entities. The suggested standing advisory committees should meet once a year and be organized primarily by major organ systems (e.g., cardiovascular, respiratory, musculoskeletal, and psychological impairments). These advisory committees should have the flexibility and resources to recommend a mini-consensus meeting of specialists to review the evidence about a given procedure or technique in cases in which the committee is divided or lacks the expertise to arrive at a recommendation.

In making this recommendation, the IOM study committee recognized that the SSA's response to the need to update the list should be related to the volume of new or improved diagnostic techniques that needed to be considered and to agency resources. Given these constraints, the committee believed that an annual review could be well served by the recommended system of advisory committees.

Eighth, the SSA should establish a standing advisory committee specifically to work on improving the methods and measures for determining the relationship between diagnosis of impairment and a person's functional ability to work. Such a group should draw upon the expertise of the organ system committees and augment it by the inclusion of individuals with strong methodological skills and from rehabilitation medicine. The SSA should also consider a mechanism for the integration of the work of the several committees, because new diagnostic techniques often apply across organ systems.

Ninth, the SSA should consider a modest but continuing program of research to support the work of the recommended standing committees. This program should address the following kinds of issues: the methods and measures of functional ability to work; the design of protocols for testing the validity of specific diagnostic techniques; and the adequacy of the data base on which the SSA makes its determinations.

Finally, it should be noted that the above recommendations are generally consistent with the recommendations of the IOM's report on Pain and Disability, especially those dealing with data collection, demonstration projects, and epidemiological, clinical, health services, and methodological research.[11] The recommendations of this report, moreover, are also

consistent with those of the Department of Health and Human Services' Pain Commission.[12]

NOTES

1. Social Security Regulations: Rules for Determining Disability and Blindness, Including Regulations No. 4, Subpart P (Title II) and Regulations No. 16, Subpart I (Title XVI), U.S. Department of Health and Human Services, Social Security Administration, Office of Disability, SSA Pub. No. 64-014, April 1986, p. 6.

2. 50 Federal Register 50118, December 6, 1985.

3. 51 Federal Register 19413, May 29, 1986.

4. 51 Federal Register 19413, May 29, 1986.

5. See M. S. Thompson, A. B. Cohen, and E. E. Fortess, "Evaluation of Diagnostic Procedures: A Review of the Issues," Evaluation and Program Planning, Vol. 4, 1981, pp. 385-396.

6. Institute of Medicine, Assessing Medical Technologies, Washington, D.C.: National Academy Press, 1985, pp. 80-89.

7. H. V. Fineberg, R. Bauman, and M. Sosman, "Computerized Cranial Tomography: Effect on Diagnostic and Therapeutic Plans," Journal of the American Medical Association, Vol. 238, 1977, pp. 224-230.

8. H. M. Sox, Jr., ed., Common Diagnostic Tests: Use and Interpretation, Philadelphia: American College of Physicians, 1986.

9. D. L. Kent and E. B. Larson, "Magnetic Resonance Imaging of the Brain and Spine: Is Clinical Efficacy Established After the First Decade?, Annals of Internal Medicine, Vol. 108, No. 3, March 1988, pp. 402-24; see also pp. 474-76 for the statement of the Health and Public Policy Committee, American College of Physicians, "Magnetic Resonance Imaging of the Brain and Spine."

10. Institute of Medicine, Medical Technology Assessment Directory, Washington, D.C.: National Academy Press, 1988.

11. Institute of Medicine, Pain and Disability: Clinical, Behavioral, and Public Policy Perspectives, Washington, D.C.: National Academy Press, 1987.

12. U.S. Department of Health and Human Services, Report of the Commission on the Evaluation of Pain, Washington, D.C.: Government Printing Office, 1987.