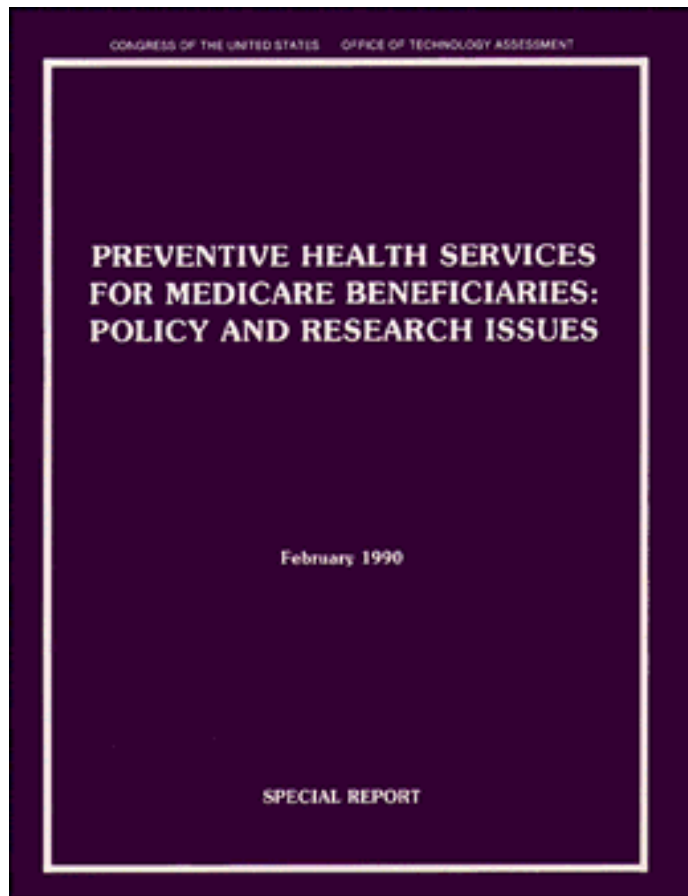


*Preventive Health Services for Medicare
Beneficiaries: Policy and Research Issues*

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Foreword

Interest in health promotion and disease prevention strategies for elderly people has grown in the past ten years, in part because of the need to find ways to moderate the rising costs of health care in this rapidly growing segment of the population. Reflecting this interest, the House Committee on Ways and Means requested that OTA analyze the effectiveness and costs of providing selected preventive health services to the elderly under the Medicare program. The Senate Labor and Human Resources Committee had earlier requested that OTA provide information on the value of preventive services for the American people. OTA responded with a study of the effectiveness and costs of four specific preventive services for the elderly: glaucoma screening; cholesterol screening; cervical cancer screening; and colorectal cancer screening. Background papers on each of these services are now or will soon be available. As mother part of the assessment, OTA prepared a staff paper on the factors affecting older people's use of preventive services, with particular emphasis on how insurance coverage could be expected to alter such patterns of use.

This Special Report analyzes policy and research issues raised in considering Medicare coverage of preventive services. OTA examines how decisions are currently made about coverage of specific preventive services under Medicare and lays out options for altering the process and criteria governing those decisions. The Special Report also reviews and critiques ongoing demonstration projects and summarizes the results of OTA studies of the costs and effectiveness of specific preventive services for the elderly.

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Medicare is prohibited by law from offering benefits for preventive services except when they are specifically added to the scope of covered benefits through amendments to the Medicare act. So far, vaccines for pneumococcal pneumonia and Hepatitis B and screening Pap smears are the only preventive services covered by Medicare. The wisdom of this blanket exclusion with legislated exceptions has been questioned by many experts.

How should decisions be made about Medicare coverage of preventive services? This question has two components:

- . What criteria should govern the decision-making process?
- . Where should the responsibility for such decisions lie?

CRITERIA FOR INCLUDING PREVENTIVE SERVICES AS COVERED BENEFITS

Because they have traditionally been excluded from insurance benefit packages, preventive services have been held to a burden of proof of effectiveness or cost-effectiveness that exceeds that required for diagnostic and therapeutic procedures.

Third-party payers, including Medicare, generally accept diagnostic or therapeutic services as “reasonable and necessary” unless obvious abuse is encountered. In contrast, for preventive services to be included in a benefit package, evidence must exist that they are at least effective, and sometimes that their medical benefits are worth their costs. This standard may seem unduly harsh, and proponents of preventive services often argue that it is unfair to hold preventive services to a higher standard than that required for other medical services. Two powerful arguments favor a tough standard for preventive services, however. First, like all services, preventive services involve potential risks as well as potential benefit. However, unlike diagnostic and therapeutic services, which are rendered in response to patient complaints or symptoms, preventive services are offered to ostensibly healthy individuals and therefore involve an implied promise that they will improve the patient’s health. Second, the more appropriate response to the double standard may be to raise the level of evidence required for diagnostic

and therapeutic services, not to lower that for preventive services. That one genie is out of the bottle is no justification for letting others out, too.

Even accepting that the decision to include preventive services as an insured benefit requires explicit evidence, criteria must be selected to govern the coverage decision and the standards of validity required of the evidence that does exist. Possible criteria include:

- effectiveness of the intervention in prolonging life or improving its quality,
- cost-effectiveness of the intervention in achieving given levels of health effects at the lowest possible cost, and
- impact of the intervention on net Medicare outlays.

The notion that a preventive health service should be effective is widely accepted by health care providers and policymakers. There is less agreement about whether the cost of such services should be considered in either coverage or clinical decisions. The U.S. Preventive Services Task Force, convened in 1984 to develop guidelines for preventive services, adopted stringent standards of effectiveness but explicitly rejected cost-effectiveness as a criterion for their task in judging these services. In fact, no professional group in the United States making recommendations on preventive services for the elderly has explicitly accepted cost-effectiveness as a criterion for making such judgments.

Using the net impact on Medicare expenditures as the criterion for coverage is unduly stringent, because it assumes that if a preventive intervention costs Medicare money, it is not worth it, regardless of whatever health benefits it provides. A highly effective preventive service could also fail the test of being cost-saving to Medicare if by prolonging life it induces additional future Medicare expenditures for unrelated illnesses.

Even specifying a criterion for decisions leaves a great deal of potential for differing judgments. Evidence on the effectiveness of preventive services is often poor and conflicting. Little effectiveness research has been conducted in elderly populations, and the validity of applying findings generated from studies of other populations to the elderly population is questionable. The Medicare Preventive Services

Demonstration Projects currently underway will not add much to the information base on the effectiveness or cost-effectiveness of these services, although they will tell a great deal about how elderly people respond to financial incentives to use such services. To collect adequate data on effectiveness of preventive services in the elderly would take many years and many millions of dollars.

Those responsible for the decision of whether to make preventive services a Medicare benefit will be taking risks either way. On the one hand, including these benefits in the Medicare package could increase Medicare outlays without appreciably reducing older people's mortality, morbidity, or disability. On the other hand, if preventive services continue to be excluded from Medicare payment, real opportunities for better health or savings in health care costs could be lost for years to come.

LOCUS OF RESPONSIBILITY FOR COVERAGE DECISIONS

Responsibility for expanding Medicare to cover preventive services currently resides with Congress. To date, such expansions have been limited to specific procedures, but Congress could authorize the Health Care Financing Administration (HCFA) to offer an "appropriate" package of preventive services to elderly Medicare beneficiaries. Authorizing legislation could include criteria for assessing the "appropriateness" of such services. For example, Congress could direct HCFA to consider the cost-effectiveness of alternative packages in its implementation of regulations.

Vesting HCFA with the authority to decide about specific packages of services would probably increase the flexibility of the Medicare program to respond to new evidence on effectiveness or cost-effectiveness as it arises. By removing specific coverage decisions from the legislative process, preventive services would not have to compete for approval directly with other uses of the Federal health budget. However, if the authority for cover-

age decisions is vested in HCFA, the resulting package of services offered to the elderly would be unpredictable. As was noted just above, conclusions about the health and cost consequences of specific preventive services depend in poorly understood ways on the composition of the recommending groups and the criteria and standards used to judge the evidence. Even directing HCFA to use cost-effectiveness as a criterion for coverage decisions would leave a great deal of uncertainty about how the available evidence would be assessed. A process administered by HCFA, however, might be no more unpredictable than the current legislative process and would still be subject to oversight by Congress.

RESEARCH PRIORITIES

The Health Care Financing Administration is currently supporting six Medicare demonstration projects that offer preventive health services to Medicare beneficiaries. Although these projects are unlikely to provide much additional evidence on effectiveness, opportunities do exist for obtaining some effectiveness data at relatively low additional cost if extended follow-up studies are funded at selected demonstration sites where participation rates have been high. Since all but one of these demonstrations were congressionally mandated, extending their length might require an amendment to the legislation.

Because effectiveness research is costly, it should be targeted to services that offer the potential for large impacts on health status or health care costs of the elderly. Research to clarify the appropriate components of and target populations for comprehensive geriatric assessments has been recommended by a National Institute of Health consensus conference panel (65). Because the costs of institutional care for the disabled elderly are high, these tertiary preventive health services are a promising subject for effectiveness and cost-effectiveness research.

Chapter 2

Introduction

As the primary source of health insurance for the Nation's 31 million elderly people, Medicare provides access to a wide range of health services for diagnosis, therapy, and rehabilitation. Medicare is prohibited by law from offering benefits for preventive services except for a small number that have been added to the scope of covered benefits through amendments to the Medicare Act. * When compelling evidence has accumulated about the health benefits or savings in health care costs achievable from specific preventive services, Congress has legislated expansions of the Medicare benefit. So far, vaccines for pneumococcal pneumonia and hepatitis B and, most recently, screening mammography² and Pap smears are the only preventive services covered by Medicare.

In recent years, the wisdom of this blanket exclusion of preventive services has been questioned by numerous experts and interested groups (5,12,13,22,40,90,96). Interest in health promotion and disease prevention for the elderly has grown as the U.S. population has aged. The high cost of providing acute and chronic health care has led researchers to search for ways to prevent or delay the need for those services. The obligation of Medicare to pay for the consequences of *not* preventing episodes of illness or disability, at the same time that it does not pay for interventions that might prevent such episodes, seems to be shortsighted. Sometimes the investment in preventive services can actually save Medicare program costs.³ Even when prevention does not save money for Medicare, it may improve the health of Medicare beneficiaries or save health care costs for other payers enough to justify the added costs.⁴

Congress has actively considered proposals to expand Medicare benefits for health promotion or preventive services. In the past 2 years, numerous proposals were made to expand coverage for such services as Pap smears, fecal occult blood testing,

and cholesterol testing. Indirect expansions of benefits have also been proposed. For example, S.358 (99th Cong.) would have raised the Medicare Part B deductible but would have allowed the cost of disease screening, immunizations, and anti-hypertension drugs to count towards that deductible. Another proposal considered for the Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360) would have allowed a long list of preventive services to count against the catastrophic deductible limit. One proposal (S. 357, 99th Cong.) would have lowered the Part B premium for nonsmokers by \$1 per month. The House considered a proposal (HR 1402) that would allow beneficiaries to purchase through Medicare a supplemental insurance option to cover the cost of an annual preventive health physician visit.

In the absence of reliable information about the health and financial consequences of such proposals, Congress has moved cautiously. Except for covering the two vaccines, Pap smears and, for a time, mammography, legislation has been limited to establishing demonstration projects to study the effects of offering packages of preventive health services to Medicare beneficiaries (Public Law 99-272) and a demonstration of the effectiveness of offering the influenza vaccine as a covered benefit (Public Law 100-203). As part of its effort to obtain information on the consequences of expanding Medicare benefits for preventive services, the House Committee on Ways and Means asked the Office of Technology Assessment (OTA) to study the effectiveness and cost of selected preventive services for the elderly. OTA selected four screening services for study: glaucoma screening; cholesterol screening; colorectal cancer screening; and cervical cancer screening. Separate papers on each of these technologies have been or soon will be released. A staff paper has also been prepared on preventive services

¹Medicare will pay for "reasonable and necessary" medical and other health services offered by certified providers if they are diagnostic, therapeutic, surgical, consultative, or rehabilitative. Some experts define preventive services broadly to include some therapies and rehabilitation. Medicare's stricture against payment for preventive services pertains to those services not offered in direct response to patient complaints, symptoms, or clinical signs.

²Screening mammography was briefly slated to become a covered benefit, but because it was enacted as part of the Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360), the benefit was repealed with the other provisions of that law late in 1989.

³For example, a 1979 OTA study of pneumococcal pneumonia vaccine in the elderly concluded that, under certain assumptions, the cost of the vaccine would be more than made up for by savings to the Medicare program (86,88).

⁴For example, a biannual mammography screening is not likely to save Medicare costs but has the potential to detect early breast cancers and prolong the life of Medicare beneficiaries (89).

utilization by the elderly. (See app. B for a brief summary of each of these papers.)

This Special Report is also part of OTA's study of preventive services for the elderly. Its purpose is to examine the strengths and weaknesses of the Medicare program as a vehicle for funding the delivery of preventive services to the elderly. Chapter 3 contains a general description of the range of preventive services that are possibly useful to the elderly. This section is not intended to evaluate the effectiveness of such services; rather, it will focus on the major health problems of the elderly and the kinds of preventive interventions that have been suggested to deal with those problems. Chapter 4 describes the elements of the Medicare program that influence the

receipt of effective and efficient preventive services by the elderly. Chapter 5 discusses issues that arise in evaluating the effectiveness and cost-effectiveness of offering preventive services to the elderly under Medicare. Chapter 6 concludes with a discussion of research priorities.

As supplementary material, this report also contains: abstracts of OTA studies of the costs and effectiveness of preventive services for the elderly (see app. B); a review and critique of the Medicare Preventive Services Demonstration Projects mandated by Congress in 1986 (Public Law 99-509) and currently underway (see app. C); and a compendium of recommendations by expert groups for preventive services for elderly people (see app. D).

Defining Preventive Service for the Elderly

Although prevention encompasses a wide variety of actions by individuals or organizations whose goal is to improve health, the term “preventive services” refers here to a narrower set of interventions comprising medical procedures, tests, or visits with health care providers that are undertaken for the purpose of promoting health, not for responding to patient signs, symptoms, or complaints. Preventive services in this report are interactions between elderly people and health care providers, not interventions such as education through the mass media, seat-belt safety laws, etc.

A distinction is also necessary between preventive services and individual preventive behavior. For example, elderly people who quit smoking are engaging in an exceedingly effective preventive behavior (41,49), but the behavior is not a preventive *service*. A smoking cessation program or counseling would constitute a preventive service as defined here. This distinction is important, because different kinds of services designed to bring about the same change in behavior may vary widely in effectiveness and costs. Medicare would pay for the service, not for the change in behavior; hence, Medicare’s interest is not only in the effectiveness of the change in behavior on health outcomes, but also in the effectiveness and costs of the service whose purpose is to bring about the change in behavior. In the case of smoking cessation for example, the effectiveness of smoking cessation counseling by physicians appears to vary widely across population groups and counseling techniques (17,20,52,53,84,1 00).¹ Advocates of increased Medicare support for preventive services often fail to distinguish between the effectiveness of behavior change and the effectiveness of services in citing evidence to support their views (13).

Preventive services have been described by two general frameworks. The traditional approach, used by most experts, classifies preventive services according to their ultimate goal (48,55):

- . *Primary preventive services* **are** intended to prevent or delay the onset of disease. Immunizations and counseling on lifestyle changes are classic examples of primary prevention.

- *Secondary preventive services* are efforts to detect a disease or condition before it is clinically recognizable to avoid or delay its further progression. Screening procedures, such as mammography or Pap smears, fall into this category.
- *Tertiary preventive services* attempt to reduce the impact of already existing disease on the quality of a person’s life by maintaining or improving his or her ability to function. These would include services such as education for diabetic patients or rehabilitation for stroke victims.

Health insurers, including Medicare, typically pay providers for undertaking defined activities, not for accomplishing goals. Many services whose goal is tertiary prevention are currently covered under Medicare as therapeutic or rehabilitative services. An alternative typology, shown in table 1, identifies preventive services that are generally excluded from Medicare coverage and are more in keeping with the fee-for-service payment system than is the traditional typology. There, selected preventive services are classified into three major categories: immunization; screening; and education or counseling. Health insurers typically offer specific services whose delivery can be audited; a “primary prevention” benefit unrelated to defined services would be too amorphous for a health insurance package.

The differences between the two taxonomies reflect the limitations of health insurance programs as mechanisms for providing appropriate preventive services. The goal-based taxonomy recognizes the importance of integrating prevention into the larger health care system. By including tertiary preventive services within the scope of prevention, the taxonomy also makes preventive services relevant for all people regardless of their health status. This is particularly important for the elderly (31).

The increasing incidence of chronic and disabling diseases with age and the frequency of multiple coexisting conditions in the elderly threaten the ability of many to live independently (see box A). In 1985, about 1 in 20 elderly residents of the United States were in nursing homes. Among people 85 years and older, however, about 1 in 5 were in

¹Note, however, that the impact of smoking cessation on life expectancy is so great that even if counseling brings forth a very small reduction in the smoking rate, it may be very cost-effective (20).

nursing homes (43). If preventive services can avert the need for some of that institutional care, the payoff in terms of both better health and lower health care costs could be high.

Recent experience with programs of comprehensive geriatric assessment for impaired elderly people (e.g., the very old, frail, hospitalized, or disabled) suggests that these services, when undertaken by a well-trained team of professionals and when coupled with adequate follow-up services, can measurably improve the health status of the served group (16,65,79). The effectiveness of such programs depend on the target group selected and the scope of services offered and actually received (14,56,65,71, 79,83,85). Because such services must be tailored to the individual needs of the patient, which must be carefully identified, they may also be costly (26,79).

Regardless of whether these services are worth their costs for some portion of the elderly population, health insurance programs, including Medicare, do not encourage their development, and the current organization of health care delivery for the elderly inhibits their use. Because it is difficult to control the content of a visit, health insurers are reluctant to pay for comprehensive health assessments and follow-up activities. The delivery of health care to the elderly is often fragmented: the patient will often see a different specialist for each particular chronic condition, and frequently no one provider is managing the overall case. The high frequency of inappropriate prescribing and use of medications in the elderly is, at least in part, a reflection of this fragmentation of care (59,95). Today, such programs are typically affiliated with medical schools, teaching hospitals, or Department of Veterans Affairs' Medical Centers. In 1985, 114 such units were identified as operating in these institutions (26).

Table 1--Selected Potential Clinical Preventive Services for the Elderly

Immunizations:

- . Influenza
- . Tetanus
- . Pneumococcus^a
- Hepatitis B^b

Screening:

- Cancer-screening:
 - Breast cancer (clinical examination; mammography)
 - Colorectal cancer (occult blood stool; sigmoidoscopy)
 - Cervical and uterine cancer (clinical examination; Pap smear; endometrial biopsy)
 - Prostate cancer (clinical examination; ultrasound)
 - Skin cancer (clinical examination)
 - Melanoma (clinical examination)
- Blood pressure measurement
- Vision examination
- Glaucoma screening
- Hearing test
- Cholesterol measurement
- Mental status/dementia
- Osteoporosis (standard X-ray; quantitative CT; other radiological techniques)
- Diabetes screening
- Asymptomatic coronary artery disease (exercise stress test)
- Dental health assessment
- Multiple health risks appraisal/assessment
- Functional status assessment
- e Depression screening
- Screening for hyperthyroidism or hypothyroidism
- Urine testing

Education and counseling:

- . Nutrition
- . Weight control
- . Smoking cessation
- . Home safety/injury prevention
- . Stress management
- . Appropriate use of medications
- . Alcohol use
- . Exercise

ABBREVIATION: CT, computed tomography.

a -currently covered by Medicare.

b -currently covered by Medicare for high risk patients.

c -coverage effective July 1, 1990.

SOURCE: Office of Technology Assessment, 1990.

Box A—Health Problems of the Elderly*

“Progressive decrements in physical, mental and social function may occur with advancing age. Multiple factors contribute to this decline. . . First, there is a physiologic age-related decline in organ function from the fourth through the ninth decades, the magnitude of which varies considerably among different persons. While these physiologic losses do not significantly compromise the overall function of an elderly person, in the event of a superimposed illness or injury they may result in more profound dysfunction and a longer recuperation time than in younger persons, Physical and mental inactivity (disuse) may also compromise organ function with advancing age. Some of the decline in organ function that has been attributed to physiologic aging may instead be due to disuse and therefore be preventable or reversible with appropriate therapy. The prevalence of chronic physical and mental illness increases dramatically with age, particularly in persons 75 and older. The rates for chronic illnesses in the elderly such as arthritis, hypertension, organic heart disease, sensory impairments and urinary incontinence are about twice the rates in persons younger than 65. Nearly 25% of community-dwelling elderly have symptomatic mental illness, including 10% with significant depression and 5% with dementia. Potentially serious psychosocial stresses are common and include undesired retirement, inadequate finances, death of a spouse or the necessity of moving away from the family home. Many elderly persons will simultaneously suffer from several of these chronic physical or mental conditions.

“The magnitude of the decrements in physical, mental and social function varies tremendously among elderly persons. The vast majority of the elderly are able to tolerate and adjust to their functional impairments or disabilities and remain independent within the community. However, a significant minority have major functional disability. Nearly 20% of the elderly aged 75 through 84 and 30% aged 85 and older are unable to carry on major activities such as leaving home, doing housework or cooking, compared with 7% with similar disability who are younger than 65. Nearly 10% to 20% of persons aged 80 and older are unable to carry on even basic activities of daily living (bathing, dressing, eating, toileting) versus 4% younger than 65. Because of this dependency many of these elderly persons will require placement in a nursing home unless adequate social support can be obtained from family, friends, or the community. Whereas only 5% of persons older than 65 years are in nursing homes, 20% older than 85 reside in them; the elderly have a 20% chance of requiring at least temporary nursing home placement at some time in their life.”

*Quoted from B.M.Stults, “Preventive Health Care for the Elderly,” *Western J. Med.*141(6):832-844, 1984.

The Medicare Program and Preventive Services

CURRENT STATUS OF MEDICARE FUNDING FOR PREVENTIVE SERVICES

Despite the statutory exclusion of preventive services from Medicare coverage, today Medicare pays for some preventive services that are not explicitly mandated by legislation, although the frequency and distribution of these reimbursed services in the elderly population have not been estimated.

First, a substantial number of procedures, particularly screening tests, may be reimbursed in part or in full as diagnostic rather than as screening procedures. Whether Medicare reimburses for a visit or procedure depends on how the visit is characterized on the Medicare claim. If a visit is initiated by a patient because of a medical complaint, the physician fee is covered. Similarly, a test is covered if it is performed because of a symptom or suspected diagnosis.

Anecdotal examples suggest that some procedures done for screening purposes may be paid for by Medicare as diagnostic procedures. A recent review of over 200 medical records of lower GI endoscopies (sigmoidoscopy and colonoscopy) performed on Medicare patients and reimbursed by Medicare found that at least 13 percent were performed for cancer *screening* purposes, not for diagnostic reasons (94).

Second, many tertiary preventive services (e.g., hypertension control or treatment of hypercholesterolemia) are reimbursable expenses under Medicare, because they are defined as therapeutic. Visits made for monitoring, counseling, or prescribing of treatment would be reimbursable by Medicare.

Finally, an unknown percentage of the almost 1 million Medicare beneficiaries currently enrolled in health maintenance organizations (HMOs) or other competitive medical plans (CMPs) may receive additional preventive care. Since 1982, Medicare has provided cavitation payments on a risk-contracting basis to HMOs and CMPs who enroll Medicare beneficiaries (Public Law 97-248). Such Medicare plans receive a fixed price per capita for

Medicare enrollees, based on age, sex, whether or not the enrollee resides in a nursing home or other institution, and whether or not the enrollee is Medicaid eligible. In exchange, the HMOs and CMPs are required to cover all part A and part B benefits, and they may also offer additional benefits such as preventive services. One large HMO reported to OTA that over one-half of its elderly enrollees had a complete check-up within the previous year and 71 percent of its elderly female enrollees had had a Pap smear within the previous 3 years (37). In some Medicare HMOs, particularly those organized as independent practice associations (IPAs), the decision regarding provision of specific services may be made by the individual physician, not by plan administrators (44). Thus, even within specific HMOs, some beneficiaries may be offered such services while others are not.

When a preventive service is legislated as a new Medicare covered benefit, beneficiaries enrolled in Medicare risk-contracting plans are automatically entitled to it. Thus, a legislative decision to add a preventive service as a covered benefit not only provides access to beneficiaries under a fee-for-service payment but also reduces the variation in the scope of services available to Medicare beneficiaries enrolled in cavitation plans.

STRENGTHS AND WEAKNESSES OF MEDICARE AS A SOURCE OF FUNDING FOR PREVENTIVE SERVICES

Paying for preventive services through Medicare is, in many respects, an efficient and simple way to provide financial access to such services for the elderly. To the extent that a service can be defined and assigned a procedure code,¹ it can be incorporated very easily into the existing payment system. It is also a relatively simple administrative task to exempt such services from the deductible and coinsurance requirements that apply to other Medicare services. For a number of reasons, however, covering a preventive service as a Medicare benefit may be insufficient to bring about appropriate patterns of use.

¹ All reimbursable Medicare procedures and visits are assigned a unique five-digit code and published as the Health Care Procedural Coding System (HCPCS), which is an expansion of the American Medical Association's *Current Procedural Terminology* (19).

The decision to use a preventive service may depend more on the information available to the consumer or physician, and the attitudes of each, than on its out-of-pocket cost. OTA's study suggests that the use of preventive services by the elderly may depend more on characteristics of the consumer, physician, and service than on the out-of-pocket costs (37). Although adding a preventive service to the list of covered Medicare benefits would certainly not reduce its utilization, it is questionable whether, in the absence of concerted efforts to educate physicians and Medicare beneficiaries about the value of such services and to encourage their use, overall rates of use would increase substantially (63,80,101).² Moreover, to the extent that people who would benefit most are the least likely to use such services, as appears to be the case with cervical cancer screening (61), the real medical benefits deriving from coverage could be minimal in some cases.

Some services are beneficial only to people with conditions or circumstances that render them particularly "at-risk" for the preventable condition, but it can be difficult and costly to limit payment for a preventive service to an at-risk population. For example, the health benefits of cervical cancer screening appear to be great for women at or near the poverty level who have never been previously screened (61), but it might be impractical to restrict Medicare coverage of cervical cancer screening to high-risk women defined in this way. Medicare is not designed as a means-tested program of benefits. A Medicare cervical cancer screening benefit may have to be offered to all women, including those who stand to gain little from repeated screening. Other approaches such as direct grant programs, or coverage of such services through Medicaid, might allow targeting of services to elderly groups most in need, but these alternatives also have limitations.³

Some preventive services (particularly screening tests) are highly effective if offered at infrequent intervals, but as the frequency of use increases, the added effectiveness declines. A Medicare benefit

can be limited to a maximum frequency, such as every 2 years, but under the existing claims payment structure of the Medicare program, it is difficult for Medicare carriers to monitor compliance with and enforce such limitations on use (42). As the technology of claims payment improves, this problem may disappear.

Like most "cognitive" medical services, counseling and education are inherently difficult to standardize or audit. Because such services would be delivered in outpatient or office settings, they could not easily be incorporated in quality assurance programs focusing on content. Hence, providers could deliver services of low quality (and low effectiveness) and still receive payment from Medicare.

Some preventive services, particularly education and counseling, may be most efficiently and effectively delivered by nonphysician personnel. The Medicare program, however, requires nonphysician services such as those of physical or occupational therapists, nurse practitioners, and clinical psychologists to be provided under the supervision of a physician.⁴ This requirement adds to the cost of providing services that may not require such supervision. In addition, most physician practices are not organized to supervise a wide variety of nonphysician personnel, and their Medicare patient loads are not large enough to justify hiring staff trained in multiple disciplines for the purpose of delivering an array of preventive services to the elderly (56).

POLICY ISSUES IN DEVELOPING A MEDICARE STRATEGY FOR PREVENTIVE SERVICES

Despite the problems with Medicare as a mechanism for implementing preventive services for the elderly, it is nevertheless a potential vehicle for enhancing access to these services. The current strategy for adding preventive services to Medicare is ad hoc and procedure specific. It is worth considering approaches to developing a more com-

²The case of pneumococcal vaccine may be instructive. Despite Medicare coverage of this vaccine in 1982 for all beneficiaries, rates of use did not increase in the United States between 1982 and 1986. In 1985, only about 11 percent of all elderly people were immunized with the pneumococcal vaccine (27).

³Direct grants to providers of services to elderly women in poverty would superimpose a separate service delivery system on the existing system of care and might interfere with the continuity of care for these women.

⁴This is largely, but not strictly, true. Since 1988 the services of clinical psychologists can be directly reimbursed if they are delivered in a Community Mental Health Clinic or a Rural Health Clinic as defined by the Public Health Service. Otherwise, clinical psychologists can be separately reimbursed for services only when the services are delivered under the supervision of a physician.

plete strategy for incorporating preventive services into the Medicare benefit package. The formulation of such a policy requires choices in the following areas:

The Unit of Payment: Individual Procedures v. Service Package

Up to now, newly covered preventive procedures have been added to the list of billable payment codes, giving physicians the power to bill for these services as they do for other medical procedures. Payment is made only for the procedure itself (e.g., the cost of administering a vaccine) and not for the physician's visit in which the procedure is administered. Implicit in this policy is the assumption that the preventive procedure will be delivered as part of a visit made for a nonpreventive purpose. This approach to adding new services is both simple and consistent with existing Medicare billing systems.

This incremental procedure-specific approach ignores the potential benefits of offering services in a package that may economize on the total cost of providing any given set of such services. If a periodic Pap smear were added to the list of covered services, for example, the additional cost of a clinical breast examination or a digital rectal examination during the same visit would be minimal. Counseling sessions on smoking cessation or appropriate medication use could be easily and inexpensively expanded to include information on nutrition. The fixed costs associated with patient scheduling and preparation, medical recordkeeping, and billing could be spread across a number of specific interventions.

Paying for a package of preventive procedures or activities in a defined visit schedule provides the physician or other provider with the opportunity to integrate related services with one another. It is also compatible with the introduction of educational materials and encounter forms for physicians as a guide for providing such services (60). This very integration also has disadvantages, however. One is that the package approach can force the patient into a rather inflexible mode of service delivery that could ultimately lower his or her use of such services. Paying by the procedure allows any physi-

cian to provide a specific preventive service, such as a vaccination, as part of a visit for another purpose. About 85 percent of elderly people made at least one ambulatory health care visit in 1980 (34). Some elderly people might accept a single quick intervention as part of another visit but might not be willing to make a special trip to the doctor each year to receive a more comprehensive package of services.

Two major preventive services demonstration projects have adopted the package approach to payment for preventive services. The frost, Project INSURE, was begun in 1980 by a consortium of public and private sources (60). An age-specific schedule of preventive visits containing a defined set of preventive services was specified for the study population. (See app. D for the package of services provided under Project INSURE for people 65 years of age and older.) Participants were eligible for and encouraged to receive the package of services at no cost; providers were paid on a fee-for-service basis for services rendered as part of the package.

A more recent set of federally funded studies currently underway at six sites is testing the feasibility and effects of offering different defined packages of preventive care to elderly Medicare beneficiaries and paying providers for the package of services delivered during the visit or over a period of time. These projects should provide information on how Medicare recipients respond to service offered in packages. (See app. C for a description of these Medicare demonstration projects.)

Standards of Evidence

Because they have traditionally been excluded from insurance benefit packages, preventive services have been held to a burden of proof of effectiveness or cost-effectiveness that is not typically required of diagnostic and therapeutic procedures. For the most part, third-party payers, including Medicare, accept diagnostic or therapeutic services as "reasonable and necessary" unless obvious abuse is encountered.⁵ In contrast, for preventive services to be included in a benefit package, evidence must exist that they are at least effective, and sometimes that their medical benefits are worth their costs. This standard may seem unduly harsh, and proponents of preventive services

⁵The situation is changing. Diagnostic and therapeutic procedures are increasingly scrutinized through utilization review and quality assurance activities undertaken by insurers or providers such as hospitals or health maintenance organizations. Medicare's process for covering new medical procedures has also recently been strengthened and revised; proposed regulations issued in January 1989 would change the criterion for coverage from effectiveness to cost-effectiveness (91).

often argue that it is unfair to hold prevention to a higher standard than that required for other medical services (48,96). Two powerful arguments favor a tough standard for preventive services, however. First, like all services, preventive services involve potential risks as well as potential benefits. However, unlike diagnostic and therapeutic services, which are rendered in response to patient complaints or symptoms, preventive services are offered to ostensibly healthy individuals and therefore involve an implied promise that they will improve the patient's health (74). Second, the more appropriate response to the double standard may be to raise the level of evidence required for diagnostic and therapeutic services, not to lower those for preventive services. That one genie is out of the bottle is no justification for letting others out, too.

Even accepting that the decision to include preventive services as an insured benefit requires explicit evidence, choices exist about the criteria that will be used to govern the coverage decision and the standards of validity required of the evidence that does exist. Possible criteria include:

- *Effectiveness (impact on health status)*--- Evidence would be required that the expected length or quality of life would be increased for the person receiving a preventive service. This criterion also requires the assessment of medical risks associated with the use of the service. X-ray screening procedures, for example, may subject the user to a small cancer risk associated with ionizing radiation; these risks would be weighed against the potential beneficial effects of the screening procedure on longevity or quality of life.
- *Cost-effectiveness*—*The* health effects of a preventive service would be arrayed against the net health care costs of achieving those effects. Whether the health effects are worth their costs is a policy judgment. If the health effects can be reduced to a single dimension (through the use of a health status index or a quality-adjusted life-years scale), the ratio of health care costs to effectiveness can be computed and used as the basis for judgments about whether the service is worth its costs. If a preventive service both improves health (i.e., lengthens life or improves the quality of a person's remaining

years) and reduces health care costs (by averting costly therapy), then it is not only cost-effective but also cost-saving to the health care system, and unequivocally desirable under this criterion.

- *Impact on Medicare outlays*—*The* net effect of the preventive service on Medicare expenditures would be the basis for a coverage decision.⁶ A preventive service would be covered if it can be expected to reduce net Medicare outlays by averting expenditures for covered diagnostic and therapeutic services. If expected net Medicare outlays are positive, policy makers would have to decide whether the health outcomes are worth the net outlay, thus implicitly returning to the cost-effectiveness criterion. Highly effective preventive services could fail the test of being cost-saving to Medicare, because in prolonging life, they could induce future Medicare expenditures for unrelated illnesses.
- *Net economic benefits*—*This* criterion combines all consequences of a preventive strategy (health effects and health care costs) into monetary values. The economic value of health benefits is compared to the cost of the strategy. If the net economic benefits are positive, then the service is worth its costs; if negative, it is not. This benefit-cost framework is attractive in principle but almost impossible to implement. Major conceptual, methodological, and social problems exist in placing dollar values on the health effects of specific strategies (99).

The notion that a preventive health service should be effective is widely accepted by health care providers and policymakers. There is less agreement about whether the cost of such services should be considered in either coverage or clinical decisions. The U.S. Preventive Services Task Force, convened in 1984 to develop guidelines for preventive services, adopted stringent standards of effectiveness but explicitly rejected cost-effectiveness as a criterion for their task in judging these services. (See app. D for a description of the Task Force and its recommendations for the elderly.) In fact, no professional group in the United States making recommendations on preventive services for the elderly has explicitly

⁶Alternatively, the decision could be based on a preventive service's net impact on total Federal expenditures, including Medicare, Medicaid, and income transfer programs.

accepted cost-effectiveness as a criterion for making such judgments.⁷

Still, expert groups making recommendations differ widely on specific preventive services. Appendix D contains a summary of such recommendations pertaining to the elderly. Recommendations for colorectal cancer screening, for example, vary widely. The U.S. Preventive Services Task Force and the Canadian Task Force on the Periodic Health Examination have concluded that the evidence does not support a recommendation for routine screening of older Americans for colorectal cancer; in contrast, the Working Guidelines adopted by the National Cancer Institute include a relatively aggressive screening schedule.

Why do such differences remain even when the criterion for judging the service---effectiveness-is the same across recommending groups? The answer seems to lie in how different groups interpret the available evidence. At one end of the spectrum is the requirement that any recommendation be buttressed by well-designed controlled trials documenting the effectiveness of an intervention; at the other is the acceptance of either anecdotes or professional opinions about the effectiveness of a procedure as sufficient to justify recommending it. For many (perhaps most) preventive services, unequivocal evidence about positive or negative health benefits does not exist; the evidence may be weak or conflicting. Even when there is general agreement about the standards of scientific validity, the application of those standards to interpretation of specific studies may differ. Studies are conducted in different populations, measure different outcomes, and apply different protocols and measurement techniques. Judgments about the importance of one study versus another are made continually, and methods for synthesizing the results of many studies are currently unstandardized.⁸

LOCUS of Responsibility for Coverage Decisions

Responsibility for expanding Medicare to cover preventive services presently resides with Congress. To date, such expansions have been limited to specific procedures, but Congress could authorize the Health Care Financing Administration (HCFA) to offer an “appropriate” package of preventive services to elderly Medicare beneficiaries. Authorizing legislation could include criteria for assessing the “appropriateness” of such services. For example, Congress could direct HCFA to consider the cost-effectiveness of alternative packages in its implementing regulations.

Vesting HCFA with the authority to decide about specific packages of services would probably increase the flexibility of the Medicare program to respond to new evidence on effectiveness or cost-effectiveness as it arises. By removing specific coverage decisions from the legislative process, preventive services would not have to compete for approval directly with other uses of the Federal health budget. However, if the authority for coverage decisions is vested in HCFA, the resulting package of services offered to the elderly would be unpredictable. As was noted just above, conclusions about the health and cost consequences of specific preventive services depend, in poorly understood ways, on the composition of the recommending groups and the criteria and standards used to judge the evidence. Even directing HCFA to use cost-effectiveness as a criterion for coverage decisions would leave a great deal of uncertainty about how the available evidence would be assessed. A process administered by HCFA, however, might be no more unpredictable than the current legislative process and would still be subject to oversight by Congress.

⁷**Evidence that** a preventive service is **actually** cost saving is often used as secondary supporting information to buttress a recommendation **made** on effectiveness grounds alone, but, to our knowledge, an effective service has never been denied a recommendation by such a group on the argument that it is too costly.

⁸**Over the past decade**, a new approach, referred to as “meta-analysis of research” has been developed to provide rules for integrating the results of many studies of the same intervention into an overall finding (36). Even with comparatively standardized **methods** for pooling the results of individual studies, however, the criteria governing inclusion or exclusion of specific studies and the comprehensiveness of the search for relevant studies can influence the outcomes of **meta-analysis** (35,36). **For example**, a **meta-analysis** of a preventive intervention that includes only studies whose results are published in peer-reviewed journals will ignore many studies in the so-called “phantom literature,” and may be biased in favor of finding that the intervention is successful (36).

Evaluating the Evidence on the Cost-Effectiveness of Preventive Services for the Elderly: Selected Issues

In the past decade, OTA has studied the effectiveness and costs of seven preventive services for the elderly.¹ The general approaches followed in these studies are consistent with the principles of economic evaluation of medical procedures laid out in recent primers on the subject (23,73,99) and will not be described here. (See app. B for a summary of these studies.) Common to all cost-effectiveness analyses are unresolved methodological issues such as how to come up with an index of effectiveness that incorporates all important dimensions of health outcomes, what discount rate to use for costs and effects expected to occur in the future, how to place a value on unpaid services provided by volunteers or family members, and which nonhealth care costs to include in the cost estimates. Applying the general principles of economic evaluation to preventive services for the elderly raises an additional set of questions that, depending on how they are resolved, may have a major influence on the final estimates of effectiveness or cost.

Issue: Under what conditions is it appropriate to generalize about the effectiveness of a service on the elderly from evidence of its effectiveness in nonelderly populations?

This issue arises frequently because so little effectiveness research is conducted on elderly populations. For example, neither mammography nor cervical cancer screening have ever been rigorously tested for effectiveness in the general population of elderly women (64a,89). To date no studies of the impact of cholesterol reduction on heart disease or death have reported on elderly patients as a separate group (32). To generalize from information on the nonelderly, assumptions are required about the natural course of the disease in the elderly relative to the nonelderly and the relative response of the elderly to preventive interventions or to therapy initiated in response to screening. Some hold the view that such extrapolations are always unacceptable, that without evidence directly pertaining to the elderly, no valid conclusions about the elderly are possible. This position seems extreme and perhaps unfair to elderly people if services are withheld because studies have never been conducted in their

age group (47). But, extrapolating evidence opens up the possibility for errors of judgment and is one reason the conclusions of different expert groups can vary widely.

Issue: How should the effects of services provided together in a package be attributed to specific procedures?

Quite often, studies of preventive services examine programs that deliver a number of procedures or interventions in a combined visit or set of visits. Unless an evaluation study has a very large number of subjects and has detailed information on the exact set of services received by each subject, it is impossible to distinguish the effects of individual components. The ongoing HCFA Preventive Services Demonstration projects, for example, which offer defined service packages to experimental groups, will not be able to determine which specific tests or services are responsible for the observed outcomes. This weakness of the evaluation studies is important because the composition of the package can have a major impact on the cost of an intervention and therefore on its estimated cost-effectiveness.

Issue: How should the costs of a visit be apportioned among the individual procedures and interventions provided in the visit?

In estimating the cost-effectiveness of a specific preventive intervention, the issue invariably arises whether some or all of the costs of the visit in which the specific services is delivered should be considered costs of the service itself. Some preventive procedures are by themselves very inexpensive. In 1986, Medicare paid less than \$7 for a total cholesterol determination, for example. The Medicare reimbursement for a Pap smear was about \$10 including a small fee for preparation. Nevertheless, the physician may charge a visit fee, and Medicare paid an average \$21 in 1986 for a "brief" visit (67). The estimated screening costs for either of these procedures would more than triple if the full cost of a brief visit were included in the estimate. Not to attribute any visit costs to the procedure implies that the visit was made for another purpose altogether

¹They are: pneumococcal pneumonia vaccination (86,88); influenza vaccination (87); mammography (89); glaucoma screening (70); cholesterol screening (32); cervical cancer screening (64a); and colorectal cancer screening (in preparation for early 1990 release).

and the delivery of the preventive service is incidental. To fully attribute the costs of the visit to the preventive intervention implies that the purpose of the visit was entirely to receive the preventive service. OTA's study of cholesterol screening costs assumed that such tests would be conducted as an incidental part of a visit for other purposes (32); conversely, the cervical cancer screening analysis assumed that a proportion of the visit costs were attributable to the procedure (64a).

Issue: What allowances in cost estimates, if any, should be made for inefficiencies inherent in the medical care system?

Preventive services are layered on an existing delivery system that may not be organized to offer such services in the least costly way possible. For example, what are the costs of providing screening mammograms to elderly women? The answer to that question presupposes a specific level of capacity utilization of mammography facilities. Reasonable geographical access to facilities, particularly in rural areas, may require some excess capacity. The estimated cost per examination will be much lower if full capacity operation is assumed than it would be if, say, only 50-percent capacity is assumed. Or, if substantial excess mammography capacity already

exists in the health care system for diagnostic uses, the extra costs of performing screening examinations might be even less than the estimated average costs of a dedicated screening facility operating at full capacity.

Issue: How should uncertainties be treated?

There is no single correct answer to the questions posed above; the most appropriate approach depends on the particular preventive service being evaluated and the context for the evaluation. In cases where the most appropriate approach is not obvious, analysts can show how changing assumptions will affect the findings (commonly referred to as sensitivity analysis), but when changing the assumptions leads to major changes in findings, sensitivity analysis may be tantamount to refusing to conclude anything about the magnitude of effectiveness and cost. Although this can be very frustrating to the users of such analyses, it is a necessary component of a sound analysis. The analysis is informing decisionmakers that better data are needed to make better decisions. At the very least, any analysis of preventive services for the elderly should explicitly identify the choices that are made in the areas enumerated above, so that the resulting findings can be held up to careful scrutiny by interested users of the analysis.

The paucity of direct evidence on the effectiveness of preventive services for the elderly is strikingly similar across all kinds of services. In response to congressional mandate, HCFA is currently supporting six demonstration projects whose goal is to assess the costs and effectiveness of providing preventive health services under the Medicare program. These projects are unlikely to provide enough evidence on effectiveness to improve the state of knowledge substantially in that regard. Problems of design, inadequate funding and follow-up periods that are too short, and basic problems of organizing services so that the elderly will use them, all suggest that the evidence arising from these studies is likely to be limited (see app. C). The demonstration projects will tell a great deal about how elderly people respond to the financial incentives to use such services, and how their use affects their preventive behaviors. At the very least, consideration should be given as soon as possible to funding extended follow-up periods at selected demonstration sites where participation rates have been high. By extending these projects, more information would be captured on the health effects of the preventive interventions. Since these demonstrations were congressionally mandated, extending their length might require a technical amendment to the legislation.

Because effectiveness research is costly, it should be targeted to services that offer the potential for large impacts on health status or health care costs of the elderly. Research to clarify the appropriate components of and target populations for comprehensive geriatric assessments has been recommended by an NIH consensus conference panel (65). Because the costs of institutional care for the disabled elderly are so high, these tertiary preventive health services are a promising research subject for effectiveness and cost-effectiveness research.

Even when direct evidence on effectiveness is available, the process of translating that evidence into guidelines for practice has a major impact on final recommendations. Not only does the composition of deciding groups appear to affect the final recommendations, but the standards used to interpret the evidence are critical. There is little consensus among professional groups that have periodically addressed issues of specific preventive services as to the standards of evidence that should guide the development of recommendations. The extent to which the net health care costs of preventive interventions should be considered in Medicare payment decisions is a question that has not been, but could be, answered explicitly.

Appendix A

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Appendix B

Summary of OTA Studies of Preventive Services for the Elderly

The Office of Technology Assessment has conducted a number of assessments of preventive services for the elderly over the past decade. This section summarizes the main findings of each study.

Breast Cancer Screening

OTA conducted an analysis of the effectiveness and costs to Medicare of breast cancer screening for Medicare beneficiaries in 1987 (89). It was estimated that a screening program begun in 1987, in which 30 percent of female Medicare beneficiaries ages 65 to 74 accepted annual screening, would result in avoidance of about 2,500 advanced-stage breast cancers every year from 1990 to 2020, with a total of 85,041 advanced-stage breast cancers prevented and 268,000 life-years saved by 2020. As far as costs to Medicare are concerned, the analysis showed that breast cancer screening cannot be expected to save enough money in decreased treatment costs to offset the costs of screening and workups. There are savings due to a reduction in initial and terminal treatment costs for breast cancer, but the cost of screening far exceeds these savings. The analysis found that a breast cancer screening program would cost Medicare about \$185 million in 1990. The cost to Medicare per life-year saved by 2020 (costs discounted at 5 percent, life-years undiscounted) would be approximately \$13,200.

Pneumococcal Vaccine

OTA analyzed the cost-effectiveness of the pneumococcal vaccine in elderly people (86,88). In 1983, the estimated net discounted costs per discounted healthy year of life gained (at 5 percent discount rate) ranged from negative net costs to \$6154, depending on the assumptions adopted regarding the percent of pneumonias that are pneumococcal and the duration of immunity conferred by the vaccine.

Influenza Vaccine

OTA performed a retrospective analysis of the cost-effectiveness of the influenza vaccination among elderly people in the 1972-78 period (87). The annual vaccination was found to be cost-saving to the medical care system when costs were discounted at 5 percent per year. If medical care costs for unrelated illnesses occurring in extended years of life gained from the vaccination are included, the vaccination would have cost \$1,782 per added healthy year of life.

Cholesterol Screening

In a study of the effectiveness and costs of cholesterol screening in the elderly, OTA found that the cholesterol level does *not* appear to be a significant predictor of

overall survival in either elderly men or women (33). The few studies of the elderly found either that the cholesterol level does not predict mortality at all or that it is a statistically significant predictor of lower mortality. There are no randomized trials of the impact of cholesterol reduction in the elderly, so the effectiveness of treatment must be inferred from the studies in middle-aged populations. While cholesterol reduction can reduce CHD incidence and death in middle-aged men, it has not been shown to lower overall mortality in this population. It may be that the studies on which such findings have been based have had insufficient power or too few years of followup, but benefits delayed for many years might not be pertinent to the elderly, who have a high rate of death from other causes.

The equivocal nature of the evidence on the effectiveness of cholesterol screening and treatment in the elderly must be considered in light of the potential costs associated with this preventive intervention. If all people 65 years of age and older were to fully comply with the National Cholesterol Education program's (NCEP) Adult Treatment Panel Guidelines, the annual national health care expenditures associated with screening and treatment would range from at least \$2.9 billion to \$14.2 billion, depending on the prevalence of certain risk factors and the mix of drugs prescribed. The costs of screening and followup alone are a small fraction of that total, about \$57 million per year. Drugs and monitoring services constitute the bulk of the annual health cost burden.

Medicare's share of national health expenditures for cholesterol screening and treatment is likely to be high. If the entire elderly population were to fully comply with the NCEP guidelines, Medicare expenditures for testing and monitoring would range from \$1 billion to \$5.4 billion per year.

Cervical Cancer Screening

OTA evaluated the costs and effectiveness of screening for cervical cancer among elderly women (64a). Studies have found that women who have been screened are two to ten times less likely than others to develop cervical cancer. The protection associated with prior screening is found in elderly women as well as younger women. Elderly women, however, are less likely to be screened than younger women and have seen less reduction in mortality rates than other groups. Medicare coverage of Pap smear screening (which was mandated in the Omnibus Reconciliation Act of 1989) might induce increased utilization of this test among elderly women. Additionally, Pap smear screening in elderly women does not appear to be very costly for the potential life years saved from this technology, although it is unlikely to actually save health care costs.

OTA estimated that a single screening of women at age 65, when they become eligible for Medicare, would save 14,400 life-years per 1 million women screened (life-years and costs discounted at 5 percent) and would cost the health care system \$1,666 per year of life saved. The incremental cost per year of life saved is least for 5-year screening (\$1,453) and is progressively greater as screening frequency increases. It amounts to \$5,956 per life-year saved for the incremental effects of a 3-year screening cycle over a 5-year cycle, and rises to \$39,693 per life-year saved for annual screening.

The cost-effectiveness ratio for Pap smear screening depends heavily on the extent to which high-risk, rather than low-risk, women are screened. Low-risk women derive some benefit from screening, but at very high cost to the health care system. Screening only high-risk women, on the other hand, has a very low cost per life-year saved.

Glaucoma Screening

OTA examined the existing evidence regarding the effectiveness and potential costs to Medicare of screening for open angle glaucoma (OAG) in the elderly (70). Three methods of screening for OAG exist: tonometry, which measures intraocular pressure (IOP); ophthalmoscopy, which identifies abnormalities of the optic disc; and perimetry, which identifies visual field defects. None of the methods has been tested for accuracy in everyday

office settings, and all have the potential to be highly inaccurate. Tonometry, for example, produces many false positives and negatives because elevated IOP and OAG are not always related. Although tonometry itself is inexpensive, diagnostic workups of individuals with false positive tests and treatment of many people who would not have developed OAG in any case result in substantial associated costs.

The accuracy of screening tests is not the only source of uncertainty. Considerable uncertainty also surrounds the effectiveness of medical treatment in preventing visual disability in individuals with high IOP or suspected OAG. The published, objective evidence on the effectiveness of treatment is highly contradictory. Many individuals suffer progression of disease despite treatment; conversely, many untreated persons go for years without suffering loss of vision. Few adequate studies of treatment have been undertaken, and those available do not show consistent results. Studies currently underway may help resolve the uncertainty.

Screening elderly individuals for OAG may well eventually prove to be a highly beneficial technology. At present, however, the contradictory evidence on the effectiveness of treatment, combined with the unknown accuracy of screening tests, makes widespread screening of the elderly a very uncertain, and probably costly, endeavor.

Appendix C

The Medicare Preventive Services Demonstration Projects

Description of the Projects

Authority and Funding

The Health Care Financing Administration (HCFA) is currently supporting six projects whose goal is to demonstrate the costs and effectiveness of providing preventive health services under the Medicare program. These projects provide a mix of health status assessments, immunizations, clinical screening services, and educational services to elderly individuals enrolled in the experimental arms of the projects.

The first of the six ongoing projects, administered by the University of North Carolina, was funded at HCFA's own initiative. HCFA solicited applications for preventive services projects in 1983 (48 FR 36660) and awarded funds to the University of North Carolina and Blue Cross/Blue Shield of Massachusetts in October 1985. The North Carolina study began offering services to the first participants in October 1986, completed recruitment of 2,400 participants in June 1988, and is now in its fourth year of operation. The Massachusetts study was ended after 18 months due to difficulty recruiting beneficiaries (64). The design of this study required participants to be randomized to one of three clinics to receive services, and many of the individuals asked to participate did not understand the purpose of the study or were unwilling to go to a provider other than their usual physician.

The remaining five of the six ongoing demonstration projects have only just begun. Unlike the North Carolina project, these projects were mandated by law (Public Law 99-272, as amended by Public Law 99-509).¹ Applications for these projects were solicited in May 1987 (52 FR 20148), and funds were awarded in May 1988 (24). Each project had a 6-month developmental phase prior to recruitment. In addition, in order to carry out the demonstration, each project must receive permission to waive the usual Medicare coverage rules (which do not permit reimbursement for most preventive services) for the duration of the study. These waivers are subject to review by the Office of Management and Budget (OMB), which did not approve them until April 1989. Thus, these five projects could not begin recruiting subjects until May 1, 1989 (24).

Project funding for fiscal year 1989 is approximately \$300,000 per study (range \$290,000 to \$330,000) (24). HCFA will renew funding on a noncompetitive basis each year subject to funding availability and to each project's ability to meet its objectives (52 FR 20148). The five

mandated studies are subject to a collective maximum funding amount of \$5.9 million for their administrative costs (Public Law 99-509), which covers items such as researchers' salaries, patient and physician recruitment, and data collection and analysis.

The costs of the actual preventive health services provided under the waivers are not reimbursed from the project research funds and are not subject to any legislated cap. HCFA estimates that the cost of these services will be approximately \$150 per person per year (24). These costs are paid out of ordinary part B Medicare funds.

Design

All six demonstration projects share certain similarities in objective and design. In each study, all study participants undergo an extensive health status assessment, performed by a nonphysician. Individuals in the experimental groups are also referred for appropriate screening, immunization, and educational services, with the exact services they receive varying by project and usually depending on their individual medical history and risk status. Control group patients get their usual care.

All studies randomize patients to experimental and control groups, although the groups being compared differ among studies (see table C-1). (In most cases, patients in both groups see their usual provider rather than being randomized to a particular provider.) In addition to examining the costs and effectiveness of preventive services, the projects test alternative methods of payment for these services (e.g., prepayment, fee-for-service) and involve a variety of different settings and health care providers in the provision of the services.

The scope of services provided by the demonstration projects is presented in table C-2. In general:

- *The North Carolina* project, which served as an example for the designs of the later projects, offers a mix of services that are fairly evenly divided between screening and counseling services. This project's design emphasizes a comparison of the effects of the broad components of a prevention program (screening alone, counseling alone, or both together) provided by a subject's usual primary care physician.
- *Seattle* incorporates the preventive services into the scope of care provided to the experimental patients in a health maintenance organization (HMO). This project offers the most comprehensive prevention package. It emphasizes immunization, cancer screen-

¹The law specified that the demonstration projects must be administered by "accredited public or private nonprofit schools of public health or preventive medicine departments accredited by the Council on Education for Public Health" (Public Law 99-272). Thirty-four programs—twenty-four schools of public health and ten programs in community health/preventive medicine—meet these requirements (18). Eleven of them submitted proposals, and five of those proposals were funded (64).

Table C-1—Design of Medicare Preventive Services Demonstration Projects

Location	Raleigh-Durham, NC	Seattle, WA	San Diego, CA	Los Angeles, CA	Baltimore, MD	Pittsburgh, PA area
Directing organization	University of North Carolina	University of Washington	San Diego State University	University of California	Johns Hopkins University	University of Pittsburgh
Service provider	Physicians' offices, clinics	Group Health of Puget Sound (HMO)	Project team personnel, in conjunction with Secure Horizons (HMO)	Health prevention clinic staff/allied health professions	Beneficiary's usual care provider	Rural hospitals, clinics, physicians' offices
Number of providing sites	13	4	5 health assessment sites; 5 screening sites; approximately 11 health promotion sites in the community	1	Many	Many
Sample pool	Elderly patients of participating practices	Elderly HMO enrollees	Elderly HMO enrollees	Elderly patients of participating physicians	Elderly Medicare beneficiaries in local area	Elderly Medicare beneficiaries in local area
Sample size (total participants)	2,538	2,250 ^a	2,400 ^a	1,800 ^a	4,400 ^a	4,500 ^a
Control group	958	1,125 ^a	1,200 ^a	900 ^a	2,200 ^a	1,500 ^a
Experimental group(s)	Screening only (307)	Receive services (1,625)	Receive services (1,200)	Receive services (900)	Receive services at usual source of care (2,200)	Receive preventive services from clinic (2,000)
	Health promotion only (317)					Receive services from private physician (2,000)
	Both screening and promotion (900)					

^aAnticipated sample size as of November 1989 (recruitment still ongoing).

SOURCE: Office of Technology Assessment, 1990. (Information from project proposals and personal communication with project and HCFA personnel. See references.)

Table C-2—Preventive Services Offered in the Medicare Demonstration Projects

Service	Raleigh-Durham, NC	Seattle, WA	San Diego, CA	Los Angeles, CA	Baltimore, MD	Pittsburgh, PA
Immunizations:						
Influenza	X	X	X	^b	X	X
Diphtheria/tetanus		X	X	^b	X	
General clinical screening:						
Risk assessment review	X	X	X	X	X	X
Height/weight	X	X	X	X	X	X
Blood pressure	X	X	X	X	X	X
Dental exam				X	X	
Vision screen	X	X	X	X	X	X
Heariscreen	X	X	X	X	X	x
Other history/physical at physician's discretion	X	X	X	X	X	X
Laboratory tests:						
Hematocrit	X	X	X			X
Cholesterol (fingerstick)		X				X
Blood sugar (fingerstick)						X
Urinalysis	X			X		X
Mean cell volume						
Creatinine						X
Thyroid (TSH)						
Cancer screening:						
Physical breast exam	X	X		^b	X	
Fecal occult blood	X	X			X	
Digital rectal exam	X	X			X	
Pap smear	X	X			X	
Pelvic exam		X			X	
Mammography				^b		
Counseling services:						
Diet/nutrition	X	X	X	X	X	X
Stress reduction	X	X	X	X	X	
Exercise	X	X	X	X	X	
Sleep regulation		X	X	X	X	
Injury prevention	X	X	X	X	X	X
Drug/alcohol abuse prevention	X	X	X	X	X	X
Mental disorder prevention		X	X	X		X
Self-care/medication use	X	X	X	X	X	X
Smoking reduction/cessation	X	X	X	X	X	X
Life planning	X	X	X	X		
Breast self-exam		X	X			
Health care utilization		X				
Disease-specific education		X				X

^a All **demonstration** projects include an assessment of immunization history and administration of or referral for pneumococcal pneumonia vaccine, if appropriate. This vaccine is already a Medicare-covered service.
^b UCLA is referring patients to their physicians for these services, as appropriate.

SOURCE: Office of Technology Assessment, 1990. (Data from project proposals and personal communications with project HCFA personnel. See references.)

ing, and extensive organized counseling sessions, but it offers only one laboratory screening test. Control and experimental patients in this study are stratified according to their usual level of health care utilization.

- *San Diego* also stresses immunization and uses a specific, privately owned education program for the counseling segment of the protocol. It is the only project that includes a thyroid screening test. All clinical screening in this project is provided by two physicians and other supporting members of the project team.

- *The Los Angeles* project is the only site offering comprehensive dental screening and services in its package of preventive services. All services are provided at a single centralized health prevention clinic. Physician involvement is minimal and centers on a review of the risk assessment results with the patient, with followup services provided at the physicians' and patients' discretion.
- *The Pittsburgh* project emphasizes disease-specific screening and counseling, particularly for hypertension and diabetes. Services are provided through rural physicians and health clinics, with two experi-

mental groups that differ according to the settings in which subjects receive the screening and counseling services.

- Finally, the *Baltimore* project includes a moderately comprehensive array of services; unlike the Pittsburgh project, however, the setting is always the one in which subjects receive their usual care. This project differs from the others in that all counseling is provided by physicians during the office visit.

Reimbursement for the services received by experimental subjects is, with only one exception, based on a pre-set fee for a specified package of waived services. In Seattle and San Diego, the two sites at which services are provided by pre-paid health plans, the package includes all services; these sites receive annual per-enrollee cavitation payments. At the Baltimore and North Carolina sites, payment is also based on annual rates per enrollee. The North Carolina payment is made in two parts, one for screening services and one for health promotion services. The Baltimore payment is an inclusive rate for all services, but there can be an additional payment for an optional follow-up counseling visit. In the Los Angeles program, where all reimbursed services under the waiver are provided at a single site, the provider is reimbursed a set fee per visit for all clinical and counseling services provided in that visit.

The exceptional program is Pittsburgh, where there are two randomized experimental groups. Subjects authorized to receive services through a clinic or hospital are covered through a single capitated amount (per enrollee per year for all services) paid to the provider. Subjects authorized to receive services from private physicians are covered through a fixed fee for each service (e.g., a pre-set amount paid to the physician for providing counseling regarding hypertension). Physicians may, at their option, refer subjects to clinics for some counseling services; in this case, the clinic is reimbursed for the individual service.

Evaluation Plans

The law mandating the five demonstration projects required the Secretary of the Department of Health and Human Services (DHHS) to submit a preliminary report to the Congress by April 7, 1989, regarding their status. That report has been submitted. Public Law 99-272 also required the Secretary to submit an evaluation of these projects to Congress by April 7, 1991. This evaluation is to include:

- an assessment of the short- and long-term costs and benefits of providing these services to Medicare beneficiaries,
- an assessment of how these services might be financed under Medicare, and

- a recommendation to Congress regarding “appropriate legislative changes to incorporate payment for cost-effective preventive health services into the Medicare program” (Public Law 99-272).

The evaluation report due April 7, 1991 will include the results of the North Carolina project as well as latest results of the five mandated projects (24).

The five demonstration projects, awarded in April 1988, were scheduled for 6 months of planning, 2 years of service provision, and 18 months of evaluation. The five projects began delivering services in the spring of 1989. Consequently, unless it is delayed, the report planned for the spring of 1991 can only give interim results of the five projects.

Each project is required to evaluate itself and report the results of its experiment. In addition, HCFA will undertake a cross-cutting evaluation of the projects. The primary experimental outcomes to be evaluated include:

- utilization of preventive services by the experimental groups;
- costs of providing the preventive services and any associated treatment;
- changes over time in health status measures of experimental patients (e.g., improved functional status, improved self-assessment of well-being, lower weight, lower cholesterol level); and
- changes in utilization of other (nonexperimental) health care services (e.g., number of hospital days in general, changes in hospital days associated with specific diseases).

Abt Associates, under contract to HCFA, will work with the individual projects to ensure comparability of reporting of results among projects. In addition, this contractor will monitor the Medicare claims of a sample of individuals outside of the five projects in order to assess the impact of background trends in health care utilization and cost (51).

Evaluation Issues

Ability To Achieve Results

The ultimate goal of all six projects is to demonstrate the costs and effectiveness of providing preventive health services to elderly Medicare beneficiaries. All projects hope to show both better health status and a trend towards lower Medicare costs as a result of providing these services. Unfortunately, the only project with a realistic chance of yielding confident results on costs and health outcomes is the North Carolina study. The other five projects are likely to be most successful in providing information on the feasibility of providing services and the utilization of these services by the elderly under various conditions.

The difficulty in obtaining meaningful results regarding costs and effectiveness from the demonstration projects is due to the fact that only the North Carolina project will likely have at least 2 full years of data on all participants in the project by the beginning of 1991, when HCFA will be composing its evaluation. It is highly unlikely that any of the other five projects will be able to show any significant trends towards lower costs by 1991, even if cost savings might eventually accrue as a result of lower utilization. It is possible that some improvements in hospital bed-days for certain diseases (e.g., influenza), fictional ability, and self-assessed quality of life might occur within the short time that exists, but the failure to find an effect would not be surprising even if an effect exists. Thus, a lack of evidence of lower costs and improved outcomes could mean that the projects did not run long enough for the effects (e.g., improved functional status) to manifest themselves in individual patients in the experimental group. HCFA has no funds budgeted at this time for long-term followup of Medicare claims of study subjects.

The short time frame for service provision and data collection of the five mandated projects at the time of the April 1991 mandated report to Congress can be traced to two factors that contributed to a delay in initiating the projects. First, the process of soliciting applications, preparing and submitting proposals, and evaluating the proposals and awarding funds occupied nearly 2 of the 5 years allotted in the law. Second, the five projects required waivers of the usual Medicare coverage rules; those waivers must be approved not only by HCFA but by the Office of Management and Budget (OMB), which evaluates them as part of the budget process. The waiver process thus added an extra administrative step to startup time.

Design Issues

The design of the demonstration projects presents a number of conceptual problems common to many experiments conducted in the community setting. The most obvious of these is the difficulty of distinguishing between the care received by control and experimental groups. There is no limit to the services that individuals in the control groups receive; they may request and receive all of the same clinical services provided to the experimental group, as long as they pay the costs themselves. Furthermore, in most cases the same physicians (and nonphysician examiners) will be seeing both experimental and control patients. The physicians and associated office personnel may change their own behavior as a result of the project, suggesting or providing more preventive services as part of the “usual care” they provide to the control groups.

The potential similarities between control and experimental groups could make an observed lack of difference

in outcomes difficult to interpret. Such a result could have any of three explanations:

1. that the preventive services provided to the experimental groups had no effect on health outcomes,
2. that the provision of enhanced services to one group leads health care providers to alter their behavior and provide enhanced services to the remainder of the population, or
3. that the “enhanced” services provided to the experimental group did not in fact differ from the usual care physicians provide to their patients.

If an effect is found, the design issues will center on what components of the enhanced service package produced the effect. Some of these components are tested explicitly within the design of individual projects. Pittsburgh, for example, is testing the comparative effects of providing services through a centralized clinic v. through private physicians’ offices. North Carolina is comparing the relative effects of providing clinical screening only, health promotion only, and both components. In this case, however, it is unlikely that the sample size will permit detailed comparisons of the effectiveness of different components among groups. Significant results will most likely be obtained only for combined screening and health promotion/no screening comparisons.

The individual effects of other components, however, will be more difficult to identify. For example, the role of the health status assessment, what it covers, and how it is administered are slightly different in each project. In addition, some projects offer an opportunity for physicians to add to the information provided in this assessment by conducting their own patient history, while others do not. It is uncertain how much the assessments and clinical screening services in the project protocols duplicate or replace a standard “history and physical exam,” what extra information they provide, and what aspects they may miss. Finally, the type and manner of services provided as a result of the information provided by the patient in the assessment differ among the projects. This diversity permits a wide variety of possible combinations to be tested, but it also increases the difficulty of determining which components contribute to the effectiveness of disease prevention, and which do not.

Implementation Issues

The demonstration projects are artificial settings in which certain services are packaged, promoted, and provided. Whatever the results of the demonstrations themselves, a major issue to be faced is whether those results will be applicable to ordinary circumstances in the general medical community, where providers will lack special preparation, intensive monitoring, and ties to

academic research centers. This problem is, of course, inherent in many experiments in medical care. A reasonable expectation is that the project outcomes will provide a maximum estimate for what can be expected to occur under ordinary conditions, where efforts to recruit and retain patients do not at present exist. In addition, the projects should provide important information about the circumstances under which participation and utilization is better or worse.

The failed Massachusetts demonstration project has already provided some indication of potential feasibility problems. In this project, a random sample of Medicare beneficiaries was to receive services at specified sites that were not linked in any way with the site where they received their usual medical care. After 18 months the project had not succeeded in recruiting enough patients to enable it to proceed, and a followup survey suggested that most individuals were unwilling to change providers, even temporarily, in order to receive preventive services. Two projects—the Los Angeles project, which uses a central service site, and the Pittsburgh project, which has experimental groups randomized either to a usual care physician or to a designated clinic site—will be testing

this hypothesis further. Even if these projects do succeed in encouraging participants to receive care at sites other than their usual providers, it will still be uncertain whether beneficiaries under ordinary conditions would do so.

Other areas in which translating project protocols to real-world circumstances may be difficult are the use of project interviewers to perform health status assessment in all projects, and the use of special training for nurses and physicians performing counseling. To duplicate these features of the demonstration projects, physicians in private practice might need to hire additional staff or coordinate with outside organizations to provide services such as extensive risk assessment and counseling.

Finally, there is some self-selection on the part of physicians participating in the projects. These physicians may be more willing than others to adjust their style of practice to include (or exclude) specified preventive services for the elderly. Whether Medicare coverage of specified preventive services will itself encourage the same level of utilization as provision of those services in an experimental setting is a question that can be answered only after the fact.

Appendix D

Summary of Recommendations for Periodic Health Examinations in the Elderly

Visit Frequency

In recent years the worth of a yearly, or regularly scheduled, physical examination by a physician has been questioned and for the most part rejected by health professionals. Instead, the concept of a periodic health examination for the delivery of certain proven preventive measures at specific intervals has been promoted. Government agencies, professional societies, and consumer groups have made or are developing recommendations either directly about periodic health examinations, or about specific screening or preventive technologies that require physician visits. Since these types of recommendations are not always specific about when physician visits are necessary or when care may be provided by a nonmedical professional, OTA has attempted to review some of the recommendations and assess how they translate into physician visits for the elderly. Table D-1 summarizes the recommendations for physician visits made by leading groups.

The Canadian Task Force on the Periodic Health Examination (CTF), which was established in 1976 and issued its first report in 1979, was the first major organization to formulate a plan for a lifetime program of periodic health assessments for the Canadian people. After studying more than 90 potentially preventable conditions, CTF made recommendations for preventive services for 78 of them. CTF determined that for the most part, procedures should be carried out as case-finding rather than screening techniques (they should be performed during a physician visit for unrelated symptoms rather than during preventive visits). There are exceptions to this methodology, however. CTF recommends that pregnant women, the very young, and the very old schedule visits specifically for preventive purposes.

The main result of the CTF's 1979 publication is a set of age- and sex-specific health packages designed to ensure the delivery of proven preventive measures at effective intervals. For the elderly, two health packages were derived; one for men and women aged 65 to 74, and one for men and women aged 75 and over. Both contain the same basic set of tests, immunizations, and health assessments with the main difference being the frequency of physician visits recommended for the old and very old. Since its first report in 1979, CTF has published updates

in 1984, 1986, 1988, and 1989, in which the appropriateness of screening for new conditions is assessed or older recommendations are reassessed.

With similar goals in mind, the U.S. Government established its own Preventive Services Task Force (USPSTF).¹ Appointed in 1984, the Task Force worked closely with CTF to develop age- and sex-specific recommendations for clinical preventive services in addition to addressing "the behavioral and structural barriers to the successful integration of preventive services into clinical practice" (57). The Task Force adopted the rules of evidence and classification developed by CTF. Since April 1987, the Task Force periodically published its recommendations on specific preventable medical conditions in the *Journal of the American Medical Association*. In addition, its final report, *Guide to Clinical Preventive Services: Report of the U.S. Preventive Services Task Force*, which contains all of its age- and sex-specific guidelines, was published early in 1989.

The task force conveys its findings in two ways: by constructing age-specific charts suggesting the optimal frequency of physician visits for different age groups, and by providing specific recommendations concerning each of the 60 illnesses and conditions reviewed and the effectiveness of the screening interventions assessed.

For the elderly, USPSTF recommends a yearly physician visit that includes screening, counseling, and immunization components. Screening, in turn, involves a history, physical examination, and laboratory procedures.² Counseling is geared toward diet, exercise, substance use, injury prevention, and dental health. Immunizations for tetanus-diphtheria (every 10 years), influenza (annually), and pneumonia are suggested. In addition, glaucoma testing by an eye specialist is recommended.

Other government-sponsored recommendations for physician visits come from the National Cancer Institute (NCI) whose published guidelines, "Working Guidelines for Early Cancer Detection," promote physician visits by encouraging physicians to use available cancer detection maneuvers. The implication of the guidelines is that the recommended tests would be done by a physician, or in conjunction with a physician visit. Since NCI suggests annual fecal occult blood tests starting at age 50 (both

¹The Task Force is a non-Federal, multidisciplinary, national panel appointed by the government to make recommendations to the Public Health Service.

²The physical exam would include: height, weight, blood pressure, visual acuity, hearing, and clinical breast exam (annually for women until age 75, unless pathology detected); laboratory procedures recommended are: nonfasting total blood cholesterol, dipstick urinalysis, mammogram (every 1 to 2 years for women until age 75, unless pathology detected), and thyroid function tests (for women). The Task Force also makes specific screening recommendations for elderly persons who are at high risk for particular conditions; these include: fasting plasma glucose, tuberculin skin test, electrocardiogram, Pap smear, fecal occult blood/sigmoidoscopy, and fecal occult blood/co\ onoscopy.

Table D-1--Recommendations for Physician Visits for the Elderly

Group	Scope of recommendations/study	Implications for physician visits	Comments
Canadian Task Force, 1979, 1984, 1986, 1988 ^a	Extensive recommendations on appropriate components of physical examination, immunizations, counseling, and laboratory investigations	Biannual physician visit from age 65 to 74; annual physician visit from age 75 on	CTF also recommends certain tests be done annually between age 65 and 74: mammography (for Women), stool occult blood test, and examination of oral cavity and counseling on oral hygiene; these could be done by other health professionals
U.S. Preventive Services Task Force, 1989 ^b	Extensive recommendations on appropriate components of physical examination, immunizations, counseling, and laboratory investigations	Annual physician visit recommended from age 65 on	For most tests screening frequency is left to physician's discretion: nonfasting cholesterol, urinalysis, vision and glaucoma screening, and thyroid function test
National Cancer Institute, 1987 ^c	Guidelines aimed at encouraging physicians to screen for cancer (melanoma and breast, cervical, prostate, colorectal, testicular, and oral cancer)	Annual physician visit implied for women starting at age 50 and men starting at age 40	NC I emphasizes that these screening maneuvers are part of a physician visit
Project INSURE, 1988 ^d	Study participants age 65 or over received physician examination and history, laboratory tests, immunizations, and patient education according to Project INSURE'S model (based on age, sex, and risk factors)	Biannual physician visit from age 65 to 74; annual physician visit from age 75 on	Mammography and stool occult blood test given annually; Pap smears given for three consecutive negative results
American Cancer Society, 1988 ^e	Recommendations for screening for colorectal, cervical, endometrial, breast, thyroid, testicular, ovarian, lymph node, oral region, and skin cancer	Annual health counseling and cancer checkup beginning at age 40	In addition, ACS advises that certain tests be done at specific intervals: sigmoidoscopy--every 3 to 5 years after two satisfactory results; stool occult blood test--annually; digital rectal examination--annually; Pap test--annually for 3 negative results then at physician's discretion; breast physical examination--annually; and mammogram--annually
Health Policy Agenda for the American People, 1986 ^f	Describes a minimum set of health insurance benefits for Americans	Annual physical examinations beginning at age 50	Specific recommendations for the components of the physical examination are not made, but Project INSURE and the Canadian Task Force on the Periodic Health Examination are cited as sources for determining the components

a Canadian Periodic Health Examination Task Force, "The Periodic Health Examination," *Can. Med. Assoc. J.* 121(9):1193-1254, 1979; 130(10):1276-1292, 1984; 134(7):724-727, 1986; 138(7):618-626, 1988.

b U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services* (Baltimore, MD: Williams & Wilkins, 1989).

c Early Detection Branch, Division of Cancer Prevention and Control, National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services, "Working Guidelines for Early Cancer Detection: Rationale and Supporting Evidence to Decrease Mortality" (Bethesda, MD: December 1988).

d Lifecycle Preventive Health services Project, "Final Report of the INSURE Project" (New York, NY: September 1988).

e American Cancer Society, *Summary of Current Guidelines for the Cancer-Related Checkup: Recommendations* (New York, NY: ACS professional Education Publication, 1988).

f Ad Hoc Committee on Basic Benefits, Health Policy Agenda, "Basic Benefits Package" (Chicago, IL, June 1988).

SOURCE: Office of Technology Assessment, 1990.

Table D-2—Published Recommendations for the Use of Selected Preventive Services by Older Adults^a

Preventive service	CDC ^b	ACP	NIH ^d	CTF ^e	USPSTF	Professional societies	Consumer organizations
Tetanus immunization	Booster every 10 years if primary series has been done	Booster every 10 years		Booster every 10 years	Booster every 10 years		
Pneumococcal immunization	Over age 66—once	Over age 65—once		High risk patients—once	Age 65 and over—once		
Influenza Immunization	Over age 65—every year	Over age 65—every year		Over age 65—every year	Age 65 and over—every year		
Occult blood in stool			NCI: over age 50—every year		Annually for those at high risk		ACS: over age 50—every year
Sigmoidoscopy			NCI: over age 50—every 3-5 years		At physician's discretion for those at high risk		ACS over age 50—every 3 to 5 years after 2 negative tests
Digital rectal exam			NCI: over age 40—every year	Not recommended for prostate cancer; no recommendation for enlarged prostate screening			ACS: over age 40—every year
Clinical breast examination		Over age 40—every year	NCI Age 40-50—every 1 to 2 years with mammography; age 50 and over—annually	Every year from age 50 to 59	Over age 40—every year	ACR, ACOG, AMA ^g Age 40-50—every 1 to 2 years with mammography; age 50 and over—annually	ACS: Age 40-50—every 1 to 2 years with mammography; age 50 and over—annually
Mammography		Over age 50—annually	NCI: Age 40-50—every 1 to 2 years with mammography; age 50 and over—annually	Between ages 50 and 59—every year	Over age 50—every 1 to 2 years	ACR, ACOG, AMA: Age 40-50—every 1 to 2 years with mammography; age 50 and over—annually	ACS: Age 40-50—every 1 to 2 years with mammography; age 50 and over—annually
Cholesterol screening		Recommended at 5-year intervals for asymptomatic, low-risk men, optional for women and elderly persons	NHLBI over age 20—every 5 years		Recommended at physician's discretion		AHA. supports NHLBI recommendations
Pap smear			NCI: over age 18 or if sexually active--3 consecutive annual Pap smears and pelvic exams with negative results, then less frequently at discretion of physician	Every 5 years from age 35 to age 60; screening should continue if prior smears have been abnormal	Every 1 to 3 years for women who have not had previous consistently negative smears	ACOG, AMA, ANA, AAFP, AND AMWA: support NCI guidelines	ACS: supports NCI guidelines
Serum glucose		Not recommended for asymptomatic healthy adults		Not recommended without family history of diabetes or previous circulatory problems	Recommended only for the markedly obese, persons with family history of diabetes, or women with history of gestational diabetes		ADA ^h people at risk should be screened (no frequency specified) AHA: every 5 years from age 20 to 75; optional after age 75 if baselines are well-documented

Table D-2--Published Recommendations for the Use of Selected Preventive Services by Older Adults--Continued

Preventive service	CDC ^b	ACP ^c	NIH ^d	CTF ^e	USPSTF ^f	Professional societies ^g	Consumer organizations ^h
Blood pressure			NHLBI: over age 18— at least every 2 years, depending previous reading	Over age 65—every 2 years	Recommended regularly at interval determined by physician		AHA: every 15 years starting at age 20
EKG		Not recommended m asymptomatic persons		Recommended for symptomatic adults only	Recommended for symptomatic adults only and other specific circumstances		AHA: at ages 20,40, and 60
Vision examination including glaucoma screening by tonometry				No recommendation to screen	Vision screening suggested at physician's discretion; glaucoma screening might be clinically prudent, frequency to be determined by physician	AOA: over age 40—every year AAO: over age 40— every 2 to 5 years	NSPB: over age 35— every 2 years

ABBREVIATIONS AAFP. American Academy of Family Physicians. AAO = American Academy of Ophthalmology; ACOG. American College of Obstetricians and Gynecologists, ACP = American College of Physicians, ACR = American College of Radiologists, ACS = American Cancer Society, ADA = American Diabetes Association, AHA = American Heart Association, AMA. American Medical Association, AMWA. American Medical Women's Association, ANA = American Nurses Association, AOA = American Optometric Association, CDC = Centers for Disease Control, CTF = Canadian Task Force, EKG = electrocardiogram, NCI = National Cancer Institute, NIH = National Institutes of Health, NSPB = National Society to Prevent Blindness, and USPSTF = United States Preventive Services Task Force

^aThis table does not include screening recommendations for all adults. In some cases where recommendations for younger age groups differ from those for the elderly. only the recommendations for the elderly are included

^bCenters for Disease Control, Public Health Service, U.S. Department of Health and Human Services, *Adult Immunizations Recommendation of the Immunization Practices Committee*, undated.

^cAmerican College of Physicians-immunizations. American College of Physicians, Committee on Immunizations, *Guide for Adult Immunization* (Philadelphia, PA: 1985); clinical breast examination and mammography D M Eddy, "screening for Breast Cancer," *Ann Intern Med* 111(5) 389-399, 1969, cholesterol A M Garber, H C Sex, and B Littenberg, "Screening Asymptomatic Adults for Cardiac Risk Factors The Serum Cholesterol Level," *Ann Intern Med* 110(8)622-639 1989; serum glucose D E Singer, J H. Samet, C M Coley et al., "Screening for Diabetes Mellitus," *Ann Intern Med* 109639-649, 1988; EKG H C %x, A M Garber, and B Littenberg, "The Resting Electrocardiogram as a Screening Test, A Clinical Analysis," *Ann Intern Med* 111(6) 469-502, 1989

^dCancer: Early Detection Branch, Division of Cancer Prevention and Control, National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services, "Working Guidelines for Early Cancer Detection Rationale and Supporting Evidence to Decrease Mortality" (Bethesda, MD December 1987), and "National Organizations Agree on Joint Mammography Guidelines," press release from the National Medical Roundtable on Mammography Screening Guidelines, June 27, 1989, cholesterol National Cholesterol Education Program, National Heart, Lung, and Blood Institute, National Institutes of Health, U.S. Department of Health and Human Services, "Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," (Bethesda, MD: October 1987); blood pressure' Joint National Committee, "The 1988 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure," *Arch Intern. Med.* 148(5):1023-1038, 1988.

^eCanadian Periodic Health Examination Task Force, "The Periodic Health Examination," *Can. Med. Assoc J* 121(9):1193-1254, 1979, 130(10):1276-1292, 1984, 134:721-729, 1986; and 141:209-216, 1989

^fU.S. Preventive Services Task Force, *Guide to Clinical Preventive Services* (Baltimore, MD: Williams & Wilkins, 1989).

^gClinical breast examination and mammography. AAFP, ACR, AMA, AMWA, "National Organizations Agree on Joint Mammography Guidelines," press release from the National Medical Roundtable on Mammography Screening Guidelines, June 27, 1989, American College of Obstetricians and Gynecologists, personal communication with Lynne Lawrence, Government Relations Representative, Washington, DC, Oct. 31, 1988; Pap smear (ACOG, ACS, NCI, AMA, ANA, AAFP, and AMWA), D.J. Fink, "Change in American Cancer Society Guidelines for Detection of Cervical Cancer," *CA-A Journal for Clinicians* 38(2):127-128, 1988; vision examination American Optometric Association, "Optometry and the Nation's Health: Recommendations for the Implementation of Congress' National Health Priorities," a working paper prepared by the National Health Division, February 1978, American Academy of Ophthalmology, Policy Statement, "Frequency of Ocular Examinations," approved Feb. 6, 1983.

^hAmerican Cancer Society, "Summary of Current Guidelines for the Cancer-Related Checkup: Recommendations" (New York: ACS professional Education Publication, 1988), D.J. Fink, "Change in American Cancer Society Guidelines for Detection of Cervical Cancer," *CA-A Journal for Clinicians* 38(2):127-128, 1988; and "National Organizations Agree on Joint Mammography Guidelines," press release from the National Medical Roundtable on Mammography Screening Guidelines, June 27, 1989, American Diabetes Association, "A.D.A. Policy on Screening for Hyperglycemia," June 1983; American Heart Association (cholesterol screening), "Public Screening Strategies for Measuring Blood Cholesterol in Adults-Issues for Special Concern," October 1987 (serum glucose, blood pressure, EKG, and physical examination), S.M. Grundy, P. Greenland, A. Herd et al., "Cardiovascular and Risk Factor Evaluation of Healthy American Adults," *Circulation* 75(6) -1362A, 1987; and American Society for the Prevention of Blindness, "Facts on Blindness and Prevention," February 1988,

SOURCE: Office of Technology Assessment, 1990.

sexes), annual mammography at age 50 (women), and annual digital rectal examination of the prostate starting at age 40 (men), an annual physician visit is implied for all adults over age 65.

In recent years, several professional groups from the private sector have taken an interest in investigating the effectiveness of preventive services. The INSURE project was an 8-year study of prevention in primary medical care, sponsored by the industry wide Network for Social, Urban, and Rural Efforts. Project INSURE provided physicians with a model for providing early detection and treatment of disease and the provision of health education that is based on each patient's age, sex, and risk factors (the model specifies the appropriate physical examinations, lab tests, immunizations, and x-ray studies to be provided) and emphasized patient education as a means of reducing the risk of coronary heart disease, cancer, stroke, and automobile injuries. The INSURE project included health packages for the study participants according to age. The package for adults age 65 to 74 consists of five physician visits (every 2 years) in addition to an annual stool occult blood test and mammography (for women). The four basic components of each visit were the following:

- history and physical examination (monitoring of weight, blood pressure measurement, breast and rectal exam, and assessment of hearing problems);
- lab tests (plasma total cholesterol and glucose, and a Pap smear every 3 years for 3 annual negatives (for women));
- immunizations (tetanus and influenza shots); and
- patient education (counseling about risk factors of cancer, heart disease, accidents, and aging).

For the elderly age 75 and over the components of the physical exam are the same but the recommended frequency is every year.

In June 1988, the Health Policy Agenda for the American People (HPA), a public and private sector

initiative aimed at identifying and addressing health care issues, and administratively supported by the American Medical Association, published its basic benefits package. It promotes periodic medical examinations based on age, sex, and risk factors. HWA recommends annual examinations for adults from age **50** onward. The content of the examinations is based on both the INSURE project model and Canadian Task Force on the Periodic Health Examination 1984 Update.

Finally, the American Cancer Society's (ACS) recommendations for appropriate cancer screening suggests an annual physician visit for men and women 40 and over for cancer 'detection. In addition, ACS' disease-specific cancer screening recommendations would also imply an annual physician visit for the elderly.

Specific Preventive Services

Table D-2 summarizes the published recommendations for the use of selected preventive services by older adults. It includes selected sets of recommendations made by professional or expert groups for older adults, primarily for those over 65 years old. The summary is not exhaustive; rather it includes a range of views on the use of preventive services. As table D-2 indicates, there is nearly complete agreement among the included groups making recommendations for immunizations for the elderly. For screening services there is a high degree of consistency among groups, but some disagreement does exist.

A more detailed comparison of recommendations for colorectal cancer screening highlights the disparities that can arise among recommending groups (see table D-3). While the National Cancer Institute, American Cancer Society, and the American Society of Gastroenterology support periodic screening for colorectal cancer, the USPSTF and Canadian Task Force are much less supportive of this approach.

Table D-3--Recommendations for Screening for Colorectal Cancer in the Elderly

Country/organization (date of organization)	Screening recommendation by procedure		
	Digital rectal examination	Fecal occult blood testing	Sigmoidoscopy
United States:			
NCI ^a (1987)	Considered part of routine physical examination	Annually	Every 3 to 5 years
ACS ^b (1988)	Annually	Annually	Every 3 to 5 years after two negative sigmoidoscopies 1 year apart
ASGE & AGAc (1988)	Frequency unspecified		Flexible sigmoidoscopy starting at 50, frequency unspecified
SPSTF ^d (1989)	Digital rectal examination is not an effective screening maneuver, Task Force found insufficient evidence to recommend for or against screening with fecal occult blood test or sigmoidoscopy in asymptomatic persons, but notes it maybe advisable to offer screening to persons 50 and older with risk factors; Task Force does not specify a screening frequency		
Canada:			
CTF ^e (1988)		Not recommended unless specified risk factors are present	Not recommended unless specified risk factors are present
Germany:			
Government ^f (1977)		Screening is suggested in those over 45, frequency not specified	

ABBREVIATIONS: ACS = American Cancer Society, AGA = American Gastroenterological Association, ASGE = American Society for Gastrointestinal Endoscopy, CTF = Canadian Task Force, NCI = National Cancer Institute, USPSTF = United States Preventive

SOURCES:

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- ^bAmerican Cancer Society, "Summary of Current Guidelines for the Cancer-Related Checkup: Recommendations" (New York: ACS Professional Education Publication), 1988.
- ^cFleischer, D., Goldberg, S., Browning, T., et al., "Detection and Surveillance of Colorectal Cancer," *J. A.M.A.* 261(4):580-585, 1969.
- ^dU.S. preventive Services Task Force, *Guide to Clinical Preventive Services* (Baltimore, MD: Williams & Wilkins, 1989).
- ^eCanadian Task Force on the Periodic Health Examination, "Early Detection of Colorectal Cancer," accepted for publication in *Can. Med. Assoc. J.* 141:209-216, 1989.
- ^fF.W. Schwartz, H. Holstein, and J.G. Brecht, "Preliminary Report of Fecal Occult Blood Testing in Germany," *Colorectal Cancer: Prevention, Epidemiology, and Screening* S. Winawer, D. Schottenfeld, and P. Sherlock (eds.) (New York, NY: Raven Press, 1980).

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