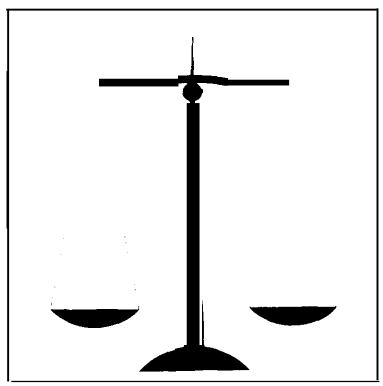
Overview of the Issues 2

DEFINING CLINICAL PREVENTIVE SERVICES

Prevention aims to prevent or delay the occurrence of disease or injury or their consequences. A three-tiered framework has traditionally been used to classify preventive services based on their ultimate goal and the point along a disease process at which the preventive intervention is applied.

- *Primary preventive services are* intended to prevent or delay the onset of disease or health problem. Immunizations and counseling on lifestyle changes are classic examples of primary prevention (191).
- *Secondary preventive services are* efforts to detect a disease or condition before it is clinically recognizable to avoid or delay its further progression. Secondary prevention focuses on incipient rather than established disorders (133). Screening procedures, such as mammography or Pap smears, fall into this category (191).
- *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 (191). These would include services such as education for diabetic patients and rehabilitation for stroke victims.



Preventive interventions have also been classified as clinical preventive strategies, behavioral strategies (health promotion), and environmental strategies (health protection) (176). This classification system distinguishes preventive interventions by the type and locus of actions taken to prevent disease. Clinical preventive services-the topic of this report-are defined by the Office of Technology Assessment (OTA) as "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" (191). They include immunizations and chemoprophylaxis (i.e., the use of chemical agents to prevent disease or other unwanted health conditions), screening tests, and health education provided by health care professionals.

Behavioral strategies include a broad array of strategies to encourage lifestyle changes, such as exercise, smoking cessation, and healthful diets (176). Behavioral strategies can be accomplished in the context of a medical office visitor through community-based interventions, such as mass media campaigns. Environmental prevention strategies typically consist of social policies, such as seat-belt laws, taxes on alcohol and tobacco use, speed limits, and restrictions on access to firearms, as well as environmental and occupational regulations.

This report examines the question of benefit design and health insurance, and therefore is focused on clinical preventive services. This narrow focus should not be taken to mean that clinical preventive services are the only, or best, way to prevent disease or unwanted health conditions. Sometimes more than one approach is available to prevent a particular condition. For example, smoking, which leads to a number of diseases, may be prevented through taxes on cigarettes (environmental strategies), antismoking campaigns (behavioral strategies), and the use of a nicotine patch (clinical strategies). Other times, trade-offs may need to be made between promoting clinical preventive services (e.g., cancer screening) or behavioral interventions (e.g., sex education programs). It is often important to view clinical preventive services in the context of the broader goals of promoting health and preventing disease, and to recognize that a specific clinical preventive service may be only one of a variety of approaches for achieving a particular goal.

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

The principal function of insurance is to transfer income across states of the world (e.g., from healthy to sick, from young to old) (150). Individuals who purchase insurance pay premiums to avoid the need to pay for services at the time of use. By paying a relatively small premium at regular intervals, individuals avoid the risk of having to pay a large amount for health care when the services are needed. Traditionally, clinical preventive services have been excluded from insurance benefits. Insurers have argued that insurance should be limited to unpredictable expenses and that coverage for predictable expenses, such as routine screens, raises premiums without increasing the protection from financial hardship. Advocates of insurance for preventive care generally contend that these concerns should not override the public health benefits that would result from removing immediate cost barriers to regular preventive care (42). Moreover, it is sometimes argued that encouraging services which may prevent or delay episodes of illness and disability would actually reduce national health care costs.

The public health argument for insurance for clinical preventive services rests on the assumption that insurance coverage will increase utilization. A number of studies have demonstrated a positive relationship between insurance coverage and the use of preventive services. Uninsured people have been shown to receive significantly fewer preventive care services than their insured counterparts (198). For example, research has shown that uninsured children receive fewer well-child visits (148,169,231) and are less likely to be immunized (231) than insured children. Uninsured women are less likely to be screened for cervical cancer **(92, 115,233)** and breast cancer (92,233,234) and are less likely to receive prenatal care (25, 152). Uninsured adults are less likely to be screened for hypertension (233) and glau-

coma (233). In addition, Medicare participants with additional insurance coverage beyond that provided by Medicare have been found more likely to receive glaucoma screening, eye exams, blood pressure measurement, Pap smears, and breast exams (189).[1] Finally, among insured people, increased cost-sharing has been shown to be negatively associated with the use of preventive services (134,203). Confounding variables do not seem capable of explaining away these findings. In several studies the positive association between having insurance and the use of preventive services persisted even after controlling for the frequency of physician visits, health status, education, and income (92,189,231,233). A caveat regarding this research is that studies only measured the presence or absence of any insurance, and not the association between coverage of specific clinical preventive services and the use of those services. Moreover, in many studies the extent, or presence, of insurance coverage of specific clinical preventive services was unknown.[2]

Although health insurance coverage may result in greater utilization of preventive services, there are other, nonfinancial barriers to access as well. These include geographic barriers, cultural and language barriers, lack of transportation, lack of knowledge concerning services, forgetfulness, inconvenience, and fear of procedures and their potential complications (103,139,189). In addition, providers often fail to promote clinical preventive services. Under-provision by providers has been attributed to their lack of adequate knowledge about preventive interventions, lack of time, forgetfulness, and their own personal health promotion and prevention practices (139, 166,171). For these reasons, insurance coverage for preventive services may be insufficient to bring about desirable patterns of use., Indeed, studies have shown that even with free care (i.e., no cost-sharing) or Medicaid coverage, many persons do not receive preventive care at recommended levels (25,134).[3]

It is also important to note that increased use of preventive interventions may not be adequate to improve health outcomes. Many preventive interventions indicate the need for additional follow-up services (e.g., treatment for cholesterol or hypertension), If these follow-up services are not received, for example, because they are not covered by a person's insurance plan, increased coverage of preventive services may not lead to improved health outcomes. Moreover, preventive services which are received may be inappropriate or ineffective. To the extent that health insurance encourages the use of ineffective preventive services, insurance may have no effect or a negative effect on health status.

CRITERIA FOR EVALUATING CLINICAL PREVENTIVE SERVICES

There is a long list of clinical preventive services which could potentially be included in benefit packages and numerous criteria for inclusion or exclusion (202). This report focuses on three criteria for choosing which clinical preventive services to cover: effectiveness, cost-effectiveness, and net costs.

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[1] This study used 1982 data; in 1982 Medicare did not cover any preventive services.

[2] The Rand Health Insurance Experiment reviewed in *Benefit Design in Health Care Reform: Background Paper—Patient Cost-Sharing* was unusual in that the insurance provided in the experiment was designed to include coverage for an atypically comprehensive array of clinical preventive services (203).

[3] Lurie and colleagues considered recommended levels as follows: diphtheria-pertussis-tetanus (DPT) and polio immunizations at 2,4,6 and 18 months; measles-mumps-rubella (MMR) vaccination at 12-18 months; and tuberculosis (TB) skin testing at 12-18 months. For adults these included: tetanus immunization every 10 years; influenza vaccine yearly for high-risk adults; Pap smears every three years for women over age 45; sigmoidoscopy every 3 years for men and women over age 45 (134). Braveman and colleagues defined prenatal care as appropriate if it was initiated during the first trimester and if an "adequate" number of visits were received, as determined by a complex formula (25).

The Role of Evidence on Effectiveness

Using available information on effectiveness to select specific services for inclusion in a benefit package is an appealing idea for a range of reasons. Simply put, it seems logical to pay for ''what works' rather than for services with little or no value. Coincident with this concept is the impression that if coverage is not service-specific, and based on effectiveness information, clinicians will provide ineffective care. This impression has been supported by recent research documenting that there is apparently a significant proportion of health care that is unnecessary, ineffective, or inappropriate.[4] Despite the appeal of using effectiveness criteria to design insurance benefits, operationalizing this idea is not straightforward. Two practical considerations are addressed in this section: 1) how does one define effectiveness, and 2) how does one determine effectiveness?[5]

Effectiveness has been defined by OTA as the *probability of a health benefit to individuals in a defined population from a health technology applied to a given health problem under ordinary conditions by the average practitioner for the typical patient (183).*[6] Health benefits can include increased life expectancy, better functional status, and reduced morbidity and suffering. Negative health outcomes are the opposites of these qualities.

The term 'appropriate' is also frequently used to describe an effective treatment. Although the term "appropriate'' is used in various ways, one definition from the Rand Corporation (as cited in 105) is as follows:

> A procedure is "appropriate" for a given indication when the expected health benefits [exceed] the expected negative consequences. . .by a sufficiently wide margin that the procedure [is] worth doing.

The term "appropriate" emphasizes that most interventions are not risk-free, that their effects vary by patient and the patient's condition, and that the determination of 'what works' in health care often involves weighing the likely benefits and harms which are typically not known with certainty. OTA's definition of effectiveness subsumes this concept of appropriateness.

The determination of effective care is difficult for several reasons. Knowledge about the effectiveness of health interventions typically advances through the replication and integration of results, rather than through the dramatic results of one study (71). The process of integrating and evaluating research, and determining effectiveness, is neither simple nor straightforward for a variety of reasons. A source of difficulty is that people have different methods for identifying, reviewing, and synthesizing the evidence on effectiveness. It is increasingly recognized that the methods for reviewing and synthesizing the evidence from various studies can critically influence the validity of the conclusions. For example, some organizations may only consider randomized clinical trials as valid evidence, while other organizations may base their decisions on the opinions of experts.

A related difficulty is that people often weigh the risks and benefits from interventions differently. Because organizations may have varying judgments about whether the potential benefits of an intervention outweigh the potential for harm, they may make different statements about the appropriateness of an intervention. In recognition of this fact, it is important that statements concerning appropriateness clearly identify the

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4 This literature is reviewed in OTA's report, *Benefit Design in Health Care Reform: Report #3—General Policy Issues (202).*

5 The assessment of the effectiveness of an intervention is a complex process and is only briefly described in this report. OTA is addressing these issues in greater depth in an ongoing study, *Prospects for Health Technology Assessment (in* progress).

6 Efficacy has been defined by OTA as the probability of a health benefit to individuals in a defined population from a health *technology* applied to a given population *under ideal conditions (183).*

magnitude of the risks and benefits and lay out the rationales for conclusions drawn.

Although tolerance for risk may differ from person to person, preventive interventions have generally been held to a higher standard of evidence regarding their effectiveness than have other diagnostic and therapeutic interventions. The principal reason for this difference is that ''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 patients' health" (191). This is not to say that diagnostic and treatment services should not be held to the same criteria of effectiveness; however, it seems harder to resist performin g these procedures in the face of an apparent symptom or disease, even in the absence of good data on their effectiveness.

Any attempt to base insurance benefits for clinical preventive services on effectiveness information should recognize the difficulty of this approach and carefully consider the process by which effectiveness information will be determined. These include the locus of decisionmaking, the methods used to identify, review and synthesize the evidence, and the explicitness of the process.

The Role of Costs

Whether and how costs should enter into decisions about health insurance coverage for preventive services are contentious issues. The following section discusses the definition of cost-effectiveness and the strengths and weaknesses of using cost-effectiveness and net cost information to make coverage decisions for preventive services.

Cost-effectiveness analysis is a method by which the benefits and costs of various interventions can be evaluated. OTA defines cost-effectiveness analysis as follows:

> An analytic technique that compares the costs of a projector of alternative projects to the resultant benefits, with costs and benefits/effectiveness not expressed by the same measure. Costs are usually expressed in dollars, but benefits/effectiveness are ordinarily expressed in terms such as ''lives saved," or "disability avoided" (183).

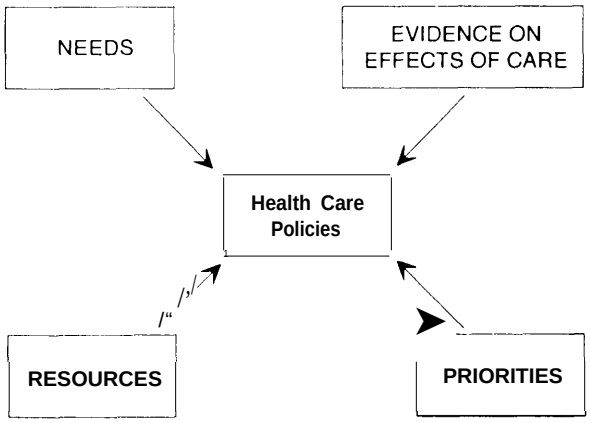
As commonly understood, a "cost-effective" service is one that is worthwhile, or a good investment relative to the alternative. However, the determination of whether the benefit is worth the cost is highly subjective and will depend on who is making the comparison, and what is being compared (55,227). Furthermore, an intervention that is "cost-effective," in the sense that it is preferred to the alternative, will not necessarily save money (222).

Cost-effectiveness analysis has some inherent weaknesses. Examples of such weaknesses include: problems with quantifying or valuing certain important but less tangible health benefits; the inability of analyses to adequately incorporate equity and political issues (183); and the potential of cost-effectiveness ratios to be misleading because they do not indicate the scale of an intervention.[7] If these limitations are overlooked, cost-effectiveness analyses can seem to provide an unambiguous or "bottom-line" answer, when in reality they may rest on ambiguous data or assumptions (183).

Because of these limitations, methodologists have recommended that cost-effectiveness be used as one tool for policy making rather than as the primary basis for decisions (183). As a component of decision-making, cost-effectiveness analysis has several advantages. First, it

[7] For example, suppose program A costs $2,000 dollars and saves 2,000 lives, while program B cons $2,000,000 dollars and saves 1,000,000 lives. The cost-effectiveness ratio for program A is 1 and that for program B is 2. It would seem that program A is more cost-effective. However, there is no reason to believe that program A can be increased in scale and still maintain the same cost-effectiveness (183). Therefore, program B might be preferred because it has a greater potential to reduce mortality.

Figure 2-l—Evidence on the Effects of Care: Essential, But Not Sufficient, For Improving Policies and Decisions in Health Care



SOURCE: U.S. Congress, Office of Technology Assessment, adapted from the Cochrane Collaboration, "Preparing, Maintaining, and Disseminating Systematic Reviews of the Effects of Health Care," figure located in promotional brochure, Oxford, England, 1993.

encourages policymakers to consider all the consequences of a benefit decision, rather than those that are most immediate or apparent. Second, it provides a structured framework for evaluating this information. Finally, it brings assumptions out into the open and provides a means to evaluate their impact. Possible ways in which cost-effectiveness might be used to design benefits are described in more detail in chapter 4. Chapter 4 also presents evidence on the cost-effectiveness and costs of specific preventive interventions.

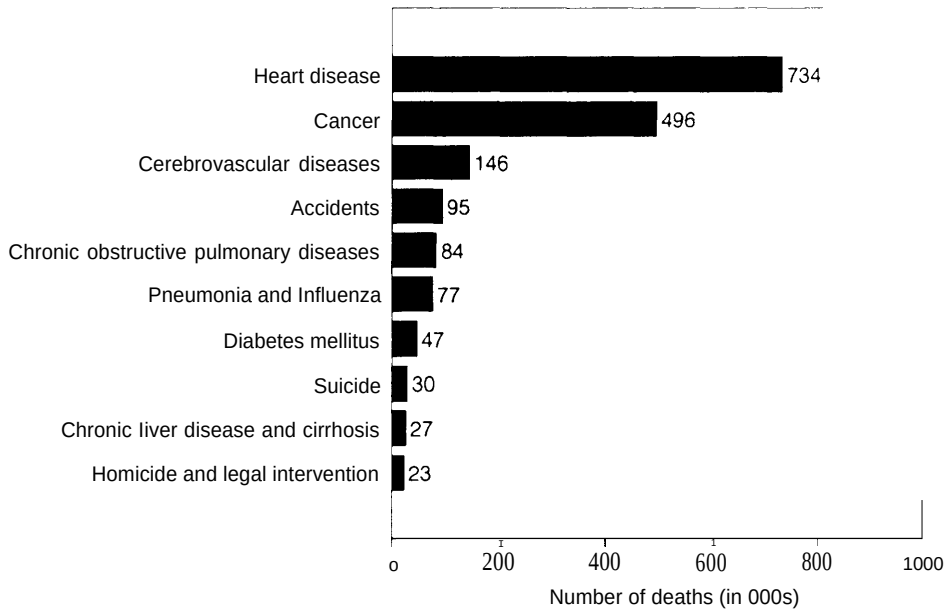
Other Criteria

Evidence on the health effects and costs of care may be an essential component of policy and benefit design decisions regarding preventive services; although this information is unlikely to be sufficient for making benefit design decisions (see figure 2-l). As previously mentioned, decisions regarding insurance coverage for clinical preventive services must be viewed within the larger context of the goals of the health care system. Thus, the burden of illness-as indicated by the incidence, prevalence, and duration of the disease or condition, and the resulting mortality and morbidity-will bean important factor in the decision to promote specific services (see figures 2-2 and 2-3). Other considerations, such as the quality of life associated with the disease state, fear of the disease, and the age at which the disease or injury usually occurs, may also be important. For example, interventions targeted at children may be of higher priority than those targeted at older adults. Similarly, some types of interventions may be preferable to other types. Policies which restrict personal freedoms, such as smoking regulations, may be perceived as less desirable than policies which can stimulate people to improve their own health without limiting their personal choices. Finally, health problems which are considered the consequence of "personal choices" (e.g., smoking, violence, "unintentional" but avoidable] injuries), may be viewed as less appropriate for insurance coverage than health problems which are perceived as ''uncontrollable' (e.g., cancer); however, society's judgments about these issues may change considerably over time (194). For these reasons, decisions concerning insurance benefits for preventive services probably cannot, and should not, be made in a completely mechanistic and scientific manner. Nevertheless, information about effectiveness and costs can be an extremely important component of the decision process.

INSURANCE BENEFIT DESIGN

The questions concerning benefit design for clinical preventive services described thus far in this report include the following: what do we want to prevent (e.g., what targeted conditions); how should we prevent it (e.g., should clinical services or other types of preventive interventions be used); should the clinical preventive service be covered by insurance (e.g., will insurance coverage stimulate utilization); and, if so, what criteria should we use to make coverage decisions concerning specific services (e.g., effectiveness,

Figure 2-2—Leading Causes of Death, 1989, All Ages (in Thousands)



SOURCE: U.S. Congress, Office of Technology Assessment, adapted from U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Center for Health Statistics, Health United States 1991 and Prevention Profile, DHHS Pub. No. (PHS) 92-1232 (Hyattsville, MD, 1992).

cost-effectiveness)? The following section moves from consideration of these questions to more practical, but equally important, issues of how to design an insurance benefit once decisions have been made about which interventions to include. In particular, this section addresses two general issues regarding benefit design:

- the specificity and detail of the benefit, and
- the unit of payment for the benefits.[8]

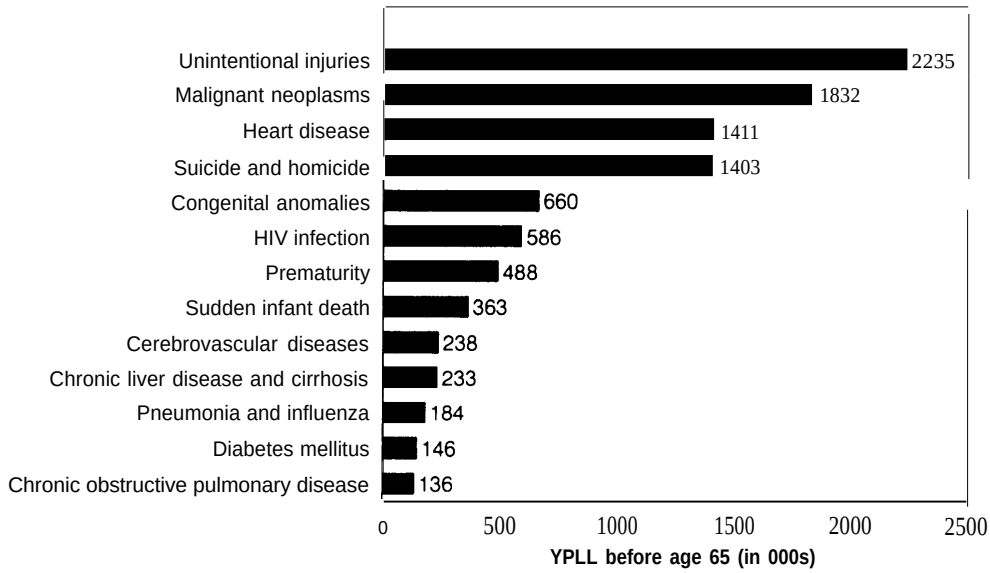
Specifying and Circumscribing the Benefits

Insurance benefits can be defined with varying degrees of specificity. At a very general level, insurance benefits could cover ''preventive services, ' "preventive services for children," or "services provided during a periodic physical examination. At a less general level, a benefit might state that it reimburses for ''breast cancer screening. " Alternatively, it could state that it does "not reimburse for lung cancer screening. " At an even more refined level, the benefit could state that it reimburses for ''breast cancer screening for women aged 50 to 65 every two years using mammography and physical breast examination." Thus the insurance benefit could simply describe the general type of service; it could describe a condition (e.g., breast cancer) and the intervention in general terms (e.g., screening); or it could specify the intervention (e.g., mammography), the patient indications (e.g., sex, age, race, behavioral characteristics, medical history), and protocols (e.g., frequency of screening, type of technology, training of the provider).

Some specific clinical preventive services are recommended for individuals based only on gender and age characteristics. These recommendations would be relatively easy to translate into

[8] Another important benefit design issue is the presence of cost-sharing. Issues pertaining to cost-sharing are addressed in the OTA background paper, *Benefit Design in Health Care Reform: Background Paper—Patient Cost-Sharing (203).*

Figure 2-3-Leading Causes of Years of Potential Life Lost (YPLL) Before Age 65,1969 (in Thousands)



SOURCE: U.S. Congress, Office of Technology Assessment, adapted from U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, "Years of Potential Life Lost Before Ages 65 and 85—United States, 1988-1980," Morbidity and Mortality Weekly Report, 41 (18):314-328, 1992.

an insurance benefit. Other services are recommended only for individuals identified as at high risk for developing the disease according to complex characteristics. For example, the USPSTF recommends children, ages 2 through 6, who are at high-risk be screened for hearing impairment, where high-risk children are defined as follows:

> children with a family history of childhood hearing impairment or a personal history of congenital perinatal infection with herpes, syphilis, rubella, cytomegalovirus, or toxoplasmosis; malformations involving the head or neck (e.g., dysmorphic and syndromal abnormalities, cleft palate, abnormal pinna); birthweight below 1500 g; bacterial meningitis; hyperbilirubinemia requiring exchange transfusion; or severe perinatal asphyxia (Apgar scores of O-3, absence of spontaneous respirations for 10 minutes, or hypotonia at 2 hours of age) (224).

Insurance contracts could include descriptions of what constitutes a high-risk individual in the case of these more complex indications. Alternatively, when the indications are complex, insurance contracts could specify that screening would be appropriate for high-risk individuals and allow the clinician to determine who constitutes a high-risk person. Finally, insurance companies could indicate that they will cover interventions provided to high-risk individuals if provided in accordance with specified guidelines, such as those of the USPSTF.

Most preventive interventions are not effective, for all patients. Moreover, factors such as the frequency, type of technology, and training of providers may greatly influence the effectiveness of an intervention. Therefore, a broadly defined benefit may leave more room for ineffective applications. At the same time, the broader the benefit, the greater the leeway for clinical judgment and patient preferences. Thus an important question is whether medical decision-making is improved when the coverage allows flexibility in tailoring interventions to individual patients.

Preventive services are indicated on the basis of risk factors, such as behavior, medical history, and race, sex, and age, where a risk factor is a characteristic which has been found in populations, on average, to be positively associated with the development of a disease or condition. In contrast, diagnostic and therapeutic interventions are indicated by the signs, symptoms, and complaints of individual patients, in addition to the factors just mentioned. Therefore, indications for using preventive interventions may be more easily specified in an insurance policy, and may require less clinical judgment, than indications for employing diagnostic and therapeutic procedures. However, it is unclear whether all the appropriate indications for preventive services could be adequately captured in an insurance contract.

The level of specificity of the benefit may also depend on the degree to which a more specific benefit allows third party payers to monitor and control utilization and costs. In general, the less specific the benefit, the less control third-party payers may have over utilization and costs. Therefore, the degree of perceived overuse may determine the need for more specific criteria. For example, some might argue that, in the case of preventive interventions, the threat of overuse and runaway costs is minimal. The literature suggests that preventive medicine and public health focus on encouraging use of clinical preventive services rather than deterring use. Because routine visits involve some cost, inconvenience, and discomfort, and are not usually a response to discomfort or pain, most patients may not seek enough services rather than receive too many. On the other hand, even seemingly minor decisions, such as those pertaining to the frequency of screening, can have an extremely large impact on the overall costs of the service, and in the absence of a circumscribed benefit, providers may err on the side of providing ‘ ‘too much’ preventive care, rather than “too little’ when a patients seeks routine care.

A third consideration is administrative feasibility. A more detailed benefit could result in a more complex claims system and potentially greater administrative costs and errors (192). Even if overuse, or inappropriate use, are problems, the ability of detailed insurance plans to limit services depends on the extent to which the system can be ‘‘gamed, ’ for example, whether clinicians can falsely describe patients as falling into given risk categories in order to receive reimbursement. The salience of these issues may depend, however, on the structure of the delivery system.

A final consideration is the evolving nature of information on health effects. The greater the specificity of the benefit, the more responsibility falls on the designers of the benefit to keep abreast of changes in information on the best application of each intervention, and to incorporate these changes into their insurance contracts.

Unit of Payment

Many preventive interventions are paid for as separate billable items. Payment is typically made only for the procedure and not for the physician’s visit at which the procedure is administered (191). In contrast to procedure-specific benefits, *a* packaged benefit would reimburse providers for a group of specified procedures or activities in a defined visit schedule.

It has been argued that a packaged benefit offers potential advantages over the incremental procedure-specific approach (29,191). One advantage of a packaged benefit is that the freed costs associated with patient scheduling and preparation, medical record keeping, and billing could be spread across a number of specific interventions (19 1). Another advantage is that it may allow services to be integrated with one another (19 1), For example, screening for sexually transmitted disorders could be integrated with sex education. Finally, it may foster greater continuity of care and tailoring of services to a patient’s medical history,

An integrated and more comprehensive appreach also has disadvantages. Specifically, a packaged benefit is less flexible and may necessitate an additional visit which could ultimately lower patients' use of preventive services (191). For patients who must visit specialists, it maybe more convenient to have some of the preventive services provided at that visit rather than having the services provided during a separate primary care visit (e.g., blood pressure, cholesterol measurement, vaccinations).