Benefit Design in Health Care Reform:
Clinical Preventive Services

September 1993

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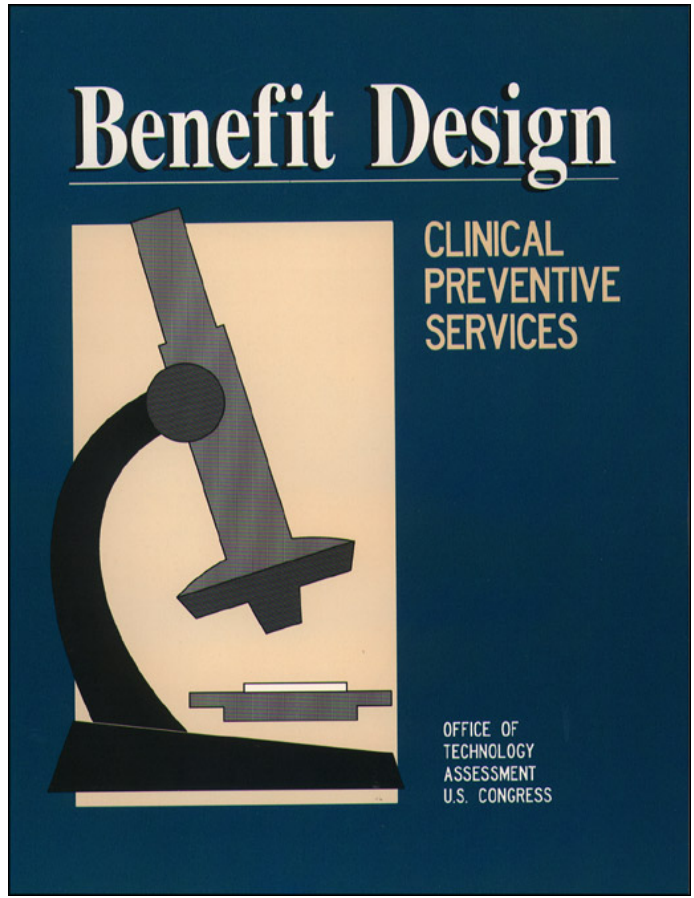

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Foreword

Health care is one of the Nation's preeminent domestic policy concerns. The contemporary health care reform debate has brought to the fore thorny issues surrounding the design of health care benefits. The scope and depth of health insurance coverage can have a substantial impact on the health services people obtain, on the costs of the health care system, and, ultimately, on the health of the Nation.

This Report is part of an OTA series on *Benefit Design in Health Care Reform* that explores the merits of using information on health effects and cost-effectiveness to formulate health insurance benefits, When it is complete, the series will include publications on general policy issues, coverage of clinical preventive services, benefits for mental health and substance abuse treatment, and patient cost-sharing requirements. The benefit design series is a component of a larger OTA assessment, *Technology, Insurance, and the Health Care System,* which was requested by the Senate Committee on Labor and Human Resources (Edward M. Kennedy, Chairman), and was endorsed by the House Committee on Energy and Commerce (John D. Dingell, Chairman), the House Committee on Ways and Means Subcommittee on Health (Willis D. Gradison, then Ranking Minority Member), and Senator Charles E. Grassley (Committees on Budget, Finance, Special Committee on Aging). Other publications related to the assessment include *Does Health insurance Make a Difference?-Background Paper* and *An Inconsistent Picture: A Compilation of Analyses of Economic Impacts of Competing Approaches to Health Care Reform by Experts and Stakeholders.*

This Report examines the evidence on the effectiveness and cost-effectiveness of selected clinical preventive services, and whether and how this information might be used to design insurance benefits. Clinical preventive services, as defined by OTA, are "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. " The Report does not aim to provide definitive advice to Congress or others about whether or not to cover specific clinical preventive services. Rather, it aims to provide a context for the Nation as it considers how to make such decisions.

OTA was assisted in the preparation of this Report by the advisory panel for the *Technology, Insurance, and the Health Care System* assessment, a group of leading health care provider, insurer, business, academic, and consumer representatives, and by numerous other health policy experts. OTA gratefully acknowledges the contribution of each of these individuals. As with all OTA reports, the final responsibility for the content of this Report rests with OTA.

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NOTE: OTA appreciates and is grateful for the valuable assistance and thoughtful critiques provided by the advisory panel members. The panel does not, however, necessarily approve, disapprove, or endorse this Report. OTA assumes full responsibility for the Report and the accuracy of its contents.

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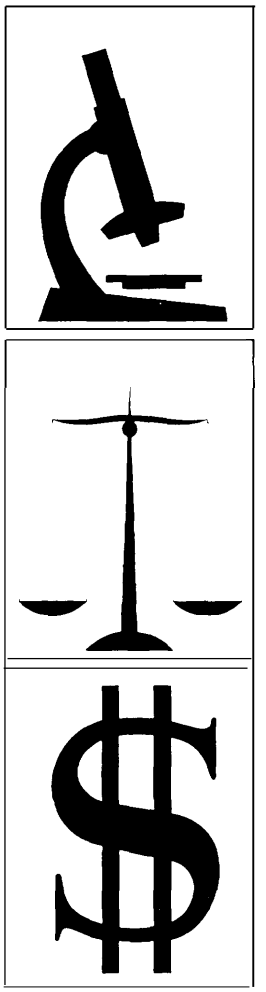

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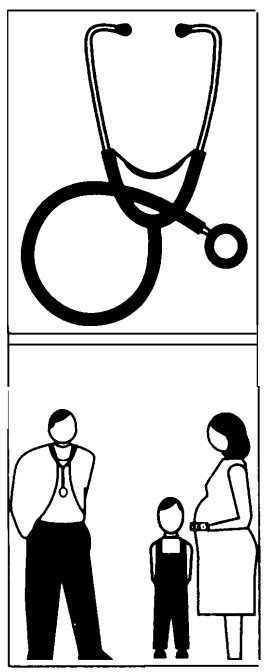

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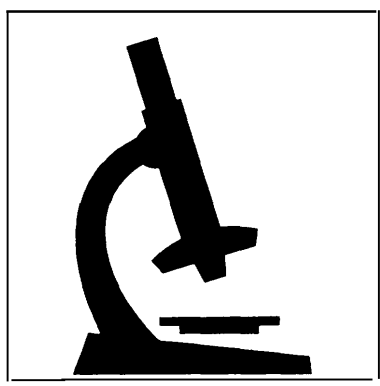
Summary and Policy Options 1

INTRODUCTION AND CONGRESSIONAL REQUEST

As reform of the Nation's health care system has risen to the top of the domestic policy agenda, the issue of what services to cover has increased in importance. Clearly, the scope and depth of services that are covered in any health insurance scheme can have a tremendous impact on how much health care people obtain, on the costs to the system, and, ultimately, on the health of the Nation's people. In order to provide Americans with an optimal level of care, at a reasonable cost to the Nation, policymakers at all levels have been rethinking traditional approaches to benefit design and considering the merits of using explicit scientific criteria to more clearly define the benefit structure.

This report is one of a series of publications on *benefit design in health care reform* being issued as part of the Office of Technology Assessment's (OTA) assessment, *Technology, Insurance, and the Health Care System. The* other publications in the Benefit Design Series are described in box l-A. The overall assessment is being conducted in response to a request from the Senate Committee on Labor and Human Resources (Senator Edward M. Kennedy, Chairman), that was endorsed by the House Committee on Energy and Commerce (Congressman John D. Dingell, Chairman), the House Committee on Ways and Means Subcommittee on Health (then-Ranking Minority Member Willis D. Gradison), and Senator Charles E. Grassley, a member of OTA Technology Assessment Board. Chairman Dingell asked OTA to assess the extent to which a minimum benefit package could be designed based on information about health effects and cost-effectiveness. Other requesters agreed that this was an important question and that OTA should address it by



Box I-A-Other Publications in the Office of Technology Assessment's Series on Benefit Design in Health Care Reform

- *Benefit Design in Health Care Reform: Report #2—Mental Health and Substance Abuse Treatment Services* (U.S. Congress, OTA, in preparation). This report has three goals. First, at the request of Congress, the report addresses the question of whether mental health and substance abuse benefits should be in a core benefit package, should there be such a package. Second, the report describes whether information on effectiveness and cost-effectiveness could be used to select specific types of mental health and substance abuse services for coverage, and the limitations of using such information. And third, the report reviews information on the effectiveness and cost-effectiveness of services for selected mental health and substance abuse conditions.
- *Benefit Design in Health Care Reform: Background Paper—Patient Cost-Sharing* (203). This background paper reviews the evidence on the effects of patient cost-sharing on the uses and costs of personal health services, as well as, to the extent possible, the effects of patient cost-sharing on patients' health.
- *Benefit Design in Health Care Reform: Report #3—General Policy Issues* (U.S. Congress, OTA, in preparation). This report uses the analyses in this report and the two publications listed above, as well as other sources (e.g., U.S. Congress, OTA, Oregon, May 1992), to gain insights into the possibilities and pitfalls associated with trying to design a benefit package based on effectiveness and cost-effectiveness information, in relation to other critical factors, such as public preferences and political considerations.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

means of an overall brief on the topic, as well as through examinations of the evidence on clinical preventive services; mental health and substance abuse treatment services; and patient cost-sharing.

This *report-Benefit Design in Health Care Reform: Report #I--Clinical Preventive Services* —addresses issues concerning coverage of clinical preventive services. Preventive services are often portrayed as providing 'good investments' and thus potentially good candidates for health insurance coverage. This report examines this perception and considers the role that information on effectiveness and cost-effectiveness can, and cannot, play in choosing specific clinical preventive services to include in a benefit package.

FOCUS AND ORGANIZATION OF THE REPORT

The focus of this report is on selected clinical preventive services for asymptomatic individuals, that is, individuals who do not exhibit signs of the health condition or disease the clinical preventive service is designed to prevent.

For the most part, the clinical preventive services that have been at greatest contention and subject to the most scrutiny are screening services designed to detect a disease at an early stage (e.g., breast cancer screening, screening for high blood pressure); thus, most of the clinical preventive services reviewed in this report are screening services.

Selected other clinical preventive services have also been debated and subject to some scientific scrutiny because of their assumed potential for preventing unwanted health conditions; several of these clinical preventive services are also reviewed in this report (e.g., immunizations, contraceptives, smoking cessation interventions, some physician counseling).

Not all possible clinical preventive services are reviewed in this report; new clinical preventive services are discovered or introduced into the coverage debate regularly. The purpose of the report is to place the issue of using scientific evidence at the forefront of the health care reform and coverage debates.

The report is organized as follows: chapter 1 summarizes the primary findings of the report and

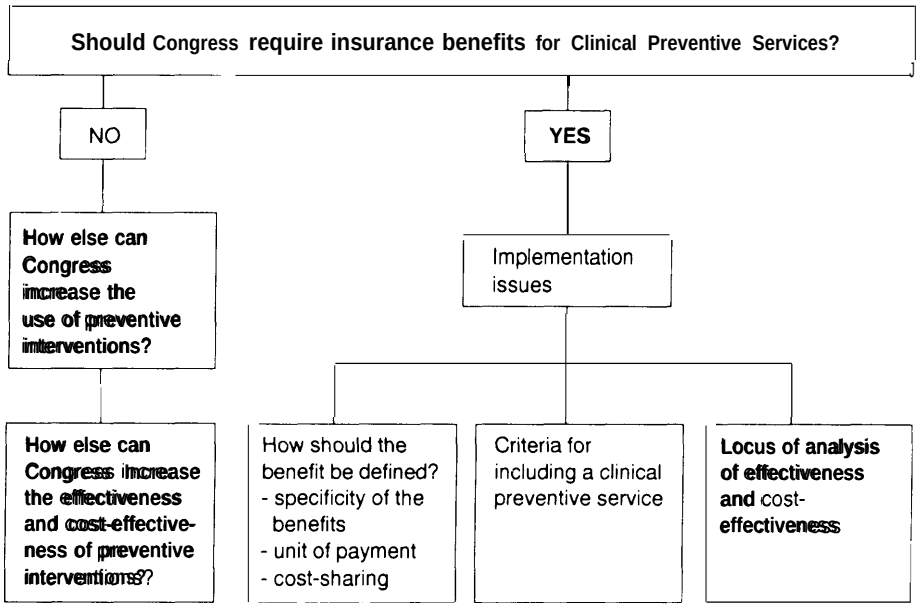
presents issues and policy options. Chapter 2 provides an overview of the issues and discusses: defining clinical preventive services in the context of prevention generally; the use of insurance as a funding source for clinical preventive services; criteria for choosing which clinical preventive services to include in an insurance package; and how insurance benefits for clinical preventive services might be designed once services have been chosen for coverage (e.g., extent of patient cost-sharing, unit of payment, limits on the frequency, limits by patient characteristics). Chapter 3 reviews the evidence on the effectiveness of a select group of clinical preventive services that are frequently proposed for insurance coverage. The last chapter, chapter 4, discusses how information on costs and cost-effectiveness might be used to design benefits for clinical preventive services and the evidence on the costs and cost-effectiveness of selected clinical preventive services.

SUMMARY OF FINDINGS

Below is a brief synopsis of the report's major conclusions:

- Many clinical preventive services have not been evaluated in terms of their effectiveness and cost-effectiveness. Therefore, whether they are effective or relatively cost-effective is simply not known.
- Some, but not all, clinical preventive services for asymptomatic individuals have been found to be effective in reducing, or delaying, the incidence and burden of disease for some patients.
- Very few clinical preventive services have been found to be cost-saving to society in terms of medical care costs when provided to individuals at average risk for the condition.
- An entity's finding that a clinical preventive service is ' 'cost-effective' should not be interpreted to mean that it is ''cost-saving. " Cost-effectiveness is always a statement about the costs of an intervention relative to its effectiveness.
- If policymakers aim to either save money or improve the health of the population, or both, they will need to: a) take care to distinguish among the preventive services that they cause or encourage to be supported; and b) consider the patient characteristics, frequency, and fee schedules for such services. The costs and cost-effectiveness of clinical preventive services may vary greatly depending on the targeted population's underlying risk for the condition and the circumstances under which the intervention is applied.
- Examples of clinical preventive services that evidence shows are effective include: screening for breast cancer (mammography and clinical breast examination) in women 50 years of age and older; screening for cervical cancer (Pap smears) for women who are or have been sexually active; cholesterol screening for certain individuals; selected smoking cessation interventions; hypertension screening for certain individuals; adult immunizations for certain individuals; and screening for sexually transmitted diseases for certain individuals. Although these services are effective—in the sense that they are likely to result in net benefits to health-all have been found likely to increase financial costs to society when applied to populations that are at average risk for the specific condition (with the exception of screening for sexually transmitted diseases which has not been extensively evaluated using cost-effectiveness analysis).
- Examples of clinical preventive *services* that are effective and can reduce aggregate (societal) medical care costs (under certain conditions) include: most childhood immunizations; newborn screening for some congenital disorders (i.e., one-time screen for congenital hypothyroidism and phenylketonuria); and prenatal care for poor women.
- If the aim is to design benefit packages based on effectiveness and cost-effectiveness, the

Figure I-I—Policy Issues Concerning Insurance Coverage for Clinical Preventive Services



SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

specifications of coverage (e.g., which services are covered and under what circumstances), are currently likely to be simpler for clinical preventive services than for therapeutic interventions (i.e., interventions used to treat disease) primarily because, to date, the indications for using preventive interventions have been based on general population characteristics rather than complex signs and symptoms. For example, the indication for mammography is based primarily on the age and gender of the patient. In contrast, selection of a treatment for breast cancer might be influenced by the extent to which the cancer has spread, whether previous treatment has been provided, the number and severity of other diseases, and the patient's tolerance for risks and side effects.

Insurance for clinical preventive services is provided primarily to encourage the use of preventive interventions, rather than to protect against the risk of a catastrophic financial event associated with medical treatment. Evidence suggests that insurance coverage will increase the use of clinical preventive services, but not, by itself, to optimal levels. Whether insurance coverage-or some other means-should be used to help encourage the use of clinical preventive services is only in part a scientific question (e.g., does insurance lead to greater use of services?). It is also a philosophical question and depends on what one considers the purpose of health insurance (e.g., to spread financial risk or to encourage use of services).

ISSUES AND OPTIONS

OTA's analysis of the implications of any of the number of alternative approaches to coverage for preventive services that Congress may or may not pursue suggests that the question is more complicated than "to cover or not to cover. " Figure 1-1 outlines key prevention-related policy issues facing Congress as it considers health care

reform. Each of these issues, and related options, are described in this section.[1]

The first issue Congress must address is whether insurance plans should be required to cover clinical preventive services. If the answer to this question is "yes," several questions follow. One question is: what are the criteria for choosing which specific preventive services to cover? The criteria evaluated in this report were effectiveness, cost-effectiveness, and net costs. A second question is: who should provide the information on effectiveness and costs? A third question is: how should the specifics of the benefit package be determined (e.g., patient cost-sharing; limits on the periodicity of screening)?

Most of the choices related to the issues raised in this report could be adapted to any of a broad range of alternative health care reform schemes. For example, even in a "single payer" system with a global budget, some entity could determine which services would be reimbursed. Some choices related to clinical preventive services may, however, fit better or be associated more with some approaches to reform than others. The following section notes when an alternative related to clinical preventive services is particularly suited or unsuited, or must be adapted to, a particular approach to health care reform.

As the implications of insurance for preventive services and Congressional options are described, it is useful to consider the possible goals of policies regarding insurance benefits for clinical preventive services. Some potential goals are listed in table 1-1.

It is important to recognize that these goals may be addressed through means other than benefit design. The following section discusses options that might aid in pursuing the objectives of greater utilization and effectiveness of clinical preventive services, regardless of decisions concerning insurance coverage. Table 1-2 provides an overview of the options discussed in this report.

Table I-l—Potential Goals of Policies Concerning Insurance for Clinical Preventive Services

1. Increase the use of clinical preventive services.
2. Improve and/or maintain the health of the population.
3. Control or minimize health care costs paid by society, taxpayers, patients, employers, and others.
4. Improve the effectiveness of preventive interventions.
5. Allow flexibility in the provision of services.
6. Allow consumers to exercise their preferences for services.
7. Minimize administrative burden on patients and physicians.
8. Encourage equitable access to services.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

Coverage Options

OPTION 1. *Congress could make no statement or requirement pertaining to coverage of clinical preventive services.*

In the absence of a federally mandated benefit package that includes clinical preventive services, choices about which insurance benefits to include may continue to be influenced by *existing* Federal regulations, State mandates, and market forces. A potential disadvantage with this decentralized and non-uniform approach is that it perpetuates variations in benefits. To the extent that clinical preventive services are effective, this approach may result in varying incentives for improving or maintaining health status and may be viewed as inequitable.[2]

An advantage of Congress not requiring benefits for clinical preventive services is that individ-

1 A broad range of health care reform alternatives was being debated while OTA was developing this report (200). This report does not presume that Congress will pass any particular national-level health care reform. To date, there have been few national-level policies related to health care coverage for specific services. Exceptions have been limited to specific subsets of populations or to specific types of insurers and include the HMO Act of 1973, as amended, and coverage for various clinical preventive services under Medicare and Medicaid. For the most pm-t decisions about coverage for specific services have been made in the private sector or legislated at the State level (202).

2 General arguments have been put forth for establishing a uniform benefit package, for example, in the context of some "managed competition' plans (172). Uniform benefits are expected to elucidate price differences between plans thus making it easier for consumers to compare and evaluate insurance plans. In addition, uniform benefits may avoid some of the problems of risk selection (202,172).

Table 1-2—Policy Options for Congressional Consideration

Coverage Options
Option 1: Congress could make no statement or requirement pertaining to coverage of clinical preventive services.
Option 2: Congress could require that all insurance plans include coverage for clinical preventive services, or establish a core benefit package that includes coverage for clinical preventive services.
Option 3: If Congress requires insurance coverage for specific clinical preventive services, coverage decisions concerning specific clinical preventive Interventions could be based on their effectiveness, cost-effectiveness, and/or net costs.
Options Regarding Sources of information on Effectiveness and Cost-Eftectiveness
Option 4: Congress could identify one or more U.S. Executive Branch agencies that would determine whether specific clinical preventive services are effective and the cost-effectiveness of those clinical preventive services.
Option 5: Congress could identify provider organization(s) that would determine whether specific clinical preventive interventions are effective and their cost-effectiveness.
Option 6: Congress could determine whether specific clinical preventive services are effective and evaluate their cost-effectiveness.
Options Regarding Specific Benefit Design Features
Option 7: Congress could identify a Federal agency to determine the specifics of the benefit package (e.g., periodicity schedules, covered populations),
Option 8: Congress could require full insurance coverage for clinical preventive services for those individuals with incomes below a given level.
Option 9: Congress could require full insurance coverage for clinical preventive services for the total insured population.
Access *Options*
Option 10: Congress could encourage the provision of clinical preventive services by directly allocating funding to programs that provide clinical preventive services, such as public clinics, school-based clinics, and work-site programs.
Option 11: Congress could encourage the provision of clinical preventive services by encouraging programs aimed at reducing nonfinancial barriers to access.
Research Options
Option 12: Congress could encourage the provision of effective clinical preventive services by promoting research on the efficacy, effectiveness, and cost-effectiveness of clinical preventive services.
Option 13: Congress could encourage the provision of effective clinical preventive services by promoting the dissemination of information on efficacy.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

uals may retain greater control over how their money is spent. For example, in the absence of Federal requirements, individuals, employee organizations, or employers could decide whether they would rather have insurance for clinical preventive services and thus lower out-of-pocket costs if they receive clinical preventive services, or whether they would rather have lower insurance premiums and higher out-of-pocket costs if they receive clinical preventive services. Whether decisions by individuals, or their employers, are "better" than decisions made by government is debatable. On the one hand, government may have greater access to information on effectiveness and cost-effectiveness, and therefore, could better weigh the costs and the benefits of coverage decisions; on the other hand, government may not be able to adequately address individual values and preferences.

OPTION 2. *Congress could require that all insurance plans include coverage for clinical preventive services, or establish a core benefit package that includes coverage for clinical preventive services.*

Congressionally mandated insurance benefits for preventive services may directly, or indirectly, affect the following areas: patients' out-of-pocket costs; the demand for, and use of services; the cost of insurance premiums; total health care costs; and the insured population's health. The impact on each of these areas is reviewed below.

In a private insurance market, one effect of covering clinical preventive services through insurance would be the reduction of the out-of-pocket price to patients of preventive care. Research suggests that reduced out-of-pocket costs tend to increase the demand for clinical preventive services, although a substantial percentage of individuals still do not receive the recommended levels of preventive care, even when covered under insurance plans.

While insurance coverage for clinical preventive services would reduce patients' out-of-pocket costs (relative to no coverage) at the time of service, average insurance premiums will likely increase. Additionally, the increased use of services, due to insurance coverage, is likely to be associated with an increase in total medical expenditures. With few exceptions, these additional costs are unlikely to be offset by savings resulting from avoided treatment.

The ultimate goals of encouraging the use of preventive services are to improve and/or maintain health. A number of clinical preventive services have been found to reduce or delay the probability of mortality and morbidity. Therefore, to the extent that mandated benefits for clinical preventive services increase the use of effective clinical preventive services, they are likely to improve or maintain the insured population's health, and for some interventions (e.g., immunizations, screening for sexually acquired disorders) may also provide health benefits to those not directly receiving the interventions.

OPTION 3. *If Congress requires insurance coverage for specific clinical preventive services, coverage decisions concerning specific clinical preventive interventions could be based on their effectiveness, cost-effectiveness, and/or* ***net*** *costs.*

Effectiveness Criteria

The principal advantage of requiring insurance coverage for clinical preventive interventions based on their net benefits to health is that this approach would deter patients from receiving ineffective or marginally effective clinical preventive services. Preventive interventions are considered effective if they reduce, or delay, the probability of mortality and/or morbidity. However, defining what constitutes effective preventive care is a complex endeavor. In order to use effectiveness as a basis for designing an insurance benefit package, some entity must review the relevant research and determine whether a given preventive intervention is effective, and under what conditions. It is critical that this entity use methods which are as evidence-based as possible. In addition, the rationales and criteria used to evaluate the evidence and draw conclusions concerning effectiveness should be made as explicit as possible.

Cost-effectiveness Criteria

Using cost-effectiveness as a criterion for coverage decisions may invoke greater recognition of the likely tradeoffs between the goals of improving or maintaining health and the goal of limiting aggregate health care costs. In addition, cost-effectiveness analysis may aid in evaluating those societal tradeoffs. Finally, cost-effectiveness analysis may encourage policymakers to consider a broader range of likely consequences of promoting a preventive intervention (e.g., costs associated with follow-up visits to treat conditions found during screening).

Cost-effectiveness analysis has some limitations and weaknesses. Specifically, cost-effectiveness analyses typically do not measure important but less tangible health benefits and do not adequately incorporate equity and political issues. If people rely too heavily on cost-effectiveness, these political concerns and intangibles may be undervalued (183). Despite these problems, on balance cost-effectiveness analysis can be one of several useful tools for making resource allocation decisions, such as those pertaining to insurance benefits.

Net Cost Criterion

Under the criterion of net cost, clinical preventive services would be covered if the costs associated with their provision were less than a given amount. For example, only those services that lead to a net reduction in medical costs might be included. Costs could be defined in several ways, including costs to society, costs to insurance plans, costs to patients, and costs to employers. One problem with this standard is that services with relatively low effectiveness per resource consumed may be covered. For example, a certain intervention may be relatively inexpensive to perform, but may result in few health benefits. Under a net cost criterion, this intervention might be covered, whereas an intervention that increased costs but conferred substantial health benefits might not be covered. This approach, therefore, implicitly returns to the question of cost-effectiveness (191).

Options Regarding Sources of Information on Effectiveness and Cost-Effectiveness

If Congress decides to make coverage decisions based on effectiveness and cost-effectiveness information, Congress could identify a source, or sources, for this information. The following options concern organizations which could provide information on effectiveness and cost-effectiveness either to Congress or to other entities and individuals making coverage and/or purchasing decisions. It is important to note that independent of the source of information, Congress could outline criteria, or methods, for evaluating evidence on effectiveness and costs, or designate some other entity to outline such criteria or methods.

OPTION 4. *Congress could identify one or more U.S. Executive Branch agencies that would determine whether specific clinical preventive services are effective and the cost-effectiveness of those clinical preventive services.*

Many agencies within the Department of Health and Human Services have been involved in efforts to evaluate the effectiveness of specific clinical preventive interventions and have issued recommendations regarding their appropriate utilization.[3] Congress could use the evaluations by one or more of these agencies to design and update a clinical preventive services benefit package. It would be useful, however to have more consistency among those agencies in the use of criteria and methods to evaluate effectiveness.

OPTION 5. *Congress could identify provider organization(s) that would determine whether specific clinical preventive interventions are effective and their* cost-effectiveness.

Many organizations representing health care providers (e.g., the American College of Physicians, the American Academy of Pediatrics) have issued recommendations regarding the use of specific clinical preventive services. Although input from providers seems an appropriate part of

3 For example, the National Institutes of Health have issued recommendations on many types of screening tests, including hypertension and cholesterol screening. The Centers for Disease Control and Prevention have developed expert panels which have issued recommendations for screening for sexually transmitted diseases and immunizations. The Agency for Health Care Policy and Research has been involved in synthesizing the information on the effectiveness of a variety of medical interventions (e.g., screening for sickle cell disease). Finally, the Office of Disease Prevention and Health Promotion (ODPHP) established, and provides staff support to, the U.S. Preventive Services Task Force (USPSTF), which evaluated the effectiveness of a number of clinical preventive services.

effectiveness assessments, there are problems with relying exclusively on provider groups. First, provider groups may have an incentive to encourage the use of services and thus there is a potential conflict of interest. Second, many provider groups have based their assessments of clinical preventive services on expert opinion rather than on comprehensive reviews of the literature and they have not clearly documented the basis for their decisions.

OPTION 6. *Congress could determine whether specific clinical preventive interventions are effective and evaluate their cost-effectiveness.*

Rather than identifying one or more U.S. Executive Branch agencies to determine whether specific clinical preventive interventions are effective, Congress could make this determination. In the past, Congressional agencies have evaluated the effectiveness of clinical preventive services,[4] However, Congressional agencies do not have the resources to design a comprehensive benefit package based on effectiveness and cost-effectiveness information.

Options Regarding Specific Benefit Design Features

Designing an insurance benefit package requires a number of decisions beyond the choice of which clinical preventive services to cover. These decisions include: whether to circumscribe coverage for particular services based on patient characteristics, frequency of use, and other parameters; whether to apply cost-sharing and, if so, to what extent; and whether to reimburse services as a package or individually. The following options relate to these decisions.

OPTION 7. Congress could identify a Federal agency to determine the specifics of the benefit package (e.g., periodicity schedules, covered populations).

Seemingly innocuous decisions about the frequency of clinical preventive services, and the populations who should receive clinical preventive services, can have a large impact on the overall costs and effectiveness of the service. Further, information about the costs and benefits of particular protocols for providing interventions is constantly changing as new research emerges. Decisions about the specifics of the benefit package could be delegated to a Federal agency.

OPTION 8. *Congress could require full insurance coverage for clinical preventive services for those individuals with incomes below a given level.*

If the primary purpose of insurance coverage for preventive services is to increase the use of these services, policymakers may want to link the degree of coverage to the degree to which use is actually increased, The effect of providing insurance may vary for different segments of the population; for example, people with lower income may increase their use of services in response to insurance to a greater extent than those at higher income levels. Moreover, the benefits of clinical preventive services may be greater for those at lower incomes due to their greater risk for particular conditions. Congress could require full insurance coverage (i.e., no cost-sharing) for prevention only for those with incomes below a given level.[5]

OPTION 9. *Congress could require full insurance coverage for clinical preventive services for the total insured population.*

Requiring full insurance for the total insured population reduces some of the administrative

[4]For example, as part of its effort to obtain information on the consequences of expanding Medicare benefits for preventive services, Congress asked OTA to study the effectiveness of selected preventive services for the elderly. OTA subsequently completed evaluations on pneumococcal vaccines, influenza vaccines, breast cancer screening, glaucoma screening, cholesterol screening, colorectal cancer screening, and cervical cancer screening in the elderly.

[5] patient cost. sharing for clinical preventive services is described more fully in the OTA Background Paper, *Benefit Design in Health Care Reform: Background Paper—Patient Cost-Sharing (203).*

OTA STAFF

Neighborhood health centers often provide clinical preventive health services.

burden associated with determining who would be eligible for insurance without cost-sharing. Moreover, it is consistent with the goal of providing insurance for clinical preventive services to increase utilization. However, because patient cost-sharing typically reduces the use of services, this option is likely to be more costly than imposing cost-sharing on some, or all, of the insured population (203).

Access Options

Insurance coverage increases the use of services by lowering the out-of-pocket price to consumers at the time of purchase. There are, however, other approaches Congress could take in order to encourage greater use of clinical preventive services, rather than, or in addition to, requiring insurance coverage for clinical preventive services. Two of these approaches are outlined below.

OPTION 10. Congress could encourage the provision of clinical preventive services by directly allocating funding to programs that provide clinical preventive services, such as public clinics, school-based clinics, and work-site programs.

The advantages and disadvantages of this approach rest on many assumptions concerning health care reform (e.g., whether the U.S. health care system continues to be primarily private, what sort of incentives providers will face, whether new delivery systems are developed).

Numerous agencies within Federal, State and local governments allocate funding to programs that provide clinical preventive services. One advantage of financing preventive services through such programs, rather than through insurance, is that prograMmatic approaches may allow greater flexibility in the delivery, and range, of interventions. For example, rather than being delivered in physicians' offices, preventive interventions could be provided at school and at work, thereby making them more accessible. In addition, programs may be more easily targeted to populations that are at ''high risk.' For example, low-income mothers may benefit more from programs to increase their use of prenatal care than other mothers.

There are several drawbacks with directly funding individual programs. First, funding may fluctuate across regions. In contrast, mandated insurance benefits, to the extent that they apply to everyone, might allow more equal access to services. On the other hand, if services were lacking in certain areas, such as rural or inner-city locations, insurance coverage might do less to encourage access than the provision of public programs.

A second potential problem is that funding school-based and work-site programs, and public clinics, might result in a more fragmented delivery system. For example, if people had their blood pressure and cholesterol measured at work, were screened for sexually transmitted diseases at public clinics, and received immunizations at a physician's office, documentation and coordination of care might suffer.

The relative costs, and costs to various parties, of directly funding programs versus providing

insurance coverage is hard to determine and will depend on the overall structure of the health care system, as well as the structure of the individual programs. Factors such as whether insurance premiums are capped, whether providers face global budgets, the presence of other provider incentives, and the structure of the programs will affect relative costs,

OPTION 11. Congress could encourage the provision of clinical preventive services by encouraging programs aimed at reducing nonfinancial barriers to access.

Nonfinancial barriers have been identified as important obstacles to receiving clinical preventive services (189). Congress could encourage the Centers for Disease Control and Prevention, or other government agencies, to develop programs aimed at reducing nonfinancial barriers to access to clinical preventive services. Efforts to reduce nonfinancial barriers include reminder systems, improved record-keeping systems, more convenient settings, the use of nonphysician medical professionals, the use of multilingual and culturally sensitive providers, physician education, and patient education.

Research Options

OPTION 12. *Congress could encourage the provision of effective clinical preventive services by promoting research on the efficacy, effectiveness, and cost-effectiveness of clinical preventive services.*

A key finding of this report is that many clinical preventive services have not been evaluated in terms of their efficacy, effectiveness, and cost-effectiveness. Congress could promote more research on the efficacy of clinical preventive services for example, by funding more randomized clinical trials or other types of studies.

OPTION *13. Congress could encourage the provision of effective clinical preventive services by promoting the dissemination of information on efficacy.*

OTA STAFF

Schools and workplaces are alternative sites for providing clinical preventive services.

This report focuses on using information on effectiveness, cost-effectiveness and net costs to define a benefit package for clinical preventive services. One of the justifications for this approach is that, in the absence of benefits that detail the services that will be covered, ineffective services will be provided and effective services will not be provided. There are, however, numerous ways in which the effectiveness of preventive medicine may be improved other than, or in addition to, using benefit design, Methods for improving effectiveness include improved methods of disseminating information resulting from technology assessments, such as through decision support tools (e.g., reminder systems, algorithms, practice guidelines), feedback systems to providers on outcomes (e.g., profiling, outcomes measurement), and continuing education. These methods were not explicitly evaluated in this report but are being evaluated, in part, in the ongoing OTA study, *Prospects for Technology Assessment.*

The advantage of improving effectiveness through the dissemination of information, in contrast to attempting to improve practice through benefit design, is that it allows greater

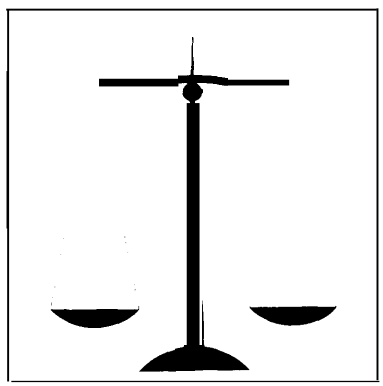
flexibility and tailoring of services to individual circumstances. Moreover, it places less burden on the developers of a benefit package to define what are effective clinical practices and to continually make timely adjustments to the benefit packages. A potential disadvantage of this approach is that most efforts to educate providers through guidelines and other means have not been extensively evaluated, and their ability to alter practice patterns is unclear.

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).

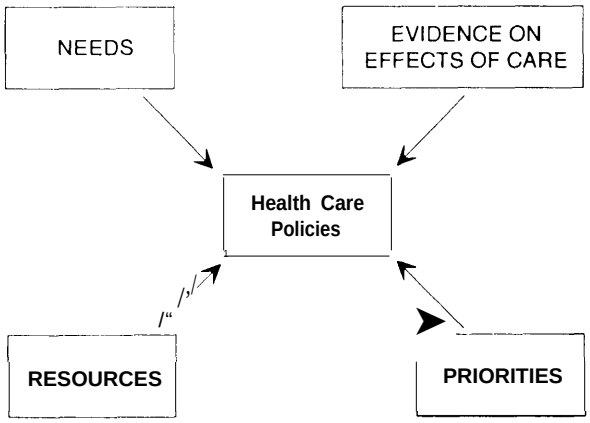
As commonly understood, a "cost-effective" service is one that is worthwhile, or a good investment relative to the alternative. However, the determination of whether the benefit is worth the cost is highly subjective and will depend on who is making the comparison, and what is being compared (55,227). 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.

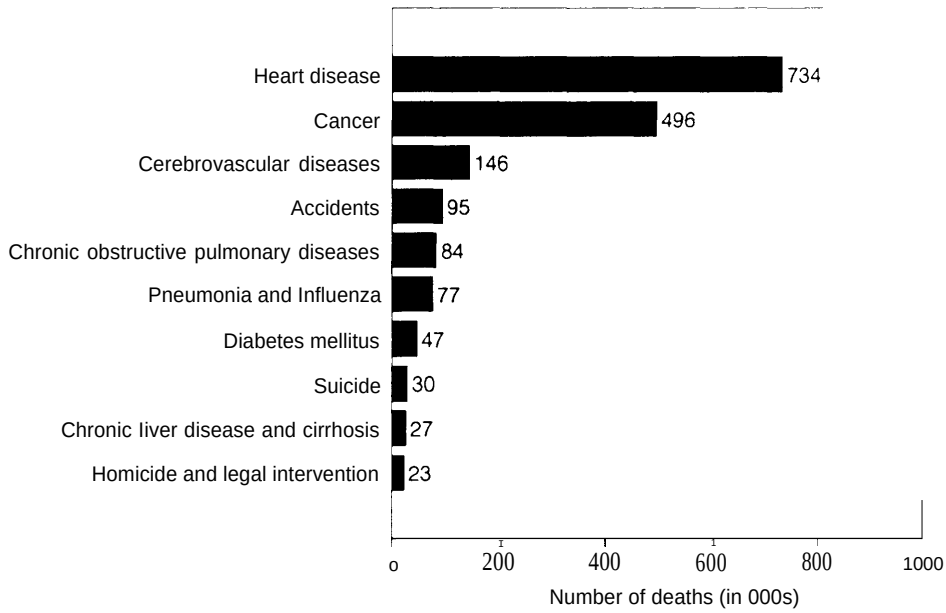
Other Criteria

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]

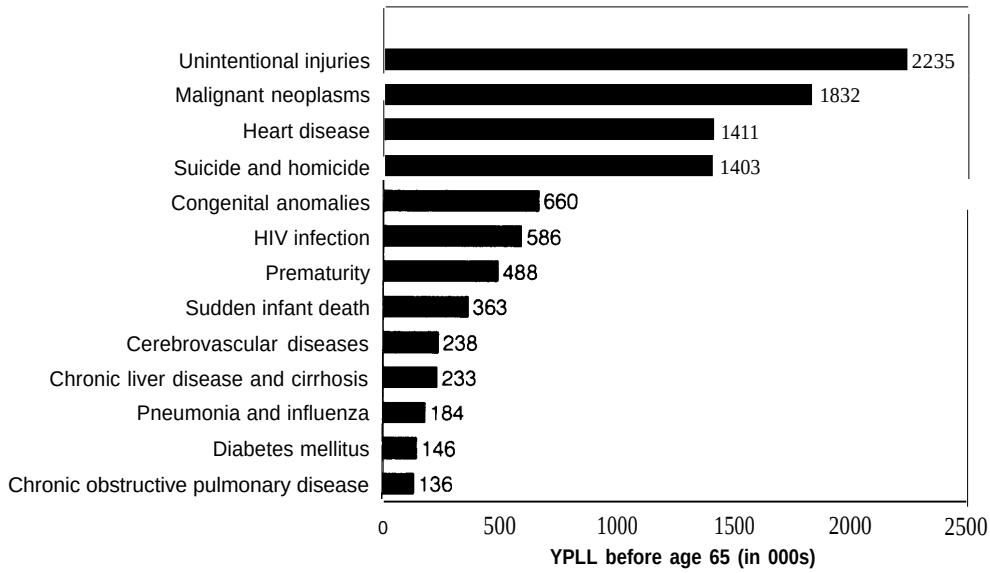
Specifying and Circumscribing the Benefits

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.

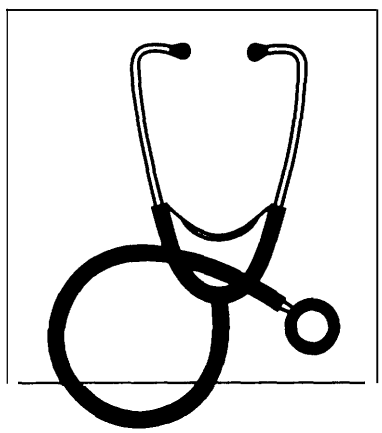
It has been argued that a packaged benefit offers potential advantages over the incremental procedure-specific approach (29,191). One advantage of a packaged benefit is that the freed costs associated with patient scheduling and preparation, medical record keeping, and billing could be spread across 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).

Evidence on the Effectiveness of a Select Group of Clinical Preventive Services

3

There is a vast literature on the effectiveness of preventive health care services. The purpose of this chapter is to present a general overview of the current state of knowledge about the effectiveness of a select group of clinical preventive services in order to address the issue of whether effectiveness criteria can and should be used to design insurance benefits for preventive services. The review relies heavily on previous reviews, particularly those that used a systematic and explicit approach to evaluating the evidence. Organizations which have reviewed the evidence on the effectiveness of clinical preventive services include the U.S. Preventive Services Task Force (USPSTF), the Canadian Task Force on the Periodic Health Examintion (CTFPHE), and the Centers for Disease Control and Prevention's (CDC) Immunization Practices Advisory Committee (ACIP) (see appendix F for a description of these groups and the methods they used to determine effectiveness). Because research has progressed since these organizations completed their reviews, subsequent studies which may have altered previous conclusions about effectiveness are identified. Conclusions of other groups, such as specialty societies and other government agencies, are also presented in order to provide a sense of the degree of consensus about the effectiveness of a particular intervention. However, most of the specialty societies, and some of the government agencies, did not base their conclusions on comprehensive reviews of the evidence, nor clearly link their recommendations to the research evidence. Therefore, although the recommendations of these organizations at-e presented, they are not used to draw conclusions about effectiveness.



This chapter reviews the evidence on effectiveness of most of the services recommended by the USPSTF for asymptomatic

individuals on the basis of individuals' sex and age, as opposed to other indications of risk such as family history (see table 3-1 for a list of the preventive interventions recommended by the USPSTF and appendix G for the periodic health examinations recommended by the USPSTF). In addition, some of the clinical preventive services which the USPSTF did not recommend for routine use are also reviewed (table 3-2 lists some of the interventions which the USPSTF did not recommend as appropriate for routine use in asymptomatic populations). Finally, all of the services included in major congressional health care reform proposals introduced in the 102d Congress are reviewed (see appendix H for a description of these proposals).

REVIEW OF THE EVIDENCE

Annual General Physical Examination

In the 1920s, the American Medical Association (AMA) and the Metropolitan Life Insurance Company first endorsed the annual physical examination as conferring long-term benefits (128). However, over the years the wisdom of this approach has been questioned. In 1979, the CTFPHE recommended that annual checkups for adults be abandoned and that primary care prevention be selectively provided according to age- and sex-specific packages of health services (29).

The CTFPHE criticized annual physical examinations on several grounds. First, they argued that the content and frequency of the examinations bore little relation to the needs of different age groups. Second, they found that there was little evidence that the tests and procedures typically included in the checkup examination were effective. Third, they found that procedures were repeated once a year even though many could have been performed equally effectively at longer intervals. In sum, they found that "the routine general annual check-up is nonspecific and casts a searching net far too broadly, particularly in the adult, is inefficient and, at times, is potentially harmful" (29).

Although the annual physical examination is no longer recommended, both the USPSTF and CTFPHE recommend periodic health examinations. The difference between the periodic health examination and the annual physical examination is that the former: 1) is provided less frequently; 2) more specifically details the interventions which should be included; 3) places a greater emphasis on tailoring interventions to individual circumstances; and 4) is limited primarily to those services which have been shown to be effective. In large part, the rest of this chapter describes the evidence on the effectiveness of services which might be included in the periodic health examination.

Breast Cancer Screening

In 1993, an estimated 183,000 new cases of breast cancer will be diagnosed and 46,300 people will die from breast cancer (20). Breast cancer is the most frequently occurring cancer in women in the United States and the second most common cause of cancer death among women (20).

There is good evidence from randomized clinical trials and case-control studies that a combination of clinical breast examinations and mammography reduce breast cancer mortality in women aged 50 and older (63,101,187,224). Most studies, however, have not shown a clear benefit of mammography and clinical breast examination for women aged 40 to 49 (see Hurley and Kaldor for a review of these studies, [101])[1] and the optimal onset for screening is controversial. Questions also remain about the optimal periodicity of screening and about the independent effects

[1] The randomized clinical trials are cited in the references at the end of this report and include refs. 168, 174, 9, 158, 76, 140, 141. The case-control studies are also cited and include 226, 47, 156.

Table 3-l-Preventive Interventions Recommended By the U.S. Preventive Services Task Force for Nonpregnant, Asymptomatic Persons, 1989[a]

SCREENING

- History
- Height and weight
- Blood pressure
- Breast examination by clinician
- Mammogram
- Papanicolaou smear
- Screening for visual acuity
- **Eye exam for amblyopia and strabismus**
- **Glaucoma testing by an eye specialist**
- **Screening for hearing loss**
- **Screening for anemia using hemoglobin and hematocrit tests**
- **Screening for phenylketonuria (PKU)**
- **Screening for congenital hypothyroidism**
- **Nonfasting total blood cholesterol**
- **Thyroid function tests**
- **Urinalysis for asymptomatic bacteriuria, hematuria, and proteinuria**

For high-risk groups only[b]

- **Complete skin exam for skin cancer**
- **Clinical testicular exam**
- **Auscultation for carotid bruits**
- **Palpation for thyroid nodules**
- **Complete oral cavity exam for oral cancer**
- **Screening for sickle cell disease**
- **Screening for diabetes using blood glucose measurement**
- **Fecal occult blood test/sigmoidoscopy**
- **Fecal occult blood test/colonoscopy**
- **Screening for lead toxicity**
- **Tuberculin skin test**
- **Rubella antibodies**
- **Syphilis testing**
- **Chlamydia testing**
- **Gonorrhea testing**
- **Counseling and testing for human immunodeficiency virus (HIV)**
- **Resting electrocardiogram**
- **Exercise stress test**
- **Radiologic screening to detect low bone mineral content**

COUNSELING

- **Counseling about diet, exercise, injury prevention, dental health, smoking cessation, substance use, sexual practices**

CHEMOPROPHYLAXIS[c] AND IMMUNIZATIONS

- **Immunizations (Diphtheria-Tetanus- Pertussis [DTP], Oral poliovirus [OPV] Measles-mumps-rubella [MM R], Haemophilus influenza type b [Hib], Hepatitis B [HBV], Tetanus-diphtheria [Td] booster, Pneumococcal vaccine, influenza vaccine)**
- **Fluoride supplements**
- **Aspirin prophylaxis to prevent myocardial infarction**
- **Chemoprophylaxis with estrogen therapy**

a The frequency of these interventions vary substantially by age and gender.
b Factors defining someone as "high risk" are factors other than age and gender, such as family history or behavioral characteristics.
c Chemoprophylaxis is the use of chemical agents (e.g., aspirin fluoride) to prevent disease.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993, adapted from U.S. Preventive Services Task For *Guide to Clinical Preventive Services* (Baltimore, MD: Williams and Wilkins, 1989).

Table 3-2—Preventive Interventions Not Recommended By the U.S. Preventive Services Task Force for Use on Asymptomatic Persons, 1989

- Routine measurement of blood pressure using intra-arterial catheters
- Routine screening for peripheral arterial disease in asymptomatic persons
- Screening for prostate cancer using transrectal ultrasound and serum tumor markers (e.g., PSA)
- Screening asymptomatic persons for lung cancer by performing routine chest radiography or sputum cytology
- Screening of asymptomatic women for ovarian cancer
- Routine screening for pancreatic cancer in asymptomatic persons
- Screening of asymptomatic persons for risk of low back injury
- Routine spinal radiographs of asymptomatic persons to screen for low back injury
- Routine prenatal screening for maternal phenylketonuria (PKU)
- Routine ultrasound screening of pregnant women at low risk for intrauterine growth retardation
- Routine electronic fetal monitoring during labor for women not at increased risk for fetal distress
- Screening for cognitive impairment among asymptomatic Persons[a]
- Performance of routine screening tests for depression in asymptomatic persons[b]
- Routine screening for suicidal intent[c]
- Routine screening interviews or examinations for evidence of violent injuries[d]
- Screening for alcohol or drug abuse using biochemical markers and drug testing

a The USPSTF recommends, however, that clinicians "remain alert for" changes in cognitive function in patients ages 65 and over.
b The USPSTF recommends, however, that clinicians "remain alert for" depressive Symptoms.
c The USPSTF recommends, however, that clinicians "remain alert for" suicidal risk factors.
d The USPSTF recommends, however, that clinicians "remain alert for" signs of physical abuse or neglect.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993, adapted from U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services* (Baltimore; MD: Williams and Wilkins, 1989).

of mammography and clinical breast examination in reducing breast cancer mortality.

The Canadian National Breast Cancer Screening study was specifically designed to prospectively examine the efficacy of screening with yearly mammography and clinical breast examination as compared to no screening in women aged 40 to 49 years old at entry (140,141). The Canadian National Breast Cancer Screening study also examined the separate effects of mammography and clinical breast examination. The study concluded that at 7 years from entry "screening with yearly mammography and physical examination of the breasts detected considerably more node-negative, small tumors than the control group, but it had no impact on the rate of death from breast cancer" for the 40 to 49 year old age group (140). Similarly, the study found that screening women aged 50 to 59 with yearly mammography in addition to physical examination of the breasts detected considerably more node-negative, small tumors than screening with physical examination alone, but it had no impact on the rate of death from breast cancer (141). The results of the Canadian trial are still being debated in the research community (1 16,160) and the study will follow patients for at least another three years (140,141).

The screening recommendations of different organizations reflect the uncertainties about the optimal protocols for breast cancer screening for average-risk women under 50 years old. The USPSTF recommended mammography screening and clinical breast examination for women age 50 and older every one or two years, concluding at approximately age 75 unless pathology has been detected. The USPSTF notes that it maybe 'prudent' to begin mammography at an earlier age for women at high risk for breast cancer. Most other groups also endorse periodic mammography screening and clinical breast examination of asymptomatic women for breast cancer; however, many recommend that screen-

ing begin at age 35 or 40.[2] These recommendations were published previous to the recent results of the Canadian National Breast Cancer Screening study and could change in light of these results.

Colorectal Cancer Screening

In 1993, an estimated 152,000 new cases of colorectal cancer will be diagnosed and 57,000 people will die from colorectal cancer in the United States (20). The detection of neoplasms (cancers and adenomatous polyps) in the colon or rectum involves either direct inspection of the colon and rectum or indirect measurement of biochemical markers for the presence of cancers or polyps (193). Today, the most common screening technologies are the fecal occult blood test (FOBT) and flexible sigmoidoscopy (193).[3]

The effectiveness of FOBT in reducing colorectal cancer morbidity is still being investigated and debated. Concerns center on the test's sensitivity, specificity and predictive capability (2). Although some medical organizations have recommended FOBT screening of asymptomatic adults (e.g., American College of Physicians, 1991 [63]; National Cancer Institute, 1991 [219]; American Cancer Society, 1991 [5]; and the American College Obstetricians and Gynecologists, 1988 [7]), the USPSTF and the CTFPHE concluded that there is insufficient evidence to recommend for, or against, FOBT in adults without risk factors for colorectal cancer (33,224). OTA concluded that FOBT screening improves the stage distribution of cancers detected, which may translate into decreases in cancer mortality; however, even in the very large trials ongoing at the time of OTA's 1990 review, no such mortality effect had been identified (193).

Results from one large randomized trial, the Minnesota Cancer Control Study, have recently been reported (135). The study randomly assigned more than 46,000 participants, 50 to 80 years of age, to either annual FOBT screening, biennial FOBT screening, or a no-screening control group. Those with a positive test were evaluated with colonoscopy. After 13 years, annual FOBT testing decreased the 13 year cumulative mortality from cancer by 33 percent. This trial may alter the previous conclusions of the USPSTF and other organizations. In addition, there are several other ongoing randomized control trials of FOBT screening of asymptomatic adults that should provide more evidence about its effectiveness (72,90,1 14,123).

The benefits of screening asymptomatic adults for colorectal cancer using sigmoidoscopy are also uncertain. The USPSTF concluded that "there is insufficient evidence to recommend either for or against fecal occult blood testing with sigmoidoscopy as effective screening tests for colorectal cancer in asymptomatic persons' (224), although they went on to state that "[it] may be clinically prudent to offer screening to persons age 50 and older with known risk factors for colorecta1 cancer' (224). Similarly, the CTFPHE concluded that there is not enough evidence on the effectiveness of sigmoidoscopy in reducing mortality to recommend it as a screening procedure in people who have no risk factors for colorectal cancer (33). In 1990, OTA concluded that there was inadequate evidence that sigmoidoscopy reduces cancer mortality rates over time; however, OTA noted that there had never been a good trial to determine the effect of screening with the flexible fiberoptic sigmoidoscopy on cancer mortality, so the lack of evidence on

[2] The American College of Physicians, 1991 (63), the American Academy of Family Physicians, 1993 (3), and the CTFPHE, 1979 (29) also recommend screening with mammography and breast physical examination beginning at age 50. The American Cancer Society, 1991 (5), National Cancer Institute, 1991 (219), and the American College of Obstetricians and Gynecologists, 1989 (7), recommend mammography beginning at age 35 or 40.

[3] Colonoscopy has also been recommended as a primary screening technique in people at increased risk of colorectal cancer based on family history (224).

outcomes should not be equated with the existence of negative evidence (193). Despite the paucity of direct evidence, some organizations have recommended regular screening with sigmoidoscopy, in conjunction with FOBT, for asymptomatic individuals who are over 50 years old (e.g., American College of Physicians, 1991 [63]; National Cancer Institute, 1991 [219]; American College of Obstetricians and Gynecologists, 1989 [7]; and American Cancer Society, 1991 [5]).

Two recent case-control studies concluded that screening by sigmoidoscopy can reduce mortality from cancer of the rectum and distal colon (149,167). Additional evidence about the efficacy of colorectal cancer screening may be provided by a large randomized trial being planned by the National Cancer Institute; however, the results from this trial will not be available for at least eight years (80).

Cervical Cancer Screening

In 1993, an estimated 13,500 new cases of cervical cancer will be diagnosed and 4,400 women will die from cervical cancer in the United States (20). The principal screening test for cervical cancer is the Papanicolaou (Pap) smear.

Although there have been no randomized clinical trials examining the effectiveness of cervical cancer screening in reducing mortality, the evidence from many case-control and observational studies over time suggest that screening is protective (62,193,224).[4]

Based on its review of the evidence, the USPSTF recommends regular Pap smears every one to three years (at the physician's discretion) for all women who are or have been sexually active, until age 65, at which age they may be discontinued if previous smears have been continuously normal (224). Pap smears have also been recommended by a number of other organizations.[5]

Prostate Cancer Screening[6]

Among men, prostate cancer is the second most common cancer and the second most common cause of death from cancer in the United States (6). During 1993, it is estimated that 165,000 new cases of prostate cancer and 35,000 prostate cancer related deaths will occur in the United States (20). Screening tests for prostate cancer which are currently in clinical use include digital rectal examination (DRE), measurement of prostate-specific antigen (PSA), and transrectal ultrasound (TRUS) (95).

None of the screening methods have been assessed in randomized clinical trials in which the control group received no screening. This lack of demonstrated efficacy, in addition to the potential for false positives, uncertainty about the natural history of the disease, and treatment of clinically insignificant disease, has led reviewers to conclude that there is currently insufficient evidence that detection and treatment of prostate cancer in its early stages, using any of the three techniques mentioned, will improve survival (41,95,224).

DRE has not been shown to be effective in clinical trials and the USPSTF and CTFPHE made no recommendation either for or against routine DRE for prostate cancer (38,224). In contrast, other organizations have advocated its use for routine screening (e.g., the National Cancer Institute recommends annual DRE beginning at age 40 [219]).

Most organizations do not recommend serum tumor markers (e.g., PSA) or transrectal ultrasound for routine screening (e.g., 219). In fact the

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[4] The studies reviewed by the USPSTF include the following references: 8, 11, 14, 43, 51, 89, 106, 124, 125, 142.

[5] The organizations which recommend Pap smears include: American Cancer Society, 1991 (5); the National Cancer Institute, 1991 (219); the American College of Obstetricians and Gynecologists, 1989 (7); the American Academy of Family Physicians, 1993 (3); and the American College of Physicians, 1991 (63).

[6] In a separate study, OTA is examining the effectiveness, safety, and costs of screening for prostate cancer in the Medicare population. The screening technologies to be considered are the digital rectal examination and prostate-specific antigen (PSA) technologies.

USPSTF and the CTFPHE recommended against using PSA and transrectal ultrasound for routine screening (38,224).7 However, the American Cancer Society recently recommended that PSA screening be done annually in conjunction with DRE on men 50 years of age and older (22). The National Cancer Institute is currently conducting a multicenter randomized trial of the value of TRUS, DRE and PSA screening, but the results from this trial will not be available for at least eight years (80,218).8

Cholesterol Screening

Despite the decline in the death rate from cardiovascular diseases over the past 15 years, cardiovascular diseases remain the number one cause of death in the United States (216). The association between elevated serum cholesterol level (hypercholesterolemia) and the risk of contracting and dying from cardiovascular disease is supported by a large body of evidence from epidemiologic, pathologic, animal, genetic, and metabolic studies (87,190).

Clinical interventions for preventing diseases associated with elevated cholesterol involve measuring blood cholesterol levels and, in patients with hypercholesterolemia, establishing a protocol for lowering cholesterol, either through diet or medication. Randomized clinical trials reveal a decrease in the incidence of coronary heart disease in middle-aged men with high blood cholesterol who are assigned to cholesterol-lowering drugs (48,75,130,131). There is also some evidence from clinical trials, albeit weaker, that lowering cholesterol through diet reduces the incidence of coronary heart disease in men (57,96,147,224).

Published clinical trials of the effects of lowering cholesterol offer little or no information about the effects of treatment on women of any age, men with borderline cholesterol elevations, children, young adults, and the elderly (39,77). Similarly, although there is indirect evidence that high blood cholesterol during childhood may increase the risk of developing coronary heart disease in adulthood, the relationship between lowering cholesterol during childhood and decreased incidence of coronary heart disease during later life has not been demonstrated in controlled studies, in part due to the difficulty of performing such studies (224). The lack of direct evidence about whether routinely screening children, women, young men, and men older than age 65 would lower their mortality must be weighed against the potential cost and adverse effects of widespread cholesterol screening of these populations. Therefore, routine cholesterol measurement in these populations is controversial (77, 78,151).

Questions also remain about the association between reducing cholesterol levels and total mortality (i.e., mortality for all causes, including coronary heart disease). None of the randomized clinical trials of the effectiveness of lowering cholesterol on health outcomes found a significant effect on total mortality (190). In part, the failure to affect total mortality was due to a trend in several studies toward higher rates of death from noncardiovascular mortality, such as from violence, accidents, trauma, suicide, and cancer, in the groups receiving treatment to lower cholesterol (98,143,15 1,153).

Clinical practice guidelines regarding the detection and treatment of hypercholesterolemia are controversial (122). The USPSTF concluded that while there is evidence to support screening for hypercholesterolernia in high-risk groups, such as middle-aged males, there is no direct evidence from clinical studies that a policy of routine screening of the general population would achieve

[7] A recent updated review by the USPSTF, not yet published, did not change its previous recommendation concerning DRE, PSA, and TRUS screening (59).

[8] The trial will consist of 74,000 subjects aged 60 to 74 at entry. Each participant will undergo digital rectal examination and PSA screening every three years. Those with either a positive DRE or PSA test will then be screened using ultrasound (218).

significant reductions in mortality and morbidity (224). In their recommendations, the USPSTF stated that periodic measurement of total cholesterol was most important for middle-aged men and it may also be clinically prudent in young men, women, and the elderly. They noted that the optimal frequency for cholesterol measurement in asymptomatic persons has not been determined on the basis of scientific evidence and they recommended leaving the decision regarding frequency to clinical discretion (224).

In 1985, the National Heart, Lung, and Blood Institute (NHLBI) organized the National Cholesterol Education Program (NCEP) with the goal of developing a national policy for cholesterol reduction in the United States. In 1987, the NCEP issued their guidelines and stated that all adults age 20 and older should have their blood cholesterol level measured at least once every 5 years (more often for those with total cholesterol levels greater than 200 mg/dL). The NCEP recommended that low density lipoprotein (LDL) cholesterol be measured in persons who are candidates for intensive interventions (65,84) and also issued specific treatment recommendations (65). The NCEP recommended screening blood cholesterol levels only in those children and adolescents whose risk of developing coronary vascular disease as adults could be identified by family history or by the coexistence of several risk factors.[9]

The chief differences between the USPSTF and the NCEP guidelines are that the USPSTF recommended intensive treatment based primarily on total cholesterol rather than LDL cholesterol, made less aggressive recommendations for screening women, and made no specific recommendations for children.

Hypertension Screening

Hypertension is a leading risk factor for coronary artery disease, congestive heart failure, stroke, renal disease, and retinopathy. As noted above, heart disease is the leading cause of death for both men and women in the United States (216), and in 1989, 733,867 people died from diseases of the heart (216). Sphygmomanometry (the blood pressure cuff) remains the most appropriate screening test for hypertension in the asymptomatic population (224).

After reviewing the evidence on the effectiveness of early detection of hypertension, the USPSTF concluded that "it is clear from several large clinical trials that lowering blood pressure is beneficial and that the population incidence of several leading causes of death can be reduced through the detection and treatment of high blood pressure" (224).

The USPSTF recommends ''regular' blood pressure measurement in all persons age 3 and above (224). They note that the optimal frequency has not been determined and leave the determination to clinical discretion (224). Most expert groups recommend blood pressure measurement in asymptomatic populations, although the recommended frequency of measurement differs among organizations.[10]

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9 The American Academy of Family Physicians recommends that healthy asymptomatic adults with no known risk factors have serum total cholesterol, fasting or nonfasting, at least every five years stinting at age 20 (3). The American College of Physicians recommends total serum cholesterol measurement at least once during early adulthood and at intervals of 5 or more years up to age 70 (63).

10 The Canadian Task Force recommends blood pressure measurement for men and women ages 16 to 64 at least every 5 years and at every visit for other reasons (29). They recommend blood pressure measurement every two years in males and females aged 65 and older (29). In contrast, the American College of Physicians recommends blood pressure measurement for all adults ages 18 and older every one to two years (63). The American Academy of Family Physicians recommends that all adult patients ages 18 and older have their blood pressure checked at every physician visit with a minimum of once every two years (3). The Joint National Committee on Detection, Evaluation, and Treatment of High Blood pressure (JNCV) recommends blood pressure measurement every 2 years for people 18 years of age and older with systolic blood pressure less than 130 mm Hg and diastolic blood pressure less than 85 mm Hg (109), The JNCV recommends more frequent blood pressure measurement if the initial measurement was shown to be higher than 130 mm Hg and diastolic blood pressure less than 85 mm Hg. For children age 3 through adolescence, the JNVC recommends that blood pressure be measured once a year.

Smoking Cessation Interventions

In 1990, approximately 46 million adults in the United States smoked (212). Smoking is the leading preventable cause of death in the United States, and it is estimated to account for about 390,000 deaths annually (206). These include 30 percent of all cancer deaths, 21 percent of deaths from coronary heart disease, 18 percent of stroke deaths, and 82 percent of deaths from chronic obstructive pulmonary disease (214).[11] In addition, smoking during pregnancy contributes to low birthweight and fetal and infant mortality (214). Many of the risks associated with smoking have been found to diminish after quitting (214).[12]

Smoking cessation methods fall into two broad categories: self-help strategies (e.g., quitting on one's own) and assisted strategies (e.g., provider-initiated smoking cessation counseling, smoking-cessation clinics, nicotine chewing gum or nicotine patch) (213). Ninety percent of successful quitters used a self-help strategy, most by quitting abruptly (70). Only ten percent of those who quit use assisted strategies (70); however, these may be people who are more severely addicted, Insurance could cover all or some of the assisted methods. For example, benefits could cover physician advice about smoking cessation, smoking cessation classes, or prescriptions for nicotine patches or nicotine chewing gum.

A meta-analysis of 39 clinical trials of several different types of smoking cessation interventions (e.g., counseling, nicotine gum, written self-help materials) found that the average difference in the cessation rates between the intervention and the control group was 8,4 percent after 6 months and 5.8 percent after 1 year (119).[13] Meta-analyses were also done for specific types of smoking cessation intervention. Programs based on face-to-face advice had the best results, followed by programs based on nicotine chewing gum and self-help books. However, the main conclusion from the overall review was that reinforcement—by increasing the number of contacts, the types of contacts, and the number of people making the contacts—rather than a particular intervention or delivery system for the smoking cessation method, produces results (1 19).

The nicotine patch is a relatively new method of smoking cessation which delivers nicotine through the skirt to prevent nicotine withdrawal symptoms. The efficacy of the nicotine patch was not evaluated in the meta-analysis by Kottke and colleagues described above, but is now widely used and has been studied in several clinical trials (1,27,53,73,102,1 11,144,146, 159,177,178). Both nicotine gum and patches are recommended by their manufacturers only for use in conjunction with behavior modification programs (12,129,136, 157). Other nicotine delivery forms which may become more widely used are nasal spray. At this time nicotine containing nasal spray for smoking cessation has not been approved by the Food and Drug Administration (54).

Although the average success rates associated with smoking cessation interventions are low, smoking cessation programs can result in a large absolute reduction in the number of smokers. For example, each year about 28 million of the 46 million smokers visit a physician (i.e., assuming 60 percent of the U.S. population has a physician office visit each year [216]). If all physicians counseled their smoking patients to quit and 3 percent of those counseled were able to quit, then physician-based efforts would potentially result

11 The relative risk calculations for these *estimates are* based on the results of a prospective study sponsored by the American Cancer Society during the period 1982 to 1986 (79).

12 For example, several prospective and retrospective epidemiologic studies have demonstrated the reduction in lung cancer risk over time following smoking cessation (214). After 10 years of abstinence, the risk of lung cancer is about 30 percent to 50 percent of the risk in continuing smokers (206), Smoking cessation for 5 or 10 years also reduces the risk of cancers of the larynx, oral cavity, esophagus, pancreas, and bladder (214).

13 The 95 percent confidence interval of the studies was plus or minus 2.8 and 2.6 percent, respectively.

in about 800,000 additional smokers quitting each year. Therefore, the overall effectiveness of smoking cessation programs, in terms of the potential to reduce mortality, may be large.

In 1989, the USPSTF recommended that smoking cessation counseling be offered on a regular basis to all patients who smoke, or use smokeless tobacco, although they left the frequency of smoking cessation counseling to clinical discretion (224). The USPSTF also outlined strategies that can increase the effectiveness of counseling regarding tobacco use, including: direct, face-to-face advice and suggestions; scheduled reinforcement; self-help materials; referral to community programs; and prescription of nicotine gum (224).

Adult Immunizations

Although the widespread implementation of childhood vaccination programs has substantially reduced the occurrence of many preventable diseases, the CDC has concluded that 'successful childhood vaccination alone will not eliminate specific disease problems' and that ''a substantial proportion of the remaining morbidity and mortality from vaccine-preventable diseases presently occurs among older adults and adolescents' (210).

The Immunization Practices Advisory Committee (ACIP) of the CDC issues recommendations for adult vaccination. The ACIP's definition of the populations who should receive vaccinations varies. Some vaccinations are indicated for persons who escaped natural infection or were not previously vaccinated (e.g., vaccines against diphtheria, tetanus, measles, mumps, rubella, and poliomyelitis). Other vaccines are recommended for all older adolescents and adults (e.g., the ACIP recommends that all adults receive tetanus and diphtheria boosters every 10 years). The use of other vaccines is indicated on the basis of age (e.g., all persons 65 and older should be immunized once for pneumococcal pneumonia and should receive influenza vaccinations). Finally, other vaccines are indicated according to individuals' occupation, environmental situations, lifestyles, immigration status, and travel to some countries.

Prenatal Care

The five leading causes of infant death in 1989 were: 1) congenital anomalies, 2) sudden infant death, 3) disorders relating to short gestation and unspecified low birthweight, 4) respiratory distress syndrome, and 5) newborns affected by maternal complications of pregnancy (216). Prenatal care encompasses a wide range of preventive, diagnostic, and therapeutic services which may include screening for potentially harmful conditions in the mother and fetus, education and counseling, and nutritional supplements (188).

Evidence suggests that earlier and more comprehensive prenatal care can reduce infant mortality and prevent low birthweight and other perinatal complications, particularly in high-risk groups (188). However, review groups have concluded that more information is needed about which specific components of prenatal care are effective (188,205).

The USPSTF recommends that the following preventive interventions be provided to all pregnant women: blood pressure measurement; hemoglobin and hematocrit; ABO/Rh typing; Rh(D) antibody testing; syphilis screening; hepatitis B surface antigen (HBsAg); urinalysis for bacteriuria; gonorrhea culture; counseling about nutrition, tobacco use, alcohol and other drug use, and safety belts; maternal serum alpha-fetoprotein

14 The glucose tolerance test is used to test for gestational diabetes. The USPSTF found that the effectiveness of treatment for gestational diabetes in preventing most of the health risks associated with gestational diabetes (perinatal mortality, neonatal metabolic derangements, congenital anomalies) had not been demonstrated in well designed clinical trials. The USPSTF argued, however, that since treatment is unlikely to result in significant maternal or fetal harm, routine screening for gestational diabetes may be a reasonable measure. In contrast, other reviewers have concluded that the test is not reliable and because of the lack of demonstrated treatment efficacy, screening of pregnant women is unlikely to make a significant impact on perinatal mortality (100). Moreover, these authors argue that a positive test may provoke unwarranted and expensive testing and anxiety.

(MSAFP), and the oral glucose tolerance test.[14] For women with selective risk factors they also recommend the following additional interventions: hemoglobin electrophoresis; rubella antibodies; chlamydia testing; counseling and testing for human immunodeficiency (HIV); ultrasound cephalometry; and ultrasound examination. The USPSTF notes, however, that their list is not exhaustive and reflects only the topics reviewed by the USPSTF.

A useful source of information about the effectiveness of prenatal care is the Cochrane Collaboration Pregnancy and Childbirth database (previously called the Oxford Database of Perinatal Trials) which comprises a register of most, if not all, of the reports of controlled trials in perinatal medicine. Very complete and systematic reviews of the efficacy of specific components of prenatal care, based on this database, were published in 1988 (40) and in 1992 (170). The Cochrane Collaboration Pregnancy and Childbirth database is being continuously updated and reviews and meta-analyses of perinatal research are published electronically, every six months, by the Cochrane Collaboration (24).

Newborn Screening for Congenital Disorders

About 4,500 cases of detectable diseases causing death or mental retardation occur in newborns each year (188). Newborn screening seeks to identify biochemical abnormalities that suggest the presence of disease in affected but as yet asymptomatic infants (188).

In most States, newborn screening is mandated by law, except in the case of parental refusal on religious or other grounds (188). In some States, the laws specify what types of testing will be done; in others, the range of tests included is determined by the health department, a government official, or a commission (10). The number of States that screen for various newborn congenital disorders is shown in table 3-3. Recently, some researchers have raised concerns about the process by which States decide what diseases to require for screening (44,99).

Table 3-3-The Number of States Screening for Specific Types of Newborn Congenital Disorders and Number of Cases Confirmed with the Diagnosis, 1990

Disorder	Number of States (and the District of Columbia, Puerto Rico, and the Virgin Islands)	Number of confirmed cases, 1990
Phenylketonuria (PKU)	52	337
Congenital hypothyroidism	52	1,190
Galactosemia	38	86
Hemoglobinopathy	42	N/A
Maple Syrup Urine Disease	22	3
Homocystinuria	21	9
Biotinidase deficiency	14	15
Congenital Adrenal Hyperplasia	8	51
Tyrosinemia	5	1
Cystic Fibrosis	2	14

SOURCE: Council of Regional Networks for Genetic Services (CORN), New York, NY, "Newborn Screening Report: 1990," supported in part by project #MCJ-361011-01-0 from the Maternal and Child Health Program (Title V, Social Security Act), Maternal and Child Health Bureau, Health Resources and Services Administration, United States Department of Health and Human Services, Rockville, MD, February 1992.

The USPSTF recommends screening all newborns for phenylketonuria (PKU) and congenital hypothyroidism (224), as does the CTFPHE (29,36). The USPSTF recommends screening newborns of Caribbean, Latin American, Asian, Mediterranean, or African descent for sickle cell diseases. However, a NIH consensus conference has recommended universal screening for sickle cell diseases (49,220). In addition, a panel convened by the Public Health Service's Agency for Health Care Policy and Research recently recommended universal sickle cell testing, arguing that a baby race or ethnic ancestry cannot be inferred by name or appearance (26). Many of the tests currently part of State newborn screening programs have not been reviewed by the USPSTF.

Childhood Immunizations

All vaccines must undergo a structured approval process before being licensed for public use, and the efficacy of most childhood vaccines

in reducing mortality and morbidity has been well established on the basis of randomized controlled trials (126). The ACIP recommends that all children receive nine different vaccines (many in combination form and all requiring more than one dose). The nine vaccines are for measles, mumps, rubella (German measles), diphtheria, tetanus toxoids, pertussis (whooping cough), polio, haemophilus influenza Type b, and hepatitis B. Recommendations are also issued by the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). In contrast to many other recommendations related to clinical preventive services, these groups attempt to keep their recommendations consistent with each other and there are only slight differences among their recommendations. [15]

Well-Child Care

When included in health reform proposals, specific services for children and adolescents are usually not individually identified, but rather are covered as a package of services termed "well child' or ''well baby' care which are offered at various points in a child's life. The components of well-child care include developmental screening, physical examinations, parent counseling, and immunizations and chemoprophylaxis (224). In its extensive 1988 review, OTA concluded that, when evaluated as a whole, there is no evidence to support the contention that well-child care (other than immunization) significantly influences mortality or morbidity among children (188), OTA noted, however, that the sample sizes, follow-up periods, and outcome measures in these studies were consistently poor, thus leaving open the possibility that some medical benefits do exist. Several individuals and organizations have reviewed evidence on specific components of well-child care. Their findings are summarized below.

General Physical Examination

Physical examination involves a series of diagnostic procedures intended to detect a variety of medical conditions (188). In its 1988 report, OTA found that "all but one of the studies examining the effectiveness of the general physical examination concluded the exam has little merit" (188).

Some specific physical diagnostic procedures are the Ortalani maneuver for identification of congenital dysplasia of the hip, forward bending for detection of scoliosis, and abdominal palpation for detection of tumors. Reviews of specific physical examination procedures have been completed by the CTFPHE and USPSTF. The CTFPHE concluded that there was good evidence to recommend screening for congenital dislocation of the hip (37), but did not recommend screening for scoliosis (29). The USPSTF recently reviewed the evidence for screening for adolescent scoliosis and concluded that there was insufficient evidence to recommend for or against routine screening of asymptomatic adolescents (225). Given the lack of evidence, the USPSTF did not recommend routine visits to clinicians for the specific purpose of screening adolescents for scoliosis. [16]

Screening For Iron-Deficiency For Anemia

Anemia is a condition that exists when hemoglobin levels drop below the normal range of values for the population (224). In unselected

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15 For example, the American Academy of Pediatrics recommends that a second dose of MMR vaccine be given at approximately 12 years of age, whereas the ACIP recommends that it be given at school entry, at ages 4 through 6, along with DTP and OPV. The second dose at 4-6 years may have two advantages: primary vaccine failures are corrected sooner and individuals maybe easier to reach when they are entering school. The different recommendations may be a result of different views on the prevalence of primary vaccine failure and on the best way to reach the population.

16 The AAP recommends that a physical examination be performed on all children at regular intervals up to age 20 and possibly beyond (4).

populations of children, the overwhelmingly predominant cause of anemia is iron deficiency (74), and in childhood, screening for anemia is recommended largely as a screen for iron deficiency (188),

Hemoglobin concentration and hematocrit are the principal tests for detecting anemia. In their review, the USPSTF concluded that there was evidence from prospective studies to support screening for anemia in infants, and some evidence, although weak, to support screening in pregnant women. They found no evidence to support screening in other populations. Therefore, the USPSTF did not recommend routine testing for anemia for asymptomatic persons, except for pregnant women and infants (224). Other groups have found evidence only to support selective screening of high-risk groups. Based on their 1988 review, the OTA concluded that "... early identification of high-risk infants (e.g., those of low socioeconomic status) with either a capillary hemoglobin/hematocrit or free erythrocyte protoporphyrin (FEP) appears reasonable, with a liberal threshold for institution of a trial of iron therapy' (188). The CTFPHE suggests hemoglobin measurement of infants who are premature, those born of a multiple pregnancy or of an iron-deficient woman, and those of low socioeconomic status (29).[17]

Screening for Amblyopia and Strabismus

Amblyopia is subnormal visual acuity. The term specifically denotes a developmental disorder of visual function arising from either sensory stimulation deprivation or abnormal binocular interaction. In the latter sense amblyopia is familiarly known as "lazy eye" (137). Strabismus is a misalignment of the eye that the patient cannot overcome without aid. The condition is a lack of parallelism of the visual axes of the eyes, which can result from neuromuscular or visual disturbances.

The USPSTF review of the literature revealed only one cohort study that addressed the effects of preschool screening for vision disorders (68). The study found that children who had been routinely screened prior to school entry had less vision impairment than did those who had not been screened. The USPSTF also indicated that there is evidence that interventions for amblyopia and strabismus are significantly less effective if started after age 5 and increase the risk of irreversible amblyopia, ocular misalignment, and other visual deficits.

The USPSTF recommends testing for amblyopia and strabismus for all children once before entering school, preferably at age 3 or 4. Screening for amblyopia and strabismus was also recommended by the CTFPHE (37).

Screening for Hearing Impairment

The USPSTF concluded that although the detection of hearing loss during infancy appears to be worthwhile, the screening tests currently available are too inaccurate for routine screening of children under age 3 (224). The USPSTF recommended hearing screening only for neonates at high risk for hearing impairment (e.g., family history of hearing impairment, congenital perinatal infections, low birthweight). In contrast, a NIH Consensus Development Conference recently recommended universal screening for hearing impairment of all infants shortly after birth (221).

The USPSTF found insufficient evidence of benefit to recommend hearing screening of asymptomatic children older than age 3 or in adolescents. Based on their review, OTA concluded in 1988 that the efficacy of screening preschool children for hearing impairment is unknown

[17] The AAP guidelines state "[p]resent medical evidence suggests the need for reevaluation of the frequency and timing of hemoglobin and hematocrit tests" (4). The AAP recommends a hematocrit or hemoglobin test once during infancy, early childhood, late childhood, and adolescence (4).

given the uncertain impact of hearing deficiency and treatment efficacy (188).

Developmental Screening

OTA reviewed the efficacy of the Denver Developmental Screening Test (DDST), which is the developmental screening tool most widely used and recommended for use by child health personnel (188). OTA concluded that while the evidence suggests that the DDST, when administered immediately prior to school entry, has a fair ability to predict developmental abnormalities accurately, there is limited evidence that the detection of **a** problem will result in improved school performance. In a 1989 review, the CTFPHE found only one randomized controlled trial that examned the effectiveness of the DDST (28,34). The study found no statistically significant differences in outcome between the control and screened groups, for example, in terms of their use of specialized educational services, academic achievement, cognitive and perceptual motor tests, and assessment of behavioral, social and emotional well-being. However, there was a statistically significant increase in worry about schoolwork among the parents of children in the intervention group. The CTFPHE recommended that the DDST not be included in the periodic health examination.

Urinalysis

Several conditions, including pyelonephritis (kidney infection) and renal scarring, are associated with asymptomatic urinary tract infection. Urinalysis is a common method of screening for urinary tract infection and is widely performed on asymptomatic children as apart of routine examinations (1 13). The USPSTF concluded that urine dipstick to detect the presence of bacteria maybe beneficial in preschool children, but further studies are needed to establish its effectiveness (224). A recent review of the effectiveness of urinalysis found that the test had limited accuracy (113). Moreover, the reviewers found no evidence of benefit from early treatment and emphasized the risks associated with treatment. The reviewers concluded that periodic screening for the presence of bacteria should not be part of routine well-child care.[18]

Frequency of VW//-Child Care Services

Scientific evidence about the optimal frequency of childhood preventive interventions is lacking (224). The CTFPHE recommended that healthy term infants have six well-baby visits within the first two years of life (37). The USPSTF recommended five visits from birth to 18 months, but stated that clinicians should exercise discretion in selecting an appropriate schedule (224). The American Academy of Pediatrics recommends nine visits from birth to age 2, yearly visits from age two to age six, and biennial visits from age 6 to age 20 (4).

Summary

In Summary, at present well-child *care may* include procedures which have been found effective, ineffective, or whose effectiveness has not been evaluated. Immunizations are highly effective and are universally recommended as a component of well-child care. There is some evidence to support screening for vision impairment (for amblyopia and strabismus), hearing impairment, congenital dysplasia of the hip, and hematocrit or hemoglobin testing for anemia in infants, particularly those at high risk. More research is needed to confirm the effectiveness of routine urinalysis, other types of physical examinations (e.g., for scoliosis), developmental behavioral assessments, and to determine the frequency of well-child care visits. The efficacy of screening for cholesterol and hypertension was reviewed elsewhere. Blood pressure measurement in children is recommended by a number of groups,

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18 The AAP has written that "[p]resent medical evidence suggests the need for reevaluation of the frequency and timing of urinalysis" (4). In the interim, the AAP recommends that urinalysis be done once during infancy, early childhood, late childhood and adolescence (4).

although screening for cholesterol is controversial.[19]

Contraceptive Services

Contraceptive services include counseling and the provision of contraception. Contraceptive methods that *are* highly efficacious include: oral contraception (birth control pills), intrauterine devices (IUDs), condoms, diaphragms, and sterilization (224). The effectiveness of contraception depends largely on its correct use (196). Counseling is one way to increase the effectiveness of methods to prevent pregnancy. Counseling can be provided in several clinical settings, including physicians' offices and family planning clinics.

No direct evidence indicates that physician counseling can lead to more effective contraceptive use or lower pregnancy rates. Despite this acknowledged lack of evidence, the USPSTF recommends that clinicians obtain a detailed sexual history from all adolescents and adult patients, and based on this information, that clinicians provide counseling on the level of risk associated with the patient's current contraceptive techniques and, when indicated, available contraceptive methods. The CTFPHE also recommends the inclusion of counseling to prevent unwanted pregnancy in the periodic health examination of adolescents (32).

Sexually Transmitted Diseases

In *the* United States, the most prevalent sexually transmitted diseases (STDs) include HIV infection, genital herpes, genital warts, syphilis, gonorrhea, and chlamydia. It has been estimated that, in the United States, 1 million persons are infected with HIV (208), 20 to 30 million with genital herpes (108), and 12 to 24 million with human papillomavirus which causes genital warts (120).[20] In addition, more than 55,000 cases of syphilis in the infectious stage, the highest number in 40 years, were reported in 1990 (112). In 1990, 700,000 cases of gonorrhea were reported by local health departments. Finally, an estimated 3 to 4 million men, women, and infants acquire chlamydia each year (207). While these prevalence statistics provide an indication of the enormity of the problem, they may underestimate the magnitude of the problem and must be viewed cautiously. Many STDs are not required to be reported, many are not easily diagnosed, and many are asymptomatic and unapparent (108,112).

Complications of STDs vary. The most serious complications from STDs include death, pelvic inflammatory disease (PID), sterility, ectopic pregnancy, chronic pelvic pain, gonococcal arthritis, blindness, cancer associated with human papillomavirus, fetal and infant death, birth defects, and mental retardation (196,206). The incidence of these complications is not trivial. For example, AIDS is the third leading cause of death in persons aged 25-44 (216), and an estimated 1 million cases of symptomatic PID occur annually in the United States (209).

The most efficacious way of preventing STDs and their complications is abstinence from sexual intercourse or maintenance of a mutually monogamous sexual relationship with an uninfected partner (196,224). For individuals who do engage in sexual intercourse, the most effective way to prevent transmission is to prevent the exchange of blood, semen or vaginal fluid (e.g., by use of a condom) (224).

Complications associated with STDs may be prevented and transmission reduced through early

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19 The American Academy of Pediatrics recommends the following components for well-child care at various points in a child's life: height and weight measurement, head circumference measurement, blood pressure, vision and hearing screening for those at high risk, developmental and behavioral assessment (by history and appropriate physical examination and, if suspicious, by specific objective developmental testing), physical examimtion, hereditary and metabolic screening according to State law, immunization, tuberculin testing for high risk groups, hematocrit or hemoglobin, urinalysis, anticipatory guidance, and initial dental referral (4).

20 More recent studies using advanced screening technologies (i.e., the polymerase chain reaction [pCR] technique) suggest that the level of prevalence of subclinical cases of papillomavirus infections is substantially greater (13).

detection and treatment. Recommendations for STD screening have been balanced by concerns about the cost of screening, low yield of positive results due to relative low prevalence, and a high probability of false-positive results in low prevalence populations (23). The USPSTF recommends screening at-risk individuals for syphilis, chlamydia, gonorrhea, and HIV. The USPSTF and most other organizations that issue guidelines for STD screening (e.g., CDC, CTFPHE) have not recommended universal screening, but rather a strategy of assessing patient risk factors, by taking a history of sexual practices, and then selectively screening. Criteria identified as risk factors for certain STDs include the following: multiple sexual partners, sexual contact with a proven case, a sexual partner with multiple sexual contacts, a history of repeated STDs, being a resident of a high prevalence area, asymptomatic persons who attend clinics for STDs, asymptomatic persons who attend other high-risk health care facilities, homosexual or bisexual man or partner of same, IV drug abuser or partner of the same, or one who received a blood transfusion between 1978 and 1985.

SUMMARY

This chapter provides an overview of the current state of knowledge about a select group of clinical preventive interventions some of which may be able to prevent or forestall a considerable amount of mortality and morbidity. The clinical preventive interventions identified in this chapter as effective for some asymptomatic individuals, include breast cancer screening, cervical cancer screening, smoking cessation interventions, cholesterol screening, hypertension screening, immunizations for adults and children, some components of prenatal care, screening for some newborn congenital disorders, some components of well-child care, contraceptive services, and screening for sexually transmitted diseases. Other services have been found to be effective, but only appropriate for persons at high risk (see table 3-1 for a list of some of these services). Not all clinical preventive interventions have been found to be effective. Moreover, even when preventive interventions are found to be effective for certain populations and applications, questions remain about their effectiveness when applied to other populations or in ways not directly studied.

The Role of Costs in Benefit Design Decisions

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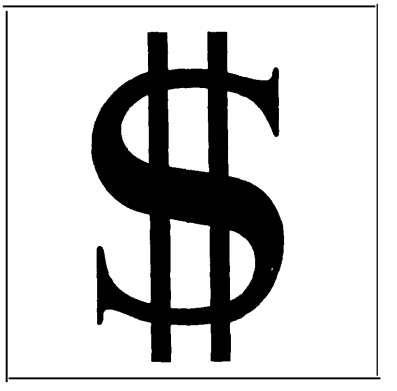
Whether and how costs should enter into decisions about health insurance coverage for preventive services are contentious issues. The following chapter discusses ways that information on costs and cost-effectiveness might inform benefit design decisions and the strengths and weaknesses of various uses.

USE OF COST-EFFECTIVENESS ANALYSES IN BENEFIT DESIGN

Cost-effectiveness analysis provides information that allows various alternatives to be compared. Comparisons could include those between:

- several different types of interventions for different conditions;
- interventions aimed at the same condition;
- an intervention and the status quo; or
- different magnitudes of the same intervention.



If they are to allow for fair comparisons among interventions, cost-effectiveness analyses must be calculated using similar methods and assumptions. Sources of variation in methodology fall into five main areas:

- the perspective taken (e. g., society, patient, third-party payer);
- estimation of treatment effects (e.g., whether estimates derive from randomized trials or opinion; use of meta-analysis);
- valuations of outcomes (e.g., life years saved, quality - adjusted life years, deaths avoided, or other valuations of outcomes);

- estimation of costs (e.g., the inclusion of indirect costs);
- discounting.

Theoretically, cost-effectiveness analyses of interventions used to prevent different conditions (e.g., screening for breast cancer, smoking cessation programs, immunizations, etc.), could be used to rank all preventive services to make coverage decisions under a budget constraint (e.g. cost-effectiveness analysis was initially used in Oregon's Medicaid proposal [197]). This would involve comparing the cost-effectiveness of different interventions and eliminating those that were the least cost-effective until the budget constraint was met.

Attempting to rank different types of interventions is a demanding usage of cost-effectiveness and may be the least viable. A major obstacle is that few cost-effectiveness analyses have used similar enough assumptions to allow fair comparisons, Furthermore, even if most of the methods used to evaluate different interventions were similar-that is, the discount rate, the types of costs included, the method used to determine effectiveness, the perspective taken-it is likely to prove difficult to incorporate all the outcomes of interest.[1] If people rely too heavily on cost-effectiveness to rank interventions, political concerns and intangibles may be undervalued (183).

A more practical use of cost-effectiveness analysis may be in making comparisons of different types of preventive interventions for the same targeted condition, such as different drugs to treat hypertension (63,132) or for reducing cholesterol (175). For example, Littenberg and colleagues found that the cost-effectiveness of screening for hypertension and treating mild hypertension can be substantially reduced by using more expensive treatment regimens (132) (table 4-7). They found that the cost-effectiveness of screening and treatment, for a 40 year old man, would be $2,131 per quality-adjusted life-year saved when the treatment costs were $50 per year, while the cost-effectiveness would be $27,599 per quality-adjusted life-year saved when the treatment cost $500 per year.[2] Based on their analysis, Littenberg and colleagues concluded that ''every effort should be made to manage hypertension with the low-cost interventions consonant with good pressure control, patient acceptability, and safety" (132).

Finally, cost-effectiveness analysis can provide information about the effects of altering the magnitude of a given intervention. This is likely to be the most practical use of cost-effectiveness analysis for benefit design decisions since the outcomes being compared are most similar. Medical interventions eventually have diminishing returns, and incremental benefits tend to fall as the intervention's scope and frequency rise (84). For example, Eddy found that the marginal cost of screening for cervical cancer, in average-risk asymptomatic women, from age 20 to age 75, every year as opposed to every two years was greater than $1,000,000 per year of life gained (63). Similarly, Fahs and colleagues found that, for low-income women 65 years of age and older, the incremental cost-effectiveness of increasing cervical cancer screening from triennially to

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[1] Attempts have been made to improve comparisons of different interventions for different conditions by using a subset of cost-effectiveness analysis called cost-utility analysis (e.g., comparisons of morbidity from cancer and morbidity from hepatitis). The difference between cost-effectiveness analysis and cost-utility analysis is in the way outputs are measured (15). In cost-effectiveness measurement is in natural units (e.g., life years 'saved') (15). In cost-utility analysis outputs are measured in terms of both the quantitative aspects of health outcomes (i.e., lives lost, number of sick days) and in the form of quality-adjusted life years or healthy years equivalent (15). The strengths and weaknesses of cost utility analysis will be described in more detail in a forthcoming OTA study, *Prospects for Health Technology Assessment (in* progress).

[2] Variations in the cost of treatment were based on differences in the wholesale costs of various common medication regimens, the dosages of medication, the mark-up by retail pharmacists, the cost of repeat visits to monitor blood pressure and observe for adverse reactions, and the use of laboratory tests to monitor therapy (132).

annually was $39,693 per year-of-life-gained (66).3

Cost-effectiveness analyses may also be informative about the effects of expanding preventive services to populations with different levels of risk. In general, the lower the risk of disease, the less cost-effective the intervention. For example, Johannesson found that the lower Swedish cut-off point for treatment of hypertension (diastolic blood pressure of greater than 95 mm Hg) would lead to roughly 50 percent higher treatment costs than the British cutoff point (100 mm Hg) (107). Similarly, Taylor and colleagues found that programs to lower cholesterol have cost-effectiveness ratios that differ 4- to 12-fold when the results of a man at high risk are compared to those for a man at low risk (175) (see table 4-5). Finally, the Office of Technology Assessment (OTA) found that screening high-risk women, 65 years old and older, for cervical cancer every 3 years could actually be cost-saving; while screening low-risk women every 3 years would have a cost-effectiveness ratio of $120,520 (192). Based on this analysis, OTA concluded that programs to identify and screen women at high risk for cervical cancer could reduce the incremental cost-effectiveness of screening (192).

Sensitivity analyses can illustrate which factors have a large effect on the cost-effectiveness of an intervention. For example, Eddy and OTA examined how the cost of various aspects of breast cancer screening and treatment influence the overall cost-effectiveness of breast cancer screening (e.g., the cost of breast physical examination, mammography, workup, initial treatment, and terminal care) (63, 187). Eddy and OTA found the cost-effectiveness ratio to be most sensitive to the unit price of breast cancer screening (63,187). Similarly, sensitivity analyses indicated that the marginal cost-effectiveness of cervical cancer screening depends greatly on Pap smear charges, the false positive rate, and the cost of working up a false-positive test result (63). These sensitivity analyses may clarify the advantages of setting reimbursement limits or requiring that tests be evaluated by laboratories which meet certain standards. Potential ways to improve the cost-effectiveness of other preventive interventions could be illuminated through similar types of analyses.

NET COSTS AS A CRITERION FOR INSURANCE COVERAGE

Rather than limiting benefits based on the effectiveness and cost-effectiveness of specific services, one could limit services to those found to reduce society's health care costs. The problem with this criterion is that few preventive services would be able to meet it. While the evidence suggests that clinical preventive services can save lives and prevent suffering, many preventive services would not result in net savings of medical costs. This does not imply that clinical preventive services are not a worthwhile investment in terms of improving health status, but rather that a criterion which states that clinical preventive services must be able to reduce the Nation's health care costs may be too stringent (191,228).

OTA's review of the literature of the cost-effectiveness of several major types of clinical preventive interventions found that none of the potentially effective cancer screening interventions would reduce medical costs (i.e., breast cancer, colorectal cancer, cervical cancer) in

[3]The high incremental cost-effectiveness of increasing the frequency of cervical cancer screening relates primarily to the assumptions concerning duration of the preclinical stage of the disease. The longer it takes for atypical cells to progress to cancer, the smaller the benefits from more frequent screening.

populations at average risk for the disease (61,63,184,192,193)! In addition, physician counseling on smoking cessation, both with and without the use of nicotine gum, was not found to be cost-saving (52,155). Studies have found that preventive treatment of high cholesterol costs more than the savings from reduced coronary heart disease; thus, cholesterol screening is unlikely to be cost-saving (154,175). In addition, hypertension screening was not found to be cost-saving (132). Even adult immunizations have been found to be cost-saving only for subsets of the general population, or under certain circumstances. For example, influenza vaccines were cost-saving only for those over 65 years of age (185). Similarly, pneumococcal vaccines, for those over 65 years of age, were only cost-saving under optimistic assumptions (186).

The three preventive services reviewed that are cost-saving (under certain conditions) are: prenatal care for poor women (188), newborn screening for some congenital disorders (i.e., phenylketonuria and congenital hypothyroidism) (188), and most childhood immunizations (188). However, even childhood immunizations, prenatal care, and newborn screening may not be universally cost-saving. For example, a recent cost-effectiveness analysis indicated that hepatitis B virus vaccination will be cost-saving only in high-risk adults and not in newborns or adolescents (17). The cost-effectiveness analyses reviewed above are described in greater detail in tables 4-1 through 4-8.

Why is the intuition that ‘an ounce of prevention is worth a pound of cure” incorrect in most circumstances? A key reason is that most screening tests (e.g., Pap smears, mammography, cholesterol and blood pressure measurement), must be done on thousands of people, most of whom do not have, and never will have, the disease, and tests must be repeated at specified intervals (161,164). Further, once the disease, or precursor condition, is detected, treatment must be undertaken and often more expensive follow-up tests performed. Finally, not everyone will benefit from preventive interventions. For example, research shows that a relatively small number of individuals given smoking advice will quit smoking (see chapter 3).

While a zero net cost criterion may be too stringent a criterion for choosing preventive services for coverage, attempting to limit net costs may be appropriate and necessary, particularly in the face of budget constraints and considering that the net costs associated with clinical preventive services can be large. For example, if the guidelines of the National Cholesterol Education Program (NCEP) were fully implemented, serum cholesterol would be measured on over 150 million American adults every five years (215). Over 40 percent of these individuals would require more expensive lipoprotein analysis, after initial measurement of total cholesterol, on a more frequent basis (232). Over 60 million American adults would require medical advice and intervention, including intensive dietary counseling and extended use of lipid-lowering drugs (232). The annua1 screening costs alone for all adults ages 20 and older would be almost $870 million, assuming full compliance with NCEP protocols (77). If the cost of treatment is included, the total expenditures might range from approximately $6 billion to $67 billion, depending on assumptions about the age group treated, the effectiveness of diet in lowering cholesterol, and when diet fails, the medications used (77).

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[4]The cost-effectiveness studies reviewed were limited to those which used the following assumptions, unless otherwise noted: (1) all costs and benefits were discounted at 5 percent, (2) the cost-effectiveness analyses took a societal perspective, (3) medical costs associated with additional years of life were excluded, (4) indirect costs were excluded (e.g., costs due to lost productivity or time costs). However, the results of these studies are only generalizable to the extent that the circumstances under which the interventions and treatments are applied (e.g., the population characteristics, price of services, effectiveness) are the same as those assumed in the analyses,

SUMMARY

Few clinical preventive services have been found to be cost-saving when applied to populations at average risk for the condition. Therefore, the use of most effective clinical preventive services will involve tradeoffs between improved health status and increased health care costs. Using explicit methods to evaluate costs in relation to benefits, such as cost-effectiveness analyses, may not make these decisions less political. However, in an environment of limited resources, cost-effectiveness analysis may be one of several useful tools for making better resource allocation decisions, such as those pertaining to insurance benefits. In particular, cost-effectiveness analyses may help shed Light on such questions as: who should receive preventive services, how often, and using what specific interventions

[5] A new panel, the Cost-Effectiveness Panel on Clinical Preventive Services (CEPCPS), has recently been established and will interact with the USPSTF and the agencies of the Public Health Service. The goal of the CEPCPS is to develop cost-effectiveness methodology and guidelines relevant to clinical preventive services; evaluate the adequacy of the literature on cost-effectiveness of selected clinical preventive services; and identify, and, when possible, direct studies of high priority areas where unresolved questions of cost-effectiveness remain (81).

Table 4-1—Selected Cost-Effectiveness Analyses of Adult Immunizations

Author[a]/ date	Target population	Treatment protocols compared	Data source(s) for effectiveness information	Other critical assumptions	Costs included	Cost-effectiveness per healthy life year gained,[b] case prevented or year of life saved (YOLS)
U.S. Congress, OTA (1981)	U.S. population, age 65+.	Influenza vaccination v. no vaccination.	Used the evidence from 3 clinical trials and 1 epidemiologic investigation; assumed a 60% efficacy rate.	5% discount rate; Vaccination costs $6 for vaccinees ≥ age 25 and $11 for vaccinees < age 25; 1 year duration of immunity.	Costs of vaccination, cost of treating side-effects, and the savings in reduced costs of treating pneumococcal pneumonia.	Cost saving.
U.S. Congress, OTA (1981)	U.S. population, aged 45 to 65.	Same as above.	Same as above.	Same as above.	Same as above.	$23 (1978 dollars).
U.S. Congress, OTA (1981)	U.S. population, age 25 to 44.	Same as above.	Same as above.	Same as above.	Same as above.	$64 (1978 dollars).
U.S. Congress, OTA (1981)	U.S. population, age 15 to 24.	Same as above.	Same as above.	Same as above.	Same as above.	$181 (1978 dollars).
U.S. Congress, OTA (1981)	U.S. population, age 3 to 14.	Same as above.	Same as above.	Same as above.	Same as above.	$196 (1978 dollars).
U.S. Congress, OTA (1981)	U.S. population, less than 3 years of age.	Same as above.	Same as above.	Same as above.	Same as above.	$258 (1978 dollars).
U.S. Congress, OTA (1984)	Persons age 65+.	23-valent pneumococcal pneumonia vaccination v. no vaccination.	8[illegible]% efficacy rate.	5% discount rate. The lowest estimate assumed that 15% of all pneumonia is pneumococcal and an 8-year duration of immunity. The highest estimate assumed that 10% of all pneumonia is pneumococcal and a 3-year duration of immunity. Vaccination cost $11.	Costs of vaccination, cost of treating side-effects, and the savings in reduced costs of treating pneumococcal pneumonia.	Cost saving to $6,154 (1983 dollars) (depending on assumptions about duration of immunity and the percentage of pneumonia that is pneumococcal).

Table 4-I-Selected Cost-Effectiveness Analyses of Adult Immunizations-Continued

Author[a]/ date	Target population	Treatment protocols compared	Data source(s) for effectiveness information	Other critical assumptions	costs included	Cost-effectiveness per healthy life year gained,[b] case prevented or year of life saved (YOLS)
Mulley et al. (1982)	Homosexual men and surgical residents.	Hepatitis B vaccination, with or without prior screening v. no vaccination.	A randomized ciinical triai of 1083 homosexual men; 87.5% efficacy rate.	6% discount rate; 5-year duration of immunity; serious reactions to vaccination would occur at a rate of 1/100,000 and 10°/0 of these would be fatal. 60% prevalence of HBV markers and 15°/0 annual attack rate of hepatitis B in the homosexual population in the absence of screening or vaccination. Cost of vaccination was $100.	Cost of vaccination. Savings from treatment of HBV infection and chronic sequelae of HBV infection.	Vaccinations will save medical costs for populations with attack rates above 5°/0 (i.e., vaccination of homosexual men and vaccination of surgical residents) (1980 dollars).
Mulley, et al. (1982)	General population.	Same as above.	Save as above.	Same assumptions except 5% prevalence of HBV markers and O.1% annual attack rate.	Same as above.	Vaccination of the general population would cost $22,469 per case of hepatitis B prevented (1980 dollars).
Bloom, et al. (1993)	U.S. high-risk adult population and general adult population.	Compared universal hepatitis B vaccination, to screening and vaccinating high-risk populations, to no vaccination.	Review of the medical literature and expert panel. Estimates of efficacy were based on randomized and historical clinical trials.	Base case assumption was 10 years of immunity; no side-effects requiring medical care; efficacy depended on the population, doses, and boosters (i.e., 60°/0 to 90%); vaccine cost $225 for adults (this included in administration fee). 5% discounting of benefits and costs.	Direct medical care costs.	Vaccination without screening is cost- saving in high-risk adults; vaccination in the general adult population would cost $257,418/YOLS and $15,001 per case prevented (1989 dollars).

ABBREVIATIONS: YOLS = year of life saved; HBV - Hepatitis B.
[a]Full cites can be found in references at the end of this report.
[b]Healthy life years were calculated as a weighted average of death, disability days with confinement to bed, disability days without confinement to bed, and full functioning.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

Table 4-2—Selected Cost-Effectiveness Analyses of Breast Cancer Screening

Author[a]/ date	Target population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	costs included	Cost effectiveness ratio per year of life saved (YOLS)
U.S. Congress, OTA (1 987)	Women age 65 to 74.	Annual Breast Physical Examination (BPE) and mammography v. no screening.	5 controlled trials and 1 uncontrolled study.	5%. discount rate. Screening mammogram and BPE cost $50. Annual screening will reduce mortality by about 50% after 5 years, 40% after 10 years and 30% after 20 years.	*Screenlng* rests, *workup* for false positives, cost of care for women with cancer, terminal care for cancer.	$34,600.
Eddy (1991a)	Women younger than 50 at average risk.	Annual BPE and mammography v. annual BPE alone.	Health Insurance Plan (HIP) and Breast Cancer Detection Demonstration Project (BCDDP) studies.	BPE costs $25, mammography costs $75, 5%. discount rate. Screening leads to a 24-60% reduction in mortality after 10 years and a 24-580/. reduction after 20 years.	*Screening* costs, *workup* for false positives, cost of care for women with cancer, terminal care for cancer.	$30,000 to $135,000 depending on whether use HIP or BCDDP.
Eddy (1991 a)	Women older than 50 at average risk.	Annual BPE and mammography v. annual BPE alone.	HIP and BCDDP studies.	Screening leads to a 30-59% reduction in mortality after 10 years and a 25-57% reduction in mortality after 20 years.	*Same as above.*	$20,000 to $90,000 depending on whether use HIP or BCDDP.

ABBREVIATIONS: BPE. Breast Physical Examination; **HIP** = Health Insurance **Plan;** BCDDP. Breast Cancer Detection Demonstration Project
[a]Full cites can be found in references at the end of this report.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

Table 4-3—Selected Cost-Effectiveness Analyses of Cervical Cancer Screening

Author[a]/ date	Target population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	Costs included	Cost-effectiveness ratio per years of life saved (YOLS)
U.S. Congress, OTA (1981)	100,000 women age 30-39.	Physician-based services, screened annually for 10 yrs. beginning at age 30 v. no screening.	Estimated using various sources and a Markov model, no RCTs.	Population was screened twice before the program began, 5% discount rate.	Screening, diagnosis and treatment (e.g., Pap test, pap cytology, colposcopy, biopsy, cryosurgery, conization, hysterectomy, hospitalization).	$51,928.
U.S. Congress, OTA (1981)	Same as above.	Screened every 10 years v. no screening.	Same as above.	Same as above.	Same as above.	$10,190.
U.S. Congress, OTA (1981)	Same as above.	"Low cost program" where health vocational nurses do the screening. Screened annually v. no screening.	Same as above.	Same as above.	Same as above.	$27,300.
U.S. Congress, OTA (1990)	Women age 65 and older.	One-time screening v. no screening.	Estimated using a Markov model and indirect evidence (e.g., the natural history of the disease, the efficacy of screening, and the efficacy of treatment).	5% discount rate; Pap smear costs $11 (in base case).	Costs of screening, costs of false-positives, cost of treatment, cost of follow-up. Costs based on Medicare average allowable charges.	$1,666 (1988 dollars).
U.S. Congress, OTA (1990)	Same as above.	Annual screening until age 110 v. no screening.	Same as above.	5% discount rate.	Same as above.	$39,693 (1988 dollars).
U.S. Congress, OTA (1990)	Same as above.	Screening every 3 years.	Same as above.	Same as above.	Same as above.	$5,956 (1988 dollars).
U.S. Congress, OTA (1990)	Women age 65 and older at high-risk.	Screening every 3 years.	Same as above.	Same as above.	Same as above.	Cost-saving.
Eddy (1991a)	Women age 29 to 75.	Screened every 4 years from age 20 to 75 v. no screening.	Based on analysis by the International Agency for Research on Cancer of several of the largest case-control and cohort screening programs.	5% discount rate; Pap smear costs $75; 0.5% false positive rate.	Charge for Pap smear, charge for working up a person with a false-positive pap smear, cost of treating a lesion, cost of initial therapy, cost of terminal care. Savings from avoided treatment costs.	$10,000.

ABBREVIATION: RCT = Randomized Clinical Trial.
[a]Full cites can be found in references at the end of this report.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

Table 4-4—Selected Cost-Effectiveness Analyses for Childhood Immunizations

Author[a]/ date	Target population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	Costs included	Cost-effectiveness per healthy life year gained[a]
Cochi, et al. (1985)	1984 U.S. children birth cohort 1-2 years old.	Hib vaccination at 18 months v. no vaccination.	Clinical and epidemiologic data and data from the bacterial meningitis surveillance system maintained by the CDC. Finland field trial of vaccine efficacy.	Cost of vaccine = $3/ dose, no additional administrative costs, 80% coverage, 75% efficacy, no discounting of acute case costs saved, long-term costs discounted at 5%.	Direct medical and social service costs.	Cost saving, both in terms of net short-term medical costs and with long-term social service costs.
Cochi, et al., (1985)	Same as above.	Hib vaccination at 24 months v. no vaccination.	Same as above.	Cost includes $10 administration fee since visit is not in conjunction with scheduled DTP visits, 80% coverage, 90% efficacy.	Same as above.	Cost saving.
White, et al. (1985)	U.S. population (examined actual 1983 data).	MMR vaccination v. single antigen vaccination v. no vaccination.		Vaccine costs: office visit = $15; measles = $4.26, rubella = $4.76; mumps = $5.57; MMR = $11.30, discounted at 10%.	Direct and indirect costs.	sav g
Bloch, et al. (1985)	U.S. popu	Measles vaccination program 1963 to 1982 v. no vaccination program 1963 to 1982.	Comprehensive review of benefits due to measles vaccination from 1963 to 1982; based on previously published studies.	Unspecified.	Direct and indirect costs.	sav g
Hinman and Koplan (1984)	Hypothetical cohort of 1 million children. Followed from birth to age 6.	Pertussis vaccination in conjunction with DT vaccines (5 doses, 0-6 years) v. no vaccination (DT only).	Incidence rate reported in England and Wales from 1976 to 1981.	Vaccine cost = $0.03/ dose. No administrative costs because administered in conjunction with DT, 90% coverage, 80% efficacy, 5% discount rate.	Direct medical costs (physician visits, hospitalization, residential care).	Cost saving (1983 dollars).
Witte and Axnick (1975)	U.S. population.	Measles vaccination as implemented in 1963 to 1972 v. no measles vaccination.		Costs of production, distribution, administration, and promotion of the vaccine is $3.00/ dose, no discounting.	Direct and indirect costs.	Cost sav g

Table 4-4—Selected Cost-Effectiveness Analyses for Childhood Immunizations-Continued

Author[a]/ date	Target population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	costs included	Cost-effectiveness per healthy life year gained[a]
Massachusetts Department of Health (1980)	Massachusetts population.	MMR vaccination program run by State v. no program.		No discounting, calculated cumulative savings since program began in 1966.		Cost saving.
Koplan and Preblud (1982)	U.S. population.	Mumps vaccine in conjunction with measles and rubella v. measles and rubella vaccine only.	Reported 1978 age-specific mumps incidence rates were used to estimate the incidence of mumps where mumps vaccine was part of routine childhood immunization and more than 750/. of children were immunized. Used average annual incidence of mumps in prevaccine years to estimate effects without vaccine.	Cost of mumps vaccination = $1.00, discounted at 5%.	Direct and indirect costs.	Cost saving.
Schoenbaum et al. (1976)	U.S. population.	Rubella vaccination of 2-year-old children as part of measles and mumps vaccine v. vaccination of 6-year-old children with monovalent vaccine v. vaccination of 12-year-old females with monovalent vaccine.	Frequency of rubella infection based on two serologic surveys performed in 1968.	Compiiance for all ages is 80°/0, herd immunity not considered, 6% discount rate, rubella vaccination costs $3/dose when administration alone and $1/dose when administered with measles vaccine.	Direct costs of vaccination, direct and indirect costs of congenital rubella syndrome, where indirect costs include lifetime earnings lost.	Cost saving.

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Table 4-4-Selected Cost-Effectiveness Analyses for Childhood Immunizations-Continued

Author'/ date	Target population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	costs included	Cost-effectiveness per healthy life year gained[a]
Koplan et al. (1979)	U.S. infant population.	Pertussis vaccination in conjunction with diphtheria and tetanus (DTP) vaccines v. DT vaccine only.	Incidence rates in a population with and without a pertussis vaccination program were based on reports to the Massachusetts Department of Public Health. Vaccine complication rates were based on data from Sweden and the Netherlands. Vaccine efficacy was based on "intrafamilial secondary cases."	90% immunization coverage, 70% efficacy, serious vaccine complications 1 in 3,500, encephalitis, 1 in 50,000; case fatality from these complications same as for pertussis.	Direct medical costs.	Cost saving.
Bloom et al. (1993)	U.S. population of newborns and 10-year-old adolescents.	Universal Hepatitis B vaccination compared with screening and vaccinating and compared with no vaccination.	Review of the medical literature and expert panel. Estimate of efficacy was based on randomized and historical clinical trials.	Base case assumption was 10 years of immunity; no side-effects requiring medical care; efficacy depended on the population, doses, and boosters (i.e., 60% to 90%); vaccine cost $160 for newborns (this included an administration fee). 5% discounting of benefits and costs.	Direct medical care costs.	Universal vaccination would cost $36,632 for newborns and $97,256 for adolescents; screening and vaccination would cost $42,067 for newborns; screening and vaccination of high-risk newborns and all adolescents would cost $3,695.

ABBREVIATIONS: DT = Diphtheria-tetanus; DTP = Diphtheria-tetanus-pertussis; Hib = Haemophilus Influenzae Type b; MMR = Measles-mumps-rubella; CDC = Centers for Disease Control and Prevention.

[a]Full cites found in references at the end of this report.

[b]Healthy life years were calculated as a weighted average of death, disability days with confinement to bed, disability days without confinement to bed, and full functioning.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993 (Adapted and updated from U.S. Congress, Office of Technology Assessment, *Healthy Children, Investing in the Future,* OTA-H-345 (Washington, DC: U.S. Government Printing Office, February 198S)).

Table 4-5—Selected Cost-Effectiveness Analyses of Cholesterol Reduction Interventions

Author[a]/ date	Target population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	costs included	Cost effectiveness ratio per year of life saved (YOLS)
Taylor, et al. (1990)	Men with given sets of risk factors for developing CHD (i.e., total serum cholesterol level, age, blood pressure, cigarette smoking,high-density lipoprotein level).	Dietary intervention. Intervention includes 10 visits to registered dietitian, 2 physician visits in the first year. After first year, 2 annual serum cholesterol measurements, 1 visit to physician, 3 visits to nutritionist. Intervention continues to age 65. Compared to no intervention.	Computed effectiveness of diet on lowering cholesterol based on the Multiple Risk Factor Intervention Trial (MRFIT), estimated the effect of lowering cholesterol on survival from the Framingham Heart study. Assumed no adverse consequences of cholesterol reduction.	Assumed that men with a given set of risk factors would be screened when visiting physician for some other reason. First-year dietary program costs $557 and each subsequent year costs $150. 5% discount rate.	Serum cholesterol tests ;visits with physician, nutritionist, lab test; Costs of initial cholesterol screen were not included. Savings from treating consequences of CHD (e.g., myocardial infarction).	Estimates ranged from $11,000 (40-year-old, high-risk[c] males with total serum cholesterol of 300 mg/dL) to $930,000 (20-year-old males at low risk with total serum cholesterol level of 180 mg/dL).
Taylor, et al. (1990)	Same as above.	Dietary intervention and drug therapy (cholestryamine) v. no intervention.	Effectiveness of dietary intervention plus cholestyramine in reducing cholesterol was based on the Lipid Research Clinics Coronary Primary Prevention Trial. Effect of lowering cholesterol on survival based on the Framingham Heart Study.	The first year of cholestyramine therapy cost $803; each subsequent year cost $755.	The costs of the dietary and medication programs. Medication program involved additional physician visits, liver chemistry determination and ocular examination (only for lovastatin).	Estimates varied from $24,000 (60-year-old man at high risk with total serum cholesterol of 240 mg/dL) to $1.4 million (20-year-old man at low risk with total serum cholesterol of 240 mg/dL).
Taylor, et al. (1990)	Same as above.	Dietary intervention and drug therapy (lovastatin) vs. no intervention.	Effectiveness of dietary intervention plus cholestyramine in reducing cholesterol was based on the work of Hoeg and colleagues.[b] Effect of lowering cholesterol on survival based on the Framingham Heart Study.	The first year of lovastatin therapy cost $1,291, each subsequent year cost $1,177.	The costs of the dietary and medication program. Medication program involves additional physician visits, liver chemistry determination and ocular examination (only for lovastatin).	Estimates varied from $20,000 (60-year-old man at high risk with total serum cholesterol of 240 mg/dL) to $1 million (20-year-old man at low risk with total serum cholesterol of 240 mg/dL).

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Table 4-5-Selected Cost-Effectiveness Analyses of Cholesterol Reduction Interventions-Continued

Author[a]/ date	Target population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	costs included	Cost effectiveness ratio per year of life saved (YOLS)
Oster and Epstein (1987)	Men in different age groups (35 to 74), without symptomatic coronary artery disease. Base case assumptions: cholesterol levels of 265-,290- and 315-mg/dL.	Cholestyramine, life-time treatment vs. no intervention.	Framingham Heart .	5% discount rate.	Costs of medication, routine office visits, cholesterol tests, visits for side-effects. The annual cost of a 16-g/d regimen of therapy is $707. Savings from treating consequences of coronary heart disease (e.g., myocardial infarction).	Cost/YOLS ranged from $56,100 (for 35 to 39-year-olds with 315 mg/dL to over $1,000,000 (for 65-69-year-olds with 265 mg/dL) (1985 dollars).

ABBREVIATIONS: CHD = coronary heart disease; dL = deciliter; mg = milligram.

[a] Full cites found in references at the end of this report.

[b] Hoeg, J. M., Maher, M. B., Bailey, K. R., et al., "Comparison of Six Pharmacologic Regimens for Hypercholesterolemia," *American Journal of Cardiology* 59:812-15, 1987 (97).

[c] High risk was defined as cigarette smoking, systolic blood pressure in 10th percentile of age- and sex-specific population distribution, high-density lipoprotein cholesterol at the 10th percentile of age- and sex-population distribution.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

Table 4-6—Selected Cost-Effectiveness Analyses of Colorectal Cancer Screening

Author[a]/ date	Target population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	Costs included	Cost-effectiveness ratio per year of life saved (YOLS)
U.S. Congress, OTA (1990)	1989 U.S. 65-year-old population.	Annual FOBT and flexible fiberoptic sigmoidoscopy every 3 years (FSIG) (using a 60 cm sigmoidoscope).	Effectiveness calculation was based on indirect evidence (i.e., accuracy of screening, natural history of disease, etc.).	5% discount rate.	Cost of screening, follow-up, polyp removal, surveillance, treatment of early and late cancers, cost of treating colonoscopy induced injuries, cost of treating surgery-related injuries.	$42,892 (1989 dollars).
U.S. Congress, OTA (1990)	Same as ab	Annual FOBT and FSIG every 5 years (using a 60 cm sigmoidoscope).	Same as bo	Same as	as above.	$42,509 (1989 dollars).
U.S. Congress, OTA (1990)	Same as above.	Annual FOBT and FSIG on entry to Medicare (using a 60 cm sigmoidoscope).	Same as above.	Same as above.	Same as above.	$47,308 (1989 dollars).
U.S. Congress, OTA (1990)	Same as above.	Annual FOBT.	am as above.	Same as	as bo	54 do

ABBREVIATIONS: FOBT = Fecal Occult Blood Test; FSIG = Flexible Fiber sco

[a]Full cites can be found in references at the end of this report.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

Table 4-7—Selected Cost-Effectiveness Analyses of Hypertension Screening

Author[a]/ date	Target population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	Costs included	Cost-effectiveness ratio per QALY[b]
Littenberg, et al. (1991)	Women 20 years of age.	Sphygmomanometry for diastolic blood pressure in range of 90- to 105- mm Hg.	Effectiveness of therapy based on previous meta-analysis of 8 community-based trials of hypertension therapy.	5% discount rate. Costs of therapy based on average wholesale costs of various medication; annual drug costs vary from $2.92 to $220.10. Total treatment costs per year for mild hypertension vary from $50 to $500, with $300 base-line estimate. Cost of screening is $5 and varies from 0 to $50.	Direct medical costs of death, myocardial infarction, and cerebrovascular accident; drug therapy; repeat visits; lab tests to monitor therapy, blood pressure measurement.	$44,412/QALY (1988 dollars).
Littenberg, et al. (1991)	Women 40 years of age.	Same as above.	Same as above.	Same as abo	Same as above.	$23,536/QALY (1988 dollars).
Littenberg, et al. (1991)	Women 6○ years of age.	Same as above.	Same as above.	Same as above.	Same as above.	$12,404/QALY (1988 dollars).
Littenberg, et al. (1991)	Men 20 years of age.	Same as above.	Same as above.	Same as above.	Same as above.	$29,291/QALY (1988 dollars).
Littenberg, et al. (1991)	Men 40 years of age.	Same as above.	Same as above.	Same as above.	Same as above.	$16,280/QALY (1988 dollars).
Littenberg, et al. (1991)	Men 60 years of age.	Same as above.	Same as above.	Same as above.	Same as above.	$8,374/QALY (1988 dollars).

ABBREVIATIONS: QALY = Quality-adjusted life year.

[a]Full cites can be found in references at the end of this report.

[b]The authors assumed that the morbidity, pain, inconvenience, and suffering associated with the average stroke is equivalent, in terms of patient utility or sense of well-being, to avoiding he stroke but suffering a loss of 1.5 years of healthy life expectancy. Likewise, they valued a heart attack at 0.5 life-year equivalents.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

Table 4-8-Selected Cost-Effectiveness Analyses of Smoking Cessation

Author[a]/ date	Target or study population	Treatment protocols compared	Effectiveness data source(s)	Other critical assumptions	costs included	Cost effectiveness ratio per year of life saved (YOLS)
Oster, et al. (1986)	Male patients age 35 to 69 who smoke.	Nicotine chewing gum as an adjunct to physi - cians' advice and counseling against cigarette smoking.	Efficacy of physician's advice was based on trials which reported rate of smoking cessation after 12 months. Efficacy of nicotine gum was based on 7 placebo-controlled trials of nicotine gum. The two rates were multiplied to derive efficacy rate of nicotine gum in a primary care setting. Estimate that 6.1 % of patients seen in primary care practice who use nicotine gum will quit.	5% discount rate.	Cost of nicotine gum, cost of office visit med ical costs avoided from quitting smoking.	*$4,113* to $6,465 (depending on age).
Oster, et al. (1986)	Female patients age 35 to 69 who smoke.	Same as above.	Same as above.	Same as above.	Same as above.	$7,073 to $9,473 (depending on age).
Cummings, et al. (1989)	Men 35 to 69 years of age who smoke.	Brief advice to quit smoking during a routine office visit and a self-help booklet.	Four randomized trials that compared patients who were given advice by a physician to quit smoking and those who received no counseling. Found an average smoking cessation rate atone year Of 2.7°/0.	5% discount rate.	Cost of physician office visit and a self-help booklet. Medical costs avoided from quitting smoking.	$705 to $988 (depending on age).
Cummings, et al. (1989)	Women 35 to 69 years of age.	Same as above.	Same as above.	Same as above.	Same as above.	$1,411 to $2,058 (depending on age).

[a]Full cites can be found in references at the end of this report.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993.

Appendix A: Overview of OTA Assessment: Technology, Insurance, and the Health Care System

Background

Congress has been concerned for many years with serious and growing problems of health care costs, access, and quality. In response to a request from the Senate Committee on Labor and Human Resources (Edward M. Kennedy, Chairman) that was endorsed by the House Committee on Energy and Commerce (John D. Dingell, Chairman), the House Committee on Ways and Means Subcommittee on Health (Willis D. Gradison, then Ranking Minority Member), and Senator Charles E. Grassley (Committees on Budget, Finance, Special Committee on Aging), the Office of Technology Assessment's (OTA's) assessment, *Technology, Insurance, and the Health Care System*, addresses these congressional concerns by focusing on the following issues:

1. What does the available literature say about the impact of health insurance on access to care and patient health outcomes?
2. Can a minimum benefit package for uninsured people be fashioned from the perspective of effectiveness and cost-effectiveness?

In addition, Senator Ted Stevens (as a member of the Technology Assessment Board) asked OTA to examine an additional question under the auspices of this assessment:

3. What cost implications do the leading types of health care reform proposals have in seven areas: health care spending and savings; Federal, State, and local budgets; employers (large and small); employment; households (low-, middle-, and upper-income); other costs in the economy; and administrative costs?

The assessment was approved by the Technology Assessment Board in April 1991, and began in July, 1991. In June 1992, the letter was received from Senator Stevens, An advisory panel for the overall assessment was formed in November 1991. The advisory panel met in January 1992, December 1992, and in May 1993.

Documents Produced as Part of the Assessment

The following documents have been or will be available as part of the assessment.

Publications Available From the U.S. Government Printing Office

Does Health Insurance Make a Difference? (OTA-BP-H-99).

This interim report, requested by the U.S. Senate Labor and Human Resources Committee, summarizes the state of the literature on the relationships among insurance coverage, access, and patient health outcomes; provides a conceptual framework for evaluating access to health care and the health effects of such access; and provides an overview of insured and uninsured populations in the United States as of 1990. The background paper is available from the U.S. Superintendent of Documents (phone number 202/275-3030; address: Washington, DC 20402; GPO stock number 052-003-01301-1, $5.00 per copy) or, for congressional purposes, from OTA (49241).

An Inconsistent Picture: A Compilation of Analyses of Economic Impacts of Competing Approaches to Health Care Reform by Experts and Stakeholders (OTA-H-540).

This report compiles and summarizes available analyses of the economic impacts of four major competing approaches to health care reform (popularly known as "single payer," "play or pay," "individual vouchers or tax credits, " and ''managed competition"). The report was requested by Senator Ted Stevens, and was released in June 1993. The report is available for public use from the U.S. Superintendent of Documents (phone number 202/783-3238; address: P.O. Box 371954, Pittsburgh, PA 15250-7954; GPO stock number 052-003-01327-4, $8.00 per copy) or, for congressional purposes, from OTA (49241).

Benefit Design Series

Publications from this series of reports explore issues involved in designing a benefit package based on effectiveness and cost-effectiveness, in relation to other critical factors in benefit design. Two of the topics (clinical preventive services; mental health/ substance abuse) were chosen in part because of Congressional interest in them as contentious, ''grey' areas in benefit design and in part because of OTA's already-existing expertise in the topics. Patient cost-sharing was in some respects a new area for OTA, but was an issue of particular importance in the benefit design debates. The general issues report will pull together lessons learned about benefit design from the other reports in the Benefit Design Series and from other sources, including previous work by OTA. The reports in this series are:

Benefit Design in Health Care Reform: Report #1—Clinical Preventive Services (September 1993).

This report addresses issues pertaining to insurance coverage of clinical preventive services. The report describes how information on effectiveness and cost-effectiveness can, and cannot, be used for purposes of insurance benefit design and for improving access to effective clinical preventive services.

Benefit Design in Health Care Reform: Background Paper-Patient Cost-Sharing (September 1993).

This background paper describes what is known, and not known, about the effects of patient cost-sharing on the use of health care services, expenditures, and health outcomes based on a review of the literature.

Benefit Design in Health Care Reform: Report #2—Mental Health and Substance Abuse Treatment Services (in preparation).

This report addresses issues pertaining to insurance coverage for mental health and substance abuse services. The report emphasizes the role that scientific data on efficacy, effectiveness, and cost-effectiveness can, and cannot, play in the design of insurance benefits for mental health and substance abuse treatment.

Benefit Design in Health Care Reform: Report #3-General Policy Issues (in preparation).

This report reviews policy issues related to the topic of designing benefit packages based on effectiveness and cost-effectiveness in relation to other factors such as public preferences, professional judgment, and political concerns.

Background Papers Available Only From OTA

These background papers are available from OTA. For Congressional use call 49241, and for public use, *Call* 202/228-6590.

Health Insurance: The Hawaii Experience--Background Paper (OTA-BP-H- 1O8). (June 1993).

This Background Paper provides a detailed look at the State that is often considered model for what other States can do to help provide universal or near-universal health insurance coverage for their residents. Unfortunately, valid data were not available to demonstrate either the overall financial costs of Hawaii's approach or the health effects on residents,

Coverage of Preventive Services: Provisions of Selected Current Health Care Reform Proposals (OTA-BP-H-1 10). (October 1992).

This background paper summarizes the provisions of selected congressional (102d Congress) and private health care reform proposals with respect to the coverage of clinical preventive services,

Contractor Papers Available From National Technical Information Service or From the Authors

Primary Care for the Uninsured: A Review of the Literature

Paper prepared under contract to OTA by David Blumenthal, M. D., M. P. P., Elizabeth Mort, M. D., M. P. H., and Jennifer N. Edwards, M. H. S., Health Policy Research and Development Unit, General Internal Medicine, Massachusetts General Hospital (May 1993).

The Relationship among Insurance Coverage, Access to Services and Health Outcomes: Case Study of Depression

Paper prepared under contract to OTA by Thomas McGuire, Ph. D., Department of Economics, Boston University, Boston, MA (July 1993).

Nonfinancial Barriers to Access to Health Care

Paper prepared under contract to OTA by Joanne Lukomnik, M. D., New York, NY (in preparation for October 1993).

Other Contractor Papers to be Available From OTA or GPO

Insurance Status and Health Care Utilization: Analysis of Four Data Bases and Cost Implications for Universal Coverage-Background Paper

Paper in preparation under contract to OTA and CRS, by Stephen Long and M. Susan Marquis, Rand Corporation, Washington, DC (in preparation).

This background paper is scheduled to be available in January 1994; plans for distribution are not yet final.

Lasers in Health Care: Coverage Decisions

The results of this survey, being conducted under contract to OTA by Neil Powe, M. D., M. B.A., M. P. H., and Claudia Steiner, M. D., M. P. H., Johns Hopkins University, are scheduled to be available in September 1994. Plans for distribution of the results are not yet final.

Appendix B: Method of the Study

This report, *Benefit Design in Health Care Reform: Report #1-Clinical Preventive Services,* is one of a series of the Office of Technology Assessment (OTA) publications on the uses of effectiveness and cost-effectiveness information in *benefit design in health care reform* that are being published as part of OTA's assessment, *Technology, Insurance, and the Health Care System,* The report addresses the available evidence on the health effects and cost-effectiveness of selected clinical preventive services for people without apparent symptoms for specific diseases, and the implications of using (and not using) such evidence in the design of a benefit package for health insurance coverage. Policy options for congressional considerations are addressed. This appendix summarizes the method used for this report.

Information on the health effects of selected clinical preventive services were based, in large part, on previous reviews. The reviews used were primarily limited to those that met the following criteria. They: 1) completed a thorough literature review, 2) provided explicit assessments of the quality, consistency, clarity, and strength of the scientific evidence, 3) weighed randomized clinical trials more heavily than observational studies, and evidence from research more heavily than expert opinion, and 4) explicitly described the relationship between the scientific evidence and the conclusions. The reviews of the U.S. Preventive Services Task Force (USPSTF) were used extensively throughout the report. In addition, many of the services discussed in this report had been previously reviewed in depth by OTA. Additional evidence that has emerged since the reviews were written was also presented, and its implications for the conclusions of the earlier reviews discussed.

The report reviewed the evidence on effectiveness of most of the clinical preventive services recommended by the USPSTF for asymptomatic individuals on the basis of individuals' sex and age, as opposed to other indications of risk such as family history. In addition, all of the services included in congressional health care reform proposals introduced in the 102d Congress were reviewed.

The evidence on cost-effectiveness was based on a comprehensive review of published cost-effectiveness analyses of clinical preventive services. The vast majority of cost-effectiveness analyses were limited to those that used the following assumptions: 1) the analyses took a societal perspective, 2) medical costs associated with additional years of life were excluded, and 3) indirect costs were excluded (e.g., costs due to lost productivity or time costs).

The draft report underwent extensive review by members of the Advisory Panel for the overall OTA assessment, as well as by individuals from the health insurance industry, the academic community, health care professionals, representatives of patients, research organizations, businesses, and Federal agencies with an interest and expertise in clinical preventive services and in the use of scientific information in health care.

Appendix C: Acknowledgments

OTA wishes to thank the Technology, Insurance, and the Health Care System Advisory Panel and the individuals and organizations listed below for their assistance with this Report. These individuals and organizations do not necessarily approve, disapprove or endorse this Report. OTA assumes full responsibility for the Report and the accuracy of its content.

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Appendix D: Abbreviations and Glossary of Terms

Abbreviations

AAFP —American Academy of Family Physicians
AAP —American Academy of Pediatrics
ACIP —Immunization Practices Advisory Committee
ACOG —American College of Obstetricians and Gynecologists
ACP —American College of Physicians
AFDC —Aid to Families with Dependent Children
AMA —American Medical Association
BCDDP —Breast Cancer Detection Demonstration Project
BLS —Bureau of Labor Statistics
BPE —Breast physical examination
CDC —Centers for Disease Control and Prevention
CEPCPS —Cost-Effectiveness Panel on Clinical Preventive Services
CHD -Coronary Heart Disease
CTFPHE —Canadian Task Force on the Periodic Health Examination
DDST —Denver Developmental Screening Test
dL —Deciliter
DT —Diphtheria-tetanus
DTP —Diphtheria-tetanus-pertussis
DRE —Digital rectal examination
EPSDT —Early and Periodic Screening, Diagnostic, and Treatment services
ERISA —Employee Retirement Income Security Act of 1974
FDA —Food and Drug Administration
FOBT —Fecal Occult Blood Test
FSIG —Flexible sigmoidoscopy
HBsAG —Hepatitis B surface antigen
HBV —Hepatitis B
HIAA —Health Insurance Association of America
Hib —Haemophilus Influenza Type b
HIP —Health Insurance Plan
HIV —Human Immunodeficiency Virus
HMO —Health maintenance organization
IPA —Independent or individual practice association
IUDs —Intrauterine devices
LDL —Low density lipoprotein
MASFP —Maternal Serum Alpha-Fetoprotein
Mg —Milligram
MMR —Measles, Mumps, and Rubella
MRFIT —Multiple Risk Factor Intervention Trial
NHLBI —National Heart, Lung, and Blood Institute
NIH —National Institutes of Health
ODPHP --Office of Disease Prevention and Health Promotion
OPV -Oral poliovirus vaccine
OTA -Office of Technology Assessment (U.S. Congress)
NCEP —National Cholesterol Education Program
PKU —Phenylketonuria
POS —Point of service
PPO —Preferred provider organization
PSA —Prostate-specific antigen
QALY -Quality-adjusted life year
RCT —Randomized clinical trials
RPR —Rapid plasma reagin (syphilis screening test)

STD —Sexually transmitted disease
TB —Tuberculosis
Td —Tetanusdiphtheria
TRUS —Transrectal ultrasonography
USPSTF —U.S. Preventive Services Task Force
VDRL —Venereal Disease Research Laboratory (syphilis screening test)

Terms

ABO blood group: The major classification system for human blood, which is based on two antigens (A and B) on the surface of red blood cells. Four blood types are defined by the presence of one (type A or B), both (type AB), or neither (type O) of these antigens.

Adenomatous polyps: Benign growths usually found in the colon.

Access to services: Potential and actual entry of a population into the health care delivery system. Elements of access include availability, affordability, and approachability.

Amblyopia: Subnormal visual acuity. The term specifically denotes a developmental disorder of visual function arising from either sensory stimulation deprivation or abnormal binocular interaction.

Anemia: A condition that exists when the level of hemoglobin in a person's blood drops to an abnormally low level.

Annual physical examinations: Examinations which are provided annually and are relatively nonspecific in terms of their content.

Antibody: A blood protein (immunoglobulin) produced by lymphocytes, a type of white blood cell, in response to the introduction of a specific antigen (e.g., invading bacteria, incompatible red blood cells, inhaled pollen grains, or foreign tissue grafts). Once produced, the antibody has the ability to combine with the specific antigen that stimulated antibody production thereby rendering it harmless. This reaction to foreign substances is part of the immune response.

Antigen: A substance that the body regards as foreign and that elicits an immune response (generating an antibody to react against the antigen or increasing lymphokine production, or both). Antigenic substances may include microorganisms, cells, tissue grafts, or toxins.

Appropriate (health care): Individuals and organizations define appropriate health care in many different ways. The Rand Corporation defines appropriate care as when "the expected health benefit [exceeds] the expected negative consequences. . .by a sufficiently wide margin that the procedure [is] worth doing" (cited in NAS, IOM Committee to Advise the PHS, "Clinical Practice Guidelines, **1990).**

Bacteriuria: The presence of bacteria in the urine.

Behavioral preventive strategies: A broad array of strategies to encourage lifestyle changes, such as exercise, smoking cessation, and healthful diets.

Benefit design: The determination of the terms of the benefit package.

Benefit package: In this report, benefit package refers primarily to the services and providers that are covered by a *health insurance plan,* and to the financial and other terms of such coverage (e.g., patient *cost-sharing,* limitations on amounts and numbers of visits or days). However, a benefit package can be said to consist in total of the terms of the contract between the *subscriber* or *enrollee* and the *insurer. The* terms of *payment* to *health care providers* may also be part of the terms of a benefit package.

Benefits: The covered health care services and the amount payable by a health insurance plan to a beneficiary under the terms of the plan.

Biochemical markers: Substances or processes characteristic of (or indicative of) physiological activity (e.g., blood in the stool as an indicator of colorectal cancer).

Biotinidase Deficiency: A congenital disorder caused by a deficiency of the enzyme needed to metabolize the B vitamin biotin leading to an overall deficiency of biotin in the body. If untreated, severe cases of biotinidase deficiency can lead to necrologic damage, resulting in coma or death in infancy. Less severe cases (resulting in developmental delay or hearing loss) and asymptomatic cases also occur.

Capillary hemoglobin/hematocrit: Test for anemia.

Carotid bruits: Clinical sign associated with atherosclerotic disease of the major arteries of the neck, and is associated with myocardial infarction and cerebrovascular disease.

Cardiovascular disease: Any of a diverse group of diseases affecting the heart, blood vessels, and/or

blood circulation. Cardiovascular disease includes diseases of the heart muscle itself, ischemic heart disease, hypertension, cerebrovascular diseases, and various other conditions.

Case-control study: Also called a retrospective study, An observational epidemiologic study that starts with the identification of a group of individuals with a disease (or other condition or ‘‘outcome variable’ of interest (“cases”), and a suitable control group of persons without the disease, but who are otherwise similar to the cases (’ ‘controls’ ‘). The relationship of a “risk factor” (which may include exposures to a chemical or physical agent, family history of disease, or other personal attribute) to the disease is evaluated by determining how frequently the risk factor is present, or if quantitative, the levels of the risk factor, in the cases and controls. Many risk factors may be studied in a single case control study.

“Categorically **needy recipients”:** Refers to Medicaid recipients receiving Aid to Families with Dependent Children (AFDC) benefits and Supplemental Security Income (SSI).

Chemoprophylaxis: The prevention of disease by the use of drugs or chemicals.

Cholestyramine therapy: Treatment in which cholestyramine medication binds to cholesterol thereby reducing high levels of cholesterol.

Clinical practice guidelines: Synthesis of literature and expert opinion for the purpose of making recommendations regarding health services.

Clinical preventive services: 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.

Cohort study: Study participants are identified by whether they are receiving the intervention, and are then followed over time in an effort to determine differences in outcome between those who received the intervention and those who did not receive it.

Coinsurance: A fixed percentage of covered expenses paid by a health plan and an enrollee for covered expenses after any deductible has been met; for example, an 80-20 coinsurance arrangement means that, after the deductible is reached, 80 percent of covered expenses are paid by the plan and 20 percent are paid by the person covered by the plan.

Colonoscope: A tube with a light and mirror at the end which is inserted into the gastrointestinal tract for direct visualization of its interior. Full visualization of the entire colon is possible with a 180 cm colonoscope.

Congenital disorders: Any abnormality, whether genetic or not, that is present at birth.

Coronary artery disease: Narrowing of the small arteries leading to the heart. Can lead to heart attacks or sudden death.

Costs: Expenses incurred in the provision of services or goods. Many different kinds of costs are defined and used (e.g., allowable, direct, indirect, and operating costs).

Cost-effectiveness analysis: An analytic technique that compares the costs of a project or 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.

Cost-sharing: The provisions of a health benefits plan that require the enrollee to pay a portion of the cost of services covered by the plan, typically exclusive of premium *cost-sharing* (sharing the cost of a health care plan premium between the sponsor and the enrollee). Usual forms of cost-sharing include deductibles, coinsurance, and copayments. These payments are made at the time the service is received or shortly thereafter, and are only made by those insured who seek treatment.

Cystic Fibrosis: A life-shortening, autosomal recessive disorder affecting the respiratory, gastrointestinal, reproductive, and skeletal systems, as well as the sweat glands. Cystic Fibrosis is caused by mutations in the Cystic Fibrosis gene.

Deductible: The amount of covered health care expenses (e.g., **$200, $500, $1,000)** that must be incurred by the health plan enrollee and his or her dependents before any health benefits become payable by the health plan. Deductible requirements apply to each individual in a family for a specific time period (usually a year). Some plans specify *family* deductibles after which no additional individual deductibles are required; family deductibles are typically equivalent to two or three times the individual deductible.

Diagnostic intervention: Clinical intervention relating to or aiding in diagnosis.

Digital rectal examination: The procedure where the clinician inspects the interior of the rectum with a finger in search of a rectal mass.

Diphtheria-Tetanus (DT) **Toxoid:** A combination immunization given to prevent diphtheria and tetanus.

Discounting: A procedure used in economic analysis to express as "present values" those costs and benefits that will occur in future years. Discounting is based on two premises: 1) individuals prefer to receive benefits today rather than in the future; and 2) resources invested today in alternative programs could earn a return over time.

Distal colon: Rear area of the colon.

Ectopic pregnancy: A pregnancy that occurs outside the uterus, usually in a Fallopian tube. Early symptoms include severe abdominal pain and vaginal bleeding; if untreated, may lead to rupture or internal hemorrhage, and shock.

Effectiveness: Effectiveness is a particular application of *efficacy,* that is, it reflects the performance of an intervention under ordinary conditions by the average practitioner for the typical patient,

Efficacy: The probability of benefit to individuals in a defined population from health technology applied to a given health problem under ideal conditions of use,

Employee Retirement **Income Security Act of 1974 (ERISA):** Exempts companies that self-insure, or fund their own insurance plans, from State regulations.

Environmental preventive strategies: Strategies for the prevention of disease or promotion of health that typically consist of social policies, such as seat belt laws, taxes on alcohol and tobacco use, speed limits, and restrictions on access to firearms, in addition to environmental and occupational regulations,

False-positive: A person without the disease who tests positive for the disease.

Family planning: A general name applied to a range of services intended to help individuals plan when to have children, from counseling concerning the advisability of initiating sexual intercourse to the provision of contraceptive methods.

Fecal occult blood test: A screening test which analyzes samples of stool for the presence of blood. Fecal occult blood tests indirectly test for the presence of colorectal cancer or polyps.

Fee-for-service: In fee-for-service health care, physicians and other providers bill separately for each patient encounter or service rendered. This system contrasts with salary, per capita, or other prepayment systems, where the payment to the practitioner does not change with the number of services actually rendered.

Fee schedule: A list of medical services in which each entry is associated with a specific monetary amount that represents the approved payment amount for the service under a given insurance plan.

Financing (of health care): Refers to where the money to pay health care providers for the delivery of health care services comes from (e.g., government, taxpayers).

Fixed costs: An operating expense that does not vary, at least over the short term, with the volume of services provided.

Flexible sigmoidoscopy: A flexible tube with a light and mirror at the end inserted into the colon through the anus to examine the distal end of the large bowl.

Free erythrocyte protoporphyrin (FEP): Refers to a screening test used to indicate iron deficiency.

Galactosemia: A deficiency of the enzyme needed to metabolize galactose, a type of sugar found in milk products. Untreated galactosemia usually leads to blood poisoning, progressive liver damage, and death within the first few weeks of life.

Global budget: Generally, an overall budget limit on health care services. Global budgets can take the form of a State or national capon total health care expenditures, but usually imply national limits. In some contexts, global budgeting has come to mean setting a limit on spending by sector (e.g., specific allocations for doctors, hospitals).

Gonococcal arthritis: Complication of gonorrhea in which the infection involves the joints.

HBV markers: Blood test which detects current or past hepatitis B virus.

Health benefits: Include increased life expectancy, better functional status, and reduced morbidity, pain, and anxiety. Negative health outcomes are the opposites of these qualities.

Health care provider: An individual or institution that provides medical services (e.g., a physician, hospital, laboratory). This term should not be confused with an insurance company which ''provides' insurance.

Health insurance: In this report, the term "health insurance' is used broadly to include various types of health plans that are designed to reimburse or indemnify individuals or families for the costs of medical care, or (as in HMOs) to arrange for the delivery of that care, including traditional private indemnity fee-for-service coverage, prepaid health plans such as HMOs, self-funded employment based plans, Medicaid, and Medicare. **Private health insurance:** With respect to health insurance, refers to a plan run or sponsored by an entity other than the government. **Public health insurance:** With respect to health insurance, refers to a government-run or -sponsored plan.

Health maintenance organization (HMO)): A health care organization that, in return for prospective per capita (cavitation) payments, acts as both insurer and provider of specified health services.

Hematocrit: The volume occupied by the cellular elements of blood in relation to the total volume.

Hemocystinuria: A congenital disorder caused by a deficiency of one of the enzymes involved in the metabolism of the amino acid homocystine. If left untreated, homocystinuria can lead to life-threatening episodes of vascular thrombosis; most untreated survivors go on to have mental deficiency, and half of them may die in early adulthood.

Hemoglobin: A protein found in red blood cells that is responsible for the transport of oxygen.

Hemoglobinopathy: A blood disorder caused by alteration in the genetically determined molecular structure of hemoglobin, which results in a characteristic complex of clinical and laboratory abnormalities and often, but not always, overt anemia.

Hepatitis B: Viral hepatitis, type B. An acute inflammation of the liver caused by infection with hepatitis B virus, which is transmitted mainly by sexual contact, parental exposure (contaminated needles or administration of blood products), and from carrier mother to baby. In some cases, infection may be severe and result in prolonged illness, destruction of liver cells, cirrhosis, and death. Formerly known as "serum hepatitis. "

Haemophilus influenza b: One of six types of infection with *Haemophilus influenza b,* a parasitic bacterium that occurs in an encapsulated form. In children and in debilitated older adults, infection may result in destructive inflammation of the larynx, trachea, and bronchi, and may also cause subacute bacterial endocarditis and purulent meningitis. Immunization against Hib is available through inoculation with *anti-Haemophilus influenzae* serum.

High risk: At greater than normal risk of contracting a specific disease or condition.

Hypercholesterolemia: An elevation of the blood cholesterol level.

Hypothyroidism: Diminished production of thyroid hormone, leading to thyroid insufficiency.

Indemnity: Benefits paid in a predetermined amount in the event of a covered loss.

Individual practice association (IPA) HMOs: A form of HMO in which participating physicians remain in their independent office settings, seeing both enrollees of the IPA and patients covered by other health insurance plans. Participating physicians may be reimbursed by the IPA on a fee-for-service or a cavitation basis.

Lipoprotein: Compounds consisting of lipids (fatty substances such as cholesterol) and proteins, the form in which lipids are transported in the blood and lymph fluid. They are classified as very low-density (VLD), low-density (LD), and high-density (HD).

Mammography: X-ray examination of the breast, used as both a screening procedure on apparently healthy females and as a diagnostic procedure in clinical situations to detect breast cancer.

Managed Competition Plan: An approach to health care reform that would combine health insurance market reform with health care delivery system restructuring. The theory of managed competition is that the quality and efficiency of health care delivery will improve if independent groups compete with one another for consumers in a government-regulated market.

Mandated insurance benefits: Minimum health insurance coverage requirements specified by government statute.

Markov model: A quantitative tool useful in describing the movements of members of a population through different states over time. The model

requires that the distribution of the population among defined states at the initiation of the model, and the probability that any one individual move into a different state between two periods of time, be known.

Maternal serum alpha-fetoprotein (MSAFP): Blood test used during pregnancy to detect possible neural tube defects.

Medicaid: A joint Federal-State program, authorized by Title XIX of the Social Security Act, of Federal matching grants to the States to provide health insurance for categories of the poor and medically indigent. States determine eligibility, payments, and benefits consistent with Federal standards.

Medicare: A Federally administered health insurance program authorized by Title XVIII of the Social Security Act of 1965 which covers the cost of hospitalization, medical care, and some related services for eligible persons over age 65, persons receiving Social Security Disability Insurance payments for 2 years, and persons with end-stage renal disease. Medicare consists of two separate but coordinated programs—hospital insurance (Part A) and supplementary medical insurance (Part B).

Meta-analysis: A systematic, typically quantitative method for combining information from multiple studies.

Morbidity: The condition of being ill or otherwise afflicted with an unhealthful condition.

Morbidity rate: The rate of illness in a population, calculated as the number of people ill during a time period divided by the number of people in the total population; used to refer to incidence or prevalence rates of disease.

Mortality rate: The death rate, often made explicit for a particular characteristic (e.g., age, sex, or specific cause of death), A mortality rate contains three essential elements: 1) the number of people in a population group exposed to the risk of death (the denominator); 2) a time factor; and 3) the number of deaths occurring in the exposed population during a certain time period (the numerator).

Neoplasm: Uncontrolled and progressive growth of tissue, either benign or malignant; a tumor.

Nicotine gum: Alternative nicotine delivery method (as opposed to cigarettes) used to ween smokers from habitual cigarette use. The gum transmits nicotine by chewing.

Nicotine patch: Alternative nicotine delivery method (as opposed to cigarettes) used to ween smokers from habitual cigarette use. The patch transmits nicotine through the skin.

Node-negative tumors: Cancers which are less likely to have spread beyond their primary site, as evidenced by the lack of involvement of lymph nodes.

Oral glucose tolerance test: Screening test for diabetes.

Ortalani maneuvers: Manual orthopedic manipulation used to relocate the femur (femoral head) into the hip joint socket.

Out-of-pocket expense: Payments made by an individual for medical services. These may include direct payments to providers as well as payments for deductibles and coinsurance for covered services, for services not covered by the plan, for provider charges in excess of the plan's limits, and for enrollee premium payments.

Papanicolaou (Pap) smear: A screening test for women for cervical cancer.

Papillomavirus: A virus which causes up to sixty types of warts. It is recognized as a sexually transmitted agent and is also believed to be a contributing factor in cervical, vaginal, and vulvar carcinoma (cancer).

Pathology: The scientific study of the cause of disease and of the associated structural and functional changes that result.

Pelvic **inflammatory disease (PID): An** infection involving the endometrium, Fallopian tubes, and peritoneum, often occurring as a complication of untreated gonorrhea, Women using intrauterine contraceptive devices are also at increased risk for the disease. Bacteria that cause gonorrhea, chlamydia, or other infections can ascend from the lower genital tract through the endometrium (causing endometriosis), to the Fallopian tubes (causing salpingitis), and possibly to the ovaries (causing oophontis), and if untreated, can result in tubal scarring, infertility, or ectopic pregnancy. Symptoms include lower abdominal pain, increased vaginal discharge, and fever.

Periodic health examination: The periodic health examination is provided in accordance with recommended schedules for specific interventions (usually less frequently than every year). It includes

relatively specific interventions, emphasizes tailoring interventions to individual circumstances, and is limited primarily to those services which have been shown to be effective.

Pertussis: An acute, infectious inflammatory respiratory disease of children caused by the bacterium *Bordetella pertussis. The* disease is characterized by explosive attacks of coughing ending in an inspiratory whoop or choking on mucus and occurs in infants and children who have not been immunized against the disease. Also known as ''whooping cough. ' '

Phenylketonuria (PKU): A genetic disorder of amino acid metabolism, characterized by the inability to metabolize the amino acid phenylalanine. Untreated or late treated PKU results in severe mental retardation in the majority of cases,

Pneumonia: Any one of several types of acute or chronic inflammation of the lungs due to infection by viruses, bacteria, or other microorganisms; a common complication of other serious illnesses and a common cause of death in the United States.

Point-of-service plan (POS): A hybrid form of managed care plan based on a mixture of cavitation and fee-for-service (FFS) payment arrangements, POS plans permit health plan enrollees to choose a FFS or HMO provider at the time he or she seeks services (rather than at the time they choose to enroll in a health plan).

Predictive capability: In screening and diagnostic tests, the probability that individuals with positive test results have the condition in question or that a person with a negative result does not have it. A test's predictive value is determined by its sensitivity and specificity and by the prevalence of the condition for which the test is used.

Preferred provider organization (PPO): Refers to a variety of different insurance arrangements under which plan enrollees who choose to obtain medical care from a specified group of 'preferred' providers receive certain advantages, such as reduced cost-sharing charges. PPO providers typically furnish services at lower than usual fees in return for prompt payment by the health insurance plan and a certain assured volume of patients.

Premium: The price or amount which must be paid periodically (e.g., monthly, biweekly) to purchase insurance coverage or to keep an insurance policy in force. Premiums paid to *health maintenance organizations* or similar organizations are often called *cavitation* payments.

Preventive interventions: Strategies for health promotion or disease prevention that include counseling, screening, immunization, or prophylactic interventions for individuals in clinical settings.

Preventive services: Services intended to prevent the occurrence of a disease or its consequences. Preventive health care includes health care programs aimed at warding off illnesses (e.g., immunizations), early detection of disease (e.g., Pap smears), or inhibiting further deterioration of the body (e.g., exercise or prophylactic surgery). Preventive medicine is also concerned with general preventive measures aimed at improving the healthfulness of the environment and with the promotion of health through altering behavior, especially using health education, Preventive health services are sometimes categorized as primary, secondary, or tertiary. Primary prevention is aimed at reducing the incidence of a disease or health problem; **secondary prevention is** aimed at reducing the prevalence of a problem by shortening the duration among those who have the problem; and tertiary prevention is aimed at reducing complications.

Primary care: A basic level of health care, usually provided in an outpatient setting, that emphasizes a patients' general health needs (e.g., preventive services, treatment of minor illnesses and injuries, identification of problems that require referral to specialists).

Prostate-specific antigen (PSA): A protein produced exclusively by the prostate gland and present at elevated levels in men with prostate cancer and other prostatic diseases. Concentrations of PSA can be determined using a blood test.

Provider: See *health care provider.*

Pyelonephritis: Inflammation of the kidney, particularly due to local bacterial infection.

Randomized clinical trial (RCT): An experiment designed to test the safety and efficacy of a medical technology in which people are randomly assigned to experimental or control groups, and outcomes are compared.

Renal disease: Disease pertaining to the kidney.

Respiratory distress syndrome: Lung problem involving fluid filling air spaces in the lungs.

Retinopathy: Noninflammatory degenerative disease of the retina.

Rh blood group: Genetically determined immunologic antigens (referred to as D or Rh+) on the surface of the red blood cells capable of inducing intense antigenic reactions when combined with blood cells lacking those antigens (no D or Rh-). The presence or absence of an Rh factor is especially important in blood transfusions (where it is a major cause of incompatibility) and in pregnancy when the mother is Rh- and the fetus is Rh+, which, if untreated, can lead to hemolytic disease of the newborn.

Risk factor: A characteristic which has been found in populations to be positively associated with the development of a disease or condition.

Scoliosis: Lateral curvature of the spine.

Screening **services: The** use of tests or physical examinations to detect the existence of one or more particular diseases or health deviations or to identify for more definitive studies those suspected of having certain diseases.

Sensitivity: The proportion of persons with a condition who correctly test "positive" when screened.

Sensitivity analysis: An analysis of the effect of changes in key assumptions or uncertainties on the findings and outcome of an overall study.

Serum tumor marker: Series of blood tests associated with various cancers.

Sickle-cell anemia: A genetic disorder of hemoglobin synthesis leading to the production of abnormal red blood cells. Infants with sickle cell anemia are at increased risk of overwhelming infection and sudden death in the first few years of life. Painful episodes of vase-occlusive crises are the hallmark of sickle cell anemia, although there is wide variability in expression of the disease in older patients.

Single-Payer System: Approach to health care reform that would provide tax-financed universal coverage with government as the sole purchaser of services. A single entity, usually government-run, reimburses all medical claims. Consumers typically pay a uniform tax rather than premiums. Money goes to a single health care trust fund, used only for health care expenditures.

Specificity: The proportion of persons without a condition who correctly test "negative" when screened.

Sphygmomanometer: Blood pressure cuff.

Sputum cytology: The anatomy, physiology, pathology, and chemistry of sputum cells. Sputum is mucus and other fluids formed in air passages and upper food passages (the mouth) and expelled by coughing.

Staff-model HMO: In this type of HMO, the majority of health plan enrollees are cared for by physicians who are typically salaried staff of the HMO.

Strabismus: A misalignment of the eye that the patient cannot overcome without aid.

Therapeutic intervention: Treatment of disease or disorders (as opposed to prevention or diagnosis).

Third-party payer: An organization (private or public) that pays for or insures at least some of the health care expenses of its beneficiaries. Third-party payers include Blue Cross/Blue Shield, c_{om}-mercial health insurers, Medicare, and Medicaid. The individual receiving the health care services is the first party, and the individual or institution providing the service is the second party.

Traditional indemnity plan: A conventional or fee-for-service health plan that typically reimburses the health care provider on a "reasonable and customary' basis or as billed.

Transrectal ultrasound (TRUS): Using high frequency ultra soundwaves to create a visual picture which can help to detect cancer in the prostate.

Tyrosinemia: A disorder of tyrosine metabolism marked by an excess of tyrosine in the blood. It occurs in two forms; Transient or Neonatal Tyrosinemia: a benign condition of newborns which responds to ascorbic acid; and Hereditary Tyrosinemia: results in liver failure or severe nodular cirrhosis, with renal tubular involvement, rickets, darkening of the skin, and slight mental retardation. It is transmitted as an autosomal recessive trait.

Ultrasound cephalometry: A procedure that measures the head size of fetus, used to assess fetal growth.

Urinalysis: Analysis of the urine.

Well-baby care: Preventive health care for children, includes immunizations, health education, parental guidance, physical examinations, and other tests that screen for illness or developmental problems. Sometimes defined as care for children less than one year of age, although the distinction between well-child care and well-baby care is not a precise one.

Well-child care: Preventive health care for children, includes immunizations, health education, parental guidance, physical examinations, and other tests that screen for illness or developmental problems. Sometimes defined as care for children one year of age and older, although the distinction between well-child care and well-baby care is not a precise one.

Appendix E: Current Coverage of Clinical Preventive Health Care Services in Public and Private Insurance

To put the debate over insurance for clinical preventive services in context, this appendix describes the extent of current coverage of preventive services in public insurance plans, specifically, Medicaid and Medicare, and in private health insurance plans, specifically, employer-based plans. Within the discussion of private insurance, current Federal and State mandates for coverage within employer-based plans and federally qualified HMOs are also described.

Public Insurance Programs

Medicaid

Federal law requires that all State Medicaid programs provide a standard benefit package to 'categorically needy recipients' [1] (179). Required preventive services include Early and Periodic Screening, Diagnostic, and Treatment services (EPSDT), and family planning services and supplies, EPSDT services consist of screening and diagnostic services to determine physical or mental defects in beneficiaries under age 21, and measures to correct or ameliorate any defects or chronic conditions discovered. At a minimum, screening services must include: comprehensive health and developmental history; comprehensive unclothed physical exam; appropriate vision testing; appropriate hearing testing; appropriate laboratory tests; and dental services for children 3 years of age and older (180). Family planning services include services for women of childbearing age, including minors who can be considered to be sexually active (180). In addition, States that cover medically needy' individuals must reimburse health care providers for prenatal care provided to recipients (179).

States also have the option of covering preventive services not already required (182). Additional preventive services are covered in 3 States for categorically needy individuals and in 20 States for both categorically and medically needy individuals (204). Presumably, the scope of these preventive services in the 23 States is fairly unlimited in the sense that Medicaid permits the health care provider to use his or her own judgment to determine whether to provide the services (55).

Federal requirements prohibit States from charging deductibles or coinsurance for all services provided to children under 18 years old, for services related to pregnancy, or for family planning services.

Medicare

Medicare covers very few clinical preventive services. Federal law prohibits Medicare from offering benefits for preventive services without an amendment to the Medicare Act (Public Law 89-97). Since 1981,

[1] Categorically needy Medicaid recipients are those receiving Aid to Families with Dependent Children (AFDC) benefits and Supplemental Security Income (SSI).

[2] States have the option of offering Medicaid to medically needy people who would be categorically needy for Medicaid but whose income and resources lie above the standards for eligibility. Each State sets its own medically needy resource and income standards up to 133.33 percent of State AFDC income standards.

several screening services and vaccinations have been added to the list of covered services for Medicare recipients. These services are: vaccines for pneumococcal pneumonia and Hepatitis B (for those at high risk for the virus), Pap smears to screen for cervical cancer, and biannual mammographies to detect breast cancer (58).

Private Insurance

Publicly and privately funded surveys of employment-based health plans are the principal source of data on insurance coverage for clinical preventive services; however, these surveys have a number of limitations. First, no one survey provides a completely representative picture of coverage provided to the Nation's workforce. Second, surveys report on only a subset of the clinical preventive services which might be covered, Further, the details of sampling and question construction in privately funded surveys are typically proprietary (i.e., not open to public scrutiny) and may have methodological problems, such as low response rates for specific questions. Fortunately, comparisons across surveys tend to provide a relatively consistent impression of coverage for specific services, thereby giving more confidence to their results.

Surveys of employer-based plans have been completed by the Health Insurance Association of America (HIAA); the U.S. Department of Labor, Bureau of Labor Statistics (BLS); and KPMG Peat Marwick. Each of these organizations uses slightly different survey methods. The BLS survey includes private sector establishments employing 100 workers or more (223). In 1991, BLS contacted 3,246 establishments and 2,144 responded (a 66 percent response rate). Information on benefits was determined from documents provided by each establishment describing their benefits plans.

HIAA surveyed 3,192 public and private firms in the spring of 1990 (excluding self-employed individuals and Federal workers) (173). The sample was nationally representative of small (defined as fewer than 100 employees), medium, and large firms and was stratified and weighted by region and standard industrial classification. Information on plans was collected through interviews.

KPMG Peat Marwick's survey included participants randomly drawn from Dun and Bradstreet's list of the Nation's private or public employers with more than 200 workers (121). KPMG Peat Marwick stratified the sample by industry, region, and number of workers. The sample included 1,057 firms, 744 of which were interviewed in 1991 and the rest in 1990. The overall response rate was 70 percent. Information on benefits was collected through telephone interviews with human resource directors.

The following section reports on the surveys' findings on coverage of preventive services. The first section discusses employer-based traditional indemnity plans. The second section discusses State- mandated benefits laws that could affect the coverage of certain benefits in private insurance plans. The third section discusses health maintenance organizations.

Traditional Indemnity Plans[3]

The surveys which included questions about well-baby care found coverage ranged from one-quarter to one-half of all employees. Peat Marwick found that 46 percent of employees with traditional indemnity insurance had coverage for well-baby care; HIAA found that 48 percent had coverage for well-baby care; and BLS found that 24 percent had well-baby care coverage (see figure E-1).[4]

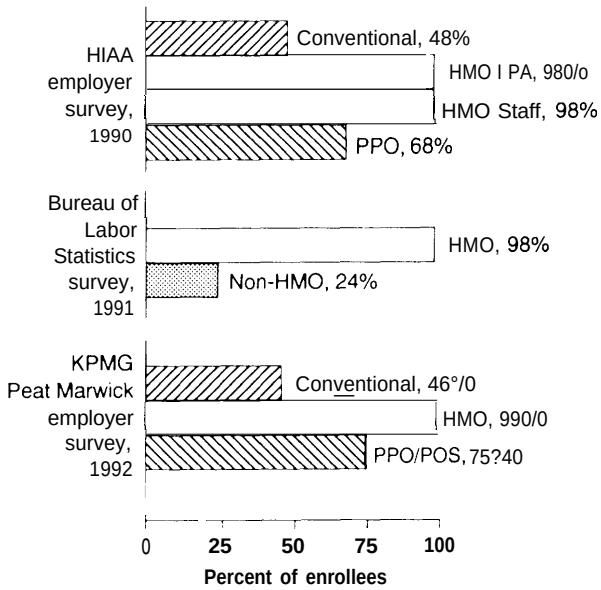
Only two of the surveys asked questions about well-child care. HIAA reported that 39 percent of employees with traditional indemnity insurance had coverage for well-child care, and Peat Marwick reported that 36 percent had coverage for well-child care[5] (see figure E-2). All three surveys asked about coverage of adult physical examinations and results ranged from 16 percent coverage (in the BLS survey) to 32 percent coverage (in the Peat Marwick Survey) (see figure E-3). To summarize, the three studies reported that roughly one-fifth to one-half of employ-

3 In this discussion, a traditional indemnity health insurance plan is a conventional or fee-for-service health plan that typically reimburses the health care provider on a "reasomble and customary' basis or as billed.

4 HIAA and Peat Marwick define well-baby care as care for children less than 1 year of age. In contrast, BLS defines well-baby care as care for children under approximately 2 years of age, excluding newborn care (18). Traditional indemnity plans often do not specify the age limits for well-baby or well-child care; therefore, the distinction is somewhat ambiguous.

5 Peat Marwick and HIAA defined well-child care as care for children between the ages Of 1 and 4.

Figure E-l—Percent of Enrollees Covered for Well-Baby Care in Employer-Based Health Insurance Plans by Plan Type, Various Surveys, Various Years



ABBREVIATIONS: HIAA = Health Insurance Association of America; HMO = health maintenance organization; IPA = independent or individual practice association; POS = point of service plan; PPO = preferred provider organization.

SOURCES: Health Insurance Association of America, Source *Book of Health Insurance Data* (Washington, DC: 1991); **KPMG** Peat **Marwick, *Health Benefits in 7992*** (Washington, DC: October 1992); U.S. Department of Labor, Bureau of Labor Statistics, ***Employee Benefits in Medium*** and ***Large Firms, 7997*** (Washington, DC: U.S. Government Printing Office, 1993).

ees with employer-based traditional indemnity plans had coverage for routine adult physical examinations, well-baby, and well-child care.

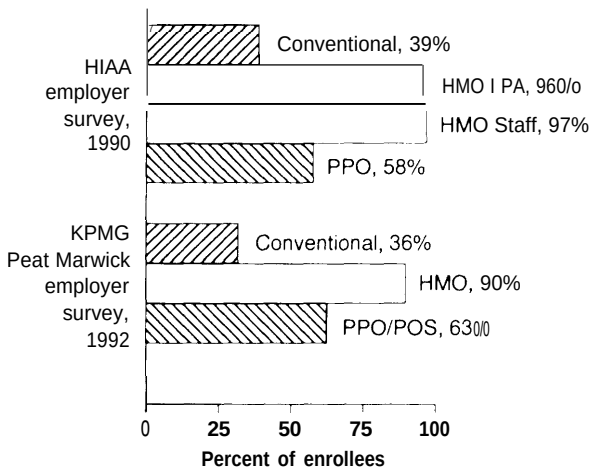
The HIAA survey, which was the only study to report on coverage for screening services, found that about half of all employees with traditional indemnity plans had coverage for Pap smears (55 percent) and mammographies (57 percent). The HIAA survey found that 47 percent of employees had coverage for childhood immunizations.

State Mandates

Many States have adopted mandated health insurance benefit laws for individual or group private insurance plans. The content of these mandates varies from State to State. Some laws may require that insurance carriers make certain benefits available as an option in employer-based plans. Others stipulate that these benefits must be covered in all plans sold to employers. Under the Employee Retirement Income Security Act (ERISA) of 1974, employers that self-fund their insurance plans are exempt from these mandates.

Currently nearly all States report at least one law mandating coverage of at least one clinical preventive service. The most frequently mandated preventive service is mammography screening (43 States) (19). Cervical cancer screening is mandated by 12 States; PKU testing is mandated in 3 States; prostate cancer screening and blood lead screening is mandated in 2 States; and 1 State requires coverage for newborn hearing testing (19), In the area of children's preventive services, 20 States currently require well-child care benefits (19). According to the Blue Cross and Blue Shield Association, States have varying definitions of well-child care; however, most include prena-

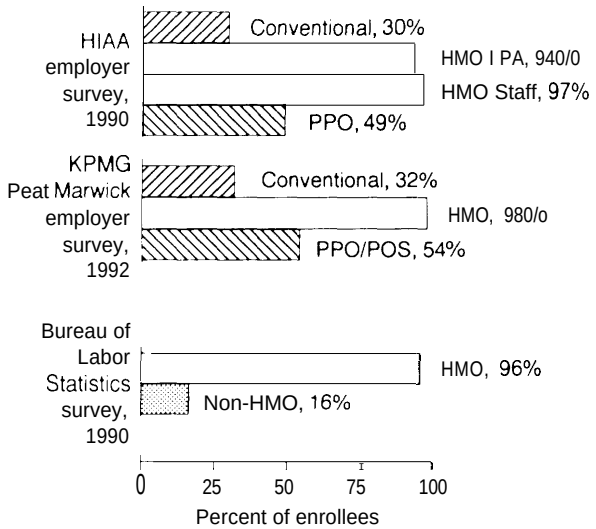
Figure E-2—Percent of Enrollees Covered for Well-Child Care in Employer-Based Health Insurance Plans by Plan Type, Various Surveys, Various Years



ABBREVIATIONS: HIAA = Health Insurance Association of America; HMO = health maintenance organization; IPA = independent or individual practice association; POS = point of service plan; PPO = preferred provider organization.

SOURCES: Health Insurance Association of America, *Source Book of Health Insurance Data* (Washington, DC: 1991)**KPMG** Peat**Marwick, *Health Benefits in 1992*** (Washington, DC: October 1992); U.S. Department of Labor, Bureau of Labor Statistics, ***Employee Benefits in Medium and Large Firms,*** **1997 (Washington,** DC: U.S. **Government** Printing Office, 1993).

Figure E-3—Percent of Enrollees Covered for Adult Physical Examinations in Employer-Based Health Insurance Plans by Plan Type, Various Surveys, Various Years



ABBREVIATIONS: HIAA = Health Insurance Association of America; HMO = health maintenance organization; IPA = independent or individual practice association; POS = point of service plan; PPO = preferred provider organization.

SOURCES: Health Insurance Association of America, *Source Book of Health Insurance Data* (Washington, DC: 1991); KPMG Peat Marwick, *Health Benefits in 1992* (Washington, DC: October 1992); U.S. Department of Labor, Bureau of Labor Statistics, *Employee Benefits in Medium and Large Firms, 1991* (Washington, DC: U.S. Government Printing Office, 1993).

tal services, well-baby care and childhood immunizations as elements of well-child care (127).

Health Maintenance Organizations

Health maintenance organizations are health care organizations that, in return for prospective per capita (cavitation) payments, act as both insurer and provider of specified health services. The Health Maintenance Organization Act of 1973 (Public Law 93-222) requires that most employers include a federally- qualified HMO, if one is available, among its health benefits options. In 1990 about 34 million individuals, or 14 percent of Americans, were enrolled in HMOs (85). About 75 percent of HMO members belong to federally-qualified HMOs (86).

The HMO Act of 1973 also established guidelines for benefit design, rating practices, and operations. Federally-qualified HMOs must provide pediatric and adult immunizations, well-baby and well-child care, periodic health evaluations for adults, abroad range of family planning services, and children's ear and eye examinations, up to age 17, to determine the need for vision and hearing correction (42 CFR 417. 101(a) (8)(i - vi)). Not all HMOs are federally qualified, however, and thus not all offer the full range of 'basic services' specified under Federal law (202).

Partially as a result of Federal requirements, HMOs are far more likely than traditional indemnity plans to cover clinical preventive services. According to four national surveys of employer-based health insurance benefits, the vast majority (over 90 percent) of employees enrolled in HMOs had coverage for routine adult physical examinations, prenatal care, well-baby and well-child care, screening services and immunizations (93,223,121) (see figures E-1, E-2, E-3), The HIAA survey found slight differences between IPA HMOs[6] and staff-model HMOs.[7] The IPA HMOs were slightly less likely to cover adult physical exams (94 percent versus 97 percent), and childhood immunizations (97 percent versus 99 percent) than the staff-model HMOs. Nevertheless, the vast majority of employees in all HMOs had coverage for these services.

Hybrid *Organizations*

During the past decade, various new financing and delivery models have been developed that blur the distinction between pure insurance plans that pay bills for services received and traditional HMOs that combine service delivery systems with a financing organization. These include preferred provider organizations (PPOs) and point of service plans (POS). A PPO refers to a variety of different insurance arrangements under which plan enrollees who choose to obtain medical care from a specified group of ' 'preferred" providers receive certain advantages, such as reduced cost-sharing charges. PPO providers typically

6 Individual Practice Association HMOs are those that contract with a number of individual physicians in independent practices Or with associations of independent physicians, Often independent physicians will contract with more than one HMO (93).

7 A staff-model HMO is one in which the health care providers are employees of the organization. This contrasts with other arrangements where providers or groups of providers contract with an HMO.

furnish services at lower than usual fees in return for prompt payment by the health insurance plan and a certain assured volume of patients. A POS is a hybrid form of managed care plan based on a mixture of cavitation and fee-for-service (FFS) payment arrangements. POS plans permit health plan enrollees to choose a FFS or HMO provider at the time he or she seeks services (rather than at the time they choose to enroll in a health plan).

Two of the three surveys also asked questions about PPOs and POSs. The Health Insurance Association of America and KPMG Peat Marwick surveys both found that PPOs and POSs were more likely than traditional indemnity plans, but less likely than HMOs, to cover clinical preventive services. The KPMG Peat Marwick survey found that in 1992, among PPOs and POSs plans combined, 54 percent offered coverage for routine adult physical examinations, 75 percent covered well-baby care, and 63 percent covered well-child care (figures E-1, E-2 and E-3). The HIAA survey found similar results. About half of employees with PPO plans were covered for adult physicals, **68** percent had well-baby care benefits, and 58 percent had well-child care benefits (figures E-1, E-2 and E-3). Also, about 70 percent had coverage for mammographies and Pap smears.

Summary

The levels of coverage for clinical preventive services within public and private health insurance plans vary by type of health plan. A summary of the discussion follows:

- State *Medicaid* programs are relatively generous in their coverage of preventive services, especially for children and pregnant women; many States offer services in excess of the Federally-defined basic services. Also, Medicaid programs are prohibited by law from imposing patient cost-sharing requirements on most preventive services.
- Since its inception in 1965, *Medicare* has covered very few preventive services, although in the past decade the Medicare Act has been amended to include some screening tests and immunizations.
- The scope of preventive benefits within *private health insurance* plans varies by service and type of plan. Evidence from employer surveys suggests that coverage for preventive benefits in traditional indemnity plans is lower than within HMO plans. Well-baby care and well-child care benefits are covered by about a quarter to half of traditional indemnity plans, while nearly 100 percent of HMOs provide these services, Also, a third, or less, of traditional indemnity plans cover routine screening adult physical examinations, while over 90 percent of HMOs offer this service.

Appendix F: Synthesizing and Assessing the Evidence and Determining Practice Policies

Syntheses of effectiveness research on clinical preventive services and clinical practice policies have been issued by a number of different organizations, including professional societies, government agencies, third-party payers, and private researchers. The specialty societies that have issued specific recommendations on prevention include the American College of Physicians, the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American College of Radiology, and the American Medical Association, Other private organizations include the Rand Corporation, the American Cancer Society, the American Heart Association, and the Institute of Medicine, National Academy of Sciences.

Several United States government agencies have organized external panels to synthesize the evidence on preventive medicine, or completed their own reviews of the evidence, often with input from outside experts. The National Institutes of Health (NIH) in the Public Health Service (PHS) in the Department of Health and Human Services (USDHHS), the National Cancer Institute in the NIH, the National Heart, Lung, and Blood Institute in the NIH, the Congressional Office of Technology Assessment (OTA), the Agency for Health Care Policy and Research, the Centers for Disease Control and Prevention (CDC), and the Office of Disease Prevention and Health Promotion (ODPHP), all have been involved in efforts to synthesize and evaluate effectiveness information.

Although the process of synthesizing the evidence on clinical practice is currently characterized by a diversity of decentralized efforts, there has been tremendous growth in interest in the methods used to synthesize and evaluate the evidence and, in general, these methods are becoming more rigorous and sophisticated. The Institute of Medicine has provisionally identified several attributes of good practice guidelines (see table F-l—Provisional Documentation Checklist for Practice Guidelines).

To assess the state of knowledge about the effectiveness of clinical preventive services, OTA looked to those organizations whose methods most reflected the criteria outlined by the Institute of Medicine. The methods employed by three different organizations, which generally took a relatively rigorous and systematic approach to reviewing the evidence on the effectiveness of preventive services, are described below. These organizations are the Canadian Task Force on the Periodic Health Examination (CTFPHE), the US. Preventive Services Task Force (USPSTF), and the Immunization Practices Advisory Committee (ACIP) of the CDC.

The Canadian Task Force on the Periodic Health Examination

The Canadian Task Force on the Periodic Health Examination (CTFPHE) was established in 1976 to recommend periodic health assessments for Canadian residents (29). The landmark contribution of CTFPHE was their use of a rigorous set of criteria to evaluate the evidence for or against the effectiveness and efficacy of any preventive intervention (83). The explicit criteria used by CTFPHE to rate the evidence on

Table F-l—Institute of Medicine Provisional Documentation Checklist for Practice Guidelines

Attribute	Item
Validity	Projected health outcomes if guidelines are followed. Information required to evaluate outcomes. Projected rests if guidelines are followed, information required to evaluate costs. Description of data, methods, and assumptions used to make projections, Explicit description of the relationship between the scientific evidence and the guidelines and explanations for any differences between the guidelines and the evidence. Explanations for any important differences between the guidelines in question and those developed by others. Thorough literature review describing scientific research including sponsors, settings, methodologies, findings, and qualifications. Description of methodology for evacuating the scientific literature and the results. Explicit assessment of the quality, consistency, clarity, and strength of the scientific evidence. Description of methodology for using expert or group judgment as a basis for evacuating scientific evidence or, in the absence of evidence, reaching a consensus based on expert opinion. Explicit description of the strength of expert consensus. Description of procedures, participants, and findings of review by experts and others not involved in the original development process. Description of methods, settings, and results of any protests of the guidelines,
Reliability/ reproducibility y	Description of methods and results of testing (1) the reliability of the development method and (2) the reproducibility of the clinical decisions reached by users of the guidelines.
Clinical applicability	Specifications by age, sex, race, clinical diagnosis, and other factors of the populations to which a set of guidelines apply. Description and analysis of the scientific literature or expert consensus that forms the basis for statements about the age, sex, and other factors of the populations to which a set of guidelines apply.
Clinical flexibility	Description and analysis of the scientific literature or expert consensus that forms the basis for statements about major foreseeable exceptions to applications of the guidelines. Listing of the basic information to be provided to patients and the kinds of patient preferences that may be appropriately considered. Listing of the data needed to document exceptions based on clinical circumstances, patient preferences, or delivery system characteristics.
Clarity	Methods and results of any testing of readability, logic, or understanding.
Multidisciplinary process	Description of the parties involved in developing the guidelines, their credentials and interests, and the methods used to solicit their views or to arrive at group judgments. Description of the procedures used to subject guidelines to review and criticism by experts not involved in the original development process, with summary of results.
Scheduled review	Timetable and method for the scheduled review. Description of the basis for arriving at the timetable or specific date.

SOURCE: Institute of Medicine, ***Clinical Practice Guidelines, Directions fora New Program,*** Field, M.J. and Lohr, K.N. (eds), (Washington, DC: National Academy Press, 1990).

effectiveness are shown in table F-2, ranked from the most to least credible.[1]

Each CTFPHE recommendation was assigned a letter grade, indicating the quality of the evidence which supported the recommendation (e.g., "A' indicated good evidence supporting the inclusion of a service, "C" indicated the evidence was poor, and "E" indicated there was good evidence that the service should be excluded). In their initial 1979 report, the Canadian Task Force issued recommendations for preventive services related to 78 potentially preventable conditions. Since their first report, CTFPHE has issued a number of updates and additional evaluations; for example, in 1993 CTFPHE issued an update on cholesterol screening (39). CTFPHE is in the process of updating the majority of their recommendations made since the original 1979 report and these will be published in mid-1994 (82).

Table F-2—Qualit y of Evidence Criteria Used by t he U.S. Preventive Services Task Force and the Canadian Task Force

I:	Evidence obtained from at least one properly randomized controlled trial.
II-1 :	Evidence obtained from well-designed controlled trials without randomization.
II-2:	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
II-3:	Evidence obtained from multiple time series studies with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin in the 1940s) could also be regarded as this type of evidence.
III:	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

SOURCE: U.S. Preventive Services Task Force, Guide *to Clinical Preventive Services.' An Assessment of the Effectiveness of 169 Interventions* (Baltimore: Williams and Wilkins, 1989).

The US. Preventive Services Task Force

In 1984, the Office of Disease Prevention and Health Promotion (ODPHP), in the U.S. Department of Health and Human Services, recommended the formation of the U.S. Preventive Services Task Force (USPSTF), a non-Federal, multidisciplinary panel of prevention experts (83). A 20-member panel was established in 1985 and in 1989 USPSTF published guidelines for the use of 169 preventive interventions,[2] USPSTF is working with CTFPHE to update their recommendations, which are scheduled for release in 1994.

The USPSTF's 1989 recommendations were based on a comprehensive literature search and the methods used to evaluate each study were systematic and explicit. To be considered effective by the USPSTF, screening tests, such as those used in cancer screening, had to be able to detect the target condition earlier than would have been the case without screening and with sufficient accuracy to avoid producing large numbers of false-positive and false-negative results (where accuracy refers to the test sensitivity, specificity, and positive predictive value) (see box F-1 for definitions of these terms). In addition, the test had to be reliable, that is, able to produce the same results when repeated. Even if a test accurately and reliably detected the disease at an early stage, it was not considered effective unless its use led to a better clinical outcome than would have occurred otherwise. That is, the interventions which followed a positive diagnosis for a condition had to be effective in preventing or delaying progress of the disease.

The USPSTF also used an explicit approach for evaluating the quality of the scientific evidence concerning the effectiveness of an intervention, and they placed the greatest confidence in evidence from randomized clinical trials (see table F-2). When there were no well-designed studies that supported an intervention, the USPSTF would recommend interventions that had demonstrated consistent benefits in a large number of studies of weaker design.

In making recommendations, the USPSTF evaluated the degree of efficacy of an intervention, the burden of illness, and the potential for negative consequences associated with its widespread, routine

[1] Note that table F-2 shows the criteria now used by the USPSTF and the CTFPHE. They arc a slightly revised version of the original criteria used by the CTFPHE in 1979. Specifically, category II-1, ''evidence obtained from well-designed controlled trials without randomization,'' was absent in the original criteria.

[2] ODPHP provides staff support for USPSTF, including background research on specific topics (232).

Box F-l—Important Concepts for Determining the Efficacy of a Screening Test

Sensitivity: The proportion of persons with a condition who correctly test positive when screened.

Specificity: The proportion of persons without a condition who correctly test "negative" when screened.

False Positives: A person without the disease who tests positive for the disease.

False Negatives: A person with the disease who tests negative for the disease.

Positive Predictive **Value: The** proportions of people correctly labeled diseased by the test. The positive productive value increases as the prevalence of the target condition in the screened population increases.

Accuracy: The USPSTF uses the term accuracy to refer to the performance of a test in terms of its sensitivity, specificity, positive predictive value, and negative predictive value.

Reliability: The ability of a test to obtain the same result when repeated.

Incidence: The number of new occurrences of the event in a specified time for a given population.

Prevalence: The ratio of the total number of all individuals who have an attribute or disease at a particular time, or during a particular period, to the population at risk for having the attribute or diseases.

SOURCES: U.S. **Preventive** Services **Task Force,** *Guide to Clinical Preventive **Services*** **(Baltimore,** *MD:* Williams and Wilkins, **1989); Maxcy-Rosenau, Last, JM. ed. Public Health and Preventive Medicine, 12th Edition (Norwalk, CT: Appleton-Century-Crofts,** 1986).

use. These negative effects may have included discomfort and physical injury, invasiveness, inconvenience, a longer period of morbidity due to early detection, overtreatment of borderline abnormalities, and anxiety from being falsely, or correctly, labeled as having the condition. For some preventive services no recommendation was made because the evidence was inadequate to decide for or against the procedure. In these cases, clinicians were advised to use their judgment to guide the application of the intervention.

Finally, interventions were often recommended for selected high-risk groups even though there was no evidence of greater effectiveness in these individuals than in the general population. The USPSTF argued that this policy was based on the recognition that the absence of evidence of effectiveness does not rule out effectiveness and if, in fact, the intervention is effective, individuals at increased risk of developing the disease are most likely to benefit.

There are several potential limitations to the USPSTF's methods. In choosing which target conditions to evaluate, the USPSTF considered both the burden of suffering from the target condition and the potential for effectiveness, but not the magnitude of the reduction in morbidity and mortality. Ideally, decisions relating to the widespread promotion of a preventive intervention may depend not only on whether the intervention is effective, but the expected magnitude of the effect, For example, the USPSTF assessed the effectiveness of cervical cancer screening, but not how many years of life would be saved if every women was routinely screened for cervical cancer.

A second limitation of the USPSTF recommendations is that they focus on interventions performed by physicians. For example, smoking education programs were not evaluated, with the exception of physician advice about smoking cessation. Other types of health education programs, such as labor and delivery and sex education classes, were not considered. In addition, preventive dental services were given little consideration, except as something which physicians should encourage. Similarly, the USPSTF's report does not explicitly evaluate the role of nonphysician providers. Nurses, social workers, physician assistants, and other health care providers may be able to provide many of the services described as appropriate by the USPSTF with equal effectiveness, and probably at lower cost, than can primary care physicians (e.g., advice regarding smoking cessation, blood pressure measurement, cholesterol measurement).

The Immunization Practices Advisory Committee

The Immunization Practices Advisory Committee (ACIP), an advisory group established by the CDC, issues recommendations on the use of new and existing vaccines. Recommendations typically describe the populations which should receive the vaccine, a schedule for vaccinations, and vaccine precautions and contraindications.

The ACIP meets several times during a year to review the evidence about the benefits and risks of vaccines and then issues its recommendations, ACIP members are selected from nominations made by professional and academic societies and represent experts in relevant disciplines (e.g., epidemiology, microbiology, public health, immunology, and public health practice). Representatives of the Food and Drug Administration (FDA) and the NIH act as ex-officio members, and the ACIP has liaison representatives from professional and governmental organizations.[3] Draft policy statements and background information are prepared by the CDC staff prior to the meetings. An attempt is made to gather all relevant background material, including both published and unpublished studies, such as unpublished studies from the vaccine manufacturer and the FDA.

The vaccines evaluated by the ACIP are licensed by the FDA, which does its own assessment of vaccine efficacy. The Center for Biologics Evaluation and Research of the FDA grants licensure for use of vaccines based upon demonstration of safety and efficacy. The approval process is complex and typically involves several sequential phases of evaluation, including initial testing of the vaccine in a small number of persons to determine its safety and immunogenicity; administration of the vaccine to a larger number of persons to obtain further data on adverse effects and the immune response; and controlled field trials with sufficient study subjects to develop reasonable estimates of safety and efficacy (104). The efficacy of a vaccine is usually measured in terms of protection against clinical disease (104). Although the FDA has primary responsibility for determining the safety and efficacy of vaccines, they do not issue recommendations concerning vaccine use, although they do provide input into the recommendations issued by the ACIP.

[3] These organizations include the American Academy of Family Physicians, American Academy of Pediatrics, the American College of Physicians, the American Hospital Association, the American Medical Association the Canadian National Advisory Committee on Immunization, the Department of Defense, and the National Vaccine Program.

Appendix G: Summary of the U.S. Preventive Services Task Force% (USPSTF) Recommendations for Services To Be Included in Periodic Health Examinations, by Age Group

The preventive services recommended by the USPSTF for inclusion in periodic health examinations are summarized in this appendix in eight tables, organized by age group. The preventive services listed reflect only those topics evaluated by the Task Force. The USPSTF specifically noted that clinicians should use individual judgment to determine what is most appropriate for each patient. The U.S. Preventive Services Task Force report, Guide *to Clinical Preventive Services,* gives more detailed information on the proper indications for specific preventive services than that provided in the tables (224).

Table G-I—Birth to 18 Months (Schedule: 2,4, 6, 15, 18 Months[a])

Screening	Parent counseling	Immunization and chemoprophylaxis	High-risk categories
Height and weight Hemoglobin and hematocrit[b] ***High-risk groups*** Hearing[c] (HR1) Erythrocyte protoporphyin (HR2)	Diet Breastfeeding Nutrient intake, especially iron-rich foods Injury prevention Child safety seats Smoke detector Hot water heater temperature Stairway gates, window guards, pool fence Storage of drugs and toxic chemicals Syrup of ipecac, poison control telephone number Dental health Baby bottle tooth decay **Other primary preventive measures** Effects of passive smoking	Diphtheria-tetanus-pertussis (DTP) vaccine[d] Oral poliovirus vaccine (OPV)[d] Measles-mumps-rubella (MMR) vaccine[f] Haemophilus influenza type b (Hib) conjugate vaccine[g] ***High-risk groups*** Fluoride supplements (HR3) **First week** Ophthalmic antibiotics Hemoglobin electrophoresis (HR4) T4/TSH [h] **Phenaylanine**[i] **Hearing (HR1)**	HR1 Infants 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). HR2 Infants who live in or frequently visit housing built before 1950 that is dilapidated or undergoing renovation; who come into contact with other children with known lead toxicity; who live near lead processing plants or whose parents or household members work in a lead-related occupation; or who live near busy highways or hazardous waste sites. HR3 Infants living in areas with inadequate water fluoridation (less than 0.7 parts per million). HR4 Newborns of Caribbean, Latin American, Asian, Mediterranean, or African descent.
This list of preventive services is not exhaustive. It reflects only those topics reviewed by the U.S. Preventive Services Task Force. **Clinicians** may wish to **add other preventive services after considering the patient's individual arcumstances.**		**Remain alert for:** **Ocular misalignment** **Tooth decay** **Signs of child abuse or neglect**	

[a] Five visits are required for immunizations- Because of lack of data and differing patient risk profiles, the scheduling of additional visits and the frequency of the individual preventive services listed in this table are left to clinical discretion (except as indicated in other footnotes):
[b] Once during infancy.
[c] At age 18-month visit, if not tested earlier.
[d] At ages 2, 4, 6, and 15 months.
[e] At ages 2, 4, and 15 months.
[f] At age 15 months.
[g] At age 18 months.
[h] At birth.
[i] Days 3 t. 6 preferred for testing.

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

Table G-2—Ages 2-6[a]

Screening	Patient and parent counseling	Immunizations and chemoprophylaxis	High-risk categories
Height and weight Blood pressure Eye exam for amblyopia and strabismus **Urinalysis for bacteriuria** ***High-risk groups*** Erythrocyte protoporphyrin[b] (HR1) Tuberculin skin test (HR2) Hearing[d] (HR3)	**Diet and exercise** Sweets and between-meal snacks, iron-enriched foods, sodium Caloric balance Selection of exercise program Injury prevention Safety belts Smoke detector Hot water heater temperature Window guards and pool fence Bicycle **safety helmets** **Storage of drugs, toxic chemicals, matches, and firearms** **Syrup of ipecac,** poison control telephone number **Dental health** Tooth brushing and dental visits **Other primary preventive measures** Effects of passive smoking ***High-risk groups*** Skin protection from ultraviolet light (HR4)	Diphtheria-tetanus-pertussis (DTP) vaccine[e] Oral poliovirus vaccine (OPV)[e] ***High-risk groups*** Fluoride supplements (HR5)	HR1 Children who live in or frequently visit housing built before 1950 that is dilapidated or undergoing renovation; who come in contact with other children with known lead toxicity; who live near lead processing plants or whose parents or household members work in a lead-related occupation; or who live near busy highways or hazardous waste sites. HR2 Household members of persons with tuberculosis or others at risk for close contact with the disease; recent immigrants or refugees from countries in which tuberculosis is common (e.g., Asia, Africa, Central and South America, Pacific Islands); family members of migrant workers; residents of homeless shelters; or persons with certain underfying medical disorders. HR3 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). HR4 Children with increased exposure to sunlight. HR5 Children living in areas with inadequate water fluoridation (less than 0.7 parts per million).
This list of preventive services Is not exhauetive. It reflects only those topics reviewed by the U.S. Preventive Services Task Force. Clinicians may wish to add other preventive services after considering the patient% medical history and other individual circumstances.		**Remain alert for:** **Vision disorders** **Dental decay, malalignment, premature loss of teeth, mouth breathing** **Signs of child abuse or neglect** **Abnormal bereavement**	

[a] One visit is required for immunizations. Because of lack of data and differing patient risk profiles, the scheduling of additional visits and the frequency of the individual preventive services listed in this table are left to clinical discretion (except as indicated in other footnotes).
[b] Ages 3-4.
[c] Annually.
[d] Before age 3, if not tested earlier.
[e] Once between ages 4 and 6.

SOURCE: U.S. Preventive Services Task Force, ***Guide to Clinical Preventive Services*** (Baltimore, MD: Williams and Wilkins, 19S9).

Table G-3—Ages 7-1 2[a]

Screening	Parent and patient counseling	Chemoprophylaxis	High-risk categories
Height and weight Blood pressure ***High-risk groups*** Tuberculin skin test (HR1)	**Diet and exercise** Fat (especially saturated fat), cholesterol, sweets and between-meal snacks, sodium Caloric balance Selection of exercise program Injury prevention Safety belts Smoke detector Storage of firearms, drugs, toxic chemicals, matches Bicycle safety helmets **Dental health** Regular tooth brushing and dental visits **Other primary preventive measures** ***High-risk groups*** Skin protection from ultraviolet light (HR2)	***High-risk groups*** Fluoride supplements (HR3)	HR1 Household members of persons with tuberculosis or others at risk for close contact with the disease; recent immigrants or refugees from countries in which tuberculosis is common (e.g., Asia, Africa, Central and South America, Pacific Islands); family members of migrant workers; residents of homeless shelters; or persons with certain underlying medical disorders. HR2 Children with increased exposure to sunlight. HR3 Children living in areas with inadequate water fluoridation (less than 0.7 parts per million).
This list of preventive services is not exhaustive. It reflects only those topics reviewed by the U.S. Preventive Services Task Force. Clinicians may wish to add other preventive services after considering the patient's medical history and other individual circumstances.		**Remain alert for:** Vision disorders Diminished hearing Dental decay, malalignment, mouth breathing Signs of child abuse or neglect Abnormal bereavement	

[a]Because of lack of data and differing patient risk profiles, the scheduling of additional visits and the frequency of the individual preventive services listed in this table are left to clinical discretion (except as indicated in other footnotes).

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

Table G-4-Ages 13-18°

Screening	Parent and patient counseling	Immunizations and chemoprophylaxis	High-risk categories
History **Dietary intake** **Physical activity** **Tobacco/alcohol/drug use** **Sexual practices** **Physical exam** **Height and weight** **Blood pressure** ***High-risk groups*** **Complete skin exam (HR1)** Clinical testicular exam (HR2) **Laboratory/diagnostic procedures** ***High-risk groups*** Rubella antibodies (HR3) VDRL (HR4) Chlamydial testing (HR5) Gonorrhea culture (HR6) Counseling and testing for HIV (HR7) Tuberculin skin test (PPD) (HR8) Hearing (HR9) Papanicolaou smear (HR 1O)[b]	Diet **and exercise** **Fat (especially saturated fat),** cholesterol, **sodium, iron,**[c] **calcium**[c] **Caloric balance** **selection of exercise** program **Substance use** **Tobacco: cessation/primary** prevention Alcohol and other drugs: cessation/primary prevention Driving/other dangerous activities while under the influence Treatment for abuse ***High-risk groups*** Sharing/using unsterilized needles and syringes (HR12) **Sexual practices** Sexual development and behavior[d] Sexually transmitted diseases: partner selection, condoms Unintended pregnancy and contraceptive options Injury prevention Safety belts Safety helmets Violent behavior[e] Firearms[e] Smoke detector **Dental health** Regular tooth brushing, flossing, dental visits **Other primary preventive measures** ***High-risk groups*** Discussion of hemoglobin testing (HR13) Skin protection from ultraviolet light (HR14)	**Tetanusdiphtheria (Td) booster**[f] ***High-risk groups*** Fluoride supplements (HR15)	**HR1 Persons** with increased recreational or occupational exposure to sunlight a family or personal history of skin cancer, or clinical evidence of precursor lesions (e.g., dysplastic nevi, certain congenital nevi). HR2 Males with a history of cryptorchidism, orchiopexy, or testicular atrophy. HR3 Females of childbearing age lacking evidence of immunity. HR4 Persons who engage in sex with multiple partners in areas in which syphilis is prevalent, prostitutes, or contacts of persons with active syphilis. HR5 Persons who attend clinics for sexually transmitted **diseases; attend other** high-risk health care facilities (e.g. adolescent and family planning clinics); or have other risk factors for chlamydial infection (e.g., multiple sexual partners or a sexual partner with multiple sexual contacts). HR6 Persons with multiple sexual partners or a sexual partner with multiple contacts, sexual contacts of persons with culture-proven gonorrhea or persons with a history of repeated episodes of gonorrhea HR7 Persons seeking treatment for sexually transmitted diseases; homosexual and bisexual men; past or present intravenous (IV) drug users; persons with a history of prostitution or multiple sexual partners; women whose past or present sexual partners were HIV infected, bisexual, or IV drug users; persons with long-term residence or birth in an area with high prevalence of HIV infection; or persons with a history of transfusion between 1978 and 1985. HR8 Household members of persons with tuberculosis or others at risk for close contact with the disease; recent immigrants or refugees from countries in which tuberculosis is common (e.g., Asia, Africa Central **and** South America Pacific Islands); migrant workers; residents of correctional institutions or homeless shelters; or persons with certain underlying medical disorders. HR9 Persons exposed regularly to excessive noise in recreational or other settings. HR1O Females who are sexually active or (if the sexual history is thought to be unreliable) aged 18 or older. **HR11 Recent divorce, separation, unemployment depression, alcohol or other** drug abuse, serious medical **illnesses, living alone, or recent bereavement.** **HR12** Intravenous drug users. **HR13 Persons of Caribbean, Latin American,** Asian, Mediterranean, or African descent HR14 Persons with increased exposure to sunlight.

Table G-4-Ages 13-18a--Continued

Screening	Parent and patient counseling	Immunizations and chemoprophylaxis	Health risk categories
			HR15 Persons living in areas with inadequate water fluoridation (less than 0.7 parts per million).
This list of preventive services Is not exhaustive. It reflects only those topics reviewed by the U.S. Preventive Services Task Force. Clinicians may wish to add other preventive services after considering the patient's medical history and other individual circumstances.		**Remain alert for:** **Depressive symptoms** **Suicidal** risk **factors** (HR11) Abnormal bereavement Tooth decay, malalignment, gingivitis Signs of child abuse and neglect	

[a]One visit is required for immunization. Because of lack of data and differing patient risk profiles, the scheduling of additional visits and the frequency of the individual preventive services listed in this table are left to clinical discretion (except as indicated in other footnotes).
bEvery 1-3 years.
[c]For females.
[d]Often best performed early in adolescence and with the involvement of parents.
eFor males.
[f]Once between ages 14 and 16.

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

Table G-5-Ages 19-39 (Schedule: Every 1-3 Years[a])

Screening	Counseling	Immunizations	High-risk categories
History Dietary intake Physical activity Tobacco/alcohol/drug use Sexual practices Physical exam Height and weight Blood pressure ***High-risk groups*** Complete oral cavity exam (HR1) Palpation for thyroid nodules (HR2) Clinical breast exam (HR3) Clinical testicular exam (HR4) Complete skin exam (HR5) Laboratory/diagnostic procedures Nonfasting total blood cholesterol Papanicolaou smear ***High-risk groups*** Fasting plasma glucose (HR6) Rubella antibodies (HR7) VDRL (HR8) Urinalysis for bacteriuria (HR9) Chlamydial testing (HRIO) Gonorrhea culture (HR11) Counseling and testing for HIV (HR12) Hearing (HR13) Tuberculin skin test (PPD) (HR14) Electrocardiogram (HR15) Mammogram (HR3) Colonoscopy(HR16)	Diet and exercise Fat (especially saturated fat), cholesterol, complex carbohydrates, fiber, sodium, iron[b], calcium[c] Caloric balance Selection of exercise program Substance **abuse** **Tobacco:** cessation/primary prevention Alcohol and other drugs: Limiting alcohol consumption Driving/other dangerous activities while under the influence Treatment for abuse ***High-risk groups*** Sharing/using unsterilized needles and syringes (HR18) Sexual practices Sexually transmitted diseases: partner selection, condoms, anal intercourse Unintended pregnancy and contraceptive options Injury prevention Safety belts Safety helmets Violent behavior[d] Firearms[d] Smoke detector Smoking near bedding or upholstery ***High-risk groups*** Back-conditioning exercises (HR19) Prevention of childhood injuries (HR20) Falls in the elderly (HR21) **Dental health** **Regular tooth brushing, flossing, dental visits**	Tetanus-diphtheria (Td) booster[e] ***High-risk groups*** Hepatitis B vaccine (HR24) Pneumococcal vaccine (HR25) Influenza vaccine[f] (HR26) Measles-mumps- rubella vaccine (HR27)	HR1 Persons with exposure to tobacco or excessive amounts of alcohol, or those with suspicious symptoms or lesions detected through self-examination. HR2 Persons with a history of upper-body irradiation. HR3 Women aged 35 and older with a family history of premenopausally diagnosed breast cancer in a first-degree relative. HR4 Men with a history of cryptorchidism, orchiopexy, or testicular atrophy. HR5 Persons with family or personal history of skin cancer, increased occupational or recreational exposure to sunlight, or clinical evidence of precursor lesions (e.g., dysplastic nevi, certain congenital nevi). HR6 The markedly obese, persons with a family history of diabetes, or women with a history of gestational diabetes. HR7 Women lacking evidence of immunity. HR8 Prostitutes, persons who engage in sex with multiple partners in areas in which syphilis is prevalent, or contacts of persons with active syphilis. HR9 Persons with diabetes. HR1O Persons who attend clinics for sexually transmitted diseases; attend other high-risk health care facilities (e.g., adolescent and family planning clinics); or have other risk factors for chlamydial infection (e.g., multiple sexual partners or a sexual partner with multiple sexual contacts, age less than 20). HR11 Prostitutes, persons with multiple sexual partners or a sexual partner with multiple contacts, sexual contacts of persons with culture-proven gonorrhea, or persons with a history of repeated episodes of gonorrhea. HR12 Persons seeking treatment for sexually transmitted diseases; homosexual and bisexual men; past or present intravenous (IV) drug users; persons with a history of prostitution or multiple sexual partners; women whose past or present sexual partners were HIV- infected, bisexual, or IV drug users; persons with long-term residence or birth in an area with high prevalence of HIV infection; or persons with a history of transfusion between 1978 and 1985. HR13 Persons exposed regularly to excessive noise.

Table G-5-Ages 19-39 (Schedule: Every 1-3 Years[a])-Continued

Screening	Counseling	Immunizations	High-risk categories
	Other primary preventive measures ***High-risk groups*** Discussion of hemoglobin testing (HR22) Skin protection from ultraviolet light (HR23)		HR14 Household members of persons with tuberculosis or others at risk for close contact with the disease (e.g., staff of tuberculosis clinics, shelters for the homeless, nursing homes, substance abuse treatment facilities, dialysis units, correctional institutions); recent immigrants or refugees from countries in which tuberculosis is common; migrant workers; residents of nursing homes, correctional institutions, or homeless shelters; or persons with certain underlying medical disorders (e.g., HIV infection). HR15 Men who would endanger public safety were they to experience sudden cardiac events (e.g., commercial airline pilots). HR16 Persons with a family history of familial polyposis coli or cancer family syndrome. HR17 Recent divorce, separation, unemployment, depression, alcohol or other drug abuse, serious medical illnesses, living alone, or recent bereavement. HR18 Intravenous drug users. HR19 Persons at increased risk for low back injury because of past history, body configuration, or type of activities. HR20 Persons with children in the home or automobile. HR21 Persons with older adults in the home. HR22 Young adults of Caribbean, Latin American, Asian, Mediterranean, or African descent. HR23 Persons with increased exposure to sunlight. HR24 Homosexually active men, intravenous drug users, recipients of some blood products, or persons in health-related jobs with frequent exposure to blood or blood products. HR25 Persons with medical conditions that increase t he risk of pneumococcal infection (e.g., chronic cardiac or pulmonary disease, sickle cell disease, nephrotic syndrome, Hodgkin's disease, asplenia, diabetes mellitus, alcoholism, cirrhosis, multiple myeloma, renal disease, or conditions associated with immunosuppression). HR26 Residents of chronic care facilities or persons suffering from chronic cardiopulmonary disorders, metabolic diseases (including diabetes mellitus), hemoglobinopathies, immunosuppression, or renal dysfunction. HR27 Persons born after 1956 who lack evidence of immunity to measles (receipt of live vaccine on or after first birthday, laboratory evidence of immunity, or a history of physician-diagnosed measles.)

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Table G-5-Ages 19-39 (Schedule: Every 1-3 Years[a])-Continued

Screening	Counseling	Immunizations	High-risk categories
This list of preventive services is not exhaustive. It reflects only those topics reviewed by the U.S. Preventive Services Task Force. Clinicians may wish to add other preventive services after considering the patient's medical history and other individual circumstances.		**Remain alert for:** **Depressive symptoms** **Suicide risk factors (HR17)** **Abnormal bereavement** **Malignant skin lesions** **Tooth decay, gingivitis** **Signs of physical abuse**	

[a]The recommended schedule applies only to the periodic visit itself. The frequency of the individual preventive services listed in this table is left to clinical discretion, except as indicated in other footnotes.
[b]Every 1-3 years.
[c]For women.
[d]For young males.
[e]Every 10 years.
[f]Annually.

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

Table G-6—Ages 40-64 (Schedule: Every 1-3 Years[a])

Screening	Counseling	immunizations	High-risk categories
History Dietary intake Physical activity Tobacco/alcohol/drug use Sexual practices Physical exam Height and weight Blood pressure Clinical breast exam[b] ***High-risk groups*** Complete skin exam (HR1) Complete oral cavity exam (HR2) Palpation for thyroid nodules (HR3) Auscultation for cartoid bruits (HR4) Laboratory/diagnostic procedures Nonfasting total blood cholesterol Papanicolaou smear[c] Mammogram[d] ***High-risk groups*** Fasting plasma glucose (HR5) VDRL (HR6) Urinalysis for **bacteriuria (HR7)** **Chlamydial testing (HR8)** **Gonorrhea culture (HR9)** **Counseling and testing** for HIV (HR1O) Tuberculin skin test (PPD) (HR11) Hearing (HR12) Electrocardiogram (HR13) Fecal occult blood/Sigmoidoscopy (HR14) Fecal occult blood/Colonoscopy (HR15) Bone mineral content (HR16)	Diet and exercise Fat (especially saturated fat), cholesterol, complex carbohydrates, fiber, sodium, calcium[e] Caloric balance Selection of exercise program Substance use Tobacco cessation Alcohol and other drugs: Limiting alcohol consumption Driving/other dangerous activities while under the influence Treatment for abuse ***High-risk groups*** Sharing/using unsterilized needles and syringes (HR19) Sexual practices Sexually transmitted diseases: partner selection, condoms, anal intercourse Unintended pregnancy and contraceptive options Injury prevention Safety belts Safety helmets Smoke detector Smoking near bedding or upholstery ***High-risk groups*** Back-conditioning exercises (HR20) Prevention of childhood injuries (HR21) Falls in the elderly (HR22) **Dental health** **Regular tooth brushing, flossing, and dental visits**	Tetanus-diphtheria (Td) booster[f] ***High-risk groups*** Hepatitis B vaccine (HR26) Pneumococcal influenza vaccine (HR27) influenza vaccine (HR28)[g]	HR1 Persons with a family or personal history of skin cancer, increased occupational or recreational exposure to sunlight, or clinical evidence of precursor lesions (e.g., dysplastic nevi, certain congenital nevi). HR2 Persons with exposure to tobacco or excessive amounts of alcohol, or those with suspicious symptoms or lesions detected through self-examination. HR3 Persons with a history of upper-body irradiation. HR4 Persons with risk factors for cerebrovascular or cardiovascular disease (e.g., hypertension, smoking, CAD, atrial fibrillation, diabetes) or those with necrologic symptoms (e.g., transient ischemic attacks) or a history of cerebrovascular disease. HR5 The markedly obese, persons with a family history of diabetes, or women with a history of gestational diabetes. HR6 Prostitutes, persons who engage in sex with multiple partners in areas in which syphilis is prevalent, or contacts of persons with active syphilis. HR7 Persons with diabetes. HR8 Persons who attend clinics for sexually transmitted diseases, attend other high-risk health care facilities (e.g., adolescent and family planning clinics), or have other risk factors for chlamydial infection (e.g., multiple **sexual** partners or a sexual partner with multiple sexual contacts). HR9 Prostitutes, persons with multiple sexual partners or a sexual partner with multiple contacts, sexual contacts of persons with culture-proven gonorrhea, or persons with a history of repeated episodes of gonorrhea. HR1O Persons seeking treatment for sexually transmitted diseases; homosexual and bisexual men; past or present intravenous (IV) drug users; persons with a history of prostitution or multiple sexual partners; women whose past or present sexual partners were HIV infected, bisexual, or IV drug users; persons with long-term residence or birth in an area with a high prevalence of HIV infection; or persons with a history of transfusion between 1978 and 1985.

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Table G-6-Ages 40-64 (Schedule: Every 1-3 Years[a])-Continued

Screening	Counseling	Immunizations	High-risk categories
	Other primary preventive measures ***High-risk groups*** Skin protection from ultraviolet light (HR23) Discussion of aspirin therapy (HR24) Discussion of estrogen replacement therapy (HR25)		HR11 Household members of persons with tuberculosis or others at risk for close contact with the disease (e.g., staff of tuberculosis clinics, shelters for the homeless, nursing homes, substance abuse treatment facilities, dialysis units, correctional institutions); recent immigrants or refugees from countries in which tuberculosis is common (e.g., Asia, Africa, Central and South America, Pacific Islands); migrant workers; residents of nursing homes, correctional institutions, or homeless shelters; or persons with certain underlying medical disorders (e.g., HIV infection). HR12 Persons exposed regularly to excessive noise. **HR13** Men with two or more cardiac risk factors (high blood cholesterol, hypertension, cigarette smoking, diabetes mellitus, family history of **CAD); men who would endanger public safety** were they to experience sudden cardiac events (e.g., commercial airline pilots); or sedentary or high-risk males planning to begin a vigorous exercise program. HR14 Persons aged 50 and older who have first-degree relatives with colorectal cancer; a personal history of endometrial, ovarian, or breast cancer; or a previous diagnosis of inflammatory bowel disease, adenomatous polyps, or colorectal cancer. HR15 Persons with a family history of familial polyposis coli or cancer family syndrome. HR16 Perimenopausal women at increased risk for osteoporosis (e.g., Caucasian race, bilateral oophorectomy before menopause, slender build) and for whom estrogen replacement therapy would otherwise not be recommended. HR17 Recent divorce, separation, unemployment depression, alcohol or other drug abuse, serious medical illnesses, living alone, or recent bereavement. HR18 Persons over age 50, smokers, or persons with diabetes mellitus. HR19 Intravenous drug users. HR20 Persons at increased risk for low back injury because of past history, body configuration, or type of activities. HR21 Persons with children in the home or automobile. HR22 Persons with older adults in the home. HR23 Persons with increased exposure to sunlight. HR24 Men who have risk factors for myocardial infarction (e.g., high blood cholesterol, smoking, diabetes mellitus, family history of early-onset CAD) and who lack a history of gastrointestinal or other bleeding problems, and or her risk factors for bleeding and cerebral hemorrhage.

Table G-6—Ages 40-64 (Schedule: Every 1-3 Years[a])—Continued

Screening	Counseling	Immunizations	High-risk categories
			HR25 Perimenopausal women at risk for osteoporosis (e.g., Caucasian, low bone mineral content, bilateral oopherectomy before menopause or early menopause, slender build) and who are without known contraindications (e.g., history of undiagnosed vaginal bleeding, active liver disease, thromboembolic disorder, hormone-dependent cancer). HR26 Homosexually active men, intravenous drug users, recipients of some blood products, or persons in health-related jobs with frequent exposure to blood or blood products. HR27 Persons with medical conditions that increase the risk of pneumococcal infection (e.g., chronic cardiac or pulmonary disease, sickle cell disease, nephrotic syndrome, Hodgkin's disease, asplenia, diabetes mellitus, alcoholism, cirrhosis, multiple myeloma, renal disease or conditions associated with immunosuppression). HR28 Residents of chronic care facilities and persons suffering from chronic cardiopulmonary disorders, metabolic diseases (including diabetes mellitus), hemoglobinopathies, immunosuppression, or renal dysfunction.
This iist of preventive services is not exhaustive. it reflects only those topics reviewed by the U.S. Preventive Services Task Force. Clinicians may wish to add other **preventive services after considering the patient's medical history and other individual circumstances.**		**Remain alert** for: Depressive symptoms Suicide risk factors (HR17) Abnormal bereavement Signs of physical abuse or neglect Malignant skin lesions Peripheral arterial disease (HR18) Tooth decay, gingivitis, loose teeth	

[a]The r-remended schedule applies only to the periodic visit itself. The frequency of the individual preventive services listed in this table is left to clinical discretion, except as indicated in other footnotes.
[b]Annually for women.
[c]Every 1-3 years for women.
[d]Every 1-2 years for women beginning at age 50.
'For women.
[f]Every 10 years.
[g]Annually.

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

Table G-7—Ages 65 and Over (Schedule: Every Year[a])

Screening

History
Prior symptoms of transient ischemic attack
Dietary intake
Physical activity
Tobacco/alcohol/drug use
Functional status at home

Physical exam
Height and weight
Blood pressure
Visual acuity
Hearing and hearing aids
Clinical breast exam
High-risk groups
Auscultation for carotid bruits (HR1)
Complete skin exam (HR2)
Complete oral cavity exam (HR3)
Palpation for thyroid nodules (HR4)

Laboratory/diagnostic procedures
Nonfasting total blood cholesterol
Dipstick urinalysis
Mammogram[f]
Thyroid function tests[d]
High-risk groups
Fasting plasma glucose (HR5)
Tuberculin skin test (PPD) (HR6)
Electrocardiogram (HR7)
Papanicolaou smear (HR8)
Fecal occult blood/Sigmoidoscopy (HR9)
Fecal occult bloodbionoscopy (HR1O)

Counseling

Diet and exercise
Fat (especially saturated fat), cholesterol, complex carbohydrates, fiber, sodium, calcium[i]
Caloric balance
Selection of exercise program

Substance use
Tobacco cessation
Alcohol and other drugs:
Limiting alcohol consumption
Driving /other dangerous activities while under the influence
Treatment for abuse

Injury prevention
Prevention of falls
Safety belts
Smoke detector
Smoking near bedding or upholstery
Hot water heater temperature
Safety helmets
High-risk groups
Prevention of childhood injuries (HR12)

Dental health
Regular dental visits, tooth brushing, flossing

Other primary preventive measures
Glaucoma testing by eye specialist
High-risk groups
Discussion of estrogen replacement therapy (HR13)
Discussion of aspirin therapy (HR14)
Skin protection from ultraviolet light (HR15)

Immunizations

Tetanus+ diphtheria (Id) booster
Influenza vaccine[g]
Pneumococcal vaccine
High-risk groups
Hepatitis B vaccine (HR16)

High-risk categories

HR1 Persons with risk factors for cerebrovascular or cardiovascular disease (e.g., hypertension, smoking, CAD, atrial fibrillation, diabetes) or those with necrologic symptoms (e.g., transient ischemic attacks) or a history of cerebrovascular disease.
HR2 Persons with a family or personal history of skin cancer, or clinical evidence of precursor lesions (e.g., dyplastic nevi, certain congenital nevi), or those with increased occupational or recreational exposure to sunlight.
HR3 Persons with exposure to **tobacco or excessive amounts of alcohol, or those with suspicious symptoms or lesions detected through self-examination.**
HR4 Persons with a history of upper-body irradiation.
HR5 The markedly obese, persons with a family history of diabetes, or women with a history of gestational diabetes.
HR6 Household members of persons with tuberculosis or others at risk forclose contact with the disease (e.g., staff of tuberculosis clinics, shelters for the homeless, nursing homes, substance abuse treatment fatalities, dialysis units, correctional institutions); recent immigrants or refugees of countries in which tuberculosis is common (e.g., Asia, Africa Central and **South** America, Pacific islands); migrant workers; residents of nursing homes, correctionai institutions, or homeless shelters; or persons with certain underlying medical **disorders (e.g., HIV** infection).
HR7 Men with two or more cardiac risk factors (high blood cholesterol, hypertension, cigarette smoking, diabetes **mellitus, family history of CAD);** men who would endanger public safety were they to experience sudden cardiac events (e.g., commercial airline pilots); or sedentary or high-risk males planning to begin a vigorous exercise program.
HR8 Women who have not had previous documented screening in which smears have been consistently **negative.**
HR9 Persons who have first-degree relatives with colorectal cancer; a personal history of endometrial, ovarian, or breast cancer; or a previous diagnosis of inflammatory bowel disease, adenomatous polyps, or colorectal cancer.
HR1O Persons with a family history of familial polyposis coli or cancer family syndrome.
HR11 Recent divorce, separation, unemployment, depression, alcohol or other drug abuse, serious medical illnesses, living alone, or recent bereavement.

Table G-7—Ages 65 and Over (Schedule: Every Year[a])---Continued

Screening	Counseling	Immunizations	High-risk categories
			HR12 Persons with children in the home or automobile. HR13 Women at increased risk for osteoporosis (e.g., Caucasian, low bone mineral content, bilateral oopherectomy before menopause or early menopause, slender bui ld) and who are without known contraindications (e.g., history of undiagnosed vaginal bleeding, active liver disease, thromboembolic disorders, hormone-dependent cancer). HR14 Men who have risk factors for myocardial infarction (e.g., high blood cholesterol, smoking, diabetes mellitus, family history of early-onset CAD) and who lack a history of gastrointestinal or other bleeding problems, or other risk factors for bleeding or cerebral hemorrhage. HR15 Persons with increased exposure to sunlight. HR16 Homosexually active men, intravenous drug users, recipients of some blood products, or persons in health-related jobs with frequent exposure to blood or blood products.
This list of preventive services is not exhaustive. It reflects only those topics reviewed by the U.S. Preventive Services Task Force. Clinicians may wish to add other preventive services after considering the patient's medical history and other individual circumstances.		**Remain alert for:** **Depressive symptoms** **Suicide risk factors (HR11)** **Abnormal bereavement** **Changes in cognitive function** **Medications that increase risk of falls** **Signs of physical abuse or neglect** Malignant skin lesions Peripheral arterial disease Tooth decay, gingivitis, loose teeth	

[a]The recommended schedule applies only to the periodic visit itself. The frequency of the individual preventive services listed in this table is left to clinical discretion, except as indicated in other footnotes.
[b]Annually for women until age 75, unless pathology detected.
[c]Every 1-2 years for women until age 75, unless pathology detected.
[d]For women.
[e]Every 1-3 years.
[f]Every 10 years.
[g]Annually.

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

Table G-8-Pregnant Women

Screening	Counselinq	Hiqh-risk categories
First prenatal visit History Dietary intake Tobacco/alcohol/d rug use Risk factors for intrauterine growth retardation and low birthweight Prior genital herpetic lesions **Physical exam** Blood pressure Laboratory/diagnostic procedures Hemoglobin and hematocrit ABO/Rh typing Rh(D) antibody test VDRL Hepatitis B surface antigen (HBsAg) Urinalysis for bacteriuria Gonorrhea culture ***High-risk groups*** Hemoglobin electrophoresis (HR1) Rubella antibodies (HR2) Chlamydial testing (HR3) Counseling and testing for HIV (HR4)	Nutrition Tobacco use Alcohol and other drug use Safety belts ***High-risk groups*** Discuss amniocentesis (HR5) Discuss risks of HIV infection (HR4)	HR1 Black women. HR2 Women lacking evidence of immunity (proof of vaccination after the first birthday or laboratory evidence of immunity). HR3 Women who attend clinics for sexually transmitted diseases, attend other high-risk health care facilities (e.g., adolescent and family planning clinics), or have other risk factors for chlamydial infection (e.g., multiple sexual partners or a sexual partner with multiple sexual contacts). HR4 Women seeking treatment for sexually transmitted diseases; past or present intravenous (IV) drug users; women with a history of prostitution or multiple sexual partners; women whose past or present sexual partners were HIV-infected, bisexual, or IV drug users; women with long-term residence or birth in an area with high prevalence of HIV infection in women; or women with a history of transfusion between 1978 and 1985. HR5 Women aged 35 and eider. HR6 Women who continue to smoke during pregnancy. HR7 Women with excessive alcohol consumption during pregnancy. HR8 Women with uncertain menstrual histories or risk factors for intrauterine growth retardation (e.g., hypertension, renal disease, short maternal stature, low prepregnancy weight, failure to gain weight during pregnancy, smoking, alcohol and other drug abuse, and history of a previous fetal death or growth-retarded baby). HR9 Unsensitized Rh-negative women. HR1O Women with multiple sexual partners or a sexual partner with multiple contacts, or sexual contacts of persons with culture-proven gonorrhea. HR11 Women who engage in sex with multiple partners in areas in which syphilis is prevalent, or contacts of persons with active syphilis. HR12 Women who engage in high-risk behavior (e.g., intravenous drug use) or in whom exposure to hepatitis B during pregnancy is suspected. HR13 Women at high risk (see HR4) who have a nonreactive HIV test at the first prenatal visit. HR14 Women with risk factors for intrauterine growth retardation (see HR8).

Table G-8--Pregnant Women—Continued

Screening	Counseling	High-risk categories
Follow-up visits **(Schedule: weeks 6-8,8-10,414-** 16, 24-28, 32, 36, 38," 39", 40,' 41") Blood pressure Urinalysis for bacteriuria Screening tests at specific gestational ages 14-16 weeks: Maternal serum alpha-fetoprotein (MSAFP)[d] Ultrasound cephalometry (HR8) 24-28 weeks: 50 g oral glucose tolerance test Rh(D) antibody (HR9) Gonorrhea culture (HR1O) VDRL(HR11) Hepatitis B surface antigen (HBsAg) (HR12) Counseling and testing forHIV (HR13) 36 **weeks:** Ultrasound exam (HR14)	Nutrition Safety belts Discuss meaning of upcoming tests ***High-risk groups*** Tobacco use (HR6) Alcohol and other drug use (HR7)	
This list of preventive services is not exhaustive. it reflects only those topics **reviewed by the U.S. Preventive Services Task Force. Clinicians may wish to add other preventive services after considering the patient's medical** history and other individual circumstances.	**Remain alert for:** **Signs of physical abuse**	

[a]Nulliparas only.
[b]Multiparas only.
[c]The recommended schedule applies only to the periodic visit itself. The frequency of the individual preventive services listed in this table is ieft to clinical discretion, except for services indicated at specific gestational "ages.
[d]Women with access to counseling and follow-up services, skilled high-resolution Ultrasound and amniocentesis capabilities, and reliable, standardized laboratories.

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

Appendix H: Preventive Services in Health Care Reform Proposals Introduced in the 102d Congress

Table H-1 lists the preventive services explicitly specified for coverage in the major congressional health care reform proposals introduced in the 102d Congress that outlined a benefit package.

All major congressional reform proposals that outlined a benefit package included coverage for prenatal care. The details of this coverage, however, were seldom clear. Several plans would have required that the Department of Health and Human Services or a quasi-public board establish a periodicity schedule or standards of care. Five proposals would have covered postnatal services and four proposals would have included family planning services. As with prenatal care, the nature of coverage for postnatal care and family planning care (i.e., the particular items and services covered, types of health care providers who could be reimbursed, or potential restrictions on coverage) was generally not specified in the proposed legislation.

All of the congressional proposals that outlined a benefit package included well-baby or well-child care.[1] Some were more specific than others in regard to the scope and details of covered services. For example, S. 1177 would have included a comprehensive set of examinations, screening tests, and immunizations, in accordance with standards set by the Secretary of the Department of Health and Human Services. On the other end of the spectrum, S. 1872 would have included only well-baby care (for infants under one year of age), including those services that ''are consistent with recommendations and periodicity schedules developed by appropriate medical experts. '

A few of the congressional proposals would have provided coverage of immunizations. Other proposals that did not explicitly identify immunizations as a covered service may have considered immunizations as covered under well-child or well-baby care.

Most, but not all legislative proposals would have included breast cancer and cervical cancer screening; six proposals would have covered colorectal cancer screening; and three proposals would have covered prostate cancer screening.

Several congressional proposals had provisions for coverage of health promotion, education or counseling services. S. 1446, and its companion bill H.R. 8, would have covered "health care and health promotion services designed to prevent or minimize the effect of illness, disease, or medical condition." H.R. 5514 included in its basic benefits package counseling for the purpose of promoting health and preventing illness or injury, as well as health education for children under 19 years old. H.R. 3229 would have included unspecified health promotion and health education, as well as advocacy, as part of a national delivery system. The guidelines for this coverage would have been established by a national oversight board created by the bill.

Few major congressional health care reform proposals explicitly excluded some or all preventive services from coverage. Exceptions were S. 1227 and S. 1872 which would have excluded routine physical examinations from the minimum benefit package.

[1] Well-baby care generally refers to care delivered to infants under one year of age. The range of ages for well-child care coverage was from 7 and younger (H.R. 5936) to 23 and younger (H.R. 8).

Table H-l-Clinical Preventive Services Included in or Specifically Excluded from[a] Congressional Health Care Reform Proposals, 102d Congress

Intervention	Proposals
Prenatal care	H.R. 3205 (Rostenkowski, D-IL) S. 1177 (Rockefeller, D-WV) S. 1227 (Mitchell, D-ME) H.R. 8 (Oakar, D-OH) S. 1446 (Kerrey, D-NE) H.R. 5524 (Dingell, D-Ml; Waxman, D-CA) S. 2320 (Wellstone, D-MN) S. 2513 (Daschle, D-SD; Wofford, D-PA) H.R. 3229 (Dellums, D-CA)
Family planning	H.R. 3205 (Rostenkowski, D-IL) S. 1177 (Rockefeller, D-WV) S. 1446 (Kerrey, D-NE) H.R. 3229 (Dellums, D-CA)
Well-baby care and well-childcare	H.R. 3205 (Rostenkowski, D-IL) S. 1177 (Rockefeller, D-WV) S. 1227 (Mitchell, D-ME) H.R. 8 (Oakar, D-OH) S. 1446 (Kerrey, D-NE) H.R. 5524 (Dingell, D-Ml; Waxman, D-CA) S. 2320 (Wellstone, D-MN) S. 2513 (Daschle, D-SD; Wofford, D-PA) H.R. 3229 (Dellums, D-CA)
Immunizations	H.R. 3205 (Rostenkowski, D-IL) S. 1177 (Rockefeller, D-WV) H.R. 8 (Oakar, D-OH) S. 1446 (Kerrey, D-NE)
Breast cancer screening	H.R. 3205 (Rostenkowski, D-IL) S. 1177 (Rockefeller, D-WV) S. 1227 (Mitchell, D-ME) H.R. 8 (Oakar, D-OH) S. 1446 (Kerrey, D-NE) S. 2320 (Wellstone, D-MN) S. 2513 (Daschle, D-SD; Wofford, D-PA)

(continued on next page)

Table H-I-Clinical Preventive Services included in or Specifically Excluded from[a] Congressional Health Care Reform Proposals, 102d Congress-Continued

Intervention	Proposals
Cervical cancer screening	H.R. 3205 (Rostenkowski, D-IL) S. 1177 (Rockefeller, D-WV) S. 1227 (Mitchell, D-ME) H.R. 8 (Oakar, D-OH) S. 1446 (Kerrey, D-NE) S. 2320 (Wellstone, D-MN) S. 2513 (Daschle, D-SD; Wofford, D-PA)
Colorectal cancer screening	H.R. 3205 (Rostenkowski, D-IL) S. 1177 (Rockefeller, D-WV) H.R. 8 (Oakar, D-OH) S. 1446 (Kerrey, D-NE) S. 2320 (Wellstone, D-MN) S. 2513 (Daschle, D-SD; Wofford, D-PA)
Prostate cancer screening	H.R. 8 (Oakar, D-OH) S. 1446 (Kerrey, D-NE) S. 2320 (Wellstone, D-MN)
Routine physical examinations	Excluded from S. 1227 (Mitchell, D-ME) and S. 1872 (Bentsen, D-TX)
Postnatal care	H.R. 3205 (Rostenkowski, D-IL) S. 1446 (Kerrey, D-NE) S. 2320 (Wellstone, D-MN) S. 2513 (Daschle, D-SD; Wofford, D-PA) H.R. 3229 (Dellums, D-CA)

a All mentions are inclusions unless specifically noted (see routine physical examinations).

SOURCE: Adapted from U.S. Congress, Office of Technology Assessment, *Coverage of Preventive Services: Provisions of Selected Health Care Reform proposals,* OTA-BP-H-110 (Washington, DC: U.S. Congress, Office of Technology Assessment, October 1992).

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