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Guide to
CLINICAL
PREVENTIVE
SERVICES

i. Overview

This report is intended for primary care clinicians: physicians, nurses, nurse practitioners, physician assistants, other allied health professionals, and students. It provides recommendations for clinical practice on preventive interventions—screening tests, counseling interventions, immunizations, and chemoprophylactic regimens—for the prevention of more than 80 target conditions. The patients for whom these services are recommended include asymptomatic individuals of all age groups and risk categories. Thus, the subject matter is relevant to all of the major primary care specialties: family practice, internal medicine, obstetrics-gynecology, and pediatrics. The recommendations in each chapter reflect a standardized review of current scientific evidence and include a summary of published clinical research regarding the clinical effectiveness of each preventive service.

Value of Prevention

Clinicians have always intuitively understood the value of prevention. Faced daily with the difficult and often unsuccessful task of treating advanced stages of disease, primary care providers have long sought the opportunity to intervene early in the course of disease or even before disease develops. The benefits of incorporating prevention into medical practice have become increasingly apparent over the past 30–40 years, as previously common and debilitating conditions have declined in incidence following the introduction of effective clinical preventive services. Infectious diseases such as poliomyelitis, which once occurred in regular epidemic waves (over 18,300 cases in 1954), have become rare in the U.S. as a result of childhood immunization.¹ Only three cases of paralytic poliomyelitis were reported in the U.S. in 1993, and none was due to endemic wild virus. Before rubella vaccine became available, rubella epidemics occurred regularly in the U.S. every 6–9 years; a 1964 pandemic resulted in over 12 million rubella infections, 11,000 fetal losses and about 20,000 infants born with congenital rubella syndrome.^{2,3} The incidence of rubella has decreased 99% since 1969, when the vaccine first became available.⁴ Similar trends have occurred with diphtheria, pertussis, and other once-common childhood infectious diseases.¹

Preventive services for the early detection of disease have also been associated with substantial reductions in morbidity and mortality. Age-ad-

justed mortality from stroke has decreased by more than 50% since 1972, a trend attributed in part to earlier detection and treatment of hypertension.⁵⁻⁷ Dramatic reductions in the incidence of invasive cervical cancer and in cervical cancer mortality have occurred following the implementation of screening programs using Papanicolaou testing to detect cervical dysplasia.⁸ Children with metabolic disorders such as phenylketonuria and congenital hypothyroidism, who once suffered severe irreversible mental retardation, now usually retain normal cognitive function as a result of routine newborn screening and treatment.⁹⁻¹⁶

Although immunizations and screening tests remain important preventive services, the most promising role for prevention in current medical practice may lie in changing the personal health behaviors of patients long before clinical disease develops. The importance of this aspect of clinical practice is evident from a growing literature linking some of the leading causes of death in the U.S., such as heart disease, cancer, cerebrovascular disease, chronic obstructive pulmonary disease, unintentional and intentional injuries, and human immunodeficiency virus infection,¹⁷ to a handful of personal health behaviors. Smoking alone contributes to one out of every five deaths in the U.S., including 150,000 deaths annually from cancer, 100,000 from coronary artery disease, 23,000 from cerebrovascular disease, and 85,000 from pulmonary diseases such as chronic obstructive pulmonary disease and pneumonia.¹⁸ Failing to use safety belts and driving while intoxicated are major contributors to motor vehicle injuries, which accounted for 41,000 deaths in 1992.¹⁷ Physical inactivity and dietary factors contribute to coronary atherosclerosis, cancer, diabetes, osteoporosis, and other common diseases.¹⁹⁻²² High-risk sexual practices increase the risk of unintended pregnancy, sexually transmitted diseases (STDs), and acquired immunodeficiency syndrome.^{23,24} Approximately half of all deaths occurring in the U.S. in 1990 may be attributed to external factors such as tobacco, alcohol, and illicit drug use, diet and activity patterns, motor vehicles, and sexual behavior, and are therefore potentially preventable by changes in personal health practices.²⁵

Barriers to Preventive Care Delivery

Although sound clinical reasons exist for emphasizing prevention in medicine, studies have shown that clinicians often fail to provide recommended clinical preventive services.²⁶⁻³² This is due to a variety of factors, including inadequate reimbursement for preventive services, fragmentation of health care delivery, and insufficient time with patients to deliver the range of preventive services that are recommended.³³⁻³⁵ Even when these barriers to implementation are accounted for, however, clinicians fail to perform preventive services as recommended,²⁸ suggesting that uncertainty among clinicians as to which services should be offered is a factor as well.

Part of the uncertainty among clinicians derives from the fact that recommendations come from multiple sources, and these recommendations often differ. Recommendations^a relating to clinical preventive services are issued regularly by government health agencies and expert panels that they sponsor,^{5,36-42} medical specialty organizations,⁴³⁻⁵⁰ voluntary associations,⁵¹⁻⁵³ other professional and scientific organizations,^{54,55} and individual experts.⁵⁶⁻⁵⁹

A second major reason clinicians might be reluctant to perform preventive services is skepticism about their effectiveness. Whether performance of certain preventive interventions can significantly reduce morbidity or mortality from the target condition is often unclear. The relative effectiveness of different preventive services is also unclear, making it difficult for busy clinicians to decide which interventions are most important during a brief patient visit. A broader concern is that some maneuvers can ultimately result in more harm than good. While this concern applies to all clinical practices, it is especially important in relation to preventive services because the individuals who receive these interventions are often healthy. Minor complications or rare adverse effects that would be tolerated in the treatment of a severe illness take on greater importance in the asymptomatic population and require careful evaluation to determine whether benefits exceed risks. This is particularly relevant for screening tests, which benefit only the few individuals who have the disorder but expose all the individuals screened to the risk of adverse effects from the test. Moreover, because recommendations for preventive services such as routine screening often include a large proportion of the population, there are potentially important economic implications.

Historical Perspective

Uncertainties about the effectiveness of clinical preventive services raise questions about the value of the routine health examination of asymptomatic persons, in which a predetermined battery of tests and physical examination procedures are performed as part of a routine checkup. The annual physical examination of healthy persons was first proposed by the American Medical Association in 1922.⁶⁰ For many years after, it was common practice among health professionals to recommend routine physicals and comprehensive laboratory testing as effective preventive medicine. While routine visits with the primary care clinician are important, performing the same interventions on all patients and performing them annually are not the most clinically effective approaches to disease prevention. Rather, both the frequency and the

^aThe recommendations cited here are illustrative only. Listings of recommendations made by other groups for each condition considered are cited in the relevant chapter.

content of the periodic health examination should reflect the unique health risks of the individual patient and the quality of the evidence that specific preventive services are clinically effective. This new approach to the periodic visit was endorsed by the American Medical Association in 1983 in a policy statement that withdrew support for a standard annual physical examination.⁶¹ The individualized periodic health visit should emphasize evidence of clinical effectiveness, and thus increased attention has turned to the collection of reliable data on the effectiveness of specific preventive services.

One of the first comprehensive efforts to examine these issues was undertaken by the Canadian government, which in 1976 convened the Canadian Task Force on the Periodic Health Examination (CTFPHE). This expert panel developed explicit criteria to judge the quality of evidence from published clinical research on clinical preventive services, and the panel used uniform decision rules to link the strength of recommendations for or against a given preventive service to the quality of the underlying evidence (see Appendix A). These ratings were intended to provide the clinician with a means of selecting those preventive services supported by the strongest evidence of effectiveness. Using this approach, the CTFPHE examined preventive services for 78 target conditions, releasing its recommendations in a monograph published in 1979.⁶² In 1982, the CTFPHE reconvened and applied its methodology to new evidence as it became available, periodically publishing revised recommendations and evaluations of new topics. These were updated and compiled in 1994 in *The Canadian Guide to Clinical Preventive Health Care*.⁶³

A similar effort began in the U.S. in 1984 when the Public Health Service commissioned the U.S. Preventive Services Task Force (USPSTF). Like the Canadian panel, this 20-member non-Federal panel was charged with developing recommendations for clinicians on the appropriate use of preventive interventions, based on a systematic review of evidence of clinical effectiveness.⁶⁴ A methodology similar to that of the CTFPHE was adopted at the outset of the project. This enabled the U.S. and Canadian panels to collaborate in a binational effort to review evidence and develop recommendations on preventive services. The first USPSTF met regularly between 1984 and 1988 to develop comprehensive recommendations addressing preventive services. The panel members and their scientific support staff reviewed evidence and developed recommendations on preventive services for 60 topic areas affecting patients from infancy to old age, published in 1989 as the *Guide to Clinical Preventive Services*.

The Second U.S. Preventive Services Task Force

The USPSTF was reconstituted in 1990 to continue and update these scientific assessments.⁶⁵ Its charge has been to evaluate the effectiveness of

clinical preventive services that were not previously examined; to reevaluate those that were examined and for which there is new scientific evidence, new technologies that merit consideration, or other reasons to revisit the published recommendations; and to produce this new edition of the *Guide*, with updated recommendations for the periodic health examination. In addition, a continuing mission of the USPSTF has been to define a research agenda by identifying significant gaps in the literature. The USPSTF has 10 members, comprising two family physicians, two internists, two pediatricians, two obstetrician-gynecologists, and two methodologists. Content experts from academic institutions and Federal agencies also joined the deliberations of the panel on an ad hoc basis. The USPSTF met quarterly between September 1990 and April 1994, with scientific support staff from the Office of Disease Prevention and Health Promotion, Public Health Service, U.S. Department of Health and Human Services, to analyze systematically scientific evidence pertaining to clinical preventive services that had been published since the first edition of the *Guide*.

The USPSTF greatly expanded its collaboration with medical specialty organizations and Federal agencies, and it has continued its close cooperation with the CTFPHE. Designated liaisons from primary care medical specialty societies (American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and American College of Physicians), the agencies of the Public Health Service, and the CTFPHE attended all of the USPSTF meetings, and their respective organizations reviewed all draft recommendations. The USPSTF and the CTFPHE, which has also recently updated its analyses of the scientific evidence and recommendations,⁶³ shared background papers and draft chapters throughout their updating processes to avoid unnecessary duplication of effort. Seventeen chapters in *The Canadian Guide to Clinical Preventive Health Care*⁶³ were based in part on background papers prepared for the USPSTF, and 21 chapters in this edition of the *Guide* are based in part on papers prepared for the CTFPHE. The USPSTF also collaborated with the American College of Physicians' Clinical Efficacy Assessment Program (CEAP), which uses a similar evidence-based methodology. A liaison from the USPSTF regularly attended CEAP meetings, and several chapter updates were based on reviews prepared for CEAP.

tices are likely to lead to substantial reductions in the incidence and severity of the leading causes of disease and disability in the U.S. Primary prevention as it relates to such risk factors as smoking, physical inactivity, poor nutrition, alcohol and other drug abuse, and inadequate attention to safety precautions holds greater promise for improving overall health than many secondary preventive measures such as routine screening for early disease.²⁵ Therefore, clinician counseling that leads to improved personal health practices may be more valuable to patients than conventional clinical activities such as diagnostic testing. In the past, the responsibility of the clinician was primarily to treat illnesses; the asymptomatic healthy individual did not need to see the doctor. In addition, personal health behaviors were often not viewed as a legitimate clinical issue. A patient's use of safety belts would receive less attention from the clinician than the results of a complete blood count (CBC) or a routine chest radiograph. A careful review of the data, however, suggests that different priorities are in order. Motor vehicle injuries affect nearly 3.5 million persons each year in the U.S.;⁶⁶ they account for over 40,000 deaths each year.⁶⁷ Proper use of safety belts can prevent 40–60% of motor vehicle injuries and deaths.^{68–70} In contrast, there is little evidence that performing routine CBCs or chest radiographs improves clinical outcome,^{71,72} and these procedures are associated with increased health care expenditures.

An important corollary of this finding is that clinicians must assist patients to assume greater responsibility for their own health. In the traditional doctor-patient relationship, the patient adopts a passive role and expects the doctor to assume control of the treatment plan. Whereas the clinician is often the key figure in the treatment of acute illnesses and injuries, the patient is the principal agent in primary prevention that addresses personal health practices. Therefore, one of the initial tasks of the clinician practicing primary prevention is shifting control to the patient. To achieve competence in the task of helping to empower patients and in counseling them to change health-related behaviors, many clinicians will need to develop new skills (see Chapter iv).

1 The clinician and patient should share decision-making. Many preventive services involve important risks or costs that must be balanced against their possible benefits. Because not all patients weigh risks and benefits the same way, clinicians must fully inform patients about the potential consequences of proposed interventions, including the possibility of invasive follow-up procedures, tests, and treatments. Incorporating patient preferences is especially important when the balance of risks and benefits, and therefore the best decision for each patient, depends greatly on the values placed on possible outcomes (e.g., prolonged life vs. substantial morbidity from treatment). Where evidence suggested that patient values were critical to the balance of risks and benefits (e.g., screening for Down syndrome or neural tube

defects, hormone prophylaxis in postmenopausal women), the USPSTF specifically recommended patient education and consideration of patient preferences in decision-making rather than a uniform policy for all patients. Shared decision-making also requires explicitly acknowledging areas of uncertainty. Patients must understand not only what is known, but also what is not yet known about the risks and benefits from an intervention, in order to make an informed decision.

‡ Clinicians should be selective in ordering tests and providing preventive services. Although certain screening tests, such as blood pressure measurement,^{73–75} Papanicolaou smears,⁸ and mammography,⁷⁶ can be highly effective in reducing morbidity and mortality, the USPSTF found that many others are of unproven effectiveness. Screening tests with inadequate specificity often produce large numbers of false-positive results, especially when performed routinely without regard to risk factors; these results might lead to unnecessary and potentially harmful diagnostic testing and treatment. Recognizing the cardinal importance of avoiding harm to asymptomatic patients (“primum non nocere”), the USPSTF recommended against a number of screening tests (e.g., serum tumor markers for the early detection of pancreatic or ovarian cancer) that had unproven benefit but likely downstream harms. Many tests that lack evidence that they improve clinical outcome, such as home uterine activity monitoring, have the additional disadvantage of being expensive, especially when performed on large numbers of persons in the population. In a few instances, the USPSTF found evidence that certain screening tests that have been widely used in the past (e.g., routine chest x-ray to screen for lung cancer, dipstick urinalysis for asymptomatic bacteriuria) are ineffective. Although the USPSTF did not base its recommendations on evidence of cost-effectiveness (see Chapter v), judging health benefit based on scientific evidence provides a rational basis for directing resources toward effective services and away from ineffective services and from interventions for which the balance of benefits and risks is uncertain.⁶⁵

In addition to weighing evidence for effectiveness, selecting appropriate screening tests requires considering age, gender, and other individual risk factors of the patient in order to minimize adverse effects and unnecessary expenditures (see Chapters ii and iii). An appreciation of the risk profile of the patient is also necessary to set priorities for preventive interventions. The need for assessing individual risk underscores a time-honored principle of medical practice: the importance of a complete medical history and detailed discussion with patients regarding their personal health practices, focused on identifying risk factors for developing disease.

‡ Clinicians must take every opportunity to deliver preventive services, especially to persons with limited access to care. Those individuals at highest risk for many preventable causes of premature disease and disability,

such as cervical cancer, tuberculosis, human immunodeficiency virus infection, and poor nutrition, are the same individuals least likely to receive adequate preventive services. Devising strategies to increase access to preventive services for such individuals is more likely to reduce morbidity and mortality from these conditions than performing preventive services more frequently on those who are already regular recipients of preventive care and who are often in better health. One important solution is to deliver preventive services at every visit, rather than exclusively during visits devoted entirely to prevention. While preventive checkups often provide more time for counseling and other preventive services and although healthy individuals might be more receptive to such interventions than those who are sick, any visit provides an opportunity to practice prevention. In fact, some individuals may see clinicians only when they are ill or injured. The illness visit provides the only opportunity to reach individuals who, due to limited access to care, would be otherwise unlikely to receive preventive services.

For some health problems, community-level interventions may be more effective than clinical preventive services. Important health problems that are likely to require broader-based interventions than can be offered in the clinical setting alone include youth and family violence, initiation of tobacco use, unintended pregnancy in adolescents, and certain unintentional injuries. Other types of interventions, such as school-based curricula,⁷⁷⁻⁸¹ community programs,⁸²⁻⁸⁴ and regulatory and legislative initiatives,⁸⁵⁻⁸⁷ might prove more effective for preventing morbidity and mortality from these conditions than will preventive services delivered in the clinical setting. There may, nevertheless, be an important role for clinicians as participants in community systems that address these types of health problems. Such a role might include becoming aware of existing community programs and encouraging patient participation and involvement; acting as a consultant for communities implementing programs or introducing legislation; and serving as an advocate to initiate and maintain effective community interventions.

A Research Agenda in Preventive Medicine

By reviewing comprehensively and critically the scientific evidence regarding clinical preventive services, the USPSTF identified important gaps in the literature and helped define targets for future clinical prevention research. Among the most important of these targets is more and better quality research evaluating the effectiveness of brief, directed counseling that can be delivered in the busy primary care practice setting. Given the importance of personal health practices, the scarcity of adequate evidence evaluating the effectiveness of brief counseling in the primary care setting

is striking. The effectiveness of such counseling in reducing smoking and problem drinking is clear.⁸⁸⁻⁹⁰ For many other behaviors, however, counseling has been tested and proven effective only in highly specialized settings (e.g., STD clinics⁹¹⁻⁹⁴) or when delivered through multiple, lengthy visits with specially trained counselors (e.g., certain cholesterol-lowering interventions^{95,96}). Whether the effects of these interventions can be reproduced by brief advice during the typical clinical encounter with a primary care provider is uncertain. Counseling to change some personal health practices (e.g., unsafe pedestrian behavior, drinking and driving) has received insufficient attention by researchers. Some personal health practices may not respond to brief clinician counseling in the context of routine health care. Therefore, research should also evaluate the effectiveness (and cost-effectiveness) of referring patients to allied health professionals with special counseling skills in their areas of expertise (e.g., dietitians, substance abuse counselors) and of using other modalities to educate patients in the primary care setting (e.g., videos, interactive software).

For screening interventions, randomized controlled trials are powerful in resolving controversy about the benefits and risks. Many important questions will be answered by major ongoing screening trials such as the Prostate, Lung, Colorectal, Ovarian Cancer (PLCO) Screening Trial of the National Cancer Institute,⁹⁷ and by ongoing trials evaluating the clinical efficacy of treating common asymptomatic conditions detectable by screening, such as high cholesterol levels in the elderly and moderately elevated blood lead levels in children. For unproven screening interventions, finding ways to streamline randomized controlled trials so that they can be performed efficiently and cost-effectively is essential.

Improving the Delivery of Clinical Preventive Services

This report will help resolve some of the uncertainties among primary care clinicians about the effectiveness of preventive services, thus removing one barrier to the appropriate delivery of preventive care. The USPSTF did not, however, address other barriers to implementing clinical preventive services, such as insufficient reimbursement for counseling or other preventive interventions, provider uncertainty about how to deliver recommended services, lack of patient or provider interest in preventive services, and lack of organizational/system support to facilitate the delivery of clinical preventive services. Many of these barriers are addressed by “Put Prevention into Practice,” the Public Health Service prevention implementation program.⁹⁸ Programs such as “Put Prevention into Practice” can help ensure that prevention is delivered at every opportunity that patients are seen. Other publications also provide useful information on the effective

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delivery of clinical preventive services.⁹⁹ The increasing formation of integrated health care systems (e.g., managed care organizations) may also create new opportunities for crafting better preventive practices.

The USPSTF explored issues of prevention for a wide range of disease categories and for patients of all ages. The comprehensive and systematic approach to the review of evidence for preventive health services is

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ii. Methodology

This report presents a systematic approach to evaluating the effectiveness of clinical preventive services. The recommendations, and the review of evidence from published clinical research on which they are based, are the product of a methodology established at the outset of the project. The intent of this analytic process has been to provide clinicians^a with current and scientifically defensible information about the effectiveness of different preventive services and the quality of the evidence on which these conclusions are based. This information is intended to help clinicians who have limited time to select the most appropriate preventive services to offer in a periodic health examination for patients of different ages and risk categories. The critical appraisal of evidence is also intended to identify preventive services of uncertain effectiveness as well as those that could result in more harm than good if performed routinely by clinicians.

For the content of this report to be useful, and to clarify differences between the U.S. Preventive Services Task Force recommendations and those of other groups, it is important to understand the process by which this report was developed, as well as how it differs from the consensus development process used to derive many other clinical practice guidelines. First, the objectives of the review process, including the types of preventive services to be examined and the nature of the recommendations to be developed, were carefully defined early in the process. Second, the Task Force adopted explicit criteria for recommending the performance or exclusion of preventive services and applied these “rules of evidence” systematically to each topic it studied. Third, literature searches and assessments of the quality of individual studies were conducted in accordance with rigorous, predetermined methodologic criteria. Fourth, guidelines were adopted for translating these findings into sound clinical practice recommendations. Fifth, these recommendations were reviewed extensively by content experts in the U.S., Canada, Europe, and Australia. Finally, the review comments were examined by the Task Force and a final vote on recom-

^a The provider of preventive services in primary care is often a physician. The term “clinician” is used in this report, however, to include other primary care providers such as nurses, nurse practitioners, physician assistants, and other allied health professionals. Although physicians may be better qualified than other providers to perform certain preventive services or to convince patients to change behavior, some preventive services may be more effectively performed by others with special training (e.g., nurses, dietitians, smoking cessation counselors, mental health professionals).

mendations was conducted. The hallmarks of this process are that it is evidence-based and explicit. Each step is examined in greater detail below.

Definition of Objectives

Systematic rules were used to select the target conditions and candidate preventive interventions to be evaluated by the Task Force.

Selection of Target ConditionsIn the first edition of this report, the Task Force identified 60 of the leading causes of death and disability in the U.S. that were potentially preventable through clinical interventions. This second edition examines most of the same conditions but also reviews evidence regarding new topics that were added to the list in recent years. The new topics were selected by a rank-order process in which topics were graded on the basis of the frequency and severity of the disease and the potential impact of preventive interventions on health outcomes. In general, the Task Force judged the importance of candidate topics on the basis of two criteria:

Burden of Suffering from the Target Condition. This report examines conditions that are relatively common in the U.S. and are of major clinical significance. Thus, consideration was given to both the *prevalence* (proportion of the population affected) and *incidence* (number of new cases per year) of the condition. Conditions that were once common but have become rare because of effective preventive interventions (e.g., poliomyelitis) were included in the review.

Potential Effectiveness of the Preventive Intervention. Conditions were excluded from analysis if the panel could not identify a potentially effective preventive intervention that might be performed by clinicians.

A number of important prevention topics have not yet been examined by the Task Force due to resource and time constraints. The absence of a discussion of these topics in this report does not imply a judgment about their relative importance or effectiveness.

Selection of Preventive ServicesFor each target condition, the Task Force used two criteria to select the preventive services to be evaluated. First, in general, only preventive services carried out on *asymptomatic persons*^b were

^bThe term “asymptomatic person” as used in this report differs from its customary meaning in medical practice. Although “asymptomatic” is often considered synonymous with “healthy,” the term is used in this report to describe individuals who lack clinical evidence of the target condition. Signs and symptoms of illnesses unrelated to the target condition may be present without affecting the designation of “asymptomatic.” Thus, a 70-year-old man with no genitourinary symptoms who is screened for prostate cancer would be designated asymptomatic for that condition, even if he were hospitalized for (unrelated) congestive heart failure. Preventive services recommended for “asymptomatic patients” therefore need not be delivered only during preventive checkups of healthy persons but apply equally to clinical encounters with patients being seen for other reasons (see Chapter iii).

reviewed. Thus, only primary and secondary preventive measures were addressed. In a clinical setting, *primary preventive measures* are those provided to individuals to prevent the onset of a targeted condition (e.g., routine immunization of healthy children), whereas *secondary preventive measures* identify and treat asymptomatic persons who have already developed risk factors or preclinical disease but in whom the condition has not become clinically apparent. Obtaining a Papanicolaou smear to detect cervical dysplasia before the development of cancer and screening for high blood pressure are forms of secondary prevention. Preventive measures that are part of the treatment and management of persons with clinical illnesses, such as cholesterol reduction in patients with coronary heart disease or insulin therapy to prevent the complications of diabetes mellitus, are usually considered *tertiary prevention* and are outside the scope of this report.

The second criterion for selecting preventive services for review was that the maneuver had to be performed in the *clinical setting*. Only those preventive services that would be carried out by clinicians in the context of routine health care were examined. Findings should not be extrapolated to preventive interventions performed in other settings. Screening tests are evaluated in terms of their effectiveness when performed during the clinical encounter (i.e., *case finding*). Screening tests performed solely at schools, work sites, health fairs, and other community locations are generally outside the scope of this report. Also, preventive interventions implemented outside the clinical setting (e.g., health and safety legislation, mandatory screening, community health promotion) are not specifically evaluated, although clinicians can play an important role in promoting such programs and in encouraging the participation of their patients. References to these types of interventions are made occasionally in sections of this book.

Preventive services were divided into three categories: screening tests, counseling interventions, and immunizations and chemoprophylaxis. *Screening tests* are those preventive services in which a test or standardized examination procedure is used to identify patients requiring special intervention. Nonstandardized historical questions, such as asking patients whether they smoke, and tests involving symptomatic patients are not considered screening tests in this report. *Counseling* interventions are those in which the patient receives information and advice regarding personal behaviors (e.g., diet) that could reduce the risk of subsequent illness or injury. The Task Force did not consider counseling that addresses the health-related behaviors of persons who have already developed signs and symptoms of the target condition. *Immunizations* discussed in this report include vaccines and immunoglobulins (passive immunization) taken by persons with no evidence of infectious disease. *Chemoprophylaxis* as primary prevention refers to the use of drugs or biologics taken by asymptomatic persons to reduce the risk of developing a disease.

Criteria for Determining Effectiveness

Preventive services must meet predetermined criteria to be considered effective. The criteria of effectiveness for the four categories of preventive services (Table 1) provided the analytic framework for the evaluation of effectiveness in the 70 chapters in this report. Each of these criteria must be satisfied to evaluate the “causal pathway”¹ of a preventive service, the chain of events that must occur for a preventive maneuver to influence health outcomes. Thus, a screening test is not considered effective if it lacks sufficient accuracy to detect the condition earlier than without screening or if there is inadequate evidence that early detection improves health outcomes. Similarly, counseling interventions cannot be considered effective in the absence of firm evidence that changing personal behavior can improve outcome and that clinicians can influence this behavior through counseling. Effective immunization and chemoprophylactic regimens require evidence of biologic efficacy; in the case of chemoprophylactic agents, evidence is also necessary that patients will comply with long-term use of the drug.

The methodologic issues involved in evaluating screening tests require further elaboration. As mentioned above, a screening test must satisfy two major requirements to be considered effective:

- 1 The test must be able to detect the target condition earlier than without screening and with sufficient accuracy to avoid producing large numbers of false-positive and false-negative results (accuracy of screening test)
- 1 Screening for and treating persons with early disease should improve the likelihood of favorable health outcomes (e.g., reduced disease-specific morbidity or mortality) compared to treating patients when they present with signs or symptoms of the disease (effectiveness of early detection)

These two requirements of screening are essential and therefore appear as headings in each of the 53 screening chapters in this report.

Table 1.
Criteria of Effectiveness

Screening tests
1 Accuracy of screening tests
1 Effectiveness of early detection
Counseling interventions
1 Efficacy of risk reduction
1 Effectiveness of counseling
Immunizations
1 Efficacy of vaccine
Chemoprophylaxis
1 Efficacy of chemoprophylaxis
1 Effectiveness of counseling

False-positive results can lead to follow-up testing that may be uncomfortable, expensive, and, in some cases, potentially harmful. If follow-up testing does not disclose the error, the patient may even receive unnecessary treatment. There may also be psychological consequences. Persons informed of an abnormal medical test that is falsely positive may experience unnecessary anxiety until the error is corrected. Labeling individuals with the results of screening tests may affect behavior; for example, studies have shown that some persons with hypertension identified through screening may experience altered behavior and decreased work productivity.^{2,3}

A proper evaluation of a screening test result must therefore include a determination of the likelihood that the patient has the condition. This is done by calculating the *positive predictive value* (PPV) of test results in the population to be screened (Table 2). The PPV is the proportion of positive test results that are correct (true positives). For any given sensitivity and specificity, the PPV increases and decreases in accordance with the prevalence of the target condition in the screened population. If the target condition is sufficiently rare in the screened population, even tests with excellent sensitivity and specificity can have low PPV in these settings, generating more false-positive than true-positive results. This mathematical relationship is best illustrated by an example (see Table 3):

A population of 100,000 in which the prevalence of a hypothetical cancer is 1% would have 1,000 persons with cancer and 99,000 without cancer. A screening test with 90% sensitivity and 90% specificity would detect 900 of the 1,000 cases, but would also mislabel 9,900 healthy persons. Thus, the PPV (the proportion of persons with positive test results who actually had cancer) would be $900/10,800$, or 8.3%. If the same test were performed in a population with a cancer prevalence of 0.1%, the PPV would fall to 0.9%, a ratio of 111 false positives for every true case of cancer detected.

Reliability (reproducibility), the ability of a test to obtain the same result when repeated, is another important consideration in the evaluation of screening tests measuring continuous variables (e.g., cholesterol level). A test with poor reliability, whether due to differences in results obtained by different individuals or laboratories (*interobserver variation*) or by the same observer (*intraobserver variation*), may produce individual test results that vary widely from the correct value, even though the average of the results approximates the true value.

Effectiveness of Early Detection Even if the test accurately detects early-stage disease, one must also question whether there is any benefit to the patient in having done so. Early detection should lead to the implementation of clinical interventions that can prevent or delay progression of the disorder. Detection of the disorder is of little clinical value if the condition is not

Table 3.
Positive Predictive Value (PPV) and Prevalence

		Testing Conditions Size of population = 100,000 Sensitivity of test = 90% Specificity of test = 90%			
		Cancer Prevalence = 1%		Cancer Prevalence = 0.1%	
		Cancer Present	Cancer Absent	Cancer Present	Cancer Absent
Positive test		900	9,900	90	9,990
Negative test		100	89,100	10	89,910
		PPV = 8.3%		PPV = 0.9%	

treatable. Thus, *treatment efficacy* is fundamental for an effective screening test. Even with the availability of an efficacious form of treatment, *early detection* must offer added benefit over conventional diagnosis and treatment if screening is to improve outcome. The effectiveness of a screening test is questionable if asymptomatic persons detected through screening have the same health outcome as those who seek medical attention because of symptoms of the disease. Studies of the effectiveness of cancer screening tests, for example, can be influenced by lead-time and length biases.

Lead-Time and Length Bias. It is often difficult to determine with certainty whether early detection truly improves outcome, an especially common problem when evaluating cancer screening tests. For most forms of cancer, 5-year survival is higher for persons identified with early-stage disease. Such data are often interpreted as evidence that early detection of cancer is effective, because death due to cancer appears to be delayed as a result of screening and early treatment. Survival data do not constitute true proof of benefit, however, because they are easily influenced by *lead-time bias*: survival can appear to be lengthened when screening simply advances the time of diagnosis, lengthening the period of time between diagnosis and death without any true prolongation of life.⁴

Length bias can also result in unduly optimistic estimates of the effectiveness of cancer screening. This term refers to the tendency of screening to detect a disproportionate number of cases of slowly progressive disease and to miss aggressive cases that, by virtue of rapid progression, are present in the population only briefly. The “window” between the time a cancer can be detected by screening and the time it will be found because of symptoms is shorter for rapidly growing cancers, so they are less likely to be found by screening. As a result, persons with aggressive malignancies

will be underrepresented in the cases detected by screening, and the patients found by screening may do better than unscreened patients even if the screening itself does not influence outcome. Due to this bias, the calculated survival of persons detected through screening could overestimate the actual effectiveness of screening.⁴

Assessing Population Benefits. Although these considerations provide necessary information about the clinical effectiveness of preventive services, other factors must often be examined to obtain a broader picture of the potential health impact on the population as a whole. Interventions of only minor effectiveness in terms of *relative risk* may have significant impact on the population in terms of *attributable risk* if the target condition is common and associated with significant morbidity and mortality. Under these circumstances, a highly effective intervention (in terms of relative risk) that is applied to a small high-risk group may save fewer lives than one of only modest clinical effectiveness applied to large numbers of affected persons (see Table 4). Failure to consider these epidemiologic characteristics of the target condition can lead to misconceptions about overall effectiveness.

Potential adverse effects of interventions must also be considered in assessing overall health impact, but often these effects receive inadequate attention when effectiveness is evaluated. For example, the widely held belief that early detection of disease is beneficial leads many to advocate screening even in the absence of definitive evidence of benefit. Some may discount the clinical significance of potential adverse effects. A critical examination will often reveal that many kinds of testing, especially among ostensibly healthy persons, have potential direct and indirect adverse effects. Direct physical complications from test procedures (e.g., colonic perforation during sigmoidoscopy), labeling and diagnostic errors based on test results (see above), and increased economic costs are all potential consequences of screening tests. Resources devoted to costly screening programs of uncertain effectiveness may consume time, personnel, or money needed for other more effective health care services. To the USPSTF, potential adverse effects are considered clinically relevant and

Table 4.
Effective of Mortality Rate on Total Deaths Prevented

Reduction in Mortality with Intervention	Deaths per Year from Target Condition	Total Deaths Prevented with Intervention
50%	10	5
1%	100,000	1,000

are always evaluated along with potential benefits in determining whether a preventive service should be recommended.

Methodology for Reviewing Evidence

In evaluating effectiveness, the Task Force used a systematic approach to collect evidence from published clinical research and to judge the quality of individual studies.

Literature Retrieval Methods Studies were obtained for review by searching MEDLARS, the National Library of Medicine computerized information system, primarily using MEDLINE (a bibliographic database of published biomedical journal articles); other MEDLARS databases such as AIDS-LINE and CANCERLIT were occasionally used. Searches for some topics involved the PSYCHINFO database and other relevant sources. Searches were generally restricted to English-language publications. Keywords used in the searches are available for most topics. The reference list was supplemented by citations obtained from experts and from reviews of bibliographic listings, textbooks, and other sources. Literature reviews for this report were generally completed by May 1995, and studies published or entered in MEDLARS subsequently are not routinely addressed.

Exclusion Criteria. Many preventive services involve tests or procedures that are not used exclusively in the context of primary or secondary prevention. Sigmoidoscopy, for example, is also performed for purposes other than screening. Thus, studies evaluating the effectiveness of procedures or tests involving patients who are symptomatic or have a history of the target condition were generally not considered admissible evidence for evaluating effectiveness in asymptomatic persons. Such tests were instead considered *diagnostic tests*, even if they were described by investigators as "screening tests." Uncontrolled studies, comparisons between time and place (ecologic or cross-cultural studies, studies with historical controls), descriptive data, and animal studies were generally excluded from the review process when evidence from randomized controlled trials, cohort studies, or case-control studies (see below) was available. *Etiologic evidence* demonstrating a causal relationship between a risk factor and a disease was considered less persuasive than evidence from well-designed *intervention studies* that measure the effectiveness of modifying the risk factor. As mentioned above, studies of preventive interventions not performed by clinicians were generally excluded from review.

Evaluating the Quality of the Evidence The methodologic quality of individual studies has received special emphasis in this report. Although all types of evidence were considered, greater weight was given to well-de-

signed studies. Studies that examined health outcomes (e.g., measures of morbidity or mortality) were considered more relevant to assessing effectiveness than studies that used intermediate or physiologic outcome measures to infer effectiveness. (Intermediate outcomes, such as changes in blood cholesterol levels, are often associated with, or precede, health outcomes, but their presence or absence does not necessarily prove an effect on health outcomes.) In addition, study designs were given greater weight if they were less subject to confounding (effects on outcomes due to factors other than the intervention under investigation). Three types of study designs received special emphasis: controlled trials, cohort studies, and case-control studies.

In *randomized controlled trials*, participants are assigned randomly to a study group (which receives the intervention) or a control group (which receives a standard treatment, which may be no intervention or a placebo). In this way, all confounding variables, known and unknown, should be distributed randomly and, in general, equally between the study and control groups. Randomization thereby enhances the comparability of the two groups and provides a more valid basis for inferring that the intervention caused the observed outcomes. In a *blinded* trial, the investigators, the subjects, or both (*double-blind study*) are not told to which group subjects have been assigned, so that this knowledge will not influence their assessment of outcome. Controlled trials that are not randomized are more subject to biases, including *selection bias*: persons who volunteer or are assigned by investigators to study groups may differ systematically in characteristics other than the intervention itself, thereby limiting the internal validity and generalizability of the results.

A *cohort study* differs from a clinical trial in that the investigators do not determine at the outset which persons receive the intervention or exposure. Rather, persons who have already been exposed to the risk factor or intervention and controls who have not been exposed are selected by the investigators to be followed *longitudinally* over time in an effort to observe differences in outcome. The Framingham Heart Study, for example, is a large ongoing cohort study providing longitudinal data on cardiovascular disease in residents of a Massachusetts community in whom potential cardiovascular risk factors were first measured nearly 50 years ago. Cohort studies are therefore *observational*, whereas clinical trials are *experimental*. Cohort studies are more subject to systematic bias than randomized trials because treatments, risk factors, and other covariables may be chosen by patients or physicians on the basis of important (and often unrecognized) factors that may affect outcome. It is therefore especially important for investigators to identify and correct for *confounding variables*, related factors that may be more directly responsible for health outcome than the intervention/exposure in question. For example, increased mortality among

persons with low body weight can be due to the confounding variable of underlying illness. Unlike randomized controlled trials, a shortcoming of cohort studies is that one can correct only for known confounding variables.

Both cohort studies and clinical trials have the disadvantage of often requiring large sample sizes and/or many years of observation to provide adequate *statistical power* to measure differences in outcome. Failure to demonstrate a significant effect in such studies may be the result of statistical properties of the study design rather than a true reflection of poor clinical effectiveness. Both clinical trials and cohort studies have the advantages, however, of generally being *prospective* in design—the health outcome is not known at the beginning of the study and therefore is less likely to influence the collection of data—and of better collection of data to ensure the comparability of intervention and control groups.

Large sample sizes and lengthy follow-up periods are often unnecessary in *case-control studies*. This type of study differs from cohort studies and clinical trials in that the study and control groups are selected on the basis of whether they have the *disease* (cases) rather than whether they have been *exposed* to a risk factor or clinical intervention. The design is therefore *retrospective*, with the health outcome already known at the outset. In contrast to the Framingham Heart Study, a case-control study might first identify persons who have suffered myocardial infarction (cases) and those who have not (controls) and evaluate both groups to assess differences in exposure to an agent (e.g., aspirin) that purportedly reduces the risk of myocardial infarction. In case-control studies of cancer screening, prior exposure to a cancer screening test is compared between patients with cancer (cases) and those without (controls). Principal disadvantages of this study design are that important confounding variables may be difficult to identify and adjust for, health outcome is already known and may influence the measurement and interpretation of data (*observer bias*), participants may have difficulty in accurately recalling past medical history and previous exposures (*recall bias*), and improperly selected control groups may invalidate conclusions about the presence or absence of statistical associations. Both case-control and cohort studies are subject to selection biases because patients who engage in preventive behaviors (or who are selected by clinicians to receive preventive services) may differ in important ways from the general population.

Other types of study designs, such as ecologic or cross-national studies, uncontrolled cohort studies, and case reports, can provide useful data but do not generally provide strong evidence for or against effectiveness. Cross-cultural comparisons can demonstrate differences in disease rates between populations or countries, but these differences could be due to a variety of genetic and environmental factors other than the variable in question. Un-

controlled studies may demonstrate impressive treatment results or better outcomes than have been observed in the past (historical controls), but the absence of internal controls raises the question of whether the results would have occurred even in the absence of the intervention, perhaps as a result of other concurrent medical advances or changes in case selection. For further background on methodologic issues in evaluating clinical research, the reader is referred to other publications.⁴⁻⁶

In summary, claims of effectiveness in published research must be interpreted with careful attention to the type of study design. Impressive findings, even if reported to be statistically significant, may be an artifact of measurement error, the manner in which participants were selected, or other design flaws rather than a reflection of a true effect on health outcome. In particular, the p-value, which expresses the probability that a finding could have occurred by chance, does not account for bias. Thus, even highly significant p-values are of little value when the data may be subject to substantial bias. Conversely, research findings suggesting ineffectiveness may result from low statistical power, inadequate follow-up, and other design limitations. A study with inadequate statistical power may fail to demonstrate a significant effect on outcomes because of inadequate sample size rather than because of the limitations of the intervention.

The quality of the evidence is therefore as important as the results. For these reasons, the Task Force used a hierarchy of evidence in which greater weight was given to those study designs that are, in general, less subject to bias and misinterpretation. The hierarchy ranked the following designs in decreasing order of importance: randomized controlled trials, nonrandomized controlled trials, cohort studies, case-control studies, comparisons between time and places, uncontrolled experiments, descriptive studies, and expert opinion. For each of the preventive services examined in this report, the Task Force assigned "evidence ratings" reflecting this hierarchy, using a five-point scale (I, II-1, etc.) adapted from the scheme developed originally by the Canadian Task Force on the Periodic Health Examination (see Appendix A).

Due to resource constraints, the Task Force generally did not perform meta-analysis or decision analysis to examine the data or to synthesize the results of multiple studies. For topics in which these techniques are appropriate, the Task Force encourages other groups to conduct such analyses. Previously published meta-analyses or decision analytic models were reviewed by the Task Force in its examination of the literature but generally did not provide the sole basis for its recommendations unless the quality of the studies and analytic model was high.

Updating the Evidence Because the first edition of the *Guide* reviewed most of the relevant supporting evidence published before 1989, the Task Force

adopted an updating process to identify important evidence and new preventive technologies to address in this edition of the report. Literature review and updating of some topics for which little new evidence had been published since 1989 were conducted off-site at academic medical centers under the supervision of Task Force members. Updating of most other topics was performed by research staff at the Office of Disease Prevention and Health Promotion.

Updating was also coordinated with the Canadian Task Force on the Periodic Health Examination, which used a similar methodology to evaluate the effectiveness of preventive services and produced a report with similar format for its Canadian audience.⁷ For a number of topics in which differences in population characteristics were not important, draft chapters developed by the Canadian panel were adapted by the U.S. Task Force for inclusion in this report. The chapters on screening for ovarian cancer and hormone replacement therapy (Chapters 14 and 68, respectively) were based on reviews conducted for the American College of Physicians.

Translating Science into Clinical Practice Recommendations

Recommendations to perform or not perform a preventive service can be influenced by multiple factors, including scientific evidence of effectiveness, burden of suffering, costs, and policy concerns. The recommendations in this report are influenced largely by only one factor, scientific evidence, recognizing that the other factors often need to be considered (see below). Task Force recommendations are graded on a five-point scale (A-E), reflecting the strength of evidence in support of the intervention (see Appendix A). Interventions that have been proved effective in well-designed studies or have demonstrated consistent benefit in a large number of studies of weaker design are generally recommended in this report as “A” or “B” recommendations. Interventions that have been proved to be ineffective or harmful are generally not recommended and are assigned “D” or “E” recommendations. Even when there is no definitive evidence that a preventive service is ineffective, a “D” recommendation may be applied if there is no proven benefit and there is a known risk of complications or adverse effects from the preventive maneuver or from the diagnostic and treatment interventions that it generates. Under these conditions of uncertain benefit and known harm, the Task Force often discourages routine performance in the asymptomatic population but recognizes that future research may later establish a favorable benefit-harm relationship that supports routine performance.

For many preventive services (and much of medical practice), there is insufficient evidence that the maneuver is or is not effective in improving outcomes (“C” recommendation). *This lack of evidence of effectiveness does not*

constitute evidence of ineffectiveness. A preventive service can lack evidence and receive a “C” recommendation because no effectiveness studies have been performed. In other cases, studies may have been performed but they may have produced conflicting results. Studies showing no benefit may lack adequate statistical power, making it unclear whether the maneuver would be proved effective if it were tested with a larger sample size. Studies showing a benefit may suffer from other design flaws (e.g., confounding variables) that raise questions about whether the observed effect was due to the experimental intervention or other factors.

In all of these instances, the Task Force gives the preventive service a “C” recommendation, noting that there is insufficient scientific evidence to conclude whether the maneuver should or should not be performed routinely. Practitioners and policy makers often need to consider factors other than science, however, in deciding how to proceed in the absence of evidence. The first of these considerations is potential harm to the patient. In the absence of proven benefit, many would consider the performance of potentially harmful preventive services (e.g., aspirin prophylaxis in pregnancy) to be inappropriate (“*primum non nocere*”). It may be entirely appropriate, however, to perform preventive services that are essentially harmless if they have a reasonable likelihood of helping the patient (e.g., patient education and counseling). Similar considerations apply to costs. Performing costly preventive services in the absence of evidence (e.g., home uterine activity monitoring for preterm labor) must be viewed differently from inexpensive maneuvers of unproven benefit (e.g., palpating the testicles in young men).

The burden of suffering from the target condition may justify the performance of preventive services, even in the absence of evidence, and similar considerations may apply to an individual patient’s risk status. Unproven preventive services that are inappropriate for the general population may be appropriate to consider for individuals at markedly increased risk of the disease. Patient preferences, which are important in all clinical decisions, are essential to consider when contemplating the performance of preventive services of unproven effectiveness. The clinician’s responsibility is to provide the patient with the best available information about the potential benefits and harms of the preventive service and to delineate what is known and not known about the probability of these outcomes. Patients can then make informed decisions about which option is appropriate, based on the relative importance that they assign to these outcomes.

These additional considerations account for the different language used by the Task Force in its wording of “C” recommendations. Although all preventive services in the “C” category are identified as having insufficient evidence to recommend for or against the maneuver, the Task Force often adds that arguments for or against the practice can be made on

“other grounds.” These include the absence of significant harm or cost, the potential of improving individual or public health, legal requirements (“other grounds” for performing the preventive service), and concerns that the potential harms and costs of the maneuver outweigh its potential benefits (“other grounds” for *not* performing the preventive service). In some cases, the Task Force maintains a completely neutral position, stating only that there is insufficient evidence to make a recommendation. The statement that “recommendations may be made on other grounds” is intended to call attention to factors that may help guide the clinical practice; *it does not constitute an explicit recommendation of the Task Force that these services be provided or omitted routinely in the absence of evidence of effectiveness.* Individual clinical decisions should be made on a case-by-case basis.

In selected situations, even preventive services of proven efficacy may not be recommended due to concerns about feasibility and compliance. Benefits observed under carefully controlled experimental conditions may not be generalizable to normal medical practice. That is, the preventive service may have proven *efficacy* (effects under ideal circumstances) but may lack *effectiveness* (effects under usual conditions of practice). It may be difficult for clinicians to perform the procedure in the same manner as investigators with special expertise and a standardized protocol. Even in randomized controlled trials, volunteer participants may differ in important respects from the population targeted by clinical preventive measures. The average patient, for example, may be less willing than research volunteers to comply with interventions that lack widespread acceptability. The cost of the procedure and other logistical considerations may make implementation of the recommendation difficult for the health care system without compromising quality or the delivery of other health care services.

Review Process

The Task Force initiated a review process early in the production of this edition by inviting primary care specialty societies and U.S. Public Health Service agencies to appoint liaisons to attend and participate in Task Force meetings. Representatives of the American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, and American College of Obstetricians and Gynecologists participated in Task Force discussions and provided expert review by members of their organizations. Similarly, ex officio liaisons of U.S. Public Health Service agencies (Agency for Health Care Policy and Research, Centers for Disease Control and Prevention, National Institutes of Health, etc.) provided access to the expertise of government researchers and databases in examining Task Force documents.

Following this initial review, Task Force recommendations were reviewed by content experts in government health agencies, academic medical centers, and medical organizations in the U.S., Canada, Europe, and Australia. More than 700 experts reviewed recommendations included in this report. Recommendations were modified on the basis of reviewer comments if the reviewer identified relevant studies not examined in the report, misinterpretations of findings, or other issues deserving revision within the constraints of the Task Force methodology. The format of this report was designed in consultation with representatives of medical specialty organizations, including the American Medical Association, the American College of Physicians, the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American College of Preventive Medicine, the American Dental Association, and the American Osteopathic Association.⁸

Conclusion

Recommendations appearing in this report are intended as guidelines, providing clinicians with information on the proven effectiveness of preventive services in published clinical research. Recommendations for or against performing these maneuvers should not be interpreted as standards of care but rather as statements regarding the quality of the supporting scientific evidence. Clinicians with limited time can use this information to help select the preventive services most likely to benefit patients in selected risk categories (see Chapter iii), but no recommendation can take into account all the factors that influence individual clinical decisions in individual patients. Sound clinical decisions should take into account the medical history and priorities of each patient and local conditions and resources, in addition to the available scientific evidence. Departure from these recommendations by clinicians familiar with a patient's individual circumstances is often appropriate.

The draft update of this chapter was prepared for the U.S. Preventive Services Task Force by Steven H. Woolf, MD, MPH.

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iii. The Periodic Health Examination: Age-Specific Charts

The periodic health visit is an important opportunity for the delivery of clinical preventive services. Identification of specific preventive services that are appropriate for inclusion in the periodic health examination has been one of the principal objectives of the U.S. Preventive Services Task Force project. The process by which these determinations were made is discussed in detail in Chapter ii. This chapter explores the services that were evaluated by the Task Force and are recommended as part of the periodic health examination of the asymptomatic individual. It includes a series of five tables listing specific preventive services that are recommended for patients in different age groups. Conditions that are likely to benefit from early identification but that are not considered appropriate for routine screening are listed in Table 6. Disorders appearing in this table are often overlooked by clinicians due to failure to recognize suggestive signs or symptoms. For example, child abuse may not be diagnosed if physical findings suggestive of abuse are overlooked during routine or symptomatic examinations.¹

The Task Force judged it especially important to emphasize those preventive services that have been proven to be effective in properly conducted studies, and to tailor the content of the periodic health examination to the individual needs of the patient. This approach is based on the recognition that the limited time afforded to patient encounters may be most constructively used if the clinician focuses on interventions of proven efficacy. The clinician can then choose from among these effective interventions for each patient according to the likeliest causes of illness and injury based on that individual's age, sex, and other risk factors. Thus, the two most important factors to consider are the potential effectiveness of clinical interventions in improving clinical outcomes and the leading causes of mortality and morbidity.

Clinical efforts directed toward promoting health and preventing disease are of limited value if the preventive intervention does not improve outcome. Thus, the major consideration in setting priorities is effectiveness of the intervention. Although suicide and homicide are important causes of death among adolescents, for example, the effectiveness of ef-

forts by primary care clinicians to prevent deaths from intentional injuries has not been established (see Chapters 50 and 59). On the other hand, there are effective measures to reduce the risk of motor vehicle injuries, a leading cause of death in this age group. Proper use of safety belts has been shown to reduce the risk of injury and death from motor vehicle crashes by as much as 40–60%.^{2–5} Alcohol intoxication is associated with nearly half of all fatal crashes.⁶ With one of three deaths among young persons occurring in motor vehicle crashes,⁷ the busy clinician seeing adolescent patients is best advised to direct attention to the use of safety belts and the dangers of driving while under the influence of alcohol, rather than to interventions of unproven effectiveness. For each recommendation in Tables 1–5, the reader is urged to refer to appropriate chapters in the text to obtain detailed information about the scientific rationale.

It is also important to consider the leading causes of morbidity and mortality for patients when establishing priorities for the periodic health examination. For example, a clinician wishing to practice prevention during the few remaining minutes of an office visit with a 56-year-old female might consider a number of different counseling interventions that are effective in changing behavior, such as counseling about reducing dietary fat or avoiding high-risk sexual behavior. A 56-year-old female is considerably more likely to die from cardiac disease than from HIV or other sexually transmitted diseases. For women age 55–64 years in the U.S. during 1993, the death rate due to heart disease was 204/100,000, making it the second leading cause of death. HIV, on the other hand, is not even among the 10 leading causes of death for women of that age group.⁷ It seems clear on the basis of mortality data alone that a few minutes with such a patient might be more productively spent by discussing dietary fat. Leading causes of death by age group are provided for each table.

While more difficult to measure than mortality, leading causes of morbidity also should guide the use of preventive services. The adolescent population provides a clear example. Over 60% of gonococcal infections occur in persons under age 25.⁸ The prevalence of chlamydial infection is highest among young women age 15–19.⁹ Each year in the U.S., about 1 million adolescent females aged 15–19 (about 8–10% of this age group) and nearly 30,000 girls under age 15 become pregnant.¹⁰ Thus, encounters with the adolescent population should target unintended pregnancy and sexually transmitted diseases as important causes of morbidity in this age group. Essential hypertension, neoplasms, and problem drinking account for a large number of office and outpatient department visits in older patients,^{11–13} while injuries and poisonings account for 32% of emergency room visits among the general population.¹⁴ Among elderly patients, commonly reported causes of chronic morbidity include visual and hearing impairments.¹¹

Individual risk factors are also important to consider in designing the periodic health examination. The leading causes of morbidity and mortality may differ considerably for persons in special high-risk groups as compared to individuals of the same age and sex in the general population. For example, minority children in central cities are 6 times as likely as non-urban non-minority children to have elevated blood lead levels.¹⁵ Therefore, periodic health examinations for members of this high-risk population should include activities to prevent lead exposure, including screening. Injection drug use is also uncommon in the general population, but among individuals with this history, acquired immunodeficiency syndrome (AIDS) is the leading cause of death¹⁶ and hepatitis B is an important cause of morbidity and mortality. Thus, essential preventive interventions in the periodic health examination of an injection drug user are counseling about measures to prevent transmission of HIV and other infectious diseases and immunization against hepatitis B virus. The differences in priorities among individuals in different age groups and risk categories and the varying effectiveness of some preventive services in different populations make it impossible to recommend a uniform periodic health examination for all persons.

Many of the preventive services appearing in Tables 1–5 are recommended only for members of high-risk groups. These are listed separately in the lower half of each table and are grouped by general patient characteristics that broadly define high-risk populations. This organization will help the clinician to identify patients who might be eligible for one or more of the interventions listed. It is crucial, however, to then read the specific high-risk definition indicated by an annotated high-risk (HR) code after each intervention because patients may share characteristics of the general high-risk grouping without actually meeting the individual high-risk definitions for every intervention within that group. For example, a 23-year-old woman whose high-risk sexual behavior is limited to having two recent sexual partners should be screened for gonorrhea and chlamydia infection, but she may not require screening for syphilis or a hepatitis A vaccine. To avoid providing unnecessary preventive services, clinicians must evaluate carefully whether patients who are potentially at risk meet the specific high-risk definitions for each potential intervention. While nonstandardized historical questions were not evaluated by the Task Force and therefore are not included in the tables, the history and physical examination can be used to identify high-risk individuals who would benefit from targeted interventions. Appropriate chapters in the text provide more detailed guidelines to help identify individuals at increased risk.

Task Force recommendations can be compared with those of other major organizations and government agencies, which are listed in each chapter under the heading *Recommendations of Other Groups*. In addition,

the *Clinical Intervention* section contains detailed recommendations and, in many cases, concise information for the clinician on: conditions to remain alert for, anticipatory guidance, currently recommended techniques, drug dosages, and other specifics for performing recommended preventive services. It is not the intent of the *Guide* to supply comprehensive information on how to provide these preventive services. The interested reader is referred to the U.S. Public Health Service's prevention implementation program, "Put Prevention Into Practice,"¹⁷ and to other published sources on the implementation of clinical preventive services.¹⁸

The preventive services examined in this report and appearing in Tables 1–5 include only those preventive services that might be performed by primary care clinicians on asymptomatic persons in the context of *routine* health care (see Chapter ii). Preventive measures involving persons with signs or symptoms and those performed outside the clinical setting are not within the scope of this report or its recommendations. While the Task Force did not evaluate all components of the physical examination, several specific screening maneuvers that might be performed as part of the physical examination are included if they were considered. The tables are not intended as a complete list of all that should occur during the periodic health examination. Rather, these recommendations encompass those preventive services that have been examined by the Task Force and that have been shown to have satisfactory evidence of clinical effectiveness, based on the methodology discussed in the preceding chapter.

At the same time, the preventive interventions listed are not exhaustive. The periodic health examination performed by most pediatricians, for example, includes a number of maneuvers that were not examined by the Task Force, such as screening for developmental disorders and anticipatory guidance; the interested reader can refer to the recommendations of other groups for further information on such topics.^{19–21} Similarly, Task Force recommendations relating to preventive services during pregnancy should not be interpreted as comprehensive guidelines for prenatal care.

Preventive services listed in each table are not necessarily recommended at every periodic visit. For example, although sigmoidoscopy is recommended for persons age 50 and over, it is not recommended annually even though periodic visits in this age group may occur once a year. Where a specific periodicity has been proven effective (e.g., annual fecal occult blood testing in persons 50 years of age and over), this information is included in the footnotes for each table. The Task Force has not attempted to design a periodicity schedule for health supervision visits because for many interventions, evidence of an optimal periodicity is lacking. In addition, periodicity for certain interventions varies with patient characteristics (age, gender, risk factors).

Although the preventive services listed in Tables 1–5 can serve as the basis for designing periodic checkups devoted entirely to health promotion and disease prevention, they may also be performed during visits for other reasons (e.g., illness visits, chronic disease checkups) when indicated. Health maintenance needs to be considered at every visit. For patients with limited access to care, the illness visit may provide the only realistic opportunity to discuss prevention. It is recognized that busy clinicians may not be able to perform all recommended preventive services during a single clinical encounter. Indeed, it is not clear that such a grouping is either necessary or clinically effective. If a sparser, evidence-based protocol is used, health maintenance can frequently be done during acute visits. Patients suffering from an acute illness or injury, however, may not be receptive to some preventive interventions. The clinician must therefore use discretion in selecting appropriate preventive services from these tables and may wish to give special emphasis to those effective interventions aimed at the leading causes of illness and disability in the age group. Recommended preventive services that cannot be performed by the clinician at the current visit should be scheduled for a later health visit.

Immunizations appearing in Tables 1–5 are those recommended on a routine basis and do not apply to persons with special exposures to infected individuals. The reader is referred to Chapter 67 for detailed guidelines on immunizations in such circumstances.

Tables 1–5 do not include interventions for which the Task Force found insufficient evidence on which to base recommendations for or against inclusion in the periodic health examination (i.e., “C” recommendations). The Task Force recognizes that there may be other grounds on which to base a recommendation for or against an intervention when scientific evidence is not available, including patient preference, costs associated with the procedure, the likelihood of benefit or harms from the procedure, and the burden of suffering from the condition. Consideration of these other grounds can guide the clinician in making decisions about the appropriate use of these interventions. The reader is referred to Chapter ii for detailed discussion of the development of “C” recommendations. For many important causes of morbidity and mortality, evidence of effective preventive interventions is lacking. There is a great need for well-controlled, randomized studies with adequate sample sizes to evaluate the effectiveness of preventive interventions for many conditions. Such topics merit attention in the planning of future research agendas.

The draft update of this chapter was prepared for the U.S. Preventive Services Task Force by Ann O’Malley, MD, MPH, and Carolyn DiGiuseppe, MD, MPH.

Table 1. Birth to 10 Years

Interventions Considered and Recommended for the Periodic Health Examination	Leading Causes of Death Conditions originating in perinatal period Congenital anomalies Sudden infant death syndrome (SIDS) Unintentional injuries (non-motor vehicle) Motor vehicle injuries
Interventions for the General Population	
<p>SCREENING Height and weight [Ch 21] Blood pressure [Ch 3] Vision screen (age 3–4 yr) [Ch 33] Hemoglobinopathy screen (birth)¹ [Ch 43] Phenylalanine level (birth)² [Ch 44] T₄ and/or TSH (birth)³ [Ch 45]</p> <p>COUNSELING Injury Prevention [Ch 57,58] Child safety car seats (age <5 yr) Lap-shoulder belts (age 5 yr) Bicycle helmet, avoid bicycling near traffic Smoke detector, flame retardant sleepwear Hot water heater temperature <120–130°F Window/stair guards, pool fence Safe storage of drugs, toxic substances, firearms, & matches Syrup of ipecac, poison control phone number CPR training for parents/caretakers</p> <p>Diet and Exercise Breast-feeding, iron-enriched formula and foods (infants & toddlers) [Ch 22,56]</p>	<p>Limit fat & cholesterol, maintain caloric balance, emphasize grains, fruits, vegetables (age 2 yr) [Ch 56] Regular physical activity* [Ch 55]</p> <p>Substance Use [Ch 54] Effects of passive smoking* Anti-tobacco message*</p> <p>Dental Health [Ch 61] Regular visits to dental care provider* Floss, brush with fluoride toothpaste daily* Advice about baby bottle tooth decay*</p> <p>IMMUNIZATIONS [Ch 65] Diphtheria-tetanus-pertussis (DTP)⁴ Oral poliovirus (OPV)⁵ Measles-mumps-rubella (MMR)⁶ <i>H. influenzae</i> type b (Hib) conjugate⁷ Hepatitis A⁸ Varicella⁹</p> <p>CHEMOPROPHYLAXIS Ocular prophylaxis (birth) [Ch 27]</p>
Interventions for High-Risk Populations	
POPULATION	POTENTIAL INTERVENTIONS
<p>Preterm or low birth weight Infants of mothers at risk for HIV Low income; immigrants TB contacts Native American/Alaska Native</p> <p>Travelers to developing countries Residents of long-term care facilities Certain chronic medical conditions</p> <p>Increased individual or community lead exposure Inadequate water fluoridation Family h/o skin cancer; nevi; fair skin, eyes, hair</p>	<p>(See detailed high-risk definitions) Hemoglobin/hematocrit (HR1) HIV testing (HR2) Hemoglobin/hematocrit (HR1); PPD (HR3) PPD (HR3) Hemoglobin/hematocrit (HR1); PPD (HR3); hepatitis A vaccine (HR4); pneumococcal vaccine (HR5) Hepatitis A vaccine (HR4) PPD (HR3); hepatitis A vaccine (HR4); influenza vaccine (HR6) PPD (HR3); pneumococcal vaccine (HR5); influenza vaccine (HR6) Blood lead level (HR7) Daily fluoride supplement (HR8) Avoid excess/midday sun, use protective clothing* (HR9)</p>

¹Whether screening should be universal or targeted to high-risk groups will depend on the proportion of high-risk individuals in the screening area, and other considerations (see Ch. 43). ²If done during first 24 hr of life, repeat by age 2 wk. ³Optimally between day 2 and 6, but in all cases before newborn nursery discharge. ⁴2, 4, 6, and 12–18 mo; once between ages 4–6 yr (DTaP may be used at 15 mo and older). ⁵2, 4, 6–18 mo; once between ages 4–6 yr. ⁶12–15 mo and 4–6 yr. ⁷2, 4, 6 and 12–15 mo; no dose needed at 6 mo if PRP-OMP vaccine is used for first 2 doses. ⁸Birth, 1 mo, 6 mo; or, 0–2 mo, 1–2 mo later, and 6–18 mo. If not done in infancy: current visit, and 1 and 6 mo later. ⁹12–18 mo; or older child without hx of chickenpox or previous immunization. Include information on risk in adulthood, duration of immunity, and potential need for booster doses.

*The ability of clinician counseling to influence this behavior is unproven.

HR1 = Infants age 6–12 mo who are: living in poverty, black, Native American or Alaska Native, immigrants from developing countries, preterm or low birth weight infants, or infants whose principal dietary intake is unfortified cow's milk (see Ch. 22).

HR2 = Infants born to high-risk mothers whose HIV status is unknown. Women at high risk include: past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual, or HIV-positive sex partners currently or in past; persons seeking treatment for STDs; blood transfusion during 1978–1985 (see Ch. 28).

HR3 = Persons infected with HIV, close contacts of persons with known or suspected TB, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), residents of long-term care facilities (see Ch. 25). See Ch. 25 for indications for BCG vaccine.

HR4 = Persons 2 yr living in or traveling to areas where the disease is endemic and where periodic outbreaks occur (e.g., countries with high or intermediate endemicity; certain Alaska Native, Pacific Island, Native American, and religious communities). Consider for institutionalized children aged 2 yr. Clinicians should also consider local epidemiology (see Ch. 65–67).

HR5 = Immunocompetent persons 2 yr with certain medical conditions, including chronic cardiac or pulmonary disease, diabetes mellitus, and anatomic asplenia. Immunocompetent persons 2 yr living in high-risk environments or social settings (e.g., certain Native American and Alaska Native populations) (see Ch. 66).

HR6 = Annual vaccination of children 6 mo who are residents of chronic care facilities or who have chronic cardiopulmonary disorders, metabolic diseases (including diabetes mellitus), hemoglobinopathies, immunosuppression, or renal dysfunction (see Ch. 66). See Ch. 66 for indications for amantadine/rimantadine prophylaxis.

HR7 = Children about age 12 mo who: 1) live in communities in which the prevalence of lead levels requiring individual intervention, including residential lead hazard control or chelation, is high or undefined; 2) live in or frequently visit a home built before 1950 with dilapidated paint or with recent or ongoing renovation or remodeling; 3) have close contact with a person who has an elevated lead level; 4) live near lead industry or heavy traffic; 5) live with someone whose job or hobby involves lead exposure; 6) use lead-based pottery; or 7) take traditional ethnic remedies that contain lead (see Ch. 23).

HR8 = Children living in areas with inadequate water fluoridation (<0.6 ppm) (see Ch. 61).

HR9 = Persons with a family history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color (see Ch. 12).

Table 2. Ages 11–24 Years

Interventions Considered and Recommended for the Periodic Health Examination	Leading Causes of Death Motor vehicle/other unintentional injuries Homicide Suicide Malignant neoplasms Heart diseases
Interventions for the General Population	
<p>SCREENING Height & weight [Ch 21] Blood pressure¹ [Ch 3] Papanicolaou (Pap) test² (females) [Ch 9] Chlamydia screen³ (females <20 yr) [Ch 29] Rubella serology or vaccination hx⁴ (females >12 yr) [Ch 32] Assess for problem drinking [Ch 52]</p> <p>COUNSELING Injury Prevention [Ch 57,58] Lap/shoulder belts Bicycle/motorcycle/ATV helmets* Smoke detector* Safe storage/removal of firearms* [Ch 50,59]</p> <p>Substance Use Avoid tobacco use [Ch 54] Avoid underage drinking & illicit drug use* [Ch 52,53] Avoid alcohol/drug use while driving, swimming, boating, etc.* [Ch 57,58]</p> <p>Sexual Behavior [Ch 62,63] STD prevention: abstinence;* avoid high-</p>	<p>risk behavior;* condoms/female barrier with spermicide* Unintended pregnancy: contraception</p> <p>Diet and Exercise Limit fat & cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables [Ch 56] Adequate calcium intake (females) [Ch 56] Regular physical activity* [Ch 55]</p> <p>Dental Health [Ch 31] Regular visits to dental care provider* Floss, brush with fluoride toothpaste daily*</p> <p>IMMUNIZATIONS [Ch 65,66] Tetanus-diphtheria (Td) boosters (11–16 yr) Hepatitis B⁵ MMR (11–12 yr)⁶ Varicella (11–12 yr)⁷ Rubella⁴ (females >12 yr) [Ch 32]</p> <p>CHEMOPROPHYLAXIS Multivitamin with folic acid (females planning/capable of pregnancy) [Ch 42]</p>
Interventions for High-Risk Populations	
POPULATION	POTENTIAL INTERVENTIONS (See detailed high-risk definitions)
High-risk sexual behavior	RPR/VDRL (HR1); screen for gonorrhea (female) (HR2), HIV (HR3), chlamydia (female) (HR4); hepatitis A vaccine (HR5)
Injection or street drug use	RPR/VDRL (HR1); HIV screen (HR3); hepatitis A vaccine (HR5); PPD (HR6); advice to reduce infection risk (HR7)
TB contacts; immigrants; low income Native Americans/Alaska Natives	PPD (HR6) Hepatitis A vaccine (HR5); PPD (HR6); pneumococcal vaccine (HR8)
Travelers to developing countries Certain chronic medical conditions	Hepatitis A vaccine (HR5) PPD (HR6); pneumococcal vaccine (HR8); influenza vaccine (HR9)
Settings where adolescents and young adults congregate Susceptible to varicella, measles, mumps Blood transfusion between 1978–1985 Institutionalized persons; health care/lab workers	Second MMR (HR10) Varicella vaccine (HR11); MMR (HR12) HIV screen (HR3) Hepatitis A vaccine (HR5); PPD (HR6); influenza vaccine (HR9)
Family h/o skin cancer; nevi; fair skin, eyes, hair Prior pregnancy with neural tube defect Inadequate water fluoridation	Avoid excess/midday sun, use protective clothing* (HR13) Folic acid 4.0 mg (HR14) Daily fluoride supplement (HR15)

¹Periodic BP for persons aged >12 yr. ²If sexually active at present or in the past: q 3 yr. If sexual history is unreliable, begin Pap tests at age 18 yr. ³If sexually active. ⁴Serologic testing, documented vaccination history, and routine vaccination against rubella (preferably with MMR) are equally acceptable alternatives. ⁵If not previously immunized: current visit, 1 and 6 mo later. ⁶If no previous second dose of MMR. ⁷If susceptible to chickenpox.

*The ability of clinician counseling to influence this behavior is unproven.

HR1 = Persons who exchange sex for money or drugs, and their sex partners; persons with other STDs (including HIV); and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology (see Ch. 26).

HR2 = Females who have: two or more sex partners in the last year; a sex partner with multiple sexual contacts; exchanged sex for money or drugs; or a history of repeated episodes of gonorrhea. Clinicians should also consider local epidemiology (see Ch. 27).

HR3 = Males who had sex with males after 1975; past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual, or HIV-positive sex partner currently or in the past; blood transfusion during 1978–1985; persons seeking treatment for STDs. Clinicians should also consider local epidemiology (see Ch. 28).

HR4 = Sexually active females with multiple risk factors including: history of prior STD; new or multiple sex partners; age under 25; nonuse or inconsistent use of barrier contraceptives; cervical ectopy. Clinicians should consider local epidemiology of the disease in identifying other high-risk groups (see Ch. 29).

HR5 = Persons living in, traveling to, or working in areas where the disease is endemic and where periodic outbreaks occur (e.g., countries with high or intermediate endemicity; certain Alaska Native, Pacific Island, Native American, and religious communities); men who have sex with men; injection or street drug users. Vaccine may be considered for institutionalized persons and workers in these institutions, military personnel, and day-care, hospital, and laboratory workers. Clinicians should also consider local epidemiology (see Ch. 66, 67).

HR6 = HIV positive, close contacts of persons with known or suspected TB, health care workers, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), alcoholics, injection drug users, and residents of long-term care facilities (see Ch. 25). See Ch. 25 for indications for BCG vaccine.

HR7 = Persons who continue to inject drugs (see Ch. 53).

HR8 = Immunocompetent persons with certain medical conditions, including chronic cardiac or pulmonary disease, diabetes mellitus, and anatomic asplenia. Immunocompetent persons who live in high-risk environments or social settings (e.g., certain Native American and Alaska Native populations) (see Ch. 66).

HR9 = Annual vaccination of: residents of chronic care facilities; persons with chronic cardiopulmonary disorders, metabolic diseases (including diabetes mellitus), hemoglobinopathies, immunosuppression, or renal dysfunction; and health care providers for high-risk patients (see Ch. 66). See Ch. 66 for indications for amantadine/rimantadine prophylaxis.

HR10 = Adolescents and young adults in settings where such individuals congregate (e.g., high schools and colleges), if they have not previously received a second dose (see Ch. 65, 66).

HR11 = Healthy persons aged 13 yr without a history of chickenpox or previous immunization. Consider serologic testing for presumed susceptible persons aged 13 yr (see Ch. 65, 66).

HR12 = Persons born after 1956 who lack evidence of immunity to measles or mumps (e.g., documented receipt of live vaccine on or after the first birthday, laboratory evidence of immunity, or a history of physician-diagnosed measles or mumps) (see Ch. 65, 66).

HR13 = Persons with a family or personal history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color (see Ch. 12).

HR14 = Women with prior pregnancy affected by neural tube defect who are planning pregnancy (see Ch. 42).

HR15 = Persons aged <17 yr living in areas with inadequate water fluoridation (<0.6 ppm) (see Ch. 61).

Table 3. Ages 25–64 Years

Interventions Considered and Recommended for the Periodic Health Examination	Leading Causes of Death Malignant neoplasms Heart diseases Motor vehicle and other unintentional injuries Human immunodeficiency virus (HIV) infection Suicide and homicide
Interventions for the General Population	
<p>SCREENING Blood pressure [Ch 3] Height and weight [Ch 21] Total blood cholesterol (men ages 35–65, women ages 45–65) [Ch 2] Papanicolaou (Pap) test (women)¹ [Ch 9] Fecal occult blood test² and/or sigmoidoscopy (50 yr) [Ch 8] Mammogram ± clinical breast exam³ (women 50–69 yr) [Ch 7] Assess for problem drinking [Ch 52] Rubella serology or vaccination hx⁴ (women of childbearing age) [Ch 32]</p> <p>COUNSELING Substance Use Tobacco cessation [Ch 54] Avoid alcohol/drug use while driving, swimming, boating, etc.* [Ch 57,58]</p> <p>Diet and Exercise Limit fat & cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables [Ch 56] Adequate calcium intake (women) [Ch 56]</p>	<p>Regular physical activity* [Ch 55] Injury Prevention [Ch 57,58] Lap/shoulder belts Motorcycle/bicycle/ATV helmets* Smoke detector* Safe storage/removal of firearms* [Ch 50,59]</p> <p>Sexual Behavior [Ch 62,63] STD prevention: avoid high-risk behavior;* condoms/female barrier with spermicide* Unintended pregnancy: contraception</p> <p>Dental Health [Ch 67] Regular visits to dental care provider* Floss, brush with fluoride toothpaste daily*</p> <p>IMMUNIZATIONS [Ch 32,66] Tetanus diphtheria (Td) boosters Rubella (women of childbearing age)</p> <p>CHEMOPROPHYLAXIS Multivitamin with folic acid (women planning or capable of pregnancy) [Ch 42] Discuss hormone prophylaxis (peri- and postmenopausal women) [Ch 68]</p>
Interventions for High-Risk Populations	
POPULATION	POTENTIAL INTERVENTIONS (See detailed high-risk definitions)
High-risk sexual behavior	RPR/VDRL (HR1); screen for gonorrhea (female) (HR2), HIV (HR3), chlamydia (female) (HR4); hepatitis B vaccine (HR5); hepatitis A vaccine (HR6)
Injection or street drug use	RPR/VDRL (HR1); HIV screen (HR3); hepatitis B vaccine (HR5); hepatitis A vaccine (HR6); PPD (HR7); advice to reduce infection risk (HR8)
Low income; TB contacts; immigrants; alcoholics Native Americans/Alaska Natives	PPD (HR7) Hepatitis A vaccine (HR6); PPD (HR7); pneumococcal vaccine (HR9)
Travelers to developing countries Certain chronic medical conditions	Hepatitis B vaccine (HR5); hepatitis A vaccine (HR6) PPD (HR7); pneumococcal vaccine (HR9); influenza vaccine (HR10)
Blood product recipients Susceptible to measles, mumps, or varicella Institutionalized persons	HIV screen (HR3); hepatitis B vaccine (HR5) MMR (HR11); varicella vaccine (HR12) Hepatitis A vaccine (HR6); PPD (HR7); pneumococcal vaccine (HR9); influenza vaccine (HR10)
Health care/lab workers	Hepatitis B vaccine (HR5); hepatitis A vaccine (HR6); PPD (HR7); influenza vaccine (HR10)
Family h/o skin cancer; fair skin, eyes, hair Previous pregnancy with neural tube defect	Avoid excess/midday sun, use protective clothing* (HR13) Folic acid 4.0 mg (HR14)

¹Women who are or have been sexually active and who have a cervix; q 3 yr. ²Annually. ³Mammogram q1–2 yr, or mammogram q1–2 yr with annual clinical breast examination. ⁴Serologic testing, documented vaccination history, and routine vaccination (preferably with MMR) are equally acceptable alternatives.

*The ability of clinician counseling to influence this behavior is unproven.

HR1 = Persons who exchange sex for money or drugs, and their sex partners; persons with other STDs (including HIV); and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology (see Ch. 26).

HR2 = Women who exchange sex for money or drugs, or who have had repeated episodes of gonorrhea. Clinicians should also consider local epidemiology (see Ch. 27).

HR3 = Men who had sex with men after 1975; past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual, or HIV-positive sex partner currently or in the past; blood transfusion during 1978–1985; persons seeking treatment for STDs. Clinicians should also consider local epidemiology (see Ch. 28).

HR4 = Sexually active women with multiple risk factors including: history of STD; new or multiple sex partners; nonuse or inconsistent use of barrier contraceptives; cervical ectopy. Clinicians should also consider local epidemiology (see Ch. 29).

HR5 = Blood product recipients (including hemodialysis patients); persons with frequent occupational exposure to blood or blood products, men who have sex with men, injection drug users and their sex partners, persons with multiple recent sex partners, persons with other STDs (including HIV), travelers to countries with endemic hepatitis B (see Ch. 66).

HR6 = Persons living in, traveling to, or working in areas where the disease is endemic and where periodic outbreaks occur (e.g., countries with high or intermediate endemicity; certain Alaska Native, Pacific Island, Native American, and religious communities); men who have sex with men; injection or street drug users. Consider for institutionalized persons and workers in these institutions, military personnel, and day-care, hospital, and laboratory workers. Clinicians should also consider local epidemiology (see Ch. 66, 67).

HR7 = HIV positive, close contacts of persons with known or suspected TB, health care workers, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), alcoholics, injection drug users, and residents of long-term care facilities (see Ch. 25). See Ch. 25 for indications for BCG vaccine.

HR8 = Persons who continue to inject drugs (see Ch. 53).

HR9 = Immunocompetent institutionalized persons aged ≥ 50 yr and immunocompetent persons with certain medical conditions, including chronic cardiac or pulmonary disease, diabetes mellitus, and anatomic asplenia. Immunocompetent persons who live in high-risk environments or social settings (e.g., certain Native American and Alaska Native populations) (see Ch. 66).

HR10 = Annual vaccination of residents of chronic care facilities; persons with chronic cardiopulmonary disorders, metabolic diseases (including diabetes mellitus), hemoglobinopathies, immunosuppression, or renal dysfunction; and health care providers for high-risk patients (Ch. 66). See Ch. 66 for indications for amantadine/rimantadine prophylaxis.

HR11 = Persons born after 1956 who lack evidence of immunity to measles or mumps (e.g., documented receipt of live vaccine on or after the first birthday, laboratory evidence of immunity, or a history of physician-diagnosed measles or mumps) (see Ch. 66).

HR12 = Healthy adults without a history of chickenpox or previous immunization. Consider serologic testing for presumed susceptible adults (see Ch. 65, 66).

HR13 = Persons with a family or personal history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color (see Ch. 12).

HR14 = Women with previous pregnancy affected by neural tube defect who are planning pregnancy (see Ch. 42).

Table 4. Age 65 and Older

Interventions Considered and Recommended for the Periodic Health Examination	Leading Causes of Death Heart diseases Malignant neoplasms (lung, colorectal, breast) Cerebrovascular disease Chronic obstructive pulmonary disease Pneumonia and influenza
Interventions for the General Population	
<p>SCREENING Blood pressure [Ch 3] Height and weight [Ch 21] Fecal occult blood test¹ and/or sigmoidoscopy [Ch 8] Mammogram ± clinical breast exam² (women 69 yr) [Ch 7] Papanicolaou (Pap) test (women)³ [Ch 9] Vision screening [Ch 33] Assess for hearing impairment [Ch 35] Assess for problem drinking [Ch 52]</p> <p>COUNSELING</p> <p>Substance Use Tobacco cessation [Ch 54] Avoid alcohol/drug use while driving, swimming, boating, etc.* [Ch 57,58]</p> <p>Diet and Exercise Limit fat & cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables [Ch 56] Adequate calcium intake (women) [Ch 56] Regular physical activity* [Ch 55,58]</p>	<p>Injury Prevention [Ch 57,58] Lap/shoulder belts Motorcycle and bicycle helmets* Fall prevention* Safe storage/removal of firearms* [Ch 50,59] Smoke detector* Set hot water heater to <120–130°F* CPR training for household members</p> <p>Dental Health [Ch 61] Regular visits to dental care provider* Floss, brush with fluoride toothpaste daily*</p> <p>Sexual Behavior STD prevention: avoid high-risk sexual behavior; use condoms* [Ch 62]</p> <p>IMMUNIZATIONS [Ch 66] Pneumococcal vaccine Influenza¹ Tetanus-diphtheria (Td) boosters</p> <p>CHEMOPROPHYLAXIS Discuss hormone prophylaxis (women) [Ch 68]</p>
Interventions for High-Risk Populations	
POPULATION	POTENTIAL INTERVENTIONS
Institutionalized persons	(See detailed high-risk definitions) PPD (HR1); hepatitis A vaccine (HR2); amantadine/rimantadine (HR4) PPD (HR1)
Chronic medical conditions; TB contacts, low income; immigrants; alcoholism	
Persons 75 yr; or 70 yr with risk factors for falls Cardiovascular disease risk factors Family h/o skin cancer; new, fair skin, eyes, hair Native Americans/Alaska Natives Travelers to developing countries Blood product recipients High-risk sexual behavior	Fall prevention intervention (HR5) Consider cholesterol screening (HR6) Avoid excess/midday sun, use protective clothing* (HR7) PPD (HR1); hepatitis A vaccine (HR2) Hepatitis A vaccine (HR2); hepatitis B vaccine (HR8) HIV screen (HR3); hepatitis B vaccine (HR8) Hepatitis A vaccine (HR2); HIV screen (HR3); hepatitis B vaccine (HR8); RPR/VDRL (HR9)
Injection or street drug use	PPD (HR1); hepatitis A vaccine (HR2); HIV screen (HR3); hepatitis B vaccine (HR8); RPR/VDRL (HR9); advice to reduce infection risk (HR10)
Health care/lab workers	PPD (HR1); hepatitis A vaccine (HR2); amantadine/rimantadine (HR4); hepatitis B vaccine (HR8)
Persons susceptible to varicella	Varicella vaccine (HR11)

¹Annually. ²Mammogram q1–2 yr, or mammogram q1–2 yr with annual clinical breast exam. ³All women who are or have been sexually active and who have a cervix: q 3 yr. Consider discontinuation of testing after age 65 yr if previous regular screening with consistently normal results.

*The ability of clinician counseling to influence this behavior is unproven.

HR1 = HIV positive, close contacts of persons with known or suspected TB, health care workers, persons with medical risk factors associated with TB, immigrants from countries with high TB prevalence, medically underserved low-income populations (including homeless), alcoholics, injection drug users, and residents of long-term care facilities (see Ch. 25). See Ch. 25 for indications for BCG vaccine.

HR2 = Persons living in, traveling to, or working in areas where the disease is endemic and where periodic outbreaks occur (e.g., countries with high or intermediate endemicity; certain Alaska Native, Pacific Island, Native American, and religious communities); men who have sex with men; injection or street drug users. Consider for institutionalized persons and workers in these institutions, and day-care, hospital, and laboratory workers. Clinicians should also consider local epidemiology (see Ch. 66, 67).

HR3 = Men who had sex with men after 1975; past or present injection drug use; persons who exchange sex for money or drugs, and their sex partners; injection drug-using, bisexual, or HIV-positive sex partner currently or in the past; blood transfusion during 1978–1985; persons seeking treatment for STDs. Clinicians should also consider local epidemiology (see Ch. 28).

HR4 = Consider for persons who have not received influenza vaccine or are vaccinated late; when the vaccine may be ineffective due to major antigenic changes in the virus; for unvaccinated persons who provide home care for high-risk persons; to supplement protection provided by vaccine in persons who are expected to have a poor antibody response; and for high-risk persons in whom the vaccine is contraindicated (see Ch. 66).

HR5 = Persons aged 75 years and older; or aged 70–74 with one or more additional risk factors including: use of certain psychoactive and cardiac medications (e.g., benzodiazepines, antihypertensives); use of 4 prescription medications; impaired cognition, strength, balance, or gait. Intensive individualized home-based multifactorial fall prevention intervention is recommended in settings where adequate resources are available to deliver such services (see Ch. 58).

HR6 = Although evidence is insufficient to recommend routine screening in elderly persons, clinicians should consider cholesterol screening on a case-by-case basis for persons ages 65–75 with additional risk factors (e.g., smoking, diabetes, or hypertension) (see Ch. 2).

HR7 = Persons with a family or personal history of skin cancer, a large number of moles, atypical moles, poor tanning ability, or light skin, hair, and eye color (see Ch. 12).

HR8 = Blood product recipients (including hemodialysis patients), persons with frequent occupational exposure to blood or blood products, men who have sex with men, injection drug users and their sex partners, persons with multiple recent sex partners, persons with other STDs (including HIV), travelers to countries with endemic hepatitis B (see Ch. 66).

HR9 = Persons who exchange sex for money or drugs and their sex partners; persons with other STDs (including HIV); and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology (see Ch. 26).

HR10 = Persons who continue to inject drugs (see Ch. 53).

HR11 = Healthy adults without a history of chickenpox or previous immunization. Consider serologic testing for presumed susceptible adults (see Ch. 65, 66).

Table 5. Pregnant Women**

Interventions Considered and Recommended for the Periodic Health Examination

Interventions for the General Population	
<p>SCREENING</p> <p>First visit Blood pressure [Ch 3,37] Hemoglobin/hematocrit [Ch 22] Hepatitis B surface antigen (HBsAg) [Ch 24] RPR/VDRL [Ch 26] Chlamydia screen (<25 yr) [Ch 29] Rubella serology or vaccination history [Ch 32] D(Rh) typing, antibody screen [Ch 38] Offer CVS (<13 wk)¹ or amniocentesis (15–18 wk)¹ (age 35 yr) [Ch 41] Offer hemoglobinopathy screening [Ch 43] Assess for problem or risk drinking [Ch 52] Offer HIV screening² [Ch 28]</p> <p>Follow-up visits Blood pressure [Ch 3,37] Urine culture (12–16 wk) [Ch 31] Offer amniocentesis (15–18 wk)¹ (age 35 yr) [Ch 41]</p>	<p>Offer multiple marker testing¹ (15–18 wk) [Ch 41] Offer serum -fetoprotein¹ (16–18 wk) [Ch 42]</p> <p>COUNSELING Tobacco cessation; effects of passive smoking [Ch 54] Alcohol/other drug use [Ch 52,53] Nutrition, including adequate calcium intake [Ch 56] Encourage breastfeeding [Ch 22,56] Lap/shoulder belts [Ch 57] Infant safety car seats [Ch 57] STD prevention: Avoid high-risk sexual behavior;* use condoms* [Ch 62]</p> <p>CHEMOPROPHYLAXIS Multivitamin with folic acid³ [Ch 42]</p>
Interventions for High-Risk Populations	
<p>POPULATION</p> <p>High-risk sexual behavior</p> <p>Blood transfusion 1978–1985 Injection drug use</p> <p>Unsensitized D-negative women Risk factors for Down syndrome</p> <p>Prior pregnancy with neural tube defect</p>	<p>POTENTIAL INTERVENTIONS (See detailed high-risk definitions)</p> <p>Screen for chlamydia (1st visit) (HR1), gonorrhea (1st visit) (HR2), HIV (1st visit) (HR3); HBsAg (3rd trimester) (HR4); RPR/VDRL (3rd trimester) (HR5) HIV screen (1st visit) (HR3) HIV screen (HR3); HBsAg (3rd trimester) (HR4); advice to reduce infection risk (HR6) D(Rh) antibody testing (24–28 wk) (HR7) Offer CVS¹ (1st trimester), amniocentesis¹ (15–18 wk) (HR8) Folic acid 4.0 mg,³ offer amniocentesis¹ (15–18 wk) (HR9)</p>

¹Women with access to counseling and follow-up services, reliable standardized laboratories, skilled high-resolution ultrasound, and, for those receiving serum marker testing, amniocentesis capabilities. ²Universal screening is recommended for areas (states, counties, or cities) with an increased prevalence of HIV infection among pregnant women. In low-prevalence areas, the choice between universal and targeted screening may depend on other considerations (see Ch. 28). ³Beginning at least 1 mo before conception and continuing through the first trimester.

*The ability of clinician counseling to influence this behavior is unproven.

**See Tables 2 and 3 for other preventive services recommended for women of childbearing age.

HR1 = Women with history of STD or new or multiple sex partners. Clinicians should also consider local epidemiology. Chlamydia screen should be repeated in 3rd trimester if at continued risk (see Ch. 29).

HR2 = Women under age 25 with two or more sex partners in the last year, or whose sex partner has multiple sexual contacts; women who exchange sex for money or drugs; and women with a history of repeated episodes of gonorrhea. Clinicians should also consider local epidemiology. Gonorrhea screen should be repeated in the 3rd trimester if at continued risk (see Ch. 27).

HR3 = In areas where universal screening is not performed due to low prevalence of HIV infection, pregnant women with the following individual risk factors should be screened: past or present injection drug use; women who exchange sex for money or drugs; injection drug-using, bisexual, or HIV-positive sex partner currently or in the past; blood transfusion during 1978–1985; persons seeking treatment for STDs (see Ch. 28).

HR4 = Women who are initially HBsAg-negative who are at high risk due to injection drug use, suspected exposure to hepatitis B during pregnancy, multiple sex partners (see Ch. 24).

HR5 = Women who exchange sex for money or drugs, women with other STDs (including HIV), and sexual contacts of persons with active syphilis. Clinicians should also consider local epidemiology (see Ch. 26).

HR6 = Women who continue to inject drugs (see Ch. 53).

HR7 = Unsensitized D-negative women (see Ch. 38).

HR8 = Prior pregnancy affected by Down syndrome, advanced maternal age (> 35 yr), known carriage of chromosome rearrangement (see Ch. 41).

HR9 = Women with previous pregnancy affected by neural tube defect (see Ch. 42).

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Table 6.
Conditions for Which Clinicians Should Remain Alert

Condition	Population	Chapter
Symptoms of peripheral arterial disease	Older persons, smokers, diabetic persons	5
Skin lesions with malignant features	General population, particularly those with established risk factors	12
Symptoms and signs of oral cancer and premalignancy	Persons who use tobacco, older persons who drink alcohol regularly	16
Subtle or nonspecific symptoms and signs of thyroid dysfunction	Older persons, postpartum women, persons with Down syndrome	20
Signs of ocular misalignment	Infants and children	33
Symptoms and signs of hearing impairment	Infants and young children (<3 yr)	35
Large spinal curvatures	Adolescents	47
Changes in functional performance	Older persons	48
Depressive symptoms	Adolescents, young adults, persons at increased risk for depression	49
Evidence of suicidal ideation	Persons with established risk factors for suicide	50
Various presentations of family violence	General population	51
Symptoms and signs of drug abuse	General population	53
Obvious signs of untreated tooth decay or mottling, inflamed or cyanotic gingiva, loose teeth, and severe halitosis	General population	61
Evidence of early childhood caries, mismatching of upper and lower dental arches, dental crowding or malalignment, premature loss of primary posterior teeth (baby molars) and obvious mouth breathing	Children	61

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iv. Patient Education and Counseling for Prevention

Today's major health care problems are increasingly the result of chronic and acute conditions related to individual behavior.¹ A significant proportion of coronary disease and cancer can be attributed to use of tobacco or unhealthy diets, and the majority of sexually transmitted diseases and injuries are related to patient behavior. While mortality from some of these conditions is decreasing, morbidity from most chronic diseases continues to increase.^{2,3} For these conditions, prevention at all levels—primary (preventing disease), secondary (early diagnosis), and tertiary (preventing or slowing deterioration)—requires active participation by the patient with guidance and support from the clinician. The patient must take responsibility for carrying out the day-to-day preventive behaviors, accurately reporting progress to the clinician, and discussing health-related problems. Effective patient participation requires education, motivation, and counseling. While busy clinicians cannot fill all the educational needs, they can be pivotal in starting and guiding the process.

Effectiveness of Clinical Counseling

Published evidence regarding counseling's effectiveness in changing specific patient behaviors is reviewed in detail in Chapters 54 through 64. For a number of important health-related behaviors (e.g., smoking, problem drinking) there is good evidence from high-quality studies that clinicians can change patient behavior through simple counseling interventions in the primary care setting.⁴⁻⁷ For many other behaviors, the effectiveness of clinician counseling has been demonstrated only over the short term⁸ or in specialized settings involving relatively intensive counseling.⁹⁻¹⁴ In many cases, the effects of counseling on specific behaviors have never been examined in appropriately designed studies. Small changes in behavior may be difficult to prove in prospective studies, yet they could have important health benefits if applied to large populations at risk. Given the safety and generally low cost of advising patients about health-related behaviors, the U.S. Preventive Services Task Force (USPSTF) recommends routinely addressing some health behaviors even when the long-term effectiveness of such counseling has not yet been definitively proven. In their updated recommendations, however, the USPSTF explicitly distinguishes between recommendations

based on good evidence of the effectiveness of counseling per se (e.g., smoking cessation) and recommendations made primarily on the basis of the strong link between behavior and disease (e.g., sexually transmitted disease prevention). The USPSTF recognizes that determining the effectiveness of counseling interventions, especially ones that are feasible in the primary care setting, is a research priority. Studies that have demonstrated benefits from brief counseling (e.g., for smoking cessation) help identify critical components of clinician counseling that may apply to other target conditions. This chapter will discuss the objectives of patient education and counseling and provide strategies that can be used in day-to-day practice, offering some examples of how these strategies can be applied.

Objectives of Patient Education and Counseling for Prevention

There are two major objectives of patient education and counseling related to primary prevention: changing health behaviors and improving health status. In addition to the studies cited above, a number of other studies of patient education have demonstrated successful health behavior change in areas such as weight control,^{15,16} exercise,¹⁷⁻¹⁹ and contraceptive use.²⁰ No area of behavior change has been studied more thoroughly than compliance with medication and with other preventive or therapeutic regimens.²¹⁻²⁴ Several general points have emerged from these and other studies of effective counseling to change behavior, which can be incorporated into strategies for effective patient counseling (see below).

A large range of health status changes can be achieved from well-implemented patient education efforts.²⁵ Various programs have been reported to: lower blood pressure;^{23,26} reduce mortality from hypertension,²⁷ melanoma,²⁸ hematologic malignancies,²⁹ and breast cancer;³⁰ reduce pain and disability from arthritis;³¹⁻³⁴ reduce the incidence of low birth weight babies;^{35,36} and maintain better blood glucose levels in diabetics.^{37,38} While many of these changes in health status are mediated by changes in health behaviors and better compliance with therapeutic regimens, it seems that some clinical benefits occur independent of these factors.³⁹ A growing body of evidence suggests that when people have confidence that they can affect their health, they are more likely to do so than those without such confidence.⁴⁰ This confidence has been termed “perceived self-efficacy.”⁴¹ Self-efficacy can be enhanced through skills mastery, modeling, reinterpreting the meaning of symptoms, and persuasion. Efficacy-enhancing strategies for use in clinical practice are included in the suggestions for patient education described below.

Patient Education/Counseling Strategies

An underlying principle of patient education and counseling is that knowledge is necessary but not sufficient to change health behaviors. If knowl-

edge alone could accomplish changes in health behavior, there would be many fewer smokers and more exercisers. Patient education involves more than simply telling people what to do or giving them an instructional pamphlet.

Few studies compare the efficacy of different types of counseling. The following recommendations have been chosen because they each have been found to be useful in changing certain health behaviors. Most of the suggested strategies can be incorporated into the practice setting without changing existing practice patterns. Many can be implemented in brief periods of time during routine health visits.

1. Frame the teaching to match the patient's perceptions. When counseling patients, the clinician should consider and incorporate, where possible, the beliefs and concerns of the patient. Research suggests that people have only a few important beliefs about any one subject.⁴² To persuade patients to change their behavior, it is first necessary to identify their beliefs relevant to the behavior and to provide information based on this foundation.⁴³ The clinician can elicit important beliefs by asking such questions as "When you think of heart disease, what do you think of?" and "What gets in the way of your eating a low-fat diet?" Once the patient's concerns and understanding of the issues are apparent, teaching can then be focused appropriately. In considering a patient's belief system, the provider is challenged to facilitate the bridging of cross-cultural gaps as well. Culturally sensitive education and counseling requires that clinicians assess their own cultural beliefs and be aware of local ethnic, regional, and religious beliefs and practices.⁴⁴ Such knowledge aids the development of culturally specific health teaching. A fixed message will not be effective for all patients. By fitting teaching and recommendations to patients' perceptions of their own health and ability to change, clinicians can enhance self-efficacy, which has been shown to improve health behaviors and health status.⁴¹ If a patient with morbid obesity complains that he or she is not able to exercise, the clinician might reframe the patient's conception of what is meant by "exercise." One might initiate a very gentle and brief exercise program, such as 1 minute of physical activity each hour.

2. Fully inform patients of the purposes and expected effects of interventions and when to expect these effects. Telling the patient when to expect to see beneficial effects from the intervention may avoid discouragement when immediate benefits are not forthcoming. When rheumatologists told patients about the purposes of their medications, 79% of them were compliant 4 months later, compared with only 33% compliance for those patients who were not given clear information about the purpose of the drugs.⁴⁹ Informing patients that the beneficial effects of a low-cholesterol diet or regular physical activity may not become apparent for several months might increase the likelihood of long-term compliance. If side effects are common, the patient should be told what to

expect, and under what circumstances the intervention should be stopped or the provider consulted.

3. Suggest small changes rather than large ones. Patients can be asked to do slightly more than they are doing now: “It is great that you are walking 10 minutes in the morning; could you add an additional 5 minutes?” When someone is very overweight, losing 100 pounds might seem like an impossible task, whereas losing 3–4 pounds in the next month seems reachable. By achieving a small goal, the patient has initiated positive change.⁴¹ The rationale for this suggestion comes from self-efficacy theory. Successful persuasion involves not only increasing a patient’s faith in his or her capabilities, but also structuring interventions so that people are likely to experience success.⁴⁵

4. Be specific. Specific and informational instructions will generally lead to better compliance.⁴⁶ For example, when suggesting a physical activity program, it is helpful to ask the patient how much he or she can comfortably do now.⁴⁷ The patient can then be asked to perform this activity 3 times a week and then add to it by 10–25% per week, until the person is doing some type of aerobic exercise 20–30 minutes 3–4 times a week. Behavior change is enhanced if the regimen and its rationale are explained, demonstrated to the patient (if appropriate), and written down for patients to take home.

5. It is sometimes easier to add new behaviors than to eliminate established behaviors.^{48,49} Thus, if weight loss is a concern, suggesting that the patient begin moderate physical activity may be more effective than suggesting a change in current dietary patterns.

6. Link new behaviors to old behaviors. For example, a clinician might suggest to patients that they exercise before eating lunch, use an exercise bike while watching the evening news, or take prescribed medications twice daily when brushing the teeth.

7. Use the power of the profession. Patients see clinicians as health experts, and they regard what the clinician says as important. The clinician need not be afraid to tell a patient, “I want you to stop smoking,” or “I want you to cut half the fat out of your diet.” These direct messages are powerful, especially if they are simple and specific.⁵ It is important to recognize that some patients lack confidence in their ability to make lifestyle changes. The clinician can be sympathetic and supportive while providing firm, definite messages.

8. Get explicit commitments from the patient. Asking patients to describe how the intended regimen will be followed encourages them to begin to think about how to integrate this new behavior into their daily schedule. Clinicians should ask patients to describe what specifically they plan to achieve this week (i.e., what, when, and how often). For example, the patient can be asked to describe what physical activity he or she will

undertake, when it will be done, and how often. The more specific the commitment from the patient, the more likely it is to be followed. After getting the commitment, the clinician can also ask the patient how sure he or she is that he or she will carry out the commitment, for example using a scale of 0 (not at all sure) to 10 (totally sure). A patient with a high degree of certainty that he or she will carry out the commitment is more likely to follow through.⁴¹ If a patient expresses uncertainty, the clinician can explore the problems that might be encountered in carrying out the regimen. This is best done in a nonjudgmental manner, e.g., “Many people have problems starting or continuing an exercise program; do you think you may have any problems? How will you begin?” The clinician and patient can then seek solutions for potential problems.

9. Use a combination of strategies. Educational efforts that integrate individual counseling, group classes, audiovisual aids, written materials, and community resources are more likely to be effective than those employing a single technique.⁵ Programs can be tailored to individual needs; for example, some patients will not attend group classes, and others may have inflexible work schedules. Written materials strengthen the message⁵⁰ and may be personalized by jotting pertinent comments in the margins; this will help to remind patients later of the clinician’s suggestions. The clinician should ensure that printed materials are accurate, consistent with their views, and at a reading level appropriate to their patient population. Printed materials cannot, however, substitute for verbal communication with patients. Multiple studies have demonstrated that clinicians’ individual attention and feedback are more useful than the news media or other communication channels in changing patient knowledge and behavior.⁵¹

10. Involve office staff. Patient education and counseling is a responsibility that is shared among physicians, nurses, clinical nurse specialists, health educators, dietitians, and other allied health professionals as appropriate. A team approach facilitates patient education. The receptionist can encourage patients to read materials that the clinician has reviewed, approved, and placed in the reception area. Staff members and the office environment can communicate consistent positive health messages.⁵² Forming a patient education committee can help to generate program ideas and promote staff commitment.⁵²

11. Refer. In a busy practice, it may not be possible to do complete patient education and counseling. In some situations, patients are best served by appropriate referrals. There are four major referral sources: community agencies, national voluntary health organizations such as the American Heart Association and the American Cancer Society, instructional references such as books and video tapes, and, finally, other patients. One of the best ways to change health behavior is to connect the patient with a role model, someone with the same problem who has made changes and is doing well.⁴¹ An up-to-

date, written list of specific referral sources (including name, address, and telephone number) can be prepared for each of the 10 or so most common counseling topics and given to patients who need referral. Clinicians should check the credibility and appropriateness of an agency, organization, or other references before referral.

12. Monitor progress through follow-up contact. Scheduling a follow-up appointment or telephone call within the next few weeks—to evaluate progress, reinforce successes, and identify and respond to problems—improves the effectiveness of clinician counseling.^{5,6} In one study, a monthly call to older persons with osteoarthritis reduced their reported pain and utilization of services.⁵³ A study in which calls were made to internal medicine patients between visits reduced visits by 19% and hospital days by 28%.⁵⁴ Provider-initiated contact may be more effective than patient-initiated phone calls.⁵⁵ Proactive calls (calls made by the provider to the patient) have been shown to reinforce behavior change effectively.^{56–59} It is also important for the clinician to follow up on referrals to monitor progress and support continued compliance.

Implementing Patient Counseling in the Practice Setting

As described in Chapter 1, clinicians face important barriers to implementing counseling interventions, such as insufficient reimbursement, provider uncertainty about how to counsel effectively, varying interest on the part of patient or staff, and lack of organizational/system support to facilitate the delivery of patient education. Many of these barriers are addressed by “Put Prevention into Practice” (PIPP), the Public Health Service’s prevention implementation program.⁶⁰ PIPP provides tools that can assist the provider in delivering appropriate counseling to change patients’ personal health practices every time patients are seen. Other publications also provide useful information on the effective delivery of prevention-related education and counseling.⁶¹

The clinician and public health community are faced with substantial morbidity and mortality from chronic, infectious, and traumatic conditions that are related to personal behaviors. With a large and growing body of literature demonstrating its effectiveness in promoting healthier behavior, patient education and counseling has become an increasingly important part of the delivery of clinical preventive services.

The draft update of this chapter was prepared for the U.S. Preventive Services Task Force by Kate Lorig, RN, DrPH.

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v. Cost-Effectiveness and Clinical Preventive Services

Documented effectiveness is—or generally should be—the most basic requirement for providing a health care service. It is a particularly important prerequisite for preventive services, where the clinician has a compelling responsibility to “do no harm” to healthy patients. The fundamental role of effectiveness for clinical decisions motivated the U.S. Preventive Services Task Force effort to evaluate the evidence of effectiveness for clinical preventive services, and the Task Force recommendations in the following chapters are reflections of this evidence.

Effectiveness alone, however, is not a sufficient basis to initiate services in most practical health care contexts. Factors other than effectiveness, reflecting the immediate trade-offs and broad implications of providing a service, are relevant to the goals and the practical constraints confronted by every decision maker. Chapter i describes several of these factors, and they are cited in the subsequent chapters when they are likely to be relevant to a clinician’s decision. The present chapter focuses on a single approach, cost-effectiveness analysis, that can combine information on the health benefits, health risks, and costs of health care services. Although cost-effectiveness analysis was not the basis of recommendations in this edition of the *Guide*, this chapter should alert readers that the Task Force believes such analyses should have an increasing role in individual and public policy decisions about providing preventive services as the analytic methodology matures.

Properly used, cost-effectiveness analysis incorporates and complements evidence of effectiveness to inform recommendations on clinical preventive and other health care services. It is intended not to substitute mechanically for complex decision-making processes but rather to be used in combination with other evidence. Efforts to enable cost-effectiveness analysis to be more easily, systematically, and usefully considered in policy decisions are under way. The work of the Panel on Cost-Effectiveness in Health and Medicine (PCEHM), convened in 1993, complements the work of the Task Force in the area of cost-effectiveness analysis. The PCEHM is working to standardize methodology, provide guidelines for cost-effectiveness analysis, and resolve technical differences among studies to improve their quality and comparability. The work of this group will be an important resource for those organizations formulating policy related to clinical preventive services.

Assessing the Cost-Effectiveness of Interventions

Cost-effectiveness analysis is a method for assessing and summarizing the value of a medical technology, practice, or policy.^{1,2} Underlying the methodology is the assumption that the resources available to spend on health care are constrained, whether from the societal, organizational, practitioner, or patient point of view. Cost-effectiveness information is intended to inform decisions about health care investments within this finite budget. The cost-effectiveness ratio summarizes information on cost and effect, allowing interventions to be compared on the basis of their worth and priority to the patient, society in general, or some other constituency. Although the cost-effectiveness ratio takes the form of a price—that is, a dollar cost per unit of effect—it is generally interpreted in the inverse manner, as a measure of the benefit achievable for a given level of resources.

The cost-effectiveness ratio encapsulates a defined set of information.³ The numerator of the ratio summarizes the costs and financial savings associated with the intervention, including the costs of the intervention itself, side effects, and savings from avoided illness and disability. These costs consist of both medical costs (e.g., physician visits, hospitalization, treatment) and nonmedical costs (e.g., transportation, caretaker) associated with the intervention or the illness.

The denominator of the cost-effectiveness ratio reflects the health effect of the intervention. This feature of cost-effectiveness analysis distinguishes it from cost-benefit analysis in which health benefits are translated into dollars. The year of life saved is probably the most commonly used measure of the health effect. Years of life saved may be adjusted for the quality of life of those years, reflecting the effects of medical interventions on morbidity as well as the length of life. Analyses that incorporate quality of life adjustment are sometimes categorized as “cost-utility” analyses.

The measurement, estimation, and valuation of the elements contained in a cost-effectiveness analysis is a complex undertaking. Chapter ii provides detail on the issues related to assessing the effect of interventions. The assessment of cost can be equally difficult. Issues include the management of indirect costs, such as hospital overhead; the identification of costs as distinct from charges, which often contain elements of profit or costs shifted among patients; and the generalizability of costs from one practice or region to other areas. The measurement of quality of life is also complex and has developed into a specialized field of study.⁴

Contexts for the Use of Cost-Effectiveness Analysis: Societal and Clinical

Cost-effectiveness analysis frequently takes a “societal” view in analyzing health care interventions. Although there is no single “societal” decision maker, various organizations and individuals make decisions that do or should reflect a range of societal goals. Public and private health insurance

systems, hospitals and other providers, and government advisory and regulatory bodies set policies and develop recommendations that influence or determine aspects of clinical practice.

The standard argument for the use of cost-effectiveness analysis in these contexts is the need to allocate resources efficiently, obtaining the most desirable set of services for a given budgetary outlay. This objective should be distinguished from that of saving money—a purpose often incorrectly ascribed to cost-effectiveness analysis.⁵ Although cost-effective-

gregating information related to effectiveness and cost. As noted earlier, it does not address all additional factors of interest to a decision maker. For example, neither an assessment of effectiveness nor of cost-effectiveness will address a policy's effect on the relative well-being of different socio-economic groups, so-called "distributional equity" effects.

Value. Cost-effectiveness information can be used to assess whether an intervention is a "good buy" compared to others or to some formal or informal standard. The cost-effectiveness ratio is a form of price in this sense. More technically, the incremental cost-effectiveness ratio indicates the additional quantity of resources that must be devoted to an intervention, compared to a less expensive but less effective alternative, in order to obtain a given additional benefit. It thus demonstrates the opportunity cost—the value of the foregone alternative use—of the investment.

For example, if a prostate cancer screening program is implemented, the opportunity cost incurred is the health benefit that could have been obtained had the funds been spent on a different program. Cost-effectiveness analysis summarizes the costs per unit of benefit for comparison with the alternatives, or simply for making a judgment about the overall "price" of the program's benefits.

In the clinical setting, the opportunity costs of clinicians' time and other resources are also relevant for the setting of priorities. Limits to such requisites as office space, the duration of the office visit, and the patient's ability to assimilate medical advice during a given visit are particularly evident for interventions such as counseling and patient teaching. To maximize the value of the visit to the patient, the clinician must consider the opportunity cost of various uses of the available resources and prioritize the interventions to be included.

A primary component of value is the magnitude of the benefit offered by an intervention. To be desirable, an intervention must be more than effective; its effect must be important enough to justify the risks and costs associated with it. An effective intervention may be clinically inconsequential, or it may help so few of the individuals to whom it is offered that it is not worth implementing. Cost-effectiveness analysis provides an insight to the magnitude of the benefit an intervention provides. Frequently, analyses report the magnitude of the benefit directly. In almost all cases, however, the cost-effectiveness ratio provides an indirect indication. If it imposes any meaningful cost, an intervention with minimal effectiveness will have a very high ratio of cost to effectiveness, alerting the decision maker to the need to examine the desirability of the intervention.

Aggregation of Effects. The ability of cost-effectiveness models to account for a wide range of an intervention's effects offers a particular advantage to decision makers in determining the value of a service. The full effect of

health care policy decisions is difficult to assess intuitively, involving benefits and costs that accrue to different persons or groups and occur at different times. Cost-effectiveness analysis offers a systematic approach to documenting and aggregating these effects.

Cost-Effectiveness Analysis and Recommendations for Clinical Preventive Services

Cost-effectiveness analysis has direct relevance for policies concerning clinical preventive services. An example is that of screening and vaccination to prevent the complications of rubella during pregnancy (see Chapter 32). On the basis of evidence of rubella vaccine effectiveness, the Task Force recommends screening all women of childbearing age and vaccinating susceptible women or, alternatively, routine vaccination of all women in this age group.

Should this recommendation be implemented? If so, under what protocol? Preventable rubella cases occur; an average of 7 cases of congenital rubella syndrome occurred in the U.S. each year during the 1980s, and a larger number during the rubella outbreak in the early 1990s.⁹ Screening and vaccination strategies could likely prevent some cases, although not all, in upcoming years.

From a broad perspective, the relevant issue is the opportunity cost of implementing this effort. If the resources available for health services were unlimited, there would be no opportunity cost and no reason to question the implementation of rubella vaccination for women of childbearing age. In fact, more intensive strategies than those the Task Force recommends, such as repeated vaccination of adult women, might be an even surer way of eliminating as many cases of rubella in pregnancy as possible. Because the level of health care spending by business, government, health care institutions, and individuals ultimately affects quality of life both directly and indirectly, however, it becomes necessary to assess whether the benefit of an intervention like rubella vaccination of adult women—or of one vaccination protocol versus another—is worth its cost.

On its face, the case of rubella vaccination prompts several questions related to cost-effectiveness. The total cost of fully implementing the Task Force recommendation would be significant because of the large population involved: some 60 million women aged 15 to 44. In addition, the attainable benefit is limited by the low incidence of preventable rubella in pregnancy. Childhood vaccination has already markedly decreased the overall incidence of the disease, and benefit is further limited in the case of a screening strategy by the occurrence of rubella infection in women with apparent immunity on screening.¹⁰ Finally, if a rubella vaccination policy were to be implemented, a strategy or protocol would need to be chosen. Routine vaccination is presumably more effective but may be more

costly than screening followed by selective vaccination. Would the added benefit justify the difference in cost?

Similar issues arise in considering many of the clinical preventive services discussed in this volume. The recommended screening of all persons over age 50 for colorectal cancer (see Chapter 8) would potentially add billions of dollars to health system costs and should be considered in light of the benefit it could provide.¹¹ Recommended counseling interventions for young adults would compete for time during office visits and should be prioritized in terms of their demands on practitioner and patient time and the benefit they offer. Recommended protocols—the frequency of interventions and the populations targeted to receive them—can greatly affect the outcomes and costs of an intervention and should be determined with regard for cost-effectiveness considerations.

In general, the policy questions regarding these interventions do not concern their inherent desirability. The effectiveness and risks of interventions recommended by the Task Force have been carefully evaluated. Instead, the question is whether there are likely to be other interventions that are more desirable—other uses of resources that are preferable. While the opportunity cost of a given service often is not apparent, the overall pressure of resource constraints in all domains of health care is becoming increasingly obvious. In many areas of medical technology, large additional expenditures have been shown to produce only small, marginal gains in health status or outcome at our current levels of health care technology.

Use of Cost-Effectiveness Analysis in the Absence of Data on Effectiveness

Evidence of effectiveness, although always desirable, is not always available. Research documenting effectiveness is frequently complex, time-consuming, and expensive. As a result, the effectiveness of many services remains to be established. For others, evidence of effectiveness is equivocal. Cost-effectiveness analysis cannot provide evidence of effectiveness where none exists. However, it can distinguish critical gaps in existing knowledge from questions that are less important for future research because a decision is not influenced by the existing uncertainty. Cost-effectiveness analysis can also illuminate dimensions of the trade-off between action and inaction.

For example, the Task Force has found insufficient evidence to recommend for or against providers counseling their patients to engage in physical activity (see Chapter 55). Cost-effectiveness analysis could summarize the conflicting considerations entering into a decision on this intervention, including the implications of both a decision to implement and not to implement exercise counseling.

In general, the decision to provide a service that has not been proven effective must consider the extent of potential benefit, the likelihood that the intervention is effective, and the type of evidence indicating probable effectiveness. These decisions must also weigh the costs and untoward effects of the intervention, including the societal costs of institutionalizing an unproven practice. Because of the possibility for harm and the cost, the provision of an unproven intervention to an asymptomatic and healthy population is seldom justified. When a *probably* effective intervention imposes little or no cost and is safe, its implementation may be warranted.

Cost-Effectiveness of Preventive versus Curative Services

Prevention is still commonly promoted on the basis of claims that it saves money, although screening, counseling, and other preventive services often cost more than they save, just as other medical services do. Given this tendency, efforts to document the cost-effectiveness of preventive measures may be interpreted to imply that the value of preventive services should be examined closely, while curative services are subjected to no such test.

Preventive and curative services should be held to the same basic standard of cost-effectiveness. A preventive service may be more cost-effective than many curative services and be a good use of health care funds, even if it is not as cost-effective as other preventive services.

Current Limits on Use of Cost-Effectiveness Analysis

Cost-effectiveness studies are currently available on many health care services. The weight of the cost-effectiveness evidence is convincing for a limited number of these, most of which are clearly cost-effective or clearly cost-ineffective in any realistic scenario.

A much larger group of services remains for which cost-effectiveness is not yet established. Information on costs and outcomes is inadequate for many interventions. For others, the cost-effectiveness analyses have not been done, or their quality is insufficient to provide conclusive evidence. Finally, the variation in cost-effectiveness analysis methodology often makes it difficult to take cost-effectiveness results at face value.

Decision makers today should consider cost-effectiveness results where adequate analysis has been done. Care should be taken in evaluating the methodology used. The reader should examine challenges to the study's validity, such as the choice of costs included in the analysis and the quality and representativeness of data on costs and effectiveness. In addition to providing specific information, cost-effectiveness analysis raises important questions about the opportunity costs of alternative choices that decision-makers should consider.

Cost-Effectiveness and Task Force Recommendations on Effectiveness

The Task Force recommendations in this *Guide* reflect the evidence of effectiveness of interventions. They are intended to inform clinicians about a basic and important aspect of clinical preventive services and contribute to the process of evaluating the priority of these services. The recommendations do not systematically incorporate other decision factors, such as cost-effectiveness or the ethical implications of recommendations, and therefore should not be viewed as comprehensive societal guidelines for clinical preventive services. Evidence of effectiveness should be supplemented when possible by information on cost-effectiveness in any decision-making context in which available resources can be used for multiple purposes.

The draft of this chapter was prepared for the U.S. Preventive Services Task Force by Joanna E. Siegel, ScD, and Donald M. Berwick, MD, MPP.

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