A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage

Overview of a Purchaser's Guide to Clinical Preventive Services

A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage (Purchaser's Guide) is an information source for employers on clinical preventive service benefit design. This document provides guidance for the selection of clinical preventive services shown to be effective by the U.S. Preventive Services Task Force (USPSTF), the Centers for Disease Control and Prevention (CDC), and other authoritative organizations.

The *Purchaser's Guide* builds upon the National Business Group on Health's previous publication, sponsored by the Robert Wood Johnson Foundation (RWJF) and reviewed by the Agency for Healthcare Research and Quality (AHRQ): *An Employer's Guide to Clinical Preventive Services — Improving Health. Improving Business* (referred to as the *Employer's Guide*).

The *Purchaser's Guide* provides several new and important components that will assist employers in improving coverage for clinical preventive services. Namely, the *Purchaser's Guide* includes the scientific evidence and detailed benefit language employers need to implement comprehensive and structured clinical preventive service benefits.

Below is an annotated table of contents that describes the information, resources, and tools provided in each part of the *Purchaser's Guide*.

Introduction

Provides an overview of how the *Purchaser's Guide* was developed and background on the sources of its recommendations.

1 *Part I: The Role of Clinical Preventive Services in Disease Prevention and Early Detection*

Provides information for employers on improving beneficiary health and reducing healthcare costs through the implementation of comprehensive and structured clinical preventive service benefits within a medical benefit plan.

In order to protect and promote beneficiary health and control healthcare costs, employers must provide coverage for clinical preventive services.

Within a given benefit plan, employers may select which preventive services are covered and at what level. Many preventive services are available. Some are known to be effective; others are known to be relatively ineffective or even harmful; others may be effective but the proof of effectiveness is weak. The *Purchaser's Guide* provides guidance for the selection of clinical preventive services proven to be clinically effective and of value to employers.

Part II: Summary Plan Description (SPD) Language Statements for Recommended Clinical Preventive Service Benefits

Provides 46 condition specific summary plan description (SPD) language statements designed to assist benefits staff as they design benefit structures, discuss clinical preventive services with a healthcare consultant, set coverage guidelines with a health plan, or negotiate covered services with a union or consumer group. The SPD language statements were adapted from recommendations of the U.S. Preventive Services Task Force (USPSTF), the Centers for Disease Control and Prevention (CDC), and other authoritative organizations.

Each preventive service SPD statement contains detailed benefit language regarding the:

- Necessary content of the recommended clinical preventive service.
- Age at which the service should be initiated and ceased.
- Recommended frequency of the service.

Applicable current procedural terminology (CPT) codes are provided for employers and health plans to facilitate the implementation and reimbursement of clinical preventive service benefits.

Part III: Evidence-Statements for Recommended Clinical Preventive Service Benefits

Provides evidence-statements for each of the 46 recommended clinical preventive service benefits. Each evidence-statement includes information about the:

- Prevalence and/or incidence of the condition.
- Risk factors associated with the condition.
- Economic burden of the condition and the economic benefit of early identification/intervention.
- Cost-benefit/cost-effectiveness of the recommended intervention.
- Cost of the recommended preventive intervention.
- Purpose of the preventive intervention.
- Benefits and risks of the preventive intervention.

Part IV: The Prioritization and Strategic Implementation of Clinical Preventive Service Benefits

Provides practical "how-to" information on the development and implementation of structured clinical preventive service benefits. Real-world examples of each prioritization method are provided.

Part V: I Statements and C and D Recommendations and of the U.S. Preventive Services Task Force (USPSTF)

Provides information on clinical preventive services that were reviewed by the USPSTF, but were not included in the *Purchaser's Guide* because the USPSTF:

1. Found that there was insufficient evidence to make a recommendation either for or against providing the service (I statement);

2. Made no recommendation regarding the provision of the service based on an analysis of evidence of effectiveness, benefits, and harms (C recommendation); or
3. Recommended against routine provision of the service for asymptomatic patients based on an analysis of the evidence of effectiveness, benefits, and harms (D recommendation).

This information may assist benefits staff in determining which clinical preventive services currently offered in their health plan(s) should be re-evaluated and, possibly, eliminated.

Part VI: Leveraging Benefits: Opportunities to Promote the Delivery and Use of Preventive Services

The *Purchaser's Guide* is designed to help employers select and implement clinical preventive services that are delivered by healthcare providers. Employers can strengthen prevention efforts by supporting public health interventions that may occur in the workplace or communities. Part VI provides information and tips for employers on promoting the delivery and use of clinical and community-based preventive services, including:

- An overview of the *Community Guide to Preventive Services*.
- A crosswalk between the recommendations proposed in the *Purchaser's Guide* and the *Community Guide*.
- Case examples of large employers who have successfully implemented worksite health promotion programs and/or supported community-based interventions.

Part VII: Resources & Tools

Provides additional information and resources on clinical preventive service benefit design, including:

- The Life Course Charts — visual guides to clinical preventive services across the lifespan
  - > Recommended Schedule of Preventive Care for Adults
  - > Recommended Schedule of Preventive Care for Children and Adolescents
  - > Recommended Schedule of Preventive Preconception, Prenatal, and Postpartum Care
- A crosswalk between the *Purchaser's Guide*, the U.S. Preventive Services Task Force's A/B recommendations, the 2007 HEDIS® Measures, the NCQA State of Healthcare Quality Report, and the U.S. Department of Health and Human Service's *Healthy People 2010* Goals.
- Clinical Preventive Services Glossary
- Links to additional resources and cost-calculators.
- A CD containing PDF versions of all the materials included in the *Purchaser's Guide*.

An Introduction to A *Purchaser's Guide* to Clinical Preventive Services

Clinical Preventive Service Topic Selection

The clinical preventive services recommended for coverage in the *Purchaser's Guide* were selected by the National Business Group on Health with the technical assistance of experts from two federal agencies, the Centers for Disease Control and Prevention (CDC) and the Agency for Healthcare Research and Quality (AHRQ).

The *Purchaser's Guide* coverage recommendations are mainly based on the U.S. Preventive Services Task Force (USPSTF) recommendations on clinical preventive services for the general asymptomatic population. The USPSTF, sponsored by the Agency for Healthcare Research and Quality (AHRQ) (part of the U.S. Department of Health and Human Services), is an independent panel of experts in primary care and prevention that makes recommendations regarding clinical preventive services after a careful review of the scientific literature. The *Purchaser's Guide* includes all of the USPSTF "A" and "B"-rated recommendations published before March 2006.

The *Purchaser's Guide* also includes clinical preventive service recommendations from other recognized sources such as the Centers for Disease Control and Prevention (CDC); other Federal agencies such as the National Health, Lung, and Blood Institute (NHLBI), a division of the National Institutes of Health (NIH); and professional organizations such as the American Academy of Pediatrics (AAP).

Recommendations from sources other than the USPSTF were added to support USPSTF recommendations, or inserted in place of a USPSTF recommendation, when:

1. No current USPSTF recommendation was available (e.g., screening for elevated blood lead levels); or
2. When a newer recommendation superseded the existing USPSTF recommendation (e.g., lipids screening).

In order to be included in the *Purchaser's Guide*, clinical preventive service recommendations were required to meet the following criteria:

1. Be based on medical evidence or recommended guidance.
2. Address a serious health threat in terms of morbidity (illness), mortality (death), or quality of life (including risk of disability).
3. Address a condition that results in substantial direct (e.g., treatment costs) or indirect costs (e.g., absenteeism, lost productivity) for payers.

Forty-six (46) services met the inclusion criteria outlined on the previous page. These services are discussed in further detail in *Part II: Summary Plan Description (SPD) Language Statements for Recommended Clinical Preventive Service Benefits and Part III: Evidence-Statements for Recommended Clinical Preventive Service Benefits*.

The evidence for clinical preventive services is growing. Purchasers are encouraged to periodically check the U.S. Preventive Services Task Force (USPSTF) website (www.ahrq.gov/clinic/uspstfix.htm) for up-to-date recommendations on clinical preventive services.

Figure A: Sources of Information Used in the *Purchaser's Guide*

- Advisory Committee on Childhood Lead Poisoning Prevention (ACCLP)
- Advisory Committee on Immunization Practices (ACIP)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Alliance for Cervical Cancer Prevention; Program for the Appropriate use of Technology in Health (PATH)
- American Academy of Audiology
- American Academy of Bariatric Surgery
- American Academy of Family Physicians (AAFP)
- American Academy of Neurology
- American Academy of Pediatric Dentistry (AAPD)
- American Academy of Pediatrics (AAP)
- American Association of Clinical Endocrinologists (AACE)
- American Cancer Society (ACS)
- American College of Cardiology
- American College of Emergency Physicians (ACEP)
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Preventive Medicine (ACPM)
- American College of Surgeons (ACS)
- American Dental Association (ADA)
- American Diabetes Association (ADA)
- American Heart Association (AHA)
- American Medical Association (AMA)
- American Psychological Association (APA)
- American Society of Addiction Medicine (ASAM)
- American Society of Clinical Oncology (ASCO)
- American Speech, Language, and Hearing Association
- Center for Medicare & Medicaid Services (CMS)
- Centers for Disease Control and Prevention (CDC)
- Committee on Educational Interventions for Children with Autism, National Research Council, National Academies
- Directors of Speech and Hearing Programs in State Health and Welfare Agencies
- Employee Benefits Institute
- Food and Drug Administration (FDA)
- George Washington University, Center for Health Services Research and Policy
- Harvard Medical School

Figure A: Sources of Information Used in the *Purchaser's Guide* (Continued)

- Health Resources and Services Administration (HRSA)
- *Healthy People 2010*, U.S. Department of Health and Human Services
- Institute of Medicine (IOM)
- Internal Revenue Service (IRS), Department of Treasury
- International Agency for Research on Cancer (IARC)
- Jacobs Institute of Women's Health (JIWH)
- Joint Committee on Infant Hearing (JCIH)
- Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
- March of Dimes
- Maternal Child Health Bureau (MCHB)
- National Academy of Sciences (NAS)
- National Academy of Sciences, Institute of Medicine (IOM)
- National Association of Pediatric Nurse Practitioners (NAPNAP)
- National Business Group on Health
- National Cancer Institute (NCI)
- National Center for Education in Maternal and Child Health
- National Center for Health Statistics (NCHS)
- National Center for Hearing Assessment and Management (NCHAM)
- National Center for Injury Prevention and Control
- National Cholesterol Education Program (NCEP)
- National Cholesterol Education Program Adult Treatment Expert Panel-III
- National Health and Nutrition Examination Survey (NHANES)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Highway Traffic Safety Administration (NHTSA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institutes of Health (NIH)
- National Institutes of Mental Health (NIMH)
- National March of Dimes Birth Defects Foundation
- National Osteoporosis Foundation (NOF)
- National Research Council, Committee on Educational Interventions for Children with Autism, Division of Behavioral and Social Sciences and Education
- Partnership for Prevention
- Peer-reviewed research
- Preeclampsia Foundation
- Royal College of Obstetricians and Gynecologists
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- U.S. Department of Agriculture (USDA)
- U.S. Department of Health and Human Services (USDHHS)
- U.S. Department of Transportation (DOT)
- U.S. Environmental Protection Agency (EPA)
- U.S. Preventive Services Task Force (USPSTF)
- U.S. Public Health Service (USPHS)
- U.S. Surgeon General
- World Health Organization (WHO)

The Evidence for Clinical Preventive Services

All of the recommendations in the *Purchaser's Guide* are based on science.

The U.S. Preventive Services Task Force (USPSTF)

Most of the recommendations featured in the *Purchaser's Guide* were adapted from the U.S. Preventive Services Task Force (USPSTF). The USPSTF is recognized as the gold-standard in clinical preventive service recommendations; it is an independent panel of experts in primary care and prevention that conducts rigorous, impartial assessments of the scientific evidence for the effectiveness of clinical preventive services.[1]

The USPSTF is mandated by Congress to evaluate preventive services and publishes recommendations and evidence synthesis, which are the culmination of an extensive literature review, debate, and analysis of critical comments from expert reviewers.[1] USPSTF recommendations are based on an objective process that weighs the benefits and the harms of a preventive service. Each recommendation is given a letter grade (A-D, I) based on the strength of evidence available to support the particular clinical preventive service and the magnitude of net benefit for that service. The net benefit of a clinical preventive service is defined as the benefits of the service (e.g., years of life saved through early cancer detection) minus the harms of the service (e.g., risks associated with false-positive test results).

By definition, the foundational source of USPSTF recommendations is research published in peer review journals. USPSTF recommendations are therefore limited to clinical preventive services that have been systematically studied and published. Services that are commonly provided in clinical practice but have not been well-studied or have been poorly documented in the literature may not be reviewed. For instance, some interventions have not been systematically studied due to ethical concerns (e.g., withholding treatment) or lack of funding for research. In other cases, evidence exists but it is conflicting. These interventions are given an "I" rating ("I" for insufficient evidence) by the USPSTF.

THE USPSTF publishes the annual *Guide to Clinical Preventive Services,* which includes abridged versions of the USPSTF's recommendations on screening, counseling, and preventive medication presented in a user friendly format for clinicians. The complete USPSTF recommendations and reviews are available on the web and provide information about which clinical preventive services should be delivered by prudent clinicians in the course of routine clinical care. For more information on the USPSTF please visit: www.ahrq.gov/clinic/prevenix.htm

Evidence-Based Recommendations, Evidence-Based Medicine, and Evidence-Based Benefits

Many of the clinical preventive service recommendations presented in the *Purchaser's Guide* are evidence-based. Evidence-based services have a longer and stronger base of research to support their efficacy, safety, and cost-effectiveness. Generally, the term "evidence-based" refers to medical interventions that scientific studies have evaluated and determined to be effective and to have a measurable effect on health outcomes.

All of the recommendations derived from the USPSTF are evidence-based. Other recommendations featured in the *Purchaser's Guide* are based on "recommended guidance." Recommended guidance is based on the best-available information for a given topic, but lacks the scientific research support needed to be considered evidence-based.

There is strong scientific evidence to support the provision of a broad range of clinical preventive services for normal-risk children, adolescents, and adults.

Definition Box B: Evidence

Evidence-based medicine: Two common definitions of evidence-based medicine include the following:

1. "Evidence-based medicine is the conscientious, explicit, and judicious use of current best-evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research."[2]

2. Evidence-based recommendations require, "First, good evidence that each test or procedure recommended is medically effective in reducing morbidity or mortality; second, the medical benefits must outweigh the risks; third, the cost of each test or procedure must be reasonable compared to its expected benefits; and finally, the recommended actions must be practical and feasible."[2] *[Note: The USPSTF does not consider cost as a factor in its recommendations.]*

Recommended guidance: A recommendation or guideline that is based on the best available information for a condition, disease, or health service, but that does not yet have the scientific research support in order to be considered evidence-based (as determined by a systematic review process). Expert opinion, expert judgment, and consensus opinion, are considered forms of recommended guidance.

Evidence-based benefit design: Aims to promote healthcare with demonstrated effectiveness by providing "…more generous coverage for services supported by strong evidence of effectiveness and less generous coverage for services that are unproven or evidence indicates may be ineffective or unsafe, given patient characteristics and history."[3]

To make the sources, types, and strength of scientific evidence used in the *Purchaser's Guide* fully transparent, each evidence-statement featured in *Part III: Evidence-Statements for Recommended Clinical Preventive Service Benefits* contains an evidence-box as a summary.

Each evidence-box contains the following information:

- A description of where the information used in the recommendation originated from (e.g., the American Academy of Family Physicians (AAFP), CDC, or the USPSTF).

- The level of evidence used in constructing the recommendation:
  - > Evidence-based research
  - > Recommended guidance
- The strength of the evidence. For example, the USPSTF grades each of its clinical preventive service recommendations on a 5-point scale (A-D, I). The grade is determined by the strength of scientific evidence supporting a clinical preventive service and the magnitude of net benefit (defined as benefits minus harms).[4]

Figure C: Sample Evidence-Boxes

Strength of Evidence for the Clinical Preventive Service (Colorectal Cancer Screening)
The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found fair to good evidence that several screening methods are effective in reducing mortality from colorectal cancer. The USPSTF concluded that the benefits from screening substantially outweigh potential harms, but the quality of evidence, magnitude of benefit, and potential harms vary with each method.

Strength of Evidence for the Clinical Preventive Service (Immunizations)
The level of evidence supporting the recommendations contained in this chapter is described below

Recommended Guidance:

Advisory Committee on Immunization Practices (ACIP)
Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Expert Consensus

- The ACIP and CDC recommend that all children and adolescents with no contraindications receive all routinely recommended childhood vaccinations. Children and adolescents who fall into high-risk groups because of health conditions, behaviors, or membership in certain communities should receive additional immunizations.
- The ACIP and CDC recommend that all adults with no contraindications receive three routinely recommended vaccines (age-dependent). Adults who fall into high-risk groups because of health conditions, behaviors or exposures, as well as those without a history of immunization for certain diseases, should receive additional immunizations.

Figure D: U.S. Preventive Services Task Force (USPSTF) Strength of Evidence Scale[5]

A *Strongly Recommended*
The USPSTF strongly recommends that clinicians provide the service to eligible patients. The USPSTF found good evidence that the service improves important health outcomes and concludes that the benefits substantially outweigh harms.

B *Recommended*
The USPSTF recommends that clinicians provide the service to eligible patients. The USPSTF found at least fair evidence that the service improves important health outcomes and concludes that the benefits outweigh harms.

C *No Recommendation Either For or Against*
The USPSTF makes no recommendation either for or against routine provision of the service. The USPSTF found at least fair evidence that the service can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D *Recommend Against*
The USPSTF recommends against routinely providing the service to asymptomatic patients. The USPSTF found at least fair evidence that the service is ineffective or that the harms associated with the service outweigh benefits

I *Insufficient Evidence in Order to Make a Recommendation*
The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing the service. Evidence that the service is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Figure E: American Academy of Family Physicians (AAFP) Strength of Evidence Scale[6]

SR *Strongly Recommended*
Good quality evidence exists which demonstrates substantial net benefit over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.

R *Recommended*
Although evidence exists which demonstrates net benefit, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost-effective and acceptable to most patients.

NR *No Recommendation Either Either For or Against*
Either good or fair evidence exist of at least a small net benefit. Cost-effectiveness may not be known or patients may be divided about acceptability of the intervention.

RA *Recommend Against*
Good or fair evidence exist which demonstrates no net benefit over harm.

I *Insufficient Evidence to Recommend Either For or Against*
No evidence of even fair quality exists or the existing evidence is conflicting.

IHB Healthy behavior is identified as desirable, but the effectiveness of physician's advice and counseling is uncertain.

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1 The Role of Clinical Preventive Services in Disease Prevention and Early Detection

Overview:
Information for employers on improving beneficiary health and reducing healthcare costs through the implementation of comprehensive and structured clinical preventive service benefits within a medical benefit plan. Sections include:

- Promoting Health and Reducing Costs
- The Importance of Preventing Chronic Disease
- The Value of Prevention: Cost-Effective, Cost-Saving, and High-Value Clinical Preventive Services
- Promoting Effective Clinical Preventive Services

1 The Role of Clinical Preventive Services in Disease Prevention and Early Detection

Clinical Preventive Services: Preventing Disease, Promoting Health, and Reducing Healthcare Costs

The goals of prevention are to:

- Encourage individuals to avoid or delay disease by practicing healthy lifestyles;
- Identify individuals who could benefit from treatment for a condition or complication about which they are unaware; and
- Prevent further disability among individuals with established disease.

There are three types of prevention: primary prevention, secondary prevention, and tertiary prevention. *Primary prevention* is the prevention of a disease before it occurs; *secondary prevention* is the early detection and treatment of disease to prevent progression; and *tertiary prevention* is an intervention to reduce the amount of disability caused by a disease.[1-2]

Definition Box 1.0: Prevention

Prevention Helps Individuals Avoid Disease

Primary prevention is aimed at preventing the onset of disease. One way of doing this is by controlling risk factors in healthy people that may lead to disease. Examples of primary prevention include 1) immunizations to prevent communicable diseases such as influenza or polio, and 2) the promotion of physical activity to prevent conditions such as obesity that can lead to disease (e.g., type 2 diabetes).

Prevention Modifies Risk

Secondary prevention is aimed at treating a disease after its onset, but before it causes serious complications. Secondary prevention includes 1) identifying individuals with established disease, and 2) treating those individuals in a timely way so as to prevent further problems (e.g., mammography screening to detect and treat breast cancer in its earliest stages).

Prevention Reduces Disability

Tertiary prevention is aimed at treating the late or final stages of a disease so as to minimize the degree of disability caused by that disease (e.g., administering a foot check to a person with diabetes to identify infections that would require amputation if left untreated).[1-2]

There are several different approaches to providing preventive services:

Clinical preventive services, the focus of this guide, include those services that are typically performed in a clinical setting and are conducted by a health professional such as a physician, nurse practitioner, physician assistant, or health educator. Although most clinical preventive services should be conducted during individual face-to-face office visits, some services may be conducted in groups, via the telephone, or by email communication.

Community-based preventive services (also known as population-based preventive services) include any kind of planned activity or group of activities (including programs, policies, and laws) designed to prevent disease or injury or promote health in a group of people (e.g., fluoridation of drinking water, bans on tobacco use in public places).[3]

Worksite-based preventive services are health promotion programs provided to employees and their dependents. The expressed purpose of these services is to improve employee health and prevent disease by providing an opportunity for employees to engage in primary prevention activities. Examples include:

- Employer-sponsored worksite fitness centers or healthy cafeteria programs that encourage healthy lifestyles.
- Employer-sponsored health risk appraisals (HRAs) that identify employees at risk for certain conditions and diseases (e.g., type 2 diabetes, heart disease, or hypertension) and refer those employees to their health plan for continuing care.
- Employer-sponsored services such as employee assistance programs (EAPs) that can help employees address health / lifestyle concerns, such as stress or substance use, before the problems escalate into a clinical disorder (e.g., substance abuse, depression).
- Employer-initiated worksite smoking bans.
- Employer-sponsored worksite influenza immunization clinics.

Preventive Interventions

There are several types of preventive interventions: screening, testing, counseling, immunization, preventive medication, and preventive treatment.

- ***Screening*** is best described as tests that assess the likelihood of the presence of a disease or condition in an apparently healthy individual. Screening methods include laboratory, X-ray, and similar technical methods; they also include questions asked by a clinician. Screening may be targeted to people at increased risk due to age, gender, family or personal history, or other factors. Each screening tool is different in design and method, affecting the sensitivity (ability to correctly identify those with the disease), specificity (ability to correctly identify those without the disease), and positive and negative predictive values of the tool. Ideally, screening tests are rapid, simple, and safe. It is important to note that, in most instances, screening is not a definitive diagnostic test and that a positive result on a screening test merely indicates that the screened individual has a higher likelihood of having the disease than a peer with a negative result. Individuals who screen positive on such tests should have confirmatory diagnostic tests to ensure an accurate diagnosis.[4]

- ***Testing*** refers to any process used to determine whether a condition is present (or not) or to assess the status of a condition. Testing may involve questioning patients (e.g., a mental status examination to determine whether thought processes are appropriate), physical examination (e.g., examining a heart to detect a murmur or performing a neurologic examination to detect nerve damage), or examining blood, body fluids, or tissues (e.g., to detect anemia, to monitor levels of blood sugar, or to see if a cancer is present in a biopsy sample). Testing may also require sophisticated technology, such as CT or MRI scans and other X-rays, or invasive procedures, such as heart catheterization to detect blockage of coronary arteries. Tests may be used to:
  - Screen individuals who have risk factors, but no indication of having the condition;
  - Diagnose individuals who have symptoms and signs of a condition but where a test will add certainty about the diagnosis; or
  - Monitor the progress of an individual who is being treated or being considered for treatment, such as monitoring blood pressure over time.
- ***Counseling*** refers to a discussion between a clinician and patient about ways that changes in personal behavior can reduce risk of illness or injury. The goal of counseling is for clinicians to educate patients about their health risks as well as to provide them with the skills, motivation, and knowledge they need to address their risk behaviors (e.g., 5A framework for tobacco cessation: Ask, Advise, Assess, Assist, Arrange). A special kind of counseling, "informed decision making," recognizes that people make different decisions even though their situations may seem to be similar. Informed decision making is structured to give an individual all the information needed to choose among different clinical options, such as whether or not to undergo genetic testing.
- ***Immunization*** protects an individual from a specific communicable disease (e.g., measles) by exposing the individual to an antigen or a trace amount of inactivated disease-causing agent, spurring the development of natural immunity.
- ***Preventive Medications*** are used to prevent the onset of disease (e.g., aspirin therapy to prevent cardiovascular events).
- ***Preventive Treatment*** involves a procedure intended to prevent the occurrence of a disease or to prevent the progression of a disease from one stage to another. Preventive treatments usually refer to the use of prescription or over-the-counter (OTC) medications, but they may also involve prescriptions for lifestyle changes (e.g., exercise, diet change) or other interventions. Some surgical procedures may be considered "preventive treatment," such as when polyps in the colon identified during a screening colonoscopy are removed in order to prevent their progression to cancer lesions.

In 2005, NCQA identified 44.5 million sick days due to suboptimal care for hypertension and diabetes, two preventable chronic diseases. The lost productivity associated with these disorders exceeded $7 billion.[6]

The Importance of Preventing Chronic Disease

Chronic diseases result in a significant amount of preventable morbidity and mortality in the United States. In 2000, 46.7% of all deaths in the United States were caused by modifiable health behaviors (see Table 1.1).[5] The U.S. Department of Health and Human Services estimates that approximately 33% of all deaths in the United States are attributable to just three modifiable health behaviors: smoking, physical inactivity, and poor eating habits.[2]

Chronic diseases are the leading cause of direct healthcare costs. In fact, researchers estimate that 75% of all healthcare costs directly stem from preventable chronic health conditions such as type 2 diabetes, hypertension, and obesity.[7-8] Chronic diseases are also a major cause of lost productivity and disability. For example:

Researchers estimate that 75% of all healthcare costs directly stem from preventable chronic health conditions, yet only 1% of the $1.9 trillion dollars spent on health care in the United States is devoted to protecting health and preventing illness and injury.[7-8]

- In 2002, the average annual healthcare cost for a person with diabetes was $13,243 as opposed to $2,560 for a person without diabetes.[9]
- It is estimated that the indirect cost of cardiovascular disease will total over $145 billion in 2006.[10]
- Each year, an estimated 39 million work days are lost to obesity-related illnesses.[11]
- In 1999, lost productivity due to smoking, and smoking-related illnesses cost employers $1,897 per smoking employee.[12] Excess medical expenses due to smoking and smoking related illnesses cost employers $1,850 per smoking employee (both figures adjusted to year 2002 dollars).[12]

Each individual's health is shaped by many factors including medical care, social circumstances, and behavioral choices. Increasingly, there is clear evidence that the major chronic conditions that account for so much of the morbidity and mortality in the United States, and the enormous direct and indirect costs associated with them, in large part are preventable — and that to a considerable degree they stem from, and are exacerbated by, individual behaviors….. As Americans see healthcare expenditures continue to increase, it is important to focus on strategies that reduce the prevalence and cost of preventable diseases.[5]

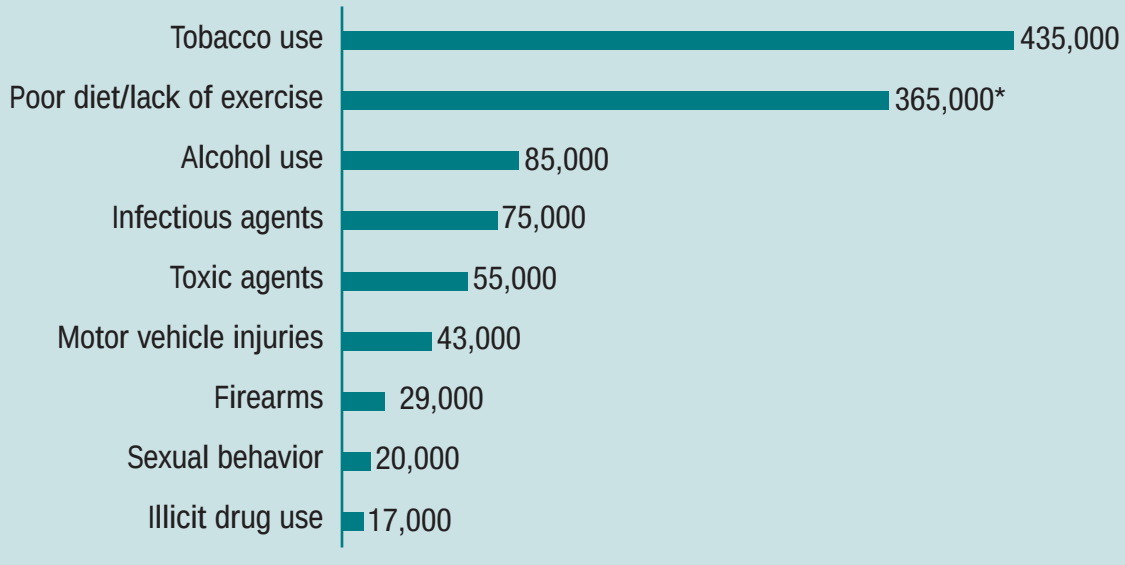
– U.S. Department of Health and Human Services, 2003
Prevention Makes Common "Cents"

Table 1.1: Percent of all Deaths in the United States Attributable to Selected Modifiable Health Behaviors, 1990-2000[13]

HEALTH BEHAVIOR	PERCENT OF DEATHS, 1990	PERCENT OF DEATHS, 2000
Tobacco use	19%	18.1%
Poor diet/physical inactivity	14%	15.2%*
Alcohol use	5%	3.5%
Infectious agents	4%	3.1%
Toxic agents	3%	2.3%
Motor vehicle injuries	1%	1.8%
Firearms	2%	1.2%
Sexual behavior	1%	0.8%
Illicit drug use	<1%	0.7%
TOTAL	**50%**	**46.7%**

Source: Mokdad A, Marks JS, Stroup DE, Gerberding JL. Actual causes of death in the United States. JAMA 2004; 291(10): 1238-1245. * Correction published: Mokdad A, Marks JS, Stroup DE, Gerberding JL. Correction: Actual causes of death in the United States 2000. JAMA 2005; 293(3): 293-294.

Figure 1.2: Underlying Causes of Death in the United States, 2000[13]



Source: Mokdad A, Marks JS, Stroup DE, Gerberding JL. Actual causes of death in the United States. JAMA 2004; 291(10): 1238-1245.* Correction published: Mokdad A, Marks JS, Stroup DE, Gerberding JL. Correction: Actual causes of death in the United States 2000. JAMA 2005; 293(3): 293-294.

The Value of Prevention

Purchasers can avoid or reduce the costs associated with preventable conditions by offering coverage for — and promoting the use of — clinical preventive services.

- Clinical preventive services can help individuals avoid disease altogether (e.g., tobacco use treatment).
- Clinical preventive services can also catch disease it in its earliest stages (e.g., cervical cancer screening). Identifying patients with early stage disease allows clinicians to begin treatment sooner, when interventions are generally more effective and less expensive. Early detection and treatment of some important infectious diseases can also prevent spread of infection to others (e.g., influenza).
- Disease avoidance and early identification have financial benefits for employers including:
  - > Averted medical costs; and
  - > Reductions in absenteeism, lost productivity, turnover, and disability.

Research shows that employees who take advantage of preventive services have lower absenteeism, higher productivity, and a stronger commitment to their employer.[14]

Like any investment aimed at keeping a workforce healthy and productive, clinical preventive services offer value. The value of a preventive service is determined by its ability to prevent a significant amount of morbidity and mortality in relation to the cost of offering the service. Because offering a clinical preventive service has a real (monetary) cost and an opportunity cost (there is a finite amount of services that can be delivered and received in a given period of time), it is important for purchasers to quantify the value of clinical preventive services in relation to one another when making coverage decisions.

The effectiveness of most clinical preventive services, particularly those considered evidence-based, is well-documented. The effectiveness of clinical preventive services recommended in the *Purchaser's Guide* is detailed in *Part III: Evidence-Statements for Recommended Clinical Preventive Service Benefits*. The cost-effectiveness (or economic value) of clinical preventive services is described below. More information on the economic value of preventive intervention can be found in each evidence-statement.

Examples of Avoided Costs

The average dollar spent on:

- Alcohol misuse screening and brief counseling interventions saves $4 in healthcare costs.[15-16]
- The Hib vaccine (to prevent invasive bacterial infections) saves $1.40 in direct medical costs and $2.00 in indirect costs.[17]
- The hepatitis B vaccine saves 50 cents in direct medical costs and $3.10 in indirect costs.[17]
- The varicella vaccine (to prevent chickenpox) saves 90 cents in direct medical costs and $5.40 in indirect costs.[17]
- Chlamydia testing and treatment saves $12 in complications arising from chlamydia.[17]

For more information on defining the value of preventive services and prioritizing services for inclusion in a medical benefit plan, please refer to ***Part IV: The Prioritization and Strategic Implementation of Clinical Preventive Service Benefits.***

Cost-Saving Clinical Preventive Services

A health intervention is cost-saving when the intervention is 1) effective and 2) costs less in the long run than the cost of not intervening. For example, the cost of vaccinating all children in a given population against measles is less than the cost of treating the children who would contract measles without the population-wide protection of immunization.

Cost-Effective Clinical Preventive Services

A medical intervention is considered cost-effective when the intervention provides a health benefit at an acceptable cost. The term "acceptable cost" is not precisely defined and involves important ethical considerations such as the value of a life. The answer to this question boils down to a concept called "willingness-to-pay": for example, how much is an individual, an employer, or a society willing to pay to extend the life of one individual for one year? Some conditions produce life- and work-altering disability, but not premature death. Economists can use willingness-to-pay methods to assess the cost-effectiveness of methods to prevent or modify disabilities as well. In the United States, there is no universally accepted answer to the "willingness-to-pay" question and, thus, no universally accepted threshold that distinguishes a cost-effective health intervention from an intervention that is not cost-effective.

In order to compare and rank various preventive interventions, economists use cost-effectiveness (CE) ratios. A CE ratio is calculated as the ratio of differences in costs and outcomes of the status quo and the proposed intervention according to the following formula:

$$\text{Cost-effectiveness ratio} = \frac{\text{(Cost with intervention – Cost without intervention)}}{\text{(Outcome with intervention – Outcome without intervention)}}$$

A CE ratio can be interpreted as the "price" of accepting a new intervention. The lower the price, the more cost-effective the new intervention.

Definition Box 1.3: Health Economics Terms

Health economists use several terms to explain the cost, benefit, and overall value of a clinical preventive service. The following terms are used throughout the *Purchaser's Guide* to describe the economic benefits of clinical preventive services.

Cost-saving: The reduction in healthcare costs resulting from the intervention or program exceeds the money required to develop, implement, and maintain the respective intervention or program.

Cost-effective: The net cost per unit of health generated is favorable relative to other health services.

High-value: An intervention that prevents a substantial amount of morbidity and/or mortality and is cost-effective.

Quality Adjusted Life Years (QALY)

Outcomes in cost-effectiveness analysis (CEA) are usually measured in terms of number of life years saved as a result of implementation of a new intervention. For interventions with multiple health endpoints (e.g., hospitalization, treatment, death, etc) an outcome measure needs to combine information on both morbidity (a measure of clinical illness) and mortality (the number of deaths in the population under consideration). The best known of these is the quality-adjusted life year or QALY. In principle, QALYs are based on the preferences or "utilities" of respondents reflecting tradeoffs among different health states (e.g., total cure, partial cure, disability, death). A preference or utility weight or score of 1.0 represents perfect health and 0 represents death. The number of QALYs is calculated as the sum of the duration spent in each health state times the utility weight for that health state. For example, if the utility weight for a chronic condition is 0.6, and an individual remains in that health state for 1 year and then dies, the number of QALYs is 0.6. QALYs provide a common currency that permits comparisons among different people and across different kinds of conditions. QALYs permit comparisons of diseases that are rapidly fatal with those that do not produce death but instead produce years of severe disability.

The results of a CEA may be interpreted to determine whether an intervention yields good value for the investment. An intervention can be considered more or less cost-effective relative to either another intervention or to a benchmark value. Cost-effectiveness (CE) ratios are usually expressed in dollars per QALY. The lower the number, the more cost-effective the intervention.

It is commonly said that an intervention that costs more than $50,000 or $100,000 per QALY is not cost-effective, but a substantial number of healthcare interventions generally accepted in the United States have higher CE ratios.[18] The use of a fixed cost-effectiveness threshold to define cost effectiveness ignores other determinants of social value such as perceptions of risk. Further, the Partnership for Prevention has estimated ranges of CE ratios using standardized methods for 25 clinical preventive services recommended for the general population by the U.S. Preventive Services Task Force (USPSTF).[19] The investigators used a utility weight of 0.7 for chronic conditions, along with other simplifying assumptions that make the results difficult to compare with the published CE ratios from studies that are reported in the *Purchaser's Guide*. The investigators found that one-fifth of all recommended clinical preventive services had CE ratios between $165,000 and $450,000 per QALY in year 2000 dollars.

High-Value Clinical Preventive Services

Many preventive services are considered to be of high-value, meaning they are both cost-effective (they cost a "reasonable" amount of money for the added quality of life or life years gained) and prevent a substantial proportion of disease or injury when delivered appropriately. The National Commission on Prevention Priorities (NCPP), a blue-ribbon panel of thought-leaders on prevention chaired by former Surgeon General Dr. David Satcher and staffed by Partnership for Prevention, recently ranked the health impact and cost-effectiveness of 25 preventive services recommended by the U.S. Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices (ACIP). Please refer to *Part IV: The Prioritization of Clinical Preventive Services in a Strategic Implementation Plan* for more information.

Table 1.4: Cost-Effectiveness Gradient Based on Partnership for Prevention's Ranking of Clinical Preventive Services Targeted to Working Age Adults[19]

HIGH-VALUE CLINICAL PREVENTIVE SERVICE	AS NOTED IN THE *PURCHASER'S GUIDE*	DESCRIPTION
CE RATIO < $0/QALY (Defined as Cost-Saving)		
Aspirin Chemoprophylaxis	Aspirin Therapy for the Prevention of Cardiovascular Disease, *Counseling*	Discuss the benefits/harms of daily aspirin use for the prevention of cardiovascular events with men ≥ 40, women ≥ 50, and others at increased risk.
Tobacco Use Screening and Brief Intervention	Tobacco Use Treatment, *Screening, counseling, and treatment*	Screen adults for tobacco use, provide brief counseling, and offer pharmacotherapy.
$0/QALY ≤ CE RATIO < $14,000/QALY		
Colorectal Cancer Screening	Colorectal Cancer, *Screening*	Screen adults aged ≥ 50 years routinely with FOBT, sigmoidoscopy, or colonoscopy.
Influenza Immunization	Immunizations (Child, Adolescent, Adult)	Immunize adults aged ≥ 50 against influenza annually.
Problem Drinking Screening and Brief Counseling	Alcohol Misuse, *Screening and counseling*	Screen adults routinely to identify those whose alcohol use places them at increased risk and provide brief counseling with follow-up.
$14,000/QALY ≤ CE RATIO < $35,000/QALY		
Hypertension Screening	Hypertension, *Screening, counseling, and treatment*	Measure blood pressure routinely in all adults and treat with antihypertensive medication to prevent incidence of cardiovascular disease.
Cervical Cancer Screening	Cervical Cancer, *Screening*	Screen women who have been sexually active and have a cervix within 3 years of onset of sexual activity or age 21 routinely with cervical cytology (Pap smears).
Calcium Chemoprophylaxis	Not included in the *Purchaser's Guide*	Counsel adolescent and adult women to use calcium supplements to prevent fractures.
$35,000/QALY ≤ CE RATIO < $165,000/QALY		
Cholesterol Screening	Lipid Disorders, *Screening, counseling, and treatment*	Routinely screen for lipid disorders among men aged ≥ 35 and women aged ≥ 45 and treat with lipid-lowering drugs to prevent the incidence of cardiovascular disease.
Breast Cancer Screening	Breast Cancer, *Screening*	Screen women aged ≥ 50 routinely with mammography alone or with clinical breast examination, and discuss screening with women aged 40 to 49 to choose an age to initiate screening.

Table 1.4: *(Continued)*

HIGH-VALUE CLINICAL PREVENTIVE SERVICE	AS NOTED IN THE *PURCHASER'S GUIDE*	DESCRIPTION
Obesity Screening	Obesity, *Screening, counseling, and treatment*	Screen all adult patients routinely for obesity and offer obese patients high-intensity counseling about diet, exercise, or both together with behavioral interventions for at least 1 year.
$165,000/QALY ≤ CE RATIO < $450,000/QALY		
Depression Screening	Depression, *Screening*	Screen adults for depression in clinical practices that have systems in place to assure accurate diagnosis, treatment, and follow-up.
Diabetes Screening	Diabetes (type 2), *Screening*	Screen for diabetes in adults with high cholesterol or hypertension, and treat with a goal of lowering levels below conventional target values.
Diet Counseling	Healthy Diet, *Counseling*	Offer intensive behavioral dietary counseling to adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease.
Tetanus-Diphtheria Booster	Immunizations (Child, Adolescent, Adult)	Immunize adults every 10 years.

Source: Maciosek MV, Coffield AB, et al. Priorities among effective clinical preventive services: results of a systematic review and analysis. Am J Prev Med 2006;31(1): 55-6.

Relevance to Business

While economic analyses of cost-effectiveness focus on the overall costs and benefits to society and the healthcare system, business case analyses of the value of clinical preventive services estimate the financial return-on-investment (ROI) to individual employers, healthcare plans, or providers. Those who pay for services are not necessarily the ones who obtain the full financial return, however. Interventions that are cost-effective or even cost-saving at the societal level do not necessarily yield a positive ROI from the business perspective, although they may provide a better value than other services.[20]

The "Value of Prevention" in the Purchaser's Guide

Each evidence-statement contains a "Value of Prevention" section that provides detailed information on the economic burden, including the workplace burden, of the condition/disease and information on the estimated cost of implementing the recommended preventive intervention. Select chapters also include information on the cost of treatment. A sample section is provided on the following page.

Obesity Sample

Value of Prevention	
Economic Burden of Condition/Disease	Obesity contributes significantly to medical costs in the United States. In 1998, 9.1% of total annual medical expenditures could be attributed to obesity.[21] Between 1987 and 2001, 27% of the growth in inflation-adjusted per-capita healthcare spending was associated with obesity.[22] The annual cost of obesity is estimated to range from $69 billion to $117 billion (including $61 billion for direct medical expenses and $56 billion for indirect expenses such as lost productivity [in year 2000 dollars]).[23] The expected lifetime costs of cardiovascular disease (including coronary heart disease, heart attack, and stroke) increase by 20% with mild obesity (class I: BMI of 30 to 34.9), 50% with moderate obesity (class II: BMI of 35 to 39.9), and nearly 200% with severe obesity (class III: BMI of 40 or higher).[24] One large health plan found that its yearly total medical claims were 18% higher for overweight individuals and 32% higher for obese than for healthy-weight individuals.[25] A 2001 study found obese adults had, on average, about 37% higher healthcare expenses per person than normal-weight adults. This excess expense increased private healthcare spending by nearly 12% (more than $36 billion).[22]
Workplace Burden of Condition/Disease	The cost to employers of obesity-related health problems in 1994 was estimated to be $13 billion per year, including $8 billion in medical claims, $2.4 billion in paid sick leave, $1.8 billion in life insurance, and almost $1 billion in disability insurance.[24] Obesity and related illnesses are also a major cause of disability. Each year, an estimated 39 million work days are lost to obesity-related illnesses.[22]
Economic Benefit of Preventive Intervention	Nutrition education, diet, and exercise counseling are effective interventions for obesity prevention and have the potential to significantly reduce the direct and indirect costs of obesity-related illnesses. Researchers have estimated that even a modest reduction of 10% in body weight in an obese individual might reduce the expected lifetime healthcare costs of major obesity-related diseases for the individual by $2,200 to $5,300, depending on age, sex, and initial BMI.[26]
Estimated Cost of Preventive Intervention	The cost of BMI screening is negligible when height and weight measurements are already recorded as part of a routine physical exam. In 2004, the private-sector cost of obesity counseling averaged $39 per session; approximately 95% of all paid claims fell within the range of $0 to $129 per session.[27]
Estimated Cost of Treatment	In the United States, the costs associated with treating obesity vary by location, provider type, and treatment modality. For example, in 2006 the average wholesale price of a 1-month supply of pharmacological therapy for obesity was $207.04 for orlistat (Xenical“) (120 mg three times daily) and $423.60 for a 3-month supply of sibutramine (Meridia“) (15 mg daily).28 In contrast, the average price of a surgical procedure for obesity in 2004 ranged from $20,000 to $35,000.[29]

Promoting Effective and Appropriate Clinical Preventive Services

The Underutilization of Preventive Care

Despite the documented benefits of timely preventive care, in 2002, only half of insured adults (52%) received preventive care and screening tests according to guidelines for their age and sex.[30] The underutilization of clinical preventive services has a negative impact on beneficiaries' health status and on employers' overall healthcare costs. For example, in 2004 the National Committee for Quality Assurance (NCQA) identified 7,600 excess cases of late-stage breast cancer, 20,000 excess cases of late-stage colorectal cancer, and 21,000 excess osteoporosis-related fractures that could have been averted if individuals received appropriate and timely preventive care.[6] Had these conditions been effectively prevented, $485.2 million in excess medical expenses could have been avoided.[6]

Reasons for the underutilization of preventive care are complex. In the past, preventive services were poorly covered by health insurance policies in comparison to care for acute services and medications. Differential coverage created perceived and real access barriers for beneficiaries. Other barriers to preventive care include patient and provider attitudes about

A recent study conducted by Milliman, C-Change, and the American Cancer Society, found that 3 to 5 lives (per 50,000 employees) could be saved each year if employers fully adopted select USPSTF cancer screening and tobacco treatment recommendations.[31] The cost to employers of achieving 100% compliance with USPSTF guidelines for tobacco use treatment as well as breast, cervical, and colorectal cancer was estimated to be $7.50 per member/per month (PMPM). Because most employers already provide some type of cancer prevention and early detection benefit, the average incremental cost of moving to 100% compliance would equal just $2.95 PMPM.[31]

the value of prevention and the healthcare system's lack of capacity to effectively track, promote, and deliver clinical preventive services. Even today, too little time and too few resources are devoted to prevention. In order to increase the utilization of clinical preventive services, all stakeholders will need to increase their investments in prevention.

Emphasizing Effective and Appropriate Clinical Preventive Services

Not only is the underutilization of effective preventive services a concern to employers, but so too is the overutilization of ineffective or unproven clinical preventive services. Providers and patients have a limited amount of time and purchasers have a limited amount of money to spend on healthcare interventions. It is therefore imperative for purchasers to cover and promote high-impact clinical preventive services that have proven benefit. Employers expanding their medical benefit plan to include preventive services should be careful to first select services with strong evidence of effectiveness. For more information on effective clinical preventive services and the prioritization of clinical preventive service benefits, please refer to *Part IV: The Prioritization and Strategic Implementation of Clinical Preventive Service Benefits.*

Employer Action Steps

Employers can reduce their total healthcare costs and improve the health of their beneficiaries through the implementation and promotion of clinical preventive service benefits. For this purpose, employers should:

- Offer a structured set of clinical preventive service benefits through their health plan(s).
- Inform employees, dependents, and retirees about the availability of clinical preventive service benefits and promote the consistent and appropriate use of recommended clinical preventive services.
- Educate employees, dependents, and retirees about the importance of preventive services and healthy lifestyles.
- Implement programs that promote healthy lifestyles and provide opportunities for employees to engage in disease prevention and health promotion outside of the clinical setting (e.g., health promotion or wellness programs, disease prevention programs, employee assistance programs).
- Support community-based and worksite-based preventive service interventions.

For more information on promoting the delivery and use of clinical preventive services, please refer to *Part VI: Leveraging Benefits: Opportunities to Promote the Delivery and Use of Preventive Services.*

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2 Summary Plan Description (SPD) Language Statements for Recommended Clinical Preventive Service Benefits

Overview:
46 clinical preventive service Summary Plan Description (SPD) language statements designed to assist benefits staff as they design, discuss, negotiate, and set benefit structures and coverage guidelines with a health plan, union, or consumer group. Sections include:

- The Purpose of Comprehensive and Structured Clinical Preventive Service Benefits
- An Overview of Employer-Sponsored ERISA Healthcare Benefits
- Communicating Health Benefits to Beneficiaries
- Federal Regulation and Preventive Services
- Clinical Preventive Services and High-Deductible Health Plans: A Unique Opportunity to Promote Use
- Clinical Preventive Service Summary Plan Description (SPD) Language
- Current Procedural Terminology (CPT) Codes

2 Summary Plan Description (SPD) Language Statements for Recommended Clinical Preventive Service Benefits

This section presents information on 1) the purpose of structured clinical preventive service benefits; 2) information on the federal rules and regulations surrounding the provision of clinical preventive services and preventive medications within employer-sponsored medical benefits; and 3) summary plan description (SPD) language for each clinical preventive service recommended in the *Purchaser's Guide*. A condition/disease-specific evidence-statement, supporting the information contained in each SPD language example, is provided in *Part III: Evidence-Statements for Recommended Clinical Preventive Service Benefits.*

The Purpose of Comprehensive and Structured Clinical Preventive Service Benefits

As a nation, increasing our investment in high-impact, cost-effective preventive services will not only save valuable healthcare dollars but, more important, will significantly improve the health status of the U.S. population.[1]

—Sam Nussbaum, WellPoint Inc.

Many of the clinical preventive services recommended in the *Purchaser's Guide* are covered by typical medical benefit plans and are well-used by beneficiaries (e.g., cervical cancer screening). Other preventive services have proven efficacy but are neither widely covered by employers nor widely used by beneficiaries (e.g., tobacco use treatment counseling).

Some types of clinical preventive services can be delivered in the course of routine medical care, such as an annual physical. For example, a patient who presents with shortness of breath may be screened for obesity and advised to lose weight. An informal screening service such as this would usually be covered by a health plan as part of routine care, not as a unique preventive service. Informal screening and counseling sessions serve an important function, but they are inadequate to address some preventable conditions that require more prevention resources. To encourage beneficiaries to consistently and appropriately use effective clinical preventive services and to incentivize providers to actively offer preventive services to their patients, it is imperative for employers to provide a structured and defined set of clinical preventive service benefits within their medical benefit plan(s) and to assure that health plans, providers, and beneficiaries know that these benefits exist and should be used.

To encourage beneficiaries to consistently and appropriately use clinical preventive services and to encourage providers to actively offer clinical preventive services to their patients, it is imperative for employers to provide structured clinical preventive service benefits within their medical benefit plan(s) and to assure that health plans, providers, and beneficiaries know that these benefits exist and should be used.

An Overview of Employer-Sponsored ERISA Healthcare Benefits

Group health plans are employee healthcare benefit plans established and maintained by employers. These plans provide coverage for eligible employees and dependents and, often, for retirees as well. The vast majority of employer-sponsored health plans are subject to the provisions of the Employee Retirement Income Security Act (ERISA) of 1974.[2] This Act provides protections and assurance to plan participants, defines the information that must be provided to beneficiaries, and defines the fiduciary responsibilities of plan administrators.

Summary Plan Descriptions (SPDs): Communicating Health Benefits to Beneficiaries

ERISA requires health plan administrators to give plan participants specific information about the benefits to which they are entitled, including covered benefits, plan rules, financial information, and documents about the plan's operation and management. This information must be provided on a regular basis, either in writing or on request.

One important document that participants are legally entitled to receive automatically is a plan summary or summary plan description (SPD). Generally, SPDs:

- Outline healthcare services covered in the plan.
- Describe how services are provided and how the plan(s) operate.
- Describe how benefits are calculated.
- Explain the portion of costs for which the plan is responsible and the portion of costs for which the participant (i.e., the beneficiary) is responsible (e.g., copays, coinsurance).
- Include information about how participants and providers should file claims.

ERISA specifically requires that SPDs include the following types of information:

1. Annual or lifetime caps or other limits on covered benefits.
2. Cost-sharing provisions, including premiums, deductibles, and coinsurance/copayment amounts for which the participant (i.e., the beneficiary) is responsible.
3. The extent to which preventive services are covered under the plan.
4. Whether, and under what circumstances, existing and new drugs are covered under the plan.
5. Whether, and under what circumstances, coverage is provided for medical tests, devices, and procedures.
6. Provisions governing the use of network providers, the composition of provider networks and whether, and under what circumstances, coverage is provided for out-of-network services.
7. Conditions or limits on the selection of primary care providers or providers of specialty medical care.

The Department of Labor requires that all SPDs be written in a way that can be understood by the average plan participant.[3] Even though plan services may be complex, the use of technical language and long, complex sentences should be avoided. Detailed technical descriptions of clinical preventive services must be made available to beneficiaries upon request.

The ERISA Act has been amended several times; the latest revisions were released on January 1, 2005 and reinforced previous requirements stating that SPDs must provide a detailed schedule of benefits, including a listing of covered preventive service benefits.[4]

Federal Regulation and Preventive Services

Federal rules and regulations govern employer-sponsored preventive services. The Department of Labor provides regulatory oversight of employer-sponsored healthcare benefits. The Internal Revenue Service (IRS) offers guidance relative to plan services and related payments. Recently, the IRS has provided rules regarding how preventive services may be structured in high-deductible health plans (HDHPs) that are used in conjunction with health savings accounts (HSAs).

Due to tax implications, the IRS has become involved in outlining preventive services in the context of consumer directed health care plans, including HSA-qualified high-deductible health plans (HDHPs), health savings accounts (HSAs), and health reimbursement arrangements (HRAs).

High-Deductible Health Plans (HDHPs) Health Savings Accounts (HSAs)

Over the past few years, employers have introduced consumer-directed healthcare (CDH) plans as an alternative to traditional health benefit plans. The purpose of these plans is to control cost increases by requiring beneficiaries to take responsibility for their healthcare spending. The most common CDH plan design involves a high-deductible health plan (HDHP) with or without an accompanying health savings account (HSA).

Health savings accounts (HSAs) are tax-advantaged, funded accounts established to support saving for future medical expenses. HSAs are funded by tax-free dollars and, if ultimately used for eligible medical expenses, these dollars remain non-taxed.[5]

To access the tax advantages of an HSA, an individual must be covered by an IRS-defined HDHP. These are health plans with deductibles of at least $1,100 for individual coverage ($2,200 for family coverage) and caps on allowable out-of-pocket spending ($5,500 for individual coverage/$11,000 for family coverage). These amounts are applicable for 2007, and are updated annually to adjust for inflation.

Clinical Preventive Services and High-Deductible Health Plans: A Unique Opportunity to Promote Use

Generally, a HDHP cannot provide benefits prior to fulfillment of the required deductible. However, the IRS has provided an exception for preventive medical care to encourage the use of preventive services. Employers have at least four options in structuring HDHP benefits to promote prevention:

1. Waive the plan deductible and eliminate copayment/coinsurance requirements (100% first-dollar coverage).
2. Waive the plan deductible and reduce required copayment /coinsurance amounts.
3. Waive the plan deductible and require the usual copayment/coinsurance amounts.

Clinical preventive services and preventive medications can be exempted from the deductible in HSA-qualified HDHPs. Employers who offer traditional health plan types (e.g., HMOs, PPOs, POS) or CDH plans that are not HSA-qualified may wish to consider waiving deductibles or lowering copay or coinsurance amounts for preventive medical care in order to promote the use of preventive services by beneficiaries in these plan types.

4. Apply the plan deductible and provide a separate financial benefit for preventive care ($500 per prevention per year, for example).

Notices 2004-23[6] and 2004-50[7] from the Department of Treasury outline a preventive care deductible safe-harbor for HDHPs under section 223(c)(2)(C) of the IRS code. The preventive care safe-harbor includes deductible exemptions for clinical preventive services, preventive medications, and treatment incidental to preventive care.

Clinical Preventive Services and Preventive Medications: Notice 2004-23

Preventive care benefits such as annual physicals, immunizations, and screening services are exempt from HDHP deductible requirements. Therefore, employers can offer HDHPs that provide 100% first-dollar coverage for clinical preventive services. This type of exemption is known as "safe-harbor" coverage.

I. Preventive care benefits are allowed to be provided by a high-deductible health plan (HDHP) without satisfying the minimum deductible. Preventive care includes, but is not limited to, the following[6]:

- Immunizations
- Obesity weight-loss programs
- Periodic health evaluations, including tests and diagnostic procedures ordered in connection with routine examinations, such as annual physicals.
- Prenatal care
- Screening services for
  - > Cancer
  - > Heart and vascular diseases
  - > Infectious diseases
  - > Mental health conditions and substance abuse
  - > Metabolic, nutritional, and endocrine conditions
  - > Musculoskeletal disorders
  - > Obstetric and gynecologic conditions
  - > Pediatric conditions
  - > Vision and hearing disorders
- Tobacco cessation programs
- Well-child care

II. Drugs prescribed to prevent diseases or conditions that have not yet manifested themselves or to prevent reoccurrence of diseases or conditions [are considered preventive] and may be covered outside of the deductible.[6]

Notice 2004-23 recognized clinical preventive services such as screening, counseling, and immunizations as "preventive medical care" and provided an exemption from deductible requirements. It also deemed drugs/medications to be "preventive medications" (and therefore excludable from deductible requirements) when taken by a person who has developed risk factors for a disease that has not yet manifested itself or not yet become clinically apparent (this is known as primary prevention) or to prevent the reoccurrence of a disease from which a person has recovered. For example, the treatment of high cholesterol with cholesterol-lowering medications (e.g., statins) to prevent heart disease may be considered preventive. Similarly, treating an initial heart attack with angiotensin-converting enzyme (ACE) inhibitors to prevent a reoccurrence may be considered preventive. In addition, drugs or medications used as part of procedures providing preventive care services, such as weight-loss programs and tobacco use treatment programs, may be considered preventive.

Treatment Incidental to Preventive Care: Notice 2004-50

Treatment that is performed along with preventive care services or screening may be provided without meeting the deductible requirements as long as it is ancillary or incidental to preventive care.[7]

Notice 2004-50 extended safe-harbor coverage to treatments that are ancillary to prevention or when a separate procedure/visit for treatment would be impractical or unreasonable. For example, the removal of polyps is an allowable preventive treatment benefit when provided as a part of a screening colonoscopy.[7]

Guidance on the Definition of "Preventive Medical Care"

Prior to the 2004 guidance and clarification notices, employers and plan administrators requested that the Department of Labor clearly define preventive medical care. The Department of Labor responded that services and medications may vary from plan to plan and are best described in the context of total plan provisions and not by regulation.[8] Rather than developing a schedule of allowable services and medications, the Department of Treasury gave employers the discretion to define them relative to need and cost within the limits set forth in Notices 2004-23 and 2004-50. Employers interested in exempting preventive services and medications from the deductibles of HSA-qualified and HDHP plans must therefore decide for themselves which services and medications qualify as preventive and which do not.

Defining Clinical Preventive Services

It is especially important for employers who offer HDHPs to clearly define clinical preventive service benefits and to inform beneficiaries about safe-harbor coverage so that the services will be optimally used.

The *Purchaser's Guide* recommends 46 clinical preventive services for inclusion in medical benefit plans. All of the recommended services qualify as preventive medical care and could be exempted from the deductible in HSA-qualified HDHP plans and other plan types. Employers who offer preventive service benefits should evaluate these benefits and exempt them from the deductible on a case-by-case basis.

Defining Preventive Medications

The National Business Group on Health recognizes that the decisions employers must make regarding the definition of medications as preventive are not always clear-cut particularly because:

- Many drugs have both preventive and curative applications. For example, beta blockers can be used to prevent stroke or treat hyperthyroidism.
- Several types of prevention exist (e.g., primary, secondary, tertiary).

A comprehensive listing of recommendations regarding preventive medication was beyond the scope of the *Purchaser's Guide*. Figure 2.0 was developed in order to provide employers with some idea of the type of medications that may be defined as preventive. It presents options employers have when selecting medications to consider preventive within a pharmacy benefit. The listing draws upon evidence from regulators (such as the Food and Drug Administration), authoritative expert groups that convene to review clinical evidence (such as the U.S. Preventive Services Task Force), or the results of systematic literature reviews (such as those produced by the Cochrane Collaboration, a reliable source of evidence in health care). In the absence of such information, the sources cited are either consensus expert opinion or important studies. The listing is intended to be a tool for benefit design and communications; it is not a comprehensive list and is not endorsed in its entirety by any of the referenced sources. In order to ensure compliance with IRS regulations, benefit managers should consult with other knowledgeable sources such as health plans, consultants, pharmacy benefit managers, and especially their internal legal departments.

Important Note on the Difference Between the Use of the Term "Preventive Medication" as a Category of Prevention and as a Pharmacy Benefit Definition

Several clinical preventive services recommended in the *Purchaser's Guide* include the prescription/use of a preventive medication. Preventive medications, as recommended in the *Purchaser's Guide*, are limited to those medications that can be used to prevent a specific condition or disease (e.g., folic acid supplementation to prevent neural tube defects). The prescription/use of these medications is thus a type of preventive intervention, in the same way that an immunization or counseling session is a type of preventive intervention.

There are many other types of medications that can be used to prevent the escalation of a condition into another type of disease or disability (e.g., asthma medications to prevent permanent damage to the airways) or to prevent a comorbidity from occurring as a result of untreated disease (e.g., anti-diabetic agents to prevent cardiovascular disease). Medications such as these can also be considered preventive and, according to the most recent Department of Treasury guidance, qualify for safe-harbor coverage in HSA-qualified HDHPs.

Figure 2.0: Preventive Medications that Employers May Select to Include in Pharmacy Benefits

COVERED DRUG CATEGORY	RATIONALE	SOURCES OF EVIDENCE	DRUGS OR THERAPEUTIC CLASSES (* = Generic Available)
Alcohol cessation agents	Prevents liver cancer and cirrhosis of the liver	SAMHSA[9]	Naltrexone*, disulfiram
Antiasthmatic agents	Prevents airway remodeling and its sequelae in asthmatics	Standard use[10]	Theophyllines*, oral beta-2 agonists*, mast cell stabilizers*, inhaled beta-2 agonists* leukotriene modifiers, inhaled corticosteroids, omalizumab
Anticoagulant agents	Prevents strokes and other poor cardiovascular outcomes	Standard use[10]	Anticoagulants*, thrombin inhibitors*, antiplatelet agents
Antidepressant agents	Prevents the reoccurrence of clinically apparent depressive episodes	Meta analysis[11]	Tricyclics*, SSRIs*, bupropion*, lithium*, maprotiline*, mirtazapine*, nefazodone*, trazodone*, SNRIs, MAOIs, venlafaxine, duloxetine
Antidiabetic agents	Prevents cardiovascular disease, retinopathy, neuropathy and nephropathy	Standard use[10]	Biguanides*, sulfonylureas*, meglitinides, thiazolidinediones and alpha-glucosidase inhibitors, injectable or inhaled insulin
Antihypertensive agents	Prevents strokes, heart attacks, kidney failure and other poor cardiovascular outcomes	JNC 7[12]	Thiazide diuretics*, loop diuretics*, potassium sparing diuretics*, ß-blockers*, CCBs*, ACEIs*, ARBs
Bone density promoters	Prevents osteoporosis and bone fractures	Standard use[10]	Calcium*, ergocalciferol*, biphosponates*, bone formation agents, parathyroid hormones, selective receptor modulators
(Medications to prevent) breast cancer	Prevents breast cancer	USPSTF[13]	Tamoxifen
Contraceptive agents	Prevents pregnancy	Peer-reviewed research[14] FDA[15]	Oral contraceptives*, contraceptive patch
Drug abuse cessation agents	Prevents liver disease	CDC[16]	Methadone*
Emergency adrenaline shots	Prevents anaphylaxic shock induced by severe allergic reactions	American Academy of Allergy, Asthma and Immunology[17]	Epinephrine auto-injector
Erythroid stimulants	Prevents chemotherapy-induced anemia and post-surgical anemia	NIH[18]	Epoetin alfa, darbepoetin alfa-albumin
Flouride supplements	Prevents dental caries	USPSTF[19]	Sodium fluoride*, pediatric combination vitamins with fluoride*

Figure 2.0: Preventive Medications that Employers May Select to Include in Pharmacy Benefits *(Continued)*

COVERED DRUG CATEGORY	RATIONALE	SOURCES OF EVIDENCE	DRUGS OR THERAPEUTIC CLASSES (* = Generic Available)
Folic acid supplements	Prevents some cardiovascular conditions Prevents neural tube defects	Standard use[10], CDC, U.S. Public Health Service[20, 24]	Folate*
Immunizations (for children, adolescents, and adults)	Prevents transmission of infectious diseases	ACIP[29]	All AClP Recommend vaccines
Lipid/cholesterol lowering agents	Prevents AMIs and other poor cardiovascular outcomes	ATP III[21] ATP III update[22], ICSI[23]	Statins*, niacin*
Medical nutrition therapy	Prevents mental retardation in persons with PKU and poor outcomes in persons with other inherited metabolic diseases	AAP[25-26]	Variable
Myeloid stimulants	Prevents chemotherapy-induced febrile neutropenia	CDC[27]	Filgrastim, pegfilgrastim, sargramostim
Prenatal supplements that include folic acid	Prevents neural tube defects, vitamin deficiencies, and preeclampsia	Cochrane Collaboration Reviews[24, 28]	Prenatal combination vitamins*
Proton pump inhibitors	Prevents esophageal damage caused by GERD	IRS[30]	Proton pump inhibitors*, histamine-2 receptor blockers*, antacids*, promotility agents*
Tobacco use cessation agents	Prevents emphysema and lung cancer	Peer-reviewed research[31] CDC, U.S. Public Health Service[32]	Bupropion*, nicotine patch, nicotine inhaler, varenicline
Weight-loss agents	Prevents poor cardiovascular outcomes	USPSTF[33]	Sibutramine, orlistat, phentermine, diethylpropion

Figure 2.1: Intervention Chart

	Screening	Testing	Counseling	Immunization	Preventive Medication/ Intervention	(Preventive) Treatment
Abdominal Aortic Aneurysm	✔					
Alcohol Misuse	✔		✔			
Aspirin Therapy for the Prevention of Cardiovascular Disease			✔			
Breast Cancer						
Breast Cancer	✔					
Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing		✔	✔			✔
Breast Cancer			✔		✔	
Cervical Cancer	✔					
Childhood Health Promotion						
Child Development	✔					
Child Immunizations				✔		
Dental Caries Prevention					✔	
Lead, Elevated Blood Level	✔					
Newborn Screening for Genetic and Endocrine Disorders	✔				✔*	✔
Newborn Hearing	✔					
Vision	✔					
Colorectal Cancer	✔					
Contraceptive Use		✔			✔	
Depression	✔					
Diabetes (type 2)	✔					
Healthy Diet			✔			
Healthy Pregnancy						
Alcohol Misuse	✔		✔			
Asymptomatic Bacteriuria	✔					
Breastfeeding			✔			
Folic Acid Supplementation			✔		✔	
Group B Streptococcal	✔				✔	

Figure 2.1: Intervention Chart *(Continued)*

	Screening	Testing	Counseling	Immunization	Preventive Medication/ Intervention	(Preventive) Treatment
Disease (GBS)						
Hepatitis B Virus (HBV)	✔			✔		✔
Human Immunodeficiency Virus (HIV)	✔		✔		✔	
Influenza				✔		
Preeclampsia	✔					
Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (NTDs)	✔	✔				
Rh (D) Incompatibility	✔				✔	
Rubella	✔					
Syphilis	✔					
Tetanus				✔		
Tobacco Use Treatment	✔		✔			
Hypertension	✔		✔			✔
Immunizations (Child, Adolescent, Adult)				✔		
Lipid Disorders	✔		✔			✔
Motor Vehicle-Related Injury Prevention			✔			
Obesity	✔		✔			✔
Osteoporosis	✔					✔
Sexually Transmitted Infections (STIs)						
Counseling to prevent STIs			✔			
Chlamydia	✔					
Gonorrhea	✔					
Human Immunodeficiency Virus (HIV)	✔		✔			
Syphilis	✔					
Tobacco Use Treatment	✔		✔			✔
Tuberculosis	✔					

*Includes medical foods in addition to medications

The clinical preventive services benefits recommended in the *Purchaser's Guide* address a range of health conditions that affect people of all ages. For a brief summary of clinical preventive services appropriate for different age groups and genders, please refer to the Life Course Charts featured in *Part VII: Resources & Tools.*

Sample Summary Plan Description (SPD) Language Statements for Recommended Clinical Preventive Service Benefits

Summary Plan Description (SPD) Language

The following pages contain condition, disease or injury specific SPD language statements for each clinical preventive service recommended in the *Purchaser's Guide*. The SPD language statements clearly outline the recommended benefits for each service.

The recommended benefits (and hence the SPDs), are a translation of the clinical guidelines featured in the corresponding evidence-statements, which outline the medical evidence for each intervention.The process of translating clinical guidelines into benefit language is difficult. The National Business Group on Health (Business Group) has made every effort to align benefits recommended in the *Purchaser's Guide* with the most current clinical guidelines and recommendations. However, because recommendation-making bodies (e.g., USPSTF, professional organizations, etc) sometimes disagree on the specifics of a particular clinical preventive service, for example, how often a service should be provided, the Business Group combined multiple recommendations to construct the detailed benefits described in the SPDs. For an exact listing of the recommendations and guidelines, please refer to the corresponding evidence-statements provided in *Part III: Evidence-Statements for Recommended Clinical Preventive Service Benefits.*

Current Procedural Terminology (CPT®) Codes

Applicable current procedural terminology (CPT) codes are provided for each recommended benefit. CPT codes are listed in alphabetical order as an appendix to the SPD language statements.

CPT codes are provided for employers and health plans to facilitate the implementation and reimbursement of clinical preventive service benefits. Employers who adopt the recommendations set forth in the *Purchaser's Guide* should ensure that their health plan administrators approve the listed CPT codes for provider reimbursement.

CPT codes are developed by the American Medical Association (AMA) for the purpose of providing a uniform language that accurately describes medical, surgical, and diagnostic services provided by physicians and other clinicians. The list of codes is updated annually. For more information on CPT codes and to view updates, please contact the CPT Information and Education Service at 1-800-634-6922 or visit: www.ama-assn.org/ama/pub/category/3113.html

A Note on SPDs

Summary plan description language does not typically include the names of covered tests or procedures. SPD language provided in the *Purchaser's Guide* includes specific information on covered tests, procedures, and medications. This information is included for educational purposes. Some employers may wish to include this information in their SPDs; other employers may wish to delete this information from their SPDs, and share it only with their health plan administrators for contracting purposes.

SUMMARY PLAN DESCRIPTION LANGUAGE

	Summary Plan Description Language: Abdominal Aortic Aneurysm (Screening)
Covered Screening	Ultrasonography of the abdomen.
Initiation, Cessation, and Interval	One-time screening ultrasound to look for abdominal aortic aneurysm in men aged 65 to 75 who have smoked at any time in their lives. The exact timing of the screen is left to the discretion of the clinician.

	Summary Plan Description Language: Alcohol Misuse (Screening)
Covered Screening	Screening for alcohol misuse is a covered benefit. Coverage includes the use of validated screening tools such as: • Single-question alcohol screens • Alcohol Use Disorders Identification Test (AUDIT) or AUDIT-C • CAGE
Initiation, Cessation, and Interval	Screening is a covered benefit beginning at age 18. Coverage is provided for younger populations depending on risk and need. For average-risk populations, one screen is covered annually. More frequent screening is covered for individuals at risk for alcohol misuse, including people with a history of alcohol misuse or alcohol-related health and social problems.

	Summary Plan Description Language: Alcohol Misuse (Counseling)
Covered Counseling	Counseling is a covered benefit for patients who meet criteria for alcohol misuse. Three levels of counseling are covered: • "Very brief" interventions that last up to 5 minutes and have no follow-up. • "Brief" counseling interventions that last 15 minutes and have no follow-up. • "Multi-contact" interventions that include one initial session lasting at least 15 minutes that is followed by several additional contacts.
Initiation, Cessation, and Interval	Eight (8) counseling sessions are covered per calendar year. Intervals between counseling sessions are at the discretion of the provider.

	Summary Plan Description Language: Aspirin for the Primary Prevention of Cardiovascular Events (Counseling)
Covered Screening	Counseling to discuss the benefits and harms of aspirin therapy is a covered benefit.
Initiation, Cessation, and Interval	All beneficiaries aged 30 and older are eligible for one counseling session every 5 years or whenever a cardiovascular risk factor is detected.

	Summary Plan Description Language: Breast Cancer (Screening)
Covered Screening	Breast cancer screening is a covered benefit and may include mammography and, as an adjunct, a clinical breast exam (CBE).
Initiation, Cessation, and Interval	Breast cancer screening is a covered benefit for average-risk women aged 40 to 80. Average-risk women are eligible for one mammography per calendar year. Women at high risk of breast cancer may qualify for screening at a younger age, if screening is deemed medically indicated.

	Summary Plan Description Language: Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing (Counseling)
Covered Counseling	Beneficiaries determined to be at high risk for breast cancer based on the results of a clinician's risk assessment are eligible for genetic counseling.
Initiation, Cessation, and Interval	Counseling is provided as medically indicated, and should be conducted at least once before and after genetic testing.

	Summary Plan Description Language: Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing (Testing)
Covered Testing	Beneficiaries determined to be at high risk for breast cancer based on the results of a clinician's risk assessment are eligible for BRCA mutation testing.
Initiation, Cessation, and Interval	BRCA mutation testing is covered once per lifetime.

	Summary Plan Description Language: Breast Cancer (Counseling on Preventive Medication and Preventive Treatment)
Covered Counseling	Beneficiaries determined to be at high-risk for breast cancer based on the results of the clinician's risk assessment or the results of BRCA mutation testing are eligible for counseling on the use of preventive medication or preventive treatments.
Initiation, Cessation, and Interval	Counseling is provided as medically indicated.

	Summary Plan Description Language: Breast Cancer (Preventive Medication)
Covered Preventive Medications	Beneficiaries determined to be at high risk for breast cancer based on the results of a clinician's risk assessment are eligible for preventive medication. Coverage is provided for all FDA-approved breast cancer preventive medications (e.g., tamoxifen).
Initiation, Cessation, and Interval	Coverage is provided for 5 years. Preventive treatment may be extended, if continued treatment is determined to be medically necessary.

	Summary Plan Description Language: Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing (Preventive Treatment)
Covered Preventive Treatment	Beneficiaries determined to be at high risk for breast cancer based on the results of a clinician's risk assessment or the results of BRCA mutation testing are eligible for preventive treatment, which may include any of the following: • Surgical removal of the breast(s) with or without reconstructive surgery • Surgical removal of the ovaries Treatment coverage includes counseling-based office visits for treatment education, decision-making, and monitoring.
Initiation, Cessation, and Interval	Preventive treatment is provided, as medically indicated.

	Summary Plan Description Language: Cervical Cancer Screening (Screening)
Covered Screening	Conventional Pap test. ***Health plans have the discretion to provide coverage for newer screening methods, such as liquid-based, thin-layer preparations (e.g., ThinPrep®) or computer-assisted screening (e.g., AutoCyte®), and human papillomavirus (HPV) tests, such as Hybrid Capture II®.
Initiation, Cessation, and Interval	Cervical cancer screening is a covered benefit for women age 21 (or women of any age 3 years within the onset of sexual activity) through age 65. Coverage beyond the age of 65 is provided for women with known risk factors, recent abnormal pap smears, inadequate previous screening, or when information about previous screening is unavailable or when screening is unlikely to have occurred in the past. Coverage allows Pap tests to be performed at least once every three years, but not more than once per calendar year.

	Summary Plan Description Language: Childhood Health Promotion (Screening, Immunization, Medical Foods, and Preventive Medication)
	Summary Plan Description Language: Child Development (Screening)
Covered Screening	Coverage is provided for developmental screening including the use of standardized instruments.
Initiation, Cessation, and Interval	Developmental screening services are covered for all children as a component of the 9, 18, and 30-month well-child care visits.
	Summary Plan Description (SPD) Language: Dental Caries Prevention through Oral Fluoride Supplementation (Preventive Medication)
Covered Preventive Medication(s)	Oral fluoride
Initiation, Cessation, and Interval	Oral fluoride is covered as prescribed by the clinician according to age and need. Coverage for supplementation is provided from 6 months to 5 years of age and may be extended through 16 years of age, if medically indicated.
	Summary Plan Description (SPD) Language: Child Immunizations (Immunization)
	Please refer to the general Immunizations SPD language.
	Summary Plan Description Language: Elevated Blood Lead Levels (Screening)
Covered Screening	Covered screening tests for lead exposure include blood lead concentration measured from capillary or venous samples.
Initiation, Cessation, and Interval	Screening is a covered benefit for children at risk for lead exposure at the following ages: 12 months, 24 months, and 36–72 months, or at any age when deemed medically necessary by a risk assessment, clinical signs or symptoms consistent with elevated BLL, or when other evidence indicates possible lead exposure. Secondary venous blood lead concentration tests, taken for confirmation, are covered for all children identified as having an elevated BLL through a capillary blood lead concentration screen.

	Summary Plan Description Language: Newborn Hearing (Screening)
Covered Screening	Hospital-based hearing screening is a covered benefit for all newborns. Newborns who are not screened in the hospital, or who require further screening, may be tested in a clinician's office. Screening may include the use of the following tests: • Automated or semiautomated audiologic screening • Auditory Brainstem Response (ABR) • Otoacoustic Emissions (OAE) Diagnostic audiological evaluation is a covered benefit for all infants and children who do not pass initial screening tests.
Initiation, Cessation, and Interval	Screening is covered for all newborns during the first 3 months of life. Additional screening is provided for at-risk children, as determined medically necessary, through age 3 years. Diagnostic audiological evaluation is covered, as medically necessary.

	Summary Plan Description Language: Newborn Screening for Genetic and Endocrine Disorders (Screening)
Covered Screening Methods	Newborn blood spot screening is a covered benefit. Screening is provided for the following conditions: phenylketonuria (PKU), congenital hypothyroidism (CH), galactosemia, sickle cell disease (SCD) and other hemoglobin disorders, congenital adrenal hyperplasia (CAH), biotinidase deficiency, and medium chain acyl-coA dehydrogenase (MCAD) deficiency. Screening for other conditions is covered, as medically indicated.
Initiation, Cessation, and Interval	Newborn screening is covered from birth through 4 months of age. Follow-up testing is covered, as medically indicated.

	Summary Plan Description Language: Newborn Screening for Genetic and Endocrine Disorders (Medical Foods)
Covered Medical Foods	Medical formulas and foods are covered for the purpose of preventing illness, disability, or death among beneficiaries with genetic or endocrine disorders.
Initiation, Cessation, and Interval	Medical formulas and foods are covered, as medically necessary.

	Summary Plan Description Language: Newborn Screening for Genetic and Endocrine Disorders (Treatment)
Covered Treatment	Medications and other forms of treatment used to prevent illness or disability among beneficiaries with genetic or endocrine disorders are covered. Case management is a covered benefit and is provided, as medically necessary, for beneficiaries with complex disorders.
Initiation, Cessation, and Interval	Medications and other forms of treatment are covered, as medically indicated.

	Summary Plan Description Language: Vision (Screening) (Child)
Covered Screening	Vision screening is a covered benefit for all children and may include use of the following screening tests: • Cover test • External inspection of the eyes and lids • Hirschberg light reflex test • Ocular history • Ocular motility assessment • Photo-screening • Pupil examination • Random Dot E test • Red reflex examination • Titmus Fly test • Vision assessment • Visual acuity tests including the Snellen Acuity Chart, the Tumbling E, the HOTV Test, Allen Cards, and LH Symbols
Initiation, Cessation, and Interval	Vision screening is covered in the newborn period and at all subsequent well-child visits. The following vision screenings are covered for children birth to 3 years of age: ocular history, vision assessment, external inspection of the eyes and lids, ocular motility assessment, pupil examination, and red reflex examination. The following vision screenings are covered for children ages 3 to 5 years: age appropriate visual acuity measurements using the Snellen Chart, Tumbling E, the HOTV Test, Allen Cards, or LH Symbols) and ophthalmoscopy.

	Summary Plan Description Language: Colorectal Cancer (Screening)
Covered Screening	• Colonoscopy • Double-contrast barium enema. • Fecal occult blood testing (FOBT) (alone or combined with flexible sigmoidoscopy) • Flexible sigmoidoscopy (alone or combined with FOBT)
Initiation, Cessation, and Interval	Colorectal cancer screening is a covered benefit for men and women aged 50 and older. Screening may be initiated at an earlier age if the beneficiary has certain risk factors and a clinician determines that the individual requires early screening. Colorectal cancer screening intervals are based on the method of screening used: Screening Method — Approved Interval for Coverage Colonoscopy — Every 10 years Flexible sigmoidoscopy — Every five years Double-contrast barium enema — Every five years Fecal occult blood tests (FOBT) — Every year Combination of flexible sigmoidoscopy and FOBT — Every five years for the flexible sigmoidoscopy and annually for the FOBT

	Summary Plan Description Language: Contraceptive Use (Counseling)
Covered Counseling	Counseling on contraceptive use is a covered benefit.
Initiation, Cessation, and Interval	Counseling is a covered benefit for all beneficiaries aged 13 to 55 years, whenever it is deemed medically indicated. Counseling should be conducted at least once a year and whenever emergency contraception is prescribed.

	Summary Plan Description Language: Contraceptive Use (Preventive Intervention)
Covered Preventive Medications/ Devices	The full range of Food and Drug Administration (FDA) approved contraceptives are covered including: • All hormonal medications (e.g., pills and patches) including emergency contraceptives • All contraceptive devices (e.g., IUD, diaphragm, vaginal ring) • Voluntary sterilization (e.g., vasectomy, tubal ligation)
Initiation, Cessation, and Interva Covered Screening	Hormonal medications (e.g., pills and patches) — including emergency contraceptives — and contraceptive devices are covered as medically necessary for the prevention of pregnancy. Voluntary sterilization (e.g., vasectomy, tubal ligation) is covered once per lifetime. Coverage may be extended if the procedure fails.

	Summary Plan Description Language: Depression (Screening)
Covered Screening	Depression screening, including the use of standardized depression screening or informal instruments, is a covered benefit.
Initiation, Cessation, and Interval	Depression screening is a covered benefit for all adults age 18 and older, when deemed medically indicated. Depression screening is covered for adolescents, as medically indicated.

	Summary Plan Description Language: Diabetes (Screening)
Covered Screening	• Fasting plasma glucose test (FBG) • 2-hour post-load plasma glucose • Oral glucose tolerance test (OGTT)
Initiation, Cessation, and Interval	Diabetes screening is a covered benefit for beneficiaries of any age with hypertension or hyperlipidemia (lipid disorders). Screening should be initiated whenever these conditions are diagnosed. Screening should be conducted, depending on risk, at least once every 3 years, but not more than once during any calendar year. Coverage for diabetes screening among those at high risk for the disease is provided beginning at age 30, if medically indicated. Screening should be conducted at least once every 2 years, but not more than once during any calendar year. Coverage for diabetes screening among individuals at normal risk for the disease is provided beginning at age 45, or earlier if medically indicated. Screening may be conducted once every 3 years. Individuals with impaired glucose function diagnosed by any test listed in "covered screening methods" qualify for a second screen to verify disease status. The secondary screening should be conducted on another day in the same calendar month.

	Summary Plan Description Language: Healthy Diet (Counseling)
Covered Counseling	Intensive behavioral dietary counseling is covered for adult beneficiaries with hyperlipidemia (lipid disorders) and other known risk factors for cardiovascular and diet-related chronic diseases.
Initiation, Cessation, and Interval	Beneficiaries who meet the criteria for counseling are eligible for 3 intensive (30-45 minute) counseling sessions per calendar year.

	Summary Plan Description Language: Healthy Pregnancy (Screening, Testing, Counseling, Preventive Medication, and Treatment)

	Summary Plan Description Language: Alcohol Misuse (Screening)
Covered Screening	Screening for alcohol misuse is a covered benefit. Coverage includes the use of validated screening tools such as the: • AUDIT

	• AUDIT-C • TWEAK • T-ACE
Initiation, Cessation, and Interval	Screening is a covered benefit during pregnancy. Normal-risk women may be screened once per pregnancy. Patients at greater risk for alcohol problems, either because they have a history of past alcohol misuse or report other risky behaviors, qualify for multiple screenings during pregnancy.
	Summary Plan Description Language: Alcohol Misuse (Counseling)
Covered Counseling	Counseling for alcohol misuse during pregnancy is a covered benefit. Three levels of counseling are covered: • "Very brief" interventions that last up to 5 minutes and have no follow-up. • "Brief" counseling interventions that last 15 minutes and have no follow-up. • "Multi-contact" interventions that include one initial session lasting at least 15 minutes that is followed by several additional contacts.
Initiation, Cessation, and Interval	Eight (8) counseling sessions are covered per calendar year. Intervals between counseling sessions are at the discretion of the provider. These covered visits are not intended to supplant mental health or addiction treatment coverage.
	Summary Plan Description Language: Asymptomatic Bacteriuria (Screening)
Covered Screening	Urine culture
Initiation, Cessation, and Interval	Screening for asymptomatic bacteriuria is a covered benefit between 12 and 16 weeks' gestation for all pregnant women. Subsequent screenings are covered, as medically indicated.
	Summary Plan Description Language: Breastfeeding (Counseling)
Covered Counseling	Structured breastfeeding education and behavioral counseling is a covered benefit for all pregnant and lactating women. Counseling may be provided in an office setting, during hospitalization for labor/delivery, or in the patient's home after the birth of their child.
Initiation, Cessation, and Interval	Counseling to promote breastfeeding initiation and continuation is a covered benefit for all pregnant women and all lactating women. There is no maximum number of sessions, provided that the care is medically necessary.

	Summary Plan Description Language: Folic Acid Supplementation (Counseling)
Covered Counseling	Counseling to promote the use of folic acid supplements (for the prevention of neural tube defects) is a covered benefit.
Initiation, Cessation, and Interval	Counseling on folic acid supplementation is a covered benefit for all women considering pregnancy and all pregnant women through the first trimester of pregnancy.
	Summary Plan Description Language: Folic Acid Supplementation (Preventive Medication)
Covered Preventive Medications	• Prescription strength folic acid • Prenatal vitamins containing folic acid
Initiation, Cessation, and Interval	Folic acid medications of any type are covered, when used to reduce the risk of having a pregnancy affected by a neural tube defect.
	Summary Plan Description Language: Group B Streptococcal Disease (Screening)
Covered Screening	All methods of GBS isolation and identification are covered.
Initiation, Cessation, and Interval	Screening for vaginal and rectal group B streptococcal (GBS) colonization is a covered benefit for all pregnant women between 35 and 37 weeks gestation, or as medically indicated.
	Summary Plan Description Language: Group B Streptococcal Disease (Preventive Medication)
Covered Preventive Medications	Intrapartum antibiotic prophylaxis is a covered benefit for all pregnant women.
Initiation, Cessation, and Interval	Intrapartum antibiotic prophylaxis to prevent GBS disease is a covered benefit for: • All pregnant women whose screening status is unknown at the time of labor if they present with any of the following risk factors: delivery at < 37 weeks gestation, membrane rupture ≥ 18 hours, or intrapartum fever ≥ 38C. • Women who have had GBS isolated from their urine at any time during their current pregnancy. • All women who have previously given birth to an infant with invasive GBS disease. • Women who are expected to deliver preterm (< 37 weeks) and found to be at risk for perinatal GBS disease.

	Summary Plan Description Language: Hepatitis B Virus (HBV) (Screening)
Covered Screening	Hepatitis B screening is a covered benefit for all pregnant women. Coverage includes the use of all validated screening tools, including the HBsAg Immunoassay and the "rapid test."
Initiation, Cessation, and Interval	Average-risk women should be screened once, ideally at the first prenatal care visits. Additional screenings are covered for women at increased risk of acquiring HBV.
	Summary Plan Description Language: Hepatitis B Virus (HBV) (Immunization)
Covered Immunizations	All types and brands of hepatitis B immunization are covered.
Initiation, Cessation, and Interval	Immunizations may be given at any time during pregnancy, as deemed appropriate by the clinician.
	Summary Plan Description Language: Hepatitis B Virus (HBV) (Treatment)
Covered Treatment	Treatment for infants born to hepatitis B (HBV)-positive women includes: • Postexposure hepatitis B immune globulin • HBV vaccination Treatment for infants born to women with unknown HbsAg status includes: • Single-antigen hepatitis B vaccine (without HBIG) *Note:* The hepatitis B vaccine (without HBIG) is a covered benefit for all infants, regardless of their mother's hepatitis status.
Initiation, Cessation, and Interval	Immune globulin and HBV immunizations are covered, as medically indicated.

	Summary Plan Description Language: Human Immunodeficiency Virus (HIV) (Screening)
Covered Screening	All FDA-licensed screens and tests, including: • Enzyme immunoassay (EIA) • Western blot test • Abbott Murex Single Use Diagnostic System HIV-1 test • Rapid assay test
Initiation, Cessation, and Interval	All pregnant women are eligible for HIV screening. One-time screening is covered for normal-risk women and should be conducted as early as possible during the pregnancy. All pregnant women with a positive screen are eligible for confirmatory testing. Women at high risk of HIV infection are eligible for additional screening/confirmatory testing during the third trimester, or as medically indicated.

	Summary Plan Description Language: Human Immunodeficiency Virus (HIV) (Counseling)
Covered Counseling	Counseling regarding HIV screening and HIV test results, risk reduction, and transmission reduction is a covered benefit for all pregnant women.
Initiation, Cessation, and Interval	All pregnant women are eligible to receive counseling and educational information on HIV and HIV screening before they are screened. All pregnant women who are screed for HIV are eligible for post-test counseling on their result and risk reduction. Pregnant women who have behaviors that place them at high risk for acquiring HIV infection (e.g., multiple sex partners, history of STDs, substance abuse, etc) are eligible for a referral to an HIV risk-reduction service (e.g., HIV centers with personnel trained in HIV counseling, drug treatment centers, etc).

	Summary Plan Description Language: Human Immunodeficiency Virus (HIV) (Preventive Medication)
Covered Preventive Medications	Antiretroviral chemoprophylaxis is a covered benefit for all infant beneficiaries who are born to women who are HIV positive or whose HIV status is unknown at the time of labor and delivery.
Initiation, Cessation, and Interval	All FDA-approved medications used for the prevention of perinatal HIV transmission are covered, as prescribed by a clinician, for exposed infants during the first 6 weeks of life (or as medically indicated).

	Summary Plan Description Language: Influenza (Immunization)
Covered Immunizations	All brands and types of influenza immunization are covered, as medically indicated.
Initiation, Cessation, and Interval	Influenza immunization is a covered benefit for all women who will be pregnant during the influenza season (October to mid-May). One influenza immunization is covered per influenza season and women should be immunized with each pregnancy, as indicated.

	Summary Plan Description Language: Preeclampsia (Screening)
Covered Screening Methods	Conventional measure using an arm cuff and an appropriately validated aneroid (containing no liquid) or digital sphygmomanometer (blood pressure meter).
Initiation, Cessation, and Interval	Blood pressure screening is covered for all pregnant women, as medically indicated.

	Summary Plan Description Language: Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (NTDs) (Screening)
Covered Screening Methods	All screening tests used to detect risk for chromosomal abnormalities and neural tube defects are covered.
Initiation, Cessation, and Interval	The timing and frequency is determined by the screening method used.

	Summary Plan Description Language: Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (NTDs) (Testing)
Covered Screening	Testing for chromosomal abnormalities and neural tube defects is a covered benefit. Coverage includes the use of all validated testing tools, including, but not limited to: • Amniocentesis • Chorionic villus sampling (CVS) • Ultrasound
Initiation, Cessation, and Interval	Testing for chromosomal abnormalities is covered for all pregnant women age 35 or older (and those who have equivalent risk) in place of, or in addition to, screening services. Testing for neural tube defects is covered for all pregnant women at elevated risk of neural tube defects based on a positive screen or other documented risk factor. Genetic counseling, when medically indicated and provided in association with testing, is also covered.

	Summary Plan Description Language: Rh (D) Incompatibility (Screening)
Covered Screening	Rh (D) blood typing and antibody testing is a covered benefit for all pregnant women.
Initiation, Cessation, and Interval	All pregnant women are eligible for Rh (D) blood typing and antibody testing at their first prenatal visit. Women known to be Rh (D)-negative and unsensitized are eligible for repeat Rh (D) antibody test at 24 to 28 weeks' gestation to determine their degree of sensitivity.

	Summary Plan Description Language: Rh (D) Incompatibility (Preventive Medication)
Covered Preventive Medications	Immune globulin
Initiation, Cessation, and Interval	Immune globulin is covered as a preventive medication for the following populations (as medically indicated): • All unsensitized Rh (D)-negative women after their repeated antibody screen at 24-28 weeks' gestation. • Rh (D)-negative mothers within 72 hours of delivering a Rh (D)-positive infant. • Rh (D)-negative mothers following amniocentesis or either induced or spontaneous abortion.

	Summary Plan Description Language: Rubella (Screening)
Covered Screening	Screening for rubella susceptibility is a covered benefit of all women of reproductive age. Screening may include: • Ascertaining an individual's risk for rubella by way of immunization history • Serologic test for antibodies
Initiation, Cessation, and Interval	All women of childbearing age, including pregnant women, are eligible for screening.

	Summary Plan Description Language: Syphilis (Screening)
Covered Screening	• Venereal disease research laboratory (VDRL) or the rapid plasma regain (RPR) on serum specimens followed by a fluorescent treponemal antibody absorbed (FTA-ABS) or *T. palladium* particle agglutination (TP-PA) for confirmation. • Enzyme-linked Immunosorbent Assay (ELISA) for treponemal antibody in serum specimens. • RPR point-of-care test for nontreponemal antibody in serum specimens. • Dark field microscope examination of lesion specimens.

Initiation, Cessation, and Interval	Syphilis screening is a covered benefit for all pregnant women at their first prenatal care visit. Women with a positive screen are eligible for a confirmatory test. Women who are at high risk for syphilis, are previously untested, or have a positive serology in the first trimester are eligible for re-screening and confirmatory testing during the third trimester and at delivery, or as medically indicated.
	Summary Plan Description Language: Tetanus (Immunization)
Covered Immunizations	All brands and types of tetanus immunization are covered as medically indicated.
Initiation, Cessation, and Interval	Coverage for tetanus vaccines is provided for all pregnant women without adequate documentation of a completed primary tetanus series and those without a tetanus vaccination within the past ten years.
	Summary Plan Description Language: Tobacco Use Treatment (Screening)
Covered Screening	Screening for tobacco use is a covered benefit for all pregnant women.
Initiation, Cessation, and Interval	There is no maximum limit on screening during pregnancy, provided that the care is medically indicated.
	Summary Plan Description Language: Tobacco Use Treatment (Counseling)
Covered Counseling	Smoking cessation counseling (5 to 15 minute sessions) is a covered benefit for all pregnant women who smoke. Counseling may be conducted during individual face-to-face office visits, in a group setting, or by telephone.
Initiation, Cessation, and Interval	Pregnant women who screen positive for tobacco use should be advised to quit at every medical encounter. There is no maximum number of counseling sessions for eligible pregnant women.
	Summary Plan Description Language: Hypertension (Screening)
Covered Screening	Conventional measure using an arm cuff and an appropriately validated aneroid (containing no liquid) or digital sphygmomanometer (blood pressure meter).
Initiation, Cessation, and Interval	Screening is a covered benefit for all children, adolescents, and adults, and may be conducted as medically indicated.

	Summary Plan Description Language: Hypertension (Counseling and Treatment)
Covered Counseling and Treatments	Covered treatment for hypertension includes: • Counseling to promote therapeutic lifestyle changes • Office visits to monitor hypertension and treatment efforts • Medications used to treat hypertension
Initiation, Cessation, and Interval	Six (6) counseling, treatment, and monitoring sessions are covered per calendar year. Additional counseling sessions are covered, as medically indicated. Beneficiaries undergoing treatment with hypertension-lowering medications qualify for additional medication management visits, as medically indicated.

	Summary Plan Description Language: Child, Adolescent, Adult Immunizations (Immunization)
Covered Screening/ Evaluation for Susceptibility and Immunization Methods	Screening/risk assessment for vaccine-preventable disease (VPD) is a covered benefit for all beneficiaries. Screening may include counseling by the provider. Screening can be accomplished by a review of vaccination history, preferably documented history, or (when appropriate) serologic testing for antibodies to VPD using accepted laboratory tests. Covered immunizations (children/adolescents): Single-antigen or combination vaccines as consistent with the most current ACIP recommendations. Currently included vaccines are: hepatitis B, diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b, polio, measles, mumps, rubella, varicella, pneumococcal disease, influenza, meningococcal disease, hepatitis A, rotavirus, human papillomavirus. Covered immunizations (adults): Single-antigen or combination vaccines as consistent with the most current ACIP recommendations. Currently included vaccines are: diphtheria, tetanus, influenza, human papillomavirus, pneumococcal disease. Also covered as necessary are: hepatitis A, hepatitis B, pertussis, measles, mumps, rubella, varicella, meningococcal disease, polio.
Initiation, Cessation, and Interval	Screening/risk assessment and immunizations are covered whenever indicated by medical conditions or other risk factors. There are no age or frequency limitations.

	Summary Plan Description Language: Lipid Disorders (Screening)
Covered Screening	9–12-hour fasting lipoprotein profile of total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides.
Initiation, Cessation, and Interval	Screening is a covered benefit for all adults aged 20 and older and may be conducted once every 5 years, or as medically indicated.

	Summary Plan Description Language: Lipids Disorders (Counseling and Treatment)
Covered Counseling and Treatments	Covered treatment for a lipid disorder includes: • Counseling to promote therapeutic lifestyle changes • Office visits to monitor lipid disorders and treatment efforts • Medications used to treat lipid disorders
Initiation, Cessation, and Interval	Six (6) counseling, treatment, and monitoring sessions are covered per calendar year. Additional counseling sessions are covered, as medically indicated. Beneficiaries undergoing treatment with lipid-lowering medications qualify for additional medication management visits, as medically indicated.
	Summary Plan Description Language: Motor Vehicle-Related Injury Prevention (Counseling)
Covered Counseling	Counseling to reduce motor vehicle related injuries is a covered benefit. Both brief clinician counseling (3 minutes or less) and intensive counseling are covered.
Initiation, Cessation, and Interval	Counseling to prevent motor vehicle-related injuries is a covered benefit for beneficiaries of driving age. Counseling should be conducted: 1) when beneficiaries first begin to drive (age 15, 16, or older depending on state law), 2) when beneficiaries first become parents, 3) when beneficiaries seek other preventive services for young children, 4) when beneficiaries present with alcohol or other drug dependencies, and 5) when beneficiaries receive trauma care for alcohol-related injuries. One counseling session is covered per year. Individuals at high risk for a motor vehicle-related injury (beneficiaries aged 18 to 33 years, parents of small children or adolescents, and substance and alcohol abusers) may be counseled more frequently, if medically indicated.
	Summary Plan Description Language: Obesity (Screening)
Covered Screening	Screening for obesity is a covered benefit and may include measurements and calculations relating to body mass index (BMI) and waist circumference.
Initiation, Cessation, and Interval	Screening is covered for all beneficiaries aged 2 and above once per calendar year. More frequent screening is covered, if medically indicated.

	Summary Plan Description Language: Obesity (Counseling)
Covered Counseling	Intensive counseling (2 or more person-to-person individual or group sessions per month, for at least 3 months) is a covered benefit for beneficiaries aged 18 and older who meet criteria for obesity (BMI > 30).
Initiation, Cessation, and Interval	Six (6) counseling sessions are covered per calendar year. Additional sessions are covered, if medically indicated.

	Summary Plan Description Language: Obesity (Treatment)
Covered Treatment Medications	All FDA-approved medications for the treatment of obesity or weight loss are are covered. Coverage is reserved for beneficiaries with a BMI higher than 30 and beneficiaries with a BMI of 27 to 29 who also have at least one additional major risk factor for cardiovascular disease. Coverage for medication is contingent on physician monitoring and participation in an individual or group counseling program.
Procedures	Surgical treatment procedures are covered. Coverage is reserved for beneficiaries aged 18 and older with class III obesity (BMI exceeding 40) and beneficiaries with class II obesity (BMI of 35 or higher) who also have at least one obesity-related illness. All obesity-related surgical procedures are subject to pre-authorization requirements.
Initiation, Cessation, and Interval	The duration of treatment is determined by the type of medication used and its dosage. Coverage is provided for medications and surgery, as prescribed by a clinician.

	Summary Plan Description Language: Osteoporosis (Screening)
Covered Screening	Screening for osteoporosis is a covered benefit. Screening may include the use of standardized instruments such as the Osteoporosis Risk Assessment Instrument (ORAI) and the Simple Calculated Osteoporosis Risk Estimation tool (SCORE) and/or use of the following: • Dual-energy x ray absorptiometry (DXA) • Peripheral dual-energy x-ray absorptiometry, • Peripheral quantitative computed tomography • Radiographic absorptiometry • Single-energy absorptiometry • Ultrasound
Initiation, Cessation, and Interval	Screening is provided for normal-risk women beginning at age 65. Screening is a covered benefit for all men beginning at age 70. High-risk women and men are eligible for screening beginning at age 60, or as otherwise medically indicated. Screening may not be conducted more frequently than once every 2 calendar years.

	Summary Plan Description Language: Osteoporosis (Treatment)
Covered Treatment	All FDA-approved medications for the treatment of osteoporosis are covered for beneficiaries aged 60 and older who meet medical necessity criteria for the treatment of osteoporosis.
Initiation, Cessation, and Interval	The duration of treatment is determined by the type of medication used and its dosage. Coverage is provided for medications, as prescribed by a clinician.

	Summary Plan Description Language: Sexually Transmitted Infections (Screening and Counseling)

	Counseling to Prevent Sexually Transmitted Infections (Counseling)
Covered Counseling	Counseling to prevent sexually transmitted infections (STIs) is a covered benefit.
Initiation, Cessation, and Interval	Counseling is a covered benefit for all adolescent and adult beneficiaries. One counseling session is covered per calendar year.

	Summary Plan Description Language: Chlamydia (Screening)
Covered Screening	Chlamydia screening is a covered benefit. The following tests are covered: • Antigen detection tests • Culture analysis of a endocervical or urethral swab • Culture of swab specimens from exposed sites • Non-amplified nucleic acid hybridization tests • Nucleic acid amplification assays • Point-of-care antigen detection tests on genital swab specimens and leukocyte esterase on urine.
Initiation, Cessation, and Interval	Annual screening is a covered benefit for all women aged 25 years and younger. Coverage is provided for women over age 25, if medically indicated.

	Summary Plan Description Language: Gonorrhea (Screening)
Covered Screening	Gonorrhea screening is a covered benefit. The following tests are covered: • Culture of swab specimens from exposed sites • Microscopic examination of Gram-stained urethral or cervical specimen • Non-amplified nucleic acid hybridization tests on genital swab specimens • Nucleic acid amplification assays • Point-of-care antigen detection tests on genital swab specimens and urine dipstick for leukocyte esterase (LE)
Initiation, Cessation, and Interval	Annual screening is a covered benefit for all women aged 25 years and younger. Coverage is provided for women over age 25, if medically indicated.

	Summary Plan Description Language: Human Immunodeficiency Virus (HIV) (Screening)
Covered Screening	HIV screening is a covered benefit. The following tests are covered: • All FDA-approved home collection kits using dried blood spots • Laboratory-based options on serum, plasma, or whole blood. • Rapid HIV tests (Uni-Gold Recombigen & Oraquick Advance) • Repeatedly reactive enzyme immunoassay • Western blot or immunoflourescent assay on serum or plasma
Initiation, Cessation, and Interval	Screening is a covered benefit for all persons aged 13 to 64. The frequency of screening should be determined by the beneficiary's risk factors, but should be conducted no more than once per calendar year.

	Summary Plan Description Language: Human Immunodeficiency Virus (HIV) (Counseling)
Covered Counseling	HIV counseling is a covered benefit.
Initiation, Cessation, and Interval	Counseling is a covered benefit for all beneficiaries aged 13 to 64 considering HIV testing. Beneficiaries are eligible for pre- and post-test counseling for a total of 3 sessions per test cycle.

	Summary Plan Description Language: Syphilis (Screening)
Covered Screening	Syphilis screening is a covered benefit. The following tests are covered: • Nontreponemal tests venereal disease research laboratory (VDRL) or the rapid plasma regain (RPR) on serum specimens followed by a fluorescent treponemal antibody absorbed (FTA-ABS) or *T. palladium* particle agglutination (TP-PA) for confirmation. • Immunochromatographic Strip (ICS) point-of-care test on blood specimen, when FDA approved. • Line Immunoassay (LIA) point-of-care test on blood specimen, when FDA approved. • Enzyme-linked Immunosorbent Assay (ELISA) for treponemal antibody in serum specimens. • RPR point-of-care test for nontreponemal antibody in serum specimens. • Dark field microscope examination of lesion specimens.
Initiation, Cessation, and Interval	Annual screening is a covered benefit for all beneficiaries at risk of infection. More frequent screening is provided, if medically indicated.

	Summary Plan Description Language: Tobacco Use Treatment (Screening)
Covered Screening	Screening for tobacco use is a covered benefit beginning at age 18. Coverage is provided for younger populations depending on risk and need.
Initiation, Cessation, and Interval	Screening may be conducted at every clinical encounter.

	Summary Plan Description Language: Tobacco Use Treatment (Counseling)
Covered Counseling	Brief counseling (in-person) and intensive counseling (in-person or over the telephone) are covered benefits for tobacco use treatment.
Initiation, Cessation, and Interval	Beneficiaries who meet criteria are eligible for 2 courses of 6 counseling sessions per calendar year, for a total of 12 sessions per calendar year.

	Summary Plan Description Language: Tobacco Use Treatment (Treatment)
Covered Treatment	All FDA-approved nicotine replacement products and tobacco cessation medications are covered.
Initiation, Cessation, and Interval	Medications are covered as prescribed by a clinician.
Treatment Services Not Covered	Neither hypnosis nor acupuncture has been demonstrated to be effective for tobacco cessation and these services are therefore not covered.

	Summary Plan Description Language: Tuberculosis (Screening)
Covered Screening	Screening for tuberculosis is a covered benefit and may include the use of the following: • Chest radiography • Intracutaneous administration of purified protein derivative {PPD} tuberculin using the Mantoux method, called the tuberculin skin test (TST) • Mycobacteriology services for smears, cultures • QuantiFERON®-TB Gold (QFT-G) • Sputum induction
Initiation, Cessation, and Interval	Screening is a covered benefit for all persons at high risk of tuberculosis and may be conducted as medically indicated. Follow up re-testing is covered as medically indicated. *Note:* Routine testing for TB or LTBI is not recommended for persons who are not at high risk of TB.

Current Procedural Terminology Codes (CPT© Codes)

Abdominal Aortic Aneurysm (Screening)	
76700	Abdominal ultrasound, complete
76705	Abdominal ultrasound, limited
Alcohol Misuse (Screening)	
99420	Administration and interpretation of health risk assessment instrument
H0001*	Alcohol and/or drug assessment
H0049*	Alcohol and other drug screening
Alcohol Misuse (Counseling)	
96150-5	Health and behavior assessment and intervention
98960-2	Education and training for patient self-management
90804-8	Psychotherapy, including medical management for some codes
99201-5	Evaluation and management, new patient
99212-5	Evaluation and management, established patient
99381-97	Preventive services
99401-5	Preventive counseling
H0050*	Brief counseling intervention
H0004*	Behavioral health counseling
Aspirin for the Primary Prevention of Cardiovascular Events (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
Breast Cancer (Screening)	
76092	Screening mammography, bilateral
76083	Computer aided detection with further physician review for interpretation, with or without digitization of film radiographic images; diagnostic mammography
0060T	Electrical impedance scan of the breast, bilateral (risk assessment device for breast cancer)

99386	Initial preventive medicine evaluation and management, 40 to 64 years, new patient
99387	Initial preventive medicine evaluation and management, 65 years and older
99396	Periodic preventive medicine evaluation and management, 40 to 64 years, established patient
99397	Periodic preventive medicine evaluation and management, 65 years and older
S8075*	Computer analysis of full-field digital mammogram and further physician review and interpretation, mammography
Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing (Testing)	
83890	Molecular diagnostics; molecular isolation or extraction
83891	Molecular diagnostics; isolation or extraction of highly purified nucleic acid
83892	Molecular diagnostics; enzymatic digestion
83893	Molecular diagnostics; dot/slot blot production
83894	Molecular diagnostics; separation by gel electrophoresis
83896	Molecular diagnostics; nucleic acid probe, each
83897	Molecular diagnostics; nucleic acid transfer
83898	Molecular diagnostics; amplification of patient nucleic acid, each nucleic acid sequence
83900	Molecular diagnostics; amplification of patient nucleic acid, multiplex, first two nucleic acid sequences
83901	Molecular diagnostics; amplification of patient nucleic acid, multiplex, each additional nucleic acid
83902	Molecular diagnostics; reverse transcription
83903	Molecular diagnostics; mutation scanning by physical properties, single segment, each
83904	Molecular diagnostics; mutation identification by sequencing, single segment, each segment
83905	Molecular diagnostics; mutation identification by allele specific transcription, single segment, each segment

83906	Molecular diagnostics; mutation identification by allele specific translation, single segment, each segment
83907	Molecular diagnostics; lysis of cells prior to nucleic acid extraction
83908	Molecular diagnostics; signal amplification of patient nucleic acid, each nucleic acid sequence
83909	Molecular diagnostics; separation and identification by high resolution technique
83912	Molecular diagnostics; interpretation and report
88271	Molecular cytogenetics; DNA probe, each
88272*	Molecular cytogenetics; chromosomal *in situ* hybridization, analyze 3 – 5 cells
S3818*	Complete gene sequence analysis; BRCA1 gene
S3819*	Complete gene sequence analysis; BRCA2 gene
S3820*	Complete BRCA1 and BRCA2 gene sequence analysis for susceptibility to breast and ovarian cancer
S3822*	Single mutation analysis (in individual with a known BRCA1 or BRCA2 mutation in the family) for susceptibility to breast and ovarian cancer
S3823*	Three-mutation BRCA1 and BRCA2 analysis for susceptibility to breast and ovarian cancer in Ashkenazi individuals
Breast Cancer Preventive Medication and Preventive Treatment (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
Breast Cancer (Preventive Medication)	
S0187*	Tamoxifen citrate, oral 10 mg
Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing (Preventive Treatment)	
19160	Mastectomy, partial
19162	Mastectomy, partial; with axillary lymphadenectomy
19180	Mastectomy, simple, complete
19182	Mastectomy, subcutaneous
19200	Mastectomy, radical, including pectoral muscles, axillary lymph nodes
19220	Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes
19240	Mastectomy, modified radical

19340	Immediate insertion of breast prosthesis following mastectomy
19342	Delayed insertion of breast prosthesis following mastectomy
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
19361	Breast reconstruction with latissimus dorsi flap, with or without prosthetic implant
19364	Breast reconstruction with free flap
19366	Breast reconstruction with other technique
19367	Breast reconstruction with transverse rectus abdmoninis myocutaneous flap, single pedicle, including closure of donor site
19369	Breast reconstruction with transverse rectus abdmoninis myocutaneous flap, double pedicle, including closure of donor site
58661	Laparoscopy, surgical; with removal of adnexal structures
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral
58940	Oophorectomy, partial or total, unilateral or bilateral
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
Cervical Cancer (Screening)	
88141	Cytopathology, cervical or vaginal, requiring interpretation by physician
88142	Cytopathology, cervical or vaginal, automated thin layer prep, manual screening under physician supervision
88143	Cytopathology, cervical or vaginal, automated thin layer prep, manual screening and rescreening under physician supervision
88147	Cytopathology smears, cervical or vaginal, screening by automated system, under physician supervision
88148	Cytopathology smears, cervical or vaginal, screening by automated system with manual rescreening under physician supervision
88150	Cytopathology slides, cervical or vaginal, manual screening under physician supervision
88152	Cytopathology slides, cervical or vaginal, manual screening and computer-assisted rescreening under physician supervision
88153	Cytopathology slides, cervical or vaginal, manual screening and rescreening under physician supervision

88154	Cytopathology slides, cervical or vaginal, manual screening and computer-assisted rescreening using cell selection and review under physician supervision
88155	Cytopathology slides, cervical or vaginal, definitive hormonal evaluation
88164	Cytopathology slides, cervical or vaginal (Bethesda), manual screening under physician supervision
88165	Cytopathology slides, cervical or vaginal (Bethesda), manual screening and rescreening under physician supervision
88166	Cytopathology slides, cervical or vaginal (Bethesda), manual screening and computer-assisted rescreening under physician supervision
88167	Cytopathology slides, cervical or vaginal (Bethesda), manual screening and computer-assisted rescreening using cell selection and review under physician supervision
88174	Cytopathology, cervical or vaginal, collected in preservation fluid, automated thin layer prep, screening by automated system under physician supervision
88175	Cytopathology, cervical or vaginal, collected in preservation fluid, automated thin layer prep, screening by automated system and manual rescreening or review under physician supervision
Childhood Health Promotion (Screening, Counseling, Immunization, Preventive Medication and Treatment)	
Child Development (Screening)	
96110	Developmental screening; limited with interpretation and report
96111	Developmental testing; extended with interpretation and report
99381	Initial comprehensive preventive medicine evaluation and management, infant (under 1 year), new patient
99382	Initial comprehensive preventive medicine evaluation and management, early childhood (ages 1 to 4), new patient
99391	Periodic comprehensive preventive medicine evaluation and management, infant (under 1 year), established patient
99392	Periodic comprehensive preventive medicine evaluation and management, early childhood (ages 1 to 4), established patient
99201–99205	Office or outpatient visit, new patient
99211–99215	Office or outpatient visit, established patient
Dental Caries Prevention through Oral Fluoride Supplementation (Preventive Medication)	
D1201	Topical application of fluoride, including prophylaxis, child
D1203	Topical application of fluoride, excluding prophylaxis, child

Elevated Blood Lead Levels (Screening)	
83655	Lead
36415	Venipuncture
Childhood Immunizations	
	See Immunizations
Newborn Hearing (Screening)	
92585	Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive
92586	Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited
92587	Evoked otoacoustic emissions; limited (single stimulus level, either transient or distortion products)
92588	Evoked otoacoustic emissions; comprehensive or diagnostic evaluation (comparison of transient and/or distortion product otoacoustic emissions at multiple levels and frequencies)
Newborn Screening for Genetic and Endocrine Disorders (Screening)	
	Screening for genetic and endocrine disorders is a covered benefit. Purchasers should refer to their health plan administrators for a current list of applicable CPT codes.
Newborn Screening for Genetic and Endocrine Disorders (Medical Foods)	
	CPT code not applicable
Newborn Screening for Genetic and Endocrine Disorders (Treatment)	
	Medications and other forms of treatment used to *prevent* illness or disability among beneficiaries with genetic or endocrine disorders are covered. Case management is a covered benefit and is provided, as medically necessary, for beneficiaries with complex disorders. Purchasers should refer to their health plan administrators for a list of applicable CPT codes.
Vision (Screening) (Child)	
92081	Visual field exam, unilateral or bilateral, limited exam
92082	Visual field exam, unilateral or bilateral, intermediate exam
92083	Visual field exam, unilateral or bilateral, extended exam
99172	Visual function screening, automated or semi-automated bilateral, quantitative
99173	Visual acuity screening, quantitative, bilateral
92002	Ophthalmological medical exam and evaluation, intermediate, new patient

92004	Ophthalmological medical exam and evaluation, comprehensive, one or more visits, new patient
92012	Ophthalmological medical exam and evaluation, intermediate, established patient
92014	Ophthalmological medical exam and evaluation, comprehensive, one or more visits, established patient
0065T	Ocular photoscreening, interpretation and report, bilateral
Colorectal Cancer (Screening)	
45378	Colonoscopy
45330	Sigmoidoscopy, flexible
74270	Barium enema, with/without KUB
74280	Radiological exam, colon, air contrast with specific high-density barium, with/without glucagon
82270	Fecal occult blood for colorectal neoplasm screening, by peroxidase activity, consecutive collected specimens with single determination
Contraceptive Use (Counseling)	
99384	Initial preventive medicine evaluation and management, adolescent (12 to 17 years), new patient
99385	Initial preventive medicine evaluation and management, 18 to 39 years, new patient
99386	Initial preventive medicine evaluation and management, 40 to 64 years, new patient
99394	Periodic preventive medicine evaluation and management, adolescent (12 to 17 years), established patient
99395	Periodic preventive medicine evaluation and management, 18 to 39 years, established patient
99396	Periodic preventive medicine evaluation and management, 40 to 64 years, established patient
Contraceptive Use (Preventive Intervention)	
11975	Insertion implantable contraceptive capsules
58300	IUD insertion
58565	Hysteroscopy; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
58600	Ligation or transection of fallopian tube(s), abdominal or vaginal approach, unilateral or bilateral

58605	Ligation or transection of fallopian tube(s), abdominal or vaginal approach, postpartum, unilateral or bilateral, during same hospitalization (separate procedure)
58611	Ligation or transection of fallopian tube(s) when done at the time of cesarean delivery or intra-abdominal surgery (not a separate procedure) (List separately in addition to code for primary procedure)
58615	Occlusion of fallopian tube(s) by device (e.g, band, clip, Falope ring) vaginal or suprapubic approach
58661	Laparoscopy; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58671	Laparoscopy, surgical; with occlusion of oviducts by device (e.g., band, clip, or Falope ring)
58700	Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)
55250	Vasectomy, unilateral or bilateral (separate procedure), including postoperative semen examination(s)
S4993	Contraceptive pills for birth control
Depression (Screening)	
99420	Administration and interpretation of health risk assessment instrument
Diabetes (Screening)	
82947	Glucose, blood (except reagent stript)
82948	Glucose, blood, reagent strip
82950	Glucose, post glucose dose
82951	Glucose tolerance test, 3 specimens
82952	Glucose tolerance test, each additional specimen beyond 3
82962	Glucose, blood, by monitoring device FDA-approved for home use
36415	Venipuncture
99385	Initial preventive medicine evaluation and management, 18 to 39 years, new patient
99386	Initial preventive medicine evaluation and management, 40 to 64 years, new patient
99394	Periodic preventive medicine evaluation and management, adolescent (12 to 17 years), established patient
99395	Periodic preventive medicine evaluation and management, 18 to 39 years, established patient
99396	Periodic preventive medicine evaluation and management, 40 to 64 years, established patient

Healthy Diet (Counseling)	
99402	Preventive medicine counseling/risk factor reduction, individual, 30 minutes
99412	Preventive medicine counseling/risk factor reduction, group, 60 minutes
99403	Preventive medicine counseling/risk factor reduction, individual, 45 minutes
99411	Preventive medicine counseling/risk factor reduction, group, 30 minutes
98960	Education and training for patient self-management by a qualified, nonphysician healthcare professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient
S9470*	Nutritional counseling, dietician visit
Healthy Pregnancy (Screening, Testing, Counseling, Preventive Medication, and Treatment)	
Alcohol Misuse (Screening)	
99420	Administration/interpretation health risk assessment instrument
Alcohol Misuse (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
Asymptomatic Bacteriuria (Screening)	
87077	Culture, bacterial; aerobic isolate, additional methods required for definitive identification, each isolate
87086	Culture, bacterial; quantitative colony count, urine
87088	Culture, bacterial; with isolation and presumptive identification of isolates, urine
87187	Susceptibility studies, antimicrobial agent; microdilution or agar dilution, minimum lethal concentration (MLC), each plate
Breastfeeding (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes

98960	Education and training for patient self-management by a qualified, non-physician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient
Folic Acid Supplementation (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
Folic Acid Supplementation (Preventive Medication)	
	CPT code not applicable
Group B Streptococcal Disease (Screening)	
87081	Culture, presumptive, pathogenic organisms, screening only
Group B Streptococcal Disease (Preventive Medication)	
	CPT code not applicable
Hepatitis B Virus (HBV) (Screening)	
36415	Venipuncture
87340	Hepatitis B surface antigen (HBsAg)
Hepatitis B Virus (HBV) (Immunization)	
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)
90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use
90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use
90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use
90746	Hepatitis B vaccine, adult dosage, for intramuscular use
90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use
Hepatitis B Virus (HBV) (Treatment)	
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)

90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use
90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use
90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use
90746	Hepatitis B vaccine, adult dosage, for intramuscular use
90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use
90371	Hepatitis B immune globulin (HBIg), human, for intramuscular use
90772	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
Human Immunodeficiency Virus (HIV) (Screening)	
36415	Venipuncture
86689	HTLV or HIV antibody, confirmatory test
86701	HIV-1 antibody
86702	HIV-2 antibody
86703	HIV-1 and HIV-2 antibody, single assay
87390	Infectious agent antigen detection, HIV-1
87391	Infectious agent antigen detection, HIV-2
S3645*	HIV antibody testing of oral mucosal transudate
Human Immunodeficiency Virus (HIV) (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
Human Immunodeficiency Virus (HIV) (Preventive Medication)	
J3485	Zidovudine, injection, 10 mg
S0104*	Zidovudine, oral, 100 mg
Influenza (Immunization)	
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)

90656	Influenza virus vaccine, split virus, preservative free, for use in individuals 3 years and above, for intramuscular use
90658	Influenza virus vaccine, split virus, for use in individuals 3 years of age and above, for intramuscular use
Preeclampsia (Screening)	
	CPT code not applicable
Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (NTDs) (Screening)	
36415	Venipuncture
82105	Alpha-fetoprotein; serum
82106	Amniotic fluid
84702	Gonadotropin, chorionic (hCG); quantitative
84703	Qualitative
86336	Inhibin A
83632	Lactogen, human placental (HPL) human chorionic somatomammotropin
59000	Amniocentesis
76946	Ultrasound guidance for amniocentesis
59015	Chorionic villus sampling
76945	Ultrasound guidance for chorionic villus sampling
59012	Cordocentesis
76941	Ultrasonic guidance for cordocentesis
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291	Greater than 5 embryos
11100–11107	Skin Biopsy
82012	ACHE
82677	Quantitative Estriol
83020	Hemoglobin Electrophoresis
83896	Nucleic Acid Probe (each)
83898	Nucleic Acid Probe w/Amplication (PCR)
83912	DNA Interpretation and Report
86316	Cancer Antigen Immunoassay

88230	Cell Culture, Lymphocytes
88233	Cell Culture, Tissue
88235	Cell Culture, Amnio/CVS
88237	Cell Culture, Bone Marrow
88239	Cell Culture, Other Tissue
88245	Blood Chromosomes, Bloom syndrome
88248	Blood Chromosomes, Fanconi syndrome
88250	Blood Chromosomes, Fra(X)
88261	Chromosome Analysis, 5 Cell, Karyotype
88262	Chromosome Analysis, Routine
88262	Chromosome Analysis, Post BMT
88262	Additional Tissue
88267	Chromosome Analysis, Mosaic
88267	Chromosome Analysis/Karyotype (Amnio)
88267	Chromosome Analysis/Karyotype (CVS)
88269	Chromosomal Analysis/Karyotype (*In situ*)
88280	Additional Karyotype
88283	Additional Banding
88285	Additional Cells Counted
88289	Additional High Resolution
88271	X 5 Molecular cytogenetics, DNA probe, each (code applied 5 times, once for each probe in the assay)
88275	Interphase *in situ* hybridization, count 100 to 300 cells
88291	Molecular cytogenetics, interpretation and report
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
S3828*	Complete gene sequence analysis; MLH1 gene
S3830*	Complete mlh1 and mlh2 gene sequence analysis for hereditary nonpolyposis colorectal cancer (HNPCC) genetic testing

S3831*	Single-mutation analysis (in individual with a known MLH1 and MLH2 mutation in the family) for hereditary nonpolyposis colorectal cancer (HNPCC) genetic testing
S3833*	Complete APC gene sequence analysis for susceptibility to familial adenomatous polyposis (FAP) and attenuated FAP
S3834*	Single-mutation analysis (in individual with a known APC mutation in the family) for susceptibility to familial adenomatous polyposis (FAP) and attenuated FAP
S3835*	Complete gene sequence analysis for cystic fibrosis genetic testing
S3837*	Complete gene sequence analysis for hemochromatosis genetic testing
S3840*	DNA analysis for germline mutations of the ret proto-oncogene for susceptibility to multiple endocrine neoplasia type 2
S3841*	Genetic testing for retinoblastoma
S3842*	Genetic testing for von Hippel-Lindau disease
S3843*	DNA analysis of the F5 gene for susceptibility to Factor V Leiden thrombophilia
S3844*	DNA analysis of the connexin 26 gene (GJB2) for susceptibility to congenital, profound deafness
S3845*	Genetic testing for alpha-thalassemia
S3846*	Genetic testing for hemoglobin E beta-thalassemia
S3847*	Genetic testing for Tay-Sachs disease
S3848*	Genetic testing for Gaucher disease
S3849*	Genetic testing for Niemann-Pick disease
S3850*	Genetic testing for sickle cell anemia
S3851*	Genetic testing for Canavan disease
S3853*	Genetic testing for myotonic muscular dystrophy
Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (NTDs) (Testing)	
9000	Amniocentesis
76946	Ultrasound guidance for amniocentesis
59015	Chorionic villus sampling
76945	Ultrasound guidance for chorionic villus sampling
76801	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (14 weeks 0 days), transabdominal approach; single or first gestation

76802	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)
76805	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; single or first gestation
76810	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; each additional gestation
76811	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation
76812	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; each additional gestation
76815	Ultrasound, pregnant uterus, real time with image documentation, limited (eg, fetal heart beat, placental location, fetal position, and/or qualitative amniotic fluid volume), one or more fetuses
76816	Ultrasound, pregnant uterus, real time with image documentation, follow-up (e.g., re-evaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, re-evaluation of organ system(s) suspected or confirmed to be abnormal on a previous scan), transabdominal approach, per fetus
76817	Ultrasound, pregnant uterus, real time image documentation, transvaginal
76818	Fetal biophysical profile; with non-stress testing
76819	Fetal biophysical profile; without non-stress testing
Rh(D) Incompatibility (Screening)	
36415	Venipuncture
86901	Blood typing, Rh(D)
Rh(D) Incompatibility (Preventive Medication)	
90384	Rho(D) immune globulin (RhIg), human, full-dose, for intramuscular use
90385	Rho(D) immune globulin (RhIg), human, mini-dose, for intramuscular use
90386	Rho(D) immune globulin (RhIgIV), human, for intravenous use
90772	Injection, intramuscular
90774	Injection, IV push

90765	Intravenous infusion, up 1 hour
90766	Intravenous infusion, each additional hour
Rubella (Screening)	
36415	Venipuncture
86762	Rubella antibody
Syphilis (Screening)	
36415	Venipuncture
86592	Syphilis, qualitative
86593	Syphilis, quantitative
86781	Treponema pallidum, confirmatory test (e.g., FTA-abs)
86403	Particle agglutination; screen, each antibody
86406	Particle agglutination; titer, each antibody\
Tetanus (Immunization)	
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)
90703	Tetanus toxoid adsorbed, for intramuscular use
90714	Tetanus and diphtheria toxoids (Td) adsorbed, preservation free, for use in individuals sever years or older, intramuscular use
90718	Tetanus and diphtheria toxoids (Td) adsorbed for use in individuals 7 years or older, for intramuscular use
Tobacco Use Treatment (Screening)	
99420	Administration/interpretation health risk assessment instrument
Tobacco Use Treatment (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
S9075*	Tobacco use treatment

Hypertension (Screening)	
	CPT code not applicable
Hypertension (Counseling, Treatment)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
99201	Office/outpatient evaluation and management visit, new patient, level 1
99202	Office/outpatient evaluation and management visit, new patient, level 2
99203	Office/outpatient evaluation and management visit, new patient, level 3
99204	Office/outpatient evaluation and management visit, new patient, level 4
99205	Office/outpatient evaluation and management visit, new patient, level 5
99211	Office/outpatient evaluation and management visit, established patient, level 1
99212	Office/outpatient evaluation and management visit, established patient, level 2
99213	Office/outpatient evaluation and management visit, established patient, level 3
99214	Office/outpatient evaluation and management visit, established patient, level 4
99215	Office/outpatient evaluation and management visit, established patient, level 5
Immunizations (Child, Adolescent, Adults)	
	This list is complete and up-to-date as of July 11, 2006. Please refer to your appropriate state or local agency, providers, or partner organizations (e.g., Medicaid, AAP, AAFP, etc.) regarding use of these codes. Please refer to AMA/CPT publications as the current, authoritative source. AMA/CPT publication information can be found online at (www.ama-assn.org/ama/pub/category/3113.html). Errata for the most recent CPT print edition can also be found online (www.ama-assn.org/ama/pub/category/3896.html). Please refer to (www.ama-assn.org/ama/pub/category/10902.html) for additional "early release" codes.
Vaccines (Toxoids)	
90281	Immune globulin (Ig), human, intramuscular use
90283	Immune globulin (IgIV), human, intravenous use
90296	Diphtheria antitoxin, equine, any route
90371	Hepatitis B immune globulin (HBIg), human, intramuscular use
90389	Tetanus immune globulin (TIg), human, intramuscular use

90396	Varicella-zoster immune globulin, human, intramuscular use
90399	Unlisted immune globulin
90632	Hepatitis A vaccine, adult dosage, intramuscular use
90633	Hepatitis A vaccine, pediatric/adolescent dosage-2 dose schedule, intramuscular use
90634	Hepatitis A vaccine, pediatric/adolescent dosage-3 dose schedule, intramuscular use
90636	Hepatitis A and hepatitis B (HepA-HepB), adult dosage, intramuscular use
90645	*Hemophilus influenza* b vaccine (Hib), HbOC conjugate (4 dose schedule), intramuscular use
90646	*Hemophilus influenza* b vaccine (Hib), PRP-D conjugate, for booster use only, intramuscular use
90647	*Hemophilus influenza* b vaccine (Hib), PRP-OMP conjugate (3 dose schedule), intramuscular use
90648	*Hemophilus influenza* b vaccine (Hib), PRP-T conjugate (4 dose schedule), intramuscular use
90649	Human papilloma virus (HPV) vaccine, types 6, 11, 16, 18 (quadrivalent) 3 dose schedule, intramuscular use.
90655	Influenza virus vaccine, split virus, preservative free, for children 6-35 months of age, intramuscular use
90656	Influenza virus vaccine, split virus, preservative free, for use in individuals 3 years of age and above, intramuscular use
90657	Influenza virus vaccine, split virus, for children 6-35 months of age, intramuscular use
90658	Influenza virus vaccine, split virus, for use in individuals 3 years of age and above, intramuscular use
90660	Influenza virus vaccine, live, intranasal use
90669	Pneumococcal conjugate vaccine, polyvalent, for children under five years, intramuscular use
90680	Rotavirus vaccine, pentavalent, 3 dose schedule, live, oral use.
90698	Diphtheria, tetanus toxoids, and acellular pertussis vaccine, haemophilus influenza Type B, and poliovirus vaccine, inactivated (DTaP - Hib - IPV), intramuscular use
90700	Diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP), for use in individuals younger than seven years, intramuscular use
90701	Diphtheria, tetanus toxoids, and whole cell pertussis vaccine (DTP), intramuscular use

90702	Diphtheria and tetanus toxoids (DT) adsorbed for use in individuals younger than seven years, intramuscular use
90703	Tetanus toxoid adsorbed, intramuscular use
90704	Mumps virus vaccine, live, subcutaneous use
90705	Measles virus vaccine, live, subcutaneous use
90706	Rubella virus vaccine, live, subcutaneous use
90707	Measles, mumps and rubella virus vaccine (MMR), live, subcutaneous use
90708	Measles and rubella virus vaccine, live, subcutaneous use
90710	Measles, mumps, rubella, and varicella vaccine (MMRV), live, subcutaneous use
90712	Poliovirus vaccine, (any type(s)) (OPV), live, oral use
90713	Poliovirus vaccine, inactivated, (IPV), subcutaneous or intramuscular use
90714	Tetanus and diphtheria toxoids (Td) adsorbed, preservative free, for use in individuals seven years or older, intramuscular use
90715	Tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap), for use in individuals 7 years or older, intramuscular use
90716	Varicella virus vaccine, live, subcutaneous use
90718	Tetanus and diphtheria toxoids (Td) adsorbed for use in individuals seven years or older, intramuscular use
90719	Diphtheria toxoid, intramuscular use
90720	Diphtheria, tetanus toxoids, and whole cell pertussis vaccine and *Hemophilus influenza* B vaccine (DTP-Hib), intramuscular use
90721	Diphtheria, tetanus toxoids, and acellular pertussis vaccine and *Hemophilus influenza* B vaccine (DTaP-Hib), intramuscular use
90723	Diphtheria, tetanus toxoids, acellular pertussis vaccine, Hepatitis B, and poliovirus vaccine, inactivated (DTaP-HepB-IPV), intramuscular use
90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, subcutaneous or intramuscular use
90733	Meningococcal polysaccharide vaccine (any group(s)), subcutaneous use
90734	Meningococcal conjugate vaccine, serogroups A, C, Y and W-135 (tetravalent), intramuscular use
90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), intramuscular use
90743	Hepatitis B vaccine, adolescent (2 dose schedule), intramuscular use
90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), intramuscular use

90746	Hepatitis B vaccine, adult dosage, intramuscular use
90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), intramuscular use
90748	Hepatitis B and *Hemophilus influenza* b vaccine (HepB-Hib), intramuscular use
90749	Unlisted vaccine/toxoid
Vaccines (Administration and Counseling)	
90465	Immunization administration under 8 years of age (includes percutaneous, intradermal, subcutaneous, or intramuscular injections) when the physician counsels the patient/family; first injection (single or combination vaccine/toxoid), per day
90466	Each additional injection (single or combination vaccine/toxoid), per day (List separately in addition to code for primary procedure)
90467	Immunization administration under 8 years of age (includes intranasal or oral routes of administration) when the physician counsels the patient/family; first administration (single or combination vaccine/toxoid), per day
90468	Each additional administration (single or combination vaccine/toxoid), per day (List separately in addition to code for primary procedure)
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)
90472	Each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)
90473	Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid)
90474	Each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)
Lipid Disorders (Screening)	
82465	Cholesterol, serum or whole blood, total
83721	Lipoprotein, direct measurement, LDL cholesterol
83719	Lipoprotein, direct measurement, VLDL cholesterol
83718	Lipoprotein, direct measurement, high density cholesterol
84478	Triglycerides

Lipid Disorders (Counseling and Treatment)	
99401	Preventive medicine counseling/risk factor reduction, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, 60 minutes
99201	Office/outpatient evaluation and management visit, new patient, level 1
99202	Office/outpatient evaluation and management visit, new patient, level 2
99203	Office/outpatient evaluation and management visit, new patient, level 3
99204	Office/outpatient evaluation and management visit, new patient, level 4
99205	Office/outpatient evaluation and management visit, new patient, level 5
99211	Office/outpatient evaluation and management visit, established patient, level 1
99212	Office/outpatient evaluation and management visit, established patient, level 2
99213	Office/outpatient evaluation and management visit, established patient, level 3
99214	Office/outpatient evaluation and management visit, established patient, level 4
99215	Office/outpatient evaluation and management visit, established patient, level 5
Motor Vehicle-Related Injury Prevention (Counseling)	
99401	Preventive medicine counseling and/or risk factor reduction, 15 minutes
99402	Preventive medicine counseling and/or risk factor reduction, 30 minutes
99403	Preventive medicine counseling and/or risk factor reduction, 45 minutes
99404	Preventive medicine counseling and/or risk factor reduction, 60 minutes
Obesity (Screening)	
99420	Administration and interpretation of health risk assessment instrument
Obesity (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, individual, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, individual, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, individual, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, individual, 60 minutes
99411	Preventive medicine counseling/risk factor reduction, group, 30 minutes
99412	Preventive medicine counseling/risk factor reduction, group, 60 minutes

Obesity (Treatment)	
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity;With small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric band
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open removal and replacement of subcutaneous port component only
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric band component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric band component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band and subcutaneous port components
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy
43645	Laparoscopy, surgical, gastric restrictive procedure with gastric bypass and small intestine reconstruction to limit absorption
Osteoporosis (Screening)	
99420	Administration and interpretation of health risk assessment instrument
76071	Computerized tomography, bone mineral density study, one or more sites; appendicular skeleton

76076	Dual energy x-ray absorptiometry (DXA), bone density study, one or more sites; appendicular skeleton
76077	Dual energy x-ray absorptiometry (DXA), bone density study, one or more sites; vertebral fracture assessment
76078	Radiographic absorptiometry (e.g., photodensitometry, radiogrammetry), one or more sites
76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method
78350	Bone density (bone mineral content) study, one or more sites; single photon absorptiometry
78351	Bone density (bone mineral content) study, one or more sites; dual photon absorptiometry, one or more sites
Osteoporosis (Treatment)	
	CPT code not applicable
Sexually Transmitted Infections (Screening and Counseling)	
Counseling to Prevent Sexually Transmitted Infections (STI)	
99401	Preventive medicine counseling/risk factor reduction, individual, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, individual, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, individual, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, individual, 60 minutes
Chlamydia (Screening)	
87270	Infectious agent antigen detection by immunofluorescent technique, Chlamydia trachomatis
87320	Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semi-quantitative, Chlamydia trachomatis
87320	Chlamydia, culture, any source
87810	Infectious agent detection by immunoassay with direct optical observation, Chlamydia trachomatis
87490	Infectious agent detection by nucleic acid; Chlamydia trachomatis, direct probe technique
87491	Infectious agent detection by nucleic acid; Chlamydia trachomatis, amplified probe technique
87800	Infectious agent detection by nucleic acid, multiple organisms; direct probe technique

87801	Infectious agent detection by nucleic acid, multiple organisms; amplified probe technique
81000	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
81001	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy
81002	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy
81003	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated without microscopy
Gonorrhea (Screening)	
87081	Culture, presumptive, pathogenic organisms, screening only
87205	Smear, primary source with interpretation; Gram or Giemsa stain for bacteria, fungi, or cell types
87800	Infectious agent detection by nucleic acid, multiple organisms; direct probe technique
87801	Infectious agent detection by nucleic acid, multiple organisms; amplified probe technique
87590	Infectious agent detection by nucleic acid (DNA or RNA); *Neisseria gonorrhoeae,* direct probe technique
87591	Infectious agent detection by nucleic acid (DNA or RNA); *Neisseria gonorrhoeae,* amplified probe technique
81003	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated without microscopy
Human Immunodeficiency Virus (HIV) (Screening)	
36415	Venipuncture
86689	HTLV or HIV antibody, confirmatory test
86701	HIV-1 antibody
86702	HIV-2 antibody
86703	HIV-1 and HIV-2 antibody, single assay
87390	Infectious agent antigen detection, HIV-1

87391	Infectious agent antigen detection, HIV-2
S3645*	HIV antibody testing of oral mucosal transudate
Human Immunodeficiency Virus (HIV) (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, individual, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, individual, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, individual, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, individual, 60 minutes
Syphilis (Screening)	
36415	Venipuncture
86592	Syphillis test, qualitative
86781	Antibody, treponemal pallidum, confirmatory test
87164	Dark field examination, any source, includes specimen collection
87166	Dark field examination, any source, without collection
Tobacco Use (Screening)	
99420	Administration/interpretation health risk assessment instrument
Tobacco Use (Counseling)	
99401	Preventive medicine counseling/risk factor reduction, individual, 15 minutes
99402	Preventive medicine counseling/risk factor reduction, individual, 30 minutes
99403	Preventive medicine counseling/risk factor reduction, individual, 45 minutes
99404	Preventive medicine counseling/risk factor reduction, individual, 60 minutes
S9075*	Smoking cessation treatment
Tobacco Use (Treatment)	
	CPT code not applicable
Tuberculosis (Screening)	
71010	Chest xray, single view
71020	Chest xray, two views, frontal and lateral
71030	Chest xray, complete, minimum of four views
86580	Skin test, tuberculosis, intradermal

86480	Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response
94640	Sputum induction for diagnostic purposes
87116	Culture, tubercle or other acid-fast bacilli (eg, TB, AFB, mycobacteria) any source, with isolation and presumptive identification of isolates
36415	Venipuncture

Source:

This publication contains CPT codes to offer information regarding coding of medical services using the CPT coding system. The CPT codes presented are based on the experience and interpretations of the publisher. The material in this manual is to assist in obtaining correct and appropriate coverage and reimbursement for healthcare goods and services. To the best of our knowledge, the information contained in the manual was correct as of the date of publication. However, there can be no assurances that it will not become outdated without notice or that the government or other payers may differ with the guidance contained in the manual. The responsibility for coding correctly lies with the healthcare provider, and we urge you to consult with your coding advisors to resolve any billing questions that you might have. Though all of the information has been carefully researched and checked for accuracy and completeness, the publisher does not accept any responsibility or liability with regard to errors, omissions, misuse or misinterpretation. Please note that CPT codes change annually, the most current CPT is available from the American Medical Association.

No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use.

Notes:

*"S" codes are national Permanent Level II HCPCS Codes that are maintained by the HCPCS National Panel, a group comprised of representatives from the Blue Cross/Blue Shield Association (BCBSA), the Health Insurance Association of America (HIAA), and the Centers for Medicare and Medicaid Services (CMS). Permanent Level II HCPCS Codes provide a standardized coding system that is managed jointly by public and private insurers, thus providing a stable system for claims processing. These codes can be used by all private and public insurers.

*"H" codes are used by Medicaid and other plans in order to identify mental health services such as alcohol and drug screening.

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3 Evidence-Statements for Recommended Clinical Preventive Service Benefits

Overview:

The scientific evidence behind each of the 46 screening, testing, counseling, immunization, preventive medication, and (preventive) treatment benefit recommendations.

3 Evidence-Statements for Recommended Clinical Preventive Service Benefits

Evidence Statements for Recommended Clinical Preventive Service Benefits

The following is a complete list of clinical preventive services covered in the *Purchaser's Guide*. These recommended clinical preventive services address a range of health conditions that affect people of all ages. For a brief summary of clinical preventive services appropriate for different age groups and genders, please refer to the Life Course Charts featured in *Part VII: Resources & Tools*.

Evidence-statements are organized in alphabetical order. Each evidence-statement has an accompanying SPD language statement. Please refer to *Part II: Summary Plan Description (SPD) Language Statements for Recommended Clinical Preventive Service Benefits*, for additional information.

Estimating the Cost of Preventive Interventions

The information provided in the "Cost of Preventive Intervention" subsection of the "Value of Prevention" section of each evidence-statement was adapted from the 2004 Medstat Marketscan health insurance claims database. The analysis used claims paid by preferred provider organizations (PPOs) to calculate average reimbursement rates and 95% confidence intervals for preventive screenings and procedures. The Medstat Marketscan database is compiled from health insurance claims of 40 self-insured employers. All 50 states are represented in the database, which captured 6 million covered life-years during 2004. Information in the "Cost of Treatment" subsection of the "Value of Prevention" section of each evidence-statement was adapted from peer-reviewed journal articles and other sources. This information may not be exclusive to commercially-insured beneficiaries.

It is important to note that the Medstat Marketscan database is a compilation of data from a commercially-insured population and does not reflect the costs or charges of patients in other populations (e.g., Medicare, Medicaid, self-insured). Medstat Marketscan data is valuable because it reflects what purchasers actually pay for healthcare and not what providers bill for their services. Paid claims data can help purchasers estimate the cost of implementing coverage for a preventive service. In some instances a billed service is not reimbursed by a payer; in these instances the Medstat Marketscan database contains a $0 value for the paid claim.

Updating Cost Estimates in the "Value of Prevention" Section to Current Year Dollars

The dollar figures presented in the "Value of Prevention" section of each evidence-statement are not directly comparable because the figures were taken from sources that were developed in different years. A proper updating of information related to the value of prevention for each disease/condition should take into account the changes in both real and monetary factors over time. For example, to update the costs of alcohol abuse from 1992 to 1998, researchers adjusted for both changes in incidence/prevalence of alcohol abuse and changes in the population over the time interval and used the consumer price index (CPI), medical care price index (MCPI), and wage compensation index to respectively update 1992 non-medical care costs, medical care costs, and productivity loss estimates to year 1998 dollars.[1] Because earnings do not increase or decrease at the same rates as the prices of goods and services, productivity losses associated with lost workdays *should not* be updated by CPI. Instead, the employment cost index (ECI) should be used as it is able to accurately measure relative changes in wages, benefits, and bonuses of workers over time and thus can be used to update productivity loss estimates to current dollars.

Table 3.1 lists annual values of CPI, MCPI, and ECI for civilian workers for the period 1985 to 2005. The table can be used to quickly update past dollar values without undertaking a detailed analysis based on changes in both real and monetary factors. For example, the total cost of obesity is estimated to be $117 billion in year 2000 U.S. dollars including $61 billion in medical care expenses and $56 billion in indirect costs (i.e., lost productivity). To get the updated value of direct medical care costs in 2005, $61 billion of direct medical care costs should be multiplied by 1.24, the ratio of 2005 MCPI and 2000 MCPI (323.2/260.8) to yield $75.6 billion. Similarly, assuming that the total number of lost work hours due to obesity stayed the same between 2000 and 2005, the $56 billion of productivity loss in 2000 would translate to approximately $67.2 billion in 2005 ($56 billion multiplied by a factor of 1.2, the ratio of 2005 ECI and 2000 ECI [100/83.6]). Thus, the total cost of obesity would sum to $142.8 billion in year 2005 dollars. For many diseases/conditions, there may be significant non-health related outcomes. The costs of these outcomes need to be updated by the general CPI. For example, the cost of crime and property damage due to alcohol abuse should be updated by general CPI. Depending on the information available, it is possible to improve the updates by using appropriate categories of CPI, MCPI, and ECI. For example, within the medical care category, separate price indices are available for medical care goods and medical care services. Similarly, separate ECIs can readily be obtained for workers in different occupations.

Figure 3.0: Current Year Value Equations

Updated Direct Cost

$$\text{Current Year Value of Direct Medical Care Cost} = \frac{\text{Current Year MCPI}}{\text{Data Year MCPI}} \times \text{Data Year Direct Medical Care Cost}$$

Updated Indirect Cost

$$\text{Current Year Value of Indirect Cost Due to Productivity Lost} = \frac{\text{Current Year ECI}}{\text{Data Year ECI}} \times \text{Data Year Indirect Cost}$$

Table 3.1: Consumer Price Index (CPI), Medical Care Price Index (MCPI), and Employment Cost Index (ECI)

Year	Consumer Price Index All Items[2]	Medical Care Price Index[3]	Employment Cost Index (Compensation) for Civilian Workers[4] Quarter Ending in December
Base Period	**1982-84=100**	**1982-84=100**	**December 2005=100**
1985	107.6	113.5	48.2
1986	109.6	122.0	49.9
1987	113.6	130.1	51.7
1988	118.3	138.6	54.2
1989	124.0	149.3	56.9
1990	130.7	162.8	59.7
1991	136.2	177.0	62.3
1992	140.3	190.1	64.4
1993	144.5	201.4	66.7
1994	148.2	211.0	68.7
1995	152.4	220.5	70.6
1996	156.9	228.2	72.6
1997	160.5	234.6	75.0
1998	163.0	242.1	77.6
1999	166.6	250.6	80.2
2000	172.2	260.8	83.6
2001	177.1	272.8	87.0
2002	179.9	285.6	90.0
2003	184.0	297.1	93.5
2004	188.9	310.1	96.9
2005	195.3	323.2	100.0

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2. Series Id: CUUR0000SA0, Not Seasonally Adjusted, Area: U.S. City Average. Bureau of Labor Statistics. [cited 2006 Sep 27]. Available from: http://data.bls.gov/cgi-bin/surveymost?cu.

3. Series Id: CUUR0000SAM, Not Seasonally Adjusted, Area: U.S. City Average. Bureau of Labor Statistics. [cited 2006 Sep 27]. Available from: http://data.bls.gov/cgi-bin/surveymost?cu.

4. Employment Cost Index: Historical Listing: Current-dollar 1975-2005. Not Seasonally Adjusted. Bureau of Labor Statistics. [cited 2006 Sep 27]. Available from: http://www.bls.gov/web/echistry.pdf.
Note: civilian workers include private industry and State and local government workers and excludes farm, household, and Federal government workers.

Alphabetical Listing of Evidence-Statements

Alphabetical Listing of Evidence-Statements

EVIDENCE-STATEMENT:

ABDOMINAL AORTIC ANEURYSM (Screening)

Why This Chapter is Important for Employers: An Overview

- An abdominal aortic aneurysm (AAA) is a potentially fatal abnormal swelling (often balloon-like) of a segment of the body's largest artery, the aorta. The wall of the artery bulges out rather than remaining straight.[1]
- Abdominal aortic aneurysms affect 4% to 8% of older men and 0.5% to 1.5% of older women.[2-6]
- Older age, smoking, male sex, and family history are the most significant AAA risk factors.[2-6]
- Approximately 69% of men in the United States age 65 to 74 years have a history of smoking (defined as lifetime consumption of more than 100 cigarettes) and are therefore at risk for AAA.[7]
- Although AAAs may be asymptomatic for years, as many as 1 in 3 eventually rupture if left untreated.[8]
- Voluntary AAA screening may reduce AAA-related mortality by 43% in men age 65 to 75 years.[9] Therefore, it is particularly important that employers who provide retiree health care coverage or who have active employees over the age of 65 provide coverage for AAA screening.
- In 2003, AAA (without rupture) was responsible for $2.7 billion in hospital charges and AAA rupture was responsible for an additional $639.71 million. Each patient treated for AAA (without rupture) costs more than $59,000; each hospital-treated patient with an AAA rupture costs more than $93,000.[10]
- The average cost of elective surgery following AAA screening is $25,000; the average cost of emergency AAA surgery following a rupture is approximately $50,000.[11]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends one-time screening for abdominal aortic aneurysm (AAA) by ultrasonography in men aged 65 to 75 who have ever smoked.[12]

Evidence Rating: **B (Recommended/ At Least Fair Evidence)**

The USPSTF found good evidence that screening for AAA and surgical repair of large AAAs (5.5 cm or more) in men aged 65 to 75 who have ever smoked (current and former smokers) leads to decreased AAA-specific mortality. There is good evidence that abdominal ultrasonography, performed in a setting with adequate quality assurance (i.e., in an accredited facility with credentialed technologists), is an accurate screening test for AAA. There is also good evidence of important harms of screening and early treatment, including an increased number of surgeries with associated clinically-significant morbidity and mortality, and short-term psychological harms. Based on the moderate magnitude of net benefit, the USPSTF concluded that the benefits of screening for AAA in men aged 65 to 75 who have ever smoked outweigh the harms.[12]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Agency for Healthcare Research and Quality (AHRQ)

- American College of Cardiology
- Harvard Medical School
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

An abdominal aortic aneurysm (AAA) is a potentially fatal abnormal swelling (often balloon-like) of a segment of the body's largest artery, the aorta. The wall of the artery bulges out rather than remaining straight.[1]

Abdominal aortic aneurysms are found in 4% to 8% of older men and 0.5% to 1.5% of older women.[2-6] Aortic aneurysms account for approximately 15,000 deaths in the United States annually; of these, 9,000 are AAA-related and the remainder are due to thoracic aortic aneurysms.[13-14]

Once an aortic aneurysm develops, it is a lifelong condition. Most abdominal aortic aneurysms grow larger with time, expanding at an average rate of .33 centimeters to .5 centimeters each year. As many as 1 in 3 AAAs eventually rupture if left untreated.[8] In about 20% of cases, an undiscovered abdominal aneurysm ruptures without warning and the patient collapses and dies from massive bleeding inside the abdomen. Most AAAs do not cause any symptoms, however when present, symptoms may include:

- Pain in the abdomen, back, or the fleshy part of sides between the bottom ribs and the hips.
- A feeling of fullness after eating a small meal.
- Nausea and vomiting.
- A pulsating mass in the abdomen.

Condition/Disease Risk Factors

Older age, smoking, male sex, and family history are the most significant AAA risk factors.[2] Other risk factors include high blood pressure, high blood cholesterol levels, and obesity.[15] Approximately 69% of men in the United States age 65 to 74 years are current or former smokers and are therefore at risk for AAA.[7] A former smoker, also called an "ever smoker" is defined as anyone with a lifetime consumption of more than 100 cigarettes.[7]

Value of Prevention

Economic Burden of Condition/Disease	An estimate of the total societal economic burden of AAA is not available. However, hospital discharge data from Health Cost and Utilization Project (HCUP) show that, in 2003, 45,986 patients were discharged with AAA (without rupture) with a mean length of stay of 6.7 days and aggregate charges of $2.7 billion.[10] Therefore, the average AAA patient staying in the hospital cost more than $59,000. Hospital discharge data also show that in 2003, 6,815 patients were discharged with a ruptured AAA with a mean length of stay of 10.7 days and total charges of $639.71 million. The average cost per discharge for a ruptured AAA exceeded $93,000. Men accounted for 75% of all discharges and 80% of aggregate charges.[10] The economic burden of AAA would be much larger if lost productivity, premature mortality, and morbidity costs were accounted for.
Workplace Burden of Condition/Disease	Detailed data on the workplace burden of AAA is not available. The workplace burden of AAA is likely to increase due to the rapidly aging workforce.
Economic Benefit of Preventive Intervention	Early detection and appropriate management of AAA through screening can prevent costs resulting from rupture or leakage. The average cost of emergency surgery for AAA is approximately $50,000, while elective surgery (following AAA screening) is only $25,000.[11]
Estimated Cost of Preventive Intervention	In 2004, the private-sector cost of screening for AAA averaged $115; approximately 95% of all paid claims fell within the range of $35 to $336.[16]
Estimated Cost of Treatment	The average cost of surgery for AAA is between $25,000 and $50,000 (in year 2004 dollars).[11]
Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention	The Oregon Evidence-Based Practice Center (EPC) conducted an evidence synthesis of AAA screening studies.[17-20] Their principal findings point to a cost-effectiveness ratio for population-based AAA screening (compared with no screening) that lies in the range of $14,000 to $20,000 per quality-adjusted life year (QALY).[15] In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, screening for AAA is cost-effective.

Preventive Intervention Information

Preventive Intervention: Purpose of Screening	Screening for AAA allows clinicians to identify affected patients and those who require preventive surgery and can thereby prevent rupture or leakage of the aneurysm.

	Early intervention reduces AAA-specific mortality[9] and is more cost-effective than emergency surgery.[11]
Benefits and Risks of Intervention	Ultrasonography of the abdomen is accurate[21-22] and reliable[23] in detecting AAAs and it does not expose patients to radiation. One-time AAA ultrasound screening and the surgical repair of large AAAs (5.5 centimeters or more) in men aged 65 to 75 who have ever smoked reduces AAA-related mortality by as much as 43%.[9] The USPSTF found good evidence of important harms associated with screening and early treatment, including an increased number of surgeries with clinically-significant morbidity and mortality, and short-term psychological harms. Based on the moderate magnitude of net benefit, the USPSTF concluded that the benefits of screening for AAA in men aged 65 to 75 who have ever smoked outweigh the harms.[12]
Initiation, Cessation, and Interval of Screening	The USPSTF recommends a one-time screening ultrasound to look for abdominal aortic aneurysm in men aged 65 to 75 who have smoked at any time in their lives. The exact timing of the screen is left to the discretion of the clinician.[12]
Intervention Process	Ultrasonography of the abdomen is used to screen for AAA. Ultrasonography should be performed in an accredited facility with credentialed technologists.
Treatment Information	Treatment depends on the size of the aneurysm. The larger the aneurysm, the more likely it is to burst (rupture). Death rates for ruptured aneurysms and emergency surgery are higher than rates for scheduled repair of unruptured aneurysms. Surgery is almost always recommended for an aneurysm that is leaking. Surgery is generally recommended for people with aneurysms larger than 5.5 centimeters in diameter unless another illness makes surgery unusually risky. Even with no symptoms, a person with an aneurysm larger than 6.5 centimeters would almost always have urgent surgery to repair the problem. People with smaller aneurysms may be monitored with ultrasound tests (every 12 months for anyone with an aneurysm smaller than 3.5 centimeters and every six months for those with aneurysms larger than 3.5 centimeters) to determine if the aneurysm is growing larger.[1] Health benefits should include provisions for follow-up and treatment.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Service Task Force (USPSTF)

Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF recommends one-time screening for abdominal aortic aneurysm (AAA) by ultrasonography in men aged 65 to 75 who have ever smoked.[12]

Authored by:

Vandiver KP, Lanza A, Sotnikov S. Abdominal aortic aneurysm evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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Why This Chapter is Important for Employers: An Overview

- Alcohol misuse contributes to illnesses and injuries and is the third most common behavior-related cause of death in the United States. Alcohol misuse was associated with 75,000 deaths and 2.3 million years of potential life lost (30 years per premature death) in 2001.[1]
- Alcohol misuse results in a variety of adverse health and social outcomes. These include increased risk of unintentional injuries, violence, liver disease, hypertension, certain cancers, and diseases of the central nervous system. Individuals who misuse alcohol are also at increased risk of a variety of adverse reproductive health outcomes.[1-7]
- Alcohol misuse is associated with high costs to employers in the form of increased absenteeism, decreased productivity and lost productivity, and increased employer-sponsored healthcare expenditures. Overall, 15.3% of U.S. workers report using or being impaired by alcohol at work at least one time during the previous year, including 9% of workers who report being hung over at work.[8] Lost productivity accounted for 73% of the total costs resulting from alcohol misuse in 1998.[9]
- Alcohol misuse is costly for health insurers and society. The cost of alcohol misuse in the United States was estimated to be $185 billion in 1998.[9] About $16 billion of this amount was spent on medical care for alcohol-related complications (not including fetal alcohol syndrome [FAS]), $7.5 billion was spent on specialty alcohol treatment services, and $2.9 billion was spent on FAS treatment. The remaining costs ($134) billion were due to lost productivity.
- Randomized trials demonstrate that brief counseling leads to reduced alcohol consumption among excessive drinkers and to reductions in adverse alcohol-related health outcomes, including excess mortality.[10-13]
- Screening and counseling for alcohol misuse reduces both societal and healthcare costs. Each $1 invested in screening and brief counseling interventions saves approximately $4 in healthcare costs.[12,14]
- Coverage for screening and brief counseling is currently offered by only 20% of employer-sponsored health plans, despite the fact that such services are among the most cost-effective clinical preventive services and have a proven impact on health outcomes.[10,15]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.[16]

Evidence Rating: **B (Recommended/ At Least Fair Evidence)**

The USPSTF found good evidence that screening in primary care settings can accurately identify patients whose levels or patterns of alcohol consumption do not meet criteria for alcohol dependence but place them at risk for increased morbidity or mortality. The USPSTF also found good evidence that brief behavioral counseling interventions with follow-up produce small-to-moderate

reductions in alcohol consumption that are sustained over 6 to 12 month periods or longer.[16]

Other Recommended Guidance

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) recommends incorporating screening for alcohol misuse and counseling into routine medical practice.[17]

Evidence Rating:

Expert Consensus

American Academy of Pediatrics (AAP)

The American Academy of Pediatrics (AAP) encourages clinicians to ask adolescents about their alcohol use and refer adolescents with suspected drinking problems for age-appropriate treatment.[18] It also encourages including substance abuse prevention counseling in routine and episodic office visits.[19]

Evidence Rating:

Expert Consensus (Committee on Substance Abuse)

American Medical Association (AMA)

The American Medical Association (AMA) recommends that primary care physicians establish routine alcohol screening and be trained to conduct brief intervention counseling and motivational interviewing.[20]

Evidence Rating:

Expert Consensus (Office of Alcohol, Tobacco and Other Drug Abuse Prevention)

American College of Surgeons (ACS)

The American College of Surgeons (ACS) recommends alcohol screening with brief counseling or referral, as appropriate, for all injured patients.[21]

Evidence Rating:

Expert Consensus (Committee on Trauma)

American College of Emergency Physicians (ACEP)

The American College of Emergency Physicians (ACEP) recommends that physicians mitigate the consequences of alcohol abuse through screening, brief interventions, and appropriate referral.[22]

Evidence Rating:

Expert Consensus (Board of Directors)

American Society of Addiction Medicine (ASAM)

The American Society of Addiction Medicine (ASAM) recommends routine screening for alcohol misuse in primary care settings, with appropriate counseling and referral.

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Agency for Healthcare Research and Quality (AHRQ)
- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American College of Emergency Physicians (ACEP)

- American College of Surgeons (ACS)
- American Medical Association (AMA)
- American Society of Addiction Medicine (ASAM)
- Center for Medicare and Medicaid Services (CMS)
- National Business Group on Health
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- Peer-reviewed research
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- U.S. Preventive Services Task Force (USPSTF)

The information contained in this document is based on a compilation of research findings. Information presented in this document should be attributed to its referenced source and should not be considered a reflection of the opinions of other organizations cited in the text.

Condition/Disease-Specific Information

Epidemiology of Condition/Disease

The term "alcohol misuse" is used to describe alcohol consumption that puts individuals at increased risk for adverse health and social consequences. The NIAAA defines alcohol misuse (which the Institute calls "at-risk drinking") as either excessive daily consumption (more than four drinks for men or more than three drinks for women), excessive total consumption (more than 14 drinks per week for men or more than 7 drinks per week for women), or both.[17] Alcohol abuse, which is a subset of alcohol misuse, is defined on the basis of having suffered negative consequences from drinking (e.g., legal problems, job loss, or family problems). Alcohol dependence (i.e., alcoholism) is also a subset of alcohol misuse and is defined on the basis of having suffered negative consequences from drinking and some combination of experiencing withdrawal symptoms, loss of control, or alcohol tolerance. Other types of alcohol misuse include alcohol consumption among high-risk populations (e.g., pregnant women, youth) and drinking prior to or during certain activities (e.g., driving a motor vehicle, operating heavy equipment).

Among adults in the United States, approximately 30% of current drinkers exceed NIAAA's daily or weekly alcohol consumption limits. Of these excessive drinkers, more than 90% report past-month binge drinking (consuming 5 or more drinks during one or more occasions),[23] approximately 15% abuse alcohol, and approximately 10% are dependent on alcohol.[24]

Alcohol misuse contributes to illnesses and injuries and is the third most common behavior-related cause of death in the United States. Alcohol misuse was associated with 75,000 deaths and 2.3 million years of potential life lost (30 years per premature death) in 2001.[1] Alcohol misuse is a risk factor for: unintentional injuries (e.g., motor vehicle crashes, falls); violence (e.g.,

homicide, suicide); liver disease; diseases of the central nervous system (e.g., stroke, dementia); hypertension; and various cancers (e.g., breast, neck, stomach, colon, and liver). Alcohol misuse is also associated with a variety of adverse reproductive health outcomes (e.g., unintended pregnancy, sexual assault, sexually transmitted infections), fetal alcohol spectrum disorders (e.g., fetal alcohol syndrome), low birth weight, and sudden infant death syndrome (SIDS). Finally, alcohol misuse often coexists with mental health problems as well as other substance abuse problems.[1-7]

Condition/Disease Risk Factors

There are multiple risk factors for alcohol misuse.[2] These include environmental and regulatory factors such as the price and availability of alcohol, marketing exposure, and the provision of alcohol in public facilities. Social factors include familial country of origin, peer group norms, religious affiliation, and other socio-cultural factors. Intrinsic (internal or personal) risk factors for alcohol misuse include personality characteristics and genetic factors.

Value of Prevention

Economic Burden of Condition/Disease

The direct and indirect costs of alcohol misuse in the United States were estimated to at $185 billion in 1998.[9] About $16 billion of this amount was spent directly on medical care for alcohol-related complications (excluding FAS), $7.5 billion was spent on specialty alcohol treatment services, and $2.9 billion was spent on the treatment of FAS. The remaining costs (73% of all costs) were due to lost productivity and costs incurred by law enforcement agencies and the criminal justice system.[9]

Workplace Burden of Condition/Disease

Lost productivity due to alcohol-related deaths and disabilities impose a greater economic burden than do healthcare costs. Lost productivity is due to 1) absenteeism and 2) to poor job performance among those who come to work drunk, hungover, or who drink on the job. Over 15% of workers in the United States report drinking on the job or being hungover at work at least once during the previous year.[8]

Economic Benefit of Preventive Intervention

The economic benefits of screening and treatment of alcohol misuse are measured in terms of savings from future reductions in medical costs and future reductions in productivity losses. These costs are considerable. For example, in 1998, the estimated cost of the medical consequences of alcohol misuse was $18 billion, lost future earnings due to premature deaths from alcohol-related causes totaled $36.5 billion, lost earnings due to alcohol-related illness totaled $86.4 billion, lost earnings due to FAS totaled $1.3 billion, and lost earnings due to alcohol-related crimes and lost productivity of incarcerated persons totaled $10 billion.[9]

Estimated Cost of Preventive Intervention

Implementing screening and brief counseling programs for alcohol misuse is relatively inexpensive compared with other clinical preventive services. Costs depend on the number of sessions, the mode of delivery (in office or by telephone), and the type of provider that delivers the counseling.

Screening for alcohol misuse using standard questions is a brief clinical activity

that is not typically reimbursable. Approximately 10% of patients in primary care settings can be expected to screen positive for alcohol misuse and accept brief counseling. In 2004, the private-sector cost of alcohol misuse counseling averaged $22 per session when counseling was provided in a separate visit and a preventive service code was used; approximately 95% of paid claims fell within the range of $0 to $81.[25] Brief counseling bundled in a primary care visit would cost less.

Estimated Cost of Treatment

The vast majority of people with alcohol misuse are not alcohol dependent. For those who are alcohol dependent, referral for specialty treatment might be appropriate. Costs of treatment for alcohol dependence are beyond the scope of this document, but treatment is generally cost-saving.

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

In economic evaluation studies of screening and counseling for alcohol misuse, outcomes are commonly converted from natural units (e.g., reduced hospitalizations) to dollars to enable direct comparison of benefits and costs. Several cost-benefit analyses of screening and brief counseling have been conducted, all of which demonstrated cost-savings. One of these studies, the Trial for Early Alcohol Treatment (Project TrEAT), was a randomized clinical trial of screening and brief counseling conducted in 64 primary care clinics in Wisconsin; study participants had non-dependent alcohol misuse. Over the study's 48-month follow-up period, each $1.00 invested in the intervention saved $4.30 by reducing future health care costs.[12] Another study assessed the cost-effectiveness of alcohol screening and counseling for injured patients treated in U.S. emergency department settings or admitted to the hospital. The cost analysis, which was restricted to medical costs, identified $3.81 in savings for each $1 spent on the intervention.[14]

Treatment of alcohol dependence also saves money when downstream medical care costs associated with non-treatment are considered. For example, a 14-year longitudinal follow-up study found that healthcare costs for alcoholics who underwent treatment declined substantially over time, while costs rose among untreated alcoholics.[26] After adjusting for the pre-treatment status of the two groups, those whose alcoholism that had been treated experienced a 25% decline in medical care costs compared to those whose alcoholism had not been treated.

Preventive Intervention Information

Preventive Intervention: Purpose of Screening and Counseling

The purpose of screening and counseling for alcohol misuse is to identify patients who drink excessively and to assist them in reducing their consumption to safer levels. Screening and counseling can also identify patients with more severe alcohol problems who may require intensive substance abuse treatment. However, most individuals with positive screening results do not meet the criteria for alcohol dependence and are thus eligible for brief counseling interventions that can be delivered in primary care settings and by telephone.

Benefits and Risks of Intervention

Most recommended screening instruments reliably identify alcohol misuse. A majority of these instruments have a sensitivity of 70% to 90% for detecting alcohol dependence, and single-question screens can detect milder forms of alcohol misuse with similar sensitivity levels. In primary care settings, 10% to 25% of patients screen positive for alcohol misuse, depending on the setting and patient population.[16,27-28]

Brief counseling with appropriate follow-up results in moderate reductions (approximately 13% to 34%) in alcohol consumption lasting 6 to 12 months or longer.[16,29] Studies also show that the extent of reductions in alcohol-related health problems may exceed the extent of reductions in alcohol consumption itself. For example, one randomized study that assessed long-term effects (48-month follow-up) of screening and brief counseling found that the intervention group had 20% fewer emergency department visits, 33% fewer nonfatal injuries, 37% fewer hospitalizations, 46% fewer arrests, and 50% fewer motor vehicle crashes than the controls.[12] These reductions exceeded the reductions experienced by these participants in alcohol consumption; the intervention group experienced a 20% reduction in binge drinking episodes, a 10% reduction in drinks per week, and a 4% increase in reporting no binge drinking episodes relative to controls. A meta-analysis found that counseling interventions also reduced mortality.[13]

The USPSTF identified two theoretical harms from regular screening and counseling for alcohol misuse: those who drink moderate amounts of alcohol might abstain from drinking alcohol altogether, thus losing any of the potential health benefits of light or moderate drinking, and those who abuse alcohol or are dependent on alcohol might under-treat their condition by drinking moderately rather than quitting. However, the USPSTF found no data showing that screening and counseling for alcohol misuse are likely to produce either of these theoretical harms. Furthermore, it should be noted that no randomized trial has demonstrated that moderate alcohol consumption reduces mortality of any type.

Although the benefits of screening for alcohol misuse (including early identification of misuse and treatment with behavioral counseling) outweigh the potential harms associated with screening,[16] fewer than half of patients in primary care settings are screened for alcohol misuse,[30] making it one of the least commonly performed of the clinical preventive services recommended by the USPSTF.[31] In the absence of screening, clinicians cannot reliably identify patients with alcohol misuse.[32]

Initiation, Cessation, and Interval Screening

The USPSTF recommends that screening begin in adulthood (i.e., at age 18).

The USPSTF found insufficient evidence to recommend for or against screening in younger populations. However, alcohol misuse is frequent among adolescents, has severe consequences in this population, and is an important predictor of adult alcohol misuse. The AAP encourages clinicians to ask adolescents about their alcohol use and refer adolescents with suspected drinking problems for age-appropriate treatment.[18]

Alcohol misuse among all women of childbearing age, whether pregnant or not, should be appropriately assessed, counseled, and treated. Furthermore, women of childbearing age should be advised to use an effective form of contraception until alcohol intake can be reduced or eliminated because pregnancy is often not recognized until a woman has been pregnant for at least a month (particularly among women who have unintended pregnancies) and fetal damage can occur during the pre-recognition period.[33] Finally, pregnant women should be screened

for alcohol use and should be advised to refrain from drinking alcohol altogether during their pregnancies.[34]

The optimal frequency of screening is unknown. The NIAAA recommends annual screening, with more frequent screening and counseling for high-risk individuals such as those with a history of previous alcohol misuse.[17]

Counseling

Those who screen positive on an alcohol screen should be counseled as medically indicated. Eight (8) counseling sessions are covered per calendar year.

Intervention Process

The NIAAA and USPSTF recommend that clinicians use the screening strategy most appropriate to their own patient population, clinical practice style, or general setting. Examples of effective screening tools include:

- Single-question screens, which address alcohol consumption that exceeds recommended daily limits. The question typically asks patients to identify the last occasion, if any, when they consumed five or more drinks (or four or more drinks for a woman). Drinking at such levels within a specified time period (e.g., three months) constitutes a positive screening result. Single-question screens are recommended by the NIAAA because of their high sensitivity for detecting both severe and less severe forms of alcohol misuse, and because having fewer questions streamlines the screening process, thereby improving its acceptability in busy practices.[17,35-37]
- The Alcohol Use Disorders Identification Test (AUDIT), which is a 10-item questionnaire that is designed to detect alcohol misuse by asking about frequency, quantity, and consequences of drinking. The AUDIT is sensitive and specific for detecting all forms of alcohol misuse. The first three questions (referred to as the AUDIT-C) comprise a validated screening approach that is less time consuming than the full AUDIT; it too has a high sensitivity for detecting all forms of alcohol misuse. The third AUDIT question can also be used as a single-question screen, although it uses a threshold of 6 or more drinks that is slightly higher than the threshold used by some other single-question screens.[28,36,38-39]
- The CAGE (feeling the need to Cut down, Annoyed by criticism, Guilty about drinking, and need for Eye opener in the morning), which is a four-item risk assessment instrument. The CAGE is reasonably sensitive and specific for detecting alcohol abuse and dependence. However, it is relatively insensitive for detecting less severe forms of alcohol misuse.[28,36,39]

Clinicians should provide counseling interventions for patients who meet the criteria for alcohol misuse (i.e., patients who drink in excess of NIAAA guidelines). The USPSTF identifies three levels of counseling intervention, differentiated by level of intensity, for these patients. Multi-contact counseling is more effective than single-contact counseling interventions, but providers should tailor counseling intensity to address individual patient needs. Intensity is determined by the duration of the initial contact and whether any follow-up occurs. “Very brief” interventions last up to 5 minutes and have no follow-up. “Brief” counseling interventions last 15 minutes and have no follow-up. “Multi-

contact" interventions include one initial session lasting at least 15 minutes and several follow-up contacts.[16]

Effective counseling for alcohol misuse in the primary care setting includes feedback, advice, goal setting, and follow-up. Alcohol misuse counseling should follow the counseling framework known as the "5 As"17:

- Providers should assess the degree of a patient's drinking, including any problems caused by alcohol and whether the person is alcohol dependent or not.
- Providers should advise patients to reduce their alcohol consumption to safer levels or to abstain altogether from drinking.
- Providers should agree with patients on their goals for reducing alcohol consumption.
- Providers should assist patients in acquiring personal motivation, self-help skills, or outside resources necessary to achieve behavior change.
- Finally, providers should arrange for patients to receive appropriate follow-up support services and counseling, depending on the nature of their alcohol misuse.

Interventions for those with alcohol dependence are more intense and time consuming. Addiction treatment was not discussed in the USPSTF document.[16]

Treatment Information

Counseling interventions for non-dependent alcohol misuse are described above. A detailed description of treatment for alcohol dependence is beyond the scope of this chapter but such treatment is accepted medical practice. The benefits of alcohol dependence treatment include a 50% reduction in alcohol consumption compared with those who do not undergo treatment.

Health benefits should include provisions for diagnostic follow-up and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)

Strength of Evidence: B (Recommended/ At Least Fair Evidence)

- The USPSTF found good evidence to support screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.[16]

Recommended Guidance:

National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Strength of Evidence: Expert Recommendation

- The NIAAA recommends incorporating screening for alcohol misuse and counseling into routine medical practice.[17]

American Academy of Pediatrics (AAP)
Strength of Evidence: Expert Consensus (Committee on Substance Abuse)

- The AAP encourages clinicians to ask adolescents about their alcohol use and refer adolescents with suspected drinking problems for age-appropriate treatment.[18] It also encourages including substance abuse prevention in routine and episodic office visits.[19]

American Medical Association (AMA)
Strength of Evidence: Expert Consensus (Office of Alcohol, Tobacco, and Other Drug Abuse Prevention)

- The AMA recommends that primary care physicians establish routine alcohol screening and be trained to conduct brief intervention counseling and motivational interviewing.[20]

American College of Surgeons (ACS)
Strength of Evidence: Expert Consensus (Committee on Trauma)

- The ACS recommends alcohol screening with brief counseling or referral, as appropriate, for all injured patients.[21]

American College of Emergency Physicians (ACEP)
Strength of Evidence: Expert Consensus (Board of Directors)

- The ACEP recommends that physicians mitigate the consequences of alcohol abuse through screening, brief interventions, and appropriate referral.[22]

American Society of Addiction Medicine (ASAM)
Strength of Evidence: Not Specified

- The ASAM recommends routine screening for alcohol misuse in primary care settings, with appropriate counseling and referral.

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EVIDENCE-STATEMENT:

ASPIRIN THERAPY FOR THE PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE (Counseling)

Why This Chapter is Important for Employers: An Overview

- Heart disease is the leading cause of death in the United States.[1]
- Each year, over 1 million Americans experience new or recurrent myocardial infarction (heart attack) or fatal coronary heart disease (CHD). Most events occur in older people and those with recognized risk factors for cardiovascular disease, including high blood cholesterol levels, hypertension, diabetes, or a history of smoking.[2]
- Coronary heart disease (CHD), which is the most common type of heart disease in the United States, is a leading cause of death and disability in the working population.
- Heart disease and stroke are expected to cost more than $403 billion in 2006.[3]
- Aspirin therapy may decrease the risk of CHD in adults who are at increased risk for heart disease, although aspirin is contraindicated for some individuals.[2]
- Adults who are at increased risk for heart disease may wish to consider aspirin therapy, but only after consultation with their medical providers.[2]
- Aspirin, when used as a preventive medication by men at average risk for cardiovascular events (men whose 10-year risk of CHD is 7.5% or higher), is both cost-saving and life-saving. A recent study found that average risk men who took therapeutic aspirin gained 15 quality-adjusted days of life at a cost that was $215 less than no therapy at all.[4]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians discuss aspirin chemoprevention with adults who are at increased risk for coronary heart disease (CHD). Discussions with patients should address both the potential benefits and harms of aspirin therapy.[2]

Evidence Rating: **A (Strongly Recommended/ Good Evidence)**

The USPSTF found good evidence that aspirin decreases the incidence of coronary heart disease in adults who are at increased risk for heart disease. They also found good evidence that aspirin increases the incidence of gastrointestinal bleeding and fair evidence that aspirin increases the incidence of hemorrhagic strokes. The USPSTF concluded that the balance of benefits and harms is most favorable in patients at high risk of CHD (5-year risk of greater than or equal to 3%) but is also influenced by patient preferences.[2]

Other Recommended Guidance American Diabetes Association (ADA)

The American Diabetes Association (ADA) recommends that physicians consider aspirin therapy in diabetic patients between that ages of 30 and 40 years, particularly when there is the presence of other cardiovascular risk factors.[5]

Evidence Rating: **E**

The ADA has designated an "E" rating as a standard of care based on expert opinion.

American Diabetes Association (ADA)

The ADA recommends that use of aspirin therapy (75-162mg/day) as a primary prevention strategy in those with either type 2 diabetes (A rating) or type 1 diabetes (B rating) who are over 40 years of age or have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria.).[5]

***Evidence Rating:* A/B**

An "A" rating is based upon clear evidence from randomized control trials.
A "B" rating is based upon supportive evidence from well-controlled cohort studies.

The American Heart Association (AHA)

The American Heart Association (AHA) recommends aspirin use, if not contraindicated, for patients who have had a myocardial infarction (heart attack), unstable angina, ischemic stroke (caused by blood clot), or transient ischemic attacks (TIAs or "little strokes"). This recommendation is based on sound evidence from clinical trials showing that aspirin helps prevent the recurrence of such events. Studies show aspirin also helps prevent these events from occurring in people at high risk.[6]

The AHA also concluded that aspirin may be warranted for patients at high risk for myocardial infarction but that health care providers must consider a patient's particular cardiovascular risk profile, the demonstrated benefits of aspirin on reducing risk for a first myocardial infarction, and known as well as unknown side effects of aspirin.[7]

Evidence Rating:

Evidence from clinical trials.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Diabetes Association (ADA)
- American Heart Association (AHA)
- Peer reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Heart disease and stroke are the most common types of cardiovascular disease and are the first and third leading causes of death for both men and women in the United States.[8] In 2002, the age-adjusted death rate was 241 per 100,000 people, equating to almost 700,000 deaths per year.[9]

Condition/Disease Risk Factors

Each year, over 1 million Americans experience new or recurrent myocardial infarction (heart attack) or fatal coronary heart disease. Most events occur in older people and those with recognized risk factors for cardiovascular disease. In 2003, approximately 37% of adults reported having at least 2 of 6 risk factors for heart disease and stroke (high blood pressure, high cholesterol, diabetes, current smoking, physical inactivity, and obesity).[10]

Decisions about aspirin therapy should take into account the overall risk for coronary heart disease. Risk assessment should include asking about the presence and severity of the following risk factors: age, sex, diabetes, elevated blood

pressure, family history (in younger adults), smoking,[2] elevated total cholesterol levels, low levels of high density lipoprotein (HDL-C) cholesterol, and high levels of low density lipoprotein (LDL-C) cholesterol.[3]

Value of Prevention

Economic Burden of Condition/Disease

In 2006, cardiovascular disease is expected to cost more than $403 billion, including expenses related to healthcare services, medications, and lost productivity.[3] The total (direct and indirect) cost of coronary heart disease was estimated at $142 billion in 2006.[3]

Workplace Burden of Condition/Disease

The workplace burden of heart diseases and stroke in 2006 included $35.6 billion in lost productivity due to morbidity and an additional $109.9 billion dollars in lost future earnings due to premature mortality.[3] Already a leading cause of death and disability in the United States working population, the workplace burden of cardiovascular diseases is expected to grow as a result of the aging workforce.[3]

Economic Benefit of Preventive Intervention

The economic benefit of counseling primarily results from the improved quality of life and the averted cost of illness with successful aspirin therapy. Most trials demonstrate a 15% to 40% reduction in cardiovascular events with chronic aspirin use.[11]

Estimated Cost of Preventive Intervention

The annual cost of an aspirin regimen is $18 and ranges from $3 to $55 per year in 2004 dollars.[12]

In 2004, the private-sector cost of prevention counseling averaged $39 per session; approximately 95% of paid claims fell within the range of $0 to $129 per session.[13]

Estimated Cost of Treatment

In 2004, the cost of treatment for all conditions with myocardial infarction as the principal diagnosis was $45,076 per discharge.[14]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Aspirin, when used as a preventive medication by men at average risk for cardiovascular events (men whose 10-year risk of CHD is 7.5% or higher), is both cost-saving and life-saving. A recent study found that average risk men who took therapeutic aspirin gained 15 quality-adjusted days of life at a cost that was $215 less than no therapy at all.[4]

According to one study, increasing the use of aspirin therapy (so that all eligible patients with coronary heart disease over 35 years of age take aspirin for 25 years) would have an estimated cost-effectiveness ratio of about $11,000 per quality-adjusted year of life gained.[15] In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, the increased prescription of aspirin for secondary prevention of CHD is cost-effective.

Preventive Intervention Information	
Preventive Intervention: Purpose of Counseling	There is good evidence that aspirin decreases the incidence of coronary heart disease in adults who are at increased risk for heart disease. Therefore, clinician discussion of the benefits and harms with their patients who are at increased risk for heart disease is indicated.[2]
Benefits and Risks of Intervention	Aspirin can prevent myocardial infarctions but adds to the risk of gastrointestinal bleeding and increases the risk of hemorrhagic stroke, especially among older people and people with hypertension. The net benefit of aspirin increases with growing cardiovascular risk.[16] Although older patients may derive greater benefits because they are at higher risk for CHD and stroke, their risk of bleeding may also be higher. Uncontrolled hypertension may attenuate the benefits of aspirin in reducing CHD,[2] and, uncontrolled hypertension and concomitant use of non-steroidal anti-inflammatory agents or anticoagulants increase risk for serious bleeding.[16] Here is an illustration of the relationship between the benefits and risks of the preventive intervention: For 1,000 patients with a 5% risk of CHD event(s) over 5 years, aspirin would prevent 14 myocardial infarctions (range 6 to 20), but would cause one hemorrhagic stroke (range 0 to 2), and 3 major gastrointestinal bleeds (range 2 to 4). In contrast, for patients with CHD risk of only 1% over 5 years, aspirin would prevent 3 myocardial infarctions (range 1 to 4), but would cause 1 hemorrhagic stroke (range 0 to 2) and 3 major gastrointestinal bleeding events (range 2 to 4).[7]
Initiation, Cessation, and Interval of Counseling	According to the USPSTF, physicians should inform adults who are at increased risk for CHD of the benefits and risks of aspirin therapy.[2] The AHA's recommendation is primarily based on physician discretion. Although the optimal timing and frequency of discussions related to aspirin therapy are unknown, reasonable options include every 5 years in middle-aged and older people or whenever cardiovascular risk factors are detected.[16]
Intervention Process	Counseling and discussion methods are left to the discretion of the clinician. Discussions about aspirin therapy should focus on potential CHD benefits, such as prevention of myocardial infarction, and potential harms, such as gastrointestinal and intracranial bleeding. Discussions should take into account individual attitudes and risk preferences about myocardial infarction, stroke, and gastrointestinal bleeding.[2]
Treatment Information	When it is determined that the benefits of intervention outweigh the risks of intervention, physicians should encourage patients to take aspirin for the prevention of cardiovascular disease events. The optimum dose of aspirin for prevention is not known. Primary and secondary prevention trials have demonstrated benefits with a variety of regimens, including 75

mg per day, 100 mg per day and 325 mg every other day. Doses of approximately 75 mg per day appear as effective as higher doses[17] whether doses below 75 mg per day are effective has not been established. Enteric-coated or buffered preparations do not clearly reduce adverse gastrointestinal effects of aspirin.[16]

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)
• The USPSTF strongly recommends that clinicians discuss aspirin chemoprevention with adults who are at increased risk for coronary heart disease (CHD).[2]

Recommended Guidance:

American Diabetes Association (ADA)

Strength of Evidence: A, B, E

E (Based on Expert Opinion)
- The ADA recommends that physicians consider aspirin therapy in patients between that ages of 30 to 40 years, particularly when there is the presence of other cardio-vascular risk factors.[5]

A (Based upon clear evidence from randomized control trials)
B (Based upon supportive evidence from well-controlled cohort studies)
- The ADA recommends the use of aspirin therapy (75-162 mg/day) as a primary prevention strategy in those with either type 2 diabetes (A rating) or type 1 diabetes (B rating) who are over 40 years of age or have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria).[5]

American Heart Association (AHA)
Strength of Evidence: Evidence from clinical trials
- The AHA recommends aspirin use for patients who have had a myocardial infarction (heart attack), unstable angina, ischemic stroke (caused by blood clot) or transient ischemic attacks (TIAs or "little strokes"), if not contraindicated. This recommendation is based on sound evidence from clinical trials showing that aspirin helps prevent the recurrence of such events. Studies show aspirin also helps prevent these events from occurring in people at high risk.[6]

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EVIDENCE-STATEMENT:

BREAST CANCER (Screening, Counseling, Testing, Preventive Medication, and Treatment)

Why This Chapter is Important for Employers: An Overview

- Breast cancer is the most commonly diagnosed non-skin cancer and the second leading cause of cancer death among women in the United States.[1]
- In 2005, 211,000 women are expected to be diagnosed with breast cancer and 40,000 women are expected to die as a result of breast cancer.[1]
- Women aged 40 to 64 years accounted for 61% of *in situ* cases, 54% of invasive breast cancer cases, and 40% of breast cancer deaths in 2005.[1] The direct medical care costs for breast cancer treatment were estimated to exceed $6 billion in 1996.[2]
- Breast cancer accounts for up to one-quarter of all cancer-related costs.[3]
- The risk of breast cancer increases with age.[4] Population aging in the next three decades is expected to increase the number of breast cancer cases and the economic burden of the disease.
- Mammography screening is a valuable early detection tool because it can identify breast cancer at an early stage, usually before physical symptoms or complications develop, when treatment is more effective and less expensive.
- Women with certain specific family history patterns have an increased risk for developing breast or ovarian cancer associated with mutations in genes known as BRCA1 and BRCA2. Although these mutations are uncommon, public interest in testing is growing.[5] Further, for women who are positive for a BRCA1 or BRCA2 genetic mutation, prophylactic surgery at a young age significantly improves survival and is cost-effective in comparison to other interventions.[6]
- For the minority of women with a clear, high risk for breast cancer, preventive medication can reduce the risk of certain types of breast cancer although such treatment can also produce serious side effects.[7] For women at low or average risk for breast cancer, the potential harms of preventive medication may outweigh the potential benefits.

Breast Cancer (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends screening mammography, with or without clinical breast examination (CBE), every 1 to 2 years for women aged 40 and older.[8]

Evidence Rating: **B (Recommended/ At Least Fair Evidence)**

The USPSTF found fair evidence that screening for breast cancer every 12 to 33 months significantly reduces mortality from breast cancer and that the benefits of screening outweigh the associated risks, for women aged 40 and older.[8]

Breast Cancer: Genetic Risk Assessment and BRCA MutationTesting (Counseling, Testing, and Preventive Treatment)

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that women whose family history is associated with an increased risk of deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.[9]

Evidence Rating: **B (Recommended/ At Least Fair Evidence) Guidance**

The USPSTF found fair evidence that women with certain specific family history patterns (increased-risk family history) have an increased risk for developing breast or ovarian cancer associated with BRCA1 or BRCA2 mutations. The USPSTF determined that these women would benefit from genetic counseling that allows informed decision making about testing and further prophylactic treatment. This counseling should be done by suitably trained healthcare providers. There is fair evidence that prophylactic surgery significantly decreases breast and ovarian cancer incidence in women who test positive for deleterious BRCA1 or BRCA2 mutations, although there is insufficient evidence to determine other health-outcome benefits from intensive screening or preventive medication in such women.[9]

Note: The U.S. Preventive Services Task Force (USPSTF) recommends *against* routine referral for genetic counseling or routine breast cancer susceptibility gene (BRCA) testing for women whose family history is not associated with an increased risk for deleterious mutations in breast cancer susceptibility. The USPSTF concluded that the potential harms of routine referral for genetic counseling or BRCA testing in these women outweigh the benefits.[9]

Other Recommended Guidance American College of Medical Genetics (ACMG)

The American College of Medical Genetics (ACMG) recommends risk assessment and genetic counseling before testing for BRCA1/BRCA2 mutations in individuals at increased risk, based on a personal or family history of breast cancer, ovarian cancer or both.[10] In a previous guideline published in 1996, the ACMG recommended testing for BRCA1 mutations in high-risk families and population screening of Ashkenazi Jews after discussion of test limitations and appropriate informed consent.[11]

Evidence Rating:

Expert Opinion

American Society of Clinical Oncology (ASCO)

The American Society of Clinical Oncology (ASCO) recommends that genetic testing be offered when an individual has a personal or family history that suggests a genetic cancer susceptibility, the test can be adequately interpreted, and its results will influence diagnosis or management of the patient or family members at risk for hereditary cancer.[12]

Evidence Rating:

Not Specified

National Comprehensive Cancer Network

The National Comprehensive Cancer Network recommends offering genetic susceptibility testing (after risk assessment and counseling) to individuals who meet the criteria for hereditary breast or ovarian cancer or both.[13]

Evidence Rating:

Not Specified

Breast Cancer: (Counseling and Preventive Medication)

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians discuss preventive medication with women at high risk for breast cancer and at low risk for adverse effects of preventive medication use. Clinicians should inform patients of the potential benefits and harms of preventive medication.[14]

Evidence Rating: **B (Recommended/ At Least Fair Evidence)**

The USPSTF found fair evidence that treatment with tamoxifen can significantly reduce the risk of invasive estrogen-receptor-positive breast cancer in women at high risk for breast cancer and that the likelihood of benefit increases as the risk for breast cancer increases. Although raloxifene is not now FDA-approved for this use, the USPSTF found consistent, but less abundant, evidence for its benefit as well. The USPSTF found good evidence that estrogen antagonists (e.g., tamoxifen) increase the risk for thromboembolic events (for example, stroke, pulmonary embolism, and deep vein thrombosis) and symptomatic side effects (for example, hot flashes) and that tamoxifen increases the risk of endometrial cancer.[14]

The USPSTF concluded that the balance of benefits and harms may be favorable for some high-risk women but will depend on breast cancer risk, risk from potential harms and individual patient preferences.[14]

Note: The U.S. Preventive Services Task Force (USPSTF) recommends against routine use of tamoxifen or raloxifene for the primary prevention of breast cancer in women at low or average risk for breast cancer.[14]

Other Recommended Guidance American Society of Clinical Oncology (ASCO)

The American Society of Clinical Oncology (ASCO) suggests that women with sufficient risk, based on the Gail Index, be offered tamoxifen to reduce their risk of breast cancer.[15] The Gail Index is a breast cancer risk tool developed by the National Cancer Institute, and is available online (http://cancer.gov/bcrisktool/) or by telephone (800-4-CANCER).

Evidence Rating:

Expert Opinion

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Cancer Society (ACS)
- American College of Medical Genetics (ACMG)
- American Society of Clinical Oncology (ASCO)
- Centers for Disease Control and Prevention (CDC)
- International Agency for Research on Cancer (IARC)
- National Cancer Institute (NCI)
- National Committee for Quality Assurance (NCQA)
- National Comprehensive Cancer Network

- National Heart, Lung, and Blood Institute (NHLBI)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Breast cancer is the most commonly diagnosed non-skin cancer and the second leading cause of cancer death among women in the United States.[1] In 2005, 211,000 women are expected to be diagnosed with breast cancer and 40,000 women are expected to die as a result of breast cancer.[1]

Condition/Disease Risk Factors

Risk factors for breast cancer (reported by the USPSTF) include[16]:

- A family history of breast cancer (especially a mother or sister with breast cancer)
- Atypical hyperplasia
- Having a first child after the age of 30
- Increasing age

Risk factors reported by other organizations include[17-19]:

- Early age at menarche
- Late age at menopause
- Overweight/obesity
- Physical inactivity
- Hormone replacement therapy
- Exposure to radiation

Another risk factor for breast cancer is the presence of genetic markers for the BRCA1 or BRCA2 genes.[19] However, only a *small* proportion of breast cancer cases are attributable to genetic susceptibility. Approximately 2% of adult women in the United States have a family history indicating they are at increased risk of a deleterious mutation in the BRCA1 or BRCA2 gene, and about1 in 10 women with these histories (2 to 3 per 1,000 adult US women) actually have a mutation.[5] Among women with a deleterious BRCA1 or BRCA2 mutation, 35% to 84% may develop breast cancer by age 70.[5]

Value of Prevention

Economic Burden of Condition/Disease

The direct medical care costs for breast cancer treatment were estimated to exceed $6 billion in 1996.[2] The total economic burden of breast cancer would be much higher if breast cancer related mortality and morbidity costs were included in this figure. In 2004, for example, the overall cost of cancer (including direct and indirect cots) was estimated to be almost $190 billion[20], and breast cancer could account for up to one-quarter of this total.[3] A small proportion of the economic burden of breast cancer is attributable to genetically-related breast cancers.

The risk of breast cancer increases with age.[4] Population aging in the coming decades is expected to increase the number of breast cancer cases and the economic burden of the disease.

Workplace Burden of Condition/Disease

Women aged 40 to 64 years accounted for 61% of *in situ* cases, 54% of invasive breast cancer cases, and 40% of breast cancer deaths in 2005.[1] The breast cancer medical care costs, productivity losses, and mortality costs among working women in this group is substantial.

Economic Benefit of Preventive Intervention Screening

Screening may reduce breast cancer treatment costs by identifying tumors in their earliest stages when treatment is more successful and less expensive. For example, a study that examined the cancer-care costs among members of a health maintenance organization (HMO) found that the net cost of initial care for breast cancer was $7,093 when the cancer was identified at the carcinoma *in situ* stage and to $10,900 when it was identified at the regional stage (both figures in year 1992 dollars).[21]

Counseling, Testing, and Preventive Treatment

The recognition of BRCA mutations through testing allows for early intervention and treatment. This is important because women who receive early treatment generally have better outcomes. For example, in one research model, a 30-year-old BRCA1 and 2 positive woman could prolong her life by about 1 year by having bilateral oophorectomy, 3.4 years by having bilateral mastectomy, and 4.3 years by having both procedures instead of surveillance alone.[7]

Preventive Medication

The use of preventive medication in carefully-selected, high-risk women can reduce their risk of breast cancer or delay the onset of breast and ovarian cancers. It is estimated that for every 100 women treated with tamoxifen for 5 years, 1.665 expected cancers are delayed or prevented. If breast cancer death is fully prevented by this strategy, then the use of preventive medication (compared to no intervention) would cost $8,479 per year of life gained.[22]

Estimated Cost of Preventive Intervention Screening

In 2004, the private-sector cost of a screening mammography averaged $51 (range $0 to $122).[23] A diagnosis of breast cancer is more costly ($451 to $2,520 in year 2002 dollars) as it requires additional tests, interpretations, and office visits.[4]

Counseling, Testing, and Preventive Treatment

In 2004, the private-sector cost of BRCA mutation testing averaged $53 per test; approximately 95% of all paid claims fell within the range of $12 to $201 per test.[23] The cost of genetic counseling averaged $39 per session; approximately 95% of all paid claims fell within the range of $0 to $129 per session.[23] The cost of a preventive mastectomy or oophorectomy varies by location and facility type.

Preventive Medication

The average wholesale price (AWP) of a 1-month supply of tamoxifen citrate is between $58.38 (generic) and $128.62 (brand — Nolvadex®).[24]

Estimated Cost of Treatment

The cost of breast cancer treatment depends on the stage of disease at diagnosis and the procedures or treatments selected. Treatment costs have been reported to range from $21,287 to $45,220 per patient. However, terminal care costs for Medicare patients were reported to be as high as $63,455 (all figures in year 2002 dollars).[4]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention Screening

The cost-effectiveness of breast cancer screening depends on the age of the population screened. Many cost-effectiveness analyses have shown that screening for breast cancer in women 65 years of age and younger reduces mortality at a reasonable cost.[1] A systematic review of cost-effectiveness analyses performed for the USPSTF noted that biennial screening after the age of 65 also reduces mortality at a reasonable cost. However, screening becomes more costly in women with significant comorbidities, such as dementia, or comorbidities that limit life expectancy. For example, the incremental costs per life-year saved for screening beyond age 65 were found to range from $34,000 to $88,000 in year 2002 dollars[4], which compare favorably with most other preventive interventions and to commonly accepted cost-effectiveness benchmarks.[1]

Counseling, Testing, and Preventive Treatment

One study, using modeling techniques, concluded that BRCA1 and BRCA2 testing is cost-effective only if women who screen positive proceed with prophylactic surgery.[25] The model further suggested that, per life-year saved, combined surgery cost $20,717, mastectomy cost $29,970, and oophorectomy cost $72,780 (all figures in year 1995 dollars).[25] Another study, which also used modeling techniques, concluded that for women who are positive for a BRCA1 or BRCA2 genetic mutation, prophylactic surgery at a young age significantly improves survival and is cost-effective in comparison to other interventions.[8]

Preventive Medication

Tamoxifen is cost-effective for women aged 40 to 50 years who are at significant risk for breast cancer.[26] Tamoxifen costs $46,619 per life-year saved for women who begin taking the medication at age 35. For women over the age of 50, the intervention costs more than $50,000 per life-year saved.[27]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Mammography screening is a valuable early detection tool because it can identify breast cancer at an early stage, usually before physical symptoms or complications develop, and when treatment is more effective and less expensive.

Purpose of Counseling, Testing, and Preventive Treatment

The purpose of family history assessment, counseling, and BRCA mutation-testing is to identify women with certain specific family history patterns that are associated with an increased risk for deleterious mutations in the BRCA1 or BRCA2 gene and an increased risk of breast or ovarian cancer. With the assistance of genetic counseling, women at risk can make an informed decision on testing and treatment options.

Purpose of Counseling and Preventive Medication

The purpose of preventive medication counseling is to educate women at high risk of breast cancer on the benefits and risks associated with tamoxifen.

Benefits and Risks of Intervention Screening

Screening allows for the early detection of breast cancer. Screening is estimated to reduce breast cancer mortality by 20% to 25% during the 10-year period following screening.[8] The risk of breast cancer increases with age. Therefore, the absolute benefit of screening also increases as a woman ages, at least from age 40 through age 70.[16] Because the risk of breast cancer is higher after age 70, mammography may offer important benefits to older women. However, these benefits may be offset by the fact that many older women, especially the very old and those with other illnesses, will die from other causes before they experience the benefits of early cancer detection.[16] Risks associated with screening include false-positive test results, which may cause undue anxiety, and the inconvenience, occasional complications, and costs associated with biopsies. False-positive test results are common among all types of cancer screening, including mammography; 80% to 90% of abnormal mammogram or clinical breast exam results are false-positive.[16]

Counseling, Testing, and Preventive Treatment

The USPSTF determined that women with certain specific family history patterns benefit from genetic counseling that allows informed decision making about testing and preventive treatment (e.g., removal of the breasts and/or ovaries).[9] The USPSTF found fair evidence that prophylactic surgery significantly decreases the incidence of breast and ovarian cancer among women with a BRCA mutation. Thus, the potential benefits of referral and discussion of testing and prophylactic treatment for these women may be substantial. The inherent risk associated with preventive treatment and surgery, such as patient anxiety and medical errors, may be substantial for some individuals.

The USPSTF concluded that for women whose family history is not associated with an increased risk of deleterious mutations, the harms of routine referral for counseling and testing outweigh the benefits.[9]

Counseling and Preventive Medication

Among women at high risk for breast cancer, an estrogen antagonist (i.e., tamoxifen) has been found to reduce the incidence of invasive breast cancer by approximately one-half.[14, 28] Estrogen antagonists increased survival by 1.6 years (range 1.0 to 2.1 years) and 2.2 years (range 1.3 to 2.8 years), respectively. Research shows that preventive medication yields more quality-adjusted life years than does prophylactic surgery, even when treatment is delayed to age 40 or 50 years.[9]

Estrogen antagonists are associated with an increased risk of venous thromboembolic disease (deep vein thrombosis and pulmonary embolism); tamoxifen is also associated with an increased risk of endometrial cancer.[14, 28]

The balance between benefits and harms varies among subgroups of women, depending on age, predicted risk of breast cancer, and hysterectomy status. In general, the balance of benefits and harms of preventive medication is more favorable for women in their 40s who are at increased risk for breast cancer and have no predisposition to thromboembolic events or women in their 50s who are at increased risk for breast cancer, have no predisposition to thromboembolic events, and do not have a uterus. Women are at lower risk for adverse effects from preventive medication if they are younger; have no predisposition to thromboembolic events such as stroke, pulmonary embolism, or deep venous thrombosis; or do not have a uterus.

The USPSTF concluded that routine use of estrogen antagonists for the primary prevention of breast cancer in women at low or average risk for breast cancer would cause more harm than benefit.[14]

Initiation, Cessation, and Interval Screening

According to the USPSTF women aged 40 and above should be screened for breast cancer with mammography, with or without CBE (clinical breast examination), every 1 to 2 years.[16] The USPSTF notes that the precise age is not known when the benefits of breast cancer screening first outweigh the associated risks and costs; thus, the specific ages at which screening should begin and cease should consider patient preferences.[16]

Counseling, Testing, and Preventive Treatment

Patients identified as high-risk through a clinician risk assessment should be referred for genetic counseling and, if appropriate, follow-up genetic mutation testing. The initiation, cessation, and frequency of counseling is left to the discretion of the clinician. A onetime BRCA test should be administered to at-risk patients who request testing. Preventive treatment including mastectomy and/or ophorectomy should be conducted, as medically necessary, at the discretion of the clinician.

Note: The USPSTF realizes that clinical decisions about patients involve more complex considerations that the evidence alone; clinicians should always understand the evidence but individualize decision making to the specific patient and situation.

Counseling and Preventive Medication

The initiation and cessation of preventive medication therapy with an estrogen antagonist is left to the discretion of the clinician (in discussion with the patient). In general, preventive medication is more favorable for women in their 40s who are at increased risk for breast cancer and have no predisposition to thromboembolic events or women in their 50s who are at increased risk for breast cancer, have no predisposition to thromboembolic events, and do not have a uterus.[14] Women younger than 40 years of age have a lower risk for breast cancer, and thus will not experience as large an absolute benefit from beast cancer preventive medication as older women.[14] Women 60 years of age and older, who have the highest risk for breast cancer also have the highest risk for complications

from preventive medication/chemoprevention with a less favorable balance of benefits and harms.[14]

The standard course of preventive medication with tamoxifen in clinical trials is 5 years.[29]

Intervention Process Screening

Approved screening methods for breast cancer include mammography and, as an adjunct, a clinical breast exam. CBE is a low-cost screening method that provides an opportunity for health professionals to discuss breast health with women.[30] Although CBE is not explicitly recommended by the USPSTF, many experts encourage routine CBE.[30] However, clinicians who perform routine CBE should understand that there is currently insufficient evidence to determine whether CBE affects breast cancer mortality and that they are likely to increase the incidence of clinical assessments and biopsies.[16] Coverage should also include diagnostic follow-up. Coverage should also include diagnostic follow-up (e.g., biopsies).

Counseling, Testing, and Preventive Treatment

The clinician should assess the patient's family history of breast cancer to determine the likelihood that the patient has a deleterious BRCA mutation.[9] If the assessment is positive, the woman should be referred for genetic counseling to help determine if she wishes to have genetic testing. Women may require further counseling after test results are received. A positive test for a deleterious mutation may result in a decision to have the surgical removal of her breasts and/or ovaries. Coverage should include clinician time to evaluate family history for possible referral to a genetic counselor, counseling on the harms and benefits of genetic testing by a qualified practitioner, and preventive treatment (e.g., complete mastectomy with or without reconstructive surgery, ophorectomy).

Preventive Medication

Clinicians should assess a patient's risk for breast cancer and the risk for adverse preventive medication effects when identifying women who may be candidates for preventive medication therapy. Clinicians can assess a patient's risk of developing breast cancer within the next 5 years using risk-factor information from the National Cancer Institute Breast Cancer Risk Tool (the "Gail Index"). Clinicians should discuss the results of the risk assessment, inform the patient of the risks associated with breast cancer, and counsel about the benefits and risks associated with the use of preventive treatment. Clinicians should counsel on the harms and benefits of preventive medication use and prescribe an FDA-approved preventive medication to eligible women who choose to use preventive medication. Coverage should include clinician time to monitor the potential harms/adverse effects associated with preventive medication use and the cost of the preventive medication approved for use by the FDA.

Treatment Information

Health benefits should include provisions for diagnostic and treatment services.

Strength of Evidence for the Clinical Preventive Service Breast Cancer (Screening)

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found fair evidence to recommend screening mammography, with or without clinical breast examination (CBE), every 1 to 2 years for women aged 40 and older.[8]

Strength of Evidence for the Clinical Preventive Service Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing (Counseling, Testing and Preventive Treatment)

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

The U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found fair evidence that women with certain specific family history patterns (increased risk family history) have an increased risk for developing breast or ovarian cancer associated with BRCA1 or BRCA2 mutations.[9]

Note: The USPSTF recommended against routine referral for genetic counseling or gene testing for women whose family history is not associated with an increased risk of deleterious mutations as the USPSTF concluded that the potential harms of routine referral for genetic counseling or BRCA testing in these women outweigh the benefits.[9]

Recommended Guidance:

The American College of Medical Genetics (ACMG)
Strength of Evidence: Expert Opinion

- The ACMG recommends risk assessment and genetic counseling before testing for BRCA1/BRCA2 mutations in individuals at increased risk, based on a personal or family history of breast cancer, ovarian cancer or both.[10] In a previous guideline published in 1996, the ACMG recommended testing for BRCA1 mutations in high risk families and population screening of Ashkenazi Jewish individuals after discussion of test limitations and appropriate informed consent.[11]

The American Society of Clinical Oncology (ASCO)
Strength of Evidence: Not Specified

- The American Society of Clinical Oncology recommends that genetic testing be offered when: an individual has a personal or family history that suggests a genetic cancer susceptibility and the test can be adequately interpreted and its

results will influence diagnosis or management of the patient or family members at risk for hereditary cancer.[12]

The National Comprehensive Cancer Network
Strength of Evidence: Not Specified

- The National Comprehensive Cancer Network recommends offering genetic susceptibility testing (after risk assessment and counseling) to individuals who meet the criteria for hereditary breast or ovarian cancer or both.[13]

Strength of Evidence for the Clinical Preventive Service Breast Cancer (Counseling and Preventive Medication)

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:
U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

B (Recommended/At Least Fair Evidence);

- The USPSTF recommends that clinicians discuss preventive medication with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention.[14]

Note: The USPSTF recommends against routine use of tamoxifen for the primary prevention of breast cancer in women at low or average risk for breast cancer.[14]

Recommended Guidance:
American Society of Clinical Oncology (ASCO)
Strength of Evidence: Expert Opinion

- The American Society of Clinical Oncology suggests that women with sufficient risk, based on the Gail Index, be offered tamoxifen to reduce their risk of breast cancer.[16]

Authored by:

Campbell KP, Coates RJ, Lanza A, Chattopadhyay S. Breast cancer evidence-statement: screening, counseling, testing, preventive medication, and preventive treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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EVIDENCE-STATEMENT:
CERVICAL CANCER (Screening)

Why This Chapter is Important for Employers: An Overview

- Cervical cancer was once the most common cause of cancer death among women in the United States. Screening, earlier detection, and more effective treatment methods reduced the death rate from cervical cancer 74% between 1955 and 1992.[1]
- Nevertheless, cervical cancer remains a concern. In 2005, it was estimated that 10,370 women would be diagnosed with cervical cancer and 3,710 women would die as a result of the disease.[1]
- The direct medical care costs associated with cervical cancer were estimated to equal $1.7 billion in year 1996 dollars.[2]
- Screening can prevent cervical cancer by allowing clinicians to identify and remove precancerous lesions before they develop into cancer. Screening can also identify cancer early in the course of the disease when treatment is more effective and the chance of recovery is high.[3]
- The cost of screening is typically less than the cost of treating cancer and, when screening identifies a lesion in its early stages, the cost of treatment is often much less expensive than if the lesion was identified at a later stage.

Clinical Preventive Service Recommendations for Screening

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) strongly recommends cervical cancer screening for all women who have been sexually active and have a cervix.[3]

***Evidence Rating:* A (Strongly Recommended/ Good Evidence)**

The USPSTF found good evidence that the benefits of screening for cervical cancer substantially outweigh the risks associated with screening.[3]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Advisory Committee on Immunization Practices (ACIP)
- Alliance for Cervical Cancer Prevention; Program for the Appropriate use of Technology in Health (PATH)
- American Cancer Society (ACS)
- National Cancer Institute (NCI)
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Cervical cancer was once the most common cause of cancer death among women in the United States, but the death rate from cervical cancer dropped 74%

between 1955 and 1992, due to screening, earlier detection and treatment, and more effective treatment methods.[1] Despite this progress, cervical cancer remains a major cause of premature morbidity and mortality among women in the United States.

In 2005, it was estimated that 10,370 women would be diagnosed with cervical cancer and 3,710 women would die as a result of the disease.[1] Cervical cancer is most common among women in their 40s to 60s, although some women develop cancer in their 30s.[4]

Cervical cancer screening has been conducted using the conventional Pap test screening method since 1940; the Pap test has proven to be one of the most successful methods of cancer prevention and early detection available.[5] More than 50% of women who develop cervical cancer have never been screened for cervical cancer and 60% of women who develop cervical cancer have not been screened in the previous 5 years.[5-6] The dose-response relationship between the number of times a woman is screened during her lifetime and her likelihood of developing cervical cancer is illustrated in the following table:

Frequency of Screening	Reduction in Cancer Rate
At least every three years *Screening interval recommended by the USPSTF	75%-88%
Five times per lifetime	61%-75%
Three times per lifetime	35%-55%
Twice per lifetime	29%-42%
Once per lifetime	17%-32%

Source: Alliance for Cervical Cancer Prevention. Cervical cancer prevention fact sheet. Seattle, WA: Program for the Appropriate use of Technology in Health (PATH); 2003.

Condition/Disease Risk Factors

The major risk factor for cervical cancer is infection with the human papillomavirus (HPV), a common sexually transmitted infection (STI). Clinical research shows that 95% to 100% of all squamous cell cervical cancers and 75% to 95% of all cervical intraepithelial neoplasia (CIN) lesions (a precursor to cervical cancer) can be linked to infection with HPV.[7]

HPV is the most common sexually transmitted disease in the United States; over 50% of adults contract an HPV infection during their lifetime.[8] In most women infected with HPV, the virus remains asymptomatic and does not progress to precancerous lesions (CIN or dysplasia) or cervical cancer.[9-10] However, approximately 5% to 10% of women with persistent HPV infection develop cervical cancer during their lifetimes if they do not have a Pap test to detect precancerous lesions and do not receive appropriate follow-up care.[10]

In 2006, the Food and Drug Administration (FDA) licensed a vaccine to reduce the risk of cervical cancer. The Advisory Committee on Immunization Practices (ACIP) has issued provisional recommendations for use of this vaccine.[11] The

vaccine is not a substitute for recommended screening services: screening is still the primary method of cervical cancer prevention.[11] Additional information on the HPV vaccine is provided in the *Immunization Evidence-Statement*.

Although cervical cancer precursor lesions only develop after HPV infection, other factors—such as age, being a smoker, starting sexual intercourse at an early age, having a large number of sexual partners, using oral contraceptives, and having seven or more live births—increase a woman's risk of cervical cancer.[9] Some research suggests that diet; a woman's immune status and genetic predisposition; and co-infection with chlamydia, HIV/AIDS, or other sexually transmitted infections (STIs) may also influence risk of developing cervical cancer.[9, 12]

Value of Prevention

Economic Burden of Condition/Disease

The direct medical care costs associated with cervical cancer were estimated to equal $1.7 billion in year 1996 dollars based on SEER (Surveillance, Epidemiology, and End Results) and Medicare-linked data.[2]

Workplace Burden of Condition/Disease

The cost of cervical cancer ($1.7 billion) would be significantly higher if work loss and premature deaths were included in the analysis. For example, 25.9 years of life are lost, on average, by each woman who dies of cervical cancer. These lost years of life—which often occur during the prime working years—translate into lost earnings for women and their families, worker-replacement costs for businesses, and are a significant cost to society.[13]

Economic Benefit of Preventive Intervention

As with most preventive services, screening for and treating cervical cancer in its early stages is much less expensive than intervening at later stages in the disease process. For example, the cost of treating a single case of localized (early-stage) cervical cancer averages $20,255, while the cost of treating a single case of distant (late-stage) disease averages $36,912 (both figures in year 2000 dollars).[14] In addition to reduced medical care costs, the years of life gained from early detection and treatment are valuable to families, businesses, and the community at large.[13]

Estimated Cost of Preventive Intervention

The cost of a conventional Pap smear test will vary depending on location, type of provider, and the patient's age. In 2004, the private-sector cost of screening for cervical cancer among women under age 65 averaged $31 including specimen collection, laboratory processing, and interpretation; approximately 95% of all paid claims fell within the range of $9 to $64.[15] For Medicare eligible women, cervical cancer screening cost an average of $28 and approximately 95% of all paid claims fell within the range of $0 to $62.[15]

Costs of vaccination are in addition to the costs for recommended screening services.

Estimated Cost of Treatment

The costs associated with an abnormal Pap test as a result of HPV infection, including the cost of physician visits, laboratory tests, colposcopies, and treatment of cervical neoplasia if present, were estimated to be $1,281 per patient in year 2000 dollars.[14]

The cost of treating established cervical cancer varies. Localized (early-stage) cervical cancer costs and average of $20,255 to treat and distant (late-stage) disease costs an average $36,912 to treat (both figures in year 2000 dollars).[14]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

The relative costs and benefits of screening will vary depending on the age of patients screened and the screening interval. A recent study (that included patient-time costs) estimated that the cost-effectiveness ratio of a conventional Pap test repeated every three years up to the age of 75 was $11,830 per quality-adjusted life year (QALY) saved (in year 2000 dollars).[7] In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, cervical cancer screening is highly cost-effective.[16]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

The purpose of screening for cervical cancer is twofold. First, screening reduces the risk of cervical cancer by identifying women with precancerous conditions that can be treated before the conditions progress to cancer. The primary precursor lesions of cervical cancer, CIN III and carcinoma *in situ*, progress slowly, often over more than 8 to 9 years. Pap test screening detects these lesions before they develop into invasive cancers and, with appropriate and timely treatment, a full recovery is likely. Second, screening can identify women with cervical cancer before symptoms appear. Early detection, which allows for early treatment, improves outcomes.[3]

Benefits and Risks of Intervention

The benefits of cervical cancer screening are substantial. Screening reduces cervical cancer incidence and mortality. When Pap test screening programs are introduced into populations for the first time, the risk of developing cervical cancer is typically reduced by 60% to 90% within 3 years.[12] Mathematical models suggest that population-wide screening with the Pap test every 3 years reduces the rate of invasive cervical cancer by 91%; screening with the Pap test every 5 years reduces the rate by 84%.[6, 12] In North America and Europe, the introduction of screening programs was associated with reductions in cervical cancer mortality of between 20% and 60%.[12]

The harms of screening for cervical cancer are small compared to the benefits. False-positive screening results may lead to unnecessary treatment of low-grade lesions, unnecessary evaluations and biopsies, and psychological stress.[12]

Screening is of little or no value among women who have undergone a hysterectomy for benign disease. The USPSTF suggests that clinicians obtain a full and accurate surgical history to confirm indication for hysterectomy and that a total hysterectomy has been performed before deciding against screening.[12]

Initiation, Cessation, and Interval of Screening

The USPSTF recommends that screening begin within 3 years of the onset of sexual activity or the age of 21, whichever occurs first, and continue until the age of 65 for adult women of normal risk. Some professional organizations recommend more frequent Pap tests, but the USPSTF found no direct evidence that annual screening achieves better outcomes than screening every 3 years. Further, although screening women who are not sexually active has little value,

many professional organizations recommend that clinicians screen all women over the age of 21 for cervical cancer because women may not always accurately report their history of sexual activity.[12]

Because the risk of cervical cancer decreases after the age of 65 in women who have a history of normal Pap test results, the risks associated with screening, including false-positive results and inconvenience, outweigh the benefits of screening for older women.[3] Screening is recommended in older women who have not been previously screened, when information about previous screening is unavailable, or when screening is unlikely to have occurred in the past (e.g., among women from countries without screening programs).[3] Evidence is limited to define "adequate recent screening." The American Cancer Society (ACS) guidelines recommend that older women who have had three or more documented, consecutive, technically satisfactory normal/negative cervical cytology tests, and who have had no abnormal/positive cytology tests within the last 10 years, can safely stop screening.[1]

Note: In addition to screening, coverage should be provided for immunization with the HPV vaccine in accordance with recommendations by the Advisory Committee on Immunization Practices (ACIP). For more information on the HPV vaccine, please refer to the *Immunization Evidence-Statement*.

Intervention Process

The approved screening method for cervical cancer is the conventional Pap test. Newer screening methods, such as liquid-based, thin-layer preparations (e.g., ThinPrep®), computer-assisted screening (e.g., AutoCyte®), and human papillomavirus (HPV) tests, such as Hybrid Capture II®, are available. Purchasers may choose to cover these screening tests in addition to the conventional Pap test.[5]

Treatment Information

Health coverage should include provisions for diagnostic and treatment services.

Strength of Evidence for the Clinical Preventive Service (Screening)

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Service Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to recommend cervical cancer screening for all women who have been sexually active and have a cervix.[3]

Authored by:

Campbell KP, Coates RJ, Chattopadhyay S. Cervical cancer evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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EVIDENCE-STATEMENT:

CHILD HEALTH PROMOTION (Screening, Counseling, Immunization, Preventive Medication, and Treatment)

Why This Chapter is Important for Employers: An Overview

Child Developmental (Screening):

- Approximately 17% of children age 17 years and younger in the United States have at least one developmental disability, and 30% of children with a developmental disability have comorbid or multiple developmental disorders.[1]
- Children with developmental delays and disabilities are at increased risk for poor health and social outcomes and added medical and education costs.
- The *lifetime* direct and indirect costs for persons born in 2000 with developmental disabilities were estimated to equal $51.2 billion for persons with mental retardation, $11.5 billion for persons with cerebral palsy, $2.1 billion for persons with hearing loss, and $2.5 billion for persons with vision impairment (all figures in year 2003 dollars).[2]
- The added time and stress associated with caring for a child with a developmental disability may result in employees experiencing higher medical claims (due to increased health problems or depression), lower productivity, increased absenteeism, or an early exit from the workforce. The mothers of children with disabling conditions are estimated to lose an average of approximately 5 hours of work per week equaling 250 hours per year.[3] Assuming an hourly cost of $12 to $20 (including fringe benefits), that implies a lost productivity cost of $3,000 to $5,000 per child, per year.[3]
- Children with developmental delays and disabilities who are identified and treated early have better long-term outcomes.

Dental Caries Prevention Through Oral Fluoride Supplementation (Preventive Medication):

- Dental caries (tooth decay) is an infectious, transmissible disease in which bacterial by-products (i.e., acids) dissolve the hard surfaces of teeth. It is the most common chronic disease of childhood; up to 27% of children aged 2 to 5 years and 49% of children aged 6 to 11 years have experienced dental caries.[4]
- Dental caries can result in pain and loss of tooth structure or teeth and can progress to acute systemic infection.
- Dental disease is particularly prevalent among young children of lower socioeconomic status.
- Fluoride supplementation prevents 32% to 81% of caries lesions in primary teeth or tooth surfaces.[5]
- Expenditures for dental services in the United States in 2004 totaled $81.5 billion, which was slightly more than 4% of the amount spent on health care that year. Private health insurance paid for $40.5 billion, or about half, of this amount.[6]
- Preventing tooth decay can reduce school absenteeism[7] and therefore reduce lost productivity among adult caregivers.
- Many preschool-aged children never visit a dentist. Primary care physicians are often the first and only health care professionals that children visit and are therefore in a unique position to address dental disease in this population.[8]

Immunizations for Children and Adolescents (Immunization):

- Approximately 11,000 babies born each day in the United States will need vaccination against fourteen diseases before age two.
- All vaccines are cost-effective, and most child and adolescent vaccines are cost-saving. The routine childhood vaccination program saves nearly $10 billion in direct medical costs and $43 billion in societal costs for every birth cohort (all children born in one year).[9]
- Approximately 24% of toddlers may be vulnerable to serious illnesses, including polio, measles, mumps, rubella, diphtheria, tetanus, pertussis, invasive *Haemophilus influenzae* type b infection, hepatitis B, and varicella because they have not completed the recommended vaccination series.[10]

Lead, Elevated Blood Lead Levels (Screening):

- The dangers of lead are well documented for all age groups, and high levels of lead exposure produce serious neurologic complications that can result in permanent disability or death. Lead affects multiple organ systems such as the cardiovascular, renal, and hepatic systems.[11-12] Lead can also reduce growth, resulting in restricted height.[13-14] Among children, elevated BLLs are associated with behavioral and reaction (attention) deficits[15-19] and intellectual impairments (lowered IQ).[20-25]
- Approximately 310,000 children between the ages of 1 and 5 years have elevated blood lead levels.[26]
- An estimated 24 million housing units have significant lead-based paint hazards and pose a serious threat to children's health. These units include 1.2 million homes occupied by low-income families with children under the age of 6 years.[26]
- Between 1988 and 1992, childhood lead poisoning was estimated to result in 53,400 hospitalization days and $41 million in inpatient treatment costs.[27]
- Screening for elevated blood lead levels helps identify children who are exposed to lead and need interventions to reduce their blood lead levels. The higher a child's BLL and the longer it persists, the greater the chance that the child will experience serious adverse neurologic effects or other problems.
- Only 33% of children ages 1 to 5 years in the United States receive recommended screening.[28]
- In most states, case identification and treatment is the responsibility of health care providers and is therefore dependent on private insurance coverage. Environmental management and education of affected families remains the responsibility of local public health departments.

Newborn Hearing (Screening):

- Congenital hearing loss affects approximately 3 per 1,000 children.[29] Hearing loss, even loss that is mild in magnitude or unilateral (only one ear affected), can affect a child's potential to develop speech, language, and social skills, and school performance.[30]
- The average lifetime cost for one person with early childhood-onset hearing loss is estimated to be $417,000 (in year 2003 dollars).[31] It is estimated that the *lifetime* cost for all people born with congenital hearing loss in the year 2000 will total $2.1 billion (in year 2003 dollars).[31]

- Screening newborn infants for hearing loss identifies most children with congenital hearing loss prior to the onset of language development, allowing their parents to access support services much earlier than otherwise.

Newborn Screening for Genetic and Endocrine Disorders (Screening, Medical Foods, and Treatment):

- Newborn screening using dried blood spot specimens collected from newborn infants' heels can detect a number of disorders such as phenylketonuria (PKU), congenital hypothyroidism (CH), galactosemia, and sickle cell disease (SCD). All states require newborn screening for at least some genetic and endocrine disorders, but the required tests differ among various jurisdictions.
- At least 4 million babies in the United States undergo newborn blood spot screening each year. Severe disorders are detected in about 3,000 newborns. Accurate screening:
  - Identifies affected babies quickly.
  - Ensures that cases are not missed.
  - Helps start treatment early to reduce negative and irreversible health problems for affected newborns.
- Disorders identified by newborn screening programs require treatment in order to prevent serious and sometimes fatal complications. Lifelong medical management (including specialized medical foods or access to specialty clinics) is required to prevent serious medical complications associated with newborn metabolic disorders.
- The economic value of the prevention of mental retardation due to just two metabolic conditions (PKU and CH) exceeds $400 million per year, more than twice the amount of money spent on all newborn screening.[32-33]
- Sickle cell disease is a major cause of hospitalizations. During 1989 to 1993, hospitalization costs for children and adults with SCD averaged $475 million per year (in year 1996 dollars).[34]

Vision (Child) (Screening):

- Visual impairment is a common condition that affects 7% to 8% of children.[35] The most common forms of visual impairment in children are refractive errors (nearsightedness, farsightedness, anisometropia, and astigmatism), amblyopia (reduced visual acuity without a detectable organic lesion of the eye), and strabismus (ocular misalignment).
- Uncorrected amblyopia may be a risk factor for future blindness in later childhood and adulthood[36] and may harm school performance, ability to learn, and later, adult self-image.[37] Further, the lack of binocular vision disqualifies individuals with amblyopia from many occupations.
- The estimated *lifetime* cost (in year 2003 dollars) for persons born in 2000 with vision impairment is $2.5 billion.[38]
- Early detection and treatment is essential for amblyopia, as treatment is highly effective in early childhood.
- Because visual impairment in children is common and believed to have an early sensitive period when interventions lead to better outcomes, much interest has focused on primary care vision screening tools for early detection, referral, and treatment.

Child Development (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

In 2006, the U.S. Preventive Services Task Force (USPSTF) found that evidence was "insufficient" to recommend for or against routine use of brief, formal screening instruments in primary care to detect speech and language delay in children up to 5 years of age.[1]

***Evidence Rating:* I (Insufficient Evidence)**

The USPSTF was unable to find studies that addressed the overarching question of whether screening for speech and language delay with brief, formal instruments improves long-term speech, language, and other non-speech-and-language outcomes. However, the USPSTF did find fair evidence to suggest that interventions can improve the results of short-term assessments of speech and language skills. The USPSTF could not find studies that addressed the potential harms of screening or interventions for speech and language delays. The USPSTF could not determine the balance of benefits and harms of screening with brief, formal screening instruments.[1]

The USPSTF did not examine other aspects of developmental screening.

Other Recommended Guidance American Academy of Pediatrics (AAP)

The American Academy of Pediatrics (AAP) recommends regular, universal developmental screening of infants and young children by primary pediatric healthcare providers at 9, 18, and 30 months, using standardized screening tools with high specificity and sensitivity, to identify children in need of further assessment and diagnosis, and appropriate referral for early intervention and education services as indicated.[2]

Evidence Rating:

Not Specified

Other professional organization such as the National Association of Pediatric Nurse Practitioners (NAPNAP)[3] and the American Academy of Neurology[4] recommend screening for developmental disorders.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Child and Adolescent Psychiatry
- American Academy of Neurology
- American Academy of Pediatrics (AAP)
- American Psychological Association (APA)
- Centers for Disease Control and Prevention (CDC)
- Committee on Educational Interventions for Children with Autism, National Research Council, National Academies of Science
- Maternal Child Health Bureau (MCHB)

- National Association of Pediatric Nurse Practitioners (NAPNAP)
- National Research Council, Committee on Educational Interventions for Children with Autism, Division of Behavioral and Social Sciences and Education
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

A developmental delay, disorder, or disability refers to the presence of one or more of a diverse group of chronic conditions that hinders a child from developing age-appropriate cognitive, emotional, social, behavioral, psychological, or motor skills such as learning, communicating with adults, playing with other children, or walking. Developmental disabilities can begin at any time during childhood and, depending on the severity of the condition, can result in delayed learning (such as a speech impediment that can be overcome with speech therapy), a physical or mental impairment (such as dyslexia), or a permanent disability (such as cerebral palsy or mental retardation).

Examples of developmental disabilities include:
- Attention deficit/Hyperactivity disorder (ADD/ADHD)
- Autism spectrum disorders
- Cerebral palsy
- Depressive or anxiety disorders
- Epilepsy
- Hearing loss
- Learning disorders such as dyslexia
- Mental retardation
- Muscular dystrophy
- Speech disorder
- Tourette syndrome and other tic disorders
- Vision impairment

Approximately 6.6% of children (aged 5 to 17 years) in the United States have ADD, 3.6% have a developmental delay (DD), 8.2% have a learning disability (LD), and 13.6% have a mental health problem.[5]

Children with developmental disabilities have poorer health outcomes, a lower level of education attainment, and higher rates of delinquency and incarceration

than do children without disabilities. Poor outcomes associated with developmental delays and disabilities include:

Reduced educational attainment
- Poor school performance
- Reduced school attendance

Poor overall health status
- Increased rate of injuries
- Increased rate of emergency room visits, doctor visits, and hospitalizations
- Longer hospital stays
- Higher rates of mental illness and behavioral problems

Social problems
- Poor peer relationships
- Increased risk of substance abuse
- Increased risk of delinquency and violence in adolescence and adulthood

Condition/Disease Risk Factors

There are multiple risk-factors for developmental delays, disabilities, and disorders.[6-8]

Value of Prevention

Economic Burden of Condition/Disease

The economic and social burden of developmental disabilities is great. The poor health and social outcomes of children with developmental disabilities result in excess medical, education, and criminal justice system costs for families, employers, and communities. The *lifetime* direct and indirect costs for persons born in 2000 with developmental disabilities were estimated to equal $51.2 billion for persons with mental retardation, $11.5 billion for persons with cerebral palsy, $2.1 billion for persons with hearing loss, and $2.5 billion for persons with vision impairment (all figures in year 2003 dollars).[9] Indirect costs for the developmentally disabled person include the value of productivity losses in the workplace and household because of premature death, inability to work, or limitation in the amount and type of work that can be performed.

The excess medical costs associated with developmental disabilities are well-documented. For example, children with ADHD have higher health-related expenses than do children without developmental delays and disabilities. In fact, compared to children who develop normally, children with ADHD have 2.6 times as many medical claims and average nearly $1,000 per year in added medical costs (the average annual per patient cost for a child with ADHD in 1998 was $1,574 compared to $541 for a child without ADHD).[10] Further, family members of children with ADHD have per-capita annual direct and indirect costs nearly twice that of the family members of children without ADHD ($2,728 compared to $1,440).[10]

	Similarly, results from Washington State Medicaid claims data show that, compared to children who develop normally, children with developmental delays: • Are at least 5 times more likely to have chronic health conditions such as gastrointestinal disorders, central nervous system disorders, and conditions of the ear, nose, and throat; • Have 1.5 times as many physician visits during their first 5 years of life; • Have more hospitalizations during their first 5 years of life, even when factors such as health status are controlled; and • Have more than 10 times the number of visits to specialty practitioners such as physical and occupational therapists, speech therapists, and audiologists.[11] This additional need for healthcare translates into added costs for employers.
Workplace Burden of Condition/Disease	While employers are not directly impacted by the societal costs of developmentally disabled children, the added cost to the healthcare system should be of major concern to employers. Further, children with developmental delays and disabilities are a source of *indirect* costs to employers due to the fact that affected children experience more health problems and therefore require more substantial parental caregiving than do children without developmental problems. The added time and stress associated with intensive caregiving may result in employees experiencing higher medical claims themselves (due to increased health problems or depression), and lower productivity, increased absenteeism, or an early exit from the workforce. For example, the mothers of children with disabling conditions are estimated to lose an average of approximately 5 hours of work per week equaling 250 hours per year.[12] Assuming an hourly cost of $12 to $20 (including fringe benefits), that implies a lost productivity cost of $3,000 to $5,000 per child, per year.[12]
Economic Benefit of Preventive Intervention	Screening and early intervention services may reduce long-term societal costs. However, there is no direct evidence to support cost-savings associated with screening or early detection.[13]
Estimated Cost of Preventive Intervention	In 2004, the private-sector cost of a well-child visit that included developmental screening averaged $83; approximately 95% of all paid claims fell within the range of $30 to $127 dollars. The private-sector cost of a limited developmental screen (e.g., Developmental Screening Test II, Early Language Milestone Test) averaged $27 and 95% of all paid claims fell within the range of $0 to $95. The private-sector cost of an extended developmental test (i.e., assessment of motor, language, social, adaptive, and/or cognitive functioning by standardized assessment instruments) averaged $144 and 95% of all paid claims fell within the range of $0 to $466.[13]
Estimated Cost of Treatment	The cost of treatment will vary widely depending on the type and severity of the condition.
Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention	Screening and early intervention services may reduce long-term societal costs. However, there is no direct evidence to support cost-savings associated with screening or early detection.[13]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening tools are designed to identify children who may have a delay or disability and thus need more intensive diagnostic assessment and possible intervention or treatment. The purpose of screening is to identify children affected by developmental delays and disabilities when they are still developmentally receptive and malleable and therefore most responsive to interventions.

Benefits and Risks of Intervention

Research has shown substantial benefits to early recognition and intervention, especially for certain conditions. For example, children with autism who are identified early in life and receive specialized interventions have significantly improved cognitive, language, and motor skills and attain a higher level of education than do autistic children who are identified later in life.[14-15] Early intervention can also improve the cognitive developmental trajectories of children with developmental disabilities and decrease conduct problems at home and in the classroom (resulting in an increased rate of high school graduation and decreased juvenile and adult arrests).[16-17]

The risks of screening for developmental delays and disabilities include the possibility of a negative influence on the parent's perception of their child, the added time and costs associated with screening and—as with all screenings—the risk of false-positives which can produce anxiety and subject the child and parent to unneeded tests and evaluations. Research has found that false-positive rates can reach 15% to 30% for developmental screening.[13] False-positive results can place an extraordinary burden on the healthcare system, erode trust in the system, and potentially influence parents' perception of their child.[18] However, some research has found children with false-positives perform substantially lower than do children with true-negative scores on measures of intelligence, language, and academic achievement indicating that while these children do not have a developmental disability they may nonetheless benefit from further assessment and referral to services such as Head Start and specialized day care.[18-19]

The benefits of early recognition and the opportunity for early intervention are expected to outweigh the risks and costs associated with screening.

Initiation, Cessation, and Interval of Screening

Research is insufficient to determine the most efficacious age at which to screen for, diagnose, and treat specific developmental disorders. The AAP recommends screening all infants and young children due to the availability and importance of 1) early intervention services for children birth to 3 years of age, and 2) early childhood education services for children age 3 to 5 years.

Developmental concerns should be addressed among other health topics at each preventive care visit during the first 5 years of life. Developmental surveillance, asking for example, "Do you have any concern about your child's development, learning, or behavior?" is important at each visit.

Structured screening should occur at the 9, 18, and 30-month visits.[2]

Intervention Process

Developmental screening consists of a brief assessment conducted by a parent and/or health care provider that can include direct observation, patient (child) elicitation (i.e., asking the child to name three colors), interviewing parents of a child expressing usual behavior, and physical testing (e.g., measuring a child's ability to visually track objects). Screening tools help a clinician assess a child's attainment of developmental milestones—the physical, cognitive, and behavioral skills that are necessary components of a child's development. Developmental screening is best conducted by a primary care provider who has knowledge of the child's health and consistent contact with the child.

Treatment Information

Providers should refer children with development disabilities to Early Intervention (EI) services and other developmentally appropriate services, as medically indicated. Health benefits should include provisions for diagnostic follow-up and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

American Academy of Pediatrics (AAP)
Strength of Evidence: Not Specified

- The AAP recommends regular, universal developmental screening of infants and young children by primary pediatric healthcare providers at 9, 18, and 30 months, using standardized screening tools with high specificity and sensitivity,to identify children in need of further assessment and diagnosis, and appropriate referral for early intervention and education services, as indicated.[2]

Note: In 2006, the U.S. Preventive Services Task Force (USPSTF) found that evidence was "insufficient" to recommend for or against routine use of brief, formal screening instruments in primary care to detect speech and language delay in children up to 5 years of age.[1] The USPSTF did not examine other aspects of developmental screening.[20]

Authored by:

Campbell KP, Lollar D, Chattopadhyay S. Child development evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Dental Caries Prevention Through Oral Fluoride Supplementation (Preventive Medication)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force (USPSTF) Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that primary care clinicians prescribe oral fluoride supplementation at currently recommended doses to preschool children older than 6 months of age whose primary water source is deficient in fluoride.[1]

Evidence Rating: **B (Recommended/ At Least Fair Evidence**

The USPSTF found fair evidence that the service improves important health outcomes and concluded that the benefits of oral fluoride supplementation outweigh the harms. The USPSTF found fair evidence that, in preschool children with low fluoride exposure, prescriptions of oral fluoride supplements by primary care clinicians lead to reduced dental caries. The USPSTF concluded that the benefits of caries prevention using oral fluoride supplementation outweigh the potential harms of dental fluorosis, which in the United States are primarily in the form of mild discoloration of the teeth.[1]

Centers for Disease Control and Prevention (CDC) Recommendation

The Centers for Disease Control and Prevention (CDC) has developed recommendations for preventing tooth decay while reducing the risk of enamel fluorosis, or the hypo-mineralization of the tooth's enamel surface that results from ingesting fluoride during tooth formation. The CDC recommends the judicious prescription of fluoride supplements in preschool-aged children, and for those at risk, supplementation may continue through 16 years of age. Fluoride supplements may be prescribed for children who are at high risk for tooth decay and whose primary source of drinking water has low fluoride concentration, based on the child's risk of developing decay without fluoride supplements; the benefit of decay prevention; the potential for enamel fluorosis; and the child's sources of fluoride, especially drinking water. Parents and caregivers should be informed of both the benefits and the risks associated with fluoride supplementation. The dosage of prescribed fluoride supplements should be consistent with the schedule established by American Dental Association (ADA), American Academy of Pediatric Dentistry (AAPD), and American Academy of Pediatrics (AAP) which is available online (www.cdc.gov/fluoridation/other/spplmnt_schdl.htm). Fluoride supplements may be prescribed for specific children (as appropriate) or they may be given through school-based programs. When practical, supplements should be prescribed as chewable tablets or lozenges to maximize the topical effects that aid with enamel remineralization.[2]

Other Recommended Guidance

The American Dental Association (ADA), American Academy of Pediatrics (AAP), and American Academy of Pediatric Dentistry (AAPD) concur with the USPSTF and CDC recommendations described above.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Pediatric Dentistry (AAPD)

- American Academy of Pediatrics (AAP)
- American Dental Association (ADA)
- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information in this document is based on research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of the opinions of other organizations cited in the text.

Condition/Disease-Specific Information

Epidemiology of Condition/Disease

Dental caries (tooth decay) is an infectious, transmissible disease in which bacterial by-products (i.e., acids) dissolve the hard surfaces of teeth.[3] It is the most common chronic disease of childhood and is five times more common than asthma and seven times more common than hay fever.[4] Dental caries can result in pain and loss of tooth structure or teeth, and can progress to acute systemic infection.

Condition/Disease Risk Factors

Populations believed to be at increased risk of dental caries are those with low socioeconomic status or low levels of parental education, those that do not obtain regular dental care, and those without dental insurance or access to dental services.[5-7] Persons can be at high risk of dental caries even if they do not have any recognized risk factors. Individual factors that might increase risk include active dental caries; a history of high levels of caries in older siblings or caregivers; high levels of infection with cariogenic bacteria; impaired ability to maintain oral hygiene; malformed enamel or dentin; reduced salivary flow because of medications, radiation treatment, or disease; low salivary buffering capacity (i.e., decreased ability of saliva to neutralize acids); and the wearing of space maintainers or dental prostheses. Risk can increase if any of these factors are combined with dietary practices conducive to dental caries, such as frequent consumption of refined carbohydrates, while risk decreases with adequate exposure to fluoride.[5,8] An individual's risk of developing caries can vary over time as his or her risk factors change.

Value of Prevention

Economic Burden of Condition/Disease

Expenditures for dental services in the United States in 2004 totaled $81.5 billion, which was slightly more than 4% of the amount spent on healthcare that year. Private health insurance paid for $40.5 billion, or about half, of this amount.[9]

Workplace Burden of Condition/Disease

In 1996, 3.7 days of restricted activity per 100 employed people aged 18 years and older were reported to be associated with an acute dental conditions and over 2.4 million work days (1.9 days per person) were lost because of an acute dental conditions.[10] These statistics do not include days that parents were absent from work to care for children with dental conditions. Parental caregiving requirements associated with child dental problems can be extensive as children

miss a significant number of school days due to dental problems. In 1996, U.S. schoolchildren missed 1.6 million days of school as a result of acute dental conditions. Preventing tooth decay can reduce school absenteeism[10] and therefore reduce lost productivity among adult caregivers.

Economic Benefit of Preventive Intervention

Fluoride modalities are most cost-effective for persons at high risk of dental caries. Limited benefit is gained by providing additional caries-preventive modalities to persons consuming fluoridated water.

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of fluoride supplementation averaged $33; approximately 95% of all paid claims fell within the range of $0 to $42).[11] This cost does not include the cost of physician time for counseling and risk assessment.

Estimated Cost of Treatment

The ADA has estimated per-capita dental care expenditures (in year 1995 dollars) at $174 per person, per year.[12] The Health Care Financing Administration (now called the Centers for Medicare and Medicaid Services) came up with a similar estimate of $164 per person, per year.[13]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

The USPSTF found consistent evidence showing that fluoride supplementation prevents 32% to 81% of caries lesions in primary teeth or tooth surfaces.[14] No long-term cost-benefit analyses are available.

Preventive Intervention Information

Preventive Intervention: Purpose of Preventive Medication

Appropriate fluoride supplementation can prevent dental caries, infections, and other complications, thereby improving overall oral and physical health. Preventing tooth decay in preschool children can have a positive impact on oral health and quality of life in later years.

Benefits and Risks of Intervention

Fluoride controls early dental caries by both preventing caries from occurring and controlling caries when they do occur. Fluoride has a pre-eruptive effect on developing tooth enamel and a post-eruptive topical effect. Although community water fluoridation is recommended as the ideal way to provide fluoride's benefits to both children and adults, fluoride supplements are an effective alternative for children who lack access to fluoridated drinking water.[2]

However, fluoride ingested during tooth development can result in a range of changes in the appearance of teeth, broadly known as enamel fluorosis. Certain extremes of enamel fluorosis are cosmetically unacceptable. Severe forms of this condition occur only when young children ingest excess fluoride, from any source, during critical periods of tooth development. The use of dietary supplements in areas with fluoridated drinking water, which is inconsistent with the recommended supplement schedule, might increase the risk of enamel fluorosis.[15] Although the studies assessing the appropriateness of primary care clinicians' prescription of fluoride supplements have uncertain external and internal validity, they indicate that the majority of physicians in the United

States, especially pediatricians, prescribe oral fluoride supplements for at least some of their patients.[2] Research shows that many physicians do not know the fluoride status of their patients or the fluoridation level of their patients' water supplies, raising the possibility of inappropriate fluoride supplement prescriptions that may lead to excessive fluoride intake.[1]

Initiation, Cessation, and Interval of Preventive Medication

When healthcare providers identify preschool children who live in non-fluoridated areas as being at high risk of dental caries, they should consider prescribing dietary fluoride supplements for these children. These supplements are normally taken once per day and are not recommended for children younger than 6 months of age. Depending on the child's level of risk, supplementation may continue from age 6 months to 16 years.[2] Fluoride supplements should not be initiated or should be discontinued if the assessed risk of dental caries decreases to a low level or if the child obtains access to fluoride through other sources, especially drinking water.

Intervention Process

When prescribing any pharmaceutical agent, primary care providers should attempt to maximize benefit and minimize harm.[16] Although fluoride's posteruptive action can benefit the primary (i.e., "baby") teeth of children aged 1 to 6 years and provide some protection for developing permanent teeth, fluoride supplements can also increase the risk of enamel fluorosis.[17-18] Before prescribing fluoride supplements, clinicians should verify that the patient is not obtaining fluoride from any source of drinking water, medications, or swallowed toothpaste.[2]

Dietary fluoride supplements in the form of tablets, lozenges, or liquids (including fluoride-vitamin preparations) have been used throughout the world since the 1940s. Sodium fluoride is the active ingredient in most supplements. Tablets and lozenges typically contain 1.0, 0.5, or 0.25 mg of fluoride. To maximize the topical effect of the fluoride, tablets and lozenges should be chewed or sucked for 1 to 2 minutes before being swallowed. For infants, supplements are available in liquid form and are dispensed with a dropper.

Treatment Information

Health benefits should include provisions for routine dental care and the treatment of dental caries and other forms of dental disease.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found at least fair evidence to recommend oral fluoride supplementation for preschool children older than 6 months of age whose primary water source is deficient in fluoride.[1]

Recommended Guidance:

Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Expert Panel

- The CDC recommends the judicious prescription of fluoride supplements in preschool-aged children, and for those at risk, supplementation may continue through 16 years of age. Fluoride supplements may be prescribed for children who are at high risk for tooth decay and whose primary source of drinking water has low fluoride concentration, based on the child's risk of developing decay without fluoride supplements; the benefit of decay prevention; the potential for enamel fluorosis; and the child's sources of fluoride, especially drinking water. Parents and caregivers should be informed of both the benefits and the risks associated with fluoride supplementation. The dosage of prescribed fluoride supplements should be consistent with the schedule established by American Dental Association (ADA), American Academy of Pediatric Dentistry (AAPD), and American Academy of Pediatrics (AAP).[2]

Authored by:

Bailey W, Maas W, Lanza A. Dental caries evidence-statement: preventive medication. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Immunizations for Children and Adolescents (Immunization)

Please refer to the Immunizations Evidence-Statement on page 337.

Lead, Elevated Blood Lead Levels (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force (USPSTF) Recommendation

In 1996, the U.S Preventive Services Task Force recommended that clinicians screen children at risk for lead exposure for elevated blood lead levels. Given the availability of new evidence, the USPSTF has decided to update its 1996 recommendation. This work is currently in progress.

CDC Recommendation

The Centers for Disease Control and Prevention (CDC) recommends blood lead testing for children at high risk for exposure from lead paint, from house dust and soils contaminated by lead paint, from industrial sources of lead (e.g., smelters), and from imported cosmetics, traditional remedies, and cultural items that contain lead.[1]

Other Recommended Guidance

Centers for Medicare and Medicaid Services (CMS)

The Centers for Medicare and Medicaid Services (CMS) requires blood lead testing of all Medicaid enrolled children at 1 and 2 years of age or at 3 years of age if not previously tested.[2]

Evidence Rating:

CMS Mandate

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Advisory Committee on Childhood Lead Poisoning Prevention (ACCLP)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Center for Medicare and Medicaid Services (CMS)
- Centers for Disease Control and Prevention (CDC)
- National Health and Nutrition Examination Survey (NHANES)
- Peer-reviewed research
- U.S. Department of Health and Human Services (USDHHS)
- U.S. Environmental Protection Agency (EPA)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

The dangers of lead are well-documented for all age groups. High levels of lead exposure produce serious neurologic complications that can result in permanent disability or death. Lead affects multiple organ systems such as the cardiovascular, renal, and hepatic systems.[3-4] Lead can also reduce growth, resulting in restricted height.[5-6] Among children, elevated blood lead levels (BLLs) are associated with behavioral and reaction (attention) deficits[7-11] and intellectual impairments (lowered IQ).[12-17] Neurologic complications associated with lead exposure and lead poisoning are irreversible, even with treatment. The association between elevated BLLs and reduced intellectual capacity is strong and has a dose-response relation, meaning that the more lead present in the blood, the more severe the impairments become.[18-19] For example, a rise in blood lead from 10 to 20 µg/dL reduces a child's score on an IQ test by an average of 2 points.[18] No "safe" BLL in children has been specified.[15-16,19]

It is estimated that 310,000 children between the ages of 1 and 5 years have elevated BLLs.[20] An estimated 24 million housing units have significant lead-based paint hazards, including 1.2 million homes occupied by low-income families with children under the age of 6 years. These units pose a serious threat to children's health.[20]

The prevalence of elevated BLLs among young children in the United States has declined 98% since 1976-1980.[20] A critical factor in reducing children's BLLs has been the reduction in the number of homes with lead-based paint, which fell from 64 million in 1990 to approximately 38 million in 2000.[20] Despite the dramatic reduction in elevated BLLs, lead exposure and lead poisoning remain serious public health problems in the United States, especially for young children, who are most susceptible to the harmful effects of lead.

Reducing BLLs and eliminating BLLs higher than 10 µg/dL in children are two of the nation's *Healthy People 2010* objectives.[21]

Condition/Disease Risk Factors

Racial and ethnic minorities (particularly African-Americans), individuals with low incomes, children living in housing built before 1950, and those living in urban centers and in the Northeast bear the highest rates of lead exposure.[22-23]

Major sources of lead exposure include dilapidated housing with lead-based paint (commonly used until 1950) and paint dust, lead-soldered pipes, and lead found in dust or soil from peeling paint, leaded gasoline, or industrial emissions. Other sources of lead exposure include lead waste brought into the home from industry,[24] ethnic remedies,[25–27] or from lead in consumer products.[28–31]

Value of Prevention

Economic Burden of Condition/Disease

The costs of providing medical care and public health services to treat adverse health outcomes constitute the immediate direct costs of lead exposure and lead poisoning. Between 1988 and 1992, childhood lead poisoning was estimated to result in 53,400 hospitalization days and $41 million in inpatient treatment costs.[32] The longer term burden to taxpayers includes the costs of special education and lost tax revenues from the lower wages of workers with intellectual deficits due to childhood lead exposure or lead poisoning. The total economic burden would be much higher if lifetime productivity losses due to cognitive impairment and premature mortality were included in cost analyses.

Workplace Burden of Condition/Disease

Lead poisoning results in dose-related reductions in IQ which, in turn, contributes to lower wages and diminished lifetime earning power. The present value of economic losses attributable to lead exposure in the birth cohort of current 5-year-olds was estimated to be $43.4 billion in 1997.[33]

Economic Benefit of Preventive Intervention

Reducing lead exposure yields economic benefits by avoiding healthcare and special education costs and by preventing reductions in children's intelligence, academic achievement, and future productivity. A recent study quantified economic benefits from projected improvements in worker productivity that resulted from the reduction in children's exposure to lead in the United States since 1976. It was estimated that, because of falling BLLs in the United States, preschool-aged children in the late 1990s had IQs that were, on average, 2.2 to 4.7 points higher than they would have been if they had the blood lead distribution observed among United States preschool-aged children in the late 1970s. It was also estimated that each IQ point raises worker productivity 1.76% to 2.38%. With discounted lifetime earnings of $723,300 for each 2-year-old in

2000 dollars, the estimated economic benefit for each year's cohort of 3.8 million 2-year-old children ranges from $110 billion to $319 billion.[34]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of blood lead screening (venous sample test) averaged $22 per specimen for shipping, handling, and laboratory analysis; approximately 95% of all paid claims fell within the range of $8 to $55.35 Including the blood draw, which costs an average of $9, the total cost for blood lead level screening averaged $31. Approximately 95% of all paid medical claims fell within the range of $10 to $69.[35]

Estimated Cost of Treatment

Chelation therapy, the standard treatment, which leeches lead from the body, costs an estimated $2,046 (in year 2001 dollars) for each child treated.[36]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

A study based on mathematical simulations of a blood lead screening program, estimated that, compared with no screening, universal screening of all 1-year old children for elevated BLLs would produce economic benefits exceeding program costs in communities where at least 11% to 17% of children had elevated BLLs.[37]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Identifying children with elevated BLLs allows parents to make necessary environmental changes to limit the child's exposure to lead and allows clinicians to begin medical treatment with chelating agents (if necessary), before lead poisoning and its serious complications occur. Environmental changes, such as lead-paint abatement and removal of lead-soldered pipes, can have beneficial effects on both exposed children and other children who live in the home.

Benefits and Risks of Intervention

Risks associated with BLL screening include increased anxiety among parents, discomfort to the child of repeated blood draws, and the inconvenience associated with office visits. As with all screening tests, a false-positive test result can lead to unnecessary treatment. However, the benefits of screening, including early identification of lead exposure and the prevention of lead poisoning, outweigh the costs and risks associated with screening.

Chelating agents can cause adverse effects, which may be severe. Thus, the benefits and risks associated with lead poisoning treatment should be carefully weighed.

Initiation, Cessation, and Interval of Screening

Children at risk for lead exposure should be screened at or before age 12 months. Clinicians should note that, on average, blood levels peak in exposed children between 18 and 24 months of age. Screening for elevated BLLs should cease when the clinician determines the child is no longer at risk for exposure based on age or environmental risk profile.

At a minimum, blood lead testing for at-risk populations should be conducted at the following ages:

- 12 months
- 24 months
- 36–72 months

Children of any age should be screening when deemed medically necessary by a clinician's risk assessment, when clinical signs or symptoms consistent with elevated BLL are present, or when other evidence indicates possible exposure.

Children with symptoms consistent with increased intracranial pressure should also be considered for screening.

Recently resettled refugee, immigrant, and internationally adopted children 6 months to 16 years of age should be tested upon arrival and again 3 to 6 months after resettlement if local conditions warrant.[38]

State screening plans can be found on the CDC Childhood Lead Poisoning Prevention Branch website (www.cdc.gov/nceh/lead).

Intervention Process

Screening for lead exposure is conducted by measuring the amount of lead circulating in the blood through either a capillary or venous blood sample. Venous samples are more accurate and are thus the preferred method of testing. However, because of the added discomfort and cost of venous samples, clinicians often screen low-risk populations by taking a capillary blood sample and by performing a confirmatory venous blood lead concentration test on samples that show elevated BLLs.

Treatment Information

The main treatment for lead exposure is to stop the exposure by removing environmental or dietary sources of lead. Lead exposure reduction may include full lead abatement in the home, special cleaning techniques, the removal of contaminated objects, or the removal of the child from the home.[40] Treatment for lead poisoning (a BLL of 45 µg/dL or higher) requires pharmacologic intervention. Chelation therapy is the most common form of lead poisoning treatment and may prevent further damage by reducing the amount of lead circulating in the blood. Clinicians may choose to begin chelation therapy for children with BLLs lower than 45 µg/dL if the children have persistently elevated BLLs that do not respond to environmental risk reduction.[39]

Health benefits should include provisions for diagnostic, surveillance, and treatment services.

Strength of Evidence for the Clinical Preventive Service

The evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

Centers for Disease Control and Prevention's (CDC) Advisory Committee on Childhood Lead Poisoning Prevention
Strength of Evidence: Not Specified

- The CDC supports routine blood lead testing for children at high risk for exposure from lead paint, from house dust and soils contaminated by lead paint, from industrial sources of lead (e.g., smelters), and from imported cosmetics, traditional remedies, and cultural items that contain lead.[1]

Center for Medicare and Medicaid Services (CMS)
Strength of Evidence: CMS Mandate

- The Centers for Medicare/Medicaid Services (CMS) requires blood lead testing of all Medicaid enrolled children at 1 and 2 years of age or at 3 years of age if not previously tested.[2]

Authored by:

Brown MJ, Chattopadhyay S. Lead, elevated blood lead level evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Newborn Hearing (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

***Evidence Rating:* I (Insufficient Evidence)**

In 2001, the U.S. Preventive Services Task Force (USPSTF) issued an "I"-rating for "insufficient" evidence to recommend for or against routine newborn hearing screening. The USPSTF found inconclusive evidence to determine whether earlier treatment resulting from screening leads to clinically important improvement in speech and language skills at ≥ 3 years of age.[1] However, the USPSTF did note that there is evidence that the average age of diagnosis is significantly reduced with newborn hearing screening.

CDC Recommendation

***Evidence Rating:* Observational Studies, Expert Opinion**

The CDC recommends screening all children for hearing loss at birth.

The CDC recommendation for screening at birth is based on evidence from observational studies that children who receive intervention services for hearing loss before the age of 6 months develop significantly better language skills.[2-4] This is supported by expert opinion of those who care for children with hearing loss and parents of children with hearing loss, who report that children with hearing loss detected as infants have better language skills than older siblings with later-diagnosed hearing loss.

Other Recommended Guidance
Joint Committee on Infant Hearing (JCIH)

The Joint Committee on Infant Hearing (JCIH) endorses early detection of and intervention for infants with hearing loss (early hearing detection and intervention, EHDI) through integrated, interdisciplinary state and national systems of universal newborn hearing screening, evaluation, and family-centered intervention. Thus, all infants' hearing should be screened using objective, physiologic measures in order to identify those with congenital or neonatal onset hearing loss. Audiologic evaluation and medical evaluations should be in progress before 3 months of age. Infants with confirmed hearing loss should receive intervention before 6 months of age from health care and education professionals with expertise in hearing loss and deafness in infants and young children.[5]

Evidence Rating:

Expert Opinion

National Institutes of Health (NIH)

A 1993 National Institutes of Health (NIH) Consensus Development Conference Statement on Early Identification of Hearing Impairment in Infants and Young Children recommended that universal newborn hearing screening be implemented.[6]

Evidence Rating:

Expert Consensus

State Legislation

At present, 38 states and territories have enacted legislation on universal screening of all infants for hearing loss, and all states have programs to promote newborn hearing screening.[7]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Audiology
- American Academy of Pediatrics (AAP)
- American Speech, Language, and Hearing Association
- Centers for Disease Control and Prevention (CDC)
- Directors of Speech and Hearing Programs in State Health and Welfare Agencies
- Joint Committee on Infant Hearing (JCIH)
- Health Resources and Services Administration (HRSA)
- National Center for Hearing Assessment and Management (NCHAM)
- National Institutes on Health (NIH)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Congenital hearing loss affects approximately 3 per 1,000 children.[8] About 30% of children with hearing loss have another condition at birth. Hearing loss, even loss that is mild in magnitude or unilateral (only one ear affected), can affect a child's potential to develop speech, language, social skills, and school performance, including grade retention.[9] Hearing loss may be present at birth or may occur later.

Condition/Disease Risk Factors

About 40% to 60% of hearing loss is due to genetic or gene-environment factors. The causes of hearing loss for many children are poorly defined, and infants may have no identifiable risk factors to prompt targeted screening. But assorted risk factors are known. Some cases occur in families with a history of permanent childhood hearing loss. Infections such as bacterial meningitis or *in utero* cytomegalovirus (CMV), herpes, toxoplasmosis, and rubella are associated with hearing loss. Anatomical anomalies, caused either by birth defects or trauma or

other factors are also associated with hearing loss. Finally, a variety of other predispositions such as severe neonatal hyperbilirubinemia (jaundice) requiring exchange transfusion or persistent otitis media are associated with hearing loss.[10]

Value of Prevention

Economic Burden of Condition/Disease

Many people with hearing loss need long-term services. The average lifetime cost for one person with early-childhood-onset hearing loss is estimated to be $417,000 (in year 2003 dollars).[11] It is estimated that the *lifetime* cost for all people with congenital hearing loss who were born in 2000 will total $2.1 billion (in year 2003 dollars).[11] These costs include both direct and indirect costs. Direct medical costs, such as doctor visits, prescription drugs, and inpatient hospital stays, make up 6% of these costs. Non-medical expenses, such as home modifications and special education, make up 30% of the costs. These estimates do not include other expenses, such as hospital outpatient visits, sign language interpreters, and family out-of-pocket expenses.

Workplace Burden of Condition/Disease

Indirect costs of hearing loss, which include the value of lost wages when a person either cannot work or is limited in the amount or type of work possible, make up 63% of total costs.[11]

Economic Benefit of Preventive Intervention

The economic benefits of newborn hearing screening include reduced special education costs associated with improved hearing and language and also lower social and community services. A new study from England has reported that average education costs among 7 to 9 year-old children with bilateral hearing loss were lower by 22% among children born in districts with universal newborn hearing screening.[12]

Estimated Cost of Preventive Intervention

The cost of screening for hearing loss depends on the location (inpatient or outpatient setting), provider type, and the screening instrument used. In 2004, the private-sector cost of screening for hearing loss in the hospital (recommended setting) averaged $84 if billed and paid separate from the labor and delivery charge; approximately 95% of paid claims fell within the range of $0 to $200.[13] If the screening was missed before discharge or needed to be repeated on an outpatient basis, the average private-sector cost was $98 (in this scenario 95% of paid claims fell within the range of $0 to $235).[13] Both figures include the cost of staff time, consumables, and the cost of the equipment. When screening is billed as a part of labor and delivery charges the incremental cost is lower.

Estimated Cost of Treatment

The cost of treatment will vary widely depending on the type and severity of the hearing loss and the kinds of interventions chosen.

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Screening programs detect approximately 3 children with hearing loss for every 1,000 infants screened. Assuming an average cost of $30, the cost per infant detected may be as low as $10,000. In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, newborn hearing screening is cost-effective.

The cost-effectiveness of early detection depends on long-term outcomes. To the extent that improved language leads to lower special education costs and to improved learning potential, the monetary benefits of screening are likely to exceed the costs.[14-15] The savings in special education costs are likely to exceed the costs of screening within 5 years.[12]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening newborn infants for hearing loss identifies most children with congenital hearing loss prior to the onset of language development, allowing their parents to access services much earlier than otherwise. In the absence of screening, the majority of children with congenital hearing loss do not receive a diagnosis until 2 to 3 years of age, by which point language development is usually seriously delayed.[16] The average deaf or hard-of-hearing adult reads at only a 4th grade level.[17] The average language development score of children who are deaf or hard of hearing in the absence of early identification is two standard deviations below the mean.[2]

Certain children have later-onset or progressive hearing loss that cannot be detected during the newborn period. Clinicians and parents should be alert to hearing, speech, language, or developmental delay and should have children tested for hearing function if they are concerned about delays regardless of previous hearing screenings.

Benefits and Risks of Intervention

With screening, most cases of hearing loss can be detected prior to 3 to 4 months of age. With early identification, parents have the opportunity to communicate with their child beginning early in infancy. This aids language development for the child and strengthens the parent-child bonding. Research suggests that most preschool-age children with hearing loss will have language development within the normal range if intervention beginnings by 6 to12 months of age.[2-4] It is widely believed that this will lead to improved school performance and occupational success.[12,14-15]

The main risk of screening is that false-positive results can lead to additional screening or evaluation, incurring unnecessary costs and inconvenience for families and providers. The expected number of newborns who do not pass the hearing screen is 40 per 1,000 births, of which 3 will have hearing loss. Following and re-testing the remaining 37 incur costs and challenge follow-up systems. On the other hand, a number of surveys of families whose children screened positive for hearing loss found that most parents support hearing screening and consider the inconvenience to be minor compared to the benefits of early recognition.[18]

Initiation, Cessation, and Interval of Screening

Hearing screening for newborn infants is mandated in many jurisdictions, and CDC recommends it for all infants.

Since hearing loss may develop or first become apparent later, infants and children and should also be screened when a clinician suspects that language or developmental delay may be related to hearing loss. Physicians should be

encouraged to see that patients at high-risk for late-onset or progressive hearing loss be screened in accordance with recommendations set forth by the Joint Committee on Infant Hearing (JCIH).[5]

It is recommended by the JCIH that infants with risk indicators for progressive or delayed-onset hearing loss should receive audiologic monitoring before age 3 years.[5] In addition, an infant who does not pass a newborn screening should get a diagnostic audiological evaluation before 3 months age at the latest.

Intervention Process

Hospital-based screening programs should use automated audiologic screening instruments approved for use with newborn infants. This type of instrumentation is also appropriate for use in pediatrician and other provider offices, but very few of these offices provide this type of screening. Those offices that do not have the appropriate instrumentation and training should refer to audiological practices that do provide this service. Infants who are suspected to have hearing loss on the basis of the initial screening test should be referred for comprehensive audiologic assessment and specialty medical evaluations to confirm the presence of hearing loss and to determine type, nature, options for treatment, and (whenever possible) etiology of the hearing loss.[5] Audiological diagnosis requires a test-battery approach to cross-check results of multiple physiologic and developmentally-appropriate behavioral measures. Early audiologic assessments rely on physiologic measures of auditory function including: Auditory Brainstem Response (ABR), Otoacoustic Emissions (OAE), acoustic immittance measures, and acoustic reflexes.[19]

Auditory Brainstem Response (ABR) is a test that checks the brain's response to sound and is measured by placing electrodes on the head to record the brain's response to sound. Older babies, as well as those who do not routinely sleep well after eating, frequently require sedation to attain accurate ABR test results.[19] Otoacoustic Emissions (OAE) is a test that checks the inner ear response to sound and is measured by placing a very sensitive microphone in the ear canal to measure the ear's response to sound. Either type of instrument can be used alone or in sequence. Evidence is mixed as to what instrument or method is most effective in accurately identifying children with hearing loss, but most instruments seem to have an adequate level of sensitivity and specificity.[19]

Treatment Information

Health benefits should include provisions for diagnostic, surveillance, and treatment services.

Infants with a diagnosed hearing loss should receive appropriate services before 6 months of age, including medical services, early intervention services (i.e., Part C services or other state approved intervention services), and audiologic services.[5,20]

Every infant with confirmed hearing loss should be referred for an otolaryngology medical evaluation to determine the etiology of hearing loss, to identify related physical conditions, and to provide recommendations for treatment as well as referral for other services, including genetics evaluation and counseling. The clinician should refer families to a source of information about qualified early intervention service providers and the state Universal Newborn Hearing

Screening (UNHS)/Early Hearing Detection and Intervention (EHDI) program. In many states, clinicians are required to report children with hearing loss to the state program.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Observational Studies, Expert Opinion

- The CDC found evidence to support universal newborn hearing screening at birth. The CDC recommendation is based on evidence from observational studies that children who receive intervention services for hearing loss before the age of 6 months develop significantly better language skills. This is supported by expert opinion of those who care for children with hearing loss and parents of children with hearing loss, who report that children with hearing loss detected as infants have better language skills than older siblings with later-diagnosed hearing loss.[2-4]

The Joint Committee on Infant Hearing (JCIH)
Strength of Evidence: Expert Opinion

- JCIH endorses early detection of and intervention for infants with hearing loss (early hearing detection and intervention, EHDI) through integrated, interdisciplinary state and national systems of universal newborn hearing screening, evaluation, and family-centered intervention. Thus, all infants' hearing should be screened using objective, physiologic measures in order to identify those with congenital or neonatal onset hearing loss. Audiologic evaluation and medical evaluations should be in progress before 3 months of age. Infants with confirmed hearing loss should receive intervention before 6 months of age from health care and education professionals with expertise in hearing loss and deafness in infants and young children.[5]

National Institutes of Health (NIH)
Strength of Evidence: Expert Consensus

- A NIH Consensus Development Conference Statement on Early Identification of Hearing Impairment in Infants and Young Children recommended that universal newborn hearing screening be implemented.[6]

State Legislation
Strength of Evidence: Not Specified

- At present, 38 states and territories have enacted legislation on universal screening of all infants for hearing loss, and all states have programs to promote newborn hearing screening.[7]

Note: In 2001, the U.S. Preventive Services Task Force (USPSTF) issued an "I"-rating for "insufficient" evidence for newborn hearing screening, as a result of a lack of randomized controlled trials evaluating outcomes from newborn hearing screening.[1] However, the USPSTF did note that there is evidence that the average age of diagnosis is significantly reduced with newborn hearing screening.

Authored by:

Grosse S. Newborn hearing evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Newborn Screening for Genetic and Endocrine Disorders (Screening, Medical Foods, and Treatment)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

In 1996, the U.S. Preventive Services Task Force recommended screening newborns for phenylketonuria (PKU), congenital hypothyroidism (CH), and hemoglobin disorders.[1] It did not considered other disorders included in state newborn screening panels.

Given the availability of new evidence, the USPSTF has decided to update its 1996 recommendation on phenylketonuria (PKU). This review is currently underway. Please refer the USPSTF website for further information (www.ahrq.gov/clinic/uspstf/uspsspku.htm).

Other Recommended Guidance American Academy of Pediatrics (AAP)

The American Academy of Pediatrics (AAP) recommends that all food for special dietary use with accepted benefit for treatment of a medical condition be reimbursed [covered] as a medical expense, provided that the costs are over and above usual foods. All expenses for medical equipment and medical supplies necessary for the delivery of foods for special dietary use should be reimbursed [covered]. Reimbursement [coverage] for foods for special dietary use should be mandatory for the following[2]:

1. Any medical condition for which specific dietary components or the restriction of specific dietary components is necessary to treat a physical, physiologic, or pathologic condition resulting in inadequate nutrition.
2. An inherited metabolic disorder, including but not limited to disorders of carbohydrate metabolism, lipid metabolism, vitamin metabolism, mineral metabolism, or amino acid and nitrogen metabolism.
3. A condition resulting in impairment of oral intake that affects normal development and growth.

Evidence Rating:

Expert Consensus (Committee on Nutrition)

American College of Medical Genetics (ACMG)

An expert group convened by the American College of Medical Genetics (ACMG) with support from the Health Resources and Services Administration (HRSA) recently recommended a core panel of 29 disorders to be screened for in newborn blood spot specimens.[3] This screening panel has been endorsed by a Department of Health and Human Services (DHHS) Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children[4] and by professional organizations, including the American Academy of Pediatrics (AAP).[5]

PKU Management

Screening newborns is just a first step. In 2000, a NIH Consensus Statement on Phenylketonuria Screening and Management stated that a "multidisciplinary approach to lifelong care…for the treatment of PKU with….continuity of care from infancy through adulthood is considered medically necessary for optimal outcomes for individuals with PKU." Treatment includes access to appropriate medical services at specialized multidisciplinary treatment centers and provision of medical formula and foods.[6]

SCD Management

NIH guidelines on the management of SCD, last revised in 2002, call for comprehensive management by a team that includes physicians, nurses, health educators, and medical social workers, as well as access to a number of specialists. NIH recommends that a mid-level practitioner coordinate preventive and primary care, pain management, transfusion and chelation therapy compliance, and education of patients and other health care providers.[7]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Pediatrics (AAP)
- American College of Medical Genetics (ACMG)
- DHHS Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children
- Government Accountability Office (GAO)
- National Institutes of Health (NIH)
- National Newborn Screening and Genetics Resource Center, funded by the Health Resources and Services Administration (HRSA)
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

All states require that providers collect dried blood spot specimens from infants soon after birth and send them to be tested at an approved screening laboratory for a panel of disorders specified by the state. All states require screening for a minimum of four disorders: phenylketonuria (PKU), congenital hypothyroidism (CH), galactosemia, and sickle cell disease (SCD) and other hemoglobin disorders. Other disorders that are mandated by the majority of states include congenital adrenal hyperplasia (CAH), biotinidase deficiency, and medium chain acyl-CoA dehydrogenase (MCAD) deficiency.[8-9] Most states are moving to adopt the core panel of disorders recommended by the ACMG.

The most common newborn genetic disorders are congenital hypothyroidism (CH), with a prevalence at birth of 1 in 2,500 newborns, and sickle cell disease (SCD), which is diagnosed in 1 in 2,600 newborns.[9] The birth prevalence of phenylketonuria (PKU) in the United States is 1 in 20,000 newborns.

If untreated, phenylketonuria (PKU) results in severe mental retardation in most children. Congenital hypothyroidism (CH) results in mental retardation as well as other forms of cognitive impairment and physical and behavioral problems in many untreated infants. Sickle cell disease (SCD) results in repeated bouts of severe pain, disability, and can increase susceptibility to blood-borne infections that can cause sepsis, meningitis, and death. SCD also results in frequent, painful crises. In addition, children with SCD are at risk of stroke, which can cause brain damage and cognitive impairment.

Condition/Disease Risk Factors

Most disorders detected by newborn blood spot screening are genetic disorders, except for congenital hypothyroidism, an endocrine disorder which is primarily non-genetic.

Value of Prevention

Economic Burden of Condition/Disease

In the absence of screening and treatment, almost all children with phenylketonuria (PKU) (about 200 births per year) would develop mental retardation. The average *lifetime* direct and indirect cost per child born with mental retardation is $1 million (in year 2003 dollars).[10] This indicates a lifetime burden of at least $200 million for each birth cohort. Prior to screening, at least 1 in every 20,000 children developed mental retardation due to congenital hypothyroidism (CH).[11] This indicates that CH and PKU have similar economic burdens and, when combined, cost at least $400 million per year.

Sickle cell disease is a major cause of hospitalizations. During 1989 to 1993, hospitalization costs for children and adults with SCD averaged $475 million per year (in year) 1996 dollars.[12]

Workplace Burden of Condition/Disease

Family caregivers for children with disabling sequelae such as mental retardation or painful sickle cell crises are liable to miss days of work, cut back hours, or leave the workforce altogether. Mothers of children with disabling conditions are

estimated to lose an average of approximately 5 hours of work per week, or 250 hours per year.[13] Assuming an hourly cost between $12 and $20 (including fringe benefits), that implies an economic cost from $3,000 to $5,000 per child, per year.[13]

Economic Benefit of Preventive Intervention

Screening for two disorders, phenylketonuria (PKU) and congenital hypothyroidism (CH), has been demonstrated to be cost-saving to public payers, with the averted costs of care exceeding the costs of providing screening and diagnostic services and treatment.[14]

Estimated Cost of Preventive Intervention

The cost of newborn screening for genetic and endocrine disorders depends on the conditions tested for, the screening instruments used, the number of specimens tested, and the type of follow-up conducted.[15]

A study by the General Accountability Office (GAO) concluded that, in 2001, state newborn screening programs spent over $120 million, or an average of $29.44 per infant.[16] All except 5 states charge a fee to birthing centers or other providers to cover the cost of providing laboratory screening and, to a varying extent, follow-up services. Some states also use the fee to subsidize the costs of providing specialist services and/or medical foods. These fees vary from $10 to over $100 per infant.[17]

Estimated Cost of Treatment

Children with phenylketonuria (PKU) require treatment from specialized metabolic disease clinics. Dietary treatment for PKU, which is recommended for life, entails special phenylalanine-free formula that is supplemented with tyrosine and medical foods. The cost for one year of formula and medical foods can reach $10,000.[18] In contrast, congenital hypothyroidism (CH) can be treated by primary care providers using inexpensive thyroid hormone medications.

Children with sickle cell disease (SCD) may be prescribed antibiotics as prophylaxis against infections, and vaccination against selected bacterial infections may also be needed. Although many children with SCD are treated by primary care providers, outcomes such as survival are improved among children who receive care from a comprehensive SCD center.[19] Federally-insured children with SCD in 1992-1993 had mean expenditures 9 times higher than other similarly insured children.[20] Most of the costs were associated with hospital and emergency department admissions, although optimal pain management has been shown to reduce those costs substantially.[21] New interventions such as hydroxyurea, transfusions, and bone marrow transplantation offer promise in the prevention of painful crises, morbidity, disability, and mortality but, those treatments require significant expertise and specialized clinical experience to be utilized appropriately.[22]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

The cost-effectiveness of newborn screening is well established. In particular, screening for phenylketonuria (PKU) and congenital hypothyroidism (CH) is cost-saving, with the averted costs of care exceeding the costs of providing screening, diagnostic services, and treatment.[14] Screening for other disorders is generally cost-effective, if not cost-saving. For example, one analysis of screening for sickle cell disease (SCD) concluded that screening all newborns for SCD results in a cost of $10,000 per discounted life year saved.[23] Another analysis of

newborn screening for medium chain acyl-CoA dehydrogenase (MCAD) deficiency found that the cost per quality-adjusted life year (QALY) is likely less than $30,000.[24]

Preventive Intervention Information

Preventive Intervention:

Newborn screening allows treatment to be initiated within the first few weeks of life thereby preventing some of the complications associated with genetic and endocrine disorders.

Purpose of Screening, Medical Foods, and Treatment

Newborn screening for phenylketonuria (PKU) and congenital hypothyroidism (CH) has been a major public health success in preventing numerous cases of intellectual disability and assuring normal development of thousands of children. Newborn screening for other disorders has saved the lives of many children who would otherwise have died in early childhood.

Benefits and Risks of Intervention

Studies have shown that treatment for phenylketonuria (PKU) and congenital hypothyroidism (CH), if begun in the first 3 weeks and adhered to subsequently, can prevent mental retardation and assure normal cognitive functioning.[25-26] Risks resulting from discontinuation or lack of adherence to treatment vary with the age of the individual and the severity of the disorder. Newborn screening for sickle cell disease (SCD), in association with parent and provider education, clinical management, and vaccine and antibiotic prophylaxis, has been shown to prevent most deaths associated with SCD in the first 3 to 4 years of life. Early identification of SCD does not prevent pain crises and strokes, and long-term outcomes are less clear.[27] Treatments for other disorders that are included in some state screening panels also have benefits and risks. For example, a recent CDC report evaluated benefits and risks of screening and early treatment for cystic fibrosis.[28]

The effectiveness of newborn screening is dependent on access to appropriate medical services and treatments, including medical foods for disorders such as PKU. Failure of payers to cover medical foods can result in serious adverse consequences, including, for example, severe intellectual disability and devastating birth defects among children born to mothers with inadequately treated PKU.[29] Similarly, access to specialized, multidisciplinary treatment centers may be needed in order to minimize mortality and medical complications.

The main risk of screening is false-positive results, which can lead to unnecessary testing and unneeded treatment. False-negative screening results, as well as missed cases, may lead to delays in diagnosis and treatment.

Initiation, Cessation, and Interval of Screening, Medical Foods, and Treatment

Screening should be initiated upon birth, or as soon thereafter as possible, because initiation of treatment within the first few months of life may be required to prevent adverse outcomes. Some states require or recommend the collection of another blood spot specimen between 1 and 4 weeks of age. Families adopting children from other countries should consult their child's healthcare provider.

Medical foods and preventive treatment should be provided as medically necessary.

Intervention Process

A variety of types of equipment, reagents, and protocols are used to screen newborns. All newborn screening laboratories are CLIA-certified, use approved technologies, and participate in a rigorous proficiency testing and quality assurance program maintained by CDC in collaboration with the Association of Public Health Laboratories.

Children with positive screening test results need to be followed up with further testing. For disorders for which early treatment is urgent, treatment may be initiated based on presumptive positive results pending final confirmation.

Treatment Information

Children with genetic and endocrine disorders may require one or more of the following:

- Medical formula or medical foods
- Medications
- Treatment from specialized metabolic clinics

Health benefits should include provisions for case management services, access to specialty clinics, medical formulas/foods, and medications — as medically indicated — for the purpose of preventing illness or disability among beneficiaries with genetic or endocrine disorders.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

Medical Foods
The American Academy of Pediatrics (AAP)
Strength of Evidence: Expert Consensus

- AAP recommends that all food for special dietary use with accepted benefit for treatment of a medical condition be reimbursed [covered] as a medical expense, provided that the costs are over and above usual foods. All expenses for medical equipment and medical supplies necessary for the delivery of foods for special dietary use should be reimbursed [covered].[2]

Screening
American College of Medical Genetics (ACMG)
Strength of Evidence: Expert Opinion

- An expert group convened by the American College of Medical Genetics (ACMG) recently recommended a core panel of 29 disorders to be screened for in newborn blood spot specimens.[3]

Management and Preventive Medication
National Institutes on Health (NIH)
Strength of Evidence: Not Specified

- NIH PKU treatment guidelines stipulate that treatment should include access to appropriate medical services at specialized multidisciplinary treatment centers and provision of medical formula and foods.[6]
- NIH guidelines on the management of SCD call for comprehensive management by a team that comprises doctors, nurses, health educators, and medical social workers, as well as access to a number of specialties. The NIH recommends coordination of care by a mid-level practitioner, including preventive and primary care, pain management, transfusion and chelation therapy compliance, and education of patients and other health care providers.[7]

Authored by:

Grosse S. Newborn screening for genetic and endocrine disorders evidence-statement: screening, medical foods, and treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Vision (Child) (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

Evidence Rating: **B (Recommended/At Least Fair Evidence)**

The U.S. Preventive Services Task Force (USPSTF) recommends screening to detect amblyopia, strabismus, and defects in visual acuity in children younger than age 5 years.[1-2]

The USPSTF found at least fair evidence that the service improves important health outcomes and concludes that benefits outweigh harms. The USPSTF found no direct evidence that screening for visual impairment in children leads to improved visual acuity. However, studies from Sweden and Israel suggest that early screening for visual impairment may reduce the prevalence of amblyopia in children.[1] Also, the USPSTF found fair evidence that screening tests have reasonable accuracy in identifying strabismus, amblyopia, and refractive error in children with these conditions; that more intensive screening compared with usual screening leads to improved visual acuity; and that treatment of strabismus and amblyopia can improve visual acuity and reduce long-term amblyopia.[1-2]

Other Recommended Guidance American Academy of Pediatrics

The American Academy of Pediatrics (AAP) recommends the following vision screening be performed at all well-child visits for children starting in the newborn period to 3 years: ocular history, vision assessment, external inspection of the eyes and lids, ocular motility assessment, pupil examination, and red reflex examination. For children ages 3 to 5 years, the AAP recommends the aforementioned screening

in addition to age-appropriate visual acuity measurement and ophthalmoscopy. All children who fail the vision assessment or who have an ocular abnormality should be referred to a pediatric ophthalmologist or an eye care specialist appropriately trained to treat pediatric patients.[3]

Evidence Rating:

Expert Opinion

Center for Medicare and Medicaid Services (CMS)

The Center for Medicare and Medicaid Services (CMS) requires that Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services be provided to all individuals under age 21 enrolled in Medicaid. The EPSDT benefit, at a minimum, must include diagnosis and treatment of defects in vision, including eyeglasses. Vision services must be provided according to a distinct periodicity schedule developed by the state and at other intervals as medically necessary.[4]

Evidence Rating:

CMS Mandate

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Pediatrics (AAP)
- Centers for Disease Control and Prevention (CDC)
- Center for Medicare and Medicaid Services (CMS)
- National Institutes of Health (NIH)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Visual impairment is a common condition that affects 7% to 8% of children.[1] Relatively severe bilateral visual impairment with a best corrected visual acuity in the better eye of 20/70 or worse occurs in about 1 per 1,000 children ages 6 to 10 years, and blindness (visual acuity worse than 20/400) occurs in about 4 per 10,000 children.[5]

Causes of visual impairment in children include amblyopia, refractive error not associated with amblyopia, and strabismus. Significant refractive errors are the most common and easily corrected vision disorder, affecting up to 20% of young children.[6] Refractive errors are eye disorders in which the shape of the eye does not allow the light that enters the eye to be focused properly, resulting in blurred vision. Types of refractive errors include myopia (nearsightedness), hyperopia (farsightedness), anisometropia (a difference in refractive error between eyes), and astigmatism (an unequal curvature of the cornea that prevents light rays from focusing clearly at one point on the retina). Refractive errors are strong risk factors for amblyopia.

Amblyopia refers to reduced visual acuity in one or both eyes that is not due to ocular structure anomalies and that is not eliminated when refractive error is corrected. The disorder is most frequently caused by uncorrected anisometropia or strabismus and can also be caused by cataracts.[1] The best estimate of the prevalence of ambylopia is 3% to 4%.[1] An untreated amblyopic eye does not develop normal vision, and the individual has impaired binocular function (ability to use the eyes together, such as in depth perception). In addition, uncorrected amblyopia may be a risk factor for future blindness in later childhood and adulthood and may harm school performance, ability to learn, and later, adult self-image.

Strabismus is present in 3% to 4% of the population.[1] It is a deviation or misalignment of the eyes resulting from the failure of the eye muscles to work together. Most strabismus develops in early childhood and some types may not be cosmetically obvious. Strabismus results in poor to absent binocular function (ability of the eyes to work together) and can result in amblyopia.[1]

Condition/Disease Risk Factors

Prematurity and low birth weight are risk factors for amblyopia and strabismus.[7-8] Risk factors for other visual impairment disorders are not well understood.

Value of Prevention

Economic Burden of Condition/Disease

The estimated *lifetime* cost (in year 2003 dollars) for persons born in 2000 with vision impairment is $2.5 billion. This is a conservative estimate because it applies only to the 1 in 1,000 children with corrected visual acuity of 20/70 or worse. The cost estimate includes both direct and indirect costs and refers to all excess costs for individuals with vision impairment.

An estimate of the excess costs attributable specifically to vision impairment in children in the United States is not available.

Workplace Burden of Condition/Disease

The workplace burden of visual impairment in children has not been effectively measured. Indirect costs of visual impairment, which include the value of lost wages when a person either cannot work or is limited in the amount or type of work he or she can do, may be substantial.

Economic Benefit of Preventive Intervention

No economic evaluation of vision screening in preschool-age children has been published. A primary benefit of screening is the early detection of amblyopia, which allows for earlier treatment and improvement of visual acuity in the affected eye.

Estimated Cost of Preventive Intervention

The cost of conducting vision screening in young children varies depending on the methods used, the setting, and the type of staff performing the screening. In 2004, the private-sector cost of vision screening averaged $71; approximately 95% of paid claims fell within the range of $5 to $133.[9]

Estimated Cost of Treatment

Treatment for visual impairment varies depending on the type, cause, and severity of impairment. For amblyopia, treatment and associated costs (in year 2001 dollars) are[10]:

- Nonsurgical amblyopia therapy – $1,452
- Nonsurgical amblyopia therapy and ocular alignment – $2,190
- Nonsurgical amblyopia therapy and cataract extraction – $2,628
- Nonsurgical amblyopia therapy and ptosis repair – $1,853

The weighted average cost of surgical and nonsurgical treatment was $1,623 in year 2001 dollars.[10]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

One cost-effectiveness analysis of treatment for amblyopia in preschool-age children has been published.[6] That study reported that treatment was associated with a mean improvement in visual acuity from 20/80 to 20/32, and an associated improvement of health-related quality of life. The estimated cost per QALY (a measure of health impact) gained from treatment was $2,281 in year 2001 dollars.[6] In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, vision screening is highly cost-effective.

Preventive Intervention Information

Purpose of Preventive Intervention

Visual impairment in children is believed to have an early sensitive period when interventions lead to better outcomes. Screening for visual impairment allows clinicians to identify affected patients early and initiate treatment.

Benefits and Risks of Intervention

The USPSTF found no evidence of harms associated with screening, judged the potential for harms to be small, and concluded that the benefits of screening are likely to outweigh any potential harms.[2]

Initiation, Cessation, and Interval of Screening

Based on their review of current evidence, the USPSTF was unable to determine the optimal periodicity of screening. They recommend screening beginning in infancy with the methods of screening depending on the child.

Based on expert opinion, the American Academy of Pediatrics (AAP) recommends the following vision screening be performed at well-child visits for children starting in the newborn period to 3 years: ocular history, vision assessment, external inspection of the eyes and lids, ocular motility assessment, pupil examination, and red reflex examination. Between the ages of 3 and 5 years, visual acuity can be screened using simple recognition charts.[3] After age 5, standard visual acuity charts such as the Snellen Acuity Chart can generally be added to the screening.[11]

Intervention Process

Various tests are used widely in the United States to identify visual defects in children, and the choice of tests is influenced by the child's age. Beginning in the first year of life, strabismus can be screened for by using the cover test, the Hirschberg light reflex test, and the red reflex test. Screening children younger than age 3 years for visual acuity is more challenging than screening older children and typically requires testing by specially trained personnel. Newer automated techniques can be used to screen these children. Photo-screening and autorefractors can detect amblyogenic risk factors such as significant refractive error and media opacities; however, these techniques do not provide acuity

information on the children screened. In children older than 3 years, stereopsis (ability of both eyes to function together) can be assessed with the Random Dot E test or Titmus Fly. Some of these tests have better test characteristics than others.

Recent results from a large, rigorous evaluation of commonly used preschool vision screening tests supported by the National Institutes of Health (NIH) indicate that some tests outperform others. The Vision in Preschoolers Study (VIP) found that the best tests were able to detect two-thirds of children with vision disorders and that select objective and subjective screening tests can be effective.[11-12]

Treatment Information

Health benefits should include provisions for follow-up and treatment services.

Significant refractive errors are easily corrected with eyeglasses and some amblyopia and strabismus may be prevented by early detection and correction of significant refractive errors.

Most amblyopia can be treated nonsurgically. Treatment strategies include covering the sound eye with patching or using pharmacologic agents such as eye drops. Amblyopia associated with refractive errors may also be treated with eyeglasses. Select types of amblyopia do require surgical treatments, such as ocular alignment and cataract extraction, in addition to nonsurgical therapy.

Treatment of strabismus largely consists of correction with eyeglasses, surgical correction, and orthoptics (optometric vision therapy). Large constant deviations present in the first few years usually require surgical intervention, while intermittent or accommodative esotropia, which most commonly develops at 2 to 3 years of age, can almost always be corrected with eyeglasses.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found at least fair evidence to recommend screening to detect amblyopia, strabismus, and defects in visual acuity in children younger than age 5 years.[2]

Recommended Guidance:

American Academy of Pediatrics (AAP)
Strength of Evidence: Expert Opinion

- The American Academy of Pediatrics (AAP) found good evidence to support the following components of vision screening at all well-child visits for

children starting in the newborn period to 3 years: ocular history, vision assessment, external inspection of the eyes and lids, ocular motility assessment, pupil examination, and red reflex examination. For children ages 3 to 5 years, the AAP recommends the aforementioned screening in addition to age appropriate visual acuity measurement and ophthalmoscopy.[3]

Center for Medicare and Medicaid Services (CMS)
Strength of Evidence: CMS Mandate

- The Center for Medicare and Medicaid Services (CMS) requires that Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services be provided to all individuals under age 21 enrolled in Medicaid. The EPSDT benefit, at a minimum, must include diagnosis and treatment of defects in vision, including eyeglasses. Vision services must be provided according to a distinct periodicity schedule developed by the state and at other intervals as medically necessary.[4]

Authored by:

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EVIDENCE-STATEMENT:

COLORECTAL CANCER (Screening)

Why This Chapter is Important for Employers: An Overview

- Colorectal cancer is the second leading cause of cancer death.[1]
- Routine screening can reduce the number of people who die of colorectal cancer. While estimates of mortality reduction due to screening vary by type of screening test, the range is approximately 15% to 60%.[2-3]
- The estimated annual national expenditure for colorectal cancer treatment is $5.5-$6.5 billion; inpatient hospital care accounts for 80% of this cost.[4]
- Because colorectal cancer is a disease of middle and old age, the costs related to colorectal cancer treatment are likely to increase as the population ages. For example, hospital admissions for colorectal cancer are expected to double by 2050.[4]
- Screening can prevent colorectal cancer by allowing clinicians to identify and remove precancerous polyps before they develop into cancer. Screening can also identify cancer early in the course of the disease when treatment is more effective and the chance of recovery is high.[2-5]
- The cost of screening is typically less than the cost of treating cancer. When screening identifies a colorectal tumor in its early stages, the cost of treatment is often much less expensive than if the tumor is detected later in the course of disease.[4]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The USPSTF strongly recommends that clinicians screen men and women 50 years of age or older for colorectal cancer.[2]

***Evidence Rating:* A (Strongly Recommended/ Good Evidence)**

The USPSTF found fair to good evidence that several screening methods are effective in reducing mortality from colorectal cancer. The USPSTF concluded that the benefits from screening substantially outweigh potential harms, but the quality of evidence, magnitude of benefit, and potential harms vary with each method.[2]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Agency for Healthcare Research and Quality (AHRQ)
- American Cancer Society (ACS)
- International Agency for Research on Cancer (IARC)
- National Academy of Sciences (NAS)
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Colorectal cancer is the second leading cause of cancer death in the United States. It is also a major cause of premature mortality; patients who die of colorectal cancer lose 13 years of life, on average.[1] The American Cancer Society (ACS) estimated that there would be 104,950 colon and 40,340 rectal cancer cases in the United States in 2005. Although mortality rates have continued to decline over the past 15 years, an estimated 56,290 deaths from colorectal cancer were predicted to occur in 2005, comprising about 10% of all cancer deaths.[1]

Condition/Disease Risk Factors

Risk factors for colorectal cancer include being male, being older, having a family history of colorectal cancer, having a personal history of inflammatory bowel disease, being overweight or obese, being physically inactive, having certain genetic conditions[3], and (possibly) consuming inadequate amounts of fruits and vegetables.[6]

Value of Prevention

Economic Burden of Condition/Disease

The annual expenditure for colorectal cancer was conservatively estimated to equal $5.3 billion in 2000.[5] However, other investigators estimated that inpatient costs alone exceeded $5 billion in 1994 and their analysis also indicated that colon cancer-related admissions were twice as long and twice as expensive as the average hospital admission in the United States.[4]

Because colorectal cancer is a disease of middle and old age, the costs related to colorectal cancer treatment are likely to increase as the population ages. Based on census projections, the annual number of colon cancer-related hospital admissions among persons aged 50 years is expected to increase from 215,000 in 1992 to 471,000 in 2050. Similarly, among persons aged 60 years and older hospital admissions for colorectal cancer are expected to increase from 192,000 in 1992 to 448,000 in 2050.[4]

Workplace Burden of Condition/Disease

Besides the health, disability, and life insurance costs for employees affected by colorectal cancer, lost productivity associated with morbidity and premature mortality contributes to significant additional costs. During 1998, colorectal patients were hospitalized for 2.3 million days — a work loss equivalent of $70.9 million in lost wages among the working-age population. This figure would increase to $106.1 million if time away from work due to care in all settings was considered.[5]

Economic Benefit of Preventive Intervention

Screening can prevent colorectal cancer by allowing clinicians to identify and remove precancerous polyps before they develop into cancer. Screening can also identify cancer early in the course of the disease when treatment is more effective and the chance of recovery is high. The cost of screening is typically less than the cost of treating cancer and, when screening identifies a colorectal tumor in its early stages, the cost of treatment is often much less expensive. For example, one study, which looked at the cancer care costs among members of a health maintenance organization (HMO), found that the net costs of initial care for colon cancer were $7,002 at the carcinoma in situ stage and $11,624 at the local stage compared to $13,367 at the regional stage, and $15,276 at the distant stage (all figures in year 1992 dollars).[7]

Estimated Cost of Preventive Intervention

The average cost of colorectal cancer screening varies by location and provider. The 5 recommended methods of screening for colorectal cancer have very different initial costs, with FOBT and colonoscopy being the least and most expensive methods respectively. However, because they are typically used at different time intervals and because colonoscopy is required to confirm results of the other methods, the 10-year overall cost for screening methods that include diagnostic colonoscopy are similar. Table 1 lists the average price of colorectal cancer screening, by type. Cost estimates are based on 2004 data from privately-insured beneficiaries.[8]

Table 1: Average Private-Sector Cost of Colorectal Cancer Screening Methods (in year 2004 dollars)[8]

Screening Technique	Average Price per Procedure	Recommended Number of Over a 10-Year Period	Average Price Over a 10-year Interval
Colonoscopy	$557 (range $150 to $1,112)*	1	$557 (range $150 to $1,112)*
Flexible sigmoidoscopy; requires a follow-up colonoscopy if polyps are found	$174 (range $54 to $392)*	2	$348 (range $108 to $784)*
Double-contrast barium enema; may require follow-up colonoscopy	$126 (range $38 to $399)*	2	$252 (range $76 to $798)*
Fecal occult blood test (FOBT); may require follow-up colonoscopy	$7 (range $2 to $16)*	10	$70 (range $20 to $160)*
Combination of flexible sigmoidoscopy and FOBT	$181 (range $56 to $408)*	2/10	$418 (range $128 to $944)*

Source: Thompson Medstat. Marketscan. 2004.*Approximately 95% of paid claims fell within the stated range.

Estimated Cost of Treatment

Not Provided

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

A systematic review of cost-effectiveness analyses for different colorectal cancer screening methods found that most common screening strategies for adults aged 50 years or more would result in an average cost-effectiveness ratio ranging from $10,000 to $30,000 per life-year saved (year 2000 dollars) compared to no screening.[9] In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, screening for colorectal cancer is cost-effective.

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

The purpose of screening for colorectal cancer is to find precancerous polyps so that they can be removed before they turn cancerous, thus preventing the development of a tumor. Screening can also identify cancer early in the course of the disease when treatment is more effective and the chance of recovery is high.

Unfortunately, screening rates for colorectal cancer are low; fewer than half of men and women over age 50 are screened at the recommended intervals.[10]

Benefits and Risks of Intervention

The benefits of screening are substantial. Routine screening can reduce the number of people who die of colorectal cancer by preventing cancer or identifying it in its earliest stages when treatment is most effective. While estimates of mortality reduction due to screening vary by type of screening test, the range is approximately 15% to 60%.[2]

The risks associated with screening depend on the type of screening method used. All of the recommended tests can produce false-positive results, which may lead to unnecessary procedures with resultant harms. Flexible sigmoidoscopy, colonoscopy, and double-contrast barium enema may cause perforation and bleeding. However, the benefits of colorectal cancer prevention and early detection outweigh the risks of every screening method.[2]

Initiation, Cessation, and Interval of Screening

Screening for colorectal cancer should be initiated at age 50 for both men and women. For individuals who are determined by their physicians to be at higher risk of the disease, screening may be initiated at an earlier age.[11] Screening has been found to be effective for people up to age 80. However, randomized trials suggest that life expectancy of at least 5 years may be required to realize the benefits of screening, so the risks and costs of screening may outweigh the benefits for people with reduced life expectancy because of age or illness.[5]

The optimal interval between screenings depends on the screening method used and is illustrated in Table 2.

Table 2: Colorectal Cancer Screening Methods and Recommended Intervals[5]

Screening Method	Recommended Interval
Colonoscopy	10 years
Flexible sigmoidoscopy	5 years
Double-contrast barium enema	5 years
Fecal occult blood tests (FOBT)	1 year
Combination of flexible sigmoidoscopy and FOBT	5 years for the flexible sigmoidoscopy and one year for the FOBT

Intervention Process

Approved methods of screening for colorectal cancer include colonoscopy, flexible sigmoidoscopy, fecal occult blood testing (FOBT), and double-contrast barium enema. FOBT may be combined with flexible sigmoidoscopy to improve the sensitivity of the tests. The approved FOBT test uses specimens collected in the patient's home.[2-3]

Treatment Information

Health benefits should include provisions for diagnostic and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found fair to good evidence that several screening methods are effective in reducing mortality from colorectal cancer. The USPSTF concluded that the benefits from screening substantially outweigh potential harms, but the quality of evidence, magnitude of benefit, and potential harms vary with each method.[2]

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EVIDENCE-STATEMENT:

CONTRACEPTIVE USE (Counseling and Preventive Interventions)

Why This Chapter is Important for Employers: An Overview

- Unintended pregnancy is a significant problem in the United States. Approximately 3 million unintended pregnancies occur each year[1] and roughly half of all pregnancies and 31% of all live births are unintended.[2]
- During the course of a singe menstrual cycle (28 days) a fertile couple has a 25% chance of pregnancy with repeated unprotected sexual intercourse.[1] Among women ages 19 to 26 (when fertility is at its peak) the chance of pregnancy following a *single* act of unprotected intercourse around the time of ovulation is approximately 50%.[1]
- Contraceptives, when consistently and appropriately used, effectively prevent pregnancy.
- Approximately 50% of all unintended pregnancies occur among women who do not use contraception.[3]
- Contraception counseling increases the consistent and correct use of contraceptives, which in turn leads to lower rates of unintended pregnancy, fewer induced abortions, and better pregnancy outcomes.[4-5] In fact, it is estimated that halving the number of women *not* using contraception would reduce the number of unintended pregnancies (per year) by one-third. The reduction in unintended pregnancies would in turn reduce the number of abortions by 500,000 per year.[6]
- Comprehensive contraceptive coverage is relatively inexpensive. The average cost of adding coverage for all reversible methods of contraception is $25.31 per employee, per year.[7]
- Researchers estimate that over a 5-year period, employers can save $9,000 to $14,000 (in year 1993 dollars) by providing comprehensive contraceptive coverage.[8] Experts suggest that employers may begin to see some savings in the first year of coverage.[8]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

In 1996, the U.S. Preventive Services Task Force (USPSTF) recommended that clinicians counsel all men and women at risk for unintended pregnancy on effective contraceptive methods. This recommendation is archived and is no longer active.

Evidence-Based Recommendations American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) recommends that primary care providers obtain a history of sexual practices and provide counseling on the prevention of unintended pregnancy and contraceptive options to all sexually active women who do not want to become pregnant and men who do not want to have a child.[9]

Evidence Rating: **R (Recommended)**

Although evidence exists which demonstrates the net benefit of counseling to prevent unintended pregnancy, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost-effective and acceptable to most patients.[9]

American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists (ACOG) strongly recommends that combination or progestin-only oral contraceptives for emergency contraception should be offered to women who have had unprotected sexual intercourse within 72 hours of intercourse.[10]

***Evidence Rating:* A (Recommended/ Good Evidence)**

ACOG found good and consistent scientific evidence to support their recommendation of emergency contraception following unprotected intercourse.[10]

Other Recommended Guidance American Academy of Pediatrics (AAP)

The American Academy of Pediatrics (AAP) notes that the comprehensive health care of adolescents should include counseling on the prevention of sexually transmitted infections (STIs), education on contraceptive methods, and family planning services for the sexually active patient.[11] Specifically:

1. Adolescents should be strongly encouraged to postpone the initiation of sexual intercourse.
2. For patients already engaged in sexual intercourse or who are contemplating having sexual intercourse, a discussion of contraceptive methods and prevention of sexually transmitted infections (STIs) (including HIV) is essential.
3. The pediatrician should support compliance, manage side effects, change the method of contraception as circumstances require, and provide referrals and frequent follow-up with periodic screening for STIs.

Evidence Rating:

Not Specified

American College of Obstetricians and Gynecologists (ACOG)

ACOG recommends that when a woman is prescribed emergency contraception, she should be counseled about effective contraceptive methods, sexually transmitted infections, and safe-sex practices.[10]

***Evidence Rating:* C (Recommended/ Evidence from Expert Opinion)**

ACOG's recommendation that women receive contraceptive counseling post emergency contraception use is based on consensus and expert opinion.[10]

American Medical Association (AMA)

The American Medical Association (AMA) recommends that healthcare professionals[12]:

1. Help women plan for pregnancy.
2. Support age-appropriate education in esteem building, decision-making and family life, ultimately introducing the concept of planning for childbearing into the educational process.

Evidence Rating:

Not Specified

Jacobs Institute of Women's Health

Due to the side-effect profile of some medications and devices, the difference in permanence and reversibility of contraceptives, and women's personal preferences, employers/health plans should [cover] the full range of Food and Drug

Administration (FDA) approved contraceptive methods including, but not limited to[7]:

- Hormonal medications (e.g., pills and patches) including emergency contraceptives
- Contraceptive devices (e.g., IUD, diaphragms, vaginal rings)
- Sterilization (e.g., vasectomy, tubal ligation)

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American College of Obstetricians and Gynecologists (ACOG)
- American Medical Association (AMA)
- Centers for Disease Control and Prevention (CDC)
- Employee Benefits Institute
- Food and Drug Administration (FDA)
- *Healthy People 2010*, U.S. Department of Health and Human Services
- Institute of Medicine (IOM)
- Internal Revenue Service (IRS), Department of Treasury
- Jacobs Institute of Women's Health
- March of Dimes
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Unintended pregnancy is a significant problem in the United States. Approximately 3 million unintended pregnancies occur each year[1] and roughly half of all pregnancies and 31% of all live births are unintended.[2]

The risk of pregnancy (unintended or intended) is high. Women in the United States, on average, are fertile from ages 15 to 44.[13] During the course of a singe menstrual cycle (28 days) a fertile couple has a 25% chance of pregnancy with repeated unprotected intercourse.[1] Among women ages 19-26 (when fertility is at its peak) the chance of pregnancy following a *single* act of unprotected intercourse around the time of ovulation is 50%.[1] Approximately 50% of all unintended pregnancies occur among women who do not use contraception. It is estimated that the overall rate of unintended pregnancy could be cut in half if these women were to use a highly effective method of contraception.[3]

A wide range of effective contraceptives are available. They include reversible methods (e.g., hormonal pills and patches, IUDs, condoms, etc.) and irreversible methods (e.g., vasectomy, tubal ligation). Nearly all women (98%) who have had sexual intercourse have, at some point, used contraception to either avoid or delay pregnancy. Approximately 82% of women have used the oral contraceptive pill and about 90% have had a partner use the male condom.[4] The birth control pill, which is used by 11.6 million women, is the most common form of birth control in the United States.[14]

Despite the availability and effectiveness of contraception, women continue to experience unintended pregnancies. Most unintended pregnancies occur as a result of contraceptive nonuse, misuse, or a noticeable contraceptive failure (i.e., condom breaks).[1] In 2001, 5% of women of reproductive age experienced an unintended pregnancy.[15] Contrary to popular belief, unintended pregnancy is not only a problem of adolescence: women of all ages experience unintended pregnancies.[8]

Healthy People 2010, the national health agenda, has set the following goals for reducing the rate of unintended pregnancy is the United States[6]:

1. To increase the proportion of pregnancies that are intended to 70%.
2. To reduce the proportion of births occurring within 24 months of a previous birth to 6%.
3. To increase to 100% the proportion of females at risk of unintended pregnancy (and their partners) who use contraception.
4. To reduce the proportion of females that get pregnant despite using a reversible contraceptive method.
5. To increase male involvement in pregnancy prevention and family planning efforts.

Condition/Disease Risk Factors

All women who are aged 13 to 44, are sexually active and fertile, and who are not trying to become pregnant are at risk of an unintended pregnancy.[2] Approximately 10.7% of women in the United States who are at risk for an unintended pregnancy do not use contraception.[2] Certain groups are at an elevated risk for unintended pregnancy, they include: teenagers and young women age 20 to 24, women age 40 years and older, black women, women with lower levels of education, unmarried women, and women with low incomes.[2]

Value of Prevention

Economic Burden of Condition/Disease

The economic burden of unintended pregnancy is substantial, both to employers and the society at large. The economic cost of an unintended pregnancy to an employer includes either A) the cost of termination *or* B) the cost of prenatal, delivery, and postpartum care for the woman *and* the cost of continuing medical care for the infant as long as s/he remains a beneficiary.

Unplanned pregnancies, compared to planned pregnancies, often result in higher total medical claims costs and lost productivity costs because women whose

pregnancies are unintended are less likely to have proper folic acid intake, are less likely to breastfeed, and are more likely to continue smoking during pregnancy.[16] The adverse health outcomes associated with these behaviors lead to higher obstetric medical claims.[14]

Workplace Burden of Condition/Disease

Unintended pregnancies result in substantial excess direct medical claims costs[17] and indirect costs such as disability, employee replacement costs, lost productivity, and presenteeism.[14]

Economic Benefit of Preventive Intervention

Providing coverage for contraceptive counseling and contraceptive medications and devices improves access and use, thereby avoiding the substantial direct and indirect costs associated with unintended pregnancies, abortions, and unwanted births. The average cost of a 1-year supply of prescription birth control pills is $240 to $300 (in year 2005 dollars) and the cost of a single prescription of emergency contraception is $20 to $150. These costs are lower than the "treatment" costs for an unintended pregnancy.[7] For example, the average cost to employers of:

- A first term abortion is approximately $468 (in year 2003 dollars).[7]
- A normal vaginal delivery (without complications) is $7,340 (in year 2005 dollars).[7]
- A cesarean delivery (without complications) is $12,257 (in year 2005 dollars).[7]
- The delivery and first year care of a premature infant is $41,610 (in year 2001 dollars).[18]

Estimated Cost of Preventive Intervention

Comprehensive contraceptive coverage is relatively inexpensive. The average total cost (including administrative costs) of adding coverage for all reversible methods of contraception is $25.31 per employee, per year.[7] The added cost to employers of providing contraception coverage (assuming 20% employee cost sharing) is $1.69 per employee, per month (all figures from 1998, adjusted to year 2005 dollars using the NASA Inflation Calculator).[7]

In 2004, the private-sector cost of preventive medicine evaluation and management averaged $107 per session; approximately 95% of paid claims fell within the range of $45 to $165 per session.[19]

Estimated Cost of Treatment

Treatment costs of an unintended pregnancy include the cost of termination ($428)[7] *or* the cost of prenatal, delivery, and postpartum care and the ongoing cost of care for the infant. The cost of labor and delivery alone ranges from $7,340[6] to $41,610 (figures in year 2003, 2005, 2001 dollars, respectively).[18] The cost of prenatal care and ongoing infant/child care varies substantially, but it can be assumed to be significant if the child remains a beneficiary until 18 to 25 years of age.

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Researchers estimate that over a 5-year period, employers can save $9,000 to $14,000 (in year 1993 dollars) by providing comprehensive contraceptive coverage.[8] Experts suggest that employers may begin to see some savings in the first year of coverage.[8]

Preventive Intervention Information

Preventive Intervention: Purpose of Counseling

Contraceptive counseling is a key component of family planning. The purpose of contraceptive counseling is to educate at-risk men and women about ways of effectively preventing an unintended pregnancy.

Purpose of Preventive Intervention

Contraceptive medications and devices reduce the occurrence of pregnancy. This allows women and their partners to avoid, limit, or delay pregnancy.

Benefits and Risks of Intervention

There are several documented benefits of contraceptive use. First, women/couples who use contraceptives and engage in family planning have lower rates of induced abortion. It is estimated that halving the number of women *not* using contraception would reduce the number of unintended pregnancies (per year) by one-third. The reduction in unintended pregnancies would in turn reduce the number of abortions by 500,000 per year.[6] Second, planned and properly spaced pregnancies are associated with improved maternal and infant health outcomes: women who wait 18 to 23 months between delivery and subsequent conception lower their risk of adverse perinatal outcomes, including low birth weight, preterm birth, and small for size gestational age.[4-5] Finally, women who are able to limit their fertility have improved opportunities to seek education and thus higher earning employment. This improves individual, family, and societal economic status.[4]

Contraceptives are effective and safe when used as directed (see discussion of side effects below). Immediate use of an emergency contraceptive following unprotected sex or a contraceptive failure can reduce the risk of unintended pregnancy to 1% to 2%.[1]

Risks associated with family planning counseling have not been well documented, but may include partner discord. There are a number of side effects associated with contraceptives. Vaginal irritation is the most common side effect associated with cervical condoms, caps, diaphragms, shields, spermicides, and sponges. Other *rare* side effects may include urinary tract infections, vaginal infections, and toxic shock syndrome (with prolonged use). Side effects associated with birth control pills include headaches, breast tenderness, nausea, vomiting, bloating, decreased sex drive (libido), and depression. Women who take birth control pills, especially those who smoke, are also at an increased risk of heart disease, high blood pressure, and blood clots. The major side effects of intrauterine devices (IUDs) are abnormal vaginal bleeding and pelvic infection.[20]

Initiation, Cessation, and Interval of Counseling

According to the American Academy of Family Physicians (AAFP) and the American College of Obstetricians and Gynecologists (ACOG):

- Clinicians should regularly ask all patients of reproductive age (men and women) about contraception needs, even at office visits initiated for other reasons.[9-10]
- Clinicians should offer emergency contraception to all women who have had

unprotected sexual intercourse within 72 hours of intercourse or as otherwise indicated.[9-10] Emergency contraception should be offered in advance of need (as a back-up method) to all women, particularly those using barrier methods of contraception.[10]

Intervention Process

Counseling

Counseling should target both men and women and be inclusive of natural and artificial, permanent and reversible techniques. Contraceptive methods recommended by a clinician should be suited to the needs and lifestyle of patients.

Specific counseling methods are left to the discretion of the clinician. The American Academy of Family Physicians (AAFP) recommends that clinicians[9]:

- Use a patient-centered strategy to help patients choose a contraceptive method, acknowledging concerns that can interfere with adherence.
- Inform patients about efficacy rates for different methods and recommend use of high-efficacy options.
- Encourage patients to call or return to the office if they experience problems with the method chosen.

The American Academy of Pediatrics (AAP) notes that the comprehensive health care of adolescents should include counseling on the prevention of sexually transmitted infections (STIs), education on contraceptive methods, and family planning services for the sexually active patient.[11] Adolescents should be strongly encouraged to postpone the initiation of sexual intercourse. For patients already engaged in sexual intercourse or who are contemplating having sexual intercourse, a discussion of contraceptive methods and prevention of sexually transmitted infections (STIs) (including HIV) is essential. For these patients the pediatrician should support compliance, manage side effects, change the method of contraception as circumstances require, and provide referrals and frequent follow-up with periodic screening for STIs.[11]

Preventive

Interventions

Clinicians should prescribe contraceptive medications (e.g., birth control pill) or devices (e.g., IUDs) or provide the appropriate surgery or intervention (e.g., vasectomy) to men and women who wish to limit their fertility. Because research indicates that women and couples are more likely to use contraception successfully if given their contraceptive method of choice,[21-22] coverage of a wide range of contraceptive options is optimal. Employers are therefore encouraged to provide coverage for the full range of Food and Drug Administration (FDA) approved methods of contraception including, but not limited to[7]:

- Hormonal medications (e.g., pills and patches) including emergency contraceptives
- Contraceptive devices (e.g., IUD, diaphragms, vaginal rings)
- Sterilization (e.g., vasectomy, tubal ligation)

Note: Condoms play an important role in unintended pregnancy prevention and STI prevention. Because condoms do not require a prescription they are not

typically covered in employer-sponsored health insurance plans. While condoms are not addressed in the 2005 IRS[23] statement of qualified medical expenses for flexible spending arrangements (FSAs), some flexible spending administrators do consider condoms a qualified medical expense.[24] Birth control pills and sterilization are designated as qualified medical expenses by the IRS.[23] Employers who offer FSAs should alert beneficiaries to their administrator's rules and regulations regarding birth control, condoms, and sterilization.

Treatment Information

Treatment for an unintended pregnancy may include either prenatal, delivery, and postpartum care or abortion.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

The American Academy of Family Physicians (AAFP)
Strength of Evidence: R (Recommended)

- AAFP recommends that primary care providers obtain a history of sexual practices and provide counseling on the prevention of unintended pregnancy and contraceptive options to all sexually active women who do not want to become pregnant and men who do not want to have a child. Counseling should also be provided regarding high-risk sexual behavior and the prevention of sexually transmitted diseases and human immunodeficiency virus (HIV) infection.[9] Although evidence exists which demonstrates the net benefit of counseling to prevent unintended pregnancy, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost-effective and acceptable to most patients.[9]

The American College of Obstetricians and Gynecologists (ACOG)
Strength of Evidence: A (Recommended/Good Evidence)

- ACOG found good and consistent scientific evidence to support the provision of emergency contraception following unprotected intercourse.[10]

Recommended Guidance:

The American Academy of Pediatrics (AAP)
Strength of Evidence: Not Specified

- The American Academy of Pediatrics (AAP) notes that the comprehensive health care of adolescents should include counseling on the prevention of sexually transmitted infections (STIs), education on contraceptive methods, and family planning services for the sexually active patient.[11] Adolescents should be strongly encouraged to postpone the initiation of sexual intercourse. For patients already engaged in sexual intercourse or who are contemplating having sexual intercourse, a discussion of contraceptive methods and prevention of sexually transmitted infections (STIs) (including HIV) is essential. For these

patients the pediatrician should support compliance, manage side effects, change the method of contraception as circumstances require, and provide referrals and frequent follow-up with periodic screening for STIs.[11]

American College of Obstetricians and Gynecologists (ACOG)
Strength of Evidence: C (Evidence Based on Expert Opinion)

- ACOG recommends that when a woman is prescribed emergency contraception, she should be counseled about effective contraceptive methods, sexually transmitted diseases, and safe-sex practices.[10]

American Medical Association (AMA)
Strength of Evidence: Not Specified

- The AMA recommends that healthcare professionals:
  1. Help women plan for pregnancy.
  2. Support age-appropriate education in esteem building, decision-making and family life, ultimately introducing the concept of planning for childbearing into the educational process.[12]

Jacobs Institute of Women's Health
Strength of Evidence: Not Specified

- Due to the side effect profile of some medications and devices, the difference in permanence and reversibility of contraceptives, and women's personal preferences, employers/health plans should [cover] the full range of Food and Drug Administration (FDA) approved contraceptive methods including, but not limited to[7]:
  - Hormonal medications (e.g., pills and patches)
  - Contraceptive devices (e.g., IUD, diaphragms, vaginal rings, condoms)
  - Sterilization (e.g., vasectomy, tubal ligation)

Authored by:

Campbell KP. Contraceptive use evidence-statement: counseling and preventive intervention. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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Why This Chapter is Important for Employers: An Overview

- In a given year, 18.8 million American adults (9.5% of the adult population) will suffer from a depressive illness.[1]
- Routine, systematic screening can successfully identify patients who are depressed, allowing them to access care earlier in the course of their illnesses.[2]
- Depression is a major cause of disability, absenteeism, and productivity loss among working-age adults.[1] Depression is estimated to cause 200 million lost workdays each year at a cost to employers of $17 to $44 billion.[3]
- Research suggests that 80% of patients with depression will improve with treatment.[4]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends screening all adults for depression in clinical practices that have systems in place to assure accurate diagnosis, effective treatment, and adequate follow-up.[5] Although not explicitly stated in the USPSTF recommendation statement, screening adults for depression should be part of an overall system to improve depression recognition and outcomes. Important system aspects include feedback, treatment advice, education, case management, access to mental health care, telephone follow-up, and an institutional commitment to quality improvement.[5]

Evidence Rating: **B (Recommended/ At Least Fair Evidence)**

The USPSTF found good evidence that screening 1) improves the accurate identification of depressed patients in primary care settings and 2) that treating depressed adults identified in primary care settings reduces clinical morbidity. The USPSTF concluded the benefits of screening are likely to outweigh any potential harms.[5]

Other Recommended Guidance

The American Academy of Family Physicians (AAFP) concurs with the U.S. Preventive Services Task Force recommendation.[6]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- National Institutes of Mental Health (NIMH)
- U.S. Preventive Services Task Force (USPSTF)
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Depression is a serious condition that affects 5% to 9% of adult patients presenting at primary care in the United States.[2] In a given year, 18.8 million American adults (9.5% of the adult population) will suffer from a depressive

illness. Approximately 5% to 12% of men and 10% to 25% of women will experience a major depressive episode at some point during their lives.[1]

Depression is a major cause of morbidity in the United States, and it is projected to become the leading cause of disability worldwide by 2020.[3]

Condition/Disease Risk Factors

Risk factors for depression include a family history of depression, female sex, unemployment, and chronic disease.[2]

Value of Prevention

Economic Burden of Condition/Disease

In 2000, over $83.1 billion dollars were spent on depression in the United States; $26.1 billion dollars (31%) for direct medical costs, $5.4 billion dollars (7%) for suicide-related mortality costs, and $51.5 billion dollars (62%) for workplace costs.[7]

Workplace Burden of Condition/Disease

Depression is a major cause of disability, absenteeism, and productivity loss among working-age adults. In a 3-month period, patients with depression miss an average of 4.8 workdays and suffer 11.5 days of reduced productivity.[1] In total, depression is estimated to cause 200 million lost workdays each year at a cost to employers of $17 to $44 billion.[3]

In addition to its direct medical and workplace costs, depression also increases healthcare costs and lost productivity indirectly by contributing to the severity of other costly conditions such as heart disease, diabetes, and stroke.

Economic Benefit of Preventive Intervention

The economic benefits of screening mainly result from averting the lost productivity costs associated with the disease.[8] Some studies suggest that treatment of depression may lead to decreased general medical costs, however, conclusive evidence is not available.

Estimated Cost of Preventive Intervention

The cost of screening for depression depends on the location, provider type, and the screening instrument used. In 2004, the private-sector cost of depression screening averaged $23; approximately 95% of paid claims fell within the range of $0 to $81.[9]

Estimated Cost of Treatment

Treatment of depression in the primary care setting (based on one initial physician visit and one follow-up visit within 3 months) costs an average of $99.68 (in year 2001 dollars). The cost of medication to treat depression varies substantially based on the type of medication chosen. Average wholesale price (AWP) figures are noted below for a 1-month supply of a few varieties of the FDA-approved selective-serotonin-reuptake-inhibitors (SSRIs) commonly used to treat depression.[10]

Drug Name	2006 Average Wholesale Price (AWP)	
	Generic	Brand
fluoxetine/Prozac®	$74.35 (20 mg)	$138.91 to $277.82
paroxetine/Paxil®	$92.50 to $105.02	$72.90 to $81.00
sertraline/Zoloft®	$7.17 (50 mg)	$86.89 (25mg–100mg)

The total cost of treatment should consider treatment-related cost-offsets due to the reduction of lost productivity, absenteeism, and other factors. For example, the indirect cost associated with an employee who is treated for depression (extrapolated from lost work days/time for medical appointments, etc) over a 3 month period averages $400, whereas the indirect cost associated with a depressed employee who does not receive treatment (extrapolated from sick days, etc) averages $840 over a 3 month period.[1] If benefits of treatment on work impairment are taken into account, the estimated cost-savings would exceed the average treatment cost of depression.[8]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

The cost-effectiveness of screening is sensitive to screening costs and achievable depression remission rates. Based on an economic modeling approach, one study found that one-time depression screening had a relatively low cost per quality-adjusted life year gained compared to no screening. However, neither annual nor periodic screening for depression were found to be cost-effective in comparison to preventive service benchmarks.[1]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening for depression identifies patients suffering from depression, allowing them to access care earlier in the course of their illness. Research suggests that 80% of patients with depression will improve with treatment.[4] The USPSTF found evidence that patient outcomes improve significantly when depression recognition and management are integrated.[2] Yet despite the value of screening, it is infrequently conducted, and hence, primary care physicians fail to identify 30% to 50% of patients suffering from depression.[5]

Benefits and Risks of Intervention

Risks of screening include false-positive results, which can lead to additional testing, incurring further costs and inconvenience. Patients may also suffer some negative effects after being labeled as depressed. However, the USPSTF felt that these potential risks were likely outweighed by the benefits of screening.[11]

Initiation, Cessation, and Interval of Screening

There is insufficient evidence to determine the optimal ages at which to begin and cease depression screening. Thus, experts agree that depression screening should be initiated and stopped when deemed appropriate by the clinician.

Evidence is also insufficient to determine the optimal interval of screening. Thus, clinicians are encouraged to use their judgment in deciding how frequently to screen patients for depression. The USPSTF notes that recurrent screening is most likely to benefit patients with a history of depression, unexplained somatic symptoms, chronic pain or other comorbid psychological conditions such as anxiety, panic attack, or substance abuse.[11]

The USPSTF found insufficient evidence to recommend for or against depression screening among children or adolescents in primary care settings. However, the USPSTF encourages physicians to remain alert for signs of depression in these populations and to treat or refer to specialty care as appropriate.[2]

While the USPSTF did not recommend screening adolescents for depression, new evidence shows that the benefits of screening in the adolescent population may outweigh the risks involved. A recent randomized controlled trial of high-school students showed that screening adolescents for depression with a standardized screening instrument did not increase suicidal ideation (thoughts or fantasies about committing suicide) or increase feelings of discomfort. Surprisingly, depressed students reported less distress at being asked questions about suicidal ideation than did non-depressed students. Identifying adolescents with suicidal ideation is an important part of youth suicide prevention.[12] Providers need to be aware that the signs and symptoms of depression in adolescents are different from those in adult populations.

Intervention Process

Several depression screening tools, called instruments, are currently available for use in the primary care setting. These instruments are composed of standardized questions that assess the number and severity of a patient's depression symptoms. Clinicians can then interpret the results to make a diagnosis of depression and to develop a treatment plan. Evidence is mixed as to what instrument or method is most effective in accurately identifying patients with depression, but most instruments seem to have an adequate level of sensitivity and specificity. Commonly used instruments, such as the Patient Health Questionnaire-9, are simple to administer and take less than 5 to 10 minutes for a patient or provider to complete.[5]

The USPTF recommends that physicians choose their preferred method of screening based on their patient population and practice setting.[2] Clinicians who do not use a standardized instrument to screen for depression may want to ask their patients the two questions below to assess their mental health status. These may be as effective as using longer screening tools.[2]

1. Over the past two weeks, have you ever felt down, depressed, or hopeless?
2. Over the past two weeks, have you felt little interest or pleasure in doing things?

Positive responses to these questions or positive responses to questions on a short standardized screening test should trigger a full diagnostic interview by the clinician so that they may identify the specific depressive symptoms experienced by the patient and make an accurate diagnosis.[2] The USPSTF recommends that clinicians use standard diagnostic criteria, such as those featured in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV).[11]

The process used in screening patients for depression is important. Screening adults for depression in clinical practices that have well functioning systems in place to assure accurate diagnosis, effective treatment, and careful follow-up, are more likely to produce benefits.[2] The USPSTF found several other clinically relevant factors pertinent to successful depression screening processes. For information on these factors please refer the USPSTF website (www.ahrq.gov/clinic/uspstf/uspsdepr.htm).

Implementing a systematic depression screening program in a clinical practice will increase the number of patients diagnosed with depression and the number

of patients treated for depression. It is important to remember that not all of the patients who screen positive for depression will be diagnosed with depression.

Considering the prevalence of depression in the primary care setting, it can be expected that 25% to 40% of patients who screen positive for depression will actually have depression.[2]

- Many screened patients will have screened false-positive, meaning that although they screened positive for depression, they are not actually depressed. These patients do not require treatment.
- Some patients who screen positive for depression may suffer from depressive illnesses other than major depression, such as adjustment reactions with depression or grief reactions, and these patients may benefit from monitoring.
- Some of the patients who screen positive for depression may have, in addition to or in place of depression, another psychological disorder such as anxiety disorder, panic attack, post-traumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD), a substance abuse disorder, or another type of mental health condition. Physicians should refer these patients to a mental health specialist.

Because of the complexities involved in screening for depression, the USPSTF recommends that clinicians follow-up all positive screens with further diagnostic work, including a full diagnostic interview such as that featured in the DSM-IV.[11]

Treatment Information

Health benefits should include provisions for diagnostic and treatment services. Most patients with depression present and are treated in the primary care setting. While depression is one of the most common disorders seen by primary care providers, research shows that the standard of care delivered is poor. In the primary care setting, 35% to 70% of patients with depression do not receive an appropriate diagnosis or adequate treatment.[1]

Patients who screen positive for depression and are diagnosed with depression as confirmed by the DSM-IV diagnostic interview should 1) begin treatment in the primary care or specialty mental healthcare setting or 2) be referred for treatment to a mental health professional. A primary care treatment plan can include pharmacological therapy (tricyclic anti depressants and selective-serotonin-reuptake-inhibitors [SSRIs], are proven to be effective in the treatment of major depression) psychotherapy, or a combination of the two.[11]

Current research points to a number of successful identification and disease-management techniques for addressing depression in primary care. Experts note that routine, systematic screening can successfully identify patients who are depressed. Patients who are identified in primary care settings as suffering from depression or other mental health conditions, can often benefit from referral to a mental health specialist. Depressed patients may also benefit from collaborative care; an approach to care that pairs a mental health specialist with a primary care provider to provide evidence-based treatment services.[12]

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found good evidence to support screening all adults for depression in clinical practices that have systems in place (such as a referral system, on-site mental health provider, or other mental health resources) to assure accurate diagnosis, effective treatment, and adequate follow-up.[5]

Authored by:

Campbell KP, Lollar D. Depression evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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EVIDENCE-STATEMENT:
DIABETES (Screening)

Why This Chapter is Important for Employers: An Overview

- Diabetes affects over 21 million Americans, 7% of the United States population.[1] In addition, 41 million adults aged 40 to 74 have prediabetes, a condition that increases the risk of diabetes, heart disease, and stroke.[1-2]
- Alarmingly, the prevalence of type 2 diabetes and gestational diabetes has increased 61% in United States since 1990.[3]
- Diabetes is a major cause of premature morbidity, disability, and death. In addition to being a direct cause of death, uncontrolled diabetes can cause heart disease, stroke, blindness, kidney failure, pregnancy complications, and amputations of toes, feet, or legs.
- The total annual economic burden of diabetes in the United States exceeds $132 billion dollars.[4]
- Diabetes is among the top 10 most costly physical health conditions for employers in various industries in terms of direct medical expenditures, absenteeism, short-term disability, and presentism.[5]
- In 2002, the average annual healthcare cost for a person with diabetes was $13,243 as opposed to $2,560 for a person without diabetes.[4]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends screening for type 2 diabetes in adults with hypertension (high blood pressure) or hyperlipidemia (high cholesterol).[6]

***Evidence Rating:* B (Recommended/At Least Fair Evidence)**

The USPSTF found good evidence that, in adults who have hypertension and clinically detected diabetes, lowering blood pressure below conventional target blood pressure values reduces the incidence of cardiovascular events and cardiovascular mortality; this evidence is considered fair when extrapolated to cases of diabetes detected by screening. Among patients with hyperlipidemia, there is good evidence that detecting diabetes substantially improves estimates of individual risk for coronary heart disease, which is an integral part of decisions about lipid-lowering therapy.[6]

Note: the USPSTF found insufficient evidence to support a recommendation for or against universal screening of adults for diabetes.

Other Recommended Guidance American Diabetes Association (ADA)

The American Diabetes Association (ADA) recommends that adults at normal risk for diabetes be screened at 3-year intervals for prediabetes and diabetes beginning at age 45. Adults at high risk (based on a family history of the disease, overweight or obesity, or other factors; see condition/disease risk factor section below) should be screened at a younger age or screened more frequently (1 to 2 year intervals).[7]

Evidence Rating:

Expert Opinion

American Association of Clinical Endocrinologists (AACE)

The American Association of Clinical Endocrinologists (AACE) recommends targeted screening beginning at age 30 for people at high risk for diabetes.[8]

Evidence Rating:

Expert Opinion

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Agency for Healthcare Research and Quality (AHRQ)
- American Association of Clinical Endocrinologists (AACE)
- American Diabetes Association (ADA)
- Centers for Disease Control and Prevention (CDC)
- Center for Medicare & Medicaid Services (CMS)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Diabetes is divided into 3 types: type 1 diabetes (previously referred to as "juvenile" diabetes), type 2 diabetes (previously referred to as "adult-onset" diabetes), and gestational diabetes (a form of diabetes that occurs only during pregnancy).

In the past, type 1 diabetes typically affected young people who had few symptoms or signs of the disease before experiencing an abrupt onset, type 2 diabetes primarily affected adults, and gestational diabetes affected pregnant women and indicated a higher-than-average risk for type 2 diabetes. While the epidemiological profiles of type 1 diabetes and gestational diabetes have remained constant, the profile of type 2 diabetes has changed dramatically in recent years. Type 2 diabetes used to be an adult-onset disorder; now type 2 diabetes affects children, adolescents, and young adults as well.

Since the onset of type 1 diabetes is usually relatively sudden and associated with symptoms that require care, screening for type 1 diabetes has not been considered useful.

Type 2 diabetes, on the other hand, has a longer asymptomatic phase. Early recognition and intervention can forestall its onset and may even prevent its emergence. For reasons not completely understood, but seemingly related (at least in part) to obesity, changing dietary habits, and levels of physical activity, the incidence of type 2 diabetes is increasing. It is also being identified at younger and younger ages.

Type 2 diabetes (hereafter referred to as *diabetes*) affects over 21 million Americans (7% of the United States population) and more than 6 million Americans with diabetes are undiagnosed. In addition, 41 million adults age 40 to 74 have

prediabetes, a condition that increases the risk of diabetes, heart disease, and stroke.[1-2] People with prediabetes have a high blood sugar level but not high enough to be classified as diabetes. Many people with prediabetes will develop clinical diabetes. Alarmingly, the prevalence of type 2 diabetes (including gestational diabetes) in the United States has increased 61% since 1990.[3]

Diabetes is a major cause of premature morbidity and disability, and uncontrolled diabetes can cause death. Diabetes is the sixth leading cause of death in the United States — each year 200,000 Americans die of complications resulting from the disease.[1]

Death rates are about 2 to 4 times higher for adults with diabetes than for those without the disease.[2] Heart disease and stroke are leading causes of diabetes-related deaths. Uncontrolled diabetes can also cause blindness, neurologic problems, kidney failure, pregnancy complications, and amputations of toes, feet, or legs. Persons with diabetes are at higher risk of acquiring influenza and pneumonia, which are additional causes of disproportionate death among diabetics. Each year, 12,000 to 24,000 people become blind, 42,813 have kidney failure, and 82,000 have leg, foot, or toe amputations.[2]

Condition/Disease Risk Factors

Diabetes disproportionately affects women, older adults, and certain racial and ethnic groups, such as African-Americans, Hispanics, and American Indians/Alaska Natives. One in five adults older than 65 has diabetes.

The risk of developing type 2 diabetes increases with[8]:

- Cardiovascular disease, high cholesterol levels, or both
- Hypertension
- High levels of triglycerides
- Low concentrations of high-density lipoprotein
- Family history of diabetes
- Impaired glucose tolerance or impaired fasting glucose
- Hispanic, African-American, Asian American, Native American, or Pacific Islander race or ethnicity
- BMI over 25kg/m2 and/or central obesity
- History of gestational diabetes
- Delivery of a baby weighing more than 9 pounds (4 kg)
- Polycystic ovary syndrome
- Sedentary lifestyle

Value of Prevention*

Economic Burden of Condition/Disease

The estimated direct and indirect costs for diabetes care in 2002 totaled $132 billion[4], 11% of the national health care expenditures for 2002. Diabetes is among the costliest physical health conditions in terms of total medical costs[9-11] and productivity losses.[4,9,12] In 2002, the average annual healthcare cost for a person with diabetes was $13,243 as opposed to $2,560 for a person without diabetes.[4]

Workplace Burden of Condition/Disease

Diabetes is among the top 10 most costly physical health conditions for employers in various industries in terms of direct medical expenditures, absenteeism, short-term disability, and presentism.[5] If pharmaceutical expenditures, costs related to absenteeism, and claims for short-term disability are combined with medical expenditures, diabetes ranks as the third most costly physical health condition for employers.[13] In addition, diabetes-related prescriptions rank in the top 2 treatment expenses for employers based on 1997-1999 claims data for inpatient and outpatient costs.[13]

Employees with diabetes who reduce their glycemic levels (the way your body's sugar level responds to certain foods) demonstrate short-term (4 to 5 months) health outcomes (quality of life improvements), work-related outcomes (reduced absenteeism and increased productivity), and cost-savings through reduced hospital visits.[14] Sustaining reduced glycemic levels for 1 year reduces primary and specialty care visits and is associated with (longer-term) cost-savings within 1 to 2 years of improvement.[15] Therefore, reduced glycemic levels in persons with diabetes has short- and long-term direct and indirect economic benefits.

More than 30% of employer costs associated with employees who have diabetes are attributable to medically related absences or disability.[16] Diabetes may affect the number of disability claims and the length of disability claims.[16-18] When stratified by age, total medical and productivity costs for beneficiaries with diabetes range from $2,589 for those younger than 18 years to $8,568 for those aged 56 through 64 years (in year 1998 dollars).[16]

People with diabetes lose income as a result of missing work and disability. The average annual earnings loss (in year 1994 dollars) for a person with diabetes is estimated at $4,306 for men and $1,865 for women.[12] In 1998 dollars, medically related work loss cost employees with diabetes an estimated $1,121 for those aged 18 through 35 years, $1,448 for those aged 36 through 45 years, $1,467 for those aged 46 through 55 years, and $1,095 for those aged 56 through 64 years.[16]

Economic Benefit of Preventive Intervention

The Diabetes Prevention Program (DPP) showed that lifestyle interventions delayed the development of diabetes by 11 years and reduced the absolute incidence by 20%.[19] Metformin, an oral medication, delayed the development of diabetes by 3 years and reduced the absolute incidence by 8% (compared to a placebo). The cost was $1,100 per quality-adjusted life year (QALY) for the lifestyle intervention and $31,300 for the metformin intervention. The lifestyle intervention included a weight reduction goal of at least 7% of initial body weight through a healthy, low-fat, lower calorie diet; and physical activity of moderate intensity (brisk walking) for at least 150 minutes/week. A 16 lesson curriculum was developed and group and individual sessions were designed to reinforce changes.[19]

Estimated Cost of Preventive Intervention

The cost of screening for type 2 diabetes varies by location and provider. In 2004, the private-sector cost of diabetes screening averaged $15 (range $0 to $40).[20] However, this is a rough average: one or two follow-up visits may be necessary (depending on test results), and if so, would increase the cost of each complete screening cycle.

Estimated Cost of Treatment

From the health system perspective, the cost of a metformin intervention (compared to placebo) is $2,191/participant over 3 years; the cost of a lifestyle intervention (compared to placebo) is $2,269/participant over 3 years.[19] It is significant to note that although the lifestyle intervention costs about 37% more than the metformin in year 1, the lifestyle intervention costs about 12% and 7% *less* than metformin intervention in years 2 and 3. Therefore, the cost of lifestyle intervention relative to metformin intervention would decrease with follow-up beyond 3 years.[19]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

It is cost-effective to screen people with hypertension in all age groups for type 2 diabetes. It is even more cost-effective to screen people with hypertension aged 55 to 75 years.[21] In year 1997 dollars, the cost per quality-adjusted life year (QALY) for targeted screening (compared to no screening) at age 55 was estimated to be $34,375. In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, diabetes screening is cost-effective.[22] In general, opportunistic screening (i.e., screening patients during routine healthcare encounters) is more cost-effective than universal or population screening, and targeted screening (i.e., screening people with particular health risk factors, such as hypertension) is the most cost-effective.[21]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening is meant to identify individuals with diabetes and individuals at high risk of diabetes. Intervention may delay the onset of diabetes and its complications among individuals at high-risk.[1] Early detection by screening allows clinicians to suggest a variety of interventions during the preclinical period, including tight glycemic control; intensive use of antihypertensive agents; aggressive use of lipid treatment and aspirin; foot care programs; and improvements in diet, increases in physical activity, and cessation of tobacco use. The efficacy of early interventions is affected by numerous variables, such as the relationship between the intervention and the timing of the specific complication: some complications typically occur early in the disease process (e.g., cardiovascular disease) and some occur late in the process (e.g., blindness).[23]

Benefits and Risks of Intervention

The USPSTF found that people at risk for cardiovascular disease benefit most from diabetes screening. Screening people with hypertension or hyperlipidemia for type 2 diabetes allows the disease to be diagnosed and treated before it causes certain complications. Evidence shows that people with hypertension and type 2 diabetes can reduce their risk of cardiovascular disease by reducing their blood pressure to a level below that recommended for people with hypertension but without diabetes. People with hyperlipidemia and type 2 diabetes can lower their risk of cardiovascular disease by beginning lipid-lowering therapy in combination with diabetes treatment.[24]

Few studies have examined the harmful effects of screening asymptomatic people for diabetes. As with all screening tests, there is a risk of false-positive results. False-positive results have the potential to cause harmful effects including a negative change in self-perception, undue stress and anxiety, risk of loss of insurability (life insurance or health insurance), and the risk of beginning unneeded treatment for diabetes.[23]

Initiation, Cessation, and Interval of Screening

USPSTF

The USPSTF found insufficient evidence in order to determine whether adults *without* hypertension or hyperlipidemia should be screened for diabetes. Therefore, when to screen individual patients is a matter of clinical judgment and patient preference.

Patients at increased risk for cardiovascular disease may benefit the most from screening for type 2 diabetes, since effective management of cardiovascular risk factors leads to reductions in major adverse cardiovascular events. For adult patients with diagnosed hypertension or hyperlipidemia, diabetes screening should be part of an integrated approach to reduce cardiovascular risk.[24]

American Diabetes Association

While acknowledging the insufficiency of evidence regarding the benefits of screening, the ADA recommends (on the basis of expert opinion) that adults at normal risk for diabetes should be screened at 3-year intervals for prediabetes and diabetes beginning at age 45. Adults at high risk (based on a family history of the disease, overweight or obesity, or other factors) should be screened at a younger age or screened more frequently (1 to 2 year intervals).[7]

There is no universally accepted interval for type 2 diabetes screening of healthy adults or adults with hypertension or hyperlipidemia. The ADA recommends that adults at normal risk for diabetes undergo screening every 3 years and adults at high-risk of diabetes undergo screening every 1 to 2 years.[7]

CMS Coverage

As of September 2006, the Centers for Medicare and Medicaid Services (CMS) covers screening tests for diabetes. This is significant because CMS's decisions frequently influence other managed care policies. Some employers also provide healthcare insurance to retirees eligible for Medicare. The CMS policy covers the following[25]:

- Two screening tests per year for individuals with diagnosed prediabetes (not less than 6 months apart).
- For those who are not diabetic or have not previously been diagnosed as pre-diabetic, Medicare covers one diabetes screening test within a 12-month period (or that at least 11 months have passed following the month in which the last Medicare covered diabetes screening test was performed).

Covered tests are the fasting blood glucose (FBG) test and the Oral Glucose Tolerance Test (OGTT).

Individuals who have any one of the following risk factors for diabetes are eligible for the CMS benefit:

- Hypertension (high blood pressure)
- Dyslipidemia (high cholesterol)

- Obesity (a body mass index equal to or greater than 30 kg/m^2)
- Elevated impaired fasting glucose intolerance

Also eligible for the CMS benefit are individuals who have at least two of the following characteristics:

- Overweight (a body mass index >25 but <30 kg/m^2
- A family history of diabetes
- Age 65 or older
- A history of gestational diabetes
- Delivery of a baby weighing more than 9 lbs

Intervention Process

Screening requires a blood glucose test. Several tests are appropriate and should be used at the discretion of the physician, they include the fasting plasma glucose test (FPG), the 2-hour post-load plasma glucose test, and the oral glucose tolerance test (OGTT).

Treatment Information

Health benefits should include provisions for diagnostic, follow-up, and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found at least fair evidence that the benefits of screening adults with hypertension or hyperlipidemia for diabetes outweigh the associated risks and costs.

Recommended Guidance:

The American Diabetes Association (ADA)
Strength of Evidence: Expert Opinion

- The ADA recommends that adults at normal risk for diabetes be screened at 3-year intervals for prediabetes and diabetes beginning at age 45. Adults at high risk (based on a family history of the disease, overweight or obesity, or other factors) should be screened at a younger age or screened more frequently (1-2 year intervals).[7]

The American Association of Clinical Endocrinologists (AACE)
Strength of Evidence: Expert Opinion

- The AACE recommends targeted screening, beginning at age 30, for people at high risk for diabetes.[8]

Authored by:

Cooksey C, Allweiss P, Campbell KP. Diabetes evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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Notes:

* The preceding are direct and indirect economic data on diabetes for employers to consider in the design of employee healthcare benefits, including conducting annual negotiations on contracts for healthcare. Some studies cited compared employers' diabetes-related costs with costs for other conditions. Because no standard method can account for the nuances associated with each disease, differing study methods, designs, and data sets create challenges for 1) researchers who compare the cost of different disease conditions and 2) executives and senior managers who may use the cost data to inform their decisions for covering specific preventive services. The study researchers acknowledged the limitations and scientifically accounted for these limitations as well as possible. In addition, the lack of standard metrics for indirect cost, such as disability and productivity, create challenges. Yet, it is for this reason that some researchers (Goetzel, et. al.) conducted their studies—to advance 1) the scientific knowledge and collection methods related to such complex data and 2) the usefulness of such data to the real world (i.e., its usefulness to employers who must make decisions related to employee health and wellness).

EVIDENCE-STATEMENT:
HEALTHY DIET (Counseling)

Why This Chapter is Important for Employers: An Overview

- Four of the 10 leading causes of death in the United States — coronary heart disease, some types of cancer, stroke, and type 2 diabetes — are associated with an unhealthy diet.[1] More than half of all deaths in 1994 were attributable to these four diseases.
- Diet also contributes significantly to the development of high cholesterol, high blood pressure, and overweight. These health conditions are associated with considerable medical expenses, disability, and premature deaths.[2]
- The total cost attributable to diet-associated coronary heart disease, cancer, stroke, and diabetes is estimated to be $70.9 billion (in year 1995 dollars).[2-3] Direct medical costs account for nearly half (47%) of this total; premature deaths account for 39% and lost productivity accounts for 13% of the remainder.[2-3] Diet-related osteoporosis and hip fractures cost an additional $5.1 to $10.6 billion each year (in year 1995 dollars).[4]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force recommends intensive behavioral dietary counseling for adults with hyperlipidemia (lipid disorders) and other known risk factors for cardiovascular and diet-related chronic diseases. Intensive counseling can be delivered by primary care clinicians or specialists such as nutritionists and dieticians.[3]

Evidence Rating: **B (Recommended/ At Least Fair Evidence)**

The USPSTF found good evidence that medium- to high-intensity counseling interventions can produce medium to large changes in average daily intake of the core components of a healthy diet (including reduced consumption of saturated fat and increased consumption of fiber, fruits, and vegetables) in adult patients at increased risk of diet-related chronic diseases.[3]

Controlled clinical trials have assessed intensive counseling interventions for at-risk adult patients. The trials involved combined nutrition education with behavioral dietary counseling provided by a nutritionist, dietician, or specially trained primary care clinician. The USPSTF concluded that such counseling is likely to improve important health outcomes and that its benefits outweigh its potential harms. No controlled trials of intensive counseling in children or adolescents were identified that measure effective dietary counseling in the primary care setting.[3]

Other Recommended Guidance

Dietary guidelines for the general population have been issued by the U.S. Department of Agriculture and the Department of Health and Human Services[5] and specific dietary objectives for the nation are outlined in *Healthy People 2010*.[6] Guidelines from the American Heart Association[7] address diets that lower the risks for heart disease, and the American Cancer Association[8] has issued guidelines on diet and cancer. All of these agencies and organizations recommend a diet that includes a variety of fruits, vegetables, and grains; is low in saturated fat and cholesterol and moderate in total fat; and balances calories with physical activity to maintain a healthy weight.

Several groups have recommended nutritional counseling or dietary advice for

patients at average risk of chronic disease, including the American College of Preventive Medicine (ACPM), American Academy of Family Physicians (AAFP), American Academy of Pediatrics (AAP), and American College of Obstetricians and Gynecologists (ACOG).[9-12] These recommendations are based primarily on the benefits of a healthy diet rather than on evaluations of counseling efficacy.[13]

Recommendations on nutritional counseling for patients at risk of diet-related chronic diseases (e.g., persons with hypertension or hyperlipidemia) have been issued by the American Dietetic Association and two panels sponsored by the National Heart, Lung and Blood Institute (NHLBI). The American Dietetic Association recommends that primary care providers screen all patients for nutrition-related illnesses and, for patients with positive screening results, prescribe diets, provide preliminary counseling on specific nutritional needs, follow up with the patients, and refer them to appropriate dietetic professionals when necessary.[14] Similarly, the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure recommends that dietary assessments be included in routine medical histories and that patients at risk of diet-related chronic diseases should be counseled about lifestyle modifications to prevent and treat high blood pressure; the lifestyle changes emphasize weight loss for those overweight, limiting alcohol intake, reducing sodium consumption, and reducing intake of saturated fat and cholesterol.[15] The National Cholesterol Education Program (NCEP) recommends that persons with elevated levels of low-density lipoprotein limit their intake of fats, particularly saturated fats and cholesterol, and increase their intake of dietary fiber.[16]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Preventive Medicine (ACPM)
- American Dietetic Association
- American Heart Association (AHA)
- *Healthy People 2010*
- Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
- National Cancer Institute (NCI)
- National Cholesterol Education Program (NCEP)
- National Institutes of Health (NIH)
- National Heart, Lung, and Blood Institute (NHLBI)
- Peer-reviewed Research
- U.S. Department of Agriculture (USDA)
- U.S. Department of Health and Human Services (USDHHS)
- U.S. Preventive Services Task Force (USPSTF)

Epidemiology of Condition/Disease

The background and supporting information in this document is based on a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of the opinions of other organizations cited in the text.

Condition/Disease-Specific Information

Epidemiology of Condition/Disease

The relationship between dietary patterns and health outcomes has been examined in a wide range of observational studies and randomized trials with patients at risk of diet-related chronic disease. The majority of these studies have shown that people who consume diets that are low in fat, saturated fat, trans-fatty acids, and cholesterol and high in fruits, vegetables, and whole-grain products containing fiber have lower rates of morbidity and mortality from coronary heart disease and, possibly, several forms of cancer than those who consume unhealthy diets.[17] In fact, 4 of the 10 leading causes of death — coronary heart disease, some types of cancer, stroke, and type 2 diabetes — are associated with unhealthy diets.[1]

Lipid Disorders

Nearly 107 million American adults (50.7% of the adult population) have a total blood cholesterol value of 200 mg/dl or above, and 37.7 million of these adults (18.3%) have a total blood cholesterol level of 240 mg/dl or above.[18] A reading of less than 200 mg/dl is considered desirable and a reading of 240 mg/dl or more is considered high.

Obesity

Obesity is epidemic in the United States. Between 1976 to 1980 and 1999 to 2002, the proportion of obese adults doubled, the proportion of overweight children (aged 6 to 11) doubled, and the proportion of overweight adolescents (aged 12 to 19) tripled.[19] Approximately half to two-thirds of obese adults have diabetes, high blood pressure, coronary artery disease, high cholesterol, or a combination of these conditions.[20]

Both lipid disorders and obesity are risk factors for cardiovascular diseases, including coronary heart disease and coronary artery disease.

Cardiovascular Disease

Coronary heart disease, a cardiovascular disease, is caused by arteriosclerosis (a thickening or hardening of the arteries) and can lead to angina pectoris (heart pain), heart attack, or both. An estimated 1.5 million adults have a heart attack each year in the United States. The American Heart Association estimates that 13.9 million adults have a history of coronary heart disease and about every minute, someone dies from a heart attack.[18] Arteriosclerosis is particularly sensitive to lipid levels.

Alcohol and caffeine use and insufficient calcium or vitamin D intake are also risk factors for osteoporosis. Please refer to the *Osteoporosis Screening and Treatment Evidence-Statement* for additional information.

Cancer

The American Cancer Society estimates that almost 1.4 million new cases of cancer will develop in 2006.[8] About one-third of the 564,830 deaths expected to result from cancer in 2006 are related to diet, physical inactivity, and overweight or obesity and are thus preventable.[8]

To reduce the risk of morbidity and mortality from coronary heart disease and to maintain a healthy weight, it is necessary to eat a healthy diet and to balance calories consumed with physical activity.[3] A healthy eating plan is one that emphasizes fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products; includes lean meats, poultry, fish, beans, eggs, and nuts; is low in saturated fats, *trans*-fats, cholesterol, salt (sodium), and added sugars; and balances caloric intake with caloric needs. The Federal publication, *Nutrition and Your Health: Dietary Guidelines for Americans* provides a good source of dietary advice[21]:

- Consume a variety of nutrient-dense foods and beverages within and among the basic food groups while choosing foods that limit the intake of saturated and *trans*-fats, cholesterol, added sugars, salt, and alcohol.
- Meet recommended intake of calories within energy needs by adopting a balanced eating pattern, such as the U.S. Department of Agriculture's Food Guide or the Dietary Approaches to Stop Hypertension (DASH) eating plan.
- Maintain a diet with less than 10% of calories from saturated fat, no more than 30% of calories from total fat, and limited consumption of trans-fatty acids.

Condition/Disease Risk Factors

Consuming a healthy diet is associated with a reduced risk of chronic disease morbidity and mortality.

Value of Prevention

Economic Burden of Condition/Disease

Unhealthy diets contribute to several diseases that impose a heavy economic burden on employers and employees.

The total cost attributable to diet-associated coronary heart disease, cancer, stroke, and diabetes is estimated to be $70.9 billion (in year 1995 dollars).[2-3] Direct medical costs account for nearly half (47%) of this total; premature deaths account for 39% and lost productivity accounts for 13% of the remainder.[2-3] Diet-related osteoporosis and hip fractures cost an additional $5.1 to $10.6 billion each year (in year 1995 dollars).[4]

Workplace Burden of Condition/Disease

Productivity losses due to unhealthy diet-associated morbidity from coronary heart disease, cancer, stroke, and diabetes cost $9.3 billion (in 1995 dollars) per year.[2-3]

The cost to employers of obesity-related health problems in 1994 was $13 billion per year, including $8 billion in medical claims, $2.4 billion in paid sick leave, $1.8 billion in life insurance, and almost $1 billion in disability insurance.[22] In addition, an estimated 39 million workdays are lost to obesity-related illnesses each year.[23]

Economic Benefit of Preventive Intervention

A randomized controlled trial of a low-cost healthy nutrition education program in the California Public Employee's Retirement System found a cost savings of 20% over 12 months.[24]

The Massachusetts Dietetic Association found that diet modification and counseling for hypercholesterolemia by a registered dietitian saved an estimated $1,300 per patient, per year.[25]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of preventive medicine counseling by a physician averaged $39 per session; approximately 95% of all paid claims fell within the rage of $0 to $129 per session.[26] Nutritional counseling by a dietician averaged $61 per session and approximately 95% of all paid claims fell within the range of $0 to $150 per session.[26]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Nutrition education from the expanded Food and Nutrition Education Program, administered by the U.S. Department of Agriculture, helps limited-resource populations acquire the knowledge, skills, and attitudes, and make the behavior changes necessary for nutritionally sound diets. The benefit-to-cost ratio of $10.64/$1.00 for a Food and Nutrition Education Program in Virginia[27] and $10.75/$1.00 in Iowa[28] shows that nutrition counseling can produce a significant return-on-investment (ROI).

Another study found that an intensive nutrition intervention in patients with type 2 diabetes had a cost-effectiveness ratio of $4.20, while the cost-effectiveness ratio of usual nutrition care was $5.32.[29-30]

Some evidence indicates that lifestyle interventions may be more cost-effective than drug treatments for some diet-related chronic illnesses.[31]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Behavioral counseling can help persons at high risk of cardiovascular disease and other diet-related chronic diseases improve their diets and thereby reduce their risk of the poor outcomes and complications associated with obesity, lipid disorders, and coronary heart disease.[3]

Benefits and Risks of Intervention

Medium- to high-intensity behavioral interventions appear to produce consistent, sustained, and clinically important changes in dietary intake of total fat, saturated fat, fruits, vegetables, and fiber.[3] It is important to note that the studies supporting these benefits were conducted in patients with known risk factors for diet-related chronic disease or in special clinics with select patients and specially trained providers. The most effective interventions generally combined education, behavior-oriented counseling, patient reinforcement, and follow-up. More intensive interventions and those of longer duration were associated with greater benefits and more sustained changes in diet.[3] The largest effects of dietary counseling in asymptomatic adults with hyperlipidemia or hypertension and those at increased risk of diet-related chronic disease have been observed with more intensive interventions (multiple sessions lasting 30 minutes or longer).[3]

Two other approaches appear promising for adult patients in primary care settings[3]:

1. Medium-intensity face-to-face dietary counseling (two to three group or individual sessions) delivered by a dietitian or nutritionist or by a specially trained primary care physician or nurse practitioner.
2. Lower intensity interventions that involve 5 minutes or less of counseling by a primary care provider and are supplemented by patient self-help materials, telephone counseling, or other interactive health communications.

However, more research is needed to assess the long-term efficacy of these treatments and to balance the benefits and harms.[3]

Possible harms of dietary counseling have not been well-defined or measured. Some researchers have suggested that a focus on reducing total fat intake but not reducing caloric intake might lead to an increased intake of carbohydrates (in the form of reduced-fat or low-fat food products), which could result in weight gain, elevated triglyceride levels, or insulin resistance.[3]

Little is known about effective dietary counseling for children or adolescents in the primary care setting. Most studies of nutritional interventions in these populations have focused on non-clinical settings, such as schools, or have used physiologic outcomes, such as cholesterol level or weight reduction, rather than indicators of a healthy diet, such as intakes of total and saturated fats.[32-33]

Initiation, Cessation, and Interval of Counseling

The USPSTF was not able to determine the ideal frequency of counseling. Other research has indicated that intensive counseling (30 to 45 minutes in duration) can reasonably be conducted at baseline, 3 months after the initial intervention, and every 6 months thereafter, as medically indicated. Thus, in any given calendar year, 3 counseling sessions could be provided.[34]

Intervention Process

Decisions about behavioral counseling should take into account the overall risk for coronary heart disease. Risk assessment should consider age, sex, and the presence and severity of the following risk factors: diabetes, elevated total cholesterol levels, low levels of high density lipoprotein cholesterol, elevated blood pressure, family history (in younger adults), and smoking.[3]

Effective interventions include individual or group counseling, which can be delivered by nutritionists, dietitians, specially trained primary care practitioners and health educators in the primary care setting, or in other clinical settings by referral.[3]

Effective interventions combine nutrition education with behavior-oriented counseling to help patients acquire the skills, motivation, and support needed to alter their daily eating and food preparation practices. Examples of behavior-oriented counseling interventions include teaching self-monitoring, training patients to overcome common barriers to selecting a healthy diet, helping patients set their own goals, providing guidance in shopping and food preparation, engaging in role playing with patients, and arranging for social support during treatment. In general, these interventions align with the "5 As"

behavioral counseling framework[35]:

- Assess dietary practices and related risk factors.
- Advise patients to change dietary practices.
- Agree on individual diet change goals.
- Assist patients in changing their dietary practices or addressing motivational barriers.
- Arrange regular follow-up and support or refer patients to more intensive behavioral nutritional counseling (e.g., medical nutrition therapy) if needed.[5,20]

Systems supports (prompts, reminders, and counseling algorithms) for primary care clinicians have been found to significantly improve their delivery of appropriate dietary counseling.[36-38]

Initial assessments and follow-up monitoring can be conducted using any of several brief dietary assessment questionnaires, which have been validated for use in the primary care setting.[39] These instruments identify dietary counseling needs, guide interventions, and monitor changes in patients' dietary patterns. Since patients enrolled in diet-change programs may exaggerate their adherence the programs, clinicians may not wish to rely on brief dietary assessment questionnaires but may find them useful to verify self-reported information.[21, 40-42]

Treatment Information

Not Applicable

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/ At Least Fair Evidence)

- The U.S. Preventive Services Task Force found good evidence to recommend intensive behavioral dietary counseling for adult patients with hyperlipidemia (lipid disorders) and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling may be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dieticians.[3]

Recommended Guidance:

American Dietetic Association
Strength of Evidence: Not Specified

- The American Dietetic Association recommends that primary care providers screen all patients for nutrition-related illnesses and, for patients with positive screening results, prescribe diets, provide preliminary counseling on specific nutritional needs, follow up with the patients, and refer them to appropriate dietetic professionals when necessary.[14]

Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure
Strength of Evidence: Not Specified

- The Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure recommends that dietary assessments be included as part of a routine medical history and that physicians counsel patients on lifestyle modifications for the prevention and treatment of high blood pressure (lose weight if overweight, limit alcohol intake, reduce sodium intake, reduce saturated fat and cholesterol intake).[15]

The National Cholesterol Education Program (NCEP)
Strength of Evidence: Not Specified

- The National Cholesterol Education Program recommends that persons with elevated levels of low-density lipoprotein limit their intake of fats, particularly saturated fats, and cholesterol and increase their intake of dietary fiber.[16]

Authored by:

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EVIDENCE-STATEMENT:

HEALTHY PREGNANCY (Screening, Testing, Counseling, Immunization, and Preventive Medication)

Why This Chapter is Important for Employers: An Overview

Alcohol Misuse (Screening and Counseling):

- Fetal exposure to alcohol during pregnancy is one of the leading causes of preventable birth defects, mental retardation, and developmental disorders in the United States.[1]
- In 2003, 10% of pregnant women reported alcohol use, including 4% who reported binge drinking.[2] Approximately 55% of women of childbearing-age age drink alcohol and 12% report binge drinking on one or more occasions in the past month.[2] Because half of all pregnancies in the United States are unintended, many women of childbearing-age who use or abuse alcohol are at risk of an alcohol-exposed pregnancy.
- The direct and indirect costs of alcohol misuse in the United States were estimated to equal nearly $185 billion in 1998. Medical consequences of fetal alcohol syndrome (FAS) accounted for approximately $2.9 billion of this amount.[3]
- Researchers estimate that the excess medical costs for a child with fetal alcohol syndrome (FAS) are $2,342 per year (in year 1997 dollars).[4]
- Randomized trials demonstrate that brief counseling leads to reduced alcohol consumption among excessive drinkers and to reductions in adverse alcohol-related health outcomes, including excess mortality.[5-7]
- It is estimated that each $1 invested in screening and brief counseling interventions saves approximately $4 in healthcare costs.[6,8]

Asymptomatic Bacteriuria (Screening):

- Urinary tract infections (UTIs) are the most common bacterial infections among pregnant and non pregnant women; each year 8 million women visit a physician for evaluation of a UTI.[9]
- Physiologic changes that occur during pregnancy make pregnant women more susceptible to UTIs, including asymptomatic bacteriuria (infection in the urine), cystitis (infection in the bladder), and pyelonephritis (infection in the kidneys).[9]
- Asymptomatic bacteriuria occurs in approximately 2% to 14% of pregnant women and 80,000 to 400,000 cases occur each year in the United States.[9]
- Bacteriuria increases the risk for preterm delivery twofold.[9] It also increases the risk of low birth weight and fetal and perinatal mortality.[9-10]
- Without treatment, asymptomatic bacteriuria can progress to pyelonephritis, a serious kidney infection. Pyelonephritis complicates 1% to 2% of all pregnancies and affects 100,000 women each year.[9]
- Early identification and treatment of asymptomatic bacteriuria improves pregnancy outcomes as it reduces the incidence of pyelonephritis and premature births.

Breastfeeding (Counseling):

- Human milk is universally recognized to be the optimal food for infants and is nutritionally superior to formula: breast milk confers immunity and protects infants from infections and allergens.

- Research shows that children who were breastfed are at significantly lower risk for childhood obesity as well as type 1 and type 2 diabetes compared to their non-breastfed peers.[11]
- Breastfeeding also has important short- and long-term health benefits for the mother. A woman's risk of breast cancer is decreased 4.3% for every 12-month increment of breastfeeding over her lifetime. Her risk of ovarian and endometrial cancer is decreased through breastfeeding as well.[12]
- Data from 2005 show that 72.9% of all new mothers initiated breastfeeding; but only 39.1% continued to breastfeed for 6 months and only 20.1% continued to breastfeed for the recommended 12-month period.[13]
- A 2001 U.S. Department of Agriculture (USDA) study estimated that at least $500 million (in year 1998 dollars) could be saved in healthcare costs if breastfeeding rates were increased to match those recommended by the Surgeon General/*Healthy People 2010* goals.[14]
- Research indicates that working outside the home reduces the initiation and duration of breastfeeding.[15] Therefore, employers should support women returning to work by offering lactation benefits (such as counseling) and programs.

Folic Acid Supplementation (Counseling and Preventive Medication):

- Neural tube defects (NTD), such as spina bifida and anencephaly, result from a failure of the neural cord to properly fuse.
- Each year, approximately 3,000 pregnancies are affected by neural tube defects (NTDs) and approximately 2,200 infants are born with NTDs.[16]
- Folic acid, a B vitamin, helps prevent NTD. Consuming the recommended daily amount of folic acid (0.4mg) can reduce a woman's chance of having a NTD-affected pregnancy by 40% to 80%.[17]
- Despite the benefits of supplementation, only 33% of women of childbearing age report taking vitamins that contain folic acid.[18]
- NTD rates are highest among the Hispanic population. Efforts to ensure supplementation among this population are important for eliminating health disparities.[19]
- The economic impact of NTDs is substantial. The average lifetime cost for a child born with spina bifida is estimated to be $636,000 (in year 2002 dollars).[20] Costs associated with NTDs are shared by parents, employers, and communities.

Group B Streptococcal Disease (Screening and Preventive Medication):

- Group B streptococcus (GBS), a bacterium, has been a leading cause of infection-related infant deaths in the United States since the 1970s.
- GBS disease is a serious infection that causes sepsis (blood poisoning), pneumonia, and meningitis in newborns.
- Each year in the United States between 1,300 and 1,600 infants contract early-onset GBS and 65 to 80 infants die from it.[21] Those who survive are often left

with lifelong disabilities such as hearing loss, vision impairments, and/or learning disabilities.

- While most women colonized with GBS are asymptomatic (meaning that they can pass the disease to their children, but are not affected by it themselves), some women become infected with GBS and are at risk of womb infections, bladder infections, and stillbirth.[21]
- By identifying women who carry group B streptococcal bacteria, clinicians can administer antibiotic prophylaxis during labor, thus preventing transmission of bacteria to the infant.
- The average neonatal intensive care cost of a GBS-infected infant was estimated to be $30,100 in 2001.[22] The cost of treating an infant with early-onset group B streptococcal sepsis (a severe form of the disease) is estimated to exceed $123,000 (in year 1993 dollars).[23]
- In 1993, researchers estimated that treating high-risk women identified through screening with intrapartum antibiotic prophylaxis could prevent 3,300 cases of GBS annually; saving approximately $16 million in direct medical costs.[24]

Hepatitis B Virus (HBV) (Screening, Immunization, and Treatment):

- Over 1 million people in the United States are chronic HBV carriers.[25]
- In 2003, 73,000 new HBV infections were reported.[25]
- Screening pregnant women for HBV, and treating the infants of HBV-positive women with post-exposure hepatitis B immune globulin prophylaxis and HBV vaccination can dramatically reduce the incidence of perinatal HBV transmission and thus the number of infants who become chronically infected with hepatitis B.[26]
- The economic burden of hepatitis B infection can be substantial depending on whether the infection is acute or chronic and what treatment is required.
- From a societal perspective, prevention of perinatal HBV infection was estimated to save $41.8 million (in year 1993 dollars) in medical and work-loss costs.[27]

Human Immunodeficiency Virus (HIV) (Screening, Counseling, and Preventive Medication)

- Approximately 120,000 to 160,000 HIV-infected women live in the United States, 80% of whom are of childbearing age. Each year between 1985 and 1995, approximately 6,000 to 7,000 HIV-infected women gave birth.[28]
- Mother-to-infant HIV transmission, called perinatal transmission, can occur during pregnancy, during labor and delivery, or through breastfeeding. Perinatal HIV transmission is almost entirely preventable.
- Despite screening and treatment advances, perinatal HIV transmission continues to occur; CDC estimates that 280 to 370 infants are born with HIV each year in the United States.[28]
- In 2000, there were 4,107 hospitalizations among HIV-infected children in the United States, which accounted for approximately $100 million in hospital charges and more than 30,000 hospital days.[29]

- The estimated average lifetime healthcare-related cost of a perinatal HIV infection is estimated to range between $100,000 and $117,000.[30]

Influenza (Immunization):

- Pregnant women are considered to be at increased risk for complications from influenza infections.
- Influenza immunization has many benefits. Foremost, when a pregnant woman is immunized during pregnancy, antibodies can be passed to her fetus and can also be passed in breast milk.[31]
- Researchers estimate that an average of 1 to 2 hospitalizations can be prevented for every 1,000 pregnant women vaccinated.[32]
- Despite the seriousness of influenza infection and the fact that the inactivated influenza vaccine is safe and effective, only 12% to 13% of pregnant woman are inoculated against influenza.[31,33]
- Immunization of healthy working adults is cost-effective and may result in cost-savings in some years.[34] Economic results are likely to be as favorable for pregnant women since they are at high risk for influenza-related complications.

Preeclampsia (Screening):

- Preeclampsia (pregnancy-related high blood pressure) affects 5% to 7% of all pregnancies.[35] If preeclampsia is not effectively treated it can lead to eclampsia, a severe condition that is characterized by maternal seizure activity, coma, and death.
- Preeclampsia/eclampsia is the third leading cause of maternal death worldwide[36] and is responsible for 18% of all maternal deaths in the United States.[37]
- Spending on pregnancy-related hypertension totaled nearly $2.3 billion in the United States in 2003.[38]
- In 2003, approximately 204,868 pregnant women were admitted to the hospital for hypertension, staying on average 3.5 days. The average per-person charge for such hospital admissions totaled $11,208.[38]
- Screening, which involves minimal cost, and early treatment can minimize and prevent otherwise costly medical conditions.

Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (NTDs) (Screening and Testing):

- Down syndrome (trisomy 21) is the most common chromosomal abnormality in the United States, affecting 1 in every 800 to 1,000 live-born babies.[39]
- Spina bifida and anencephaly are common, permanent, and potentially fatal birth defects. Both are neural tube defects (NTD) resulting in failure of the neural cord to properly fuse. Each year in the United States, approximately 3,000 pregnancies are affected by NTDs and approximately 2,200 infants are born with neural tube defects.[16]
- The purpose of screening and testing is to identify affected

pregnancies. Early identification of an affected pregnancy allows parents and providers to prepare for the birth of a special needs infant or to terminate the pregnancy.[40]

- Chromosomal abnormalities and NTDs have a substantial economic impact. For example, the average *lifetime* cost for a child born with spina bifida is estimated to be $636,000 (in year 2002 dollars).[41]
- Employers also face productivity losses associated with workdays lost by employees who must care for affected infants and children.[42]

Rh(D) Incompatibility (Screening and Preventive Medication):

- Rh(D) incompatibility occurs in 9% to 10% of all pregnancies, depending on the race of the pregnant woman and fetus, and may cause severe destruction of an affected fetus's red blood cells.[43]
- Without treatment, 25% to 30% of affected fetuses will experience hemolytic anemia and hyperbilirubinemia (jaundice) and an additional 20% to 25% will be hydropic and will either die in the womb or shortly after birth.[43]
- Early identification of Rh(D) incompatibility allows clinicians to begin treatment before damage is done to the fetus. This prevents otherwise expensive medical treatment, lifelong disability, and even death.

Rubella (Screening):

- When contracted during early pregnancy, rubella can cause serious complications including miscarriage, stillbirth, and congenital rubella syndrome (CRS) – a constellation of birth defects that includes hearing impairment, growth retardation, developmental delays, and heart and eye defects.[44]
- CRS and its complications have substantial health consequences and economic costs. A large rubella outbreak in 1964-65 cost an estimated $840 million.[45] In 2006, the estimated lifetime cost of treating a child born with CRS exceeded $200,000.[45]
- Screening allows clinicians to identify childbearing-age women who are at risk for rubella and to immunize them before they become pregnant. Screening pregnant women allows clinicians to identify at-risk women and to encourage them to be immunized immediately after delivery, thereby offering protection during subsequent pregnancies.

Syphilis (Screening):

- In addition to sexual transmission, syphilis can be passed from an infected pregnant woman to her infant during pregnancy and delivery.
- Congenital syphilis is particularly severe and results in fetal or infant death in 40% of cases.[46]
- In 2002, 451 cases of congenital syphilis were reported in the United States.[47]
- The average annual national cost of treating infants with congenital syphilis is approximately $18.4 million (in year 1995 dollars).[48]
- Screening for syphilis allows clinicians to identify affected patients and begin

treatment earlier in the course of disease, thereby improving outcomes and avoiding the health and economic consequences of latent disease. Further, ensuring that all women receive prenatal care and are screened for syphilis during pregnancy will reduce the incidence of congenital syphilis.[47]

Tetanus (Immunization):

- Neonatal tetanus is a severe and often fatal disease; it accounted for an estimated 200,000 deaths worldwide in 2000[49] but is extremely rare in the United States.[50]
- Nearly all neonatal tetanus occurs in infants born to women who are not adequately immunized against tetanus. Therefore, it is important for all pregnant women to be vaccinated against tetanus.[51]
- There are few economic data on the burden of tetanus disease and no data about the costs of neonatal tetanus in the United States. A recent economic evaluation of the 7-vaccine routine childhood immunization schedule in the United States estimated that, if there had not been a tetanus vaccination program in the U.S., 153 cases of tetanus and 23 deaths from tetanus would have occurred in each birth cohort (all children born in one year) at a total cost of $29 million (direct and indirect costs in year 2001 dollars).[52]
- Tetanus immunization offers long-term protection against tetanus for the vaccinated woman, and maternal vaccination confers significant protection to the fetus.[53]

Tobacco Use Treatment (Screening and Counseling):

- Twenty-five percent (25%) of all childbearing-age women in the United States smoke. Depending on demographic factors, between 11% and 20% of all pregnant women in the United States smoke.[54]
- Women who smoke during their pregnancies are 83% more likely to deliver a low-birth-weight infant, 129% more likely to deliver an infant that will die of SIDS, 30% more likely to deliver an infant with respiratory distress syndrome, and 41% more likely to deliver an infant with a perinatal respiratory condition than are women who do not smoke during pregnancy.
- Each pregnant smoker incurs an additional $704 in healthcare costs (in year 1996 dollars)[55] and, annually, smoking-attributable neonatal costs (defined as all costs related to labor/delivery and the care of infants within the first few months of life) are estimated to meet or exceed $367 million in the United States.[56-57]
- Tobacco use treatment is considered to be one of the most cost-effective preventive services.[54] Clinical trials have shown that $6 are saved in healthcare costs for every $1 invested in smoking cessation programs for pregnant women.[58]
- A smoking cessation program that could achieve an annual drop of 1 percentage point in smoking prevalence has been estimated to produce an economic benefit of $21 million in direct medical costs solely by reducing the number of low-birth-weight live births. In 7 years, the cumulative undiscounted saving in direct medical costs would become $572 million through the prevention of 57,200 low-birth-weight infants (all figures in year 1995 dollars).[59]

Alcohol Misuse (Screening and Counseling)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.[1]

***Evidence Rating:* B (Recommended/At Least Fair Evidence)**

The evidence on the effectiveness of counseling to reduce alcohol consumption during pregnancy is limited; however, studies in the general adult population show that behavioral counseling interventions are effective among women of childbearing age. The USPSTF concluded that the benefits of behavioral counseling interventions to reduce alcohol misuse by adults outweigh any potential harms.[1]

The USPSTF recommendation is supported by the American Academy of Family Physicians (AAFP).[2]

Recommended Guidance U.S. Surgeon General

The Surgeon General of the United States recommends that clinicians 1) screen pregnant women for alcohol use, 2) inform them of the risks of alcohol consumption, and 3) advise them not to drink alcohol during their pregnancy.[3]

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- Centers for Disease Control and Prevention (CDC)
- National Institute of Alcohol Abuse and Alcoholism (NIAAA)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)
- U.S. Surgeon General

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

No amount of alcohol can be considered safe during pregnancy: alcohol consumed during any stage of pregnancy increases the risk of alcohol-related birth defects.[3] Fetal exposure to alcohol during pregnancy is one of the leading causes of preventable birth defects, mental retardation, and developmental disorders in the United States.[4]

Despite the documented risks associated with fetal alcohol exposure 10% of pregnant women reported consuming alcohol in 2003.[5] Annually, 55% of

women of childbearing age report alcohol use, and 12% report binge drinking.[5] This statistic is of particular concern because half of all pregnancies in the United States are unplanned and are at particular risk of unintentional prenatal alcohol exposure. Therefore, experts recommend that women of childbearing age consult their physicians and take steps to reduce the possibility of an alcohol-exposed pregnancy by either 1) using an effective form of contraception or 2) reducing or eliminating alcohol use.[5]

Prenatal alcohol use can lead to one or more fetal alcohol spectrum disorders (FASD). FASD is characterized by permanent disabilities of varying degrees of severity. FASD may result in subtle defects, such as learning disabilities or mild physical abnormalities, or it may result in fetal alcohol syndrome (FAS), the most severe form of FASD, which is characterized by mental retardation, abnormal facial features, growth retardation, and central nervous system complications.[3]

FASD is identified in 2 of every 1,000 live births, and FAS is identified in between 0.5 to 2 of every 1,000 live births.[3] Because many alcohol-related deficits are not identified at the time of birth, the actual prevalence of alcohol-related disorders is much higher. In fact, researchers estimate that, for every case of FAS documented at birth, there are 3 additional cases that are not identified until later in life.[3]

Condition/Disease Risk Factors

Alcohol misuse (in the form of binge drinking, heavy drinking, alcohol abuse, or alcohol dependence) before pregnancy is highly predictive of continued use.[4]

Value of Prevention

Economic Burden of Condition/Disease

The direct and indirect costs of alcohol misuse in the United States were estimated to equal nearly $185 billion in 1998. Medical consequences of fetal alcohol syndrome (FAS) accounted for about $2.9 billion of this amount and approximately $1.3 billion were attributed to lost earnings due to FAS.[6]

Workplace Burden of Condition/Disease

Data are limited about presenteeism and absenteeism stemming from parental caregiving requirements for FASD/FAS-affected children, but parents are likely to take time off from work to attend to special needs children.

Economic Benefit of Preventive Intervention

The economic benefits of screening and counseling mainly result from:

- The averted costs of medical care for FAS and related disorders.
- Cost-savings in neonatal care and the management of developmental delays and birth defects.
- Cost-savings associated with special education, the criminal justice system, alcohol and/or drug abuse treatment, and mental health services.

Interventions directed toward alcohol misuse that occur during pregnancy may also improve a pregnant woman's long-term drinking behavior. A permanent or long-term reduction/elimination of alcohol use would generate additional cost-savings due to averted long-term healthcare costs.

Estimated Cost of Preventive Intervention

Screening patients for alcohol misuse in primary care settings is relatively inexpensive. The cost of follow-up counseling sessions depends on the number of sessions, their mode of delivery (in-office or by telephone), and on the type of provider who delivers the counseling. In 2004, the private-sector cost of the initial health risk assessment and counseling averaged $23; approximately 95% of all paid claims fell within the range of $0 to $81.[7]

Estimated Cost of Treatment

Treatment costs for pregnant women who misuse alcohol should not differ from general alcohol treatment costs unless there are other pregnancy-related complications.

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Screening and counseling for alcohol misuse have a greater impact and are more cost-effective than most clinical preventive services.[8] Screening and counseling for alcohol misuse among all adults (not just pregnant women) reduce both societal and healthcare costs. It is estimated that each $1 invested in screening and brief counseling interventions saves approximately $4 in healthcare costs.[9-10] Furthermore, researchers estimated that the excess medical costs for a child with fetal alcohol syndrome (FAS) are $2,342 per year (based on North Dakota Health Claims data for 1996 and 1997). This suggests that a alcohol-reduction program that costs $50,000 and is able to prevent one case of FAS each year would have paid for itself in 6 years by generating healthcare savings. The benefits are returned even faster if the prevention of alcohol-related conditions other than FAS are included in the analysis.[11]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening and Counseling

Screening for alcohol misuse allows clinicians to identify women who misuse alcohol early in the course of pregnancy (or during the pre- or interconception periods). Pregnant women who misuse alcohol can be counseled to reduce or eliminate their use and referred to treatment services as needed.

Benefits and Risks of Intervention

The benefits of screening and intervention include the prevention of FASD and FAS in addition to the maternal benefits accrued from identifying and intervening with their alcohol misuse. Randomized trials demonstrate that brief counseling leads to reduced alcohol consumption among excessive drinkers and to reductions in adverse alcohol-related health outcomes, including excess mortality.[9, 12-13] The USPSTF found little direct evidence regarding harms of screening for alcohol misuse or behavioral counseling interventions to reduce or eliminate alcohol use in general populations.[14]

Initiation, Cessation, and Interval of Screening

All women should be screened for alcohol use with each pregnancy. Because the optimal frequency of screening is unknown, screening is left to the discretion of the clinician. Patients at greater risk for alcohol problems, either because they have a history of past alcohol misuse or may report other risky behaviors, may benefit from re-screening during pregnancy.[14] Counseling should be conducted as medically indicated. A total of 8 counseling sessions are covered each calendar year.

Intervention Process

Screening

There are several effective screening tools currently available for assessing alcohol use in primary care settings. Non-pregnant women of childbearing age seen in primary care settings should be screened with general tools such as a single questions screen (e.g., AUDIT or AUDIT-C).[15] Pregnant women seen in primary care settings should be screened with a pregnancy-specific tool such as the TWEAK or T-ACE. The TWEAK, a 5-question tool, and the T-ACE, a 4-question tool, were specifically designed to screen pregnant women for "risky drinking", "harmful drinking", and alcohol abuse disorders. The T-ACE is very sensitive and has been shown to outperform unaided clinicians in identifying pregnant women who use alcohol.

All pregnant women and women considering pregnancy should be advised of the harmful effects of alcohol on the fetus. Because safe levels of alcohol consumption during pregnancy are unknown, pregnant women should be advised to refrain from drinking alcohol altogether.[5,14] Non pregnant women should also be advised to use contraception until their drinking can be reduced or eliminated.

Counseling

Clinicians should provide counseling interventions for patients who meet the criteria for alcohol misuse. The USPSTF identifies 3 levels of counseling intervention, differentiated by level of intensity, for these patients. Multi-contact counseling is more effective than single-contact counseling interventions, but providers should tailor counseling intensity to address individual patient needs. Intensity is determined by the duration of the initial contact and whether any follow-up occurs. "Very brief" interventions last up to 5 minutes and have no follow-up. "Brief" counseling interventions last 15 minutes and have no follow-up. "Multi-contact" interventions include one initial session lasting at least 15 minutes and several follow-up contacts.[1] More intensive interventions are typically recommended for those meeting criteria for alcohol dependence.

Effective counseling for alcohol misuse in the primary care setting includes feedback, advice, goal setting, and follow-up. Alcohol misuse counseling should follow the counseling framework known as the "5 As"[15]:

- Providers should assess the degree of a patient's drinking, including any problems caused by alcohol and whether the person is alcohol dependent or not.
- Providers should advise patients to reduce their alcohol consumption to safer levels or to abstain altogether from drinking.
- Providers should agree with patients on their goals for reducing alcohol consumption.
- Providers should assist patients in acquiring personal motivation, self-help skills, or outside resources necessary to achieve behavior change.
- Finally, providers should arrange for patients to receive appropriate follow-up support services and counseling, depending on the nature of their alcohol misuse.

Treatment Information

Health benefits should include provisions for diagnostic assessment, follow-up, and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

The U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found at least fair evidence to support screening and behavioral counseling all adults, including pregnant women, for alcohol misuse.[1]

This recommendation is supported by the:

- American Academy of Family Physicians (AAFP)[2]

Recommended Guidance:

The U.S. Surgeon General
Strength of Evidence: Not Specified

- The U.S. Surgeon General recommends that clinicians should routinely 1) screen pregnant women for alcohol use, 2) inform them of the risks of alcohol consumption, and 3) advise them not to drink alcohol during their pregnancy.[3]

Authored by:

Campbell KP, Naimi T, Chattopadhyay S. Alcohol misuse during pregnancy evidence-statement: screening and counseling. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage.* Washington, DC: National Business Group on Health; 2006.

Asymptomatic Bacteriuria (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation.[1]

***Evidence Rating:* A (Strongly Recommended/ Good Evidence)**

The USPSTF found good evidence that screening pregnant women for asymptomatic bacteriuria with urine culture significantly reduces symptomatic urinary tract infections, low birth weight, and preterm delivery. The benefits of screening and treatment substantially outweigh any potential harm.[1]

Evidence-Based Recommendation American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) strongly recommends that all pregnant women be screened for asymptomatic bacteriuria using urine culture at 12 to 16 weeks' gestation or at the first prenatal visit if after that time.[2]

***Evidence Rating:* SR (Strongly Recommends)**

Good quality evidence exists which demonstrates the substantial net benefit of screening for asymptomatic bacteriuria over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[2]

Recommended Guidance American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists (ACOG) recommends that clinicians screen all pregnant women for asymptomatic bacteriuria by taking a urine culture at the first prenatal visit. They further recommend that a repeat urine culture be obtained during the third trimester.[3]

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- American College of Obstetricians and Gynecologists (ACOG)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Asymptomatic bacteriuria in pregnancy is defined at the presence of a significant amount of bacterial growth in a urine culture taken from a urine sample[4] and the absence of symptoms of a urinary infection such as pain or urgency.[5]

Asymptomatic bacteriuria occurs in approximately 2% to 14% of pregnant women and 80,000 to 400,000 cases occur each year in the United States.[6]

Without treatment, 20% to 40% of asymptomatic bacteriuria cases among pregnant women progress to pyelonephritis, a serious kidney infection. Pyelonephritis complicates 1% to 2% of all pregnancies and affects 100,000 women each year.[6] It is also a leading cause of antepartum hospitalization.[1] With appropriate screening and treatment, only 3% of bacteriuria cases will progress to pyelonephritis.[6]

Condition/Disease Risk Factors

Bacteriuria increases the risk for preterm delivery and low birth weight and may also increase the risk of fetal and perinatal mortality.[1,6] If fact, the risk of preterm delivery is twice as high among women who had asymptomatic bacteriuria at some point during pregnancy compared to those who did not.[6]

Risk factors for asymptomatic bacteriuria during pregnancy include low socioeconomic urinary tract infections (UTIs) in childhood. Other risk factors include preexisting medical conditions such as diabetes, sickle cell disease, immunosuppression (e.g., HIV/AIDS), urinary tract anatomic anomalies, and spinal cord injuries. UTIs experienced before pregnancy are predictive of the diagnosis of asymptomatic bacteriuria at the first prenatal visit.[6]

Value of Prevention

Economic Burden of Condition/Disease

Specific data about the economic burden of UTIs among pregnant women are not available. The annual cost of all community-acquired urinary tract infections in 1995 was estimated to be approximately $1.6 billion, including $659 million in direct costs and $936 million in indirect costs.[7] The direct and indirect costs of acute pyelonephritis were estimated to be $2.14 billion (in year 2000 dollars).[8]

Workplace Burden of Condition/Disease

Lost productivity due to absenteeism associated with pregnancy-related complications of UTIs among working women (in addition to the increased medical care costs of such complications) has important financial ramifications for employers. Specific data on the workplace burden of pregnancy-related UTIs are not available.

Economic Benefit of Preventive Intervention

The preventive treatment of asymptomatic bacteriuria during pregnancy produces economic benefits such as preventing cases of cystitis, pyelonephritis, and premature births. In addition, preventing cases of mild and serious pyelonephritis produce significant improvements in quality of life.[9]

Estimated Cost of Preventive Intervention	In 2004, the private-sector cost of screening for bacteriuria averaged $17 per screen; approximately 95% of all paid claims fell within the range of $1 to $45 per screen.[10]
Estimated Cost of Treatment	One cost-effectiveness study estimated the cost of antibiotic treatment to be $11, based on a 7-day course of the generic form of commonly used antibiotics for the treatment of asymptomatic bacteriuria (in year 1994 dollars).[7]
Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention	Research shows that screening for asymptomatic bacteriuria using urine culture, when compared with use of dipstick analysis, is cost-effective among populations where the prevalence of asymptomatic bacteriuria is at least 9%.[6]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening	The purpose of screening for and treating asymptomatic bacteriuria in pregnancy is the prevention of poor maternal and infant outcomes associated with infection including pyelonephritis and prematurity.
Benefits and Risks of Intervention	Good evidence exists that screening pregnant women for asymptomatic bacteriuria with urine culture (rather than urinalysis) — and treating those with the infection — significantly reduces symptomatic urinary tract infections, low birth weight, and preterm delivery. A urine specimen obtained at 12 to 16 weeks' gestation will detect approximately 80% of patients with asymptomatic bacteriuria.[6,11] The USPSTF did not identify any information on the potential harms of screening for asymptomatic bacteriuria.[11]
Initiation, Cessation, and Interval	All pregnant women should be screened for asymptomatic bacteriuria at 12 to 16 weeks' gestation.[1,3] The optimal frequency of subsequent urine testing during pregnancy is uncertain and is thus left to the discretion of the clinician. The American College of Obstetricians and Gynecologists (ACOG) recommends that clinicians re-screen all pregnant women for asymptomatic bacteriuria by performing a urine culture during the third trimester.[3]
Intervention Process	Urine culture is the gold standard for detecting asymptomatic bacteriuria.[1] Other types of screening tests commonly used in the primary care setting (such as dipstick analysis and direct microscopy) are not as accurate for detecting bacteriuria in asymptomatic persons.[1]
Treatment Information	Asymptomatic bacteriuria can be treated with a range of antibiotics. A Cochrane Collaboration review of 14 randomized trials of asymptomatic bacteriuria in pregnant women showed that antibiotic treatment was significantly associated with decreased incidence of pyelonephritis. The review also determined that antibiotic treatment reduced the rate of preterm delivery and low birth weight.[12] Health benefits should include provisions for diagnostic and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation.[1] The USPSTF found good evidence that screening pregnant women for asymptomatic bacteriuria with urine culture significantly reduces symptomatic urinary tract infections, low birth weight, and preterm delivery. The benefits of screening and treatment substantially outweigh any potential harm.[1]

The American Academy of Family Physicians (AAFP)
Strength of Evidence: SR (Strongly Recommended)

- AAFP strongly recommends that all pregnant women be screened for asymptomatic bacteriuria using urine culture at 12 to16 weeks' gestation or at the first prenatal visit if after that time. Good quality evidence exists which demonstrates the substantial net benefit of screening for asymptomatic bacteriuria over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[2]

Recommended Guidance:

American College of Obstetricians and Gynecologists (ACOG)
Strength of Evidence: Not Specified

- The American College of Obstetricians and Gynecologists (ACOG) recommends that clinicians screen all pregnant women for asymptomatic bacteriuria by taking a urine culture at the first prenatal visit. They further recommend that a repeat urine culture be obtained during the third trimester.[3]

Authored by:

Campbell KP, Chattopadhyay S. Asymptomatic bacteriuria evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Breastfeeding (Counseling)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians provide structured breastfeeding education and behavioral counseling to all pregnant and postpartum women to promote the initiation and continuation of breastfeeding.[1]

***Evidence Rating:* B (Recommended/ At Least Fair Evidence)**

The USPSTF found fair evidence that programs which combine breastfeeding education with behaviorally-oriented counseling increase the rates of the initiation and continuation of breastfeeding for up to 3 months. The USPSTF notes that effective programs involve at least one in-person session; are usually 30 to 90 minutes in duration; follow structured protocols; and include practical behavioral skills training, problem-solving, and didactic instruction.[1]

The USPSTF also found fair evidence to suggest that continued support via in-person visits or telephone contact with a clinician or counselor increases the proportion of women who continue breastfeeding their infants for 6 months.[1]

CDC Recommendation

The CDC *Guide to Breastfeeding Interventions* recognizes the critical role returning to work plays in women's infant feeding decisions, and identifies a strong need to establish lactation support in the workplace.[2]

Evidence Rating:

Not Specified

Other Evidence Based Recommendations American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) recommends structured breastfeeding education and behavioral counseling programs to promote breastfeeding.[3]

***Evidence Rating:* R (Recommends)**

Although evidence exists which demonstrates the net benefit of counseling to promote breastfeeding, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost-effective and acceptable to most patients.[3]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- Centers for Disease Control and Prevention (CDC)
- *Healthy People 2010*, U.S. Department of Health and Human Services
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document

should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Breastfeeding provides protective immune globulins from the mother to the infant, completing the development of the infant's immune system after birth and thereby reducing the risk that the infant will acquire some serious infections. This immunologic protection is impossible to replicate with infant formula. Infants who are breastfed are thus better prepared to fight off infections and allergens than their non-breastfed counterparts. Additionally, human breast milk is universally recognized to be the optimal food for infants and is nutritionally superior to formula. Evidence suggests that breastfed infants are less likely to develop obesity, and type 1 and type 2 diabetes than bottle-fed infants.[2] Further, children who were breastfed have lower rates of otitis media (ear infections), respiratory infections, gastroenteritis, and eczema (a skin disorder).[2]

Despite the benefits of breastfeeding for both women and infants, breastfeeding rates in the United States remain suboptimal, especially among certain subpopulations. Data from 2005 show that 72.9% of all new mothers initiated breastfeeding and 39.1% continued to breastfeed for 6 months.[4] However, only 63.5% of low income mothers and 55.4% of African-American mothers initiated breastfeeding. Further, only 29.7% of low income mothers and 24.8% of African-American mothers continued to breastfeed their infants for the recommend 6-month period.[4]

The *Healthy People 2010* goals for breastfeeding aim to increase breastfeeding rates so that 75% of all new mothers initiate breastfeeding, 50% continue breastfeeding for at least 6 months postpartum, and 25% continue to breastfeed at least 1 year postpartum.[5]

Breastfeeding rates should be of paramount importance to employers as working outside the home negatively affects initiation and duration of breastfeeding.[6] Furthermore, one-third of working mothers return to work within 3 months of the birth of their child, and two-thirds return within 6 months, the exact time period when breastfeeding is most critical.[6]

Condition/Disease Risk Factors

The mothers at highest risk for not breastfeeding are first-time mothers, those who have less formal education, those who are non-white, and those who are ill postpartum.[7]

Value of Prevention

Economic Burden of Condition/Disease

Healthcare costs of treating respiratory tract infections, ear infections, and gastrointestinal illnesses represent the majority of healthcare expenses for children less than one year of age.[8] Because all of these illnesses are significantly more common among formula-fed infants than breastfed infants, support of breastfeeding initiation and continuation saves healthcare dollars.[8] Indirect costs include time and income lost from work to take care of a sick child.

Workplace Burden of Condition/Disease

Children who are not breastfed contribute to huge additional healthcare expenditures for the employers of their parents. Their parents are also responsible for significant productivity losses in the workplace associated with absenteeism and presenteeism. A study that compared infant feeding among employed mothers found that 75% of all 1-day maternal absences were among formula-feeding mothers.[9] The study also found that infants who were formula fed were much more likely to fall ill. In fact, only 14% of infants with no illnesses were formula-fed (comparatively 86% of infants with no illnesses were breastfed).[9]

Economic Benefit of Preventive Intervention

Breastfeeding offers important economic benefits to families, employers, and society at large. Breastfeeding allows the family to save the money that otherwise would be spent on infant formula, other human milk substitutes, and feeding equipment.

Further, a 2001 U.S. Department of Agriculture (USDA) study estimated that at least $3.6 billion (in year 1998 dollars) would be saved if breastfeeding rates were increased from the current rates to those recommended by the U.S. Surgeon General (75% in-hospital and 50% at 6 months). This estimate includes $3.1 billion is savings from prevented premature deaths, $500 million in savings from reduced healthcare costs (e.g., hospital visits, etc), and savings from averted indirect costs such as forgone earnings of parents.[8]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of counseling to promote breastfeeding initiation and continuation averaged $23 per session; approximately 95% of all paid claims fell within the range of $0 to $81 per session.[10]

Estimated Cost of Treatment

Not Applicable

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

A study based on 1993-1994 data from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) in Colorado found that compared with formula-feeding, breastfeeding each infant enrolled in WIC saved $478 in WIC costs and Medicaid expenditures during the first 6 months of the infant's life, or $161 after consideration of the formula manufacturers' rebate.[11] The cost saving was realized by the averted WIC costs for formula and foods for infants and mothers as well as reduced administrative expenses and lower Medicaid health care costs including costs for pharmacy reimbursement for the breastfed infants.[11]

Preventive Intervention Information

Preventive Intervention: Purpose of Counseling

The purpose of counseling is to educate women on the benefits of breastfeeding and to provide support and skills-training for women who choose to breastfeed, thereby increasing the number of women who initiate and maintain breastfeeding for the minimum recommended period of 12 months.

Benefits and Risks of Intervention

Breastfeeding has important short- and long-term health outcomes for children. Research shows that children who were breastfed are at significantly lower risk for childhood obesity as well as type 1 and type 2 diabetes than their non-breastfed

peers. Breastfed infants and children also have lower rates of otitis media (ear infections), respiratory infections, gastroenteritis, and eczema (a skin disorder).[12]

Breastfeeding also has important short- and long-term health benefits for the mother. A woman's risk of breast cancer is decreased 4.3% for every 12-month increment of breastfeeding over her lifetime.[12] Her risk of ovarian and endometrial cancer is decreased by breastfeeding as well. Breastfeeding improves uterine tone, helps to stop post-birth bleeding, assists postpartum weight loss, and temporarily suppresses ovulation to aid in child-spacing.[2]

Educational programs have been shown to increase the proportion of women who initiate breastfeeding immediately after birth by 23% and the number of women who continue to breastfeed for 1 to 3 months by 39%. The efficacy of education programs is enhanced by ongoing support for breastfeeding initiation and continuation.[13]

There are no known risks of counseling to promote breastfeeding. In the United States, only women with the following conditions should be advised to avoid breastfeeding: women who are HIV positive; are taking antiretroviral medications; have untreated, active tuberculosis; are infected with human T-cell lymphotropic virus type I or type II; are using illicit drugs; are taking prescribed cancer chemotherapy agents that interfere with DNA replication; and whose infants who are diagnosed with galactosemia. Women undergoing radiation therapies need to temporarily interrupt breastfeeding but do not need to discontinue breastfeeding permanently.[14]

Initiation, Cessation, and Interval of Counseling

Counseling to promote breastfeeding should be offered to all women of childbearing age. It should begin during prenatal care and continue throughout the intrapartum hospital stay and into the postpartum period. Counseling should be given, according to need, throughout the course of lactation.

Intervention Process Counseling

Counseling should include breastfeeding initiation advice as well as skills and referrals to support breastfeeding continuation. The most effective breastfeeding education and counseling interventions last approximately 30 to 90 minutes and feature directive health education combined with behaviorally-oriented skills training and problem-solving.[1]

Effective breastfeeding education and behavioral counseling programs[1]:

- Begin during the prenatal period.
- Use face-to-face individual or group sessions.
- Are led by specially trained nurses, midwives, or lactation specialists.
- Sessions last 30 to 90 minutes.
- Include education on the benefits of breastfeeding for mother and infant, basic physiology, technical training on positioning and latch-on techniques, skills on how to overcome common barriers, skills to garner social support, how to use basic lactation support equipment such as breast pumps, etc.

Treatment Information

Not Applicable

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found at least fair evidence to support the provision of structured breastfeeding education and behavioral counseling to all pregnant and postpartum women to promote the initiation and continuation of breastfeeding.[1]
- The USPSTF also found at least fair evidence to suggest that continued support via in-person visits or telephone contact with a clinician or counselor increases the proportion of women who continue breastfeeding their infants for 6 months.[1]

The American Academy of Family Physicians (AAFP)
Strength of Evidence: R (Recommended)

- AAPF recommends structured breastfeeding education and behavioral counseling programs to promote breastfeeding. Although evidence exists which demonstrates the net benefit of counseling to promote breastfeeding, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost-effective and acceptable to most patients.[3]

Authored by:

Campbell KP, Chattopadhyay S. Breastfeeding evidence-statement: counseling. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Folic Acid Supplementation (Counseling and Preventive Medication)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

In 1996, the U.S. Preventive Services Task Force (USPSTF) recommended that all women of childbearing age who are capable of becoming pregnant (even those currently using contraception) consume 0.4 micrograms of folic acid per day to reduce the risk of a pregnancy affected by either spina bifida, anencephaly, or another neural tube defect.

This recommendation is archived and considered out of date.

CDC Recommendation

The CDC concurs with the U.S. Public Health Service (see description below).

Evidence-Based Recommendation American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) recommends that clinicians prescribe 0.4-0.8 mg/day of folic acid supplementation from at least 1 month prior to conception through the first trimester of the pregnancy to women who have not had a previous pregnancy affected by a neural tube defect.[1]

Evidence Rating: **SR (Strongly Recommends)**

Good quality evidence exists which demonstrates the substantial net benefit of folic acid supplementation over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[1]

American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) recommends that clinicians prescribe 0.4 mg folic acid supplementation to women not planning a pregnancy but of childbearing potential who have not had a previous pregnancy affected by a neural tube defect.[1]

Evidence Rating: **R (Recommended)**

Although evidence exists which demonstrates the net benefit of folic acid supplementation, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost-effective and acceptable to most patients.[1]

American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) recommends that clinicians prescribe 4 mg/day of folic acid supplementation from 1 to 3 months prior to conception through the first trimester of pregnancy to women who are planning a pregnancy and have had a previous pregnancy affected by a neural tube defect.[1]

Evidence Rating: **SR (Strongly Recommended)**

Good quality evidence exists which demonstrates the substantial net benefit of folic acid supplementation over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[1]

Other Recommended Guidance U.S. Public Health Service

The U.S. Public Health Service recommends that[2-3]:

- All women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other neural tube defects.
- Women who have had a prior NTD-affected pregnancy are at high risk of having a subsequent affected pregnancy and should consult their physicians when planning to become pregnant again.

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- American College of Obstetricians and Gynecologists (ACOG)
- Centers for Disease Control and Prevention (CDC)
- National March of Dimes Birth Defects Foundation
- Peer-reviewed research
- U.S. Public Health Service (USPHS)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Spina bifida and anencephaly are severe, potentially fatal birth defects. Both are neural tube defects (NTD) resulting in failure of the neural tube to fuse correctly. Approximately 3,000 pregnancies are affected by NTDs, and approximately 2,200 infants are born with neural tube defects each year.[4] Many NTD-affected pregnancies do not result in a live birth because they are electively or spontaneously aborted (commonly referred to as a miscarriage) or result in fetal death or stillbirth.[4]

Anencephaly is always fatal and affected infants die shortly after birth. The majority of infants born with spina bifida grow into adulthood, but have severe medical complications such as paralysis and varying degrees of bowel and bladder incontinence.[2]

Folic acid, a B vitamin, prevents NTDs. Evidence (from populations not consuming foods fortified with folic acid) shows that consuming the recommended daily amount of synthetic folic acid (0.4 mg) through folic acid supplements can reduce a woman's chance of having a NTD-affected pregnancy by 40% to 80%.[5]

Synthetic folic acid can be consumed via folic acid supplements, folic acid-containing multivitamins, cereals that have been fortified with folic acid, and fortified grains. The natural form of this vitamin, folate, can be found in foods such as green leafy vegetables, orange juice, and beans. Synthetic folic acid vitamin supplementation is recommended because it is easier for the body to absorb than folate found in food and because up to 50% of naturally occurring folate is lost during cooking.[6]

Condition/Disease Risk Factors

Despite the known benefit of folic acid, only 33% of women of childbearing age report taking vitamins that contain folic acid and certain subpopulations have even lower rates of vitamin supplementation.[7]

NTD rates are highest among the Hispanic population. Efforts to ensure supplementation among this population are important for eliminating health disparities.[8]

Value of Prevention

Economic Burden of Condition/Disease

The economic burden of NTDs is substantial. The total lifetime cost for a child born with spina bifida is estimated to be $636,000 (in year 2002 dollars).[9] Applying the prevalence rate for spina bifida from the National Birth Defect Prevention Network data[10] to the 4 million live births each year, that amounts to $814 million in lifetime costs for each one-year cohort of births (all children born in one year).[9] Costs associated with NTDs are shared by parents, employers, and communities.

Workplace Burden of Condition/Disease

Apart from the excess medical costs for affected children, employers face productivity loss costs associated with employees' absences to care for children with spina bifida. The present value of the cost of such caregiver time was estimated to be $252,000 per child (in year 1993 dollars).[11]

Economic Benefit of Preventive Intervention

The economic benefit of folic acid supplementation is based on the cost savings that result from averted direct and indirect costs of each NTD that is prevented with supplementation.

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of counseling to promote folic acid supplementation averaged $23 per session; approximately 95% of all paid claims fell within the range of $0 to $81 per session.[12]

The cost of supplementation is highly variable, depending on the type of vitamin supplement that is taken and for how long. The cost of over-the-counter vitamins is relatively cheap and is an out-of-pocket cost for beneficiaries. Prescription strength folic acid (recommended for women who have had a previous pregnancy affected by a NTD) costs approximately $100 per year.[13]

Estimated Cost of Treatment

Not Provided

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

At present there is no evidence on the incremental cost-effectiveness of folic acid supplementation. A study undertaken before the implementation of the folic acid fortification program, examined a public and provider education program as a possible strategy to increase folic acid consumption through consumption of vitamin supplements and estimated that, compared to no program, the cost-effectiveness of supplementation was approximately $5,000 per quality-adjusted life year (QALY).[11]

Preventive Intervention Information

Preventive Intervention: Purpose of Counseling and Preventive Medication

Encouraging a woman to increase her folic acid intake prior to pregnancy via support, counseling, and/or prescription vitamins can lead to improved nutrition, thereby improving her chance of a healthy pregnancy and reducing her risk of an NTD-affected pregnancy.

Benefits and Risks of Intervention

A double-blind, placebo-controlled, randomized trial showed that folic acid supplementation before and during pregnancy decreased the risk of a first occurrence of a neural tube defect.[14-15] The efficacy of such folic acid supplementation has since been confirmed by many other studies.

The South Carolina NTD prevention program has reported great success in preventing the recurrence of isolated NTDs by providing counseling and vitamins to women who have had a previous NTD-affected pregnancy.[16]

Initiation, Cessation, and Interval of Counseling and Preventive Medication

Folic acid supplementation is believed to have minimal risks. Folic acid is considered nontoxic even at very high doses and is rapidly excreted in the urine.

Folic acid supplementation information should be provided during routine healthcare visits and throughout the first trimester of pregnancy. Folic acid supplements should be prescribed/recommended, as medically indicated.

Intervention Process, Counseling, and Preventive Medication

Clinicians should 1) advise all women of child-bearing age who are capable of becoming pregnant about the importance of folic acid supplementation and 2) provide them with guidance on folic acid supplementation and, if needed, a prescription for folic acid supplements.

Treatment Information

Not Applicable

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

The American Academy of Family Physicians (AAFP)
Strength of Evidence: SR (Strongly Recommended), R (Recommended)
SR (Strongly Recommended)

- AAFP recommends that clinicians prescribe 0.4-0.8 mg/day of folic acid supplementation from at least 1 month prior to conception through the first trimester of the pregnancy to women planning to become pregnant who have not had a previous pregnancy affected by a neural tube defect. Good quality evidence exists which demonstrates the substantial net benefit of folic acid supplementation over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[1]

R (Recommended)

- AAFP recommends that clinicians prescribe 0.4 mg folic acid supplementation to women not planning a pregnancy but of childbearing potential who have not previously had a baby with a neural tube defect. Although evidence exists which demonstrates the net benefit of folic acid supplementation, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost-effective and acceptable to most patients.[1]
- AAFP recommends that clinicians prescribe 4 mg/day of folic acid supplementation from 1-3 months prior to conception through the first trimester of pregnancy to women who are planning a pregnancy and had a previous pregnancy affected by a neural tube defect.[1] Good quality evidence exists which demonstrates the substantial net benefit of folic acid supplementation over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[1]

Recommended Guidance:

U.S. Public Health Service (USPHS)
Strength of Evidence: Not Specified

- The U.S. Public Health Services recommends that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other neural tube defects. Women who have had a prior NTD-affected pregnancy are at high risk of having a subsequent affected pregnancy, and should consult their physicians when planning to become pregnant again.[2-3]

Authored by:

Campbell KP, Grosse S, Chattopadhyay S. Folic acid supplementation evidence-statement: counseling and preventive medication. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Group B Streptococcal Disease (GBS) (Screening and Preventive Medication)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

Not Applicable

CDC Recommendation

The Centers for Disease Control and Prevention (CDC) recommends that clinicians screen all pregnant women for vaginal and rectal group B streptococcal (GBS) colonization at 35 to 37 weeks' gestation.[1]

- Women should be tested for GBS at each pregnancy as colonization at a prior pregnancy is not an indication for antibiotic prophylaxis in subsequent pregnancies.
- Women who are identified through screening as GBS carriers should be given intrapartum antibiotic prophylaxis.
- Women whose screening status is unknown at the time of labor should receive intrapartum antibiotic prophylaxis if they present with any of the following risk factors: delivery at less than 37 weeks' gestation, membrane rupture ≥18 hours, or intrapartum fever ≥38C.
- Women with GBS isolated from the urine at any time in the current pregnancy should also be given intrapartum antibiotic prophylaxis.
- Women who have previously given birth to an infant with invasive GBS disease should receive intrapartum antibiotic prophylaxis.
- Women who are expected to deliver preterm (less than 37 weeks' gestation) should be assessed for their need for intrapartum antibiotic prophylaxis to prevent perinatal GBS disease.
- GBS colonized women who have a planned cesarean before rupture of the membranes are at a low risk for delivering an infant with early-onset GBS disease and should thus not routinely receive intrapartum antibiotic prophylaxis.

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Centers for Disease Control and Prevention (CDC)
- Royal College of Obstetricians and Gynecologists
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Group B streptococcus (GBS), a bacterium, has been a leading cause of infection-related infant death in the United States since the 1970s.[1] GBS disease is a serious infection that causes sepsis (blood poisoning), pneumonia, and meningitis in newborns. GBS can be lethal: 1 in every 20 babies born with GBS dies. Each year in the United States between 1,300 and 1,600 infants contract early-onset GBS and 65 to 80 infants die from it.[1] Those who survive are often left with lifelong disabilities such as hearing loss, vision impairments, and/or learning disabilities.[1]

In the 1980s, scientists discovered that administering antibiotics during labor to women who carry GBS could prevent early-onset GBS disease from developing in newborns. One in every 4 to 5 pregnant women carries GBS in her vagina or rectum.[1] While most women colonized with GBS are asymptomatic (meaning that they can pass the disease to their child, but are not affected by it themselves), some women become infected with GBS and are at risk of womb infections, bladder infections, and stillbirth.[1]

Condition/Disease Risk Factors

Pregnant women are at a higher risk of delivering an infant with GBS disease if they have GBS in their urine, are colonized with GBS at the time of labor, have a fever during labor, rupture their membranes 18 hours or more before delivery, or if they have previously had a baby with GBS disease.[1]

Value of Prevention

Economic Burden of Condition/Disease

While the rate of neonatal GBS infections has declined since the 1990s due to widespread screening and treatment, GBS continues to have an economic toll in the United States.[2] The average neonatal intensive care cost of a GBS-infected infant was estimated to be $30,100 in 2001.[3] The excess average discounted lifetime healthcare cost for an infant disabled by an early-onset GBS (over that for a healthy infant) was estimated to equal $261,000 (in year 2001 dollars).[4]

Workplace Burden of Condition/Disease

Productivity losses associated with absenteeism and presenteeism for parents of GBS-affected children have not been quantified.

Economic Benefit of Preventive Intervention

Preventing a case of infant disability due to GBS can reduce the discounted lifetime healthcare costs for an infant by $261,000, on average (year 2001 dollars).[4] In 1993, researchers estimated that treating high-risk women identified through screening with intrapartum antibiotic prophylaxis could prevent 3,300 cases of GBS annually; saving approximately $16 million in direct medical costs.[2]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of screening for GBS averaged $13 per screen; approximately 95% of all paid claims fell within the range of $4 to $33 per screen.[6] When women with a positive test result are treated with antibiotic therapy during labor (an initial dose of 2g of ampicillin intravenously, followed by 1g every 4 hours) the preventive mediation costs are estimated to equal $63 per course of therapy.[4]

Estimated Cost of Treatment

The cost of treating an infant with early-onset group B streptococcal sepsis (a severe form of the disease) was estimated to exceed $123,000 (in year 1993 dollars).[4]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Screening to prevent early-onset GBS is estimated to cost less than $12,000 (in year 1997 dollars) per prevented case. Preventive intervention may also generate net cost-savings if the high cost of managing a case of early-onset GBS is considered.[3]

In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, screening for GBS is cost-effective.

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Identifying women who carry group B streptococcal bacteria allows clinicians to administer antibiotic prophylaxis during labor, thus preventing transmission of the bacteria to the infant. Vaccines to prevent GBS disease are under development but are not currently available. Thus, universal prenatal GBS culture-based screening is the best available prevention strategy.[1]

Benefits and Risks of Intervention

The risks of screening for GBS colonization are minimal. However, there are risks associated with intrapartum antibiotic prophylaxis. Severe anaphylaxis is associated with the use of penicillin in some women. Anaphylaxis occurs in 1 out of every 10,000 treatments and can be fatal. Also, the widespread use of antibiotics, particularly broad-spectrum antibiotics such as ampicillin, contributes to the development of resistant organisms.[1]

Despite the risks associated with prevention, screening for group B streptococcal colonization and intrapartum antibiotic prophylaxis can reduce the rate of neonatal infection death and prevent infants from significant disability. These significant benefits outweigh the risks and costs associated with screening.

Initiation, Cessation, and Interval of Screening and Preventive Medication

All pregnant women should be screened for vaginal and rectal group B streptococcal (GBS) colonization between 35 and 37 weeks' gestation. Preventive medication should be given to colonized women, as medically indicated.

Intervention Process Screening

All women should be screened for vaginal and rectal group B streptococcal colonization using recommended laboratory methods for GBS isolation and identification. Women should be screened for GBS with each pregnancy as colonization at a prior pregnancy is not an indication for antibiotic prophylaxis in subsequent pregnancies.

Preventive Medication

Intrapartum antibiotic prophylaxis should be given, as medically indicated, to:

- Women who are identified as GBS carriers.
- Women whose screening status is unknown at the time of labor *if* they present with any of the following risk factors: delivery at less than 37 weeks' gestation, membrane rupture ≥18 hours, or intrapartum fever ≥ 38C.

- Women with GBS isolated from the urine at any time in the current pregnancy.
- Women who have previously given birth to an infant with invasive GBS disease.

Women who are expected to deliver preterm (less than 37 weeks gestation) should be assessed for their need for intrapartum antibiotic prophylaxis to prevent perinatal GBS disease.

GBS colonized women who have a planned cesarean before rupture of the membranes are at a low risk for delivering an infant with early-onset GBS disease and should thus not routinely receive intrapartum antibiotic prophylaxis.[1]

Treatment Information

Health benefits should include provisions for treatment services for affected women and infants.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

The Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Not Specified

- The CDC recommends screening all pregnant women for vaginal and rectal group B streptococcal (GBS) colonization between 35 and 37 weeks' gestation.[1]

Authored by:

Campbell KP, Chattopadhyay S. Group B streptococcal disease evidence-statement: screening and preventive medication. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Hepatitis B Virus (HBV) (Screening, Immunization, and Treatment)

Clinical Preventive Service Recommendations

Preventive Services Task Force Recommendation

Evidence Rating: A (Strongly Recommended/ Good Evidence)

Screening

The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit.[1]

The USPSTF found good evidence that universal prenatal screening for HBV infection using HBsAg substantially reduces prenatal transmission of HBV and the subsequent development of chronic HBV infection. The current practice of vaccinating all infants against HBV infection and post-exposure prophylaxis with hepatitis B immune globulin administered at birth to infants of HBV-infected women substantially reduces the risk for acquiring HBV infection.[1]

Immunization

The U.S. Preventive Services Task Force (USPSTF) defers to the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) on recommendations surrounding immunization.

CDC Recommendation

Advisory Committee on Immunization Practices (ACIP)

Screening

The Advisory Committee on Immunization Practices (ACIP) recommends that all pregnant women be tested routinely for hepatitis B surface antigen (HBsAg) during an early prenatal visit (i.e., first trimester) in each pregnancy, even if they have been previously vaccinated or tested. Women who were not screened prenatally, those who engage in behaviors that put them at high risk for infection (e.g., injection-drug use, having had more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually transmitted infection [STI], or recent or current injection-drug use) and those with clinical hepatitis should be tested at the time of admission to the hospital for delivery.[2,3]

Immunization

The ACIP further recommends the hepatitis B vaccine for pregnant women at risk for hepatitis B virus infection. Pregnant women who are identified as being at risk for HBV infection during pregnancy (see list of risk factors in preceding paragraph) should be vaccinated. Pregnant women at risk for HBV infection during pregnancy should be counseled concerning other methods to prevent HBV infection.[2,3]

Management of Exposed or Potentially Exposed Infants/Treatment

The ACIP recommends that all infants born to HBsAg-positive women should receive single-antigen hepatitis B vaccine and hepatitis B immune globulin prophylaxis (HBIG) (0.5 mL) within the first 12 hours following the birth, administered at different injection sites.[2,3]

Women admitted for delivery without documentation of HBsAg test results should have blood drawn and tested as soon as possible after admission. While test results are pending, all infants born to women without documentation of HBsAg test results should receive the first dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours following the birth.[2-3]

A summary of guidelines for the immunization of pregnant women can be found online (www.cdc.gov/nip/publications/preg_guide.htm).

Evidence Rating: Expert Consensus

Other Evidence-Based Recommendations American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit.[5]

***Evidence Rating:* SR (Strongly Recommended)**

Good quality evidence exists which demonstrates the substantial net benefit of screening for HBV over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[5]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Advisory Committee on Immunization Practices (ACIP)
- American Academy of Family Physicians (AAFP)
- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Over 1 million people in the United States are chronic carriers of HBV.[4] In 2003, an estimated 73,000 new HBV infections were reported in the United States.[4] Hepatitis infection can lead to liver disease, including liver cancer, which without treatment can result in death. Between 4,000 and 5,000 chronic carriers of HBV die each year in the United States.[4] Hepatitis B can be treated with medications if diagnosed early, but some individuals do not respond to treatment and require liver transplants to survive.

The severity of hepatitis B infection depends on the age at which an individual becomes infected and the presence of other comorbid conditions such as alcohol abuse, HIV/AIDS, or other types of liver disease.[6] Most adolescents and adults with acute HBV infections recover fully, but 30% of children aged 1 to 5 years

and 2% to 6% of adults become chronically infected with hepatitis B.[7] Immunization against HBV is the single most effective way of preventing hepatitis B infection and its consequences.[2]

Condition/Disease Risk Factors

The risk factors for hepatitis B include intravenous drug use, concurrent infection with a sexually transmitted infection (STI), multiple sexual partners, household contact with an infected person, and being a healthcare worker with exposure to bodily fluids. However, 30% to 40% of infected individuals have no identified risk factors.[6]

Infants can contract hepatitis B from an infected woman during labor and delivery and as many as 90% of infants infected through perinatal transmission become chronic carriers of HBV.[2]

Value of Prevention

Economic Burden of Condition/Disease

The economic burden of hepatitis B infection depends on whether the infection is acute or chronic and what treatment is required. The direct medical cost of outpatient treatment for symptomatic acute hepatitis B has been estimated at $272 per occurrence, while the cost of hospitalization for symptomatic hepatitis B infection is $8,080 per occurrence (both in year 2000 dollars).[8] If a patient develops liver disease as a result of chronic HBV infection, the direct medical cost of treatment is estimated to be $59,308 (before discounting)[8] and patients who require a liver transplant can have first-year billed charges of up to $244,600 (in year 1999 dollars).[9]

Workplace Burden of Condition/Disease

HBV is also responsible for disability costs, costs associated with work-loss and absenteeism, and other indirect costs.

Economic Benefit of Preventive Intervention

Screening pregnant women for HBV, and treating the infants of HBV-positive women with post-exposure hepatitis B immune globulin prophylaxis and HBV vaccination can dramatically reduce the incidence of perinatal HBV transmission and thus the number of infants who become chronically infected with hepatitis B.[2] The additional recommended step of vaccinating all infants with HBV at birth also serves as a safety net to prevent perinatal hepatitis B transmission.[2] The averted direct and indirect costs of illness from each case of HBV prevented constitute the predominant economic benefit of the preventive intervention. From a societal perspective, prevention of perinatal HBV infection was estimated to save $41.8 million (in year 1993 dollars) in medical and work-loss costs.[10]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of[11]:

- Screening for HBV via the hepatitis B surface antigen test averaged $22; approximately 95% of all paid claims fell within the range of $0 to $64 per test.
- An adult HBV vaccine averaged $35; approximately 95% of all paid claims fell within the range of $0 to $77.
- Vaccine administration averaged $10; approximately 95% of all paid claims fell within the range of $0 to $20 (3 doses are usually needed for full protection).

	In 2004, the private-sector cost of post-exposure hepatitis B immune globulin prophylaxis (for infants born to HBV-positive women) averaged $178 and approximately 95% of all paid claims fell within the range of $0 to $514.[11]
Estimated Cost of Treatment	The cost of therapeutic treatment of chronic hepatitis B varies according to the medication required; a single course of interferon therapy costs $5,570 including provider visits and laboratory costs (in year 1995 dollars).[12]
Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention	The estimated cost of preventing a perinatal HBV infection is $164 per year of life saved, (in year 1993 dollars).[10] In comparison to other preventive interventions and to commonly accepted cost-effectiveness benchmarks, hepatitis B screening is highly cost-effective.

Preventive Intervention Information

Preventive Intervention: Purpose of Screening and Immunization	Screening pregnant women for HBV, immunizing women at high-risk of HBV, and treating the infants of HBV-positive women with post-exposure hepatitis B immune globulin prophylaxis and HBV vaccination, can dramatically reduce perinatal HBV transmission and, thus, the number of infants who become chronically infected with hepatitis B.[2]
Benefits and Risks of Intervention	The benefits of screening, immunization, and treatment are substantial; an untreated maternal hepatitis B viral infection may result in severe disease for the woman and chronic infection for the newborn.[2] There is no apparent risk of adverse effects for developing fetuses when a hepatitis B vaccine is administered to a pregnant woman.[3]
Initiation, Cessation, and Interval Screening	Screening for hepatitis B should be conducted at the first prenatal visit in each pregnancy. Women at increased risk of acquiring HBV may be screened again during the third trimester and/or during labor and delivery and should be offered the hepatitis B vaccine. Household contacts of women with a positive HBsAg test should also be screened for HBV infection. Women admitted for delivery without documentation of HBsAg test results should have blood drawn and tested as soon as possible after admission.[2]
Immunization	HBV immunization should be given to high-risk pregnant women as deemed appropriate by the clinician.[2] All infants should receive their first hepatitis B immunizations at the time of birth. Infants born to HBV-infected women should be immunized and given immune globulin within 12 hours of birth. Infants born to women with unknown HBsAg status should receive one dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours of birth, while awaiting the woman's test results.[2]
Treatment	Post-exposure hepatitis B immune globulin prophylaxis should be given, as medically indicated.[2]

Intervention Process Screening

The principal screening test for detecting an HBV infection (acute or chronic) is the identification of HBsAg in the blood. Testing methods include the HBsAg Immunoassay and the "rapid test," an assay that detects HBsAg and the hepatitis B e-antigen HBeAg simultaneously.

Immunization

HBV immunizations are administered via injection.

Treatment

Post-exposure hepatitis B immune globulin prophylaxis.

Treatment Information

Please refer to the "Intervention Process" section for information on preventive treatment.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

The U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence that universal prenatal screening for HBV infection using HBsAg substantially reduces prenatal transmission of HBV and the subsequent development of chronic HBV infection. The current practice of vaccinating all infants against HBV infection and post-exposure prophylaxis with hepatitis B immune globulin administered at birth to infants of HBV-infected women substantially reduces the risk for acquiring HBV infection.[1]

The American Academy of Family Physicians (AAFP)
Strength of Evidence: SR (Strongly Recommended)

- AAFP strongly recommends screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit.[5] Good quality evidence exists which demonstrates the substantial net benefit of screening for HBV over harm; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[5]

Recommended Guidance:

The Advisory Committee on Immunization Practices (ACIP)
Strength of Evidence: Expert Consensus

Screening

The ACIP recommends that all pregnant women be tested routinely for HBsAg during an early prenatal visit (e.g., first trimester) in each pregnancy, even if they have been previously vaccinated or tested. Women who were not screened prenatally, those who engage in behaviors that put them at high risk for infection (e.g., injection-drug use, having had more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually transmitted infection [STI], or recent or current injection-drug use) and those

with clinical hepatitis should be tested at the time of admission to the hospital for delivery.[2,3]

Immunization

The ACIP recommends the hepatitis B vaccine for pregnant women at risk for hepatitis B virus infection.

This recommendation is supported by:
The U.S. Preventive Services Task Force (USPSTF)

Management of Exposed Infants/Treatment

The ACIP recommends that all infants born to HBsAg-positive women should receive single-antigen hepatitis B vaccine and HBIG (0.5 mL) within 12 hours of birth, administered at different injection sites.[2]

The ACIP recommends that all infants born to women without documentation of HBsAg test results should receive the first dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours of birth, while the woman's test results are pending.[2]

Authored by:

Campbell KP, Lindley MC, Lentine D, Bhatt A. Hepatitis B virus evidence-statement: screening, immunization, and treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Human Immunodeficiency Virus (HIV) (Screening, Counseling, and Preventive Medication)

Clinical Preventive Service Recommendations (Screening)

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force recommends that clinicians screen all pregnant women for HIV.[1]

***Evidence Rating:* A (Strongly Recommend/Good Evidence)**

The USPSTF found good evidence that both standard and FDA-approved rapid screening tests accurately detect HIV infection in pregnant women and fair evidence that introduction of universal prenatal counseling and voluntary testing increases the proportion of HIV-infected women who are diagnosed and are treated before delivery. There is good evidence that recommended regimens of highly active antiretroviral therapy (HAART) are acceptable to pregnant women and lead to significantly reduced rates of mother-to-child transmission. Early detection of maternal HIV infection also allows for discussion of elective cesarean section and avoidance of breastfeeding, both of which are associated with lower HIV transmission rates. There is no evidence of an increase in fetal anomalies or other fetal harm associated with currently recommended antiretroviral regimens (with the exception of efavirenz). Serious or fatal maternal events are rare using currently recommended combination therapies. The USPSTF concluded that the benefits of screening all pregnant women substantially outweigh potential harms.[1]

CDC Recommendation

The Centers for Disease Control and Prevention (CDC) recommends that clinicians screen all pregnant women for HIV.[2]

- HIV screening should be a routine part of prenatal care for all women. Providers should inform all of their obstetric patients of the substantial benefit that knowledge of HIV status has for the health of a woman and her infant.
- HIV screening should occur as early as possible during pregnancy so that informed therapeutic decisions can be made and treatment can begin early. For women at high-risk of HIV infection (e.g., women who have a history of sexually transmitted infections [STIs], women who exchange sex for money or drugs, women who have multiple sex partners during pregnancy, and women who use illicit drugs during pregnancy) should be re-tested during the third trimester (at or before 36 weeks' gestation).
- Women who are admitted for labor and delivery who have not been screened for HIV or whose HIV status is unknown should be tested immediately so that timely prophylactic treatment can be initiated if appropriate. In such cases, rapid testing or the expedited return of standard testing results is recommended. After delivery, the standard confirmatory testing should be completed.
- HIV screening should be voluntary and free of coercion. Women should not be tested without their knowledge, and a woman's decision to decline testing must not have detrimental consequences for the quality of prenatal care or labor and delivery care she receives.

CDC recommends that all pregnant women receive counseling and educational information on HIV and HIV screening *before* they are screened/tested.[2]

- Information regarding HIV and the risks of HIV infection should be given to all pregnant women as a part of routine prenatal care health education.
- Pregnant women who have behaviors that place them at high risk for acquiring HIV infection (e.g., multiple sex partners, history of STIs, substance abuse, etc) should be referred to an HIV risk-reduction service (e.g., HIV centers with personnel trained in HIV counseling, drug treatment centers, etc).

Other Recommended Guidance

The U.S. Public Health Service concurs with the CDC recommendations regarding screening and counseling.

Important Screening Information

Regulations, laws, and policies regarding HIV screening of pregnant women and infants differ throughout the United States and its territories. Healthcare providers should adhere to local laws and regulations concerning maternal HIV screening.[3]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Public Health Service (USPHS)
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Approximately 120,000 to 160,000 HIV infected women live in the Unites States, 80% of whom are of childbearing age.[3] Each year between 1985 and 1995, approximately 6,000 to 7,000 HIV infected women gave birth. Infected women can pass on HIV to their infants (called perinatal HIV transmission) during pregnancy, during labor and delivery, or after delivery through breastfeeding.[3]

During the early 1990s, before preventive medication was available to prevent HIV transmission from an infected pregnant woman to her infant, an estimated 1,000 to 2,000 infants were born with HIV infection each year and the risk for mother-to-child transmission ranged from 16% to 25%.[3] Widespread universal screening and perinatal use of combination antenatal antiretroviral drugs and/or zidovudine combined with cesarean section sharply reduced transmission risk and thus the number of perinatally acquired HIV infections.[3] By 2001, the perinatal transmission rate was reduced to less than 2%.[3]

However, despite important screening and treatment advances, perinatal HIV transmission continues to occur; the CDC estimates that each year in the United

States 280 to 370 infants are born with HIV.3 Most exposed infants are born to women who were not tested for HIV prenatally or whose test results were unknown at the time of delivery.[3]

Condition/Disease Risk Factors

Risk factors for perinatal HIV transmission include immunologically or clinically advanced HIV disease in the woman, a high plasma viral load, preterm delivery, injection drug use during pregnancy, and breastfeeding. The risk of perinatal transmission also increases with protracted labor after the rupture of membranes, maternal infection with a secondary STI, and the use of certain obstetrical procedures.[3]

Value of Prevention

Economic Burden of Condition/Disease

Analysis of the KIDS Inpatient Database of the Healthcare Cost and Utilization Project (HCUP) estimated that there were 4,107 hospitalizations among HIV-infected children in the United States in 2000, which accounted for approximately $100 million in hospital charges and more than 30,000 hospital days.[4]

The estimated *lifetime* health care related cost of a pediatric HIV infection is estimated to range between $100,000 and $117,000 (in year 1994 dollars). The total costs depends on how rapidly an infant's HIV progresses to AIDS and the length of his or her life.[5]

Workplace Burden of Condition/Disease

Not Provided

Economic Benefit of Preventive Intervention

The economic benefit of the preventive intervention includes the value of life years saved plus savings that accrue by avoiding the lifetime cost of managing an HIV infection.

Estimated Cost of Preventive Intervention

The cost of screening, testing, and treating HIV varies significantly, depending on where the test is administered, whether counseling is also provided, and what treatment protocol is followed. In 2004, the private-sector cost of HIV screening averaged $29 (range $4 to $90); the cost of counseling averaged $39 (range $0-to $129).[6]

Estimated Cost of Treatment

The average wholesale price (AWP) for a 1-month supply of oral zidovudine (ZDV) tablets is $219.02 (generic) or $410.54 (brand – Retrovir®).[7] The AWP for 6 weeks worth of zidovudine syrup — the recommended treatment for exposed infants — is $48.13 (generic) or $54.73 (brand – Retrovir®). Retrovir® treatment for HIV-positive women during labor/delivery is $246.71 (cost varies depending on dose, which is based on the woman's weight).[7]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Researchers studied the costs associated with screening and treating HIV/AIDS in pregnant women and found that universal screening can be cost-saving in this population. For example, compared to no screening, a universal screening program targeting pregnant women would save an estimated $3.69 million dollars and prevent 64.6 cases of pediatric HIV infection for every 100,000 pregnant women screened.[8]

Preventive Intervention Information	
Preventive Intervention: Purpose of Screening, Counseling, and Preventive Medication	The purpose of screening is to identify infected women early in the course of pregnancy. Early identification and the administration of preventive medication can reduce perinatal transmission rates to less than 2%.[3] Counseling services are required to educate women on the benefits and risks of screening, risk reduction strategies, and, for those who screen positive, treatment options.
Benefits and Risks of Intervention	The risks associated with screening for HIV include the potential negative consequences of HIV infection such as discrimination and stigmatization, loss of relationships, domestic violence, and adverse psychological reactions such as depression or anxiety. The benefit of identification and early treatment — both necessary to prevent perinatal HIV transmission — outweigh the risks and costs associated with screening. Further, many of the aforementioned risks can be reduced through appropriate education and counseling.[3]
Initiation, Cessation, and Interval of Screening	HIV screening should occur as early as possible during pregnancy so that informed therapeutic decisions can be made and treatment can begin early. For women at high risk of HIV infection (e.g., women who have a history of STIs, women who exchange sex for money or drugs, women who have multiple sex partners during pregnancy, and women who use illicit drugs during pregnancy) should be re-tested during the third trimester (at or before 36 weeks' gestation). Women who are admitted for labor and delivery who have not been screened for HIV or whose HIV status is unknown should be tested immediately so that timely prophylactic treatment can be initiated if appropriate. In such cases, rapid testing or the expedited return of standard testing results is recommended. After delivery, the standard confirmatory testing should be completed.[2]
Counseling	Counseling should be provided before and after screening, as medically indicated.
Preventive Medication	Preventive medication should be provided, as medically indicated, to prevent perinatal transmission.
Intervention Process: Screening	Screening for HIV should be conducted with an Food and Drug Administration (FDA)-licensed enzyme immunoassay (EIA). If positive, the EIA should be followed by a confirmatory test with an FDA-licensed supplemental test such as the Western blot test. If a woman is being screened for the first-time during labor and delivery, a rapid assay test should be used in place of the EIA. A rapid test can provide a definitive negative result and a preliminary positive result, thus identifying women who could benefit from antiretroviral treatment and a cesarean delivery, and identifying infants who could benefit from antiretroviral prophylactic treatment. Rapid tests should be confirmed by a supplemental test, but, due to time constraints, suspected HIV positive women may be offered treatment before the results of the supplemental test are received. Only one FDA-approved rapid HIV test is currently available in the United States, the Abbott

Murex Single Use Diagnostic System HIV-1 test. Other tests are pending approval.[2]

Counseling

All pregnant women should receive counseling and educational information on HIV and HIV screening before they are screened.[2] Pregnant women who have behaviors that place them at high risk for acquiring HIV infection (e.g., multiple sex partners, history of STIs, substance abuse, etc) should be referred to an HIV risk-reduction service (e.g., HIV centers with personnel trained in HIV counseling, drug treatment centers, etc).[1] HIV-infected pregnant women should receive HIV prevention counseling. This counseling should include discussion of the risk for perinatal HIV transmission, ways to reduce this risk, and the prognosis for infants who become infected. HIV-infected pregnant women should be counseled regarding antiretroviral therapy during pregnancy to improve their health and prevent perinatal transmission.[3]

Preventive Medication

The primary strategy to prevent perinatal transmission (in addition to avoidance of breastfeeding) is antiretroviral chemoprophylaxis using zidovudine (ZDV), now often part of a combined antiretroviral therapy regimen that reduces viral load as low as possible near the time of delivery. ZDV should be administered orally to the mother during the second and third trimesters of pregnancy; intravenous administration of ZDV should be given to the woman during labor and delivery. Infants born to HIV-positive women should be given ZDV during the first 6 weeks of life.[3]

Treatment Information

Health benefits should include provisions for ongoing treatment for HIV-positive women and their infants.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to recommend that clinicians screen all pregnant women for HIV.[1]

Recommended Guidance:

The Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Not Specified

- The CDC recommends that clinicians screen all pregnant women for HIV.[2]
- The CDC recommends that all pregnant women receive counseling and educational information on HIV and HIV screening before they are screened/tested.[2]
- The CDC recommends that zidovudine be administered orally to HIV-positive pregnant women during the second and third trimesters of pregnancy and

intravenously during labor and delivery. The CDC also recommends that oral ZDV be administered to exposed infant during the first 6 weeks of life.[2]

These recommendations are supported by the:

- U.S. Public Health Service

Authored by:

Lentine D, Campbell KP. Human immunodeficiency virus evidence-statement: screening, counseling, and preventive medication. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Influenza (Immunization)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

Not Applicable – The U.S. Preventive Services Task Force defers to the Advisory Committee on Immunization Practices and the CDC on recommendations surrounding immunization.

CDC Recommendation

The Advisory Committee on Immunization Practices (ACIP) recommends that all women who are pregnant during the influenza season (October to mid-May) be vaccinated with trivalent inactivated influenza vaccine.[1] Because this population is considered at risk for influenza-related complications, it should be given priority access to the vaccine in case of shortage.[2]

Note: Live attenuated influenza vaccine (LAIV) is contraindicated during pregnancy. Because the intranasal vaccine spray contains live virus, it should not be administered to pregnant women.[1]

A summary of guidelines for the immunization of pregnant women can be found online (www.cdc.gov/nip/publications/preg_guide.htm).

Evidence Rating:

Expert Consensus

Other Recommended Guidance

The American Academy of Family Physicians (AAFP) and the American College of Obstetricians and Gynecologists (ACOG) concur with the ACIP recommendations.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Advisory Committee on Immunization Practices (ACIP)
- American Academy of Family Physicians (AAFP)
- American College of Obstetricians and Gynecologists (ACOG)
- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Influenza is a viral respiratory tract infection that occurs during the winter months in temperate climates. Uncomplicated cases of the illness usually resolve within several days to weeks and include fever, cough, sore throat, headache, muscle aches, and tiredness.

Influenza infection can exacerbate other underlying medical conditions and can lead to hospitalization or even death.[1] Throughout the 1990s in the United States, influenza infection was associated with an average of 36,000 deaths and over 200,000 hospitalizations per year.[3-4]

Pregnant women are considered to be at increased risk for complications from influenza infection. Healthy pregnant women in their third trimester are hospitalized for influenza at rates as high as 250 per 100,000 reported cases.[1] Rates are higher among pregnant women with other underlying medical conditions. Researchers estimate that an average of 1 to 2 hospitalizations can be prevented for every 1,000 pregnant women vaccinated.[5]

Despite the seriousness of influenza infection and the fact that the inactivated influenza vaccine is safe and effective, only 12% to 13% of pregnant woman are inoculated against influenza.[1,6]

Condition/Disease Risk Factors

All pregnant women who are not immunized against influenza are at risk of infection.

Value of Prevention

Economic Burden of Condition/Disease

The overall national economic burden of influenza-attributable illness for adults aged 18 to 64 years is $4.6 billion in direct medical costs and an additional $5.6 billion in lost productivity resulting from 17 million missed workdays.[7] Furthermore, adult hospitalizations from influenza-attributable illness result in 3.1 billion dollars per year in direct hospitalization costs (in year 2003 dollars).[7]

Workplace Burden of Condition/Disease

Influenza-related complications during pregnancy increase medical care costs and productivity losses triggered by lost work days. An infected employee may also spread infection to other employees or family members.

Economic Benefit of Preventive Intervention

Although no study specifically examined the case for pregnant women, studies of the economic benefit of immunization in working adults commonly include reduced hospitalizations, physician visits, and lost workdays; and an increase in quality-adjusted days due to symptom relief from influenza-like illness.[8-9]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of an adult influenza vaccine averaged $13 and approximately 95% of all paid claims fell within the range of $3 to $24 per vaccine.[10] Vaccine administration averaged $10 per dose and approximately 95% of all paid claims fell within range of $0 to $20 per dose.[10]

Estimated Cost of Treatment

Zanamivir and oseltamivir, the antiviral medications recommended for treatment of influenza, have not been studied in pregnant women. Because of the unknown effects of these drugs, they should only be used during pregnancy if the potential benefit justifies the potential risk to the embryo or fetus.[1]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

A review of several economic studies shows that vaccination of healthy working adults is cost-effective and may result in cost-savings in some years.[11] Though no specific study was conducted with reference to pregnant women, economic results are likely to be at least as favorable for this group since pregnant women are at high risk for influenza-related complications.

Preventive Intervention Information

Preventive Intervention: Purpose of Immunization

Immunization against influenza reduces the chance that a pregnant woman will contract influenza thereby reducing her chance of experiencing influenza-related illness, hospitalization, and associated costs.

Benefits and Risks of Intervention

There are many benefits to influenza vaccination. First, when a pregnant woman is immunized during pregnancy, antibodies can be passed to her fetus and can also be passed in breast milk.[6] Because children under 6 months are at high risk of complications from influenza, but cannot be vaccinated themselves, the vaccination of persons who may transmit influenza to infants is recommended.[1] That includes parents, siblings, and other caregivers. Second, healthy, working adults who receive influenza shots (in a year when the vaccine is well matched to the circulating influenza viruses) experience significantly fewer days of influenza-like illness (ILI), make fewer doctor visits for such illnesses, and take fewer days off from work due to ILIs, compared to unvaccinated workers.[8-9]

Influenza vaccination with inactivated virus is considered to be safe for both pregnant women and their fetuses. Two studies with a total of over 2,250 pregnant women found no adverse events after vaccination, regardless of when during pregnancy the vaccine is given.[6,12]

No studies have been conducted on the safety of LAIV in pregnant women.

Initiation, Cessation, and Interval of Immunization

All women who will be pregnant during the influenza season (October to mid-May) should be given the inactivated influenza vaccine at some point during pregnancy. This single-dose vaccine may be administered during any trimester.[1] The ideal time to vaccinate is October and November, although vaccination in December or even later can still be beneficial since influenza activity peaks in February or later in most years.[1]

It is important to note that a woman should receive an influenza vaccination with each pregnancy to protect herself and her fetus. Immunity gained from the influenza vaccine does not carry from year to year. Influenza vaccination is also recommended for all household contacts of children less than 5 years of age and particularly for households with children less than 6 months of age since infants are at very high risk of influenza complications but are too young to receive the influenza vaccine.[1]

Intervention Process

Inactivated influenza vaccine is administered via intra-muscular injection. Injections can be administered in various settings including doctor office visits or at the worksite.

Treatment Information

Influenza-specific antiviral medications are available, but no safety studies have been conducted in pregnant women. Because of the unknown effects of these drugs on fetuses, they should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus.[1]

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

Advisory Committee on Immunization Practices (ACIP)
Strength of Evidence: Expert Consensus

- The ACIP recommends vaccinating all women who are/will be pregnant during the influenza season (October to mid-May) with trivalent inactivated influenza vaccine.[1]

This recommendation is supported by the:

- American Academy of Family Physicians (AAFP)
- American College of Obstetricians and Gynecologists (ACOG)
- U.S. Preventive Services Task Force (USPSTF)

Authored by:

Lindley MC, Bhatt A. Influenza evidence-statement: immunization. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Preeclampsia (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

In 1996, the U.S. Preventive Services Task Force (USPSTF) recommended that clinicians screen all pregnant women for preeclampsia by taking a blood pressure measurement at the first prenatal visit and periodically throughout the pregnancy.[1]

Given the availability of new evidence, the USPSTF decided to update its 1996 recommendation. This work is in a queue to be scheduled for review.

Other Recommended Guidance American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists (ACOG) recommends that clinicians monitor blood pressure at the first prenatal visit, every 4 weeks until 28 weeks' gestation, every 2 to 3 weeks until 36 weeks' gestation, and weekly thereafter.[2]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Pediatrics (AAP)
- American College of Obstetricians and Gynecologists (ACOG)
- Agency for Healthcare Quality and Research (AHRQ)
- National Vital Statistics
- Peer-reviewed research
- Preeclampsia Foundation
- World Health Organization (WHO)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Preeclampsia occurs when a woman with normal blood pressure experiences acute hypertension (140 mm Hg or higher systolic or 90 mm Hg or higher diastolic) or an increase blood pressure (an increase of $\geq$ 30 mm Hg in systolic blood pressure or $\geq$ 15 mm Hg in diastolic blood pressure) after 20 weeks' of gestation.[3] While more common towards the end of pregnancy, preeclampsia can appear as early as 20 weeks' gestation. Symptoms of the condition include the presence of protein in the urine, swollen extremities, sudden weight gain, headaches, and changes in vision. However, many women report no symptoms.[4]

Preeclampsia affects 5% to 7% of all pregnancies.[5] Women with preeclampsia are at an increased risk for placental abruption, acute renal failure, cerebral hemorrhage, disseminated intravascular coagulation, pulmonary edema,

circulatory collapse, and progression to full-blown eclampsia, an extremely serious condition characterized by maternal seizure activity, coma, and death. Preeclampsia can also cause severe problems for the fetus such as delayed growth, low birth weight, and the risk of premature birth.[6]

Preeclampsia/eclampsia is the third leading cause of maternal death worldwide[1] and is responsible for 18% of all maternal deaths in the United States.[7] In the United States during 2002, preeclampsia/eclampsia caused:

- Maternal death in 56 out of every 100,000 live birth.[8]
- Neonatal death in 71 out of every 100,000 live births.[9]

Condition/Disease Risk Factors

Research indicates that women that are pregnant for the first time, women with multiple gestations, molar pregnancy or fetal hydrops, chronic hypertension or diabetes, and those with a personal or family history of eclampsia or preeclampsia are at increased risk for preeclampsia and eclampsia. Overweight and obese women are also at increased risk of preeclampsia.[10]

Value of Prevention

Economic Burden of Condition/Disease

According to the Hospital Cost Utilization Project (HCUP) Nationwide Inpatient Survey (NIS), spending on hypertension during pregnancy totaled nearly $2.3 billion in the United States in 2003.[11] During that year, approximately 204,868 pregnant women were admitted to the hospital for hypertension, staying an average of 3.5 days. The average per-person charge for such hospital admissions totaled $11,208.[11] Few data are available about the incremental costs for infants because of preeclampsia or the value of years of life lost due to preeclampsia and its complications, including maternal or neonatal deaths.

Workplace Burden of Condition/Disease

The medical care costs of maternal and neonatal complications due to preeclampsia impose an additional financial burden on employer-sponsored health insurance plans.

Pregnancy-related complications affecting their own health or the health of their children may also require working mothers to take significant time off from work, resulting in additional productivity losses at the workplace.

Economic Benefit of Preventive Intervention

Screening, which involves minimal cost, and early treatment can minimize and prevent otherwise costly medical conditions. For example, although there is a lack of recent research, there is acceptance of the finding that women with preeclampsia or eclampsia stay in the hospital substantially longer than do normotensive women (i.e., women having blood pressure typical of the group to which they belong), regardless of their method of delivery. The longer hospital stays and higher rates of cesarean section delivery among women with preeclampsia and eclampsia lead to more costly obstetric medical claims. For example, 217,700 excess hospital days for delivery admissions were attributable to preeclampsia and eclampsia in 1986.[10]

Estimated Cost of Preventive Intervention	Blood pressure screening is a standard procedure at each office visit and involves minimal cost. Screening for preeclampsia is conducted as a part of routine prenatal care and does not require a separate visit.
Estimated Cost of Treatment	Not Provided
Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention	Complete cost-effectiveness analyses are not available.

Preventive Intervention Information

Preventive Intervention: Purpose of Screening	Screening allows clinicians to identify affected women early in the course of their pregnancies and begin treatment, thereby reducing the risk of complications for affected women *and* their infants.
Benefits and Risks of Intervention	Regular blood pressure screening during pregnancy is used to detect preeclampsia. Early detection of hypertension permits continuous monitoring and early intervention (e.g., bed rest, medications, early delivery). Although studies have not shown that early identification of hypertension and preeclampsia is associated with better outcomes, clinical experience suggests that to be the case. As such, the medical community considers regular blood pressure screening to be in the best interest of both mother and fetus. At the same time, blood pressure screening is simple, inexpensive, and acceptable to patients.
Initiation, Cessation, and Interval of Screening	ACOG recommends that clinicians monitor blood pressure at the first prenatal visit, every 4 weeks until 28 weeks' gestation, every 2 to 3 weeks until 36 weeks' gestation, and weekly thereafter.
Intervention Process	Screening for preeclampsia can be conducted via conventional measures (arm cuff and a mercury calibrated aneroid or digital sphygmomanometer) or ambulatory blood pressure monitoring. Before a diagnosis of preeclampsia can be made, the patient must have two elevated blood pressure readings (defined as $\geq$ 140/90 mmHg) taken at least 6 hours apart. Preeclampsia may also be diagnosed if a woman has undergone an increase of 30 mmHg or more in systolic pressure or 15 mmHg or more in diastolic pressure since becoming pregnant. Clinicians should be aware that overweight and obese patients may need to be monitored more closely, especially if they have preexisting hypertension, due to their increased risk of preeclampsia.[2]
Treatment Information	Treatment methods for preeclampsia include bed rest, medication, and delivery. Health benefits should include provisions for follow-up and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

The American College of Obstetricians and Gynecologists (ACOG)
Strength of Evidence: Not Specified

- The American College of Obstetricians and Gynecologists recommends screening pregnant women for preeclampsia by monitoring blood pressure at the first prenatal visit, every 4 weeks until 28 weeks' gestation, every 2 to 3 weeks until 36 weeks' gestation, and weekly thereafter.[2]

Authored by:

Campbell KP, Chattopadhyay S. Preeclampsia evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (Screening and Testing)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendations

In 1996, the U.S. Preventive Services Task Force (USPSTF) recommended that clinicians offer serum multiple marker screening to all pregnant women at low risk for Down syndrome and amniocentesis or chorionic villus sampling (CVS) testing to all pregnant women at high risk for Down syndrome.

This recommendation is considered out of date and has been archived.

In 1996, the U.S. Preventive Services Task Force recommended that clinicians offer neural tube defect screening to all pregnant women who have access to adequate prenatal care, counseling, and follow-up services.

Screening for neural tube defects during pregnancy is currently considered part of standard prenatal care. The USPSTF knows of no reason at the present time to update its 1996 recommendation.

Recommended Guidance

Offering pregnant women screening and testing (prenatal diagnosis) to detect chromosomal abnormalities is standard clinical practice. All pregnant women are candidates for screening services. Most clinical guidelines recommend that women age 35 and older (and those who have equivalent risk) be offered testing in place of, or in addition to, screening.[1]

Offering all pregnant women (irrespective of age) screening services to detect neural tube defects (NTDs) and offering testing services (prenatal diagnosis) to women at elevated risk is standard clinical practice.[2]

There are several screening and prenatal diagnosis methods available. There is no single current authoritative source on which of the various methods provides the best outcome. Therefore, it is recommended that employers provide healthcare coverage for all screening and testing methods, including — but not limited to — the following:

- All types of maternal serum screening tests
- Amniocentesis
- Chorionic villus sampling (CVS)
- Ultrasound

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Obstetricians and Gynecologists (ACOG)
- Centers for Disease Control and Prevention (CDC)
- March of Dimes
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)
- U.S. Public Health Service

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Chromosomal Abnormalities

Down syndrome (trisomy 21) is the most common chromosomal abnormality in the United States, affecting 1 in every 800 to 1,000 live-born babies.[3] Children with Down syndrome have physical abnormalities including heart defects, short stature, characteristic facial abnormalities, and varying degrees of mental retardation. Although Down syndrome and its complications cannot be cured, early intervention programs that begin in infancy may help those living with Down syndrome achieve certain developmental milestones in a more timely fashion.

Life expectancy among individuals with Down syndrome has increased substantially over the past three decades. In 1983, the average life expectancy for an individual with Down syndrome was 25 years; by 1997, life expectancy had risen to 49 years.[4] However, life expectancy gains have not been equal among individuals with Down syndrome, and large survival disparities have been noted between white and black infants.[4]

Other chromosomal abnormalities include trisomy 13, trisomy 18, and sex-chromosome abnormalities. Trisomy 13 and 18 are very severe and usually cause fetal or infant death.[5] Sex-chromosome abnormalities are the most mild form or chromosomal abnormality and occur in approximately 1 in every 2,000 to 2,500 female infants and 1 in every 600 to 800 male infants.[5] These abnormalities lead to sexual development problems (including infertility) and, sometimes, behavioral or learning problems.[5]

Neural Tube Defects (NTDs)

Spina bifida and anencephaly are common and permanent neural tube defects (NTDs) which result from the failure of the neural cord to properly fuse. Each year in the United States, approximately 3,000 pregnancies are affected by NTDs and approximately 2,200 infants are born with neural tube defects.[6] Many NTD-affected pregnancies do not result in a live birth since they are electively or spontaneously aborted (commonly referred to as a miscarriage) or result in fetal death or stillbirth.

Anencephaly is fatal; all affected infants die shortly after birth. Approximately 92% of infants born with spina bifida survive with varying degrees of disability. Debilitating medical complications associated with spina bifida include paralysis and bowel and bladder incontinence.[7]

Condition/Disease Risk Factors

Chromosomal Abnormalities

The risk of Down syndrome increases dramatically with advancing maternal age. For example, the risk of delivering a baby with Down syndrome is about 1 in 1,250 for a 25-year-old woman, 1 in 1,000 for a 30-year-old woman, 1 in 400 for a 35-year-old woman, and 1 in 100 for a 40-year-old woman.[8] Risk factors other than age are poorly understood, and 97% of Down syndrome pregnancies occur in families with no previous history of the syndrome.[1]

As with Down syndrome, the risk of trisomy 13 and trisomy 18 increases with advancing maternal age; women age 35 or older are most at risk for these conditions.[5]

Neural Tube Defects (NTDs)

Inadequate folic acid consumption is the major risk factor for NTDs. Consuming the recommended daily amount of folic acid (0.4-0.8mg) can reduce a woman's chance of having a NTD-affected pregnancy by 40% to 80%.[9] However, only 33% of childbearing-age women report taking vitamins that contain folic acid.[9]

Spina bifida, the most common type of NTD, occurs most frequently among Hispanics and European whites and least frequently among African-Americans and Asians. Low socioeconomic status has been reported to be a risk factor for NTDs.[10]

Value of Prevention

Economic Burden of Condition/Disease

The economic impact of chromosomal abnormalities and NTDs is substantial.

The *lifetime* cost of live-born infants with Down syndrome includes the incremental medical, developmental, and special education costs as well as lost productivity and earnings due to death and disability. The total *lifetime* cost for all cases of Down syndrome (based on 1988 cross-sectional data) was estimated to exceed $1.8 billion in year 1992 dollars.[11]

The total lifetime cost for a child born with spina bifida is estimated at $636,000 (in year 2002 dollars).[12] Applying that cost to the prevalence rate for spina bifida from National Birth Defect Prevention Network data[13] (4 million live births each year) yields an estimated $814 million in *lifetime* costs for each cohort.[12] Costs associated with NTDs are shared by parents, employers, and communities.

Workplace Burden of Condition/Disease

Lost productivity attributable to premature morbidity and mortality due to Down syndrome was estimated to total $1.18 billion in 1992 dollars, comprising nearly 64% of total *lifetime* cost for all cases of Down syndrome.[11]

Apart from the incremental excess cost of medical care for affected children, employers face productivity losses of employees who must care for affected children. The present value of lost workdays for a typical caregiver was estimated to be $252,000 in year 1993 dollars.[14]

Economic Benefit of Preventive Intervention

The economic benefit of prenatal screening is defined as the averted cost from preventing the birth of a child with a chromosomal abnormality or NTD. These averted costs include savings from the direct costs of medical, developmental, and special education services as well as the indirect costs associated with lost productivity due to morbidity and mortality.[12]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of[15]:

- Screening for NTDs via ultrasound averaged $155; approximately 95% of all paid claims fell within the range of $41 to $352 per ultrasound.
- Screening for chromosomal abnormalities averaged $56; approximately 95% of all paid claims fell within the range of $0 to $158 per test. The full range of tests totaled, on average, $8,255.
- Genetic testing (including complete gene sequence analysis) averaged $408 per test; approximately 95% of all paid claims fell within the range of $0 to $1,852. The full range of tests totaled, on average, $5,013.
- Genetic counseling averaged $39; approximately 95% of all paid claims fell within the range of $1 to $129.
- An amniocentesis averaged $296.
- Chorionic villus sampling averaged $355.

Estimated Cost of Treatment

When birth defects are detected, the cost of treatment may include costs associated with genetic counseling and termination.

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

California is one of two states with a public prenatal screening program, which is supported by fees paid by prenatal care providers and insurers. In 1998, the fee paid by payers was $105, which covered the cost of the State's expanded screening program for chromosomal abnormalities and NTDs. The fee covered both the initial screening and reimbursements for genetic counseling, ultrasound, amniocentesis, and genetic testing.[16] The California prenatal screening program estimated a benefit-to-cost ratio of 2.7, meaning that, on average, each $1 spent on the program would be offset by $2.70 in economic benefits calculated using a discount rate of 5% per year.[16]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening and Testing

The major benefit of screening for and diagnosing chromosomal abnormalities and NTDs is the opportunity to inform women and their partners of the likelihood that they are carrying an affected fetus. The usefulness of this information depends on the values and preferences of the parents. With appropriate information and counseling, parents can decide whether to terminate or continue a pregnancy. Parents who decide to continue the pregnancy have an opportunity to prepare emotionally and financially for the birth of their child.

Benefits and Risks of Intervention

The knowledge gained by screening can help women and their families make an informed decision as to whether or not to undergo prenatal diagnosis (testing). In turn, prenatal diagnosis can help women and their families make an informed decision about whether to continue or terminate the pregnancy. Prenatal diagnosis of a chromosomal abnormality or NTD may preclude trauma associated with the unexpected delivery of an affected infant.[1] Furthermore, information gained from prenatal diagnosis may help providers better prepare for the delivery of an affected infant.[1,17] For example, some studies show reduced severity of paralysis in infants with spina bifida delivered by cesarean section compared with those having vaginal delivery.[17]

The risks of screening and prenatal diagnosis depend on the method used. The major risk associated with screening is the chance of a false-positive result, which can lead to unnecessary anxiety.[16] Thus, confirmatory testing (prenatal diagnosis) is considered to be essential. Risks of prenatal diagnosis include the risks associated with amniocentesis or CVS (in very rare cases the fetus can be injured, suffer an infection, or miscarry), the psychological effects for the woman and her partner of a positive result, and the risks associated with abortion.

Many women who test positive for an NTD-affected pregnancy choose to terminate their pregnancy. Screening thus leads to the prevention of the births of affected infants. In fact, some studies have shown that the availability of screening, testing, and the opportunity for termination reduces the number of infants born with NTDs by up to 70%.[16] However, termination rates vary depending on the ethnic and religious backgrounds of the families and many other factors. In one study of an ethnically diverse population in California, termination rates for spina bifida averaged 67%.[16] It is important to remember that many women who choose to carry the pregnancy to term will have either a stillborn fetus or an infant who will die in the first few hours or days after birth.

Initiation, Cessation, and Interval of Screening and Testing

The screening and testing process is defined by several factors: the type of test utilized, whether there is need for follow-up testing, and the risk-status of the pregnant woman. Timing is left to the discretion of the physician and should be determined by the pregnant woman's needs and the stage of pregnancy when she began prenatal care.

Intervention Process

Several screening methods are used to determine risk for chromosomal abnormalities and NTDs. Most methods examine biological markers in maternal blood samples.

Down syndrome can be diagnosed prenatally by identifying an extra chromosome 21 through a cell sample. Fetal cell samples can be obtained through an amniocentesis, chorionic villus sampling (CVS), or cordocentesis.[1]

Treatment Information

Health benefits should include provisions for follow-up services such as:

- Genetic counseling
- Termination *or* continuing prenatal care and labor and delivery.

Cures for chromosomal abnormalities and NTDs are not available, but various interventions can be used to improve the functioning or quality of life of those who are affected.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

Offering pregnant women screening and testing (prenatal diagnosis) to detect chromosomal abnormalities is standard clinical practice. All pregnant women are candidates for screening services. Most clinical guidelines recommend that women age 35 and older, (and those who have equivalent risk) be offered testing in place of, or in addition to, screening.[2-3]

Offering all pregnant women (irrespective of age) screening to detect neural tube defects (NTDs) and offering testing (prenatal diagnosis) to women at elevated risk is standard clinical practice.[2-3]

There are several screening and prenatal diagnosis methods available. There is no single current authoritative source on which of the various methods provides the best outcome. Therefore, it is recommended that employers provide healthcare coverage for all screening and testing methods, including — but not limited to — the following:

- All types of maternal serum screening tests
- Amniocentesis
- Chorionic villus sampling (CVS)
- Ultrasound

Authored by:

Campbell KP, Grosse S, Chattopadhyay S. Prenatal diagnosis of chromosomal abnormalities and neural tube defects evidence-statement: screening and testing. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Rh (D) (Screening and Preventive Medication)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.[1]

The USPSTF also recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women between 24 and 28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.[1]

***Evidence Rating:* A (Strongly Recommend/Good Evidence)**

The USPSTF found good evidence that Rh (D) blood typing, anti-Rh (D) antibody testing, and intervention with Rh (D) immunoglobulin, as appropriate, prevents maternal sensitization and improves outcomes for newborns. The benefits substantially outweigh any potential harms.[1]

B (Recommend/At Least Fair Evidence

The USPSTF found fair evidence that repeated antibody testing for unsensitized Rh (D)-negative women (unless the father is also known to be Rh [D]-negative) and intervention with Rh (D) immunoglobulin, as appropriate, provides additional benefit over a single test at the first prenatal visit in preventing maternal sensitization and improving outcomes for newborns. The benefits of repeated testing substantially outweigh any potential harms.[1]

The American Academy of Family Physicians (AAFP) concurs with the USPSTF.

Other Recommended Guidance American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists (ACOG) concurs with the U.S. Preventive Service Task Force (USPSTF) recommendations, with the exception that ACOG strongly recommends that clinicians administer immunoglobulin to Rh (D)-negative pregnant women after undergoing invasive procedures such as chronic villus sampling or fetal blood sampling.[2]

ACOG further recommends that immunoglobulin be administered following a possible spontaneous or elective abortion, second or third trimester bleeding, external cephalic version, or abdominal trauma.[2]

Evidence Rating:

Expert Consensus

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatricians (AAP)
- The American College of Obstetricians and Gynecologists (ACOG)
- National Institutes of Health (NIH)
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Rh (D) incompatibility refers to a condition that develops when a pregnant women with Rh-negative blood type carries a fetus with an Rh-positive blood type. In reaction to what is perceived to be a foreign substance, the woman's body makes antibodies that attack fetal red blood cells (isoimmunization). Since it takes time to build up antibodies, first pregnancies are typically not affected by Rh incompatibility. However, in subsequent pregnancies, Rh incompatibility may cause destruction of fetal red blood cells (hemolysis), which leads to anemia and an accumulation of bilirubin in the fetus's bloodstream (hyperbilirubinemia) that produces jaundice. Extreme jaundice leads to kernicterus, a form of brain damage associated with cerebral palsy and mental retardation. The hemolytic destruction of red blood cells can also lead to hydrops fetalis, a severe anemia resulting in fetal heart failure, total body swelling, respiratory distress or total circulatory collapse, and often death.[3]

Rh incompatibility occurs in approximately 10% of all pregnancies, depending on the race of the pregnant woman and her fetus. Without treatment, 25% to 30% of these fetuses will show various degrees of hemolytic anemia and hyperbilirubinemia. An additional 20% to 25% will be hydropic and will either die *in utero* (resulting in a stillbirth) or shortly after birth. Hemolytic disease of the fetus accounts for 4 to 5 deaths per 100,000 births in the United States.[3]

Condition/Disease Risk Factors

Only Rh-negative women are at risk of having a baby with Rh disease. If an Rh-negative woman and Rh-positive man conceive an Rh-positive fetus, there is a chance that some of the fetus's Rh-positive red blood cells may enter the woman's blood stream, which stimulates the woman's immune system to produce antibodies against the fetus's Rh-positive cells. The risk of Rh disease becomes greater with each subsequent pregnancy.[4]

Value of Prevention

Economic Burden of Condition/Disease

No data exist that estimate the total direct or indirect costs of Rh (D) incompatibility in the United States.

	The value of life years lost due to fetal loss, stillbirth, neonatal and post-neonatal deaths, and productivity loss associated with disability constitute the major components of the economic burden of Rh (D) incompatibility. Costs would be even higher if the additional medical care costs and productivity losses of working pregnant women are considered.
Workplace Burden of Condition/Disease	In addition to the incremental medical care utilization costs due to complications from Rh (D) incompatibility, there can be significant productivity losses at the workplace when working parents need to take time off from work to care for short- or long-term health problems of their children.
Economic Benefit of Preventive Intervention	Early identification of Rh (D) incompatibility allows clinicians to begin treatment before damage is done to the fetus. This prevents otherwise expensive medical treatment, lifelong disability, and even death.
Estimated Cost of Preventive Intervention	In 2004, the private-sector cost of screening for Rh (D) incompatibility averaged $15 per screen; approximately 95% of all paid claims fell within the range of $0 to $38. The cost of immune globulin averaged $111 and approximately 95% of all paid claims fell within the range of $0 to $178.[5]
Estimated Cost of Treatment	Not Provided
Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention	A review undertaken on behalf of the National Institute of Clinical Excellence in the United Kingdom, the governmental unit responsible for producing evidence-based recommendations for the UK, found that routine antenatal anti-D preventive medication (immunoglobulin) provides a cost-effective intervention for preventing the incidence of hemolytic disease of the newborn in pregnancies of Rh (D)-negative women.[6]
Preventive Intervention Information	
Preventive Intervention: Purpose of Screening and Preventive Medication	Early identification of Rh (D) incompatibility allows clinicians to begin treatment before damage is done to the fetus. This prevents otherwise expensive medical treatment, lifelong disability, and even death.
Benefits and Risks of Intervention	Early detection of Rh (D)-negative blood type in a pregnant woman is of substantial benefit (when the woman is not yet isoimmunized and the father of the fetus is not known to be Rh (D)-negative) because it makes prevention of isoimmunization possible. Clinicians can administer anti-D immune globulin to Rh (D)-negative pregnant women, thereby preventing the maternal isoimmunization that would adversely affect subsequent pregnancies. This course of treatment prevents isoimmunization in 96% of women at risk.[4] Screening and treatment with immunoglobulins have few adverse affects.[4]
Initiation, Cessation, and Interval	The USPSTF strongly recommends that all pregnant women undergo Rh (D) blood typing and antibody testing at their first prenatal visit. Furthermore, the

USPSTF recommends that women known to be Rh (D)-negative and unsensitized undergo a repeat Rh (D) antibody test between 24 and 28 weeks' gestation to determine their degree of sensitivity. This second step is unnecessary if the fetus's father is known to be Rh (D)-negative.

A full dose (300mg) of immunoglobulin should be administered to[1-2]:

- All unsensitized Rh (D)-negative women after their repeated antibody screen between 24 and 28 weeks' gestation.
- D-negative women within 72 hours of delivering a Rh (D)-positive infant.
- D-negative women following amniocentesis or either induced or spontaneous abortion (a 50 mg dose should be administered when abortion occurs prior to 13 weeks).

Clinicians have discretion regarding the provision of immunoglobulin to Rh (D)-negative pregnant women after undergoing invasive procedures such as chorionic villus sampling or fetal blood sampling and/or following a possible spontaneous or elective abortion, second or third trimester bleeding, external cephalic version, or abdominal trauma.[2]

Intervention Process

Rh (D) blood typing and antibody testing is conducted via an analysis of the blood. Immunoglobulin is administered to those at risk of Rh disease through an injection.

Treatment Information

Health benefit coverage should include provisions for follow-up and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

The U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence), B (Recommended/At Least Fair Evidence)

A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to support Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.[1]

B (Recommended/At Least Fair Evidence)

- The USPSTF found fair evidence to support Rh (D) antibody testing for all unsensitized Rh (D)-negative women between 24 and 28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.[1]

This recommendation is supported by the:

- American Academy of Family Physicians (AAFP)

Recommended Guidance:

The American College of Obstetricians and Gynecologists (ACOG)
Strength of Evidence: Expert Consensus

- The ACOG concurs with the USPSTF recommendations, with the exception that ACOG strongly recommends that clinicians 1) administer immunoglobulin to Rh (D)-negative pregnant women after undergoing invasive procedures such as chorionic villus sampling or fetal blood sampling, and 2) administer immunoglobulin following a possible spontaneous or elective abortion, second or third trimester bleeding, external cephalic version, or abdominal trauma.[2]

Authored by:

Campbell KP, Chattopadhyay S. Rh (D) incompatibility evidence-statement: screening and preventive medication. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Rubella (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

Not Applicable – The U.S. Preventive Services Task Force defers to the Advisory Committee on Immunization Practices and the CDC on recommendations surrounding immunization.

CDC Recommendation

Rubella vaccine is contraindicated during pregnancy. Because the vaccine contains live virus, it should not be administered to pregnant women.[1]

The Advisory Committee on Immunization Practices (ACIP) recommends that clinicians screen all women of childbearing age, including pregnant women, for rubella susceptibility during their first clinical encounter. A history of vaccination (proved by written documentation of receipt of $\geq$ 1 dose of a rubella-containing vaccine after the age of 1 year) or a serologic test for antibodies (offering laboratory evidence of immunity) can be used to document immunity against rubella. Susceptible, nonpregnant women should be vaccinated, and susceptible pregnant women should be vaccinated immediately after delivery or at the end of their pregnancies (such as following miscarriage). Nonpregnant women may be offered vaccination without serologic screening.[1]

A summary of guidelines for the immunization of pregnant women can be found online (www.cdc.gov/nip/publications/preg_guide.htm).

Evidence Rating:

Expert Consensus

Other Recommended Guidance

The American Academy of Family Physicians (AAFP) concurs with the ACIP recommendations.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Advisory Committee on Immunization Practices (ACIP)
- American Academy of Family Physicians (AAFP)
- Centers of Disease Control and Prevention (CDC)
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

For most people, rubella is a mild illness. However, when contracted during early pregnancy, particularly during the first trimester, rubella can cause serious complications including miscarriage, stillbirth, and congenital rubella syndrome (CRS) – a constellation of birth defects that include hearing impairment, growth retardation, developmental delays, and heart and eye defects.[2] Because rubella infection can affect all the organs of a developing fetus, the earlier a woman is infected with rubella during her pregnancy, the more severe the complications are for the developing fetus. Approximately 90% of infants born to women who contracted rubella during the first 11 weeks of pregnancy develop CRS and about 20% of infants born to women who contracted rubella during the first 20 weeks of pregnancy develop CRS.[2]

In 1964-1965, an epidemic of rubella hit the United States: over 12 million individuals were infected resulting in 11,000 fetal losses (as a result of miscarriage or abortion) and 20,000 cases of CRS.[3]

In 1969, rubella vaccines were licensed in the United States to protect individuals from rubella. Widespread vaccine use led to a 99% reduction in the number of rubella cases over 3 decades; this reduced the rubella caseload from a high of 57,686 cases in 1969 to only 271 cases in 1999.[2]

Since universal childhood immunization was initiated in 1969, there has not been another rubella epidemic, although isolated outbreaks do occur. The United States experienced a resurgence of rubella in the early 1990s with 1,124 cases reported in 1990 and 1,412 in 1991. During this time period 66 infants were born with CRS.[4]

In 2004, an expert panel convened by CDC concluded that rubella and CRS have been eliminated from the United States; however, continued vaccination of susceptible women and children is necessary to maintain this success.[3]

Because pregnant women are most susceptible to the complications of rubella, experts recommend the targeted screening and vaccination of childbearing-aged women. Such a practice would reach those individuals who were not vaccinated in childhood. The rubella vaccine is contraindicated for use during pregnancy due to the theoretical possibility that the live virus rubella vaccine could cause fetal infection and CRS; however, there have been no documented cases of CRS related to use of the rubella vaccine.[1]

Condition/Disease Risk Factors

Since the mid-1990s, rubella and CRS has disproportionately affected foreign-born ethnic minorities. In 1999, 73% of all rubella cases in the United States occurred among Hispanics, most of whom were from Mexico and Central America (CDC, unpublished data). Between 1998 and 2000, over 90% of all CRS cases occurred among infants of Hispanic women 96% of whom were foreign-born.[3]

Value of Prevention

Economic Burden of Condition/Disease

CRS and its complications have substantial health consequences and economic costs. A large rubella outbreak in 1964-1965 cost an estimated $840 million.[5] In 2006, the estimated *lifetime* cost of treating a child born with CRS exceeded $200,000.[5]

Workplace Burden of Condition/Disease

Rubella and CRS result in excess direct medical costs. Indirect costs constitute the major workplace burden of rubella, however. Indirect costs include permanent disability caused by CRS as well as productivity losses associated with the missed work time of employed caregivers attending to their sick children.

Economic Benefit of Preventive Intervention

The economic benefits of immunization result from reducing hospitalizations and outpatient visits and by avoiding productivity losses caused by rubella or CRS-related disabilities.

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of screening for rubella antibodies averaged $21; approximately 95% of paid claims fell within the range of $0 to $50.[6] The cost of the rubella vaccine averaged $20 and approximately 95% of all paid claims fell within the range of $0 to $40 per dose (1 to 2 doses are required for protection against rubella).[6]

Estimated Cost of Treatment

In 2006, the *lifetime* cost of treating a child born with CRS exceeded $200,000.[5]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Although there is a lack of economic evidence about the cost-effectiveness of screening pregnant women, one study that investigated the current 2-dose MMR vaccination program for children through a decision-tree-based analysis demonstrated that the program resulted in substantial cost-savings and high benefit-to-cost ratios. The estimated total cost savings to society of $7.6 billion (in year 2001 dollars) included a savings of $549 million from rubella and CRS prevention.[7]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening	Screening allows clinicians to identify childbearing-age women who are at risk for rubella and to immunize them before they become pregnant. Screening pregnant women allows clinicians to identify at-risk women and to encourage them to be immunized immediately after delivery, thereby offering protection during subsequent pregnancies.
Benefits and Risks of Intervention	Screening for rubella susceptibility involves minimal risk, although false-positive test results may lead to unnecessary treatment. The rubella vaccine is very effective; more than 90% of individuals vaccinated show long-term protection from the illness.[1] Adverse reactions to the rubella vaccine may include pain at the injection site or temporary rash, which are usually mild in both children and adults, although adults — particularly women — commonly complain of temporary joint pain after vaccination.
Initiation, Cessation, and Interval of Screening	All women of childbearing age, including pregnant women, should be screened for rubella susceptibility during their first clinical encounter. All women of childbearing age who are not pregnant should be vaccinated at their first clinical encounter if not immune to rubella. A susceptible pregnant woman should be vaccinated immediately after delivery or at the end of her pregnancy (e.g., miscarriage).
Intervention Process Screening	Screening is conducted by ascertaining an individual's risk for rubella. Immunity to rubella can be documented by 1) a history of immunization (proved by written documentation of receipt of ≥1 dose of a rubella-containing immunization after the age of 1 year), or 2) a serologic test for antibodies (offering laboratory evidence of immunity). Individuals who cannot document immunity are considered at risk for rubella.
Immunization	Rubella immunization is administered via an injection.
Treatment Information	Health benefits should include provisions for treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

Advisory Committee on Immunization Practices (ACIP)
Strength of Evidence: Expert Consensus

The ACIP recommends that clinicians screen all women of childbearing age, including pregnant women, for rubella susceptibility during their first clinical encounter. Susceptible non-pregnant women should be vaccinated and susceptible pregnant women should be vaccinated immediately after delivery or at the end of their pregnancy (e.g., miscarriage).[1]

This recommendation is supported by the:
- U.S. Preventive Services Task Force (USPSTF)

Authored by:

Campbell KP, Lindley MC, Bhatt A, Chattopadhyay S. Rubella evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage.* Washington, DC: National Business Group on Health; 2006.

Syphilis (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen all pregnant women for syphilis infection.[1]

***Evidence Rating:* A (Strongly Recommended/ Good Evidence)**

The USPSTF found good evidence that screening pregnant women decreases the proportion of infants with clinical manifestations of syphilis infection and those with positive serologies. The USPSTF concludes that the benefits of screening substantially outweigh the potential harms.[1]

CDC Recommendation

The Centers for Disease Control and Prevention (CDC) recommends a serologic test for syphilis for all pregnant women at the first prenatal visit. Women who are at high risk for syphilis morbidity, are previously untested, or have a positive serology in the first trimester should be screened again early in the third trimester (28 weeks gestation) and at delivery. Infants should not be discharged from the hospital unless the syphilis serologic status of the mother has been determined at least one time during pregnancy and preferably again at delivery.[2]

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:
- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Syphilis is a serious sexually transmitted infection (STI) that, if left untreated, may result in cardiovascular and neurological complications leading to disability and ultimately death.[1]

In addition to sexual transmission, syphilis can be passed from an infected mother to her infant during pregnancy and delivery. Congenital syphilis is particularly severe and results in fetal or infant death in 40% of cases.[1] In 2002, 451 cases of congenital syphilis were reported in the United States.[3] Of these cases, 333 (73.8%) occurred because the mother had no documented treatment or received inadequate treatment of syphilis before or during pregnancy.[3] Infected infants who survive may suffer serious central nervous system abnormalities, deafness, bone and joint deformities, skin abnormalities, blood disorders, and other problems.[3]

Condition/Disease Risk Factors

Populations at increased risk for syphilis infection (as determined by incidence rates) include commercial sex workers, persons who exchange sex for drugs, and those in adult correctional facilities.

The prevalence of syphilis infection varies widely among communities and patient populations.[1] Some populations have a particularly high risk of infection, specifically African-Americans and people living in the Southeastern United States.[4]

Value of Prevention

Economic Burden of Condition/Disease

The average annual national cost of treating infants with congenital syphilis is approximately $18.4 million (in year 1995 dollars).[5]

Workplace Burden of Condition/Disease

The health, disability, and life insurance costs of syphilis-infected employees impose a significant economic burden on employers. Affected women may also lose work time in order to seek treatment for themselves or for their affected infants.

Economic Benefit of Preventive Intervention

Screening and early detection are key to averting costs associated with disease progression, long-term complications, and neonatal transmission. For example, treatment for early stage syphilis ($41.26) is much less expensive than treatment for later stage disease ($2,062) (both figures in year 2001 dollars).[6]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of screening for syphilis averaged $12; approximately 95% of all paid claims fell within the range of $0 to $32.[7]

Estimated Cost of Treatment

The cost of treating syphilis will vary depending on the medication used and other factors. For azithromycin therapy, the 2001 public-sector price of the 1-g sachet formulation was $11.50 and the wholesale price for a 1-g dose ranged from $17.32 for the sachet formulation to $27.89 for tablets. The public sector cost of standard IM benzathine penicillin therapy ranged from $18.64 to $22.22 (in year 2001 dollars).[6]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Serological screening of pregnant women is cost-effective even when there is a very low prevalence of maternal infection because screening is inexpensive but treating congenital syphilis is costly.[8]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening for syphilis allows clinicians to identify affected patients and begin treatment early in the course of disease. Early intervention improves outcomes and avoids the health and economic consequences of latent disease in the mother and the occurrence of congenital syphilis.[2] Treatment also reduces the risk of transmission between the affected woman and her sexual partner(s).

Benefits and Risks of Intervention

No studies have documented harms associated with screening for syphilis. Theoretical harms include partner discord, stigma, unnecessary anxiety, treatment in the case of a false-positive result, and opportunity costs (in terms of time and resources) to both the clinician and patient. Harms of treatment include allergic reactions to penicillin and other side effects of treatment medications such as the Jarisch-Herxheimer reaction (fever, headache, and pain that occurs during the 24 hours after initiating antibiotic treatment for syphilis and is caused by the release of fragments of the dead, infective microorganism into the bloodstream).[1]

The benefits associated with screening are substantial. Screening allows for early detection and treatment, prevention of complications that may occur in later stages of the disease, and prevention of neonatal transmission. Antibiotic treatment for syphilis is effective, and inexpensive. Therefore, the USPSTF concluded that the benefits of screening pregnant women for syphilis infection substantially outweigh the potential harms.[1]

Initiation, Cessation, and Interval of Screening

All pregnant women should be screened for syphilis at their first prenatal care visit. For women in high-risk groups, repeat serologic testing may be necessary in the third trimester (28 weeks) and again at delivery.[1-2] Follow-up serologic tests should be obtained to document successful treatment.[1]

Intervention Process

A variety of syphilis tests are available and in development. Screening for syphilis typically involves the use of 2 different tests, a nontreponemal test and a treponemal-specific test, for screening and confirmation. For example, a nontreponemal blood test such as the venereal disease research laboratory (VDRL) or the rapid plasma reagin (RPR) may be performed. A second, different kind of test, such as the fluorescent treponemal antibody absorbed (FTA-ABS) or the *T. palladium* particle agglutination (TP-PA) may then be used to confirm the results of the nontreponemal test.[1,4]

Syphilis screening tests that are approved by the Food and Drug Administration (FDA) or are pending FDA approval include[1,4]:

- Nontreponemal test such as the venereal disease research laboratory (VDRL) or the rapid plasma regain (RPR) on serum specimens followed by a fluorescent treponemal antibody absorbed (FTA-ABS) or *T. palladium* particle

agglutination (TP-PA) for confirmation.

- Immunochromatographic Strip (ICS) point-of-care test on blood specimen, when FDA approved.
- Line Immunoassay (LIA) point-of-care test on blood specimen, when FDA approved.
- Enzyme-linked Immunosorbent Assay (ELISA) for treponemal antibody in serum specimens.
- RPR point-of-care test for nontreponemal antibody in serum specimens.
- Dark field microscope examination of lesion specimens.

Follow-up tests should be performed using the same nontreponemal test initially used to document infection (e.g., VDRL or RPR) to ensure comparability.[1]

Treatment Information

Syphilis should be treated with an antibiotic regimen appropriate for the woman's stage of disease. Some experts recommend additional therapy (e.g., a second dose of benzathine penicillin 2.4 million units IM) one week after the initial dose, particularly for those women in the third trimester of pregnancy and for women who have secondary syphilis during pregnancy.[9]

Infants should be treated for presumed congenital syphilis if they were born to mothers who, at delivery:

- Had untreated syphilis;
- Were treated with a non-recommended antibiotic regimen;
- Were treated less than one month prior to delivery; or
- Had evidence of relapse or reinfection after treatment.

Recommended treatment regimens for infants include aqueous crystalline penicillin G (administered every 12 hours during the first 7 days of life and every 8 hours thereafter) for 10 to14 days or procaine penicillin G (administered daily in a single dose for 10 to 14 days). If more than one day of therapy is missed, the entire course should be restarted.[10]

Health benefits should include provisions for treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence that screening pregnant women decreases the proportion of infants with clinical manifestations of syphilis infection and those with positive serologies. The USPSTF concludes that the benefits of screening substantially outweigh the potential harms.[1]

Recommended Guidance:

Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Not Specified

- The CDC recommends a serologic test for syphilis on all pregnant women at the first prenatal visit. Women who are at high risk for syphilis morbidity, are previously untested, or have a positive serology in the first trimester should be screened again early in the third trimester (28 weeks gestation) and at delivery. Infants should not be discharged from the hospital unless the syphilis serologic status of the mother has been determined at least one time during pregnancy and preferably again at delivery.[2]

Authored by:

Choucair J, Lentine D, Campbell KP, Chattopadhyay S. Syphilis evidence-statement: screening. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Tetanus (Immunization)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

Not Applicable – The U.S. Preventive Services Task Force defers to the Advisory Committee on Immunization Practices and the CDC on recommendations surrounding immunization.

CDC Recommendation

The Advisory Committee on Immunization Practices (ACIP) recommends that all previously vaccinated pregnant women who have not been vaccinated against tetanus in the past 10 years receive a booster vaccination against tetanus.[1-2] Pregnant women who have not completed a three-dose primary vaccination series against tetanus should complete the series.[1-2] Pending guidance from ACIP, pregnant women should receive the Td vaccine in preference to the Tdap vaccine.[3]

A summary of guidelines for the immunization of pregnant women can be found online (www.cdc.gov/nip/publications/preg_guide.htm).

Evidence Rating:

Expert Consensus

Other Recommended Guidance American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) supports the ACIP recommendation.[1]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Advisory Committee on Immunizations (ACIP)
- American Academy of Family Physicians (AAFP)
- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Tetanus is generally characterized by painful muscle rigidity and uncontrollable spasms. Between 1998 and 2000, 18% of persons in the United States who contracted tetanus died as a result of the disease.[4] Neonatal tetanus is a severe and often fatal disease; it accounted for an estimated 200,000 deaths worldwide in 2000 but is extremely rare in the United States.[5] Because nearly all neonatal tetanus occurs in infants born to mothers who are not adequately immunized against tetanus, it is important that all pregnant women be vaccinated against tetanus.[4]

Condition/Disease Risk Factors

All pregnant women who are not fully immunized are at risk of infection.

Value of Prevention

Economic Burden of Condition/Disease

There are few economic data on the burden of tetanus disease and no data about the costs of neonatal tetanus in the United States. A recent economic evaluation of the 7-vaccine routine childhood immunization schedule in the United States estimated that, if there had not been a tetanus vaccination program in the United States, 153 cases of tetanus and 23 deaths from tetanus would have occurred at a total cost of $29 million (direct and indirect costs in year 2001 dollars) based on a hypothetical 2001 birth cohort of 3.8 million infants that was followed from birth to death.[6]

Workplace Burden of Condition/Disease

Not Provided

Economic Benefit of Preventive Intervention

The averted mortality and morbidity costs due to prevented tetanus cases constitute the major economic benefit of immunization.

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of an adult tetanus vaccine (usually given as Td) averaged $15; approximately 95% of all paid claims fell within the range of $0 to $28.[7] The additional cost of vaccine administration averaged $10 and 95% of paid claims fell within the range of $0 to $20.[7]

Estimated Cost of Treatment

Not Provided

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

In one analysis, it was estimated that administering tetanus booster immunizations every 10 years ('decennial' boosters) is associated with a cost of $143,138 per year of life saved. Although decennial boosters are more expensive than once-in-a-lifetime booster immunizations, they also prevent more than twice the number of tetanus cases that would be prevented by a single lifetime booster.[8]

Preventive Intervention Information

Preventive Intervention: Purpose of Immunization

Tetanus immunization offers long-term protection against tetanus for the vaccinated woman, and maternal vaccination confers significant protection to the fetus. In fact, field assessments have reported 70% to 100% effectiveness of the vaccine in preventing neonatal tetanus among the children of women receiving at least two doses of tetanus vaccine.[9] Notably, in all three cases of neonatal tetanus that have occurred in the United States since 1989, the infant's mother was not fully immunized against tetanus.[4]

Benefits and Risks of Intervention

The benefits of tetanus immunization are substantial. Adverse reactions to tetanus vaccination can include local swelling or pain; extensive swelling and systemic reactions are rare, however.[10] Although no evidence exists that tetanus immunization during pregnancy causes harm to the fetus, delaying needed tetanus immunizations to the second or third trimester is a reasonable precaution to minimize any concerns about the theoretical possibility of such adverse effects.[11]

Initiation, Cessation, and Interval of Immunization

Women should be assessed for risk of tetanus at their first prenatal care visit. Pregnant women without adequate documentation of a completed primary tetanus series and a tetanus vaccination within the past ten years should be immunized against tetanus in the second or third trimester.

Intervention Process Risk Assessment

Clinicians should assess all pregnant women for susceptibility to tetanus. Pregnant women are considered susceptible to tetanus if they have an uncertain immunization history (i.e., they cannot provide written proof of immunization) or if they have not had a tetanus booster in the previous 10 years.

Immunization

Susceptible women who have not completed a primary series of immunizations against tetanus should complete a three-dose series; women who have completed the primary series but have not been vaccinated against tetanus in the past ten years should receive a booster dose.[1-2]

In 2005, two new tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccines were licensed for use in the United States. Pending guidance from ACIP on the use of Tdap during pregnancy, pregnant women should receive Td vaccine in preference to the Tdap vaccine.[3]

Tetanus vaccinations are given via injection.

Treatment Information

Health benefits should include provisions for treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Recommended Guidance:

Advisory Council on Immunization Practices (ACIP)
Strength of Evidence: Expert Consensus

- The ACIP recommends that all adults with an uncertain history of a complete tetanus vaccination series receive a three-dose primary tetanus series, and that all adults receive periodic tetanus boosters every 10 years.[1-2]

This recommendation is supported by the:

- American Academy of Family Physicians (AAFP)
- U.S. Preventive Services Task Force (USPSTF)

Authored by:

Lindley MC, Bhatt A, Campbell KP, Chattopadhyay S. Tetanus immunization evidence-statement. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Tobacco Use Treatment (Screening and Counseling)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.[1]

Evidence Rating: **A (Strongly Recommended/ Good Evidence**

The USPSTF found good evidence that extended or augmented smoking cessation counseling (5 to15 minutes) using messages and self-help materials tailored for pregnant smokers, compared with brief generic counseling interventions alone, substantially increases abstinence rates during pregnancy, and leads to increased birth weights. Although relapse rates are high in the postpartum period, the USPSTF concluded that reducing smoking during pregnancy is likely to have substantial health benefits for both the baby and the expectant mother. The USPSTF concluded that the benefits of smoking cessation counseling outweigh any potential harms.[1]

The American Academy of Family Physicians (AAFP)[2], the American College of Preventive Medicine (ACPM)[3], and the U.S. Surgeon General concur with the USPSTF recommendations.[4]

Other Evidence-Based Recommendations American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) strongly recommends that clinicians counsel smoking parents with children in the house regarding the harmful effect of smoking and children's health.[2]

Evidence Rating: **SR (Strongly Recommended)**

Good quality evidence exists which demonstrates the substantial net benefit (compared with harm) of counseling to prevent exposure to secondhand smoke; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[2]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- American College of Preventive Medicine (ACPM)
- Centers for Disease Control and Prevention (CDC)
- National Institutes of Health (NIH)
- Peer-reviewed research
- Smoke Free Families
- U.S. Public Health Service (USPHS)
- U.S. Surgeon General

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Twenty-one percent (21%) of all childbearing-aged women in the United States smoke.[4] Depending on demographic factors, between 11% and 20% of all pregnant women in the United States smoke.[4]

Tobacco use during pregnancy causes significant damage to the developing fetus, putting the future infant at risk for an array of severe short- and long-term health problems. Compared to non-smokers, women who smoke during their pregnancy are 83% more likely to deliver a low-birth-weight infant, 129% more likely to deliver an infant that will die of SIDS, 30% more likely to deliver an infant with respiratory distress syndrome, and 41% more likely to deliver an infant with a perinatal respiratory condition.[5] And children whose mothers smoked during pregnancy and/or smoke in the home shortly after birth are at increased risk of asthma, impaired lung function, stunted growth, ear infections, and upper respiratory problems.[6-7]

Prenatal tobacco use is a known risk factor for low birth weight, which itself is a significant risk factor for neonatal morbidity and mortality. In 2003, 12.4% of all women, 13% of Hispanic women, and 20.2% of black women who smoked during pregnancy delivered a low-birth-weight infant.[8]

Table 1.0 Infant Deaths Resulting from Tobacco Use

Health Problem	Percent of Cases Caused by Smoking	No. of Infants who Died as a Result of a Smoking Induced Health Problem (2001)	Years of Potential Life Lost due to Smoking Induced Health Problem	Estimated Cost per Case
Low birth weight (LBW)	9.1%	400	20,732	$32,000-$90,000*
Sudden infant death syndrome (SIDS)	13.4%	299	22,909	
Respiratory distress syndrome	3.5%	35	2,686	$8,500 per day of intensive care**
Other respiratory problem	4.7%	71	5,444	

Source: Centers for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion: Division of Reproductive Health. MCH health outcomes report. Maternal and Child Health Smoking-Attributable Mortality, Morbidity, and Economic Costs. Atlanta, GA: Centers for Disease Control and Prevention; 2005.

* March of Dimes. Perinatal statistics. [cited 2005 Jul 8]. Available from: http://www.marchofdimes.com/aboutus/680_2203.asp.

**Discovery labs (distributors of surfactant, a medicine used to treat RDS in infants. [cited 2005 Jul 8]. Available from: http://www.discoverylabs.com/2002pr/071802-PR.pdf.

Condition/Disease Risk Factors

Women who smoke during pregnancy are likely to be young (18 to 24 years of age), have low levels of education, and be from racial or ethnic minorities. Level of education is highly correlated with prenatal smoking. For example, while only 2% of college-educated non-Hispanic white women smoke during pregnancy, 42.7% of non-Hispanic white women with only 9 to 11 years of education smoke during one or more of their pregnancies.[9]

Value of Prevention

Economic Burden of Condition/Disease

The economic burden of prenatal tobacco use is substantial. In 1996, maternal smoking accounted for 2.3% of all neonatal medical expenditures.[10] Each pregnant smoker incurs an additional $704 in healthcare costs (in year 1996 dollars)[5] and, annually, smoking-attributable neonatal costs (defined as all costs related to labor /delivery and the care of infants within the first few months of life) are estimated to meet or exceed $367 million in the United States.[10-11]

The direct costs of care for mothers and their children exposed to environmental tobacco smoke (ETS) (also known as secondhand smoke) also add to the overall cost of smoking, although exact cost figures are not known.

Workplace Burden of Condition/Disease

Smoking-attributable neonatal costs impose a heavy burden on employer-sponsored health insurance spending. Moreover, working parents are required to

take additional time off from work to attend to the health care needs of children affected by neonatal smoke exposure. This results in productivity losses in the workplace.

Economic Benefit of Preventive Intervention

A smoking cessation program that could achieve an annual drop of 1 percentage point in smoking prevalence has been estimated to produce an economic benefit of $21 million in (in year 1995 dollars) direct medical costs solely by reducing the number of low-birth-weight live births. In 7 years, the cumulative undiscounted saving in direct medical costs would become $572 million through the prevention of 57,200 low-birth-weight infants.[12]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of tobacco risk assessment and prevention counseling averaged $62; approximately 95% of all paid claims fell within the range of $0 to $139.[13] In 2004, the private-sector cost (per pregnant smoker) for tobacco use treatment averaged $39 and approximately 95% of all paid claims fell within the range of $0 to $134.[13]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Tobacco cessation treatment for pregnant women is considered one of the most cost-saving preventive services.[4,14] Clinical trials have shown that $6 are saved in healthcare costs for every $1 invested in smoking cessation programs for pregnant women.[15]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening and Counseling

Screening allows clinicians to identify smokers and offer them cessation services in order to improve their chances of quitting. Quitting smoking reduces the risk of serious smoking-related health problems for the individual and — with regards to pregnant smokers — reduces the fetus's risk of smoking-related health problems such as pre-term birth, low birth weight, and SIDS.

Benefits and Risks of Intervention

The benefits of tobacco use screening and counseling are substantial. Tailored tobacco cessation programs that feature patient education and support have been proven to be effective in reducing the number of women who smoke during pregnancy. For example, one health plan's tobacco cessation program saw a massive reduction in smoking among participants; 81% of participants reported that they stopped smoking altogether or cut the number of cigarettes they smoked each day in half. Women in the program who stopped smoking completely had fewer preterm deliveries and fewer low-birth-weight babies compared to the pregnant smokers who did not participate in the program.[16]

Counseling interventions (as compared to printed self-help materials) are especially effective for smokers at high risk of complications from smoking, such as pregnant women. Notably, 21% of pregnant women who receive physician counseling successfully quit, which is double the quit rate of their nonpregnant counterparts.[3]

There are no documented risks to screening pregnant women for tobacco use. Risks of tobacco cessation counseling are few but include the possibility of a

negative self-perception and perceived feelings of discrimination.

The benefits of screening and counseling, including early identification and early treatment, far outweigh the risks associated with screening and counseling.

Initiation, Cessation, and Interval of Screening and Counseling

All adults, including pregnant women, should be screened for tobacco use at every preventive care visit or as deemed appropriate by the clinician.[1,3] Pregnant women who screen positive for tobacco use should be advised to quit at every medical encounter and referred to 1-800-Quit-Now, the national portal number that refers callers to their state's quitline service. All pregnant women who screen positive for tobacco use should be counseled.

Intervention Process Screening

The USPSTF recommends the use of the "5-A" behavioral counseling framework for tobacco screening and counseling. This framework is composed of 5 steps aimed at engaging the patient in a discussion about their tobacco use and their intention to quit:

- Ask about tobacco use
- Advise to quit through clear and personalized messages
- Assess the patient's willingness to quit
- Assist to quit
- Arrange for follow-up and support services

The USPSTF further recommends that clinicians provide problem-solving guidance for smokers to develop a quit plan and to overcome common barriers to quitting. Practices that complement the "5-A" framework include motivational interviewing or other methods of intensive counseling, referral for quitters that may need extra help, and referral to quitlines for adjunct counseling.[1,5]

Counseling

Effective counseling interventions for pregnant smokers include individual face-to-face, group, and telephone counseling.[17] The most effective type of smoking cessation interventions for pregnant women are multi-component programs that feature: 1) healthcare provider reinforcement, 2) printed self-help materials, and 3) follow-up in-person or telephone counseling.[11] Physician counseling has been shown to increase quit rates among patients in primary care. The more intensive the counseling is (as measured by length of counseling session) the higher the quit rate. For example, 10.5% of patients who receive less than 3 minutes of physician counseling quit smoking, 12.1% of patients who receive 3 to 10 minutes quit, and 18.7% of patients who receive over 10 minutes of counseling quit.[3]

Pharmacologic therapy can enhance the effectiveness of tobacco-cessation interventions and can be used when the physician and patient concur that medication use would be beneficial. Because there have not been adequate studies to ensure the safety of tobacco cessation medications among pregnant women, patient education and provider counseling remain the primary methods of tobacco use treatment. Postpartum women who are not breastfeeding may want to consider using medication to enhance their likelihood of a successful quit attempt.[17]

Treatment Information

Please refer to the "Intervention Process" section.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this section is described below.

Evidence-Based Research:

The U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence that extended or augmented smoking cessation counseling (5 to 15 minutes) using messages and self-help materials tailored for pregnant smokers, compared with brief generic counseling interventions alone, substantially increases abstinence rates during pregnancy, and leads to increased birth weights.[1]

This recommendation is supported by the:

- American Academy of Family Physicians (AAFP)
- American College of Preventive Medicine (ACPM)
- U.S. Public Health Service (USPHS)

The American Academy of Family Physicians (AAFP)
Strength of Evidence: SR (Strongly Recommended)

- AAFP strongly recommends that clinicians counsel smoking parents with children in the house regarding the harmful effect of smoking and children's health.[2] Good quality evidence exists which demonstrates the substantial net benefit of counseling to prevent exposure to secondhand smoke; the intervention is perceived to be cost-effective and acceptable to nearly all patients.[2]

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EVIDENCE-STATEMENT:

HYPERTENSION (Screening, Counseling, and Treatment)

Why This Chapter is Important for Employers: An Overview

- Hypertension (high blood pressure) is the most common primary diagnosis in the United States and is responsible for 35 million office visits each year.[1]
- Nearly 1 in 3 U.S. adults has high blood pressure.[2-3]
- Adults with untreated or poorly controlled hypertension are at increased risk of heart disease and stroke, peripheral artery disease, end-stage renal disease, retinopathy, and aortic aneurysm.[3]
- The diagnosis and management of hypertension cost $63.5 billion in 2006, including $47.5 billion in direct medical expenses and $16 billion in lost productivity.[3]
- Hypertension is one of the 10 most expensive health conditions for U.S. employers. Its complications are a major cause of preventable absenteeism, reduced productivity, and disability.[4]
- Screening for hypertension allows clinicians to identify affected patients and begin treatment early.
- Controlling blood pressure with medications is one of the most cost-effective methods of reducing premature cardiovascular morbidity and mortality.[1,5] A 12 to 13-point reduction in blood pressure can reduce the number of heart attacks by 21%, strokes by 37%, and all deaths from cardiovascular disease by 25%.[1]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force recommends that clinicians screen all adults aged 18 years and older for hypertension.[6]

***Evidence Rating:* A (Strongly Recommended/ Good Evidence)**

The U.S. Preventive Services Task Force found good evidence that (1) screening for high blood pressure can identify adults at increased risk for cardiovascular disease, (2) treating high blood pressure can significantly decrease the prevalence of cardiovascular disease, and (3) the benefits of screening outweigh the harms.[6]

Centers for Disease Control and Prevention (CDC) Guidance

The Centers for Disease Control and Prevention (CDC) supports the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure[1] recommendations for blood pressure screening, prevention, and control (described in the next section).[7] More information on the CDC's hypertension-related guidance is available online (www.cdc.gov/dhdsp/library/fs_bloodpressure.htm).

Other Recommended Guidance

Like the U.S. Preventive Services Task Force, the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends that clinicians screen all adults aged 18 years and older for hypertension.[1]

Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-7)

Guidance for the prevention and management of hypertension is provided in the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.[1] In this report, the Committee recommends that clinicians incorporate its recommendations into the management plans of their patient groups by (1) ensuring that screening and detection of hypertension is provided in the medical practice and community; (2) evaluating all patients with hypertension for accompanying risk factors and target organ damage; (3) promoting lifestyle management to prevent hypertension; (4) setting a target blood pressure for each patient with hypertension and monitoring progress toward that goal; (5) recognizing that a blood pressure goal of less than 130/85 mm Hg is appropriate for many patients; (6) monitoring special diseases and conditions, such as diabetes, congestive heart failure, and renal dysfunction; (7) considering combination therapy for patients with hypertension; (8) maximizing staff efforts to enhance patient adherence to hypertension therapy; and (9) encouraging patient, family, and community activities to promote healthy lifestyles and blood pressure control. In addition, clinicians should encourage persons with pre-hypertension, defined as systolic pressure of 120–139 or diastolic pressure of 80–89 mm Hg, to adopt lifestyle modifications to prevent the development of hypertension.[1]

Evidence Rating:

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure is based on peer-reviewed scientific literature, including observational studies and clinical trials (from January 1997 through April 2003), and on expert opinions from 33 national hypertension leaders.[1]

National High Blood Pressure Education Program Working Group on Children and Adolescents

The authors of the Fourth Report from the National High Blood Pressure Education Program Working Group on Children and Adolescents recommend that children older than 3 years have their blood pressure measured at least once during every healthcare visit.[8] Although the U.S. Preventive Services Task Force did not find evidence to support screening children, many professional organizations such as the American Academy of Pediatrics, the American Heart Association, and the American Medical Association (AMA) recommend that children aged 3 years and older who are seen in medical care settings should have their blood pressure measured at least once during every healthcare episode.[9]

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American Dietetic Association
- American Heart Association
- American Medical Association (AMA)
- Centers for Disease Control and Prevention (CDC)

- Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
- National Heart, Lung, and Blood Institute (NHLBI)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information in this document is based on a compilation of research findings. All information presented in this document should be attributed to its referenced sources and should not be considered a reflection of the opinions of other organizations cited in the text.

Condition/Disease-Specific Information

Explanation of Condition

Blood pressure is often expressed as two numbers — the top (systolic) number represents the pressure while the heart is beating, while the bottom (diastolic) number represents the pressure when the heart is resting between beats. Normal blood pressure is a systolic blood pressure less than 120 mm Hg and a diastolic blood pressure less than 80 mm Hg.

A person is considered to have high blood pressure (also called hypertension) when he or she has a systolic pressure of 140 mm Hg or above, a diastolic blood pressure of 90 mm Hg or above, or both.[3] Once hypertension occurs, it generally remains a life-long, chronic condition. A person who is being treated for high blood pressure, even though repeated blood pressure readings are recorded in the normal range, still has high blood pressure.[3] If treatment stops, the hypertension will almost invariably recur.

Pre-hypertension is defined as systolic pressure of 120–139 mm Hg or diastolic pressure of 80–89 mm Hg.[3] Persons with pre-hypertension are at increased risk of progressing to hypertension. About 28% of American adults aged 18 and older have pre-hypertension.[3]

Information on the classification and management of blood pressure for adults aged 18 years and older is provided in Table 1. The table lists lifestyle modification and drug therapy recommendations for adults by risk category.

Table 1: Classification and Management of Blood Pressure for Adults Aged 18 Years and Older

Blood Pressure Classification	Lifestyle Modifications (e.g., Increasing Physical Activity, Reducing Dietary Salt Intake)	Recommended Drug Therapy for Patients Without a Compelling Indication	Recommended Drug Therapy for Patients With Compelling Indications (Heart Failure, Post-Myocardial Infarction, High Coronary Disease Risk, Diabetes, Chronic Kidney Disease, Recurrent Stroke)
Normal: systolic blood pressure <120 mm Hg and diastolic pressure <80 mg Hg	Encourage		
Pre-hypertension: systolic blood pressure 120–139 mm Hg or diastolic pressure 80–89 mm Hg	Yes	No antihypertensive drug indicated	Drug(s) should be given for the compelling indications. Patients with chronic kidney disease or diabetes should be treated with antihypertensive drugs to achieve a blood pressure of less than 130/80 mm Hg.
Stage 1 hypertension: systolic blood pressure 140–159 mm Hg or diastolic pressure 90–99 mm Hg	Yes	Thiazide-type diuretics are appropriate for most patients with stage 1 hypertension. Clinicians may consider angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers, β-blockers, calcium channel blockers, or a combination of these drugs.	Drug(s) should be given for the compelling indications. Other antihypertensive drugs (diuretics, angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers, β-blockers, calcium or channel blockers) should be given as needed.
Stage 2 hypertension: systolic blood pressure 160 mm Hg or higher, or diastolic pressure 100 mm Hg or higher	Yes	Two-drug combinations (usually thiazide-type diuretics and angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers, or β-blockers) are recommended for most patients with stage 2 hypertension. Initial combined therapy should be used cautiously in those at risk of orthostatic hypotension.	Drug(s) should be given for the compelling indications. Other antihypertensive drugs (diuretics, angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers, β-blockers, calcium or channel blockers) should be given as needed.

Note: Initial treatment should be determined by the patient's highest blood pressure category (e.g., a patient with a systolic blood pressure of 110 mm Hg and a diastolic blood pressure of 90 mm Hg should be treated for stage 1 hypertension).

Source: Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. JAMA 2003;289:2560-72.

Epidemiology of Condition/Disease

Nearly 1 in 3, or 65 million, adults in the United States has high blood pressure.[2] High blood pressure affects about 2 in 5 African-Americans, 1 in 5 Hispanics and Native Americans, and 1 in 6 Asians.[3] High blood pressure was the primary or a contributing cause of death for 277,000 people in the United States in 2002.[3]

Hypertension is the most common ambulatory care primary diagnosis in the United States and is responsible for 35 million office visits each year.[1] Although hypertension is the most common chronic medical condition to be treated in primary care settings, only about 34% of people with hypertension have their blood pressure controlled to a level of less than 140/90 mm Hg, and another 30% are unaware of their condition.[1] As a result, about two-thirds of Americans with hypertension are at increased risk of heart disease and stroke, which are both leading causes of death in the United States. They also have an increased risk of developing peripheral artery disease, end-stage renal disease, retinopathy, and aortic aneurysm.[3]

Condition/Disease Risk Factors

Risk factors for hypertension include increased age, smoking, heavy alcohol use, family history, obesity, physical inactivity, and moderate salt intake.[1,3] The prevalence of hypertension in African-Americans in the United States, in people with low levels of education or low socioeconomic status, and in those who live in the southeastern United States is among the highest in the world.[3] The rate of fatal strokes is 1.8 times higher in blacks than whites, while their rates of death from heart disease are 1.5 times higher and of kidney disease are 4.2 times greater. These disparities are caused, in part, by their higher prevalence of hypertension.[10]

Value of Prevention

Economic Burden of Condition/Disease

The costs associated with hypertension accounted for $63.5 billion of the total costs associated with cardiovascular diseases in 2006.[3] This figure includes $47.5 billion in direct medical expenses and $16 billion in lost productivity.[3] When the costs of other conditions and diagnoses attributable to hypertension were included, the direct healthcare expenses associated with hypertension were $108.8 billion in 1998.[11]

Workplace Burden of Condition/Disease

Hypertension is one of the 10 most expensive health conditions for U.S. employers. Its complications are a major cause of preventable absenteeism, reduced productivity, and disability.[4]

A recent study found that the overall economic burden of illness to employers was higher for hypertension than for nine other conditions — $392 per eligible employee per year (based on average impairment and prevalence estimates using 2001 average hourly wages and benefits). On-the-job productivity losses (employees with uncontrolled hypertension who were less productive at work than healthy employees) accounted for 63% of this total.[12]

Economic Benefit of Preventive Intervention

Screening, detection, and early treatment can significantly reduce the medical care costs associated with hypertension and the other diseases for which people with hypertension are at increased risk. Estimates of full economic benefits

should also take into account productivity gains due to better on-the-job performance and added years of life, as well as to declines in disability, absenteeism, and employee turnover.

A meta-analysis of four trials involving more than 20,000 patients with hypertension showed that reducing their blood pressure led to a 15% reduction in major cardiovascular events, a 20% reduction in strokes, and a 10% reduction in coronary heart disease events.[4] According to another study, reducing blood pressure from less than 140/90 mm Hg to less than 130/85 mm Hg in high-risk individuals would increase life expectancy by 16.5–17.4 years and decrease total lifetime medical costs by $1,450.[13] A third study found that total life expectancy was about 5 years longer for adults with normal blood pressure than those with hypertension.[14]

These studies suggest that reducing blood pressure in patients with hypertension saves money and extends life expectancy. They also suggest that the medical, economic, and human costs of untreated and inadequately controlled high blood pressure are enormous.[13,15-16]

Estimated Cost of Preventive Intervention

The cost of screening for blood pressure in a clinician's office as part of a routine physical examination is minimal.

Estimated Cost of Counseling and Treatment

Lifestyle counseling to promote a healthy diet and physical activity is usually the first step in preventing or treating hypertension and remains important throughout all stages of treatment. The cost for these services varies.[1] In 2004, the private-sector cost of preventive medicine counseling averaged $39; approximately 95% of all paid claims fell within the range of $0 to $129.[17]

If lifestyle changes do not achieve blood pressure control, antihypertensive medications are typically used. Many types of antihypertensive medications are currently available. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure states that thiazide diuretics are among the most effective drugs for hypertension, are available in generic form, and are also among the least expensive.[1,16] The JNC-7 further states that more than one antihypertensive medication may be needed in order to achieve hypertension control, the combination of which should be based on the physician's treatment decisions in order to achieve the most optimal results.

The cost of follow-up or treatment-related appointments varies by type of provider, location, and practice setting.

Disease management programs and centralized blood pressure control clinics have been judged to be useful to encourage compliance with treatment and to meet treatment goals. The costs of these services also vary considerably.

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Controlling blood pressure with medications is one of the most cost-effective methods of reducing premature cardiovascular morbidity and mortality.[1,5] This is particularly true for older men and women and those with high pretreatment blood pressure levels.[13,18] The ALLHAT Study concluded that thiazide-type diuretics are at least as effective as newer drugs in preventing one or more forms of cardiovascular disease and are less expensive.[19]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening and Treatment

Screening for hypertension allows clinicians to identify affected patients and begin treatment early in the disease course to prevent the serious consequences of high blood pressure, including stroke, coronary artery disease, heart attack, and heart and kidney failure.[1]

High blood pressure is easily detectable and can be controlled by lifestyle modifications, such as increasing physical activity or reducing dietary salt intake, and a variety of medications.

Benefits and Risks of Intervention, Risk Reduction, and Treatment

The benefits of screening and detecting high blood pressure are substantial. Screening identifies patients with hypertension and allows them to begin treatment for their condition early in the course of the disease.

Some studies have suggested that screening for hypertension and labeling individuals as having hypertension could result in adverse psychological effects and transient increases in absenteeism.[20] However, these studies had inconsistent results and the causes of absenteeism related to screening and diagnosis were not well established.[20] The risk of false-positive classification can be reduced by multiple measurements.[1]

The benefit-to-harm ratio of treating hypertension overwhelmingly argues for treatment. A 12 to 13-point reduction in blood pressure can reduce the number of heart attacks by 21%, strokes by 37%, and all deaths from cardiovascular disease by 25%.[1] In clinical trials, antihypertensive therapy has been associated with a 35% to 40% mean reduction in stroke incidence, a 20% to 25% reduction in myocardial infarction incidence, and a decrease of more than 50% in heart failure incidence.[1,21-22] Providing antihypertensive medications to adults with severe hypertension reduces their odds of developing congestive heart failure by 86% and active treatment of isolated systolic hypertension in elderly patients reduces the incidence of both stroke and coronary heart disease events by 30%, coronary vascular disease by 18%, and total mortality by 13%.[9,23]

The side effects of antihypertensive medications (such as dizziness, lightheadedness, or fainting) can interfere with patient adherence, but side effects can usually be minimized by patient education and by modifying medications or their dosages. Serious side effects (such as fever or chills, joint or stomach pain) are rare and can be reduced or eliminated by switching medications or reducing drug dosage.[20] Clinicians should also discuss with their patients the benefits of adopting a healthy lifestyle (such as increasing physical activity and reducing dietary salt intake) to prevent and treat high blood pressure.[1]

Initiation, Cessation, and Interval Screening

Blood pressure screening should be conducted routinely among all patients aged 18 or older, or as deemed necessary by a physician. Children older than 3 years who are seen in medical care settings should have their blood pressure measured at least once during every health care epidsode.[8-9] Evidence is insufficient to determine the optimal interval for screening. Expert opinion captured in the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure indicates that people with a systolic blood pressure of under 130 mm Hg and a diastolic blood pressure of under 85 mm Hg should be screened every 2 years, while people with elevated blood pressure (130/85 mm Hg or above) should be screened more frequently.[1]

Counseling and Treatment

All patients with diagnosed hypertension should be counseled and encouraged to make therapeutic lifestyle changes in order to lower their blood pressure. Many patients will also require antihypertensive drug therapy. Once this is initiated, most patients should return for follow-up and adjustment of medications at monthly intervals or less until the blood pressure goal is reached. More frequent visits are necessary for patients with stage 2 hypertension or with complicating comorbid conditions. Comorbidities such as heart failure, diabetes, and the need for laboratory tests influence the frequency of visits. Other cardiovascular risk factors should be monitored and treated to their respective goals. After blood pressure is at goal and stable, follow-up visits can usually be at 3- to 6-month intervals, or more often if necessary.[1]

Intervention Process Screening

Blood pressure screening is usually conducted in a clinician's office using an arm cuff and a calibrated sphygmomanometer (blood pressure meter). Ambulatory blood pressure measurement techniques, conducted outside of the clinical setting, can be particularly helpful in identifying patients who have elevated blood pressures only in the clinic environment, known as "white-coat hypertension."[24] However, due to its high costs, ambulatory blood pressure monitoring is rarely used to screen for high blood pressure.[24] Due to natural variability in blood pressure in humans and the possibility of equipment or observer error, the U.S. Preventive Services Task Force recommends that a diagnosis of high blood pressure be made only after two or more elevated readings are obtained on two or more occasions over a period of several weeks.[9]

Counseling and Treatment

Beginning at the initial visit with a patient who has hypertension, the clinician should counsel and encourage the patient to make therapeutic lifestyle changes — such as dietary changes, increased physical activity, tobacco avoidance, and weight control — and monitor the patient's progress. Therapy begins with lifestyle modification. If the blood pressure goal is not achieved thiazide-type diuretics should be used as initial therapy for most patients, either alone or in combination with one of the other class of medications that have also been shown in clinical trials to reduce one or more hypertensive complications.[1]

Persons who are diagnosed with hypertension should start a treatment plan to lower their blood pressure. Treatment plans usually include non-pharmacological therapies, pharmacological therapies, or a combination of the two.[1]

Lifestyle Interventions (Initial Treatment/"First-Line" Therapy): Healthy lifestyles are critical in preventing and managing hypertension.[1] Lifestyle interventions decrease blood pressure, enhance antihypertensive drug efficacy, and decrease cardiovascular risk. The major lifestyle modifications that have been shown to reduce blood pressure are listed in Table 2. They include weight reduction in obese or overweight individuals,[5] programs to assure adequate physical activity, and adoption of the "Dietary Approaches to Stop Hypertension Eating Plan," which calls for reduced consumption of saturated fat, cholesterol, and total fat and increased consumption of potassium and calcium,[25] reduced intake of dietary sodium,[26] increased physical activity,[27] and moderation of alcohol consumption.[28] The Plan has been clinically proven to enhance blood pressure reduction.[1] Information about the "Dietary Approaches to Stop Hypertension Eating Plan" is available online (www.nhlbi.nih.gov/health/public/heart/hbp/dash/).

- Lifestyle modification is encouraged for those with a systolic blood pressure greater than 120 mm Hg or a diastolic blood pressure greater than 80 mm Hg.
- People with multiple coronary heart disease risk factors that place them at high risk for coronary heart disease (10-year cardiovascular event risk of 10% to 20%) should be encouraged to change their lifestyles to achieve their blood pressure goals. If lifestyle changes are unsuccessful, drug therapy should be considered.
- People with coronary heart disease (10-year cardiovascular event risk greater than 20%) need to reduce their blood pressure to the target level and should consider drug therapy *in addition to* lifestyle interventions if their systolic blood pressure exceeds 140 mm Hg or their diastolic blood pressure is higher than 90 mm Hg.

A risk assessment tool is available online (http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof).

Table 2: Lifestyle Modifications to Prevent and Manage Hypertension*

Modification	Recommendation	Approximate Systolic Blood Pressure Reduction Range
Weight reduction	Maintain normal body weight (body-mass index of 18.5 to 24.9)	5–20 mm Hg per 10-kg weight loss
Adopt Dietary Approaches to Stop Hypertension eating plan	Consume a diet is rich in fruits, vegetables, and low-fat dairy products, with little saturated and total fat	8–14 mm Hg
Dietary sodium reduction	Reduce dietary sodium intake to no more than 2.4 grams of sodium or 6 grams of sodium chloride. (6 grams of sodium equals about 1 teaspoon of table salt (sodium chloride)	2–8 mm Hg
Physical activity	Engage in regular aerobic physical activity, such as brisk walking, at least 30 minutes per day on most days of the week	4–9 mm Hg
Moderation of alcohol consumption	Limit consumption to no more than two drinks per day (1 ounce or 30 ml ethanol [e.g., 24 ounces of beer, 10 ounces of wine, or 3 ounces of 80-proof whiskey]) for most men and no more than one drink per day for women and lighter-weight persons.	2–4 mm Hg

*Note: For overall cardiovascular risk reduction, individuals should stop smoking. The effects of implementing these modifications depend on dose and duration.

Source: Dietary Approaches to Stop Hypertension. JAMA 2003;289:2560-72.

Pharmacologic Treatment: Lifestyle interventions may not be sufficient to reduce blood pressure in many patients. In those cases, the addition of pharmacological therapy to a treatment plan is often beneficial. In fact, most people with hypertension require two or more antihypertensive medications to achieve their target blood pressure.[29-30] Clinical trial outcome data indicate that several classes of drugs — including angiotensin-converting enzyme inhibitors, angiotensin-receptor blockers, β-blockers, calcium channel blockers, and thiazide-type diuretics — can reduce the complications of hypertension. A detailed list of antihypertensive drugs and recommended dose ranges is provided in Table 6 of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure Express (www.nhlbi.nih.gov/guidelines/hypertension/jncintro.htm). The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends that patients with pre-hypertension or stage 1 hypertension return for follow-up and adjustment of medications approximately once a month until they reach their blood pressure goal. More frequent visits are necessary for patients with stage 2 hypertension (160/90 mm Hg or higher) or who have complicating comorbid conditions.

Other Important Information

The most effective therapy prescribed by clinicians will control hypertension only if the patient takes the prescribed medication as instructed and establishes and maintains a health-promoting lifestyle. Electronic and paper clinician decision support systems, flow sheets, feedback reminders, and involvement of nurse clinicians and pharmacists are important program components aimed at controlling hypertension.[31] Furthermore, cost-effective healthcare interventions to prevent and control hypertension can only be implemented if the capacity of primary health care system, policy environment, and financing enable delivery of services.[32]

For more information on medication adherence, please refer to Part VI of the *Purchaser's Guide*, "Leveraging Benefits: Promoting the Delivery and Use of Preventive Services."

For more information on healthy diets, refer to the National Heart, Lung, and Blood Institute (NHLBI) tipsheets which are available online (www.nhlbi.nih.gov/chd/Tipsheets/daily.htm).

Strength of Evidence for the Clinical Preventive Service

The levels of evidence supporting the recommendations in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to support the routine screening of all adults, aged 18 and above, for hypertension.[6]

Recommended Guidance:

Seventh report of Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
Strength of Evidence: The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure is based on peer-reviewed scientific literature on observational studies and clinical trials (conducted in January 1997 through April 2003) and on expert opinion from 33 national hypertension leaders.

Screening

- The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends that all adults aged 18 and above be routinely screened for hypertension.[1]

Treatment

- The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends that clinicians provide primary

and secondary prevention services to reduce elevated blood pressure, including lifestyle consultations and medications.[1]

National High Blood Pressure Education Program Working Group on Children and Adolescents
Strength of Evidence: Not Specified

Screening

- The National High Blood Pressure Education Program Working Group found evidence to support routine screening for hypertension in children aged 3 and older and adolescents during routine preventive care visits and at every episodic healthcare visit in medical care settings.[8]

This recommendation of the National High Blood Pressure Education Program Working Group is supported by the:

- American Academy of Pediatrics (AAP)
- American Heart Association (AHA)
- American Medical Association (AMA)

Authored by:

Matson Koffman D, Chattopadhyay S. Hypertension evidence-statement: screening and treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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EVIDENCE-STATEMENT:

CHILD, ADOLESCENT, ADULT IMMUNIZATIONS (Immunizations)

Why This Chapter is Important for Employers: An Overview

- Prevention of vaccine-preventable diseases is one of 10 great public health achievements of the 20th century.[1]
- Approximately 11,000 babies born each day in the United States will need vaccination against fourteen diseases before age two.
- An average of 36,000 deaths and over 200,000 hospitalizations associated with influenza occur each year in the United States, the majority among adults aged 65 years and older.[2] Influenza vaccination of healthy working adults younger than 65 years can reduce the rates of influenza-like illness, lost workdays, and physician visits.[3]
- Vaccines are cost-effective, and most child and adolescent vaccines are cost-saving. The routine childhood vaccination program saves nearly $10 billion in direct medical costs and $43 billion in societal costs for every birth cohort (all children born in one year).[4]
- Among adults, influenza in particular results in extensive direct and indirect costs. The overall national economic burden of influenza-attributable illness for adults 18 to 64 years old is $10.2 billion. Each year, 17 million workdays are lost to influenza-related illness at a cost of $5.6 billion.[5]
- Approximately 24% of toddlers may be vulnerable to serious illnesses, including polio, measles, mumps, rubella, diphtheria, tetanus, pertussis, invasive *Haemophilus influenzae* type b infection, hepatitis B, and varicella because they have not completed the recommended vaccination series.[6]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

Not Applicable — The U.S. Preventive Services Task Force (USPSTF) defers to the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) on recommendations for immunizations.

Advisory Committee on Immunization Practices (ACIP) and CDC Recommendation

ACIP and CDC recommend that all children and adolescents with no contraindications receive all routinely recommended childhood vaccinations. Children and adolescents who fall into high-risk groups because of health conditions, behaviors, or membership in certain communities should receive additional vaccines.

ACIP and CDC recommend that all adults with no contraindications receive three routinely recommended vaccines (age-dependent). Adults who fall into high-risk groups because of health conditions, behaviors or exposures, as well as those without a history of immunization for certain diseases, should receive additional vaccines.

Please refer to Appendix 1 for specific information on child, adolescent, and adult immunizations and schedules for their administration. Please note these schedules are abbreviated and may not reflect the most current ACIP recommendations. Current ACIP recommendations are provided on the ACIP website (www.cdc.gov/nip/publications/acip-list.htm).

Evidence Rating:

Expert Consensus

Information Sources

The recommendations and supporting information contained in this chapter came from several sources, including the:

- Advisory Committee on Immunization Practices (ACIP)
- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American College of Obstetricians and Gynecologists (ACOG)
- Centers for Disease Control and Prevention (CDC)
- Partnership for Prevention
- Peer-reviewed research

The background and supporting information contained in this chapter is a compilation of research findings. All information presented in this chapter should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Prevention of vaccine-preventable diseases is one of 10 great public health achievements of the 20th century.[1] In 2006, Partnership for Prevention evaluated 25 clinical preventive services based on the clinical burden that could be prevented by the intervention and the cost-effectiveness of the intervention. Childhood immunization was one of three services to receive a perfect score, and adult influenza and pneumococcal vaccinations were also highly ranked.[7] Today, most vaccine-preventable diseases (VPD) occur at record or near-record low levels. However, high rates of vaccination must be constantly maintained: countries that have reduced or discontinued use of certain vaccines have experienced large, costly outbreaks of VPD as a result of waning vaccination coverage.[8]

Children

Approximately 11,000 babies born each day in the United States will need vaccination against fourteen diseases before age two. Approximately 24% of toddlers may be vulnerable to serious illnesses, including polio, measles, mumps, rubella, diphtheria, tetanus (lockjaw), pertussis (whooping cough), invasive *Haemophilus influenzae* type b infection, hepatitis B, and varicella (chickenpox) because they have not completed the recommended vaccination series.[6]

Adolescents

Traditionally, vaccines have been associated with protecting young children, but recently many vaccines targeted toward adolescents have been recommended. In 2005, the meningococcal conjugate vaccine (MCV4) was recommended for 11 to 12 year-olds at the pre-adolescent visit, and for older adolescents and college freshman in dormitories, as these groups experience higher rates of meningococcal disease than the general population.[9] Invasive meningococcal disease has a 10% death rate, and up to 19% of survivors can suffer serious aftereffects like deafness or loss of limbs.[10] Also recommended in June 2005 was a

new tetanus-diphtheria-acellular pertussis vaccine meant to combat waning immunity to pertussis in adolescents. It is also important for adolescents to receive certain "catch-up" immunizations if they were not fully vaccinated in childhood (please refer to www.cdc.gov/nip/recs/child-schedule.htm#catchup for more information). In June 2006, a vaccine against the human papillomavirus (HPV), which causes cervical cancer, was recommended by the ACIP for use among adolescent girls and young women (ages 9 to 26). Clinical trials including approximately 20,000 adolescent girls and women showed that among those not previously infected, the vaccine prevented 100% of pre-cancerous lesions from the two types of HPV that cause the majority of cervical cancer in the United States.[11-12]

Adult

The burden of vaccine-preventable disease in adults in the United States is substantial. Recent estimates indicate that an average of 36,000 deaths and over 200,000 hospitalizations associated with influenza occur each year in the United States, the majority among adults aged 65 years and older.[2] When combined, pneumonia and influenza were the fifth leading cause of death in 2002 among all persons aged 65 years and older (estimate based on national mortality data).[13] Among all age groups, influenza and pneumonia were the seventh leading cause of death in the United States in 2002, accounting for over 65,000 deaths (2.7% of all deaths).[13]

Condition/Disease Risk Factors

Risk factors vary for each vaccine-preventable disease.

Value of Prevention

Economic Burden of Condition/Disease

Childhood vaccine-preventable diseases were once extremely costly. For example, a large outbreak of rubella in 1964-1965 cost an estimated $840 million.[14] Today, the lifetime cost to treat a single case of congenital rubella syndrome (CRS) is estimated to exceed $200,000.[14] Using published studies and hospital discharge data, an economic analysis of the DTaP (diphtheria, tetanus, and acellular pertussis) vaccine showed that in the absence of immunizations, over $23 million dollars would be spent to treat disease among all the children born in a single year.[15]

Among adults, influenza in particular results in extensive direct and indirect costs. The overall national economic burden of influenza-attributable illness for adults is $10.2 billion.[5] Direct medical costs for influenza total $4.6 billion including $3.1 billion for adult hospitalizations resulting from influenza-attributable illness.[5]

Workplace Burden of Condition/Disease

Influenza is also responsible for substantial indirect costs, which mainly result from lost productivity. Each year, among adults age 18 to 64 years, 17 million workdays are lost to influenza-related illness at a cost of $5.6 billion.[5]

Economic Benefit of Preventive Intervention

Children/Adolescents

Vaccines are cost-effective, and most child and adolescent vaccines are cost-saving. The routine childhood vaccination program saves nearly $10 billion in

direct medical costs and $43 billion in societal costs for every birth cohort (all children born in one year).[4] This cost-savings estimate includes reduced costs from lost productivity. The introduction of new vaccines has led to a substantial decline in medical spending for some conditions. For example, in 1995, a vaccine to protect against varicella (chickenpox) was added to the childhood schedule. In 1994-1995, the total estimated direct medical cost of varicella hospitalizations and ambulatory visits was almost $85 million; in 2002, after the vaccine was introduced, the cost declined to $22.1 million.[16]

Although not cost-saving, the 2005 recommendation for routine adolescent meningococcal vaccination is expected to prevent an estimated $18 million in direct costs and $50 million in lost productivity caused by meningococcal disease.[17]

Adults

A randomized controlled trial showed that healthy, working adults who received influenza shots (in a year when the vaccine was well matched to circulating influenza viruses) experienced significantly fewer days of influenza-like illness (ILI), made fewer doctor visits for such illnesses, and took fewer days off from work due to ILIs, compared with workers who were not vaccinated.[3] Furthermore, among persons aged 65 to 79 years who were members of a Medicare managed care plan, influenza immunization was estimated to save about $80 per year, per person vaccinated by preventing hospitalizations from influenza-related illnesses.[18] This is consistent with other studies showing economic benefits from vaccinating persons 65 and older against influenza.

Table 1 details the direct and indirect savings (per dollar spent) of many vaccines routinely administered to children and adolescents.

Table 1: Direct and Indirect Savings per Dollar Spent on Select Vaccines

Vaccine	Direct Medical Savings	Direct & Indirect* Savings
Diphtheria-Tetanus-Pertussis (DTaP)	$9.00	$27.00
Measles-Mumps-Rubella+(MMR)	$14.20	$26.00
Haemophilus influenzae type b (Hib)	$3.40	$5.40
Hepatitis B		
Perinatal	$1.40	$14.70
Infant	$0.90	$5.10
Adolescent	$0.50	$3.80
Varicella	$1.20	$4.40
Inactivated Polio Virus (IPV)	$3.03	$5.45
All Routine#	$5.30	$16.50

* Indirect savings include prevention of work loss, death, and disability
\+ Includes second dose of MMR
\# Includes recommended doses of DTaP, Td, Hib, IPV, MMR, HepB, varicella vaccines (completed series)

Sources: Ekwueme DU, Strebel PM, Hadler SC, Meltzer MI, Allen JW, Livengood JR. Economic evaluation of use of diphtheria, tetanus, and acellular pertussis vaccine or diphtheria, tetanus, and whole-cell pertussis vaccine in the United States, 1997. Arch Pediatr Adolesc Med 2000;154:797-803. (DTaP); Zhou F, Reef S, Massoudi M, Papania MJ, Yusuf HR, Bardenheier B, et al. An economic analysis of the current universal 2-dose measles-mumps-rubella vaccination program in the United States. J Infect Dis 2004; 189(Suppl 1):S131-45. (MMR); Zhou F, Bisgard KM, Yusuf HR, Deuson RR, Bath SK, Murphy TV. Impact of universal *Haemophilus influenzae* type b vaccination starting at 2 months of age in the United States: an economic analysis.Pediatrics 2002; 110(4):653-61. (Hib); Zhou F, Santoli J, Messonnier ML, Yusuf HR, Shefer A, Chu SY, et al. Economic evaluation of the 7-vaccine routine childhood immunization schedule in the United States, 2001. Arch Pediatr Adolesc Med 2005; 159:1136-44. (all routine); CDC unpublished data. (hepatitis B, varicella, IPV)

Estimated Cost of Immunization

Based on catalog prices current as of 7/10/2006, the average private-sector cost to vaccinate a healthy child through adolescence with universally recommended vaccines is approximately $1,600 to $1,700, depending on the brand of vaccine given.[19]

Based on catalog prices current as of 7/10/2006, the average private-sector cost to vaccinate a healthy adult through age 74 with universally recommended vaccines is approximately $380 to $480, depending on the brand of vaccine given.[20]

In 2004, the private-sector cost per vaccination averaged $36 per dose and ranged from $20 for the oral polio vaccine to $270 for the hepatitis B vaccine for immunocompromised patients. Vaccine administration averaged $10; approximately 95% of paid claims fell within the range of $0 to $20.[21]

Estimated Cost of Treatment

Not Provided

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Please refer to "Economic Benefit of Preventive Intervention" for information on the cost-effectiveness of immunizations.

Preventive Intervention Information

Preventive Intervention: Purpose of Immunizations

The purpose of immunizing children, adolescents, and adults, is to prevent vaccine-preventable diseases.

All routinely recommended childhood vaccines have been demonstrated to be efficacious, and noticeable reductions in rates of disease have occurred following consistent, widespread use of vaccines.[22] In each birth cohort (all children born in one year), the routine childhood immunization program prevents at least 13.6 million cases and 33,000 deaths from vaccine-preventable diseases.[4] Influenza vaccination of healthy working adults younger than 65 years can reduce the rates of influenza-like illness, lost workdays and physician visits.[3]

Benefits and Risks of Intervention

The benefits of vaccination include partial or complete protection against the consequences of infection for the vaccinated person, as well as overall benefits to society as a whole through reduced transmission of disease. Individual benefits include protection from symptomatic illness, improved quality of life and productivity (fewer lost workdays), and prevention of death. Societal benefits include creation and maintenance of herd immunity against communicable diseases (which protects people who themselves are not able to be immunized), prevention of disease outbreaks, and reduction in healthcare-related costs.[22]

No vaccine is 100% effective or completely without risk. The risks of screening for susceptibility to vaccine-preventable diseases are minimal for both examination of vaccination history and serologic testing, although false-positive or false-negative results are possible. Immunization risks range from common, minor, and local adverse effects to rare, severe, and life-threatening conditions. Thus, recommendations for immunization practices balance scientific evidence of benefits for each person and to society against the potential costs and risks of vaccination programs.[22]

The potential for significant adverse reactions to immunization can be minimized by adherence to the recommendations and contraindications for immunizations stipulated by ACIP. Information on vaccine contraindications is available online (www.cdc.gov/nip/recs/contraindications_guide.pdf).

Initiation, Cessation, and Interval of Immunization

Patients of all ages, beginning at birth and throughout the lifespan, can benefit from screening and appropriate immunization. Screening for susceptibility to rubella should occur at the first clinical encounter with any woman of childbearing age.

All indicated vaccines should be offered at every visit. It is important for persons of all age groups who have not received all recommended vaccines to receive "catch-up" vaccinations.

One or more vaccinations may be deferred when medically contraindicated or when a parent, guardian, or patient refuses on religious, philosophical, or other grounds. Providers should document deferrals and exemptions in accordance with state and local requirements.

Intervention Process

Most vaccines are administered via injection. There are several approved vaccine types and brands. Please refer to the accompanying SPD for more information.

Treatment Information

Health benefits should include provisions for treatment services.

Other Important Information

For children, CDC's National Center for Immunization and Respiratory Diseases (NCIRD) provides an automatic scheduler that uses a child's birth date to calculate the appropriate dates of administration for each routinely recommended childhood vaccination. The scheduler is available online (www.cdc.gov/nip/scheduler_online_child.htm).

The NCIRD website provides a self-administered questionnaire for adults to determine which immunizations they may need. It asks questions about age, work environment and travel plans, and information about certain health conditions and risk factors ("Do you have asthma?" "Has your spleen been damaged or removed?") that may affect which immunizations are indicated. The quiz is available online (www2.cdc.gov/nip/adultImmSched/).

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Recommended Guidance:

Advisory Committee on Immunization Practices (ACIP)
Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Expert Consensus

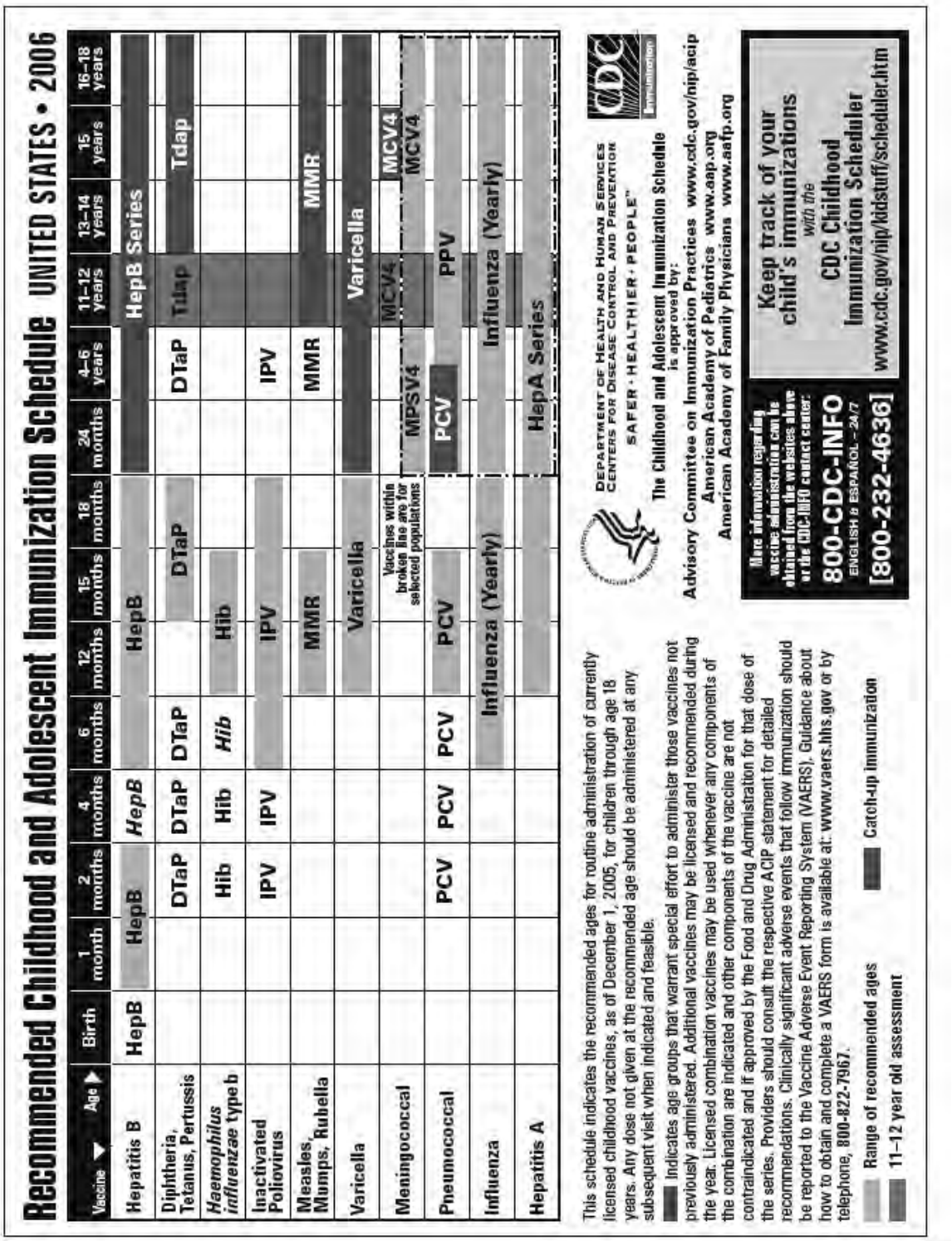
- The ACIP and CDC recommend that all children and adolescents with no contraindications receive all routinely recommended childhood vaccinations. Children and adolescents who fall into high-risk groups because of health conditions, behaviors, or membership in certain communities should receive additional immunizations.
- The ACIP and CDC recommend that all adults with no contraindications receive three routinely recommended vaccines (age-dependent). Adults who fall into high-risk groups because of health conditions, behaviors or exposures, as well as those without a history of immunization for certain diseases, should receive additional immunizations.

Authored by:

Lindley MC, Bhatt A. Child, adolescent, and adult immunizations evidence-statement. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

Appendix 1: Abbreviated Child/Adolescent and Adult Schedules

Note: The Recommended Childhood and Adolescent Immunization Schedule below does not include existing ACIP recommendations for routine immunization with rotavirus and human papillomavirus vaccines, and for a routine second dose of varicella vaccine. Current ACIP recommendations may be obtained from: www.cdc.gov/nip/publications/acip-list.htm.



FOOTNOTES

1. **Hepatitis B vaccine (HepB).** ***AT BIRTH:*** **All newborns** should receive monovalent HepB soon after birth and before hospital discharge. **Infants born to mothers who are HBsAg-positive** should receive HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. **Infants born to mothers whose HBsAg status is unknown** should receive HepB within 12 hours of birth. The mother should have blood drawn as soon as possible to determine her HBsAg status; if HBsAg-positive, the infant should receive HBIG as soon as possible (no later than age 1 week). **For infants born to HBsAg-negative mothers,** the birth dose can be delayed in rare circumstances but only if a physician's order to withhold the vaccine and a copy of the mother's original HBsAg-negative laboratory report are documented in the infant's medical record. ***FOLLOWING THE BIRTH DOSE:*** The HepB series should be completed with either monovalent HepB or a combination vaccine containing HepB. The second dose should be administered at age 1–2 months. The final dose should be administered at age ≥24 weeks. It is permissible to administer 4 doses of HepB (e.g., when combination vaccines are administered after the birth dose); however, if monovalent HepB is used, a dose at age 4 months is not needed. **Infants born to HBsAg-positive mothers** should be tested for HBsAg and antibody to HBsAg after completion of the HepB series at age 9–18 months (generally at the next well-child visit after completion of the vaccine series).
2. **Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).** The fourth dose of DTaP may be administered as early as age 12 months, provided 6 months have elapsed since the third dose and the child is unlikely to return at age 15–18 months. The final dose in the series should be administered at age ≥4 years.

   Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap – adolescent preparation) is recommended at age 11–12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a Td booster dose. Adolescents aged 13–18 years who missed the age 11–12-year Td/Tdap booster dose should also receive a single dose of Tdap if they have completed the recommended childhood DTP/DTaP vaccination series. Subsequent **tetanus and diphtheria toxoids (Td)** are recommended every 10 years.
3. ***Haemophilus influenzae*** **type b conjugate vaccine (Hib).** Three Hib conjugate vaccines are licensed for infant use. If PRP-OMP (PedvaxHIB® or COMVAX® [Merck]) is administered at ages 2 and 4 months, a dose at age 6 months is not required. DTaP/Hib combination products should not be used for primary immunization in infants at ages 2, 4 or 6 months but can be used as boosters after any Hib vaccine. The final dose in the series should be administered at age ≥12 months.
4. **Measles, mumps, and rubella vaccine (MMR).** The second dose of MMR is recommended routinely at age 4–6 years but may be administered during any visit, provided at least 4 weeks have elapsed since the first dose and both doses are administered beginning at or after age 12 months. Children who have not previously received the second dose should complete the schedule by age 11–12 years.
5. **Varicella vaccine.** Varicella vaccine is recommended at any visit at or after age 12 months for susceptible children (i.e., those who lack a reliable history of chickenpox). Susceptible persons aged ≥13 years should receive 2 doses administered at least 4 weeks apart.
6. **Meningococcal vaccine (MCV4).** Meningococcal conjugate vaccine (MCV4) should be given to all children at the 11–12-year-old visit as well as to unvaccinated adolescents at high school entry (aged 15 years). Other adolescents who wish to decrease their risk for meningococcal disease may also be vaccinated. All college freshmen living in dormitories should also be vaccinated, preferably with MCV4, although **meningococcal polysaccharide vaccine (MPSV4)** is an acceptable alternative. Vaccination against invasive meningococcal disease is recommended for children and adolescents aged ≥2 years with terminal complement deficiencies or anatomic or functional asplenia and for certain other high-risk groups (see *MMWR* 2005;54 [RR-7]:1-21); use MPSV4 for children aged 2–10 years and MCV4 for older children, although MPSV4 is an acceptable alternative.
7. **Pneumococcal vaccine.** The heptavalent **pneumococcal conjugate vaccine (PCV)** is recommended for all children aged 2–23 months and for certain children aged 24–59 months. The final dose in the series should be administered at age ≥12 months. **Pneumococcal polysaccharide vaccine (PPV)** is recommended in addition to PCV for certain high-risk groups. See *MMWR* 2000; 49(RR-9):1-35.
8. **Influenza vaccine.** Influenza vaccine is recommended annually for children aged ≥6 months with certain risk factors (including, but not limited to, asthma, cardiac disease, sickle cell disease, human immunodeficiency virus [HIV], diabetes, and conditions that can compromise respiratory function or handling of respiratory secretions or that can increase the risk for aspiration), healthcare workers, and other persons (including household members) in close contact with persons in groups at high risk (see *MMWR* 2005;54[RR-8]:1-55). In addition, healthy children aged 6–23 months and close contacts of healthy children aged 0–5 months are recommended to receive influenza vaccine because children in this age group are at substantially increased risk for influenza-related hospitalizations. For healthy persons aged 5–49 years, the intranasally administered, live, attenuated influenza vaccine (LAIV) is an acceptable alternative to the intramuscular trivalent inactivated influenza vaccine (TIV). See *MMWR* 2005;54(RR-8):1-55. Children receiving TIV should be given a dosage appropriate for their age (0.25 mL if aged 6–35 months or 0.5 mL if aged ≥3 years). Children aged ≤8 years who are receiving influenza vaccine for the first time should receive 2 doses (separated by at least 4 weeks for TIV and at least 6 weeks for LAIV).
9. **Hepatitis A vaccine (HepA).** HepA is recommended for all children at 1 year of age (i.e., 12–23 months). The 2 doses in the series should be administered at least 6 months apart. States, counties, and communities with existing HepA vaccination programs for children 2–18 years of age are encouraged to maintain these programs. In these areas, new efforts focused on routine vaccination of 1-year-old children should enhance, not replace, ongoing programs directed at a broader population of children. HepA is also recommended for certain high-risk groups (see *MMWR* 1999; 48[RR-12]1-37).

Recommended Adult Immunization Schedule, by Vaccine and Age Group
UNITED STATES, OCTOBER 2005–SEPTEMBER 2006

Vaccine ▼ / Age group ▶	19–49 years	50–64 years	≥ 65 years
Tetanus, diphtheria (Td)[1]*	1-dose booster every 10 yrs		
Measles, mumps, rubella (MMR)[2]*	1or 2 doses	1 dose	
Varicella[3]*	2 doses (0, 4–8 wks)	2 doses (0, 4–8 wks)	
Vaccines below broken line are for selected populations			
Influenza[4]*	1 dose annually	1 dose annually	
Pneumococcal (polysaccharide)[5,6]	1–2 doses		1 dose
Hepatitis A[7]*	2 doses (0, 6–12 mos, or 0, 6–15 mos)		
Hepatitis B[8]*	3 doses (0, 1–2, 4–6 mos)		
Meningococcal[9]	1 or more doses		

NOTE: This schedule should be read along with the footnotes, which can be found at www.cdc.gov/nip/recs/adult-schedule.htm
*Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., based on medical, occupational, lifestyle, or other indications)

This schedule indicates the recommended age groups and medical indications for routine administration of currently licensed vaccines for persons aged ≥19 years. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations, consult the manufacturers' package inserts and the complete statements from the ACIP (www.cdc.gov/nip/publications/acip-list.htm).

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available by telephone, 800-822-7967, or from the VAERS website at www.vaers.hhs.gov.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/osp/vicp or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington D.C. 20005, telephone 202-357-6400.

Additional information about the vaccines listed above and contraindications for vaccination is also available at www.cdc.gov/nip or from the CDC-INFO Contact Center at 800-CDC-INFO (232-4636) in English and Spanish, 24 hours a day, 7 days a week.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

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20. CDC unpublished data. Assumptions: 6 doses Td, 24 doses influenza, 1 dose PPV. Adults are persons between 19 and 74 years of age. Estimate does not include vaccines for persons with medical conditions or exposure indications that require specific vaccinations. Vaccine cost per dose for private sector (catalog prices) available from: http://www.cdc.gov/nip/vfc/cdc_vac_price_list.htm (price calculated on 7/11/2006).

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EVIDENCE-STATEMENT:

LIPID DISORDERS (Screening, Counseling, and Treatment)

Why This Chapter is Important for Employers: An Overview

- Lipid disorders result from abnormal levels of cholesterol in the blood.
- Cardiovascular disease is caused by atherosclerosis, a thickening or hardening of the arteries, and is particularly sensitive to lipid (including cholesterol) levels. Coronary heart disease, a type of cardiovascular disease, can lead to angina pectoris (heart pain), heart attack, or both.[1]
- The American Heart Association estimates that more than 70 million women and men in the United States have some form of cardiovascular disease and 927,000 die of the disease every year. Heart disease and stroke, the major forms of cardiovascular disease, account for nearly 38% of all reported deaths nationally in the United States.[1]
- Several large studies have found that patients who take cholesterol-lowering drugs for 5 to 7 years can decrease their risk of heart disease by about 30%.[2]
- The estimated direct and indirect costs of all types of cardiovascular disease in 2006 totaled $403.1 billion; this included the costs associated with coronary heart disease, which exceed $142 billion.[1]
- Screening for lipid disorder allows patients and clinicians to begin lipid-lowering treatment. Reducing low-density lipoprotein cholesterol levels to a normal level reduces the risk of coronary heart disease and thereby reduces a person's risk of cardiovascular disease events, such as heart attacks and strokes.

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force strongly recommends that clinicians screen men aged 35 and older and women aged 45 and older for lipid disorders and that they treat abnormal lipid levels in persons who are at increased risk of coronary heart disease (based on such factors as age, total or low-density lipoprotein cholesterol level, high-density lipoprotein cholesterol level, smoking status, and systolic blood pressure).[3]

Evidence Rating: **A (Strongly Recommended/Good Evidence)**

The USPSTF found good evidence that lipid measurement can identify asymptomatic middle-aged people at increased risk of coronary heart disease and good evidence that lipid-lowering drug therapy substantially decreases the incidence of coronary heart disease in such people with abnormal lipids and causes few major harms. The USPSTF concluded that the benefits of screening for and treating lipid disorders in middle-aged and older people substantially outweigh harms.[3]

The USPSTF recommends that clinicians routinely screen younger adults (men aged 20 to 35 and women aged 20 to 45) for lipid disorders if they have other risk factors for coronary heart disease.[3]

Evidence Rating: **B (Recommended /At Least Fair Evidence)**

The USPSTF found good evidence that lipid measurement can identify younger people at increased risk for coronary heart disease, that risk is highest in those with other risk factors, and that the absolute benefits of lipid-lowering treatment depend on a person's underlying risk of coronary heart disease. The USPSTF concluded that benefits of screening for and treating high-risk young adults outweigh harms.[3]

Note: The National Cholesterol Education Program's Adult Treatment Expert Panel-III is the most recent national guideline for lipid screening and treatment.[4] Please refer to the "Other Recommendations" section.

Centers for Disease Control and Prevention (CDC) Guidance

The Centers for Disease Control and Prevention (CDC) supports the National Cholesterol Education Program's Adult Treatment Expert Panel-III recommendations. More information is available on the CDC website (www.cdc.gov/dhdsp/library/fs_cholesterol.htm).

Other Recommendations National Cholesterol Education Program Adult Treatment Panel-III

Since the release of the U.S. Preventive Services Task Force recommendation in 2001, the National Heart, Lung, and Blood Institute's (NHLBI) National Cholesterol Education Program (NCEP) has updated its guidelines for lipid screening and treatment. The NCEP's Adult Treatment Expert Panel-III recommends that clinicians routinely screen all adults aged 20 and older for elevated blood cholesterol levels every 5 years.[4] Screening should involve a complete lipoprotein profile that includes low-density lipoprotein cholesterol levels.[4]

The Adult Treatment Expert Panel-III also recommends that clinicians counsel all patients at risk for cardiovascular disease about healthy lifestyles, including methods for lowering saturated fat intake, losing weight, and increasing exercise levels. Persons considered at high risk include those with elevated low-density lipoprotein or diminished high-density lipoprotein cholesterol levels.[4]

Evidence Rating:

The Adult Treatment Expert Panel-III contains both evidence statements and recommendations based on those statements. The panel's recommendations are based on large randomized controlled clinical trials, prospective epidemiological studies, and smaller clinical trials. An expert panel assigned each statement to a category of type of evidence (based on the source of the evidence) and strength of evidence as follows[4]:

Category of Type of Evidence:

A	Large randomized controlled clinical trials.
B	Smaller clinical trials and meta-analyses of clinical trials.
C	Observational and metabolic studies.
D	Clinical experience.

Strength of Evidence:

1	Very strong evidence.
2	Moderately strong evidence.
3	Strong trend.

The Adult Treatment Expert Panel-III states that the benefits of screening for lipid disorders outweigh the risks and costs[1] for the reasons listed below. The codes for type of evidence and strength of evidence are provided for each statement.

1. Elevated low-density lipoprotein cholesterol levels increase a person's risk of coronary heart disease, coronary artery disease, and other forms of cardiovascular disease {A1, B1, C1}.

2. Total cholesterol levels in young adults correlate with coronary heart disease rates in later life {C1}.
3. Screening for lipid disorders can identify persons at increased risk of coronary heart disease {A1, B1, C1}.
4. Treating abnormal lipids in persons at increased risk of coronary heart disease can substantially decrease their risk of cardiovascular disease events, such as heart attacks, and their risk of coronary heart disease mortality {A1, B1}.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Agency for Health Care Research and Quality (AHRQ)
- American Heart Association
- Centers for Disease Control and Prevention (CDC)
- National Center for Health Statistics (NCHS)
- National Cholesterol Education Program Adult Treatment Expert Panel-III
- National Heart, Lung, and Blood Institute (NHLBI)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information in this document is based on a compilation of research findings. All information presented in this document should be attributed to its referenced sources and should not be considered a reflection of the opinions of other organizations cited in the text.

Condition/Disease-Specific Information

Explanation of Condition

Lipid disorders, which result from abnormal levels of cholesterol in the blood, increase the risk of cardiovascular diseases, including coronary heart disease. Some amount of cholesterol in the blood is normal and, in fact, necessary. However, high levels of low-density lipoprotein cholesterol increase the risk of — and can even cause — coronary heart disease. In contrast, low levels of high-density lipoprotein cholesterol are strongly associated with increased risks of coronary heart disease and high levels of high-density lipoprotein are associated with protection. Elevated serum triglycerides are associated with increased risk of coronary heart disease.[4]

Table 1: Classification of Low-Density Lipoprotein Cholesterol, High-Density Lipoprotein Cholesterol, Total Cholesterol, and Triglyceride Levels

Low-Density Lipoprotein (bad) Cholesterol Levels (mg/dL)	Classification by Association with Cardiovascular Disease Risk
Less than 100	Optimal
100-129	Near or above optimal
130-159	Borderline high
160-189	High
190 and above	Very high
High-Density Lipoprotein (good) Cholesterol Levels (mg/dL)	**Classification by Association with Cardiovascular Disease Risk**
Less than 40	Low (major risk factor for coronary heart disease)
60 and above	High (protective against heart disease)
Total cholesterol levels (mg/dL)	
Less than 200	Desirable
200-239	Borderline high
240 and above	High
Triglyceride levels (mg/dL)	
Less than150	Desirable
150-199	Borderline high
200-499	High
500 and above	Very high

Adapted from: National Heart, Lung, and Blood Institute's *Third Report of the National Cholesterol Education Program (NCEP) on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III);* May 2001, p. 3.

Reducing low-density lipoprotein cholesterol levels to normal reduces the risk of coronary heart disease and cardiovascular events such as heart attacks and strokes. Because low-density lipoprotein cholesterol levels are so strongly correlated with coronary heart disease and reducing low-density lipoprotein cholesterol has been shown to reduce coronary heart disease risk, goals and thresholds for low-density lipoprotein cholesterol have been established.[4] Please refer to Table 2 for information about recommended target low-density lipoprotein cholesterol levels.

Epidemiology of Condition/Disease

Between 1999 and 2002, about 17% of adults aged 20 years and over in the United States had high cholesterol levels (total cholesterol 240 mg/dL or higher).[5]

Clinical studies have repeatedly shown a strong and graded relationship between increasing levels of low-density lipoprotein cholesterol ("bad" cholesterol) and increasing risk of coronary heart disease events. Low levels of high-density lipoprotein cholesterol levels are strongly associated with increased risks of coronary heart disease. Evidence from clinical trials suggests that increasing high-density lipoprotein cholesterol ("good" cholesterol) levels reduces the risk of coronary heart disease.[1]

Elevated lipid levels contribute to the development of cardiovascular diseases, including coronary heart disease, stroke, and coronary atherosclerosis.[6] Coronary heart disease, which kills more Americans than any other single disease, can lead to angina pectoris (heart pain), heart attack, or both.[1] One American has a heart

attack about every 26 seconds, and about 40% will die from the heart attack in any given year.[1] At age 40, a man in the United States has a 49% chance and a woman has a 32% chance of having a coronary heart disease event (such as a heart attack) in his or her lifetime.[7]

About 65 million adults require therapeutic lifestyle changes (such as dietary changes, increased physical activity, and weight control) to reduce their low-density lipoprotein cholesterol levels. Of these people, about 36 million also require both drug therapy and therapeutic lifestyle changes to reduce their low-density lipoprotein cholesterol levels to safe amounts.

Condition/Disease Risk Factors

Risk factors that are associated with high cholesterol levels include a family history of cardiovascular disease (including familial hypercholesterolemia, an inherited genetic condition), older age, male sex, a diet high in fats, overweight, and lack of exercise.

Many of these risk factors including diet, overweight, and lack of exercise are modifiable[4]:

- Diets high in saturated fat increases low-density lipoprotein (low-density lipoprotein) cholesterol levels more than any other factor in the human diet. Trans-fatty acids, formed when vegetable oil is hydrogenated to harden it, also increase cholesterol levels. These fatty acids are found in such foods as stick margarine, crackers, and French fries. Cholesterol is found in foods from animal sources, such as egg yolks, meat, and cheese.
- Being overweight tends to increase low-density lipoprotein levels, decrease high-density lipoprotein levels, and increase total cholesterol levels.
- Lack of regular exercise can lead to weight gain, which can increase low-density lipoprotein cholesterol levels. Poor physical fitness appears to be associated with cardiovascular disease, even if it has not produced overweight or obesity.

Value of Prevention

Economic Burden of Condition/Disease

The economic burden of lipid disorders is substantial due to the impact of lipid levels on the risk of cardiovascular disease and coronary heart disease events. The direct and indirect costs of all types of cardiovascular disease in 2006 were estimated to be $403.1 billion, including costs associated with coronary heart disease (estimated to exceed $142 billion annually).[1] The cost of cardiovascular disease exceeds that of many other high-cost medical conditions. For example, in 2004, the estimated total cost of all cancers was $190 billion and in 1999, the estimated total cost of HIV infections was $28.9 billion.[1]

Workplace Burden of Condition/Disease

Heart disease and stroke are not only a major cause of premature death in persons younger than 65 years but are also major causes of serious disability in the United States.[1] The indirect costs of cardiovascular disease, including those related to lost productivity, are enormous; it is estimated that the indirect cost of cardiovascular disease will total over $145 billion in 2006.[1]

Economic Benefit of Preventive Intervention

Cost-effectiveness analyses show that reducing low-density lipoprotein cholesterol levels can reduce costs in three ways[4]:

1) Direct economic savings from decreased hospital and ambulatory services from angina, myocardial infarction, revascularization procedures, stroke, and heart failure.
2) Prevention of coronary heart disease mortality, which increases rates of gainful employment and productivity.
3) Prevention of the disability, distress, and pain associated with coronary heart disease, which increases quality-adjusted life expectancy as well as rates of gainful employment and productivity.

Estimated Cost of Preventive Intervention

The cost of implementing a lipid screening program varies by location, provider base, method of screening, which cholesterol measurements are taken, and other factors. The average cost of a single cholesterol or lipid profile test is relatively low but the cumulative costs of screening can be substantial, especially if all recommended screening and follow-up procedures are followed.[8] In 2004, the private-sector cost of cholesterol and lipids screening averaged $13; approximately 95% of all paid claims fell within the range of $0 to $32.[9] Preventive medicine counseling averaged $39 and approximately 95% of all paid claims fell within the range of $0 to $129.[9]

Estimated Cost of Counseling and Treatment

The total cost of reducing low-density lipoprotein includes the costs of physician services, lifestyle counseling, screening, case finding and monitoring, dietary and exercise modifications, medications, and treatment of side effects. The annual cost of statin drugs to reduce low-density lipoprotein cholesterol levels can range from $100 to $1,500 per year.[4] The cost of follow-up or treatment-related appointments varies by type of provider, location, and practice setting. Although the cost of reducing low-density lipoprotein cholesterol levels can be high, it is much lower than the direct and indirect costs of cardiovascular disease.

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

In 2002, the National Cholesterol Education Program (NCEP) panel found that, based on current retail prices for lipid-lowering drugs, low-density lipoprotein-lowering drug therapy is *highly cost-effective* for persons with established coronary heart disease (including a prior coronary heart disease event); *cost-effective* for the primary prevention of coronary heart disease in persons with a coronary heart disease risk equivalent (the person does not have coronary heart disease but does have an absolute 10-year risk of developing major coronary events, such as myocardial infarction and coronary death, equal to that of persons with coronary heart disease), and those at high risk for coronary heart disease; and *acceptable* for the primary prevention of coronary heart disease in persons whose 10-year risk of "hard coronary heart disease" (heart attack and death from coronary heart disease) is between 10% and 20%.[4,10]

The National Cholesterol Education Program recommends using dietary therapy, which is more cost-effective than low-density lipoprotein-lowering drugs, as the first-line therapy in persons with a 10-year risk of coronary heart disease that is less than 10% per year. (Information about dietary therapy is found in the Other Important Information section of this document).

Preventive Intervention Information

Preventive Intervention: Purpose of Screening, Counseling, and Treatment

Screening for lipid disorders allows patients and clinicians to begin lipid-lowering treatment before cardiovascular disease develops or progresses. Most patients agree to be screened for lipid disorders, even when the screening involves fasting.[7]

Benefits and Risks of Intervention

Clinical trials have shown that reducing low-density lipoprotein levels reduces coronary heart disease risk, but the benefits of increasing high-density lipoprotein levels have not yet been fully demonstrated. In short-term clinical trials, a 1% reduction in low-density lipoprotein cholesterol levels, on average, reduced the risk of hard coronary heart disease events by about 1%. Persons who take low-density lipoprotein cholesterol-lowering drugs for about 5 years reduce their low-density lipoprotein levels by approximately 30% and decrease their risk of cardiovascular disease, including heart attacks, by about 30%.[2] However, only about half of those who would benefit from lipid treatment receive it.[11]

In persons with established coronary heart disease, low-density lipoprotein-lowering therapy reduces risk of stroke by about 30%.[7] Statin therapy for the primary and secondary prevention of cardiovascular disease can reduce adverse cardiovascular events (including heart attacks and stokes) by 32% among patients aged 65 and older.[12] Primary prevention trials using statins have shown a significant reduction in coronary heart disease mortality, no increase in non-coronary heart disease mortality, and a strong trend toward lower overall mortality.

Initiation, Cessation, and Interval Screening

All adults aged 20 and older should be screened for abnormal lipid and elevated blood cholesterol levels every 5 years. Evidence is insufficient to determine the age at which screening is no longer necessary; therefore decisions regarding when to stop screening are left to the discretion of the clinician.[4]

Counseling and Treatment

Beginning at the initial visit with a patient who has a high level of cholesterol, the clinician should counsel and encourage the patient to make therapeutic lifestyle changes — such as dietary changes, increased physical activity, and weight control — and monitor the patient's progress.[4,11] The clinician should evaluate the patient's low-density lipoprotein cholesterol level at the 6-week, 12-week, and 4 to 6-month follow-up visits, or more often if necessary.[4]

Intervention Process Risk Assessment

Low-density lipoprotein cholesterol levels should be the primary target of cholesterol-lowering therapy.[4] The first step in selecting a low-density lipoprotein-lowering therapy is assessing the patient's coronary heart disease risk status, which requires measuring low-density lipoprotein cholesterol levels as part of lipoprotein analysis; identifying risk factors, such as family history; and determining whether the patient has coronary heart disease, other clinical forms of atherosclerotic disease, or the major risk factors for coronary heart disease other than low-density lipoprotein cholesterol.[4]

Patients are considered to be at high risk of coronary heart disease if they have coronary heart disease or coronary heart disease risk equivalents (the person does

not have coronary heart disease but does have an absolute 10-year risk of developing major coronary events, such as myocardial infarction and coronary death, equal to that of persons with coronary heart disease), including:

- Other clinical forms of atherosclerotic disease (such as peripheral arterial disease, abdominal aortic aneurysm, or symptomatic carotid artery disease).
- Diabetes.
- Multiple risk factors that confer a 10-year risk of coronary heart disease of at least 20%.

Risk status in persons *without* coronary heart disease or other forms of atherosclerotic disease is determined by a two-step procedure.

First, the clinician counts the number of risk factors for coronary heart disease, including:

- Cigarette smoking.
- Hypertension (blood pressure of 140/90 mmHg or higher, or the patient is taking antihypertensive medication).
- Diminished high-density lipoprotein cholesterol level (less than 40 mg/dL).
- Family history of premature coronary heart disease (in male first degree relative younger than 55 or a female first degree relative younger than 65).
- Age (men aged 45 years or older; women aged 55 years or older).

If the clinician determines that the patient has at least two of these risk factors, the Framingham scoring is used to determine the patient's 10-year risk of coronary heart disease.[4] Risk factors used in Framingham scoring include age, total or low-density lipoprotein cholesterol level, high-density lipoprotein cholesterol level, smoking status, systolic blood pressure, and whether the individual is taking antihypertensive therapy. Persons with several of these risk factors are assigned to one of three categories of 10-year risk of coronary heart disease: higher than 20%, 10% to 20%, or less than 10%. A person with 10-year risk that is higher than 20% is categorized as "coronary heart disease risk equivalent," meaning that the person does not have coronary heart disease but does have an absolute 10-year risk of developing major coronary events, such as myocardial infarction and coronary death, equal to that of persons with coronary heart disease, or the person has diabetes. Framingham scoring is the most reliable method available for identifying high-risk persons to determine the appropriate low-density lipoprotein level goal and treatment intensity.[4] A Framingham-based risk assessment tool is available online (http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof).

Screening

Lipid measurement should include a comprehensive lipoprotein profile in addition to assessing other risk factors such as family history, smoking status, weight, blood pressure, and age.

The National Cholesterol Education Program (NCEP) recommends a 9 to 12-hour fasting lipoprotein profile of total cholesterol, low-density lipoprotein, high-density lipoprotein cholesterol, and triglycerides every 5 years for adults aged 20 and over,

although total cholesterol and high-density lipoprotein cholesterol can be measured on either fasting or non-fasting samples (venous or capillary blood samples). The results of the lipoprotein profile should be used to assess coronary heart disease risk as recommended in the Adult Treatment Expert Panel-III guidance.

Counseling and Treatment

Beginning at the initial visit with a patient who has a high level of cholesterol, the clinician should counsel and encourage the patient to make therapeutic lifestyle changes — such as dietary changes, increased physical activity, and weight control — and monitor the patient's progress.[4,11] The clinician should evaluate the patient's low-density lipoprotein cholesterol level at the 6-week, 12-week, and 4 to 6-month follow-up visits, or more often if necessary.[4]

Target goals for low-density lipoprotein levels and treatment are based on the person's 10-year risk of coronary heart disease, as described in the "Risk Assessment" section.

The first line of therapy for elevated low-density lipoprotein cholesterol levels is therapeutic lifestyle changes; drug therapy can be combined with therapeutic lifestyle changes if additional low-density lipoprotein reduction is required.

Therapeutic Lifestyle Interventions (Initial Treatment/"First-Line" Therapy): On the therapeutic lifestyle change diet, saturated fat should account for no more than 7% of calories, no more than 200 mg of cholesterol should be consumed per day, and total fat intake may range from 25% to 35% of all calories.[4,11] Trans-fat intake should be as low as possible. The person's diet should also include 2–3 g/day of plant stanol esters (sitostanol and sitostanol esters, found in soft margarine), 10–25 g/day of soluble fiber (fruits, vegetables, and whole grains), and 400 mg/day of folate consumed largely from dietary sources. Carbohydrates should be limited to 60% of total calories. Therapeutic lifestyle interventions also include smoking cessation, weight management, regular physical exercise, and moderation of alcohol intake — no more than two drinks per day for men and one drink per day for women (one alcoholic drink is defined as 5 ounces of wine, 12 ounce of beer, or 1.5 ounces of hard liquor). If, after 3 months, therapeutic lifestyle interventions in a patient who is not at high risk have not reduced low-density lipoprotein cholesterol levels sufficiently, the addition of drug therapy to the treatment plan should be considered. In high-risk patients, drug therapy should be considered together with therapeutic lifestyle changes at the initiation of treatment if the low-density lipoprotein level is at least 100 mg/dL. The intensity of risk-reduction therapy should be adjusted to an individual's absolute 10-year risk of coronary heart disease, which is based on age, lipoprotein profile, previous history of coronary heart disease events, and other risk factors.

A combination of sustained changes in diet, weight loss, and exercise can lower low-density lipoprotein cholesterol levels by as much as 20% to 30%.[4]

If the patient's target low-density lipoprotein cholesterol level has not been achieved by the 6-week visit, the clinician should intensify the low-density lipoprotein-lowering therapy by adding plant stanol/sterol esters and viscous

(soluble) fiber to the diet (refer to "Treatment Information and Therapeutic Lifestyle Interventions" for more information). If the low-density lipoprotein goal is not achieved by the 12-week follow-up visit, the therapeutic lifestyle changes should be intensified by increasing the emphasis on physical activity and weight control. Drug treatment, such as statins, should also be considered. After the 12-week visit, adherence to therapeutic lifestyle changes and drug treatment should be monitored every 4 to 6 months, or more often if necessary.[4]

The recommended first-line therapy for elevated serum triglycerides is therapeutic lifestyle changes, including reduced intake of fat, avoidance of very high carbohydrate intake (no more than 60% of calories), increased physical activity, weight control, and restriction of alcohol intake.

Therapeutic lifestyle changes and drug therapy by risk category are summarized in Table 2.

Table 2: Target Low-Density Lipoprotein Cholesterol Levels and Treatment Recommendations

Risk Category	Target Low-Density Lipoprotein Level (mg/dL)	Low-Density Lipoprotein Levels (mg/dL) at Which to Initiate Therapeutic Lifestyle Changes	Low-Density Lipoprotein Levels (mg/dL) at Which to Consider Drug Therapy
High Risk: Coronary heart disease or a 10-year coronary heart disease risk equivalent (including diabetes or two or more risk factors and a 10-year risk of at least 20%)	<100 (<70 optional goal for patients with coronary heart disease)	≥100	≥100 (if lipoprotein levels are <100, a lipid-lowering drug is a therapeutic option, based on clinical trials)
Moderately High Risk: Two or more risk factors (10-year risk 10% to 20%)	<130	≥130	≥130 (after 3 months of therapeutic lifestyle changes)
Moderate Risk: Two or more risk factors (10-year risk <10%)	<130	≥130	≥160 (after 3 months of therapeutic lifestyle changes)
Lower Risk: No risk factors or one risk factor	<160	≥160	≥190 (after 3 months of therapeutic lifestyle changes) (at 160-189 mg/dL, low-density lipoprotein-lowering drugs are optional)

Table adapted from: Grundy SM, Cleeman JI, Merz CN, Brewer HB Jr, Clark LT, Hunninghake DB, Implications of recent clinical trials for the National Cholesterol Education Adult Treatment Panel III (ATP III) guidelines. Circulation 2004; 110:227-39.

Other Important Information

Physicians should have primary responsibility for implementing the Adult Treatment Expert Panel-III treatment guidelines. In addition, a multidisciplinary team, potentially including nurses, dieticians, nurse practitioners, pharmacists, and health educators, should be involved in and reimbursed whenever possible for these services. The model of a multidisciplinary case management approach for patients with lipid disorders encompasses primary and secondary prevention across the lifespan and nutritional and exercise management, defines the indications for pharmacological therapy, and emphasizes the importance of treatment adherence.[13] Use of this collaborative approach for the treatment of lipid disorders will ultimately reduce cardiovascular and cerebrovascular (stroke) morbidity and mortality.

More information on adherence methods that payers can use to improve beneficiary adherence to lipid-lowering treatments is available in Part VI of the *Purchaser's Guide, Leveraging Benefits*.

More information on the therapeutic lifestyle intervention diet is available in the National Heart, Lung, and Blood Institute tipsheets (www.nhlbi.nih.gov/chd/Tipsheets/daily.htm).

Information on ways to reduce low-density lipoprotein cholesterol levels is available in *Your Guide to Lowering your Cholesterol Level with Therapeutic Lifestyle Changes* (www.nhlbi.nih.gov/health/public/heart/chol/_tlc.pdf).

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

The U.S. Preventive Services Task (USPSTF)
Strength of Evidence: A (Strongly Recommended / Good Evidence)

- The USPSTF force strongly recommends that clinicians screen men aged 35 and older and women aged 45 and older for lipid disorders and that they treat abnormal lipid levels in persons who are at increased risk of coronary heart disease (based on such factors as age, total or low-density lipoprotein cholesterol level, high-density lipoprotein cholesterol level, smoking status, and systolic blood pressure).[3]

Recommended Guidance:

Adult Treatment Expert Panel-III, National Cholesterol Education Program (NCEP) Strength of Evidence: The Adult Treatment Expert Panel-III recommendations are based on large randomized controlled clinical trials, prospective epidemiological studies, and smaller clinical trials. An expert panel assigned each recommendation to a category of type of evidence (based on the

source of the evidence) and strength of evidence as follows[4]:

Category of Type of Evidence:

A	Major randomized controlled clinical trials.
B	Smaller randomized controlled clinical trials and meta-analyses of clinical trials.
C	Observational and metabolic studies.
D	Clinical experience.

Strength of Evidence:

1	Very strong evidence.
2	Moderately strong evidence.
3	Strong trend.

The Adult Treatment Expert Panel-III recommended that:

- Clinicians screen all adults aged 20 and older for elevated blood cholesterol levels every 5 years {A1, B1, C1}.[4] Screening should involve a complete lipoprotein profile, including an evaluation of low-density lipoprotein cholesterol level.[4]
- Clinicians treat all patients with abnormal lipid levels to decrease their risk of cardiovascular disease events, such as heart attacks. The first line of treatment should be counseling about healthy therapeutic lifestyle changes.[4]
- Reducing low-density lipoprotein cholesterol levels should be the primary target of cholesterol-lowering therapy {A1, B1, C1}.[4]

These recommendations are supported by the:

- Centers for Disease Control and Prevention (CDC)

Authored by:

Matson Koffman D. Lipid disorders evidence-statement: screening, counseling, and treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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EVIDENCE-STATEMENT:

MOTOR VEHICLE-RELATED INJURY PREVENTION (Counseling)

Why This Chapter is Important for Employers: An Overview

- Motor vehicle-related injuries kill more children and young adults than any other single cause in the United States.[1] In 2004, 1,638 children ages 14 years and younger died as occupants in motor vehicle-related crashes, and approximately 214,000 were injured resulting in an average of 6 deaths and 673 injuries each day.[2]
- In a given year, 41,000 Americans will die in motor vehicle crashes, 500,000 will have crash injuries requiring hospitalization, and 4 million will have crash injuries requiring a visit to an emergency department.[1]
- Motor vehicle-related deaths and injuries cost the United States a total of $230 billion dollars per year (in year 2000 dollars).[3] Costs due to motor vehicle-related injuries in children are estimated to approach $20 billion annually. The average cost, per child, for a motor-vehicle related injury is estimated to be $10,600 (updated to year 2000 dollars).[4]
- The workplace burden of motor vehicle-related crashes is also substantial: each year, motor vehicle-related crashes result in $61 billion in lost productivity and $5 billion in workplace administrative costs (in year 2000 dollars).[3]
- Motor vehicle-related fatal and nonfatal injuries are highly preventable. Seatbelts, child safety seats, safety helmets (for motorcycles), and not driving while impaired by alcohol or drugs, are proven to reduce the risk of motor vehicle-related injuries.[5-11]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force

The U.S. Preventive Services Task Force (USPSTF) issued a recommendation on counseling to prevent motor vehicle crash injuries in 1996. Given the availability of new evidence, the USPSTF decided to update its 1996 recommendation. This work is currently in progress. Please refer to the USPSTF website for updates (www.ahrq.gov/clinic/prevenix.htm).

American Academy of Family Physicians (AAFP)

The American Academy of Family Physicians (AAFP) recommends that physicians counsel all parents and patients over the age of 2 years regarding accidental injury prevention including, as appropriate: child safety seats, lap and shoulder belt use, bicycle safety, motorcycle helmet use, and driving while intoxicated.[12]

***Evidence Rating:* R (Recommended)**

Although evidence exists which demonstrates net benefit, either the benefit is only moderate in magnitude or the evidence supporting a substantial benefit is only fair. The intervention is perceived to be cost effective and acceptable to most patients. The AAFP Summary of Recommendations for Clinical Preventive Services (RCPS) originated in the Commission on Clinical Policies and Research and was approved by the AAFP Board of Directors in August 2005.

The starting point for the recommendations is the rigorous analysis of scientific knowledge available as presented by the U.S. Preventive Services Task Force (USPSTF) in their *Guide to Clinical Preventive Services*, 2nd Edition and ongoing releases of evidence reports and recommendations from the 3rd Edition.

The AMA urges physicians to educate their patients about the dangers of alcohol abuse and operating a motor vehicle while under the influence of alcohol.[13]

Other Recommended Guidance American Medical Association (AMA)

The AMA recommends that all adolescents receive health guidance annually to promote the reduction of injuries.[14] Health guidance for injury prevention includes the following:

- Counseling to avoid the use of alcohol or other substances while using motor or recreational vehicles, or where impaired judgment may lead to injury;
- Counseling to use safety devices, including seat belts, and motorcycle and bicycle helmets.

Evidence Rating:

Expert Opinion. The AMA developed its recommendations with contributions from a Scientific Advisory Panel, comprised of national experts, as well as representatives of primary care medical organizations and the health insurance industry. The body of scientific evidence indicated that the periodicity and content of preventive services can be important in promoting the health and well-being of adolescents.

American Academy of Pediatrics (AAP)

The American Academy of Pediatrics (AAP) recommends that pediatricians counsel parents of most children (those who weigh more than 12 lbs at 4 months of age) to encourage use of a convertible car safety seat that will accommodate them rear facing at higher weights.[15] Further, the AAP encourages pediatricians to emphasize to parents and teenagers repeatedly the paramount importance of safe driving behavior. During office visits, pediatricians can address risk factors, especially driving while impaired by alcohol or other drugs and nighttime driving. Pediatricians are encouraged to counsel parents that adolescents, despite their physical maturity, are still developing their driving skills and need time to master this complex task by practicing while supervised in a low-risk environment. The pediatrician should address the tendency of some parents to deny that their teenagers might be unsafe drivers. Pediatricians should advise parents that their parenting responsibilities include the following[15]:

- Setting a good driving example (e.g., no drinking and driving, no speeding, and requiring all occupants to use safety belts);
- Establishing driving behavior limits on their teenagers, such as limiting the number and age of passengers, restricting nighttime driving for novice drivers, and delaying the onset of unsupervised driving as they see fit;
- Showing that they expect responsible driving behavior from their teenagers and imposing penalties for irresponsible actions; Supervising novice drivers in a vehicle;
- Ensuring the mechanical safety of any car used by a teenager.

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American Medical Association (AMA)
- Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control
- National Highway Traffic Safety Administration (NHTSA)
- Peer-reviewed research
- U.S. Department of Transportation (DOT)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Injury

Motor vehicle-related injuries kill more children and young adults (18 to 34 years of age) than any other single cause in the United States.[1] In a given year, 41,000 Americans will die in motor vehicle crashes, 500,000 will have crash injuries requiring hospitalization, and 4 million will have crash injuries requiring a visit to an emergency department.[1]

In the United States during 2004, 1,638 children ages 14 years and younger died as occupants in motor vehicle-related crashes, and approximately 214,000 were injured resulting in an average of 6 deaths and 673 injuries each day.[2]

During 2004, 16,694 people in the United States died in alcohol-related motor vehicle crashes, representing 39% of all traffic-related deaths.[16] Drugs other than alcohol (e.g., marijuana and cocaine) are involved in about 18% of motor vehicle deaths. These drugs are usually used in combination with alcohol.[17] Nearly three quarters of those convicted of driving while impaired are either frequent heavy drinkers (alcohol abusers) or alcoholics (alcohol dependent).[17]

Injury Risk Factors

Risk factors for motor vehicle-related injuries among children include failing to use occupant protection, improper use of occupant protection, and being a passenger in a vehicle driven by a person under the influence of alcohol or other drugs. Restraint use among young children often depends upon the driver's restraint use. Almost 40% of children riding with unbelted drivers were themselves unrestrained.[18] Even children who do use child restraints are at risk if they are improperly secured. A survey of more than 17,500 children found that only 15% of children in safety seats were correctly harnessed into correctly installed seats.[18]

Value of Prevention

Economic Burden of Injury

The economic burden of motor vehicle-related deaths and injuries is enormous, costing the United States more than $230 billion each year (year 2000 dollars).[3] Of the estimated $230 billion, $61 billion is due to lost workplace productivity, $59 billion due to property damages, $34 billion due to medical expenses, $25 billion due to delayed transit, $20 billion due to lost household productivity, $15 billion due to insurance administration, $11 billion due to legal fees, and $5 billion due to workplace administration.[3]

Costs due to motor vehicle injuries in children are estimated to approach $20 billion annually. Costs per child injured (when a child occupies a vehicle involved in a crash) are estimated at $10,600 per injury (updated to year 2000 dollars).[4]

Alcohol-involved crashes pose a great economic burden in the United States. The economic costs for motor vehicle injuries involving alcohol are estimated at $50.9 billion annually (year 2000 dollars).[3]

Workplace Burden of Injury

As stated above, the workplace burden of motor vehicle-related crashes is substantial. Each year, motor vehicle-related crashes result in $61 billion in lost productivity and $5 billion in workplace administrative costs (year 2000 dollars).[3]

Economic Benefit of Preventive Intervention

The savings associated with preventable medical-care costs, lost productivity, and other injury-related expenditures constitute the major economic benefit of counseling to prevent motor vehicle-related injuries. Including intangible consequences such as pain and suffering, the total value of preventing a motor vehicle-related death was estimated to be $3.4 million (in year 2000 dollars) per life saved.[19]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of injury prevention counseling averaged $38 per session; approximately 95% of paid claims fell within the range of $0 to $129 per session.[19]

Estimated Cost of Treatment

The cost of motor-vehicle injuries varies tremendously depending on the type and severity of the injury.

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Injury prevention counseling by pediatricians has been shown to be cost-saving in some studies. The studied intervention included 11 brief sessions of approximately 1.5 minutes each, one of which was related to the use of child safety seats. Cost savings from the child safety seat counseling session ranged from $24 to $69 per child counseled. These counseling costs are comparable with the costs of counseling for other prevention messages.[20-22]

Counseling trauma patients (an injured patient treated in an emergency department or admitted to a hospital) on the dangers of alcohol was estimated to have a net cost-savings of $330 per patient intervention due to reduced future alcohol related trauma. The counseling included a brief screening and intervention session by a healthcare professional.[23]

Preventive Intervention Information

Preventive Intervention: Purpose of Counseling

Motor vehicle-related fatal and nonfatal injuries are highly preventable. Seatbelts, child safety seats, safety helmets (for motorcycles), and not driving while impaired by alcohol or drugs, are proven to reduce the risk of motor vehicle-related injuries.[5-11] The rates of fatal and non-fatal motor vehicle-related injuries have declined in recent years, partially due to program and policy interventions designed to prevent these injuries.[5-11] For example, over 80% of all adults use seat belts. However, children remain at high risk for motor-vehicle related injuries because only 15% of children are correctly harnessed into correctly installed safety seats.[18]

Benefits and Risks of Intervention

Several studies have evaluated counseling parents to increase seat belt usage among their children[24-29] and to use safety seats for infants and newborns.[30-40] Other studies have shown that counseling adolescents and adults can increase seat belt usage.[26,41-44] In general, most of the evidence suggests that there is a relatively short-term effect of clinician counseling on the use of occupant restraints, indicating the need for periodic reinforcement of this message.

While little is known about how effectively clinicians can influence patients to refrain from driving while impaired by alcohol or other drugs, there is good evidence that brief clinician counseling can reduce alcohol consumption in problem drinkers, which may, in turn, result in reduced drinking and driving.[45-47] Studies also find that counseling provided as a component of trauma care (care delivered to an injured patient in an emergency department of through hospitalization) significantly reduces injuries and the rate of trauma recidivism (re-injury).[48-50] Further, despite the fact that there are over 159 million episodes of alcohol-impaired driving each year, only 1.5 million persons are arrested annually for driving under the influence of alcohol.[51] Thus, it is likely that many patients would benefit from clinician counseling to modify their behaviors as drivers and passengers in motor vehicles. Since motor vehicle crashes represent a leading cause of death and nonfatal injury in the United States, even modest successes through clinical interventions could have major public health benefits.

Initiation, Cessation, and Interval of Counseling

Although the harms associated with counseling are not well-studied, they may include stigma, psychological stress, and anxiety. It is likely that these risks are minimal, and the harms associated with counseling are far outweighed by the benefits.

There is insufficient evidence to determine the optimal ages at which to begin and cease counseling to prevent motor vehicle-related injuries. Experts agree that counseling for motor vehicle-related injuries should be initiated and stopped when deemed appropriate by the clinician.

Likely initiation periods might be: 1) when patients first begin to drive (age 15, 16 or older depending on state law), 2) when patients first become parents, 3) when patients seek other preventive services for young children, 4) when patients present with alcohol or other drug dependencies, and 5) when patients receive trauma care for alcohol-related injuries.

Evidence is insufficient to determine the optimal interval to counsel patients about motor vehicle-related injuries. Thus, clinicians are encouraged to use their judgment in deciding how frequently to counsel patients for motor vehicle-related injuries. Clinicians should be encouraged to periodically reinforce prevention messages with all patients (at least once per year), particularly with those patients at high-risk of motor vehicle-related injuries (patients aged 18 to 33 years, parents of small children or adolescents, and substance and alcohol abusers).

Intervention Process

The specific method of counseling is left to the discretion of the clinician. Common methods of counseling include brief clinician counseling (3 minutes or less) and intensive counseling.

The provider of any patient who has suffered an alcohol-related motor vehicle crash should screen the individual for alcohol misuse. For more information on alcohol misuse screening and counseling please refer to the *Alcohol Misuse Screening and Counseling Evidence-Statement*.

Treatment Information

Not Applicable

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

American Academy of Family Physicians (AAFP)
Strength of Evidence: R (Recommended)

- The AAFP recommends that physicians counsel all parents and patients over the age of 2 years regarding accidental injury prevention including, as appropriate: child safety seats, lap and shoulder belt use, and driving while intoxicated.[12]

Recommended Guidance:

American Medical Association (AMA)
Strength of Evidence: Not Specified

- The AMA urges physicians to educate their patients about the dangers of alcohol abuse and operating a motor vehicle while under the influence of alcohol.[2]
- The AMA recommends that all adolescents receive health guidance annually to promote the reduction of injuries.[14] Health guidance for injury prevention includes the following:
  - > Counseling to avoid the use of alcohol or other substances while using motor or recreational vehicles, or where impaired judgment may lead to injury;

> Counseling to use safety devices, including seat belts, and motorcycle and bicycle helmets.

American Academy of Pediatrics (AAP)
Strength of Evidence: Not Specified

- The AAP recommends that pediatricians counsel parents of most children (those who weigh more than 12 lb at 4 months of age) to encourage use of a convertible car safety seat that will accommodate them rear facing at higher weights.[5]
- The AAP encourages pediatricians to emphasize to parents and teenagers repeatedly the paramount importance of safe driving behavior. During office visits, pediatricians can address risk factors, especially driving while impaired by alcohol or other drugs and nighttime driving. Pediatricians are encouraged to counsel parents that adolescents, despite their physical maturity, are still developing their driving skills and need time to master this complex task by practicing while supervised in a low-risk environment. The pediatrician should address the tendency of some parents deny that their teenagers might be unsafe drivers.[5]

Authored by:

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Why This Chapter is Important for Employers: An Overview

- Obesity is epidemic in the United States. Between 1976 to 1980 and 1999 to 2002, the proportion of adults classified as obese doubled. During that period, the proportion of children (aged 6 to 11 years) classified as overweight doubled and the proportion of overweight adolescents (aged 12 to 19 years) tripled.[1]
- Nearly 80% of obese adults suffer from diabetes, high blood pressure, coronary artery disease, high cholesterol, osteoarthritis, or a combination of these conditions.[2]
- Because it contributes to so many other serious conditions, obesity is considered to be one of the most important, underlying, and preventable causes of poor health and premature death.[3]
- Obesity contributes significantly to medical costs in the United States.[4]
- The cost to employers of obesity-related health problems in 1994 was estimated to be $13 billion per year, including $8 billion in medical claims, $2.4 billion in paid sick leave, $1.8 billion in life insurance, and almost $1 billion in disability insurance.[5]
- Each year, an estimated 39 million work days are lost to obesity-related illnesses.[6]
- For adults, losing excess weight has positive effects on overall health status. A 5% to 7% reduction in body weight decreases the risk of type 2 diabetes, reduces blood pressures, and improves lipid profiles.[7] Among patients with existing glucose intolerance, weight loss through lifestyle change is associated with as much as a 58% reduction in incidence of diabetes.[8]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.[9]

Evidence Rating: **B (Recommended/At Least Fair Evidence)**

The USPSTF found good evidence that body mass index (BMI), calculated as weight in kilograms divided by height in meters squared, is reliable and valid for identifying adults at increased risk for mortality and morbidity due to overweight and obesity. There is fair to good evidence that high-intensity counseling — about diet, exercise, or both — together with behavioral interventions aimed at skill development, motivation, and support strategies produces modest, sustained weight loss (typically 3 to 5 kg for 1 year or more) in adults who are obese (as defined by BMI $>$ 30 kg/m^2). Although the USPSTF did not find direct evidence that behavioral interventions lower mortality or morbidity from obesity, the USPSTF concluded that changes in intermediate outcomes, such as improved glucose metabolism, lipid levels, and blood pressure, from modest weight loss provide indirect evidence of health benefits.[9]

Other Evidence-Based Research Food and Drug Administration (FDA)

The FDA has approved two medications for the treatment of obesity that can reduce patient weight by an average of 2.6 to 4.8 kg (5.7 to 10.6 lbs) for at least 2 years: orlistat (Xenical®) and sibutramine (Meridia®).[10-11]

Evidence Rating:

Clinical Trials

Recommended Guidance The National Heart, Lung, and Blood Institute (NHLBI)

The NHLBI recommends that surgical procedures for obese patients be reserved for patients with class III obesity (BMI > 40) and patients with class II obesity (BMI of 35 to 39.9) who also have at least one obesity-related illness.[12]

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- American Academy of Bariatric Surgery
- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American Medical Association (AMA)
- Food and Drug Administration (FDA)
- National Academy of Sciences, Institute of Medicine (IOM)
- National Center for Education in Maternal and Child Health
- National Heart, Lung, Blood Institute (NHLBI)
- Peer-reviewed research
- U.S. Department of Health and Human Services
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information in this document is based on a compilation of research findings. All of the information presented in this document should be attributed to its referenced source and should not be considered a reflection of the opinions of other organizations cited in the text.

Condition/Disease-Specific Information

Epidemiology of Condition/Disease

The Body Mass Index (BMI) is widely used as an index of body composition and weight. BMI's in the range of 18.5 to 24.9 are generally considered to be optimal for adults. "Underweight" is generally defined as a BMI less than 18.5, "overweight" as BMI between 25 to 29.9, and "obesity" as a BMI greater than 30. Age- and gender-specific standards also exist for children and adolescents that take into account the changes in body composition that occur as children grow (See "Other Important Information," below).

Obesity is epidemic in the United States. Between 1976 to 1980 and 1999 to 2002, the proportion of adults classified as obese doubled.[1] Nearly 80% of obese

adults suffer from diabetes, high blood pressure, coronary artery disease, high cholesterol, osteoarthritis, or a combination of these conditions.[2] Research has also documented that obesity is associated with decreased quality of life.[13]

During this period, the proportion of children (aged 6 to 11 years) classified as overweight doubled and the proportion of overweight adolescents (aged 12 to 19 years) tripled.[1] The complications of being overweight are particularly severe for children due to the years of life they are at risking of losing as a result of early-onset chronic diseases, such as diabetes[14] and cardiovascular disease.[15]

For adults, losing excess weight has positive effects on overall health status. A 5% to 7% reduction in body weight decreases the risk of type 2 diabetes, reduces blood pressures, and improves lipid profiles.[7] Among patients with existing glucose intolerance, weight loss through lifestyle change is associated with as much as a 58% reduction in incidence of diabetes.[8] The USPSTF found limited data on the positive effect that weight loss may have on overall mortality, mental health, and daily functioning.[9]

Condition/Disease Risk Factors

Obesity is more common among adult women, Native Americans, African-Americans, Native Hawaiians, and Hispanics than other populations.[7]

Value of Prevention

Economic Burden of Condition/Disease

Obesity contributes significantly to medical costs in the United States. In 1998, 9.1% of total annual medical expenditures could be attributed to obesity.[4] Between 1987 and 2001, 27% of the growth in inflation-adjusted per-capita healthcare spending was associated with obesity.[6] The annual cost of obesity is estimated to range from $69 billion to $117 billion (including $61 billion for direct medical expenses and $56 billion for indirect expenses such as lost productivity [in year 2000 dollars]).[16]

The expected lifetime costs of cardiovascular disease (including coronary heart disease, heart attack, and stroke) increase by 20% with mild obesity (class I: BMI of 30 to 34.9), 50% with moderate obesity (class II: BMI of 35 to 39.9), and nearly 200% with severe obesity (class III: BMI of 40 or higher).[5] One large health plan found that its yearly total medical claims were 18% higher for overweight individuals and 32% higher for obese than for healthy-weight individuals.[17]

A 2001 study found obese adults had, on average, about 37% higher healthcare expenses per person than normal-weight adults. This excess expense increased private healthcare spending by nearly 12% (more than $36 billion).[6]

Workplace Burden of Condition/Disease

The cost to employers of obesity-related health problems in 1994 was estimated to be $13 billion per year, including $8 billion in medical claims, $2.4 billion in paid sick leave, $1.8 billion in life insurance, and almost $1 billion in disability insurance.[5]

Obesity and related illnesses are also a major cause of disability. Each year, an estimated 39 million work days are lost to obesity-related illnesses.[6]

Economic Benefit of Preventive Intervention

Nutrition education, diet, and exercise counseling are effective interventions for obesity prevention and have the potential to significantly reduce the direct and indirect costs of obesity-related illnesses. Researchers have estimated that even a modest reduction of 10% in body weight in an obese individual might reduce the expected lifetime healthcare costs of major obesity-related diseases for the individual by $2,200 to $5,300, depending on age, sex, and initial BMI.[18]

Estimated Cost of Preventive Intervention

The cost of BMI screening is negligible when height and weight measurements are already recorded as part of a routine physical exam. In 2004, the private-sector cost of obesity counseling averaged $39 per session; approximately 95% of all paid claims fell within the range of $0 to $129 per session.[19]

Estimated Cost of Treatment

In the United States, the costs associated with treating obesity vary by location, provider type, and treatment modality. For example, in 2006 the average wholesale price of a 1-month supply of pharmacological therapy for obesity was $207.04 for orlistat (Xenical“) (120 mg three times daily) and $423.60 for a 3-month supply of sibutramine (Meridia“) (15 mg daily).28 In contrast, the average price of a surgical procedure for obesity in 2004 ranged from $20,000 to $35,000.[21]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

The cost-effectiveness of screening for and treating obesity is unclear. Because obese individuals are at risk for serious and costly complications, such as diabetes and cardiovascular disease, screening for obesity and early intervention to reduce excess weight could improve lives and increase the cost-effectiveness of healthcare dollars. However, few studies have tested the cost-effectiveness of screening for and treating obesity in the United States, although several cost-effectiveness studies have been conducted in England, Australia, and Northern Europe. The studies conducted abroad applied their-effectiveness analyses to morbidly obese patients (i.e., persons with BMIs $\geq$ 40, which is approximately 100 pounds over normal weight for a typical person). The studies found that a range of interventions (such as pharmacotherapy, surgery, and intensive diet and behavioral therapy) can be inexpensive or even cost-saving, depending on the population's risk and the interventions used.[22] These results cannot be generalized to patients who are not morbidly obese. Further, the results may not be generalizable to the U.S. population because of differences between the populations studied and the U.S. population and differences in healthcare system funding and delivery mechanisms in the countries studied.

Preventive Intervention Information

Preventive Intervention: Purpose of Screening and Counseling

Because obesity is a modifiable major risk factor for several serious conditions, screening for obesity and treating it successfully can be expected to produce significant health benefits. Screening for obesity allows clinicians to identify patients at risk and begin treatment before serious weight-related complications occur. Unfortunately, weight is frequently overlooked in primary care practice; only 42% of obese patients report receiving advice to lose weight during a routine check-up in the previous year.[23]

Benefits and Risks of Intervention

Although the USPSTF did not find direct evidence that behavioral interventions lower mortality or morbidity from obesity, the USPSTF concluded that changes in intermediate outcomes, such as improved glucose metabolism, lipid levels, and blood pressure, from modest weight loss provide indirect evidence of health benefits.[9]

The USPSTF was unable to find studies that suggested harms associated with screening or counseling obese patients.[24] However, the USPSTF notes that because obesity carries a stigma, there is a potential risk in labeling patients as obese. The USPSTF found evidence that dieting among overweight and obese adults *does not* lead to problems in psychological functioning or eating disorders. However, the USPSTF notes that the evidence is limited and conflicting on the harms of weight cycling (losing and then regaining a large amount of weight). In addition, the USPSTF notes that some forms of treatment, specifically pharmacological therapy and surgical intervention, carry potential harm.[24]

The USPSTF concluded that the benefits of screening and behavioral interventions outweigh potential harms.

Initiation, Cessation, and Interval Screening

The USPSTF did not find evidence to determine the optimal times for the initiation, cessation, or interval of obesity screening. Several health organizations, including the American Academy of Family Physicians (AAFP),[25] the American Heart Association (AHA),[26] and the American College of Preventive Medicine (ACPM),[27] agree on the importance of screening for obesity and recommend periodically measuring the height and weight of all patients. Some authorities have recommended that height and weight be recorded and BMIs calculated at every healthcare visit.

Counseling

High-intensity counseling is defined by the USPSTF as 2 or more person-to-person sessions per month for at least the first 3 months of treatment for a total of 6 counseling sessions per calendar year.

Intervention Process

The USPSTF notes that the most effective interventions for obesity combine nutrition education, diet and exercise counseling, and behavioral strategies to help obese patients acquire the skills they need to successfully change their eating habits and to become more physically active.[9]

Screening

The preferred method of screening an adult patient for obesity is to measure their body-mass index (BMI). This is a reliable and valid measurement of adult weight status. BMI is defined as weight in pounds divided by height in inches squared and multiplied by 703, or as weight in kilograms divided by height in meters squared. BMI charts provide completed calculations and can be used to determine BMI by simply entering weight and height. The following definitions from the *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*[12] should be used to classify weight status:

Screening for obesity may also include measurement of waist circumference because central adiposity (excess fat around the middle) can also increase an individual's risk of developing cardiovascular disease. A waist circumference

greater than 102 centimeters for men and 88 centimeters for women is associated with an increased risk of cardiovascular disease. However, waist measurements are not reliable indicators of cardiovascular disease risk in obese patients with a BMI of 35 or above.[24]

BMI Chart for Adults	
Classification	BMI
Underweight	Less than 18.5
Healthy	18.5 to 24.9
Overweight	25 to 29.9
Obese (class I)	30 to 34.9
Obese (class II)	35 to 39.9
Obese (class III)	40 and above

Counseling and Treatment Information

The most effective behavioral interventions for obesity combine nutrition education, diet and exercise counseling, and behavioral strategies to help obese patients acquire the skills they need to change their eating habits and become more physically active.[28]

Clinicians should offer a treatment plan of intensive counseling and behavioral interventions to obese patients. Intensive counseling is defined as 2 or more person-to-person individual or group sessions per month for at least 3 months.[24] If clinicians are unable to offer obese patients intensive counseling and behavioral interventions, they should refer patients to a program or provider that can offer these services. However, this should not undermine the existing patient-physician relationship because research has shown that clinicians' advice plays a role in many health outcomes.[29-30]

No evidence exists to show that one counseling method is better than another for obese patients. Clinicians must therefore use their own judgment to select an appropriate counseling method for a given patient. The "5-A" framework[31] that is used for smoking cessation counseling might be useful for the initial evaluation and counseling of an obese patient and might be helpful in broaching the subject of weight loss with patients:

- Assess the patient's weight by measuring his or her BMI and waist and evaluate the patient's factors that affect choice of behavior change goals/methods.
- Advise the patient to lose weight through physical activity and a healthy diet using clear, specific, and personalized messages.
- Agree with the patient on specific changes he or she can make to reach his or her target weight.
- Assist the patient in making changes by offering support services, education, and resources.
- Arrange for follow-up and support services.

Experts recommend that pharmacological therapy for obesity, such as medications that induce weight loss or suppress appetite, only be used as part of a

treatment plan that also includes lifestyle modifications such as intensive diet, exercise, and behavioral counseling.[9] The Food and Drug Administration (FDA) has approved two medications for the treatment of obesity that can reduce patient weight by an average of 2.6 to 4.8 kg (5.7 to 10.6 lbs) for at least 2 years: orlistat (Xenical®) and sibutramine (Meridia®).[10-11] While these drugs are effective, they may produce unwanted side effects and few data are available on the safety of their long-term use.

The National Heart, Lung, and Blood Institute (NHLBI) recommends that surgical procedures be reserved for obese patients with class III obesity (BMI greater than 40) and patients with class II obesity (BMI of 35 to 39.9) who have at least one obesity-related illness. Surgical procedures, such as bariatric surgery, are effective for treating obesity in the short-term (on average, extremely obese patients lose 10 to 159 kg [22 to 349.8 lbs] in 1 to 5 years).[12]

Bariatric surgery produces improvements in health for most of the patients. For example, a meta-analysis of bariatric surgery studies found that 60% to 70% of patients lost all of their excess weight and that diabetes was brought under control in almost 77% of patients who had had diabetes prior to the surgery.[32] Although the long-term health effects of surgery for obesity are not well characterized, surgical cohort studies suggest that large amounts of weight loss may be linked to dramatic improvements in glucose metabolism. In addition, some evidence indicates that surgically treated patients are more likely to have resolution of diabetes, hypertension, and certain lipid disorders than patients who do not undergo surgery.[28]

However, bariatric surgery is associated with serious risks, including the risk of death, and 25% of patients may need a second operation within 5 years.[28]

Other Important Information

The USPSTF concluded that the evidence was insufficient to recommend for or against routine screening for overweight in children and adolescents as a means to prevent adverse health outcomes.[33]

The USPSTF found 1) fair evidence that BMI is a reasonable measure for identifying children and adolescents who are overweight or are at risk for becoming overweight, 2) fair evidence that overweight adolescents and children (≥ 8 years old)are at increased risk for becoming obese adults, 3) insufficient evidence for the effectiveness of behavioral counseling or other preventive interventions with overweight children and adolescents that can be conducted in primary care settings or to which primary care clinicians can make referrals, and 4) insufficient evidence to ascertain the magnitude of the potential harms of screening or prevention and treatment interventions. The USPSTF was unable to determine the balance between potential benefits and harms of routine screening of children and adolescents for overweight.

Although the USPSTF found insufficient evidence to recommend for or against screening children and adolescents for overweight, many health organizations

have created guidelines for this type of screening. For example, the American Academy of Family Physicians (AAFP),[34] American Academy of Pediatrics (AAP),[35] National Center for Education in Maternal and Child Health,[36] and American Medical Association (AMA) have developed guidelines that include recommendations for measuring height and weight as part of periodic health examinations for children and adolescents.

In 2003, the AAP published a policy statement on the prevention of pediatric overweight and obesity. In this report, the AAP stated that a BMI between the 85th and 95th percentiles for age and sex indicates that the child or adolescent is at risk for overweight and a BMI at or above the 95th percentile indicates that the child or adolescent is overweight or obese.[35] Because obesity is associated with significant health problems in children, the AAP proposed strategies to foster prevention and early detection of overweight and obesity. In addition to the healthy nutrition recommendations, the AAP developed a policy statement on active healthy living for the prevention of childhood obesity.[37] According to this policy, physicians and other healthcare professionals should advocate for policy changes at the community, state, and national levels to support healthy nutrition, reduce sedentary time, and increase physical activity levels in children and adolescents while providing education and supervision of the child's health on the importance of regular physical activity and reduced sedentary time to families.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found fair to good evidence to support screening all adult patients for obesity and offering intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.[9]

Food and Drug Administration (FDA)
Strength of Evidence: Clinical Trials

The FDA has approved two medications for the treatment of obesity that can reduce patient weight by an average of 2.6 to 4.8 kg (5.7 to 10.6 lbs) for at least 2 years: orlistat (Xenical®) and sibutramine (Meridia®).[10-11]

Recommended Guidance::

The National Heart, Lung, and Blood Institute (NHLBI)
Strength of evidence: Not Specified

- The NHLBI recommends that surgical procedures for obese patients be reserved for patients with class III obesity (BMI >40) and patients with class II obesity (BMI of 35 to 39.9) who also have at least one obesity-related illness.[12]

Authored by:

Tohill BC, Campbell KP, Chattopadhyay S. Obesity evidence-statement: screening, counseling, and treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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EVIDENCE-STATEMENT:

OSTEOPOROSIS (Screening and Treatment)

Why This Chapter is Important for Employers: An Overview

- Approximately 44 million Americans — 55% of the adult population over the age 50 — have either osteoporosis or osteopenia. Many of the 10 million Americans who have osteoporosis are undiagnosed.[1]
- Approximately 50% of postmenopausal women will suffer a fracture as a result of osteoporosis at some point during their lifetime.[2] Twenty-five percent (25%) of these women will suffer a deformity in their spines and 15% will fracture their hips.[3]
- Fractures are a costly and common events associated with osteoporosis. Approximately 1.5 million osteoporotic fractures occur in the United States each year, which result in more than 500,000 hospitalizations, over 800,000 emergency room visits, more than 2,600,000 physician office visits, and nearly 180,000 nursing home admissions.[4]
- The estimated annual direct-care expenditure for osteoporotic fractures ranges from $12 billion to $18 billion (in year 2002 dollars).[4] In 2001, the cost of osteoporotic care delivered in hospitals and nursing homes totaled $17 billion.[5]
- Osteoporosis will continue to grow as a major public health problem for both women and men as the population ages.[1] By the year 2020 experts predict that, combined, osteoporosis and osteopenia will affect 61 million Americans over the age of 50 and by the year 2040 the number of hip fractures is estimated to triple or quadruple.[4]
- Screening offers the opportunity to intervene early in the course of disease and prevent further weakening of the bones, thus reducing an individual's risk of fracture.
- Osteoporosis can be effectively treated with medication to improve bone density and reduce the risk of fractures.

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all women over the age of 65 for osteoporosis. The USPSTF also recommends that clinicians screen women at high risk of osteoporosis beginning at age 60. Age and lower body weight (less than 70 kg) are the best predictors of low bone density. There is some evidence to support other risk factors, such as white race, smoking, weight loss, family history, decreased physical activity, alcohol or caffeine use, or low calcium and vitamin D intake.[6]

Evidence Rating: **B (Recommended / At Least evidence)**

The USPSTF found good evidence that the risk for osteoporosis and fracture increases with age and other factors, that bone density measurements accurately predict the risk for fractures in the short-term, and that treating asymptomatic women with osteoporosis reduces their risk for fracture. The USPSTF concluded that the benefits of screening and treatment are of at least moderate magnitude for women at increased risk by virtue of age or presence of other risk factors.[6]

Other Evidence-Based Research Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) has approved the following classes of medications for the treatment of osteoporosis[4,7]:

- Bisphosphonates such as alendronate (Fosomax®), risedronate (Actonel®), and ibandronate (Boniva®).

- Selective Estrogen Receptor Modulators (SERMs) such as raloxifene (Evista®).
- Calcitonin (Miacalcin®)
- Parathyroid hormone (Forteo®)

Evidence Rating:

FDA-approved drug therapies have been shown through clinical trials to effectively reduce osteoporotic or fragility fractures at various sites in the body.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Agency for Healthcare Research and Quality (AHRQ)
- Food and Drug Administration (FDA)
- National Osteoporosis Foundation (NOF)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)
- U.S. Surgeon General

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Osteoporosis is a common and serious disease associated with aging; it is a skeletal disorder characterized by compromised bone strength.[4] Osteoporosis weakens the bones though a thinning of the bone mass, thereby increasing an individual's chance of experiencing a fracture.[2] Fractures occur at different and often multiple sites including the hip, vertebrae, wrist, and forearm. Osteoporosis can also cause chronic pain and loss of height due to compression of the spine. Osteoporosis is defined as a bone mineral density (BMD) 2.5 standard deviations or more below the mean BMD of healthy adult women. Authoritative diagnostic criteria for men are not established, but a BMD value 2.0 to 2.5 below normal for men with an appropriate clinical history has been proposed as a threshold for intervention.[8] Osteopenia is a milder reduction in bone mass (BMD 1- 2.5 SD's below mean of healthy persons), which results in some increased risk of fracture, but not as great as the increased risk associated with osteoporosis. Because osteopenia covers a wide range of BMD values, not everyone with osteopenia is at the same risk of fracture, and therefore the best approach to minimize fracture risk in this group will vary.

Approximately 44 million Americans — 55% of the adult population over the age 50 — have either osteoporosis or osteopenia. Many of the 10 million Americans who have osteoporosis are undiagnosed.[1] Although women have a higher risk of developing osteoporosis than do men, osteoporosis is not only a disease of women and many men experience osteoporotic fractures.

Osteoporosis will continue to grow as a major public health problem for both women and men as the population ages.[1] By the year 2020 experts predict that, combined, osteoporosis and osteopenia will affect 61 million Americans over the age of 50.[4] With such a rise in prevalence, the number of osteoporotic fractures — particularly hip fractures — is likely to increase. In fact, by the year 2040 the number of hip fractures is estimated to triple or quadruple.[4]

There is a strong and direct relationship between declining bone density and increasing risk of fracture. According to a recent research study, women diagnosed with osteoporosis are 4 times as likely to suffer a fracture in the year after they are diagnosed with osteoporosis compared to their peers without osteoporosis.[3] Approximately 50% of postmenopausal women will suffer a fracture as a result of osteoporosis at some point during their lifetime.[2] Twenty-five percent (25%) of these women will suffer a deformity in their spines and 15% will fracture their hips.[3]

Each year, 1.5 million Americans suffer a fracture as a result of bone diseases such as osteoporosis and osteopenia including[1,4]:

- 700,000 vertebral fractures
- 300,000 hip fractures
- 250,000 wrist fractures
- 300,000 fractures at other sites

Vertebral fractures range in severity and can cause severe pain and disfigurement. Vertebral fractures cause 150,000 hospitalizations each year for adults over the age of 65, require approximately 161,000 physician office visits, and lead to over 5 million days of restricted activity.[9]

Hip fractures are one of the most serious complications of osteoporosis. Approximately 10 million men and women over the age of 50 suffer from osteoporosis of the hip, and an additional 33.6 million Americans suffer from osteopenia of the hip.[4] Hip fractures are associated with high mortality rates and are a major cause of disability. Individuals who suffer hip fractures have a 2.8 to 4 greater risk of dying during the first 3 months after the fracture than do fracture-free individuals of similar age, gender, and health status. Individuals who survive a hip fracture often suffer pain, loss of independence, and a reduced quality of life. For example, only 15% of patients are able to walk across a room without assistance six months after a hip fracture.[1] It is estimated that 1 in 5 individuals who suffer a hip fracture is forced to enter a nursing home.[4] Further, hip fractures often initiate a downward spiral in health; 24% of individuals who suffer a hip fracture die within a year of the fracture.[1]

Condition/Disease Risk Factors

Two major risk factors for the presence and severity of osteoporosis are gender and increasing age. Eighty-percent (80%) of those affected by osteoporosis are women.[1] Osteoporosis strikes mainly postmenopausal women in their 60s, 70s, and 80s and the percentage of women with osteoporosis increases markedly with age. Nearly 70% of white women age 80 and older have osteoporosis.[1]

Another major risk factor for osteoporosis is personal history. Individuals who

experienced a fracture in adulthood are at high risk of experiencing a subsequent fracture. Because of this relationship, it is recommended that any individual with a history of a low-trauma fracture should be assessed for osteoporosis if they have not been previously evaluated.[4] Unfortunately, many of those at risk for subsequent fractures fail to be evaluated and treated for osteoporosis.

Other major risk factors for osteoporosis include low body weight, no current use of estrogen, and Caucasian descent. Physical inactivity, tobacco use, weight loss, a family history of osteoporosis and osteoporotic fractures, alcohol and caffeine use, and insufficient calcium or vitamin D intake are also risk factors.[4]

Certain medications, particularly glucocorticoids and other steroids, can induce osteoporosis. Other medications such as those used to treat rheumatoid arthritis, endocrine disorders, and seizure disorders may also increase an individual's risk of osteoporosis.

Rates of osteoporosis vary by ethnicity. The prevalence of osteoporosis is highest in elderly white women. African-American women experience osteoporosis at half the rate of white women, but other ethnic minorities such as Mexican-Americans experience rates similar to whites.[3]

Value of Prevention

Economic Burden of Condition/Disease

The economic burden of fractures resulting from osteoporosis is substantial. Each year there are approximately 1.5 million osteoporotic fractures in the United States, which result in more than 500,000 hospitalizations, over 800,000 emergency room visits, more than 2,600,000 physician office visits and nearly 180,000 nursing home admissions. Hip fractures are the most severe osteoporotic fracture, accounting for 60% of all osteoporotic hospitalizations each year.[4] A recent study that analyzed a private insurance claims database and the Medicare Supplemental and Coordination of Benefits (COB) database, found that osteoporosis patients with concurrent fractures represent just 7% of all osteoporosis patients but are responsible for 61% of the costs attributable to the disease.[10] The estimated annual direct-care expenditure for osteoporotic fractures ranges from $12 billion to $18 billion (in year 2002 dollars).[4] In 2001, the cost of osteoporotic care delivered in hospitals and nursing homes totaled $17 billion.[5] The indirect costs associated with osteoporosis have not been well-studied but would likely raise the direct cost estimates by several billion dollars.[1]

Workplace Burden of Condition/Disease

Osteoporosis dramatically reduces an individual's functional status. Many individuals who suffer fractures are unable to care for themselves during their recuperation, and some are unable to care for themselves ever again. The burden of care often falls on family members who must take time off work to care for affected parents or spouses. Osteoporosis can thus be a direct or indirect cause of lost productivity and absenteeism. While it is rare for working-age adults to suffer severe fractures as a result of osteoporosis, it can — and does — happen, resulting in lost work time and possibly long-term disability. As the workforce ages, the workplace burden of osteoporosis is certain to increase unless preventive measures are implemented.

Economic Benefit of Preventive Intervention

The economic benefits of screening for osteoporosis mainly result from decreases in treatment and rehabilitation costs associated with a reduction in osteoporotic fractures. A full analysis of the economic benefits of screening and early treatment should also include averted mortality and morbidity costs.

Estimated Cost of Preventive Intervention

The cost of screening for osteoporosis varies depending on locality, provider type, and measurement tool used. In 2004, the private-sector cost of the initial health risk assessment averaged $23 and approximately 95% of all paid claims fell within the range of $0 to $81.[11] In 2004, the private-sector cost of osteoporosis screening, bone density scans, and ultrasonography averaged $55 and approximately 95% of all paid claims fell within the range of $0 to $132.[11]

Estimated Cost of Treatment

The cost of treatment varies substantially depending on the type of medication used and its dosage. Average wholesale price (AWP) figures are noted below for a 1-month supply of FDA-approved medications for the treatment of osteoporosis.[12]

Drug Name	2006 Average Wholesale Price (AWP)
alendronate (Fosomax®)	$72.23
calcitonin (Miacalcin®)	$47.08
ibandronate (Boniva®)	$80.90
parathyroid hormone (Forteo®)	$608.72
raloxifene (Evista®)	$80.64
risedronate (Actonel®)	$64.28 (dose pack)
risedronate (Actonel®)	$68.86 (daily)

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

A recent study found that, compared to no intervention, universal screening with bone densitometry combined with alendronate therapy for those diagnosed with osteoporosis is highly cost-effective for women aged 65 years and older and may be cost-saving for ambulatory women age 85 and older.[5]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening and Treatment

Screening for osteoporosis allows clinicians to identify affected patients and begin treatment early in the course of disease. Established treatments can reduce bone loss and improve bone density, thereby reducing the risk of fractures and their associated complications.

Benefits and Risks of Intervention

While no controlled studies have specifically evaluated the effect of screening for osteoporosis on fracture-related mortality, screening does offer the opportunity to intervene early in the course of disease and prevent further weakening of the bones, thus reducing an individual's risk of fracture.

Screening for and treating osteoporosis does carry risks. Women who are diagnosed with osteoporosis report increased fear and anxiety in their daily lives. As with all screening tests, false-positive results can precipitate unnecessary treatment.[7] In the past, women who were screened for osteoporosis were more likely to begin hormone replacement therapy than women who were not screened.

Hormone replacement therapy (HT) carries additional risks. Some of the medications used to treat osteoporosis increase the risk of other serious medical complications such as gastrointestinal disorders, ulcer disease, thromboembolic events, endometrial cancer, and cholecystis.[3] Despite these risks, experts agree that the benefits of screening for osteoporosis and treating osteoporosis in its earliest stages have substantial benefits that outweigh the risks involved.

Initiation, Cessation, and Interval Screening

Screening for osteoporosis should begin for normal-risk women at age 65 and for high-risk women at age 60. The benefits of screening increase with age because osteoporosis affects older women more frequently than younger women and because osteoporosis is more likely to result in fractures in older women.[3] The age at which screening no longer offers substantial benefit is not known and there is little information on screening or treating women over the age of 85 for osteoporosis. Clinicians should cease screening for osteoporosis when a woman and her physician agree that the risks of screening outweigh the benefits of screening. Although there is not yet wide consensus regarding screening in men, some groups have recommended screening healthy men starting at age 70, with earlier testing of men with risk factors such as fracture, primary hyperparathyroidism, or use of GNRH agonists or glucocorticoids.[4]

Treatment

The optimal interval for screening has not been established. Evidence suggests that screening intervals of no less than 2 years is reasonable because the bone density tests are not precise enough to measure a change in bone density reliably in a shorter period of time. Evidence suggests that less frequent screening may be reasonable in younger women.[7]

Intervention Process Screening

Medications used to treat osteoporosis should be used — and covered — as prescribed by a clinician.

Several methods of screening for osteoporosis are currently used. The best predictor of hip fracture is the dual-energy x-ray absorptiometry of the hip (DXA). Other bone density tests include DXA of the spine, whole body or forearm, ultrasound, radiographic absorptiometry, single-energy absorptiometry, peripheral dual-energy x-ray absorptiometry, and peripheral quantitative computed tomography.[3] The likelihood of a diagnosis of osteoporosis depends on the type of measurement tool used, the site of the measurement, the number of sites tested, the brand of the measurement tool, and the relevance of the reference range.[3]

Physician- or self-administered verbal or written screening instruments used to detect and assess the risk of low bone density generally have high sensitivity but low specificity; therefore false-positive results are a greater problem than false-negative results. One validated instrument is the Osteoporosis Risk Assessment Instrument (ORAI), a 3-item tool that uses an individual's age, weight, and hormone replacement therapy history to quantify the risk of osteoporosis. Another instrument is the Simple Calculated Osteoporosis Risk Estimation tool (SCORE), a similar 6-item measure of risk based on age, weight, ethnicity, estrogen use, presence of rheumatoid arthritis, and history of fractures.[3]

Treatment

Health benefits should include provisions for treatment services.

Osteoporosis can be effectively treated with medication to improve bone density and reduce the risk of fractures. The Food and Drug Administration (FDA) has approved the following classes of medications for the treatment of osteoporosis[4,7]:

- Bisphosphonates such as alendronate (Fosomax®), risedronate (Actonel®), and ibandronate (Boniva®)
- Selective estrogen receptor modulators (SERMs) such as raloxifene (Evista®)
- Calcitonin (Miacalcin®)
- Parathyroid hormone (Forteo®)

Any decision to use hormone therapy (HT) must take into consideration its impact on overall health outcomes, including its potential to reduce the risk of fractures and its potential to increase the risk of other health problems. The FDA has advised that postmenopausal women who use, or are considering using, estrogen or estrogen with progestin discuss the therapy's benefits and risks with their physicians. These products are approved therapies for relief from moderate to severe hot flashes and symptoms of vulvar and vaginal atrophy. Although HT is effective for the prevention of postmenopausal osteoporosis, it should only be considered for women at significant risk of osteoporosis who cannot take non-estrogen medications. The FDA recommends that estrogens and progestins should be used at the lowest possible doses for the shortest amount of time needed to achieve treatment goals. It is not yet clear whether following this advice will lead to long-term benefits for bone health.[4]

Note: The USPSTF recommends against ("D" rating) routine use of HT to prevent chronic diseases in postmenopausal women because the harmful effects of unopposed estrogen are likely to exceed the chronic disease prevention benefits in most women.[13]

Treatment Information

Because the purpose of treating osteoporosis it to *prevent* the poor health outcomes associated with fractures, treatment is considered a preventive intervention. Please refer to "Intervention Process" for information on treatment services.

In addition to medications, physical activity, in general, and resistance-weight-training, in particular, is very helpful in preventing fractures. Resistance training helps retard bone loss. Moreover, physical activity reduces the risks of falls by a variety of mechanisms (e.g., increased agility, increased strength, etc), thereby indirectly influencing fracture rates. While there is no direct mechanism for purchasers to cover the promotion of physical activity through health plan benefits, purchasers should encourage their at-risk beneficiaries to partake in physical activity.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The USPSTF found good evidence to support screening all women over the age of 65 for osteoporosis. The Task Force also recommends that clinicians screen women at high-risk of osteoporosis beginning at age 60. Age and lower body weight (less than 70 kg) are the best predictors of low bone density. There is some evidence to support other risk factors, such as: white race, smoking, weight loss, family history, decreased physical activity, alcohol or caffeine use, or low calcium and vitamin D intake.[6]

Food and Drug Administration (FDA)
Strength of Evidence: FDA approved drug therapies have been shown through clinical trials to effectively reduce osteoporotic or fragility fractures at various sites in the body.

- The Food and Drug Administration (FDA) has approved the following classes of medications for the treatment of osteoporosis[4,7]:
  - Bisphosphonates such as alendronate (Fosomax®), risedronate (Actonel®), and ibandronate (Boniva®)
  - Selective estrogen receptor modulators (SERMs) such as raloxifene (Evista®)
  - Calcitonin (Miacalcin®)
  - Parathyroid hormone (Forteo®)

Authored by:

Campbell KP, Lanza A, Looker A. Osteoporosis evidence-statement: screening and treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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EVIDENCE-STATEMENT:

SEXUALLY TRANSMITTED INFECTIONS (Screening and Counseling)

Why This Chapter is Important for Employers: An Overview

This chapter covers screening and counseling interventions for the following sexually transmitted infections: chlamydia, gonorrhea, human immunodeficiency virus (HIV), and syphilis.

- Sexually transmitted infections (STIs) are among the most common infections that occur in the United States today, and they affect men and women of all backgrounds and economic levels.
- Untreated STIs can result in significant complications including major infections, infertility, and death.
- Screening allows for early identification and treatment, which improves outcomes and can prevent transmission of infections to others. Generally, early treatment is also less expensive. For example, the baseline cost of treating early-stage syphilis was estimated to be $41.26 (in year 2001 dollars) compared to $2,061.70 for late-stage syphilis.[1]
- Sexually transmitted infections are a substantial economic burden to the U.S. healthcare system and to employers.
- The most recent estimate of the annual cost of chlamydial infection and its sequelae is $460 million.[2]
- In women, some STIs can progress to pelvic inflammatory disease (PID). A conservative estimate of $1,334, based on a national insurance claims dataset, was reported as the cost per case of PID in year 2000 dollars.[2] The average *lifetime* cost for women who develop major complications of PID is $6,350 for chronic pelvic pain, $6,840 for an ectopic pregnancy, and $1,270 for infertility. Approximately 79% of these costs occur within 5 years of the precipitating infection.[3]
- HIV/AIDS often affects people during their prime working years and HIV/AIDS-induced morbidity and mortality can result in significant economic losses to businesses. Considering only the changes in insurance premiums, disability payments, unemployment benefits, retirement and pension benefits, and lost productivity, a recent study found that, in 2002, an asymptomatic HIV-infected employee would cost an employer in the United States an estimated $37,320 and a symptomatic HIV-infected employee would cost $50,347 per person-year.[4]
- Screening for sexually transmitted infections is especially important because many people with STIs do not experience symptoms in the early phases of disease. For example, it is estimated that 70% to 90% of women and a substantial percentage of men with chlamydia do not have symptoms.[5]

Counseling to Prevent Sexually Transmitted Infections(STIs) (Counseling)

Physicians and other healthcare providers play a critical role in preventing and treating sexually transmitted infections (STIs).[1] Clinicians have the opportunity to provide client education and counseling and to participate in identifying and treating persons with STIs as well as their infected sex partners.

The USPSTF recommends that clinicians educate all adolescents and adults on the risk factors for HIV and other sexually transmitted infections (STIs) and counsel patients on effective measures to reduce their risk of infection. Counseling should be tailored to the needs of the individual and should take into consideration the abilities of each patient.[2]

Interactive counseling approaches directed at a patient's personal risk, the situations in which risk occurs, and use of goal-setting strategies are effective in STI prevention.[3] Results from randomized controlled trials demonstrate that, compared with traditional approaches to providing information, certain brief risk-reduction counseling approaches can reduce the occurrence of new sexually transmitted infections by 25% to 40% among STI clinic patients.[4]

Physicians and other providers should counsel their sexually active patients on the following STIs: chlamydia, gonorrhea, hepatitis B, HIV, and syphilis.

Chlamydia (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians routinely screen all sexually active women aged 25 years and younger for chlamydia.[1] Other asymptomatic women at increased risk (e.g., prior history of a sexually transmitted disease, having cervical ectopy, having multiple or new sex partners, using barrier contraceptives inconsistently) should also be screened for chlamydial infection. However, the USPSTF suggests clinicians consider the characteristics of the communities they serve, particularly prevalence information, in determining appropriate screening strategies.

***Evidence Rating:* A (Strongly Recommended/ Good Evidence)**

The USPSTF found good evidence that screening women at risk for chlamydial infection reduces the incidence of pelvic inflammatory disease (PID) and fair evidence that community-based screening reduces prevalence of chlamydial infection. The USPSTF concluded that the benefits of screening substantially outweigh the potential harms, such as adverse effects of a false-positive or false-negative diagnoses on patients and their partners, and adverse reactions to antibotic treatment.[1]

CDC Recommendation

CDC also recommends screening all sexually active women aged 25 years and younger and older women with risk factors (e.g., those who have a new sex partner or multiple sex partners).[2] All pregnant women should be routinely tested at the first prenatal visit. Pregnant women aged 25 years and younger and those at increased risk should be re-tested during the third trimester to prevent maternal postnatal complications and chlamydial infection in the infant.[2]

Evidence Rating:

Not Specified

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Chlamydia is the most commonly reported bacterial STI in the United States. In 2004, 930,000 cases of chlamydia were reported by state health departments in the United States; a 5% increase compared to 2003.[3] If untreated, chlamydia can result in significant complications in both men and women.

Among women, 20% to 40% of cases of untreated chlamydia infection may progress to pelvic inflammatory disease (PID), a serious condition resulting in chronic pelvic pain, an increased risk of ectopic pregnancy due to scaring of the fallopian tubes, and infertility.[4] Approximately 8% of U.S. women are diagnosed with PID in their lifetime, and over 1 million women are treated for PID each year.[5] Among pregnant women, there is some evidence that chlamydial infection increases the risk of pregnancy complications including premature rupture of the membranes, pre-term delivery, low-birth-weight infants, and postpartum endometritis. A chlamydial infection can be transmitted to an infant by an infected mother during labor and delivery and may cause neonatal conjunctivitis (a severe eye infection) and/or pneumonia.

In men, untreated chlamydia infection can lead to urethritis or acute epididymitis, which can result in infertility, chronic prostatitis, reactive arthritis, and problems with the urethra.[6]

Infection with chlamydia increases both men and women's susceptibility to HIV.

Condition/Disease Risk Factors

Adolescents (of both sexes) and women under the age of 20 are at the highest risk for chlamydial infection; the highest reported rates occur in girls aged 15 to19 years.[7] Chlamydial infections are also prevalent among women aged 20 to 25 years.[6] The prevalence of chlamydia is also higher among African-American populations and among individuals who are unmarried, have a prior history of STIs, have multiple sexual partners, suffer from cervical ectopy, and/or who use barrier contraceptives incorrectly or inconsistently.[6]

Value of Prevention

Economic Burden of Condition/Disease

The most recent estimate of the annual cost of chlamydial infection and its sequelae is $460 million.[8] The *lifetime* medical cost of chlamydia has been estimated at $20 per case for men and $244 per case for women (in year 2000 dollars).[8]

Up to 40% of untreated and 6% of treated cases of acute chlamydia may progress to pelvic inflammatory disease (PID), a serious condition that is expensive to treat. It is estimated that treatment for a single case of PID costs between $1,060 and $3,626.[9] A conservative estimate of $1,334, based on a national insurance claims dataset, was reported as the cost per case of PID in year 2000 dollars.[9]

Workplace Burden of Condition/Disease

The reproductive and other health problems of chlamydia impose a significant cost to employers by way of health and disability insurance costs. The lifetime productivity losses for young working-age adults suffering from the long-term health effects of chlamydial infection are high. An untreated case of chlamydia is estimated to result in $130 in lost productivity costs and an acute case of PID is estimated to result in $632 in lost productivity costs (in year 2001 dollars).[10]

Economic Benefit of Preventive Intervention

Because screening allows for the early recognition of disease and subsequently an earlier initiation of treatment, it can prevent the costly complications of late-stage disease such as PID and infertility.

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of chlamydia screening averaged $42; approximately 95% of all paid claims fell within the range of $0 to $87.[11]

Estimated Cost of Treatment

The estimated direct cost (including office visits, diagnostic testing, and medication) of acute care ranges from $23 to $109 per case.[8]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Annual screening among women 15 to 29 years of age followed by semiannual screening for those with a history of infection was estimated to cost less than $25,000 per quality-adjusted life year (QALY) compared with the annual screening only.[12]

A review of 10 cost-effectiveness studies found that screening was more cost-effective than simply testing symptomatic women. The models showed that in some instances, screening was cost-saving (compared to testing symptomatic women) even at prevalence rates as low 1.1%.[10]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening for chlamydia allows clinicians to identify affected patients and begin treatment earlier in the course of disease, thereby improving outcomes and avoiding the health and economic consequences of latent disease such as PID and infertility. In fact, a recent well-designed randomized trial demonstrated that screening women at risk for chlamydia reduces the incidence of PID by 50%.[13]

Routine screening for chlamydia is especially important because of its asymptomatic nature. It is estimated that 70% to 90% of women (and a substantial percentage of men) with chlamydia do not have symptoms.[6]

Benefits and Risks of Intervention

Few studies have documented the risks associated with screening for chlamydia. Potential risks include partner discord, stigma, and side effects of treatment. As with all types of screening, the risk of false-positive results may cause undue anxiety or unnecessary treatment. The benefits of screening for chlamydia substantially outweigh the harms. Screening allows for early recognition and treatment, reducing complications and long-term effects. Screening programs can lead to reduced person-to-person transmission of infection and can substantially lower infection rates at the population level; states implementing new screening programs have reported up to a 67% decrease in new chlamydial infection rates.[7] Reducing the rate of chlamydia within a population has substantial positive health effects including lower rates of PID.

Initiation, Cessation, and Interval of Screening

Average-risk women should be screened annually from the onset of sexual activity through age 25. Women with known risk factors and women who have experienced a previous infection should continue screening beyond the age of 25, as medically indicated. Re-screening at 6 to 12 months may be appropriate for previously infected women because of high rates of reinfection.[6]

Asymptomatic sex partners of individuals infected with chlamydia should also be screened.

The optimal time for screening during pregnancy is unknown. Screening for chlamydia early in pregnancy offers greater opportunities in reducing the risk of low birth weight and premature delivery. However, screening during the third trimester is thought to be more effective in preventing transmission to the infant during labor and delivery.

Intervention Process

Several effective methods of screening for chlamydia are currently available[6]:

- Nucleic acid amplification tests (NAAT) such as polymerase chain reaction (PCR), strand displacement assay (SDA), and transcription-mediated amplification (TMA) on endocervical/urethral or urine specimens.
- Non-amplified nucleic acid hybridization tests on endocervical specimens.
- Culture analysis of an endocervical or urethral swab.
- Antigen detection tests such as direct fluorescent antibody (DFA) assay and enzyme immunoassay (EIA) on endocervical specimens.
- Point-of-care antigen detection tests on endocervical specimens and leukocyte esterase on urine.
- Culture of swab specimens from exposed sites urethra (male), endocervix, throat, or rectum (male).

Treatment Information

Health benefits should include provisions for diagnostic and treatment services. Treatment, usually a 7-day course of oral antibiotics or a single dose of azithromycin, is easy, inexpensive, and noninvasive. Side effects of treatment (gastrointestinal distress, nausea) occur infrequently. Moreover, treatment is highly effective (97% of nonpregnant women and men treated for chlamydia are cured).[6]

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendation in this section is described below.

Evidence-Based Research:
U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to support routine screening of all sexually active women age 25 years and younger and other asymptomatic women at increased risk for infection.[1]

Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Not Specified

- CDC recommends screening all sexually active women aged 25 years and younger and older women with risk factors (e.g., those who have a new sex partner or multiple sex partners).[2] All pregnant women should be routinely tested at the first prenatal visit. Pregnant women aged 25 years and younger and those at increased risk should be re-tested during the third trimester to prevent maternal postnatal complications and chlamydial infection in the infant.[2]

Gonorrhea (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors).[1]

***Evidence Rating:* B (Recommended/ At Least Fair Evidence)**

The U.S. Preventive Services Task Force found at least fair evidence that screening tests can accurately detect gonorrhea infection and good evience that antibiotics can cure gonorrhea infection. There is at least fair evidence that screening pregnant women at high risk for gonorrhea, including women at high risk because of younger age, may prevent other complications associated with gonococcal infection during pregnancy, such as preterm delivery and chorioamnionitis.[1]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Preventive services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Approximately 335,000 cases of gonorrhea were reported by state health departments in the United States in 2004, a slight decrease when compared to 2003 data.[2]

Complications of gonorrhea for women include pelvic pain, pelvic inflammatory disease (PID), ectopic pregnancy, and infertility. Pregnant women infected with gonorrhea are at an increased risk for pregnancy complications such as chorioamnionitis, premature rupture of membranes, preterm labor, and stillbirth.[3] Infected women may also pass the disease to their infants during pregnancy, labor, and delivery. Gonococcal opthalmia can cause conjunctivitis leading to corneal scarring and blindness.

In men, gonorrhea can cause urethritis or epididymitis, but few serious or long-term complications.

Gonorrhea also increases both men and women's susceptibility to other STIs, including HIV.

Condition/Disease Risk Factors

Risky sexual behavior is the major risk factor for gonorrhea. As with most STIs, younger populations are at highest risk. The highest reported rates of gonorrhea are among female adolescents 15 to 19 years of age and adult males and females 20 to 24 years of age.[1] The rate of gonorrhea among African-Americans is 20 times higher than the rate among whites.[1] Persons with other types of STIs (e.g., chlamydia) may be more susceptible to contracting gonorrhea.

Value of Prevention

Economic Burden of Condition/Disease

The *lifetime* medical care cost of gonorrhea has been estimated at $53 per case for men and $266 per case for women (in year 2000 dollars).[4]

Workplace Burden of Condition/Disease

In addition medical and disability-related costs, the workplace burden of the disease includes:

- Productivity losses among gonorrhea-infected employees;
- Direct medical costs for infected adolescents who are covered by their parent's insurance plan; and
- Productivity losses associated with the time employee caregivers dedicate to attending to sick dependents (i.e., children or spouses).

Economic Benefit of Preventive Intervention

Because screening for gonorrhea allows for the early recognition of disease and leads to earlier treatment, it may prevent the costly complications of late-stage disease such as PID. The average lifetime cost of PID has been estimated to range

from $1,060 to $3,626 in year 2000 dollars.[4] The average lifetime cost for women who develop major complications of PID is $6,350 for chronic pelvic pain, $6,840 for an ectopic pregnancy, and $1,270 for infertility; 79% of these costs have been found to occur within 5 years of the precipitating infection.[5]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of screening for gonorrhea screening averaged $17; approximately 95% of paid claims fell within the range of $0 to $63.[6]

Estimated Cost of Treatment

The cost of treatment for gonorrhea will vary depending on the type of antibiotic chosen.

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

A recent study that focused on gonorrhea screening in urban emergency departments found that screening women between 15 and 29 years of age using urine-based nucleic acid amplification tests (NAAT) saved $177 (in year 2002 dollars) per patient compared to no screening.[7]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening for gonorrhea allows clinicians to identify affected patients and begin treatment earlier in the course of disease, thus potentially improving outcomes and avoiding the health and economic consequences of latent disease. Screening is particularly important for women because many women who are infected with gonorrhea have no symptoms and are thus unaware of their condition.[8]

Benefits and Risks of Intervention

The benefits of screening for gonorrhea are substantial. Screening allows for early recognition and treatment, dramatically reducing complications, other long-term effects, and the transmission of the infection to others. Few studies have documented the risks associated with screening for gonorrhea. Possible risks include partner discord, stigma, opportunity costs (in terms of time and resources) for both the clinician and the patient, and side effects of treatment. As with all types of screening, the risk of false-positive results may cause undue anxiety or unnecessary treatment. The USPSTF found that the benefits of screening outweigh the risks associated with screening.[1]

Initiation, Cessation, and Interval of Screening

Routine screening for gonorrhea is recommended for all women under the age of 25 and women over the age of 25 who are at risk of infection, especially women who are in one or more of the following established high-risk groups: commercial sex workers, women with a prior history of gonorrhea, and women who live in regions where infection rates are high.

The frequency of screening is left to the discretion of the provider and should be based on the individuals' risk factors and previous history of STIs.

All pregnant women at risk for gonorrhea should be screened during the first trimester, ideally during the first prenatal care visit. Pregnant women at continued risk of infection should be re-screened again during the third trimester.[1]

Intervention Process

Several effective methods of screening for gonorrhea are currently available[1]:

- Culture of swab specimens from exposed sites (urethra [male], endocervix, throat or rectum [male]).
- Nucleic acid amplification assays such as polymerase chain reaction (PCR), strand displacement assay (SDA), and transcription-mediated amplification (TMA) on genital swab or urine specimens.
- Microscopic examination of Gram-stained urethral or cervical specimen.
- Non-amplified nucleic acid hybridization tests on genital swab specimens.
- Point-of-care antigen detection tests on genital swab specimens and urine dipstick for leukocyte esterase (LE).

Treatment Information

Gonorrhea can be effectively treated with antibiotics. Health benefits should include provisions for diagnostic, follow-up, and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendation in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: B (Recommended/At Least Fair Evidence)

- The U.S. Preventive Services Task Force found at least fair evidence that screening tests can accurately detect gonorrhea infection and good evidence that antibiotics can cure gonorrhea infection. There is at least fair evidence that screening pregnant women at high risk for gonorrhea, including women at high risk because of younger age, may prevent other complications associated with gonococcal infection during pregnancy, such as preterm delivery and chorioamnionitis.[1]

Human Immunodeficiency Virus (HIV) (Screening and Counseling)

Clinical Preventive Service Recommendations

Special Notice

This special notice is included to alert readers about differences between Centers for Disease Control and Prevention (CDC) and U.S. Preventive Services Task Force (USPSTF) HIV screening recommendations for individuals who are not at increased risk for HIV infection.

In 2006, the CDC issued new HIV testing guidance for healthcare settings that recommends screening all patients aged 13 to 64 years for HIV. In 2005, the USPSTF considered HIV screening and issued a "C"-rating, thereby making no recommendation for or against routinely screening adults and adolescents who are not considered to be at increased risk for HIV infection.

The *Purchaser's Guide* recommendation reflects the broader CDC recommendation. The CDC recommendation is preferred because clinicians are not consistently able to distinguish between high- and no-risk testing candidates[1-2] and because spread often occurs between individuals who do not know that they are infected.[3]

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians screen all adolescents and adults with an increased risk of infection for human immunodeficiency virus (HIV). Increased risk is defined by the USPSTF as having one or more individual risk factor STIs or receiving healthcare in a high-prevalence or high-risk clinical setting. Please refer to the "Condition/Disease Risk Factors" section for additional information.[4]

The USPSTF recommends that clinicians screen all pregnant women for HIV.[4]

***Evidence Rating:* A (Strongly Recommended/Good Evidence)**

The USPSTF found good evidence that both standard and U.S. Food and Drug Administration (FDA)-approved rapid screening tests accurately detect HIV infection. The USPSTF also found good evidence that appropriately timed clinical intervention, particularly highly active antiretroviral therapy (HAART), lead to improved health outcomes for many of those screened, including reduced risk for clinical progression and reduced mortality.[4]

***Evidence Rating:* A (Strongly Recommended/Good Evidence)**

The USPSTF found good evidence that both standard and FDA-approved rapid screening tests accurately detect HIV infection in pregnant women and fair evidence that the introduction of universal prenatal counseling and voluntary testing increases the proportion of HIV-infected women who are diagnosed and are treated before delivery. There is good evidence that recommended regimens of HAART are acceptable to pregnant women and lead to significantly reduced rates of mother-to-child transmission.[4]

CDC Recommendation

The Centers for Disease Control and Prevention (CDC) recommends that providers screen all patients aged 13 to 64 years for HIV unless prevalence of undiagnosed HIV infection among the provider's patient population has been documented to be less than 0.1%.[5]

Subsequent HIV tests should be provided to all persons likely to be at high risk (i.e., sex partners of HIV infected persons, men who have sex with men, heterosexuals who themselves or whose sex partners have had a new sex partner or more than one sex partner since their most recent HIV test, injection drug users, and persons who exchange sex for money or drugs) all patients seeking treatment for an STI, and those who are initiating a new sexual relationship.[5]

The Centers for Disease Control and Prevention (CDC) also recommends that clinicians screen all pregnant women for HIV.[6]

Evidence Rating:

CDC recommendations were developed with guidance from the scientific literature and expert technical opinion. Information was also drawn from a survey CDC conducted with HIV CTR practitioners. Internal CDC edits and public comments were obtained.[5]

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS), is a retrovirus that attacks helper T cells of the immune system. It causes immune deficiency because it reduces the number and functionality of CD4 lymphocytes. HIV is transmitted when the infected blood, semen, or vaginal secretions of an infected person comes into contact with the broken skin or mucous membranes of an uninfected person. Infected pregnant women can pass HIV to their babies during pregnancy or delivery, or when breastfeeding.

HIV is known to affect between 1,039,000 and 1,185,000 persons in the United States; a quarter of those infected with the virus are unaware of their status.[7] There are approximately 40,000 new HIV infections diagnosed each year in the United States.[8] Untreated HIV infection eventually develops into AIDS and ultimately leads to death.[9] More than 500,000 people in the United States have died from AIDS; 18,000 in 2003 alone.[8]

While antiretroviral therapies can slow the damage that HIV does to the body's immune system by decreasing the amount of virus is the body, HIV infection is not curable. An HIV-positive person will develop AIDS when CD4 lymphocyte levels have dropped so low as to allow opportunistic infections and/or cancers.

Condition/Disease Risk Factors

HIV infection is more common in certain segments of the U.S. population. There is some evidence that about half of all HIV infections are acquired by those under the age of 25.[6] Of newly diagnosed HIV infections in 2003, CDC estimates that 63% were among men who have sex with men (MSM), 50% were among blacks, 32% were among whites, and 16% were among Hispanics.[10]

Individual risk factors include:

- Men who have had sex with men (MSM) after 1975.
- Men and women who have unprotected sex with multiple partners.
- Past or present injection drug users.
- Men and women who exchange sex for money or drugs or have sex partners who do.

- Persons whose past or present sex partners were HIV-infected, bisexual, or injection drug users.
- Persons being treated for sexually transmitted infections (STIs).
- Persons with a history of blood transfusion between 1978 and 1985.

Persons who request an HIV test despite reporting no individual risk factors may also be considered at increased risk. High-risk settings include STI clinics, correctional facilities, homeless shelters, tuberculosis clinics, clinics serving men who have sex with men, and adolescent health clinics with a high prevalence of STIs. High-prevalence settings are defined by the CDC as those known to have a 1% or greater prevalence of infection among the patient population being served.

Value of Prevention

Economic Burden of Condition/Disease

The economic burden of HIV in the United States is substantial. The average *lifetime* cost per case (in year 2000 dollars) is estimated at $199,800.[11] Accounting for the 15,000 new cases reported annually among 15 to 24-year-olds, the total direct cost of HIV in the United States was approximately $3.0 billion in 2000.[11]

Workplace Burden of Condition/Disease

HIV/AIDS often affects people during their prime working years and HIV/AIDS-induced morbidity and mortality can result in significant economic losses to businesses. Considering only the changes in insurance premiums, disability payments, unemployment benefits, retirement and pension benefits, and lost productivity, a recent study found that, in 2002, an asymptomatic HIV-infected employee would cost an employer in the United States an estimated $37,320 and a symptomatic HIV-infected employee would cost $50,347 per person-year.[12]

Economic Benefit of Preventive Intervention

Earlier diagnosis of HIV infection is associated with less expensive treatment. For those with CD4 counts greater than 500, monthly expenditures for treatment total approximately $500. This figure increases to $2,300 per month for those with CD4 counts less than 50. Generally, the earlier HIV infection is detected, the higher the CD4 count.[13]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of HIV screening averaged $23; approximately 95% of all paid claims fell within the range of $4 to $75.[14] In 2004, the private-sector cost of HIV counseling averaged $39 and approximately 95% of all paid claims fell within the range of $0 to $129.[14]

Estimated Cost of Treatment

The average annual cost of treating an HIV-infected patient is estimated to range between $18,000 and $20,000.[15]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Researchers studied the costs associated with screening and treating HIV/AIDS in pregnant women and found that universal screening can be cost-saving in this population. For example, compared to no screening, a universal screening program targeting pregnant women would save an estimated $3.69 million dollars and prevent 64.6 cases of pediatric HIV infection for every 100,000 pregnant women screened.[16]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening allows for the earlier diagnosis of HIV infection, which is associated with less expensive treatment, better health outcomes, and reduced risk of spread of infection to other persons.

Purpose of Counseling

Counseling services are required to educate screening candidates on 1) the benefits and risks of screening, 2) risk reduction strategies, and, for those who screen positive, 3) treatment options.

Benefits and Risks of Intervention

The benefit of screening and counseling includes early diagnosis of HIV infection, the potential for a longer life (due to earlier initiation of treatment), and the opportunity to prevent disease transmission. Counseling also allows prevention and risk-reduction messages to be conveyed. The benefits associated with screening pregnant women are also substantial. Screening allows for early detection and treatment and can prevent mother-to-child transmission. There is no evidence of an increase in fetal anomalies or other fetal harm associated with recommended antiretroviral regimens.[4]

Risks associated with screening for HIV include false-positive test results and partner discord. Information about the effects of false-positive test results (e.g., anxiety, labeling) is predominately anecdotal. The standard method of diagnosing HIV infection (a repeatedly-reactive enzyme immunoassay followed by confirmation Western blot of immunoflourescent assay) has a 1 in 250,000 test chance of false-positive identification in a low prevalence setting.[8] Newer HIV detection technologies, specifically the rapid HIV tests, are similar to traditional tests with extremely low false-positive rates. False- and true-negative test results may give false reassurance to those engaging in high-risk behavior, leading to its continuation. Finally, notification of a positive HIV test can cause emotional or psychological distress.

Initiation, Cessation, and Interval Screening

Although no studies have evaluated the optimal frequency of screening for HIV/AIDS, it is recommended that screening be conducted at the discretion of a clinician with frequency determined by an individual's risk factors and the characteristics of the region in which the clinician practices.

All pregnant women should be screened as early as possible, ideally at the first prenatal care visit.[17] Pregnant women at high risk for infection or all women living in an area with high HIV prevalence among women of childbearing age should be re-tested during the third trimester.[17]

Counseling

Counseling should be provided before and after screening, as medically indicated.

Intervention Process Screening

The standard method of screening for HIV/AIDS uses an enzyme immunoassay on serum or plasma; if the enzyme immunoassay is repeatedly reactive, a confirmatory Western blot or immunoflourescent assay is then performed. Several HIV tests that provide results within 10 to 30 minutes are available. The

Food and Drug Administration (FDA) has also approved a home collection kit, which uses a blood sample from a finger prick for testing purposes.

There are three approved methods of screening for HIV, including:

- Repeatedly-reactive enzyme immunoassay followed by confirmatory Western blot or immunoflourescent assay on serum or plasma.
- Rapid HIV tests with result in 10-30 minutes; two point-of-care rapid tests are available (Uni-Gold Recombigen & Oraquick Advance) and one rapid test is intended for laboratory use.
- A home collection kit (Home Access) that uses a dried blood spot.

Counseling

All patients should receive counseling and educational information on HIV and HIV screening before they are screened. Patients that have behaviors that place them at high risk for acquiring HIV infection (e.g., multiple sex partners, history of STIs, substance abuse, etc) should be referred to an HIV risk-reduction service (e.g., HIV centers with personnel trained in HIV counseling, drug treatment centers, etc).[18]

Treatment Information

Health benefits should include provisions for follow-up and treatment services.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendation in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to support routine screening for HIV among all adolescents and adults with an increased risk of infection for human immunodeficiency virus (HIV).[4]
- The USPSTF found good evidence to support routine screening for HIV among all pregnant women.[4]

Recommended Guidance:

Centers for Disease Control and Prevention (CDC)
Strength of Evidence: CDC recommendations were developed with guidance from the scientific literature and expert technical opinion. Information was also drawn from a survey CDC conducted with HIV CTR practitioners. Internal CDC edits and public comments were obtained.

- The CDC found good evidence to support routine screening for HIV among all pregnant women.[5]
- The CDC found good evidence to support the provision of HIV-related counseling, testing, and referral (CTR) to all patients on a routine basis to ensure that those clients that may benefit from the service have the opportunity to do so.[5]

Syphilis (Screening)

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen all persons at increased risk for syphilis infection. Increased risk includes men who have sex with men (MSM) and engage in high-risk sexual behavior, commercial sex workers, persons who exchange sex for drugs, and those in adult correctional facilities. Clinicians should consider the characteristics of the communities they serve in determining appropriate screening strategies.[1]

The USPSTF strongly recommends that clinicians screen all pregnant women for syphilis infection.[1]

***Evidence Rating:* A (Strongly Recommended/Good Evidence)**

Although the USPSTF found no new direct evidence that screening for syphilis infection leads to improved health outcomes in persons at increased risk, there is adequate evidence that screening tests can accurately detect syphilis infection and that antibiotics can cure syphilis.[1]

A (Strongly Recommended/Good Evidence)

The USPSTF found observational evidence that the universal screening of pregnant women decreases the proportion of infants with clinical manifestations of syphilis infection and those with positive serologies.[1]

CDC Recommendation

CDC also recommends screening of all pregnant women, and all persons at increased risk for syphilis infection, per the USPSTF definition.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Approximately 33,289 cases of syphilis were reported by state health departments in the United States in 2004, a slight decrease when compared to 2003 data.[2] Syphilis rates vary dramatically by region and are highest in the Southeastern United States and in concentrated pockets of metropolitan areas such as Atlanta, Baltimore, Chicago, Detroit, Indianapolis, Memphis, New Orleans, Newark, Richmond, St. Louis, and Washington, D.C.[3] Surveillance data from the Centers for Disease Control and Prevention (CDC) indicate that the rate of syphilis increased nationwide by 19% between 2000 and 2003.[4]

Syphilis is a serious condition that, if left untreated, may result in cardiovascular and neurological complications leading to disability and ultimately death.[1] Syphilis can be transmitted from an infected mother to her infant during labor and delivery. Congenital syphilis can be particularly severe and results in fetal or infant death in 40% of cases.[1] Infants who survive may suffer serious central nervous system abnormalities, deafness, bone and joint deformities, skin abnormalities, blood disorders, and other problems.

Condition/Disease Risk Factors

Populations at increased risk for syphilis infection (as determined by incident rates) include men who have sex with men and engage in high-risk sexual behavior, commercial sex workers, persons who exchange sex for drugs, and those in adult correctional facilities.[1]

The prevalence of syphilis infection varies widely among communities and patient populations.[1] Some populations have a particularly high risk of infection, specifically African-Americans and people living in the Southeastern United States.[5] In 2004, the incidence of P&S syphilis was highest among women aged 20 to 24 years (3.0 cases per 100,000 population) and among men aged 35 to 39 years (12.4 cases per 100,000 population).[6]

Value of Prevention

Economic Burden of Condition/Disease

The lifetime cost per case of syphilis has been estimated at $444 (in year 2000 dollars).[7] The economic burden of syphilis would be much higher if the costs of congenital syphilis and HIV infections occurring from the facilitating effect of syphilis were included in cost analyses.

Workplace Burden of Condition/Disease

The health, disability, and life insurance costs of syphilis-infected employees impose a significant economic burden on employers. Lost productivity may also accrue when infected employees seek medical attention for their condition.

Economic Benefit of Preventive Intervention

Screening and early detection are key to averting costs associated with disease progression and long-term complications. The avertable syphilis-attributable HIV cost was estimated to be $4,653 (in year 1996 dollars) for each new syphilis case.[8] Treatment for early stage syphilis is also much less expensive than treatment for later stage disease: the baseline cost of treating early syphilis was estimated to be $41.26 (in year 2001 dollars) compared to $2,061.70 for late syphilis.[9]

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of screening for syphilis averaged $12; approximately 95% of all paid claims fell within the range of $0 to $32.[10]

Estimated Cost of Treatment

The cost of treating syphilis will vary depending on the treatment medication and other factors. The public-sector cost of standard IM benzathine penicillin therapy (first-line treatment) ranged from $18.64 to $22.22 (in year 2001 dollars).[9] Treatment for late-stage syphilis can cost upwards of $2,000 (in year 2001 dollars).[9]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

One study compared the per-case cost and cost-effectiveness of two alternative strategies – selective screening and partner notification — from the perspective of a health department. When prophylactic treatment of sexual contacts was not considered, selective screening proved to be more cost-effective. Cost, in general, was low for both strategies for all cases of infectious syphilis considered.[11]

Serological screening of pregnant women can be cost-effective even when there is a very low prevalence of maternal infection because screening is inexpensive while treating congenital syphilis is costly.[12]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening for syphilis allows clinicians to identify affected patients and begin treatment earlier in the course of disease, potentially improving outcomes and avoiding the health and economic consequences of latent disease. Treatment also reduces the likelihood of spread to others.

Benefits and Risks of Intervention

No studies have documented the harms associated with screening for syphilis. Potential harms include partner discord, stigma, unnecessary anxiety or treatment in the case of a false-positive result, and opportunity costs (in terms of time and resources) to both the clinician and the patient. Harms of treatment include allergic reaction to penicillin, and side effects of the medication including the Jarisch-Herxheimer reaction (fever, headache, and pain that occurs during the 24 hours after initiating antibiotic treatment for syphilis due to the release of treponema antigens).[1]

The benefits associated with screening are great. Screening allows for early detection and treatment, preventing complications that may occur in later stages of disease, and it reduces the risk that syphilis will be spread to others. Antibiotic treatment for syphilis is effective and inexpensive. The USPSTF concluded that the benefits of screening persons at increased risk for syphilis infection substantially outweigh the potential harms.[1]

Initiation, Cessation, and Interval of Screening

The optimal screening interval for syphilis is unknown. Experts recommend that clinicians base the frequency at which they screen patients for syphilis on the patient's risk factors and the characteristics of the community in which they practice. Pregnant women at risk of syphilis should be screened at the first visit of every pregnancy and, if at high risk, again during the third trimester (28 weeks) and at delivery.[5]

Intervention Process

A variety of syphilis tests are available and in development. Screening for syphilis typically involves the use of 2 different tests, a nontreponemal test and a treponemal-specific test, for screening and confirmation. For example, a nontreponemal blood test such as the venereal disease research laboratory (VDRL) or the rapid plasma reagin (RPR) may be performed, a second, different kind of test, such as the fluorescent treponemal antibody absorbed (FTA-ABS) or the *T. palladium* particle agglutination (TP-PA) may then be used to confirm the results of the nontreponemal test.[1]

The tests for syphilis screening that are approved or pending FDA approval include:

- Nontreponemal test such as the venereal disease research laboratory (VDRL) or the rapid plasma regain (RPR) on serum specimens followed by a fluorescent treponemal antibody absorbed (FTA-ABS) or *T. palladium* particle agglutination (TP-PA) for confirmation.
- Immunochromatographic strip (ICS) point-of-care test on blood specimen, when FDA approved.
- Line Immunoassay (LIA) point-of-care test on blood specimen, when FDA approved.
- Enzyme-linked immunosorbent assay (ELISA) for treponemal antibody in serum specimens.
- RPR point-of-care test for nontreponemal antibody in serum specimens.
- Dark field microscope examination of lesion specimens.

Follow-up tests should be performed using the same nontreponemal test initially used to document infection (e.g., VDRL or RPR) to ensure comparability.

Treatment Information

Syphilis is treated with penicillin. Health benefits should include provisions for treatment.

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendation in this section is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to support screening for syphilis among all persons at increased risk for syphilis infection.[1]
- The USPSTF found good evidence to support screening for syphilis among all pregnant women.[1]

Authored by:

Campbell KP, Lentine D. Sexually transmitted infections (STIs) evidence-statement: screening and counseling. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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EVIDENCE-STATEMENT:

TOBACCO USE TREATMENT (Screening, Counseling, and Treatment)

Why This Chapter is Important for Employers: An Overview

- Tobacco use is the leading cause of preventable death in the United States. Each year, approximately 440,000 individuals die as a result of smoking[1], accounting for 20% of all deaths in the United States annually.[2]
- In the United States the direct medical costs associated with smoking total $75.5 billion per year.[2] Smoking also costs an estimated $92 billion per year in lost productivity due to sickness and premature death.[3]
- Smokers who successfully stop smoking reduce their potential medical costs associated with cardiovascular disease by an average of $47 during the first year and approximately $853 during the following 7 years (in year 1995 dollars).[4]
- Cost analyses have shown that tobacco-cessation benefits, from an employer's perspective, are cost-saving.[5] An employer's cost to implement a tobacco-cessation program becomes cost-neutral at 3 years and begins to save healthcare dollars at 5 years.[6]
- Screening for tobacco use allows clinicians to identify tobacco users and offer them effective cessation treatments such as counseling and pharmacotherapy (nicotine replacement products or cessation medications). Counseling and pharmacotherapy have each been proven to double quit rates.[7]

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation (USPSTF)

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco products.[8]

Evidence Rating: **A (Strongly Recommended/ Good Evidence)**

The USPSTF found good evidence that brief smoking cessation interventions, including screening, brief behavioral counseling (less than 3 minutes), and pharmacotherapy delivered in primary care settings, are effective in increasing the proportion of smokers who successfully quit smoking and remain abstinent after 1 year. The USPSTF and the Surgeon General's Report on the Health Consequences of Smoking found good evidence that smoking cessation lowers the risk for heart disease, stroke, cancer, and lung disease.[9-10] The USPSTF concluded that there is good evidence that even small increases in the quit rates from tobacco cessation counseling and/or medication would produce important health benefits.[8]

The USPSTF strongly recommends that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.[8]

The USPSTF found good evidence that extended or augmented smoking cessation counseling (5 to 15 minutes) using messages and self-help materials tailored for pregnant smokers, compared with brief generic counseling interventions alone, substantially increases abstinence rates during pregnancy and leads to increased birth weights. Although relapse rates are high in the post-partum period, the USPSTF concluded that reducing smoking during pregnancy is likely to have substantial health benefits for both the baby and the expectant mother.

CDC Recommendation

The *Community Guide to Preventive Services* strongly recommends providing coverage for tobacco dependence treatment and initiating provider reminder systems to enhance treatment.[11]

***Evidence Rating:* Strongly Recommended/ Strong Evidence**

Recommendations are based on the strength of the evidence of effectiveness found through a systematic review of published studies conducted by a team of experts on behalf of the Task Force. Strong evidence indicates that there are a number of supportive studies that recommend the action.[12]

Other Recommended Guidance U.S. Public Health Service

The U.S. Public Health Service Clinical Practice Guideline, *Treating Tobacco Use and Dependence* (PHS Guideline) strongly recommends screening for tobacco use and providing tobacco cessation treatment (including counseling and/or medication).[13] The U.S. Public Health Service found good evidence that benefits covering screening for tobacco use and providing cessation treatment (counseling and pharmacotherapy) to those who use tobacco are effective in increasing the proportion of smokers who successfully quit and remain abstinent at one year.[7]

***Evidence Rating:* Strongly Recommended/ Strong Evidence**

Recommendations are based on research from multiple, well-designed randomized clinical trials, directly relevant to the recommendation that yielded a consistent pattern of findings.

Centers for Medicare and Medicaid Services (CMS)

The Centers for Medicare and Medicaid Services (CMS) recommends that physicians provide tobacco screening, counseling, and treatment services. Medicare provides coverage for 2 cessation attempts per year. Each attempt includes a maximum of 4 intermediate or intensive counseling cessations for a total maximum benefit of 8 counseling sessions in a 12-month period. Medicare Part D covers all smoking cessation medications that are prescribed by a physician.[13]

Evidence Rating:

CMS Mandate

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Center for Medicaid and Medicare Services (CMS)
- Centers for Disease Control and Prevention (CDC)
- *Community Guide to Preventive Services*
- George Washington University, Center for Health Services Research and Policy
- Partnership for Prevention
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)
- U.S. Public Health Service (PHS)
- U.S. Surgeon General

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Tobacco use contributes to many diseases and is the primary underlying cause of death in the United States. Each year, approximately 440,000 individuals die as a result of smoking[1], accounting for 20% of all deaths in the United States annually.[2] Approximately 155,000 of these deaths result from cancer, 80,000 result from ischemic heart disease, and 17,000 result from cerebrovascular disease.

Among the estimated 43.4% (91.5 million) of persons alive in 2003 who had ever smoked, 50.3% (45.9 million) were former smokers and 49.7% (45.4 million) were current smokers. Current smokers make up 20.9% of the adult population in the United States. If these current smokers continue smoking, half will die due to their tobacco use.[2]

Tobacco use also affects the health of non-smokers. Second-hand smoke exposure at work or at home (also called environmental tobacco smoke) increases non-smokers' risk of developing heart disease by 25% to 30% and increases their risk of lung cancer by 20% to 30%.[14] Second-hand smoke exposure contributes to the deaths of 38,000 people each year; 3,000 die as a result of lung cancer and 35,000 die as a result of cardiovascular disease.[2] In addition, each year in the United States 300,000 children suffer from respiratory tract infections and asthma as a result of being exposed to secondhand smoke.[15] Smoking during pregnancy is particularly dangerous because it increases the risks of premature birth, miscarriage, stillbirth, and low birth weight.[10] Prenatal tobacco use resulted in an estimated 1,007 infant deaths annually between 1995 and 1999.[16]

There is substantial evidence that smoking cessation improves health by lowering an individual's risk for diseases caused by smoking such as heart disease, stroke, and cancer.[1] Yet despite the documented risks of smoking, 20.8% of the United States population continues to smoke.[2] Seventy percent (70%) of smokers say they want to quit and each year 41% of smokers make a quit attempt of at least 24 hours.[6] Without assistance, only 7% are abstinent at 1 year.[17]

Condition/Disease Risk Factors

There are numerous risk factors for cigarette smoking, including: younger age, male sex, race, a lower level of education, and low socioeconomic status.[18]

Young adults (18 to 24-year-olds and 25 to 44-year-olds) are more likely to smoke than older adults (45 to 64-year-olds and persons above the age of 65).[18] Nearly 80% of all adult smokers began smoking before they were 18 years old, and it is estimated that more than 2,000 adolescents become daily smokers each day.[19] During 2005, 23% of high school students smoked cigarettes daily.[20]

Men are also at increased risk of tobacco use; while 23.4% of men smoke cigarettes, only 18.5% of women smoke.[18]

The prevalence of cigarette smoking by race is highest among American Indians/Alaska Natives (33.%), followed by whites (22.2 %), African-Americans (20.2%), Hispanics (15%), and Asians [excluding Native Hawaiians and other Pacific Islanders] (11.3%).[18]

Approximately 39.6% of adults with a General Education Development (GED) diploma and 34% of adults with 9 to 11 years of education smoke, while only 11.7% of adults who complete an undergraduate degree and 8% of adults who complete a graduate college degree smoke.[18] Cigarette smoking is also more common among adults who live below the poverty level (29.1%) than among those living at or above the poverty level (20.6%).[18]

Value of Prevention

Economic Burden of Condition/Disease

The cost of smoking-related illnesses and the loss of productivity associated with smoking are considerable. In the United States, the direct medical costs associated with smoking are $75.5 billion per year.[3] During 1997 to 2001, these expenditures plus productivity losses exceeded $167 billion per year.[3]

Individuals who smoke have higher total medical expenses than do nonsmokers due to their higher burden of illness. Men who smoke incur $15,800 and women who smoke incur $17,500 more in lifetime medical expenses than do nonsmokers (in year 2002 dollars).[3]

Workplace Burden of Condition/Disease

In addition to direct medical costs, smokers incur higher costs related to disability, lost productivity, and absenteeism than do nonsmokers. For example, men who smoke use 4 more sick days per year than do nonsmoking males, and women who smoke use 2 more sick days per year than do nonsmoking females.[6] In 1999, lost productivity due to smoking and smoking-related illnesses cost employers $1,897 per smoking employee. Excess medical expenses due to smoking and smoking-related illnesses cost employers $1,850 per smoking employee (both figures are adjusted to year 2002 dollars).[3]

Economic Benefit of Preventive Intervention

Smokers who successfully stop smoking reduce potential medical costs associated with cardiovascular disease by about $47 during the first year and by about $853 during the following 7 years (in year 1995 dollars).[4,21] An annual drop of 1 percentage point in smoking prevalence among pregnant women would prevent 1,300 low birth weight live births and save 21 million in direct medical costs in the first year of a smoking cessation program.[22] Besides the savings in healthcare costs, economic benefits of preventive intervention include reductions in absenteeism costs, on-the-job productivity loss, life-insurance costs, and costs associated with fire and property damage due to smoking.[6,23]

Estimated Cost of Preventive Intervention

The cost of implementing a comprehensive tobacco cessation program including screening, counseling, and treatment, will vary by location and provider base, but is generally considered to be low. Research has shown

that the average cost of providing a comprehensive tobacco cessation program for all employees ranges from 10 cents to 40 cents per member, per month.[24]

In 2004, the private-sector cost of screening for tobacco use averaged $39; approximately 95% of all paid claims fell within the range of $0 to $129.[25] In 2004, the private-sector cost of counseling averaged $39 per session; approximately 95% of all paid claims fell within the range of $0 to $134 per session.[25]

The cost of pharmacological interventions vary depending on type and dosage. The average wholesale price (AWP) of a 1-month supply of bupropion ranges from $86.54 to $196.07 depending on the brand and type chosen; a 1-month supply of varenicline (Chantix™) is $89.60.[26]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

Research has shown that tobacco screening and cessation-treatment efforts are cost-effective from a societal perspective. Cost analyses have shown that the provision of tobacco-cessation benefits are cost-saving from an employer's perspective.[12] The cost to employers of implementing a tobacco cessation program equalizes at 3 years and begins to save healthcare dollars at 5 years.[6]

Smokers who successfully stop smoking reduce potential medical costs associated with cardiovascular disease (including heart attack and stroke) by about $47 during the first year and by about $853 during the following 7 years.[4] In fact, treating tobacco use ranked the highest among adult preventive services in terms of health impact, cost-effectiveness and cost, yet, according to a recent study by the Partnership for Prevention, the service is provided to less than 35% of tobacco users.[12]

The most cost-effective population to target for smoking cessation programs is pregnant women.[4] Pregnant women incur an additional $704 in neonatal healthcare costs compared to nonsmokers. Clinical trials have shown that, for every $1 invested in smoking cessation programs for pregnant women, $7.75 are saved in short-term medical costs and an additional $7.63 (in year 2002 dollars) are saved in long-term costs by preventing disability among low birth weight infants who survive.[5]

The manner in which tobacco cessation programs are crafted influences their cost-effectiveness. For example, reducing the patient out-of-pocket costs for effective cessation therapies provides a net benefit of $362 to $1,449 per enrollee.[27] In fact, subsidizing the out-of-pocket expense for patients who wish to quit smoking increases the use of effective cessation therapies, increases the number of people who attempt to quit, and — most importantly — increases the number of people who quit successfully.[28]

Preventive Intervention Information

Preventive Intervention: Purpose of Screening, Counseling, and Treatment

Screening for tobacco use allows clinicians to identify tobacco users and offer them effective cessation treatments such as counseling and pharmacotherapy (nicotine replacement products or cessation medications). Counseling and pharmacotherapy have each been proven to double quit rates.[7]

Despite the strong evidence supporting tobacco use screening, cessation counseling, and medication use, and the fact that 70% of smokers report they want to quit smoking, few adults receive recommended care for tobacco use treatment. For example, only 71.2% of smokers are advised to quit by their providers and only 39% of smokers are offered prescription medication or counseling to support the quitting process.[29-30]

Benefits and Risks of Intervention

The benefit of screening for tobacco use and cessation counseling and treatment is substantial. Smoking cessation is proven to lower an individual's risk for diseases caused by smoking such as heart disease, stroke, and cancer.[1] There are no documented risks to screening for tobacco use.

The benefit of providing smoking-cessation coverage is considerable. As mentioned above, subsidizing the out-of-pocket expense for patients who wish to quit smoking increases the use of effective cessation therapies, increases the number of people who attempt to quit, and — most importantly — increases the number of people who quit successfully.[28] Additional workplace interventions, such as establishing smoke-free workplaces, add even more benefit. Smoke-free workplaces and the provision of comprehensive coverage presumably act together to reduce smoking, and they have been demonstrated to increase quit attempts.[11]

Initiation, Cessation, and Interval Screening

All adults should be screened for tobacco use at every provider visit. Adults who screen positive for tobacco use should be advised to quit and offered counseling and medication at every medical encounter.[10] There is limited evidence on the efficacy of screening and counseling children and adolescents for tobacco use. However, because most adult smokers began smoking during their teenage years, the USPSTF recommends that clinicians screen and counsel this population at their discretion.[10]

Counseling

At least two courses of 4 to 6 counseling sessions of at least 30 minutes each should be provided annually, for a total of 12 sessions per calendar year until the patient successfully quits smoking. Some patients may require additional sessions.

Treatment

Guidelines for the duration of medication treatment are specified in the PHS Guideline and differ depending on the medication type.[10]

Patients identified as recently quit should be eligible for up to 4 additional counseling sessions and/or 4 to 8 weeks of medication to maintain tobacco abstinence (depending on the medication).[10]

Intervention Process

Screening

The USPSTF10 and the PHS Guideline[7] recommend the use of the "5-A's" behavioral counseling framework for tobacco screening and counseling. This framework is composed of 5 steps aimed at engaging the patient in a discussion about their tobacco use and their intention to quit:

- Ask about tobacco use.
- Advise the patient to quit through clear and personalized messages.
- Assess the patient's willingness to quit.
- Assist to quit, develop a quit plan, and set a quit date.
- Arrange for medications and support services.

Counseling

The PHS Guideline recommends several effective methods of tobacco cessation counseling including brief counseling (3 minutes or under), intensive counseling (5 to 15 minutes), telephone based counseling (4 to 6 sessions), and tailored counseling (with information and support specific to the population, e.g., pregnant women).[7] The USPSTF further recommends that clinicians provide problem-solving guidance for smokers to develop a quit plan and to overcome common barriers to quitting. Practices that complement the 5-A framework include provision of medications, motivational interviewing or other methods of intensive counseling, referral for those who may need extra help, and referral to telephone quitlines.[10]

The USPSTF and the PHS Guideline note that there is a dose-response relationship between the intensity and frequency of counseling and tobacco abstinence rates.[7,10] For example, brief counseling interventions (under 3 minutes) are more effective than no counseling, but intensive counseling sessions (5 to 15 minutes) are more effective than brief counseling sessions. The more time a patient is exposed to counseling, the more likely it is that the patient will be successful in quitting.[7] Although there is limited evidence on the optimal amount of counseling, there is evidence that counseling up to 300 minutes per course of treatment has the most effectiveness.[7]

Treatment

Counseling and pharmacotherapy have each been proven to double quit rates[7]: therefore, a tobacco use treatment benefit should include brief counseling (in-person) and intensive counseling (in-person or telephonic) as described above, and:

- All first-line FDA-approved over-the-counter (OTC) and prescription nicotine replacement products such as nicotine replacement gum, patches, lozenges, inhalers, and nasal sprays.
- All FDA-approved tobacco cessation prescription medications such as bupropion (e.g., Wellbutrin® and Zyban®)[7] and varenicline (Chantix™).

Because reducing out-of-pocket costs for tobacco use treatment medications and nicotine replacement products has proven to further reduce quit rates[27], FDA-approved medications/products should not be subject to the deductible and copayments should be reduced or eliminated.

Prescription and Over-the-Counter Tobacco Cessation Medications Approved by the Food and Drug Administration (FDA)

Type	Form	Common Brand Name(s)	Availability
Nicotine Replacement Therapy	Gum	Nicorette®	Over-the-counter (OTC)
	Patch	Nicoderm® Habitrol® Prostep® Nicotrol®	OTC and prescription
	Inhaler	Nicotrol®	Prescription
	Nasal Spray	Nicotrol®	Prescription
	Lozenge	Commit®**	OTC
Buproprion SR$^{\Phi}$	Pill	Zyban® Wellbutrin®	Prescription
Varenicline	Pill	Chantix™***	Prescription

***Received FDA approval in October 2002; therefore not addressed in the 2000 PHS Guidelines.*

**** Received FDA Approval in May 2006; therefore not addressed in the 2000 PHS Guidelines.*

Some populations of smokers require specialized and tailored interventions. For example, pregnant women who smoke should be offered tailored and intensive counseling (5 to 15 minutes) and self-help materials as brief counseling has been found to be less effective in this population.[7] The PHS Guideline recommends that pharmacotherapy be considered on a case-by-case basis for tobacco cessation during pregnancy.[7]

Strength of Evidence for the Clinical Preventive Service

The level of evidence supporting the recommendations contained in this chapter is described below.

Evidence-Based Research:

U.S. Preventive Services Task Force (USPSTF)
Strength of Evidence: A (Strongly Recommended/Good Evidence)

- The USPSTF found good evidence to recommend that clinicians screen all adults for tobacco use and provide tobacco cessation interventions (counseling, medication, and follow-up) for those who use tobacco products.[8]
- The USPSTF found good evidence to recommend that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.[8]

The Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Strong Evidence (Systematic review of published studies conducted by a team of experts).

- The *Community Guide to Preventive Services*[11] strongly recommends establishment of provider reminder systems within health care systems,

provision of telephone counseling services and establishment of effective media campaigns.

U.S. Public Health Service (USPHS)
Strength of Evidence: Strong Evidence (Research from multiple, well designed randomized clinical trials, directly relevant to the recommendation that yielded a consistent pattern of findings).

- The Public Health Service Clinical Practice Guideline, *Treating Tobacco Use and Dependence* (PHS Guideline)[3] strongly recommends screening for tobacco use and providing tobacco cessation treatment (counseling and medication).

Recommended Guidance:

The Centers for Medicare and Medicaid Services (CMS)
Strength of Evidence: CMS Mandated

- CMS recommends that physicians provide tobacco screening, counseling, and treatment services. Medicare provides coverage for two cessation attempts per year. Each attempt includes a maximum of 4 intermediate or intensive counseling cessations for a total maximum benefit of 8 counseling sessions in a 12-month period. Medicare Part D covers all smoking cessation medications that are prescribed by a physician.[13]

Authored by:

Rosenthal AC, Campbell KP, Chattopadhyay S. Tobacco use treatment evidence-statement: screening, counseling, and treatment. In: Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage*. Washington, DC: National Business Group on Health; 2006.

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EVIDENCE-STATEMENT:

TUBERCULOSIS (Screening)

Why This Chapter is Important for Employers: An Overview

- An estimated 3% to 5% of persons (or 9.8 to 15.1 million persons) residing in the United States have latent tuberculosis infection (LTBI),[1] a condition in which an individual is infected with *Mycobacterium tuberculosis* but does not currently have tuberculosis (TB) disease. Individuals who have LTBI have no signs or symptoms and cannot spread TB. Approximately 5% to 10% of persons with LTBI will develop clinical TB disease at some point in their lifetime.[2-3] When active TB disease occurs, these persons may become infectious and then transmit the infection to others.
- The global TB burden is substantial and increasing. Immigration to the United States from areas of the world where TB is common is continually supplementing the pool of persons in the United States with TB and LTBI.
- Preventing TB involves preventing those with LTBI from *progressing* to TB disease. Therefore, testing and treatment for LTBI is recommended for those at high risk for TB disease, especially those from regions with high TB rates.
- Identifying and properly treating persons with TB disease early can prevent extensive transmission and costly contact investigations.
- Businesses that employ workers from countries or regions where TB is common or that are based in those countries may face a heightened risk of a TB outbreak. In addition, businesses that employ workers at high risk for TB (such as HIV-infected or other immunosuppressed persons or low-income minorities) or have clients who are at high risk for TB need to be aware and knowledgeable about TB and include prevention activities in their plans.

Clinical Preventive Service Recommendations

U.S. Preventive Services Task Force Recommendation

In 1996, the U.S. Preventive Services Task Force (USPSTF) recommended screening for LTBI with tuberculin skin testing (TST) for asymptomatic high risk persons.[4]

The USPSTF recognizes the importance of targeted screening for tuberculosis. However, the USPSTF has decided not to update its 1996 recommendation and rather defers to the guidelines of the Centers for Disease Control and Prevention (CDC) referenced below.

CDC Recommendation

CDC has published guidelines on screening for LTBI,[2] preventing transmission in health-care settings,[5] investigating contacts of infectious TB patients,[6] treating TB disease,[7] and controlling TB in the United States.[8]

The CDC recommends conducting targeted testing of persons at high risk for TB (see below) to identify LTBI and TB disease early and treating those who have TB and LTBI to prevent transmission and prevent progression of LTBI to disease.[2] Targeted testing programs should be conducted among groups at risk for recent infection with *M. tuberculosis* and those who, regardless of duration of infection, are at increased risk for progression to TB disease.

The CDC does not recommend targeted testing of persons at low risk for TB, with the exception of initial (baseline) testing of persons whose future activity will place them at increased risk of exposure, such as some healthcare workers who may require serial screening.

Evidence Rating:

Not Specified. Each of the referenced CDC guidelines describes the evidence basis for the recommendations, but not all provide ratings.

Information Sources

The recommendations and supporting information contained in this document came from several sources, including the:

- Centers for Disease Control and Prevention (CDC)
- Peer-reviewed research
- U.S. Preventive Services Task Force (USPSTF)

The background and supporting information contained in this document is a compilation of research findings. All information presented in this document should be attributed to its referenced source and should not be considered a reflection of other organizations cited in the text.

Condition/Disease Specific Information

Epidemiology of Condition/Disease

Tuberculosis is a bacterial disease caused by *Mycobacterium tuberculosis,* which usually attacks the lungs (pulmonary TB) but can attack any part of the body, including the kidney, spine, and brain. Symptoms of TB disease include a productive cough lasting more than 2 to 3 weeks, chest pain, coughing up blood, fever, chills, night sweats, appetite loss, weight loss, and easy fatigue. A person who has developed infectious pulmonary or laryngeal TB disease can spread infection to others through coughing, sneezing, speaking, or singing.

When exposure to infectious TB occurs, the health department conducts a contact investigation.[6] Studies of contact investigations in the United States reveal that 30% to 40% of close contacts of persons having infectious TB disease become infected with LTBI (as evidenced by a positive tuberculin skin test or "TST") and identify an additional two percent with active TB disease.[9-10] Approximately 5% to 10% of persons with LTBI will progress to clinically active TB disease at some point in their lives.[2-3] About half of those who progress will do so in the first 2 years after initial infection (i.e., recent infection). Treatment of LTBI reduces the risk of developing TB disease by 70% to 90%.[2]

Populations at high risk for TB include persons who had recent close contact with an infectious TB patient, foreign-born persons from areas where TB is common, HIV-infected and other immunosuppressed persons, homeless persons, substance users (e.g., injection drug users, crack cocaine users, alcoholics), low-income minorities, young children exposed to high-risk adults, health care workers who serve high-risk clients, residents and employees of high-risk congregate settings such as homeless shelters, correctional institutions, nursing homes, or mental institutions.

The proportion of TB cases in the United States occurring among foreign-born persons increased progressively during the 1990s; in 2004, persons born outside the United States accounted for 54% of reported cases.[11] Although foreign-born persons who received a diagnosis of TB in 2004 were born in approximately 150 countries worldwide, 5 countries of origin accounted for over half of foreign-born persons with TB: Mexico (25%), the Philippines (11%), Vietnam (8%), India (7%), and China (5%). The number of states in which greater than 50% of the total reported cases occurred among foreign-born persons increased from 5 (10%) in 1992 to 22 (44%) in 2004.[11] Among U.S. states and cities, this profile can change rapidly, reflecting changes in patterns of immigration and refugee settlement.[12] Globally, half of new TB cases each year occur in India, China, Indonesia, Bangladesh, and Pakistan.[13]

In the United States, the majority of healthcare workers do not have a high risk for TB, but some, such as respiratory therapists, appear to be at greater risk.[5,14] Persons who work in, or are served by, clinics or community health organizations providing care to HIV-infected persons are considered a priority population for targeted testing and treatment of TB and LTBI because of the risk of transmission to this highly vulnerable population.[8]

Condition/Disease Risk Factors

An individual at high risk for TB has one or more of the following characteristics: recent exposure to a person having infectious TB; history of previous TB disease or positive tuberculin skin test or QuantiFERON-TB Gold result; HIV infection or other immunosuppressive medical condition; being a young child with contact to a high-risk adult; history of injection or non-injection drug use; birth outside the United States in a region where TB is common; being a resident or employee of a high-risk congregate setting; being a member of a low-income minority population; or being a health care worker who serves high-risk persons. However, TB should be suspected in any patient who has had a persistent cough for more than 2 to 3 weeks, with at least one additional symptom, including fever, night sweats (sufficient to require changing of bed clothes or sheets), weight loss, or hemoptysis (coughing up blood).

Value of Prevention

Economic Burden of Condition/Disease

From the late 1980s through the early 1990s, outbreaks of TB among HIV-infected persons in the United States contributed to a surge in TB, reversing a steadily declining trend. Billings or charges for inpatient TB care increased 3.2-fold from 1985 through 1990.[15] During that period, an estimated 77,700 TB hospitalizations resulted in about 1.1 million days of care. The total direct medical expenditures for TB in a 1991 study of TB outpatient treatment, screening, and treatment for LTBI, contact investigation, and surveillance were estimated at $703 million and TB costs were estimated at $574 million (in year 1991 dollars.) In addition, 20,803 TB hospitalizations resulting in 413,980 days of inpatient care occurred.[16] Extrapolating from a 1996 study at 10 mostly urban sites, an estimated 12,631 TB hospitalizations and approximately 270,650 days of inpatient care occurred in the United States in 1996.[17] A study in 2000 estimated that there were over 11,000 TB hospitalizations resulting in more than 160,000 inpatient days.[18] Approximately half of TB patients are hospitalized,

which adds approximately $19,000 to the cost of treatment.[17] While it appears that there might be a slight downward trend in TB hospitalizations as management practices have improved and the total number of TB patients declines each year, TB still places a substantial burden on the U.S. economy.

More recently, direct medical TB costs have been estimated (and updated to 2004 dollars) from several studies[17-21] with the costs varying according to the kinds of treatment needed. Direct medical costs of LTBI screening and treatment caused by exposure to strains susceptible to normally-used drugs were approximately $208 to $311 per person without directly observed treatment (DOT).[19] DOT improves the likelihood of completion of a full course of treatment. If drug susceptible TB disease is diagnosed, outpatient treatment costs are approximately $4,000 under daily DOT.[20]

Costs associated with MDR TB are likely to be much higher than for drug-susceptible tuberculosis due to longer hospitalization, longer and more complex treatment with more expensive and toxic medications, and higher mortality. Direct medical costs associated with MDR TB hospitalization range from $15,000 to $137,000 per case.[21] In-patient MDR TB costs average $30,740 per person and $1,232 per person-day of hospitalization. Outpatient costs average $22,625, or $52 a day per person. Direct medical costs for both inpatient and outpatient MDR TB care average approximately $53,000 per person. For each infected contact of a patient with multidrug-resistant (MDR) TB in California, the cost of two years of follow-up and treatment to prevent the development of MDR TB was estimated to be $11,125.[22]

These direct medical costs are underestimates because they exclude the additional public health program costs of providing culturally appropriate outreach, interpreters, and transportation services. Also, in areas where the cost-of-living is much higher, such as San Francisco and New York City, medical costs may be 80% to 95% higher.[23] Additional costs to society include the productivity losses associated with TB deaths and productivity losses for the 6 months of treatment when patients are unable to work.

Workplace Burden of Condition/Disease

The workplace burden of TB includes lost productivity, absenteeism, high hospitalization costs, and disease transmission to other employees. Hospitalization burdens include not only direct medical costs, but also the lost productivity of workers during hospitalization days. Outpatient care involves workers' lost productivity due to clinic visits or fatigue and other effects of the illness. In fact, productivity losses may last for months or longer if permanent physical effects are experienced.[24] Disease transmission may result in a costly contact investigation as well as stigmatization and disruption of business. However, the risk of TB transmission in the workplace is highly variable, depending on factors such as the TB risk of clients served, the activities conducted by the business, and the TB risk posed by coworkers.[5]

Economic Benefit of Preventive Intervention

Successfully completing a treatment regimen for LTBI and thereby eliminating the preventable direct medical cost of illness due to TB disease saves $4,000 per case.[20] Benefits rise if the case of disease that is prevented would have required hospitalization ($19,000 benefit) and even more if that case would have required treatment of a multi-drug-resistant strain ($15,000 to $137,000 benefit).[17, 21] Additional benefits include the reduction of worker productivity losses due to illness and the avoidance of stigmatization or work disruption that often follows a TB outbreak in a worksite.

Early identification of TB disease can also be expected to substantially reduce the costs of contact investigations, which would be less extensive than if the patient were undiagnosed for a long period, and costs of secondary TB cases among contacts, which would be fewer than for contacts of later diagnosed cases.

Estimated Cost of Preventive Intervention

In 2004, the private-sector cost of tuberculosis screening averaged $22; approximately 95% of all paid claims fell within the range of $0 to $49 per screen.[25]

Estimated Cost of Treatment

Direct medical costs of LTBI screening *and* treatment (without DOT) for infection by presumed *M. tuberculosis* strains that can be treated by first-line drugs are approximately $208 to $311 per person.[19] If employees miss work for the screening and treatment, productivity losses for the standard 9 months of treatment might also occur. The direct medical cost of illness due to TB disease is approximately $4,000 per case of drug susceptible TB disease treated by DOT.[20] Costs rise if the case of disease requires hospitalization ($19,000) and even more for treatment of a multi-drug-resistant strain ($15,000 to $137,000).[17, 21]

Cost-Effectiveness and/or Cost-Benefit Analysis of Preventive Intervention

For individuals at high risk for TB, the benefits of screening for LTBI and completion of treatment outweigh the costs if treatment reduces the risk of — and costs associated with — TB disease and hospitalization.[26] Reducing the risk of medication-induced adverse events and any potential productivity losses associated with LTBI treatment would add to the benefit.

Preventive Intervention Information

Preventive Intervention: Purpose of Screening

Screening/testing individuals at high risk for TB allows clinicians to identify affected persons and begin treatment. Early identification and treatment of TB disease improves outcomes and reduces the risk of transmission. Identification of LTBI and completion of LTBI treatment reduces an individual's risk of developing TB disease by 70% to 90%.[2]

Benefits and Risks of Intervention

Clinicians should individualize their decision to conduct targeted testing and treatment for TB and LTBI to the specific patient's risks and environment. Routine testing for TB or LTBI is not recommended for persons who are not at high risk for TB. The TST is subject to variability like all medical tests, but many of the inherent variations in administering and reading tests can be avoided by careful attention to details and the clinical provider should be aware of these details. Interferon gamma release assays (IGRA), such as the QuantiFERON-TB®

(QFT) Gold blood test can be used instead of the TST for LTBI screening. CDC has published guidelines for the use of approved IGRAs,[27] and will do so for additional tests as they become available. For individuals at high risk for TB, the benefits of LTBI screening and completion of treatment outweigh the costs.[26]

Screening high-risk populations for TB disease by asking about the major TB symptom, a cough of 2 to 3 weeks duration, has been shown to be effective,[28] and is likely to be cost-effective over routine screening using chest radiographs. This intervention is simple, inexpensive, and is potentially cost-effective in many settings.

Initiation, Cessation, and Interval of Screening

TB and LTBI testing programs should be conducted among groups at high risk for recent infection with *M. tuberculosis* and those who, regardless of duration of infection, are at increased risk for progressing to TB disease (e.g., HIV-infected or other immunosuppressed persons with certain medical conditions, injection drug users, those with a history of inadequately treated TB disease).

Workers in health-care settings who have face-to-face contact with patients with suspected or confirmed TB disease or clinical TB specimens should be included in a screening program.[5] In settings where routine screening is mandated but classified as low risk for TB exposure (where persons with TB disease are not expected to be encountered), workers should receive baseline testing using a two-step TST or an IGRA upon hiring (with appropriate follow-up evaluation for those found to have positive TST or IGRA results); additional screening is not necessary unless TB exposure occurs. In settings classified as medium risk (where workers will or will possibly be exposed to persons with TB disease or TB clinical specimens), workers should receive baseline two-step TST and annual screening for TB symptoms; workers who are TST-negative at baseline should also receive annual TST. If the setting has potential ongoing TB transmission, more frequent TST may be needed until infection control lapses have been corrected.[5]

Intervention Process

For the majority of infected persons, the only evidence of LTBI is an immune response to mycobacterial antigens, demonstrated by a positive TST or IGRA result. In the United States, the preferred skin test for LTBI is the intradermal, or Mantoux method, injection of 0.1 ml (5 TU) of purified protein derivative (PPD). Tests should be read by a trained professional 48 to 72 hours after the skin test has been applied. Multiple puncture tests (e.g., Tine and Heaf) and PPD strengths of 1 TU and 250 TU should not be used.[2]

IGRAs have been shown to have a lower likelihood of giving false-positive readings.[27] IGRAs provide significant advantages in delivery (e.g., no patient return for test reading) that may actually make them more cost-effective than the TST in populations that are likely to have high rates of false-positive TST results because of prior vaccination with the Bacille Calmette-Gerin (BCG). However, data on IGRA performance in high-risk populations are being evaluated.

Screening high-risk populations for TB disease by asking about the major TB symptom, a cough of 2 to 3 weeks duration, is simple, inexpensive, and is potentially cost-effective in many settings.

Treatment Information

Health benefits should include provisions for follow-up and treatment services.

A daily 9-month regimen of isoniazid (300 mg for adults, 10 to 15 mg/kg up to 300 mg for children) is recommended for treatment of LTBI caused by isoniazid-susceptible strains of *M. tuberculosis*. Completion of 270 doses within a 12-month period is optimal.[2] Twice-weekly dosing is an acceptable alternative (76 doses within 12 months).[2] A daily regimen of rifampin (10 to 20 mg/kg, 600 mg maximum) for 4 months is also an acceptable alternative and is the recommended choice for contacts to isoniazid-resistant TB patients; completion is considered optimal with 120 doses taken within 6 months.[2] Directly-observed treatment (DOT) improves the outcome of TB disease treatment and is therefore recommended over self-administered therapy (SAT), and has been shown to be cost-effective to prevent the development of drug resistant TB disease.[29] DOT is also recommended for LTBI treatment of vulnerable populations, such as HIV-infected persons or young children.

Strength of Evidence for the Clinical Preventive Service

The strength of evidence for the recommendations contained in this chapter is described below.

Recommended Guidance:

Centers for Disease Control and Prevention (CDC)
Strength of Evidence: Not Specified. Each of the referenced CDC guidelines describes the evidence basis for the recommendations, but not all provide ratings.

- The CDC recommends conducting targeted testing of persons at high risk for TB and treating those who have TB and LTBI to identify TB disease early, prevent transmission, and prevent progression of LTBI to disease.[2]
- The CDC recommends, if routine TB screening is mandated in low-risk settings, the provision of baseline LTBI testing upon hiring, with the addition of annual screening for TB symptoms in medium-risk settings.[5]

Authored by:

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4 The Prioritization and Strategic Implementation of Clinical Preventive Service Benefits

Overview:
Practical advice about the prioritization and strategic implementation of clinical preventive service benefits. Sections include:

- The Purpose and Process of Prioritizing Recommended Clinical Preventive Services in order to:
  - Provide Economic and Health Value
  - Address Demographic Needs
  - Address Beneficiary Risk and Reduce Specific Healthcare Costs
- Employer Scenarios

4 Prioritization of Clinical Preventive Services in a Strategic Implementation Plan

The Purpose and Process of Prioritizing Recommended Clinical Preventive Services

Employers with limited resources, or those facing competing demands, may not be able to add all of the 46 recommended clinical preventive service benefits in a single benefit revision cycle. These employers should consider a strategic implementation approach and prioritize benefit expansion.

There are multiple ways to prioritize the clinical preventive services recommended in the *Purchaser's Guide*. Several methods of prioritization are listed below. Prioritization methods are not listed in preferential order; nor are they mutually exclusive. Each method has its own strengths and weaknesses and employers may want to consider combining multiple approaches. Employers should evaluate their current clinical preventive service benefits and the needs of their own beneficiary population, before selecting prioritization methods.

Health outcomes in the United States could be improved at less expense if the healthcare system, clinicians, and patients gave priority to services that were most beneficial and offered the greatest value.[1]

Partnership for Prevention Priorities for America's Health, 2006

Value – An Important Variable

Like any investment aimed at keeping a workforce healthy and productive, clinical preventive services offer value. The "value" of an individual preventive service is determined by its ability to prevent a significant amount of morbidity and mortality in relation to the cost of offering the service. Because offering a clinical preventive service has a real (monetary) cost and an opportunity cost (there is a finite amount of services that can be delivered/received in a given period of time), it is important for purchasers to quantify the value of clinical preventive services in relation to one another when making coverage decisions.

Employer Guidance

Strength of evidence for a given clinical preventive service should be the first filter used in prioritization and strategic implementation efforts. The U.S. Preventive Services Task Force (USPSTF) uses a lettered grading system:

A-B: Employers should implement coverage for all services recommended in the *Purchaser's Guide*, (particularly the USPSTF "A" and "B" recommendations and all ACIP recommended services immediately.)

I: Employers have discretion as to whether to provide coverage for services with limited or conflicting evidence (services that received an "I" rating). The provision of coverage for "I"-rated services should be secondary to the provision of coverage for all recommended services featured in the *Purchaser's Guide* ("A" and "B"-rated services and equivalencies*).

C: Employers should provide coverage for USPSTF "C"-rated services only if there is a population-specific and compelling reason to do so as there appears to little or no health value derived from these interventions. The provision of coverage for "C"-rated services should be secondary to the provision of coverage for all recommended services featured in the Purchaser's Guide ("A" and "B"-rated services and equivalencies*).

D: Employers should not provide coverage for "D"-rated clinical preventive services for their asymptomatic beneficiary population. However, employers may choose to cover these services on a case-by-case basis as determined by beneficiary risk or medical necessity criteria. Further, these services should be covered when part of a medical treatment plan for an existing condition/disease or when an individual is determined to be at high risk for the respective condition/disease.

*Other organizations have comparable rating systems. For example, the American Academy of Family Physicians (AAFP) uses a SR (Strongly Recommended), R (Recommended), NR (No Recommendation), RA (Recommend Against), I (Insufficient Evidence to Recommend Either For or Against) rating system. For more information on AAFP's grading system please refer to the Introduction of the *Purchaser's Guide*.

Figure 4.0: Methods of Prioritization in a Strategic Implementation Plan

Method of Prioritization	Explanation	Purpose	Requires
Provide Economic and Health Value	Rank order clinical preventive services by their economic value and health impact.	Provide cost-effective and life-saving benefits	Current list of high-value clinical preventive services
Address Demographic Needs	Rank order clinical preventive services by their ability to meet the needs of a defined population based on age and gender.	Address population-specific needs based on age and gender	Beneficiary demographic data
Address Beneficiary Risk and Reduce Specific Healthcare Costs	Rank order clinical preventive services by their ability to address 1) the risk profile of a population based on results from an employer-sponsored health risk appraisal (HRA) and/or 2) conditions and diseases frequently seen in healthcare cost data.	Address population-specific needs based on risk; Address preventable healthcare costs	HRA data Medical claims data Disability claims data

Methods of Prioritization: An Overview

Rank order clinical preventive services by their economic and health value. The National Commission on Prevention Priorities has rank-ordered clinical preventive services according to their cost-effectiveness and ability to prevent disease, injury, or premature death. "High-value" services are those services that, when delivered appropriately, are both cost-effective and reduce the burden of disease within a population. ***Employers interested in providing coverage for the clinical preventive services that provide a good value for their money should consider this method.***

Provide Economic and Health Value

Rank order clinical preventive services by their ability to meet the needs of a defined population based on age and gender. Many employers have beneficiary populations that are demographically homogeneous (i.e., their beneficiary population is mostly male or mostly female, mostly young adults [20s, 30s, 40s], mostly older adults [50s, 60s, 70s]). Similarly, many clinical preventive services are relevant only for one age or gender group (e.g., cervical cancer screening is only recommended for women). ***Employers who have a relatively homogenous beneficiary population and who want to provide coverage for the clinical preventive services that are most likely to meet the needs of that population should consider this method.***

Address Demographic Needs

Rank order clinical preventive services by their ability to address the risk profile of a population based on results from a population risk assessment such as an health risk appraisal (HRA) or conditions and diseases frequently seen in healthcare cost data. Employers who sponsor HRAs can use the results of the assessment to establish a beneficiary risk profile. This group risk profile can then inform the selection of clinical preventive service benefits. Similarly, analyzing healthcare cost data (e.g., medical claims data, disability claims data) can alert employers to high-frequency and/or high-cost claims that are a result of a preventable disease (e.g., hospitalization for chickenpox) or modifiable behavior (e.g., tobacco use). Clinical preventive service benefits can then be prioritized for implementation based on their ability to address the preventable conditions reflected in the employer's healthcare cost data. ***Employers interested in providing coverage for clinical preventive services that 1) address the specific health risks of their beneficiary population and/or 2) address their beneficiaries' preventable healthcare costs should consider this method.***

Address Beneficiary Risk & Reduce Specific Healthcare Costs

Provide Economic and Health Value

Rank order clinical preventive services by their economic and health value.

The National Commission on Prevention Priorities (NCPP), a blue-ribbon panel of thought-leaders on prevention chaired by former Surgeon General Dr. David Satcher and staffed by Partnership for Prevention, recently ranked the 25 preventive services recommended by the U.S. Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices (ACIP) according to health impact and cost-effectiveness.

NCPP used a rigorous methodology to rank the selected clinical preventive services. A clinical preventive services was deemed "high-value" when it was determined to be both cost-effective (it cost a "reasonable" amount of money for the added quality of life or life-years gained) and impacts the clinical preventable burden of a disease (the service prevented a substantial proportion of disease, injury, or premature death when delivered appropriately). Employers interested in maximizing the value of their investment in preventive services, within a large population and over a sustained period of time, may want to consider using this approach to prioritization.

Additional information on the **National Commission on Prevention Priorities** is available online at: www.prevent.org/content/view/46/96/

Figure 4.1: Top 25 High-Value Preventive Services (evaluated in terms of the preventable burden of disease and cost-effectiveness)[2]

High-Value Clinical Preventive Service	As noted in the *Purchaser's Guide*	Clinically Preventable Burden of Disease (CPB) Max Score = 5	Cost-Effectiveness (CE) Max Score = 5	Combined Score (CPB) and CE, Max Score = 10
Aspirin Chemoprophylaxis	Aspirin Therapy for the Prevention of Cardiovascular Disease, *Counseling*	5	5	**10**
Childhood Immunization Series	Immunizations (Child, Adolescent, Adult)	5	5	**10**
Tobacco Use Screening and Brief Intervention	Tobacco Use Treatment, *Screening, counseling, and treatment*	5	5	**10**
Problem Drinking Screening and Brief Counseling	Alcohol Misuse, *Screening and counseling*	4	4	**8**
Colorectal Cancer Screening	Colorectal Cancer, *Screening*	4	4	**8**
Hypertension Screening	Hypertension, *Screening, counseling, and treatment*	5	3	**8**

Continued on next page

Figure 4.1: Top 25 High-Value Preventive Services (evaluated in terms of the preventable burden of disease and cost-effectiveness)[2] *(Continued)*

High-Value Clinical Preventive Service	As noted in the *Purchaser's Guide*	Clinically Preventable Burden of Disease (CPB) Max Score = 5	Cost-Effectiveness (CE) Max Score = 5	Combined Score (CPB) and CE, Max Score = 10
Influenza Immunization	Immunizations (Child, Adolescent, Adult)	4	4	**8**
Pneumococcal Immunization	Immunizations (Child, Adolescent, Adult)	3	5	**8**
Vision Screening (Adults)	Not included in the *Purchaser's Guide*	3	5	**8**
Cervical Cancer Screening	Cervical Cancer, *Screening*	4	3	**7**
Cholesterol Screening	Lipid Disorders, *Screening, counseling, and treatment*	5	2	**7**
Breast Cancer Screening	Breast Cancer, *Screening*	4	2	**6**
Calcium Chemoprophylaxis	Not included in the *Purchaser's Guide*	3	3	**6**
Chlamydia Screening	Chlamydia, *Screening*	2	4	**6**
Vision Screening (Children)	Vision, *Screening*	2	4	**6**
Folic Acid Chemoprophylaxis	Folic Acid Supplementation, *Counseling and preventive medication*	2	3	**5**
Obesity Screening	Obesity, *Screening, counseling, and treatment*	3	2	**5**
Depression Screening	Depression, *Screening*	3	1	**4**
Hearing Screening	Newborn Hearing, *Screening*	2	2	**4**
Injury Prevention Counseling	Motor Vehicle-Related Injury Prevention, *Counseling*	1	3	**4**
Osteoporosis Screening	Osteoporosis, *Screening and treatment*	2	2	**4**
Cholesterol Screening (High-Risk)	Lipid Disorders, *Screening, counseling, and treatment*	1	1	**2**
Diabetes Screening	Diabetes (type 2), *Screening*	1	1	**2**
Diet Counseling	Healthy Diet, *Counseling*	1	1	**2**
Tetanus and Diphtheria Booster	Immunizations (Child, Adolescent, Adult)	1	1	**2**

Method suggested for: Employers with large and diverse populations (in terms of age and gender) and who want to provide services with the greatest value to their employees.

Employer Scenario: Employer *A* has 100,000 employees, 60,000 dependents, and 10,000 retirees. Employer *A* provides health insurance coverage for all beneficiaries, including Medicare Part B coverage for retirees. The beneficiary population is very diverse: 49% of beneficiaries are female and the average age of a beneficiary is 35 (but ranges from 0 to 81 years). After reviewing HRA information and medical claims data, no single preventable condition emerges as a major health or cost problem. Rather, many preventable conditions affect the population. Employer *A* is facing cost cutbacks relative to medical spending and wants to ensure it receives a good value for any new benefit it implements. In order to receive the most value from its clinical preventive service benefit expansion, employer *A* decides to implement "high-value" clinical preventive services that received a score of ≥ 8 immediately, and then implement the remaining services over the next two benefit revision cycles.

In the abovementioned scenario, employer *A* would implement benefits for the following services:

Immediate Implementation

High-Value Clinical Preventive Service	As noted in the *Purchaser's Guide*	Combined Score (CPB) and CE, Max Score =10
Aspirin Chemoprophylaxis	Aspirin Therapy for the Prevention of Cardiovascular Disease, *Counseling*	**10**
Childhood Immunization Series	Immunizations (Child, Adolescent, Adult)	**10**
Tobacco Use Screening and Brief Intervention	Tobacco Use Treatment, *Screening, counseling, and treatment*	**10**
Problem Drinking Screening and Brief Counseling	Alcohol Misuse, *Screening and counseling*	**8**
Colorectal Cancer Screening	Colorectal Cancer, *Screening*	**8**
Hypertension Screening	Hypertension, *Screening, counseling, and treatment*	**8**
Influenza Immunization	Immunizations (Child, Adolescent, Adult)	**8**
Pneumococcal Immunization	Immunizations (Child, Adolescent, Adult)	**8**
Vision screening (Adults)	Not included in the *Purchaser's Guide*	**8**

Subsequent Implementation – Benefit Revision Cycle 2

High-Value Clinical Preventive Service	As noted in the *Purchaser's Guide*	Combined Score (CPB) and CE, Max Score =10
Cervical Cancer Screening	Cervical Cancer, *Screening*	**7**
Cholesterol Screening	Lipid Disorders, *Screening, counseling, and treatment*	**7**
Breast Cancer Screening	Breast Cancer, *Screening*	**6**
Calcium Chemoprophylaxis	Not included in the *Purchaser's Guide*	**6**
Chlamydia Screening	Chlamydia, *Screening*	**6**
Vision Screening (Children)	Vision, *Screening*	**6**

Subsequent Implementation – Benefit Revision Cycle 3

High-Value Clinical Preventive Service	As noted in the *Purchaser's Guide*	Combined Score (CPB) and CE, Max Score =10
Folic Acid Chemoprophylaxis	Folic Acid Supplementation, *Counseling and preventive medication*	**5**
Obesity Screening	Obesity, *Screening, counseling, and treatment*	**5**
Depression Screening	Depression, *Screening*	**4**
Hearing Screening	Newborn Hearing, *Screening*	**4**
Injury Prevention Counseling	Motor Vehicle-Related Injury Prevention, *Counseling*	**4**
Osteoporosis Screening	Osteoporosis, *Screening and treatment*	**4**
Cholesterol Screening (High-Risk)	Lipid Disorders, *Screening, counseling, and treatment*	**2**
Depression Screening	Depression, *Screening*	**2**
Diabetes Screening	Diabetes (type 2), *Screening*	**2**
Diet Counseling	Healthy Diet, *Counseling*	**2**
Tetanus and Diphtheria Booster	Immunizations (Child, Adolescent, Adult)	**2**

Address Demographic Needs

Rank order clinical preventive services by their ability to meet the needs of a defined population based on age and gender.

Many clinical preventive services are specifically intended for a particular group of people based on their age, gender, or other risk factor. For example, newborn hearing screening is only relevant for beneficiaries who have (or who are) infants that will need this age-dependent service. When an employer's beneficiary population is relatively homogenous (e.g., mostly male, mostly old) it may be wise to first implement the specific clinical preventive services that are most relevant for the majority population.

Method suggested for: Employers with a homogenous beneficiary population that is heavily weighted towards one gender or age group.

Employer Scenario: Employer *B* has 7,000 employees and provides health insurance for an additional 2,000 dependents, and 4,000 retirees. The beneficiary population is homogenous; the average age of a beneficiary is 53 and 73% of the beneficiary population is male. In order to best address the needs of the majority population, employer *B* decides to implement clinical preventive services recommended for normal risk males in their 40s, 50s, and 60s in the first year of the implementation program and then add benefits for clinical preventive services that address the needs of other populations over the subsequent 5 years.

In the abovementioned scenario, employer *B* would implement benefits for the following services immediately. Examples are listed in alphabetical order, but could be implemented according to health impact and economic value.

- Abdominal Aortic Aneurysm, *Screening*
- Alcohol Misuse, *Screening and counseling*
- Aspirin Therapy for the Prevention of Cardiovascular Disease, *Counseling*
- Colorectal Cancer, *Screening*
- Depression, *Screening*
- Diabetes (type 2), *Screening*
- Healthy Diet, *Counseling*
- Hypertension, *Screening, counseling, and treatment*
- Influenza, *Immunization*
- Lipid Disorders, *Screening, counseling, and treatment*
- Obesity, *Screening, counseling, and treatment*
- Pneumococcal disease, *Immunization*
- Tobacco Use Treatment, *Screening, counseling, and treatment*

Address Beneficiary Risk and Reduce Specific Healthcare Costs

Rank order clinical preventive services by their ability to address:

1. The risk profile of a population based on results from a population risk assessment such as an health risk appraisal (HRA); and/or
2. Conditions, diseases, or behaviors frequently seen in healthcare cost data.

Analyzing healthcare cost data can help employers identify the specific health problems that are afflicting their beneficiaries. Targeting these behaviors, conditions, or diseases may provide the "biggest bang for the buck" by reducing beneficiaries' burden of disease and overall healthcare costs simultaneously.

Method suggested for: Employers who currently have a HRA (or other population risk assessment tool) in place and the ability to analyze those data to determine a beneficiary population risk profile and employers who are able to analyze their healthcare cost data and determine which preventable behaviors, conditions or disease account for a substantial proportion of medical, disability, or other health-related claims costs.

Employer Scenario 1: Employer *C* has 15,000 employees and provides health insurance for an additional 13,000 dependents. For the past three years, employer *C* has required all beneficiaries to complete an HRA. Employer *C* carefully analyzed the group data from the past year's HRA and determined the following,

1. Beneficiaries are significantly overweight; the average BMI of a beneficiary is 30 kg/m2.
2. Beneficiaries do not get an adequate amount of physical activity; the average beneficiary reports only 15 minutes of physical activity per week.
3. Beneficiaries report unhealthy diets; they consume excess amounts of total fat, saturated-fat, and cholesterol, and inadequate amounts of fruits, vegetables, and whole grains.
4. Forty-five percent (45%) of employees use tobacco products, far above the national average.
5. Thirty-seven percent (37%) of adult beneficiaries consume more than 7 alcoholic beverages per week.

Based on this data, employer *C* knows that its beneficiary population is at high risk for alcohol misuse, cancer, obesity, type 2 diabetes, heart disease, hypertension, and smoking-related illnesses. To best address the risks of its beneficiary population, employer *C* decides to immediately implement benefits for the clinical preventive services that address these behaviors and diseases, including (examples are listed in alphabetical order, but could be implemented according to health impact and economic value):

- Alcohol Misuse, *Screening and counseling*
- Breast Cancer, *Counseling and preventive medication*

- Breast Cancer, *Screening*
- Cervical Cancer, *Screening*
- Colorectal Cancer, *Screening*
- Diabetes (type 2), *Screening*
- Healthy Diet, *Counseling*
- Hypertension, *Screening, counseling, and treatment*
- Lipid Disorders, *Screening, counseling, and treatment*
- Motor Vehicle Related Injury Prevention, *Counseling*
- Obesity, *Screening, counseling, and treatment*
- Tobacco Use Treatment, *Screening, counseling, and treatment*

Employer Scenario 2: Employer *D* provides health benefits for 36,000 employees and 40,000 dependents. Over three-quarters of the employee population is female and most are relatively young. Further, employee demographic data show that 45% of beneficiaries are African-American. A large portion of employer *D*'s medical claims are for labor and delivery charges and a large proportion of employer *D*'s disability claims are paid for short- and long-term disabilities related to complications of pregnancy. Employer *D*'s beneficiaries have a higher than normal rate of preterm births and neonatal intensive care (NICU) admissions. Employer *D* knows that African-Americans are at increased risk for poor birth outcomes including preterm birth, low birth weight, and infant mortality.[3] Employer *D* would like to reduce its medical claims related to pregnancy complications and reduce racial and ethnic disparities in healthcare by ensuring that all its beneficiaries have access to high-quality preconception, prenatal, and postpartum care.

To promote access, employer *D* decides to immediately implement benefits for all clinical preventive services related to pregnancy, infant care, and childhood health promotion. Further, employer *D* decides to provide "safe-harbor" coverage for preventive services in HDHP and HSA-qualified plans and to eliminate copays for preventive care in HMO, PPO, and POS plans.

Clinical preventive services aimed at promoting healthy pregnancies include:

- Alcohol Misuse, *Screening and counseling*
- Asymptomatic Bacteriuria, *Screening*
- Breastfeeding, *Counseling*
- Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (NTDs), *Screening and testing*
- Folic Acid Supplementation, *Counseling and preventive medication*
- Group B Streptococcal Disease (GBS), *Screening and preventive medication*
- Hepatitis B Virus (HBV), *Screening, immunization, and treatment*
- Human Immunodeficiency Virus (HIV), *Screening, counseling, preventive medication*
- Influenza, *Immunization*

- Preeclampsia, *Screening*
- Rh (D) incompatibility, *Screening and preventive medication*
- Rubella, *Screening*
- Syphilis, *Screening*
- Tetanus, *Immunization*
- Tobacco Use Treatment, *Screening and counseling*

Clinical preventive services specific to infants and children include:

- Child Development, *Screening*
- Child Immunizations, *Immunization*
- Dental Caries Prevention through Oral Fluoride Supplementation, *Preventive medication*
- Lead, Elevated Blood Level, *Screening*
- Newborn Screening for Genetic and Endocrine Disorders, *Screening, medical foods, and treatment*
- Newborn Hearing, *Screening*
- Vision, *Screening*

The United States spends billions on healthcare services of questionable value while basic, evidence-based preventive services are not getting done as often as they should. Yet the time available to deliver healthcare services is limited. Brief clinician office visits must address chronic conditions, acute illness, and preventive are. In this environment, prioritization of healthcare services is occurring, but it is rarely systematic or rational. And the consequences of misplaced priorities are high: people die and illnesses worsen because the most important preventive services do not get done.[1]

Partnership for Prevention
Priorities for America's Health: Capitalizing on Life-Saving, Cost-Effective Preventive Services, 2006

References:

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3. Alexander GR, Kogan M, Bader D, Carlol W, Allen M, Mor J. U.S. birth weight/gestational age-specific neonatal mortality: 1995–1997 rates for whites, Hispanics, and blacks. Pediatrics 2003; 111(1): e61-e66.

5 I Statements and C and D Recommendations of the U.S. Preventive Services Task Force (USPSTF)

Overview:
Information on clinical preventive services that were reviewed by the USPSTF, but not included in the *Purchaser's Guide*. This information may assist benefits staff in determining which clinical preventive services currently offered in their health plan(s) should be re-evaluated.

5 I Statements and C and D Recommendations of the U.S. Preventive Services Task Force (USPSTF)

The vast majority of recommendations featured in the *Purchaser's Guide to Clinical Preventive Services* are recommended by the U.S. Preventive Services Task Force (USPSTF).

For more information on the U.S. Preventative Services Task Force (USPSTF) please refer to the Introduction of the *Purchaser's Guide*.

The USPSTF grades clinical preventive services based on the strength of evidence available to support a particular clinical preventive service and the magnitude of net benefit for that service. The net benefit of a clinical preventive service is defined as the benefits of the service (e.g., years of life saved through early cancer detection) minus the harms of the service (e.g., risks associated with false-positives). The USPSTF assigns each clinical preventive service it reviews a grade. The *Purchaser's Guide* includes all USPSTF "A" (Strongly Recommended) and "B" (Recommended) rated recommendations (as of March 2006).

The USPSTF also identifies other services that, for one reason or another, are not recommended:

- "I"-rated (Insufficient Evidence to Recommend For or Against)
- "C"-rated (No Recommendation Either For or Against)
- "D"-rated (Recommend Against)

In a resource-constrained environment, employers must carefully consider which preventive services to offer. Many preventive services are available. Some are known to be effective; others are known to be relatively ineffective or even harmful; others may be effective but the proof of effectiveness is weak. In addition to adding coverage for services recommended in the *Purchaser's Guide*, employers should evaluate their current preventive service benefits and consider removing benefits for services that are ineffective or harmful ("D"-rated services).

Important Note:

Several services recommended in the *Purchaser's Guide* received an "I" rating from the U.S. Preventive Services Task Force (USPSTF). These services are recommended for inclusion in benefit plans by the National Business Group on Health because they are recommended by other respected organizations, but they are not endorsed by the USPSTF.

Employer Action

I **Employers have discretion as to whether to provide coverage for services with limited or conflicting evidence (services that received an "I" rating)**. The provision of coverage for "I" rated services should be secondary to the provision of coverage for all recommended services featured in the *Purchaser's Guide*.

It is important to remember that "insufficient evidence" means just that: the evidence is not now adequate for evidence-based decisions. On occasion, employers may need to resort to the informed opinions of unbiased experts about such interventions. There are several reasons why an intervention may have insufficient evidence. It may be a new intervention for which there has been insufficient time to conduct and publish the large, rigorous studies needed to assess it. In other instances, such as with vaccines that have been widely used for decades, it is generally agreed that it would be unethical to conduct controlled studies, where a vaccine would be tested against a placebo. Similarly, if a preventive intervention has made a condition so rare that it almost never occurs, but experience suggests that removing the preventive intervention from use would threaten the health of people, the preventive service would be imprudent to test in the United States. It is also possible that an intervention has minimal effectiveness and that, despite considerable study, its small effects have been insufficient to allow a decision about its value.

C **Employers should provide coverage for "C"-rated services only if there is a population-specific and compelling reason to do so.** The USPSTF issues a "C" rating to services in which the balance of benefits and harms is too close to justify a general recommendation. Therefore, the provision of coverage for "C"-rated services should be secondary to the provision of coverage for all recommended services featured in the *Purchaser's Guide*.

D **Employers are discouraged from providing coverage for clinical preventive services that received a "D" rating from the USPSTF, as these services have been found to be ineffective or to have more harms than benefits.**

Important Note:

"D"-rated services are *not* recommended for the general asymptomatic population and therefore should not be covered as preventive services within a medical benefit plan. However, these services may play an important role in the *treatment* or *management* of existing conditions and *should* be covered for all populations under the health plan's treatment benefit.

Figure 5.0: U.S. Preventive Services Task Force (USPSTF) Ratings

A *Strongly Recommended*

The USPSTF strongly recommends that clinicians provide the service to eligible patients. The USPSTF found good evidence that the service improves important health outcomes and concludes that the benefits substantially outweigh harms.[1]

B *Recommended*

The USPSTF recommends that clinicians provide the service to eligible patients. The USPSTF found at least fair evidence that the service improves important health outcomes and concludes that the benefits outweigh harms.[1]

C *No Recommendation Either For or Against*

The USPSTF makes no recommendation either for or against routine provision of the service. The USPSTF found at least fair evidence that the service can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.[1]

D *Recommend Against*

The USPSTF recommends against routinely providing the service to asymptomatic patients. The USPSTF found at least fair evidence that the service is ineffective or that the harms associated with the service outweigh benefits.[1]

I *Insufficient Evidence in Order to Make a Recommendation*

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing the service. Evidence that the service is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.[1]

I Statements of the USPSTF

Explanation: The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.[1]

Employers have discretion to cover these services if they choose. However, the provision of coverage for "I"-rated services should be secondary to the provision of coverage for all recommended services featured in the Purchaser's Guide ("A" and "B"-rated services and equivalencies).

Important Note: Several services recommended in the *Purchaser's Guide* received an "I" rating from the U.S. Preventive Services Task Force (USPSTF). These services are recommended for inclusion in benefit plans by the National Business Group on Health because they are recommended by other respected organizations, but they are not endorsed by the USPSTF.

Clinical Preventive Services with Insufficient Evidence Available to Make a Recommendation	Explanation
***Alcohol Misuse,** *Screening and behavioral counseling interventions*	The USPSTF concludes that the evidence is insufficient to recommend for or against screening and behavioral counseling interventions to prevent or reduce alcohol misuse by adolescents in primary care settings.
Bacterial Vaginosis in Pregnancy, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routinely screening high-risk pregnant women for bacterial vaginosis.
Breast Cancer, *Screening*	The USPSTF concludes that evident is insufficient to recommend for or against routine clinical breast exam (CBE) alone to screen for breast cancer.
Breast Cancer, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against teaching or performing routine breast self-examination.
Breastfeeding, *Behavioral interventions to promote*	The USPSTF found insufficient evidence to recommend for or against the following interventions to promote breastfeeding: brief education and counseling by primary care providers; peer counseling used alone and initiated in the clinical setting; and written materials, used alone or in combination with other interventions.

*Recommended for coverage in the *Purchaser's Guide*

I Statements of the USPSTF (continued)

Cervical Cancer, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of new technologies to screen for cervical cancer.
Cervical Cancer, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of human papillomavirus (HPV) testing as a primary screening test for cervical cancer.
Coronary Heart Disease, *Screening*	The USPSTF found insufficient evidence to recommend for or against routine screening with electrocardiography (ECG), exercise treadmill test (ETT), or electron-beam computerized tomography (EBCT) scanning for coronary calcium for either the presence of severe Coronary Artery Stenosis (CAS) or the prediction of Coronary Heart Disease (CHD) events in adults at increased risk for CHD events.
Chlamydial Infection, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routinely screening asymptomatic men for chlamydial infection.
Dental Caries (in preschool children), *Preventive medication*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine risk assessment of preschool children by primary care clinicians for the prevention of dental disease.
Depression, *Screening*	The USPSTF concludes the evidence is insufficient to recommend for or against routine screening of children or adolescents for depression.
Developmental Dysplasia of the Hip, *Screening*	The USPSTF concludes that evidence is insufficient to recommend for or against routine screening for developmental dysplasia of the hip in infants as a means to prevent adverse outcomes.
Diabetes Mellitus Type 2, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routinely screening asymptomatic adults for type 2 diabetes, impaired glucose tolerance, or impaired fasting glucose.
Diet, *Behavioral counseling*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine behavioral counseling to promote a healthy diet in unselected patients in primary care settings.

I Statements of the USPSTF (continued)	
Dementia, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for dementia in older adults.
Family and Intimate Partner Violence, *Screening*	The USPSTF found insufficient evidence to recommend for or against routine screening of parents or guardians.
Gestational Diabetes Mellitus, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for gestational diabetes.
Gonorrhea, *Screening*	The USPSTF found insufficient evidence to recommend for or against routine screening for gonorrhea infection in men at increased risk for infection.
Gonorrhea, *Screening*	The USPSTF found insufficient evidence to recommend for or against routine screening for gonorrhea infection in pregnant women who are not at increased risk for infection.
Hepatitis C, *Screening*	The USPSTF found insufficient evidence to recommend for or against routine screening for hepatitis C virus (HCV) infection in adults at high risk for infection.
***High Blood Pressure,** *Screening*	The USPSTF concludes that evidence is insufficient to recommend for or against routine screening for high blood pressure in children and adolescents to reduce the risk of cardiovascular disease.
Iron Deficiency Anemia, *Screening children and pregnant women*	The U.S. Preventive Services Task Force (USPSTF) concludes that evidence is insufficient to recommend for or against routine screening for iron deficiency anemia in asymptomatic children aged 6 to 12 months.
Iron Supplementation for Children and Pregnant Women, *Preventive medication*	The USPSTF concludes that evidence is insufficient to recommend for or against routine iron supplementation for asymptomatic children aged 6 to 12 months who are at average risk for iron deficiency anemia. The USPSTF concludes that evidence is insufficient to recommend for or against routine iron supplementation for non-anemic pregnant women.

*Recommended for coverage in the *Purchaser's Guide*

I Statements of the USPSTF (continued)	
***Newborn Hearing,** *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening of newborns for hearing loss during the postpartum hospitalization.
Obesity, *Counseling*	The USPSTF concludes that the evidence is insufficient to recommend for or against the use of moderate- or low-intensity counseling together with behavioral interventions to promote sustained weight loss in obese adults.
Obesity, *Counseling*	The USPSTF concludes that the evidence is insufficient to recommend for or against the use of counseling of any intensity and behavioral interventions to promote sustained weight loss in overweight adults.
Oral Cancer, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routinely screening adults for oral cancer.
***Overweight in Children and Adolescents,** *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for overweight in children and adolescents as a means to prevent adverse health outcomes.
Physical Activity, *Behavioral counseling*	The USPSTF concludes that the evidence is insufficient to recommend for or against behavioral counseling in primary care settings to promote physical activity.
Prostate Cancer, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for prostate cancer using prostate specific antigen (PSA) testing or digital rectal examination (DRE).
Skin Cancer, *Counseling*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine counseling by primary care clinicians to prevent skin cancer.

*Recommended for coverage in the *Purchaser's Guide*

I Statements of the USPSTF (continued)

Skin Cancer, *Counseling*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine counseling by primary care clinicians to prevent skin cancer.
Skin Cancer, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for skin cancer using a total-body skin examination for the early detection of cutaneous melanoma, basal cell cancer, or squamous cell skin cancer.
Speech and Language Delay in Preschool Children, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine use of brief, formal screening instruments in primary care to detect speech and language delay in children up to 5 years of age.
Suicide Risk, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening by primary care clinicians to detect suicide risk in the general population.
Thyroid Disease, *Screening*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for thyroid disease in adults.
***Tobacco Use (adolescents),** *Screening, counseling, and intervention*	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for tobacco use or interventions to prevent and treat tobacco use and dependence among children and adolescents.
Vitamin Supplementation to Prevent Cancer and Cardiovascular Disease, *Preventive medication*	The USPSTF concludes that the evidence is insufficient to recommend for or against the use of supplements of vitamins A, C, or E; multivitamins with folic acid; or antioxidant combinations for the prevention of cancer or cardiovascular disease.

*Recommended for coverage in the *Purchaser's Guide*

C Recommendations of the USPSTF

Explanation: The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.[1]

Employers have discretion to cover "C"-services if they choose. However, the provision of coverage for "C"-rated services should be secondary to the provision of coverage for all recommended services featured in the Purchaser's Guide ("A" and "B"-rated services and equivalencies

Clinical Preventive Services with No Recommendation	Explanation
Abdominal Aortic Aneurysm, *Screening*	The USPSTF makes no recommendation for or against screening for AAA in men aged 65 to 75 who have never smoked.
Chlamydial Infection, *Screening*	The USPSTF makes no recommendation for or against routinely screening asymptomatic low-risk women in the general population for chlamydial infection.
Chlamydial Infection, *Screening*	The USPSTF makes no recommendation for or against routine screening for asymptomatic, low-risk pregnant women aged 26 years and older for chlamydial infection.
***Human Immunodeficiency Virus (HIV) Infection,** *Screening*	The USPSTF makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection.
***Lipid Disorders in Adults,** *Screening*	The USPSTF makes no recommendation for or against screening for lipid disorders in younger adults (men aged 20 to 35 years or women aged 20 to 45 years) in the absence of known risk factors for coronary heart disease.
Osteoporosis (in postmenopausal women), *Screening*	The USPSTF makes no recommendation for or against routine osteoporosis screening in postmenopausal women who are younger than 60 or in women aged 60 to 64 who are not at increased risk for osteoporotic fractures.

*Recommended for coverage in the *Purchaser's Guide*

D Recommendations of the USPSTF

Explanation: The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.[1]

Employers should not provide coverage for these clinical preventive services for their general asymptomatic beneficiary population. However, employers may choose to cover these services on a case-by-case basis as determined by beneficiary risk or medical necessity criteria. Further, these services should be covered when part of a medical treatment plan for an existing condition/disease or when an individual is determined to be at high-risk for the respective condition/disease.

Non-Recommended Clinical Preventive Service	Explanation
Abdominal Aortic Aneurysm, *Screening*	The USPSTF recommends against routine screening for AAA in women.
Asymptomatic Bacteriuria, *Screening*	The USPSTF recommends against the routine screening of men and nonpregnant women for asymptomatic bacteriuria.
Bacterial Vaginosis in Pregnancy, *Screening*	The USPSTF recommends against routinely screening average-risk asymptomatic pregnant women for bacterial vaginosis.
Bladder Cancer, *Screening*	The USPSTF recommends against routine screening for bladder cancer in adults.
Breast Cancer, *Preventive medication*	The USPSTF recommends against routine use of tamoxifen or raloxifene for primary prevention of breast cancer for women at low or average risk for breast cancer.
Cervical Cancer, *Screening*	The USPSTF recommends against routinely screening women older than age 65 for cervical cancer if they have had adequate recent screening with normal Pap smears and are not otherwise at high risk.
Cervical Cancer, *Screening*	The USPSTF recommends against routine Pap smear screening in women who have had a total hysterectomy for benign disease.

D Recommendations of the USPSTF (continued)	
Coronary Heart Disease, Screening	The USPSTF recommends against screening with resting electrocardiography (ECG), exercise treadmill test (ETT), or electron-beam computerized tomography (EBCT) scanning for coronary calcium for either the presence of severe coronary artery stenosis (CAS) or the prediction of coronary heart disease (CHD) in adults at low risk for CHD events.
Gonorrhea, *Screening*	The USPSTF recommends against routine screening for gonorrhea infection in men and women who are at low risk for infection.
Genetic Risk Assessment and *BRCA* Mutation Testing for Breast and Ovarian Cancer Susceptibility	USPSTF recommends against routine referral for genetic counseling or routine breast cancer susceptibility gene *(BRCA)* testing for women whose family history is not associated with an increased risk for deleterious mutations in breast cancer susceptibility gene 1 *(BRCA1)* or breast cancer susceptibility gene 2 *(BRCA2)*.
Hepatitis B Virus Infection, *Screening*	The USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection.
Hepatitis C, *Screening*	The USPSTF recommends against routine screening for hepatitis C virus (HCV) infection in asymptomatic adults who are not at increased risk (general population) for infection.
Hormone Therapy, *Prevention of chronic conditions in postmenopausal women*	The USPSTF recommends against the routine use of combined estrogen and progestin for the prevention of chronic conditions in postmenopausal women. The USPSTF recommends against the routine use of unopposed estrogen for the prevention of chronic conditions in postmenopausal women who have had a hysterectomy.
Idiopathic Scoliosis, *Screening*	The USPSTF recommends against the routine screening of asymptomatic adolescents for idiopathic scoliosis.
Ovarian Cancer, *Screening*	The USPSTF recommends against routine screening for ovarian cancer.

D Recommendations of the USPSTF (continued)	
Pancreatic Cancer, *Screening*	The USPSTF recommends against routine screening for pancreatic cancer in asymptomatic adults using abdominal palpation, ultrasonography, or serologic markers.
Peripheral Arterial Disease, *Screening*	The USPSTF recommends against routine screening for peripheral arterial disease (PAD).
Syphilis Infection, *Screening*	The USPSTF recommends against routine screening of asymptomatic persons who are not at increased risk for syphilis infection.
Testicular Cancer, *Screening*	The USPSTF recommends against routine screening for testicular cancer in asymptomatic adolescent and adult males.

Source: Agency for Healthcare Research and Quality. The Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. Rockville, MD: Agency for Healthcare Research and Quality; 2005.

6 Leveraging Benefits: Opportunities to Promote the Delivery and Use of Preventive Services

Overview:
Actions employers can take to strengthen prevention efforts. Sections include:

- The Importance of Supporting Community-Level Interventions
- The *Guide to Community Preventive Services*
- Employer Action in the Absence of Evidence-Based Guidelines
- General Advice to Employers about Health Improvement and Maximizing the Value of Health Coverage
- *Community Guide* Recommendations
- Employer Case Examples, Success Stories, and Action Examples

6 Leveraging Benefits: Opportunities to Promote the Delivery and Use of Preventive Services

Employers have opportunities to promote the delivery and use of preventive services beyond the provision of medical benefits.

The previous sections of the *Purchaser's Guide* include the scientific evidence and detailed benefit language employers need to implement comprehensive and structured clinical preventive service benefits within their medical benefit plan(s). They provide actionable strategies for improving health and reducing healthcare costs, and information on 46 conditions, diseases and injuries, that can be prevented through appropriate screening, testing, counseling, immunizations, preventive medication, and preventive treatment.

Providing coverage for clinical preventive services is an essential step to improving overall employee health. But, while coverage is necessary to promote the delivery and use of preventive services, it is not sufficient to optimize the health of employees. Employers are in a position to affect health behavior and lifestyle choices in multiple ways.

The Importance of Supporting Community-Level Interventions

Community-level preventive services include a diverse array of activities that:

- Educate people about the availability or use of preventive services.
- Encourage people to seek preventive services.
- Encourage providers, health plans, and health systems to offer preventive services.

Employers are in a unique position to assure the use of clinical preventive services and promote the use of community- or population-level preventive services. By supporting community-level interventions employers can improve the overall health and safety of the communities in which they reside, thereby improving the health and quality of life of current and future employees. Supporting community-level interventions may also benefit employers. Employers may develop important relationships with potential business partners in the area, they may increase the positive image of their companies, and they may develop a new set of knowledge, skills, and abilities that further enhances or improves their business strategies.

Employers can — and should — enhance the health of the communities in which they operate by supporting population-level health interventions. Improving community health will protect and promote the health of present and future employees.

The *Guide to Community Preventive Services*

The *Guide to Community Preventive Services (Community Guide)*, published by the Centers for Disease Control and Prevention (CDC), is an important resource for all stakeholders about population health issues. It addresses ways to increase the use of clinical and community preventive services and complements the work of the *Guide to Clinical Preventive Services (Clinical Guide)*, a publication of the U.S. Preventive Services Task Force (USPSTF), and the *Purchaser's Guide*.

The Guide to Community Preventive Services (www.thecommunityguide.org) provides recommendations about population interventions that have the potential to positively affect community health by preventing injury, disease, disability, and premature death.

Our understanding of opportunities for population-level prevention is growing. Therefore, the *Community Guide* is a work in progress. As new information on the effectiveness of community level interventions is gathered the *Community Guide* will evolve and expand. *Community Guide* recommendations are published in peer-reviewed journals and posted on the *Community Guide* website (www.thecommunityguide.org) as they are developed.

The *Community Guide* is developed by the independent and nonfederal Task Force on Community Preventive Services, which is composed of experts from a range of health promotion and related fields. Recommendations contained in the Community Guide are based on rigorous and systematic reviews of scientific literature.

The *Community Guide* directs purchasers to evidence-based population health recommendations and other activities that may complement their investments in clinical preventive services. Some of these activities are described in Appendix A. Implementing the *Community Guide's* evidence-based recommendations provides the potential to improve community health by preventing injury, disease, disability, and premature death.

Employer Action in the Absence of Evidence-Based Guidelines

The presence of an evidence-based guideline generally means that objective measures of several experiences have credibly and consistently shown that the intervention or policy improves important health or behavioral outcomes.

Evidence-based guidelines do not exist for every important topic because studies or evaluations have not been conducted, such experiences have not been published or otherwise shared, or results across interventions have not been synthesized. As a result, employers will often have to consider how to act in the absence of an evidence-based guideline. When making such judgments, employers should first consider whether there are evidence-based guidelines that can meet some of their needs.

If there are no guidelines available, employers should consider using general advice (provided below) to inform the design and implementation of interventions. Appendix B includes case examples and of worksite population health interventions implemented by large employers. These brief examples describe just a few of the many population health interventions that can be effectively implemented in the workplace.

Promoting and protecting the health of employees and beneficiaries is critical to the continued health of American businesses. Providing coverage for clinical preventive services is the first step to improving overall beneficiary health. Employers should carefully consider integrating population-level health programs and policies into both their coverage packages and their overall worksite health promotion plans. This integrative effort should enhance the effectiveness of medical benefits and increase the likelihood that beneficiaries will appropriately use the coverage they have.

General Advice to Employers about Health Improvement and Maximizing the Value of Health Coverage

Employers can ensure health improvement and maximize coverage value in many ways. At a minimum, an employer's healthcare strategy should include:

1. Educating beneficiaries about the importance of clinical preventive services and healthy lifestyles.
2. Encouraging beneficiaries to use their covered preventive services appropriately.
3. Supporting community-wide disease prevention and health promotion activities.

To promote the appropriate use of clinical preventive services among beneficiaries, employers should:

- Provide referrals to community-based support services and prevention programs, as needed (e.g., tobacco quitlines).
- Encourage health plans to promote clinical preventive services.
- Encourage providers to increase the use of appropriate preventive services (e.g., time-appropriate reminders to patients).
- Increase preventive service access points (e.g., worksite immunization programs).

To more broadly promote health among their beneficiaries, employers should:

- Make information, data, and recommendations about prevention available to employees and their families.
- Support employee participation in programs of clinical or community prevention (e.g., incentives).
- Support healthy worksites (e.g., offer a healthy cafeteria program).
- Support evidence-based health policies (e.g., require smoke-free workplaces).

To promote health generally, employers can:

- Work to increase awareness of critical health problems among employees, health plans, providers, beneficiaries, other purchasers, and the general public.
- Provide in-kind or financial support to develop or continue evidence-based health programs and policies benefiting broader communities. Consider:
  - Sponsoring or providing supplies for school health programs.
  - Partnering with other business and community agencies to develop environmental health promotion strategies (e.g., changing the physical environment by creating walking and biking trails, encouraging increases in cigarette taxes and banning of cigarette smoking in public spaces).

- Promote public policies that aim to prevent illness, injury, and death (e.g., minimum legal drinking age laws).
- Encourage employees to participate in health promotion programs available in their communities.

Appendix A: Links Between Selected Topics with Particular Relevance to Purchasers and *Community Guide* Recommendations

Table 6.0: *Community Guide* Recommendations that may Complement Clinical Preventive Services Recommended in the *Purchaser's Guide*

TOPICS IN THE PURCHASER'S GUIDE	RELATED COMMUNITY GUIDE RECOMENDATIONS
Breast, cervical, and colorectal cancers	To increase cancer screenings (client-oriented): • Use client reminders • Use multicomponent interventions using media, education and enhanced access • Reduce structural barriers • Use client incentives (with reminders) • Use small media • Reduce out-of-pocket costs • Provide one-on-one education • Offer provider reminder recalls • Offer provider assessment and feedback *Note:* these approaches have differential effectiveness for different types of screening. Visit the *Community Guide* website for more information.
Diabetes	To improve the care of persons with type 2 diabetes: • Ensure that disease management and case management programs are provided in healthcare systems. • Provide diabetes self-management education in community gathering places (e.g., community centers or faith institutions) for adults. Also see the entry for obesity (below) for more type 2 diabetes-related information.
Immunizations	To increase community demand for immunizations: • Provide client recalls and reminders • Institute multicomponent interventions with education • Require immunizations for attendance at child care and school To enhance access to immunization services: • Reduce out-of-pocket costs • Institute multicomponent interventions for expanding access • Offer via home visits To improve provider-based interventions: • Institute a provider reminder and recall system • Provide assessment and feedback for providers • Establish standing orders to vaccinate adults

Table 6.0: *Community Guide* Recommendations that may Complement Clinical Preventive Services Recommended in the *Purchaser's Guide (Continued)*

TOPICS IN THE PURCHASER'S GUIDE	RELATED COMMUNITY GUIDE RECOMENDATIONS
Injury prevention: Motor vehicle occupant injury	The *Community Guide's* systematic review of the effectiveness of selected population-based interventions addressing motor vehicle occupant injuries focused on interventions within three areas: • Increasing the proper use of child safety seats • Increasing the use of safety belts • Reducing alcohol-impaired driving
Obesity	The *Community Guide* has recommended numerous population-based interventions for families, schools, and communities, which are proven effective in promoting physical activity. It also has a growing portfolio of work related to nutrition and obesity. To increase physical activity, the *Community Guide* recommends: • Use of community-wide campaigns • Use of point-of-decision prompts to increase stair use • Use of health behavior change programs adapted for individual needs • School-based physical education • Social support in community settings • Creation and/or enhanced access to places for physical activity combined with informational outreach To control overweight or obesity: • Offer worksite programs combining nutrition and physical activity
Tobacco use	To increase tobacco cessation: • Increase unit price for tobacco products • Develop mass media campaigns and use with other interventions (e.g., excise tax increase, other community educational programs) • Establish provider reminder systems • Establish provider reminder systems with provider education • Reduce patient costs for treatments • Make available telephone support for quitting smoking and use with other interventions (e.g., cessation counseling) • Make available telephone support for quitting with the possible provision of cessation medications To decrease environmental tobacco smoke (ETS): • Implement smoking bans or restrictions

Note: *Community Guide* content is a work in progress. Additional content will become available over time. Please check the website (www.thecommunityguide.org) for updated information.

Appendix B: Employer Case Examples, Success Stories, and Action Examples

Many employers around the country have implemented programs, policies, or procedures to promote their employees' health. Some of the approaches used have been evaluated and published. Other approaches have been reviewed systematically by the *Community Guide* or through another systematic review mechanism. In 2005, the *Community Guide* began a set of reviews to examine the effectiveness of interventions conducted in worksite settings or made available by employers. The results of these reviews will begin to be available in late 2006.

Listed below are a few examples of evidence-based practices applied to worksite settings and examples of worksite health promotion practices that will inform evidence-based practices in the future.

Employer Case Examples and Success Stories

Tobacco Cessation: Supporting Quit Attempts

Tobacco use, responsible for approximately 440,000 deaths per year, remains the leading preventable cause of death in the United States.[1] There is substantial evidence that smoking cessation improves health by lowering an individual's risk for diseases caused by smoking such as heart disease, stroke, and cancer.[4] Helping tobacco users to quit is one important goal of a comprehensive effort to reduce morbidity and mortality associated with tobacco use.[2] Approximately 70% of tobacco users want to quit[3] and efforts to quit are frequent, although it is rare for a smoker to quit permanently on a single attempt.

Tobacco use affects productivity and absenteeism, increases use of disability leave, and increases overall healthcare costs among workers.[1] Good quality evidence-based recommendations are available for clinical and community interventions designed to motivate and assist the cessation efforts of tobacco users. Many community-based interventions designed to assist smokers in quitting are directly applicable to the worksite.

The *Community Guide* recommends providing coverage for tobacco use treatment and routine treatment of tobacco use in healthcare systems as two effective interventions to increase tobacco cessation.[5] The Public Health Service Clinical Practice Guideline, *Treating Tobacco Use and Dependence*, recommends individual, group, and proactive telephone

Employer Success Story: Union Pacific Railroad

Union Pacific Railroad experienced **a decrease from 40% to 25% in smoking prevalence among its employees** in the 7-year period during which it has offered a cessation benefit as part of a comprehensive tobacco cessation program. The program included smoking bans and restrictions and reduced beneficiary out-of-pocket costs for nonsmokers. The program was implemented incrementally, starting with the removal of smoking areas, the addition of coverage for tobacco dependence treatment, and finally the move to smoke-free buildings.[4]

counseling along with the use of Food and Drug Administration (FDA) approved cessation medications (e.g., bupropion—Wellbutrin® or Zyban® and varenicline—Chantix™).[7] The USPSTF strongly recommends that clinicians screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco.[5] There is also evidence that nicotine replacement medications (e.g., Nicorette® gum) increase successful quit rates and increase tobacco abstinence rates.[6]

Purchasers can support tobacco cessation efforts by implementing evidence-based guidelines:

- Promote a smoke-free workplace and campus.[7]
- Provide coverage for the full range of counseling options (individual, group, and by telephone) and reduce or eliminate copays and deductibles for counseling.[6]
- Ensure that all FDA-approved tobacco cessation medications are available in formularies and reduce or eliminate copays and deductibles for medications.[6]
- Educate employees about using flexible spending account (FSA) funds to pay for tobacco cessation medication and nicotine replacement products.
- Provide employees with tobacco quitline numbers and contract with a quitline vendor to provide services for employees.
- Become active in the communities where workplaces exist: support implementation of smoke-free workplace laws, appropriate school-based initiatives (including smoke-free campuses and curricula), and increased excise taxes on cigarettes and tobacco products.[5]

Purchasers can ensure that their health plans and delivery systems:

- Aggressively educate plans' providers and enrollees about the availability of tobacco cessation benefits.

Purchasers can ensure that their medical offices and employee clinics:

- Integrate tobacco dependence treatment into disease management initiatives.
- Follow the Public Health Service Clinical Practice Guideline, *Treating Tobacco Use and Dependence*, which recommend that providers[6]:
  - **Ask** every patient, at every visit, if they use tobacco
  - **Advise** to quit
  - **Assess** readiness to quit
  - **Assist** with the quit process
  - **Arrange** for follow-up with counseling and medications

Employer Case Example: Centers for Disease Control and Prevention (CDC)[7]

The Centers for Disease Control and Prevention (CDC) recently implemented a tobacco-free campus in all CDC-owned buildings nationwide. This included provision of free over-the-counter nicotine replacement medications to federal employees, negotiations with labor unions to remove previously negotiated smoking huts, provision of smoking cessation classes, and encouraged access to the national network of tobacco quitlines (1-800-QUIT NOW).

Additional information about coverage for tobacco treatment can be found on the CDC website (www.cdc.gov/tobacco/educational_materials/cessation/index.html.). Employers interested in making their worksite smoke free can also reference *Making Your Workplace Smokefree – A Decision Makers Guide* (www.cdc.gov/tobacco/research_data/environmental/etsguide.htm.)

Lipid Disorders: Screening and Treatment Adherence

Lipid disorders, which result from abnormal levels of cholesterol in the blood, increase the risk of cardiovascular disease (CVD), including coronary heart disease (CHD) and coronary artery disease (CAD). Arteriosclerosis (a thickening or hardening of the arteries) is particularly sensitive to lipid levels. From 1999 to 2002, about 17% of the U.S. adult population had high cholesterol (total cholesterol 240 mg/dL or higher).

The National Cholesterol Education Program (NCEP) Adult Treatment Expert Panel-III (ATP-III) recommends that clinicians routinely screen all adults aged 20 years and above for elevated blood cholesterol once every 5 years.[9] The goal of screening is to identify and treat individuals with lipid disorders in order to decrease their risk for CVD events, such as heart attack.

The NCEP ATP-III Treatment Guideline states that the first line of therapy for elevated LDL cholesterol levels is therapeutic lifestyle changes (e.g., diet, exercise, weight loss, smoking cessation). Drug therapy (e.g., cholesterol-lowering medication), may be used, when appropriate, to further reduce cholesterol levels. Both therapeutic lifestyle changes and cholesterol-lowering medications are proven effective for improving lipid profiles and reducing the risk of heart disease. Yet, the benefits of lowered cholesterol can only be realized with quality care and adherence to treatment.

NCEP ATP-III also includes a series of recommendations to increase adherence to recommended treatments. The ATP III recommendations are based on large, randomized, control clinical trials, prospective epidemiological studies, and smaller clinical trials.[9] An expert panel qualified each recommendation according to a category of evidence, which can be found at the NCEP website: (http://nhlbi.nih.gov/guidelines/cholesterol/atp3_rpt.htm.)

Employer Success Story: Fieldale Farms[10]

Fieldale Farms, a poultry processor in Georgia, offered mobile screening, a gift card, and other incentives to all employees participating in its Wellness Program. Those with elevated cholesterol were offered follow-up nutrition counseling and company-paid fitness memberships. Over a 5-year evaluation period, 26% of the participating employees with high cholesterol normalized their cholesterol levels through diet changes, and/or medications. **In 2004, the overall healthcare cost for an employee participating in the Fieldale Farms Wellness Program was $3,052 per year — less than half the national average healthcare cost for a manufacturing employee ($6,900).**

Employer Success Story: Johnson & Johnson[11]

Johnson & Johnson, a manufacturer of healthcare products, offered a comprehensive health and wellness program to its employees. The program offered on-site fitness centers, an internet-based lifestyle management program, and a $500 premium incentive to those who completed a health risk appraisal (HRA) and enrolled in a high-risk intervention program (as needed). For those with chronic medical conditions, such as hyperlipidemia, the program also offered lifestyle counseling with a registered nurse, and a comprehensive disease and care management program. Over a 2.75 year period, the program yielded a 9% decrease in the number of participating employees with high cholesterol levels. Medical expenses decreased by $225 per participating employee, per year, over four years. **As a result, Johnson & Johnson saw a savings of approximately $8.5 million per year due to reduced inpatient hospital use, fewer mental health visits, and fewer outpatient doctor's office visits. Job absenteeism also decreased.**

Employer Action Examples

Opportunities to Supporting Breastfeeding

Human breast milk is universally recognized to be the optimal food for infants and is nutritionally superior to formula. Breast milk confers immunity and protects infants from infections and allergens. Further, research shows that children who were breastfed are at significantly lower risk for many conditions and diseases such as childhood obesity and type 2 diabetes compared to non-breastfed children.[12] Breastfeeding also has important short- and long-term health benefits for the mother. A woman's risk of breast cancer is decreased 4.3% for every 12-month increment of breastfeeding over her lifetime. Her risk of ovarian and endometrial cancer is decreased through breastfeeding as well.[13-14]

Children who are not breastfed contribute to additional healthcare expenditures and productivity losses for the employers of their parents. A 2001 U.S. Department of Agriculture (USDA) study estimated that at least $500 million (in year 1998 dollars) could be saved in healthcare costs if breastfeeding rates were increased to match those recommended by the Surgeon General and the *Healthy People 2010* goals.[15]

Breastfeeding and Employment: Barriers and Opportunities

Despite the well-documented benefits of breastfeeding, only 70% of new mothers initiate breastfeeding and only 36% continue to breastfeed for the recommended 6-month minimum.[1] Women who — at the birth of their child — intend to return to work full-time are even less likely to initiate breastfeeding.[16] Employed women also have a shorter duration of breastfeeding than do women who do not work outside the home.[16] Low rates of breastfeeding among working women should be of great concern to employers. Mothers are the fastest growing segment of the U.S labor force and approximately 70% of employed mothers with infants or toddlers work full-time.[16] Further, one-third of working mothers

return to work within 3 months of the birth of their child and two-thirds return within 6 months, the exact time period when breastfeeding is most critical.[16] The negative effect of part- and full-time work on breastfeeding rates is not absolute. Employers who provide employees with worksite lactation programs effectively increase the number of their employees who continue breastfeeding after returning to work.

Employers can support breastfeeding mothers in multiple ways:

1. Purchasers can include breastfeeding counseling as a component of their medical benefit plan. For more information about breastfeeding counseling, please refer to the breastfeeding subsection of the "Health Pregnancy" chapter located in Parts II and III of the Purchaser's Guide.
2. Employers can ensure that their beneficiaries have access to baby-friendly hospitals that promote the initiation of breastfeeding. The World Health Organization (WHO) provides guidelines on hospital breastfeeding policies and several domestic organizations track hospitals who comply with this well-recognized international guideline.[17] Employers can preferentially select baby-friendly hospitals to include in their health plan networks and encourage their beneficiaries to choose baby-friendly hospitals through education, incentives, or reduced copays/coinsurance.
3. Employers can provide a worksite lactation program.

Employer Action Example: Worksite Lactation Program[16]

The implementation of a worksite lactation program is one way an employer can support its breastfeeding employees. The essential components of a worksite lactation program include:

SPACE

A nursing mother's room (NMR) or other designated space that is centrally located, has adequate lighting, ventilation, and privacy; has a sink, an electrical outlet, and a designated refrigerator.

EQUIPMENT

Breast-pumps (employers may provide single or multi-user pumps, subsidize employee purchased pumps, or require employees to bring their own pumps).

WRITTEN COMPANY POLICIES REGARDING

- Breastfeeding
- Maternity leave
- Use of vacation days, flex time, sick days, personal time, and FMLA.
- Breaks for expressing milk (two breaks and a lunch period for each 8-hour work period).

EDUCATION

- Communicate the breastfeeding support policy to all employees.
- Provide a list of community resources available to support breastfeeding women.
- Train supervisors and managers on the company breastfeeding policy.

Other services such as access to a lactation specialist on an as needed basis at the worksite or in the beneficiary's home can further support breastfeeding.

Employer Action Example: Hospital Network Selections to Support Breastfeeding[12,17]

The World Health Organization (WHO)/UNICEF's Baby-Friendly Hospital Initiative seeks to acknowledge hospitals that promote breastfeeding through a variety of programs, policies, and supports. To qualify as "baby-friendly," hospitals and birthing centers must prove that they follow the WHO's *Ten Steps to Successful Breastfeeding Guideline* as follows:

- Have a written breastfeeding policy that is routinely communicated to all healthcare staff.
- Train all healthcare staff in skills necessary to implement this policy.
- Inform all pregnant women about the benefits and management of breastfeeding.
- Help mothers initiate breastfeeding within one hour of birth.
- Show mothers how to breastfeed and how to maintain lactation even if they should be separated from their infants.
- Give newborn infants no food or drink other than breast milk, unless medically indicated.
- Practice rooming-in (allowing mothers and infants to remain together 24 hours a day).
- Encourage breastfeeding on demand.
- Give no artificial treats or pacifiers to breastfeeding infants.
- Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

To ensure beneficiary access to baby-friendly hospitals that comply with the WHO breastfeeding guideline, employers should:

- Direct health plans to include baby-friendly hospitals in-network.
- Work with healthcare consultants, health plans, and benefits staff to develop a mechanism to encourage women to birth at baby-friendly hospitals. To steer beneficiaries toward baby-friendly hospitals employers can:
  - > Educate beneficiaries on the benefits of delivering their baby at a baby-friendly hospital.
  - > Educate beneficiaries on the importance of breastfeeding initiation and maintenance.
  - > Provide monetary or other types of incentives (e.g., baby car-seats) to beneficiaries who birth at baby-friendly hospitals.
  - > Reduce copayment/coinsurance amounts for services rendered at baby-friendly hospitals.

A list of Baby-friendly hospitals located in the United States can be found at: www.babyfriendlyusa.org

Employer Success Story: CIGNA[18]

CIGNA, an insurance and benefits company based in Philadelphia, offers a corporate lactation program for all employees who breastfeed. The program was created in 1995 when CIGNA employees asked for assistance in continuing to breastfeed after returning from maternity leave. To date, over 1,000 women have enrolled in the Working Well Moms program in more than 250 CIGNA offices. The program provides consultation for mothers with a professional lactation consultant before and after birth and access to a private room equipped with a hospital-grade breast pump, refrigerator, carrying case, and supplies.

The Working Well Moms program has enabled CIGNA to surpass the *Healthy People 2010* 6-month breastfeeding objective by 45%. Breastfeeding duration for women enrolled in the Working Well Moms program is 72.5% at 6 months post-birth (nationally only 21.1% employed mothers continue breastfeeding for 6 months). And 36% of women enrolled in the Working Well Moms continue to breastfeed through the first year of their baby's life; nationally only 10.1% of employed mothers breastfeed their babies to 1-year of age.

As a result of the Working Well Moms program, **CIGNA saw a savings of $300,000 in annual healthcare expenses for breastfeeding mothers and their children. The program also reduced absenteeism among breastfeeding mothers.**

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7 Resources & Tools

Overview:
Additional information for employers on clinical preventive services, including:

- Life Course Maps
  - Recommended Schedule of Preventive Care for Adults
  - Recommended Schedule of Preventive Care for Children and Adolescents
  - Recommended Schedule of Preventive Preconception, Prenatal and Postpartum Care
- Comparison of *A Purchaser's Guide to Clinical Preventive Services,* USPSTF Recommendations, NCQA HEDIS® Measures, NCQA Industry Trends and Analysis, and *Healthy People 2010 Goals*
- Glossary
- Links to Additional Resources and Cost-Calculators

7 Resources & Tools

Life Course Charts

Visual guides to clinical preventive services across the lifespan:

- Recommended Schedule of Preventive Care for Adults
- Recommended Schedule of Preventive Care for Children and Adolescents
- Recommended Schedule of Preventive Preconception, Prenatal, and Postpartum Care

Crosswalk

A crosswalk between the recommendations proposed in the Guide, the 2007 HEDIS® Measures, the NCQA State of Healthcare Quality Report, and the Department of Health and Human Service's *Healthy People 2010* Goals.

Clinical Preventive Services Glossary

Definitions and examples of scientific, medical, and business terms used throughout the *Purchaser's Guide*.

Cost-Calculators and Additional Resources

Life Course Chart: Adults

AGE	18	19-20	21	25	30	35	40	45	50	55	60	65	70	75
Abdominal Aortic Aneurysm										Men who have ever smoked: screen once				
Alcohol Misuse	All adults: screen annually													
	Adults who screen positive for alcohol use: 8 counseling sessions per calendar year													
Aspirin Therapy for the Prevention of Cardiovascular Disease					All adults: 1 counseling session every 5 years or whenever a cardiovascular risk factor is detected									
Breast Cancer														
• **Screening**							All women: screen with mammography at least once every two years							
• **Counseling on BRCA Mutation Testing**					High-risk women: provided as medically indicated at least once before & after genetic testing									
• **Testing for BRCA Mutations**					High-risk women: once per lifetime									
• **Counseling on Preventive Medication and Preventive Treatment**					High-risk women: as medically indicated									
• **Preventive Medication**					High-risk women: as prescribed by a clinician									
• **Preventive Treatment**					High-risk women: as recommended by a clinician									
Cervical Cancer	All women aged 21 to 65 or within 3 years of the onset of sexual activity: screen at least once every 3 years, no more than once per calendar year											High-risk women: screen as medically indicated		
Colorectal Cancer									All adults: screen every 5 to 10 years depending on method					
Contraceptive Use	All adults: counsel at least once per year & whenever emergency contraception is prescribed													
	All women: medications and devices as medically necessary for the prevention of pregnancy All adults: voluntary sterilization covered once per lifetime													
Depression	All adults: screen whenever medically indicated													
Diabetes (type 2)									All adults: screen once every 3 years					
					High-risk adults: screen once every 2 years									
Healthy Diet	Adults with hyperlipidemia & other risk factors for cardiovascular & diet-related chronic disease: 3 intensive counseling sessions per calendar year													
Hypertension	All adults: routine screening													
	Adults with diagnosed hypertension: 6 counseling, treatment, and monitoring sessions per calendar year													
	Adults with diagnosed hypertension: drug therapy as medically indicated													
Immunizations[1]														
• **Hepatitis A**	*	At-risk adults: 2 doses (2nd dose given 6-12 months, or 6-18 months after initial dose)												
• **Hepatitis B**	*	At-risk adults: 3 doses (2nd dose 1-2 months after initial dose, 3rd dose 4-6 months after initial dose)												
• **Influenza**	*	At-risk adults: 1 dose annually							All adults: 1 dose annually					
• **Measles, mumps, and rubella**	*	All adults: 1 or 2 doses if no evidence of immunity							At-risk adults: 1 dose					
• **Meningococcal**	*	At-risk adults: 1 or more doses												
• **Pneumococcal**	*	At-risk adults: 1-2 doses										All adults: 1 dose		
• **Tetanus**	*	All adults: 1-dose booster every 10 years												
• **Varicella**	*	All adults: 2 doses (2nd dose given 4-8 weeks after initial dose) if no evidence of immunity							At-risk adults: 2 doses (2nd dose given 4-8 weeks after initial dose)					
Lipid Disorders			All adults: screen once every 5 years											
			Adults with a lipid disorder: 6 counseling, treatment, and monitoring sessions per calendar year											
			Adults with a lipid disorder: drug therapy as medically indicated											
Medical Foods for Persons with Genetic or Endocrine Disorders	Adults with genetic or endocrine disorders: medical foods provided as medically indicated													
Motor Vehicle-Related Injury Prevention	All adults: counsel as medically indicated and reinforce prevention messages annually													
Obesity	All adults: screen once per calendar year													
	All obese (BMI>30) adults: 6 counseling sessions per calendar year													
	All obese adults with a BMI > 40 or BMI > 35 & at least one obesity-related illness: drug therapy and or surgery. Subject to pre-authorization requirements.													
Osteoporosis											High-risk adults: screen every 2+ years			
											All women: screen every 2+ years			
											All men: screen as medically indicated			
Sexually Transmitted Infections (STIs)														
• **Counseling to prevent STIs**	All adults: education on the risk factors for HIV and other STIs & counseling on effective measures to reduce risk of infection													
• **Chlamydia**	All women from onset of sexual activity through age 25: screen annually													
				At-risk women: screen as medically indicated										
• **Gonorrhea**	All women from onset of sexual activity through age 25: screen annually													
				At-risk women: screen as medically indicated										
• **Human Immunodeficiency Virus (HIV)**	All adults: screen as medically indicated, at least once per lifetime													
	All adults undergoing screening: pre- and post-test counseling, maximum of 3 sessions per test cycle													
• **Syphilis**	High-risk adults: screen as medically indicated													
Tobacco Use Treatment	All adults: screen at every medical encounter													
	All adults who use tobacco: 12 counseling sessions per calendar year													
	All adults who use tobacco: nicotine replacement products/medications and/or tobacco cessation medication, as medically indicated													
Tuberculosis	High-risk adults: targeted testing													

Screening: **Testing:** **Counseling:** **Immunization:** **Preventive Treatment:** **Preventive Medication/ Intervention**

Notes: * Please refer to the life course chart for children and adolescents for immunization recommendations for this age group.
1. The immunization schedule listed on this chart is a graphic representation of recommendations in force at the time the chart was made. Visit the ACIP website (www.cdc.gov/nip/acip/) for up-to-date recommendations.

Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage.* Washington, DC: National Business Group on Health; 2006. Available online at: www.businessgrouphealth.org/prevention/purchasers

Chart A

Life Course Chart: Children & Adolescents

AGE	At Birth	1 Month	2 Months	4 Months	6 Months	9 Months	12 Months	15 Months	18 Months	24 Months	30 Months	36 Months	4-6 Years	11-12 Years	13-15 Years	16-18 Years
Alcohol Misuse													Screen as medically indicated			
Cervical Cancer	All adolescents within 3 years of the onset of sexual activity: screen at least once every three years, no more than once per calendar year.															
Childhood Development						Screen			Screen		Screen					
Contraceptive Use													Counsel as medically indicated			
													Prescribe as medically indicated			
Dental Caries Prevention						At-risk: oral fluoride supplementation as prescribed by a clinician										
Depression													Screen as medically indicated			
Elevated Blood Lead Levels[1]							At-risk: Screen			At-risk: Screen		At-risk: Screen				
Immunization[2]																
• **Diphtheria, Tetanus, Pertussis**			DTaP	DTaP	DTaP		DTaP (between 12-18 months, provided 6 months have elapsed since 3rd dose)						DTaP	Tdap[3]	Tdap (catch-up)	
• ***Haemophilus influenzae* type b**			Hib	Hib	Hib		Hib									
• **Hepatitis A**							HepA Series									
• **Hepatitis B**	HepB[4]	HepB			HepB							HepB Series (catch-up)				
	Exposed infants: HBIG prophylaxis[5]															
• **Human papillomavirus**														HPV Series	HPV Series (catch-up)	
• **Inactivated Poliovirus**			IPV	IPV	IPV								IPV			
• **Influenza**					Influenza (annually)											
• **Measles, Mumps, Rubella**							MMR						MMR	MMR (catch-up)		
• **Meningococcal**														MCV4	MCV4 (catch-up)	
• **Pneumococcal**			PCV	PCV	PCV		PCV									
• **Rotavirus**			Rota	Rota	Rota											
• **Varicella (Chicken Pox)**							Varicella						Varicella	Varicella (catch-up)		
Motor Vehicle-Related Injury Prevention								Counsel as medically indicated, reinforce prevention messages annually								
Newborn Hearing	Screen	At-risk: re-screen as medically indicated														
Newborn Screening for Genetic and Endocrine Disorders	Screen	At-risk: re-screen as medically indicated														
	All children and adolescents with genetic or endocrine disorders: medications and medical foods, as medically indicated															
Obesity										Screen as medically indicated						
Sexually Transmitted Infections (STIs)																
• **Counseling to prevent STIs**				Educate on the risk factors for HIV and other STIs & counsel on effective measure to reduce risk of infection												
• **Chlamydia**						All female adolescents from onset of sexually activity through age 25: screen annually										
• **Gonorrhea**						All female adolescents from onset of sexually activity through age 25: screen annually										
• **Human Immunodeficiency Virus (HIV)**													Screen as medically indicated			
				All adolescents undergoing screening: pre- and post-test counseling, maximum of 3 sessions per test cycle												
• **Syphilis**											High-risk adolescents: screen as medically indicated					
Tobacco Use													Screen at every medical encounter			
													Counsel as medically indicated			
				Provide nicotine replacement products/medications and/or tobacco cessation medication, as medically indicated												
Vision	Screen at all well-child visits															

Screening: **Testing:** **Counseling:** **Immunization:** **Preventive Treatment:** **Preventive Medication/ Intervention**

Notes:
1. Screen at any age when deemed medically necessary by a risk assessment, clinical signs or symptoms consistent with elevated BLL, or when other evidence indicates possible lead exposure.
2. The immunization schedule listed on this chart is a graphic representation of recommendations for routine vaccination in force at the time the chart was made. Visit the ACIP website (www.cdc.gov/nip/acip/) for up-to-date recommendations.
3. For those children who have completed the recommended childhood DTP/DTaP vaccination series and have not received a Td booster dose.
4. All newborns should receive the hepatitis B vaccine soon after birth and before hospital discharge.
5. Infants born to mothers who are HBsAg-positive should receive the hepatitis B vaccine with HBIG within 12 hours of birth. Infants born to mothers whose HBsAg status is unknown should receive the hepatitis B vaccine within 12 hours of birth.

Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage.* Washington, DC: National Business Group on Health; 2006. Available online at: www.businessgrouphealth.org/prevention/purchasers

Life Course Chart: Pregnancy

RECOMMENDED SCHEDULE OF PRECONCEPTION, PRENATAL, AND POSTPARTUM CARE

PERIOD	Preconception/ Interconception	1st Prenatal Visit	Continuing Prenatal Care								Post-partum
TRIMESTER		TRIMESTER 1			TRIMESTER 2			TRIMESTER 3			
MONTH		1	2	3	4	5	6	7	8	9	10
Alcohol Misuse	All women: screen at the beginning of each pregnancy (and thereafter at the clinician's discretion) All pregnant women and women considering pregnancy: advise on the harmful effects of alcohol At-risk: counsel throughout pregnancy										
Asymptomatic Bacteriuria				All women: screen via urine culture at 12-16 weeks				All women: repeat urine culture			
Breastfeeding	All women: offer structured breastfeeding education and behavioral counseling to promote breastfeeding										
Folic Acid Supplementation	All women: provide information on folic acid during routine healthcare visits and prenatal care visits through the 1st trimester of pregnancy All pregnant women and women planning a pregnancy: folic acid, as medically indicated										
Group B Streptococcal Disease											All women: screen for colonization at 35-37 weeks All colonized women: intrapartum antibiotic prophylaxis, as medically indicated
Hepatitis B*		All women: screen for infection						All women at increased risk: repeat screen			
		All pregnant women at risk of infection: immunize at some point during pregnancy									All infants: immunize[1]
								All exposed infants: provide HBIG prophylaxis			
HIV		All women: screen						All pregnant women at risk of infection: repeat screen			
Influenza*		All women who will be pregnant during influenza season (October to mid-May): immunize with trivalent inactivated influenza vaccine									
Preeclampsia		All women: screen		All women: repeat screening every 4 weeks until week 28, every 2-3 weeks until week 36, and weekly thereafter (until delivery)							
Prenatal Diagnosis of Chromosomal Abnormalities & NTDs		All women: offer screening to detect chromosomal abnormalities and NTDs All pregnant women at increased risk: offer testing in place of, or in addition to, screening									
Rh(D) Incompatibility		All women: screen for blood type and antibodies					All women: screen to confirm Rh(D) antibody status, if medically indicated				
Rubella*	All women: screen at 1st clinical encounter All nonpregnant women[2]: immunize at 1st clinical encounter if not otherwise immune to rubella										Immunize susceptible women immediately after delivery
Syphilis		All women: screen						All women in high-risk groups: repeat screen at 28 weeks and at labor and delivery			
Tetanus*		All women: screen			All susceptible women: immunize during the 2nd or 3rd trimester						
Tobacco Use	All women: screen at every medical encounter All pregnant women who use tobacco: counsel to quit at every medical encounter										

Screening: **Testing:** **Counseling:** **Immunization:** **Preventive Medication:**

*The immunization schedule listed on this chart is a graphic representation of recommendations in force at the time the chart was made. Visit the ACIP website (www.cdc.gov/nip/acip/) for up-to-date recommendations.

1. All infants need to receive a single dose of the hepatitis B vaccine. All infants born to women with unknown HBsAG status need to receive a single dose of the hepatitis B vaccine (without HBIG).
2. All women are advised not to become pregnant until 4 weeks after the rubella vaccination.

Campbell KP, Lanza A, Dixon R, Chattopadhyay S, Molinari N, Finch RA, editors. *A Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage.* Washington, DC: National Business Group on Health; 2006. Available online at: www.businessgrouphealth.org/prevention/purchasers

Chart C

Crosswalk

A crosswalk between the recommendations proposed in the Guide, the 2007 HEDIS® Measures, the NCQA State of Healthcare Quality Report, and the Department of Health and Human Service's *Healthy People 2010* Goals

Categories	*Purchaser's Guide* Recommendations	USPTSF Recommendation	HEDIS® 2007 Measures	NCQA 2006 State of Health Care Quality % of beneficiaries in the commercially-insured population who received service (2004-2005)[2]	*Healthy People 2010 Goal*
Cancer	• Breast Cancer, *Screening* • Breast Cancer Genetic Risk Assessment and BRCA Mutation Testing, *Counseling, testing, and preventive treatment* • Breast Cancer, *Counseling and preventive medication*	• Administer screening mammography, with or without clinical breast examination (CBE), every 1-2 years to women aged 40 and older. • Women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes should be referred for genetic counseling and evaluation for BRCA testing.	• Breast cancer screening	• Breast cancer screening: 72.0%	2000: 67% of women age 40 and above have had a mammogram within the past 2 years^ 2010 target: increase proportion to 70%^
	• Cervical Cancer, *Screening*	• Screen for cervical cancer among women who are/have been sexually active and have a cervix.	• Cervical cancer screening	• Cervical cancer screening: 81.8% (women aged 21 to 64)	2000: 79% of women age 18 and above have had a pap smear within the past 3 years^ 2010 target: increase proportion to 90%^
	• Colorectal Cancer, *Screening*	• Screen men and women 50 years of age or older for colorectal cancer.	• Colorectal cancer Screening	• Colorectal cancer screening: 52.3% of adults aged 50 years and older.	2000: 24% of adults age 50 and above have received a fecal occult blood test within the past two years^ 2010 target: increase proportion to 33% 1998: 37% of adults age 50 and above have received a sigmonoscopy at some point during their life^ 2010 target: increase proportion to 50%

Categories	*Purchaser's Guide* Recommendations	USPTSF Recommendation	HEDIS® 2007 Measures	NCQA 2006 State of Health Care Quality % of beneficiaries in the commercially-insured population who received service (2004-2005)[2]	*Healthy People 2010 Goal*
Cardiovascular Health	• Abdominal Aortic Aneurysm, *Screening*	• One-time screening by ultrasonography for men aged 65 to 75 who have ever smoked.			
	• Aspirin Therapy for the Prevention of Cardiovascular Disease, *Counseling*	• Discuss aspirin chemoprevention with adults who are at increased risk for coronary heart disease			
	• Healthy Diet, *Counseling*	• Behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease.			
	• Hypertension, *Screening, counseling, and treatment*	• Screen adults aged 18 and older for high blood pressure.	• Controlling high blood pressure	• 68.8% of adults age 46-85 have controlled blood pressure (140/90 mm Hg or lower)	2000: 26% of adults age 20 and above have high blood pressure^ 2010 target: reduce proportion to 14% 2000: 25% of adults age 18 and above with high blood pressure have it under control 2010 target: increase proportion to 68%^
	• Lipid Disorders, *Screening, counseling, and treatment*	• Screen men aged 35 years and older and women aged 45 years and older for lipid disorders and treat abnormal lipids in people who are at increased risk of coronary heart disease.	• Cholesterol management for patients with cardiovascular conditions	• LDL-C screening: 92.3% • LDL-C control (<130 mg/dL) 67.5% • LCL-C control (<100 mg/dL) 43.8%	2000: 67% of adults age 18 and above have had their blood cholesterol checked in the past 5 years^ 2010 target: increase proportion to 80%^
Diabetes	• Diabetes (type 2), *Screening*	• Screen for type 2 diabetes in adults with hypertension or hyperlipidemia.	• Comprehensive diabetes care	Comprehensive diabetes care: • Eye exams: 54.8% • HbA1c testing: 87.5% • LDL-C screening: 92.3% • LDL-C control (<130 mg/dL) 67.5% • LCL-C control (<100 mg/dL) 43.8%	2000: 64% of adults age 20 and above with diabetes have been diagnosed^ 2010 target: increase rate to 78%^ 2000: there are 5.5 new cases of diabetes per 1,000 population aged 18-84 2010 target: reduce incidence to 3.8 new caser per 1,000 population per year^

Categories	*Purchaser's Guide* Recommendations	USPTSF Recommendation	HEDIS® 2007 Measures	NCQA 2006 State of Health Care Quality % of beneficiaries in the commercially-insured population who received service (2004-2005)[2]	*Healthy People 2010 Goal*
Immunizations Adult (for information on child and adolescent immunization please refer to Infant, Child, & Adolescent Care)	• Immunizations (Adults)	• N/A – the USPSTF defers to ACIP.	• Flu shots for adults age 50–64 • Flu shots for older adults • Pneumonia vaccination status for older adults	• Flu shots for adults: 36.3%.	2002: 66% of adults age 65 and above receive an influenza vaccine 2010 target: increase proportion to 90% 2004: 56% of adults age 65 and above receive a pnemoncoccal vaccine 2010 target: increase proportion to 90% 1998: 87% of children age 19 to 35 months received 3 does of hepatitis B vaccine in 1998. 2010: Increase proportion to 80%
Infant, Child, & Adolescent Care	• Newborn Screening for Genetic and Endocrine Disorders, *Screening, medical foods, and treatment* • Newborn hearing, *Screening* • Lead, Elevated Blood Levels, *Screening* • Dental Caries, *Preventive medication* • Child Development, *Screening* • Immunizations • Vision, *Screening* • The *Purchaser's Guide* also recommends screening and counseling adolescents as mediacally indicated for alcohol misuse, depression, obesity, and tobacco use.	• The USPSTF determined that the evidence was insufficient to recommend for or against routine screening of newborns for hearing loss during postpartum hospitalization. • N/A – the USPSTF defers to ACIP. • Primary care clinicians should prescribe oral fluoride supplementation at currently recommended doses to preschool children older than 6 months of age whose primary water source is deficient in fluoride.	• Well-child visits in the first 15 months of life • Well-child visits in the third, fourth, fifth and sixth years of life • Childhood immunization status • Annual dental visits • Adolescent well-care visit • Adolescent immunization status	• Child immunizations (combination 2): 77.7% • Childhood immunization for chickenpox (VZV): 89.9% • Adolescent immunizations status (combination 2): 53.7% • Adolescent immunization for chickenpox (VZV): 60.2%	2010 target: Ensure that all newborns are screened at birth for conditions mandated by their State-sponsored newborn screening programs^ 1998: 87% of children age 19 to 35 months received 3 does of hepatitis B vaccine in 1998. 2010: Increase proportion to 90% 1994: 4.4% of children aged 1-5 years have blood lead levels exceeding 10 mg/dL^ 2010 target: reduce proportion to 0% 1998: 73% of children receive all vaccines that have been recommended for universal administration for at least 5 years (DTaP, polio. MMR, Hib and HepB vaccines)^ 2010 target: increase proportion to 90%^ 1994: 131 per 10,000 children born suffers from mental retardation and 32.2 per 10,000 suffer from cerebral palsy^ 2010 target: reduce rate of mental retardation to 124 cases per 10,000 live births and reduce the rate of cerebral palsy to 31.5 cases per 10,000 live births^ 2001: 66% of newborns receive screenings for hearing loss before age 1 month, 56% receive audiologic evaluation before age 3 month, and 57% are enrolled in appropriate intervention services by age 6 months. 2010 target: increase the proportion of newborns who are screened for hearing loss by age 1 month to 90%, have audiologic

Categories	*Purchaser's Guide* Recommendations	USPTSF Recommendation	HEDIS® 2007 Measures	NCQA 2006 State of Health Care Quality % of beneficiaries in the commercially-insured population who received service (2004-2005)[2]	*Healthy People 2010 Goal*
Infant, Child, & Adolescent Care *(Continued)*					evaluation by age 3 months to 70%, and are enrolled in appropriate intervention services by age 6 months to 85%. 2002: 36% of children aged 5 years and under had ever had their vision screened in 2002. 2010 target: increase the Increase the proportion of preschool children aged 5 years and under who receive vision screening to 52%. 1997: 48% of adolescents aged 13-15 years received 3 or more doses of hepatitis B vaccine, 89% received 2 or more doses of MMR, 93% received 1 or more tetanus –diphtheria booster, and 45% received 1 or more doses of varicella (for chicken pox)^ 2010 target: increase proportions for all vaccines to 90%^ 2002: 26% of adolescents in 12th grade smoke[1] 2010 target: reduce smoking rate to 16%
Mental Health and Substance Abuse	• Depression, *Screening*	• Screen adults for depression in clinical practices that have systems in place to assure accurate diagnosis, effective treatment, and follow-up.			1997: 23% of Adults aged 18 years and older with depression receive treatment 2010 target: increase proportion to 50%
	• Alcohol Misuse, *Screening and counseling*	• Screen all adults (including pregnant women) for alcohol misuse and provide behavioral counseling interventions to reduce alcohol misuse in primary care settings.		• Initiation of treatment: 44.5%	2002: 51% of individuals age 12 and above consume alcohol 2002: 17.6% of adolescents ages 12-17 consume alcohol 2002: 10.7% of adolescents aged 12 to 17 binge drink (5 or more drinks on the same occasion within the past 30 days) 2010 target: Reduce adolescents engaging in binge drinking during the past month to 3.1%^ 1998: 24.3% of adults aged 18 and older binge drink^ 2010 target: reduce proportion to 13.4% ^

Categories	*Purchaser's Guide* Recommendations	USPTSF Recommendation	HEDIS® 2007 Measures	NCQA 2006 State of Health Care Quality % of beneficiaries in the commercially-insured population who received service (2004-2005)[2]	*Healthy People 2010 Goal*
Nutrition/ Physical Activity	• Obesity, *Screening, counseling, and treatment*	• Screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.			2002: 65% of U.S. adults, aged 20 and above, are overweight 2010 target: reduce proportion to 15% 2002: 31% of adults aged 20 and above are overweight 2010 target: reduce proportion to 15%
Pregnancy	• Alcohol Misuse, *Screening and counseling* • Asymptomatic Bacteriuria, *Screening* • Breastfeeding, *Counseling* • Folic Acid Supplementation, *Counseling and preventive medication* • Group B Streptococcal Disease, *Screening and preventive medication* • Hepatitis B Virus (HBV), *Screening, immunization, and treatment* • Human Immunodeficiency Virus (HIV), *Screening, counseling, and preventive medication* • Influenza, *Immunization* • Preeclampsia, *Screening* • Prenatal Diagnosis of Chromosomal Abnormalities and Neural Tube Defects (NTDs), *Screening and testing* • Rh (D) Incompatibility, *Screening and preventive medication* • Rubella, *Screening* • Syphilis, *Screening* • Tetanus, *Immunization* • Tobacco Use Treatment, *Screening and counseling*	• Screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings. • Provide structured breastfeeding education and behavioral counseling programs to promote breastfeeding. • Routinely screen all sexually active women aged 25 years and younger, and other asymptomatic women at increased risk for infection, for chlamydial infection. • Screen for hepatitis B virus (HBV) infection among pregnant women at their first prenatal visit. • Screen all pregnant women for HIV. • Rh (D) blood typing and antibody testing should be conducted at the first prenatal visit for all pregnant women. • All women of childbearing age should be assessed for rubella susceptibility by history of vaccination or by serology at their first clinical encounter.	• Prenatal and postpartum care • Frequency of ongoing prenatal care	• Timelines of prenatal care: 91.8% • Timeliness of postpartum care: 81.5%	2004: 84% of pregnant women received timely prenatal care 2010 target: increase rate to 90% 2002: 43% of mothers breastfeed exclusively for 3months^ 2010 target: increase proportion to 60%^ 2002: 13% of mothers breastfeed exclusively for 6 months^ 2010 target: increase proportion to 25%^ 1995: 93% of females 15 to 44 who are at risk of unintended pregnancy use contraception. 2010 target: increase rate to 100% 1994: 21% of non-pregnant women ages 15 to 44 consume at least 400 mg of folic acid per day 2010 target: increase rate to 80% 2010 target: Increase the proportion of pregnant females screened for sexually transmitted diseases (including HIV infection and bacterial vaginosis) during prenatal health care visits, according to recognized standards. 2000: 1,682 chronic hepatitis B virus infections in children under age 2 years were reported in 1995. 2010 target: Reduce chronic hepatitis B virus infections in infants and young children (perinatal infections) to 400 infections. 1996: 6 cases of spina bifida or other NTD per 10,000 live births 2010 target: reduce the number of spina bifida cases to 3 per 10,000 live births

Categories	*Purchaser's Guide* Recommendations	USPTSF Recommendation	HEDIS® 2007 Measures	NCQA 2006 State of Health Care Quality % of beneficiaries in the commercially-insured population who received service (2004-2005)[2]	*Healthy People 2010 Goal*
Pregnancy *(Continued)*		• Screen all pregnant women for syphilis infection at the 1st prenatal visit • Screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke.			2002: 11% of pregnant women smoke*, 1997: 14% of pregnant women drink alcohol, 1% binge drink, and 2% use illicit drugs 2010 target: reduce smoking rate to 1%, alcohol use rate to 6%, binge drinking rate to 0%, and illicit drug use rate to 0% 1997: fetal alcohol syndrome occurs in 0.4 per 1,000 live births^ 2010 target: reduce incidence to 0.1 cases per 1,000 live births^
Sexually Transmitted Infection, (STIs)	• Counseling to Prevent STIs, *Counseling*	• Educate all adolescents and adults on the risk factors for HIV and other sexually transmitted infections and counsel these patients on effective measures to reduce their risk of infection.			
	• Chlamydia, *Screening*	• Screen all sexually active women aged 25 years and younger, and other asymptomatic women at increased risk, for chlamydial infection.	• Chlamydia screening in women	• Chlamydia screening: 16 to 20 years: 34.4% 21 to 25 years: 35.2%	2002: 25% of sexually active women aged 25 and under enrolled in commercial managed care organizations are screened for Chlamydia infection^ 2010 target: increase proportion to 62%^
	• Gonorrhea, *Screening*	• Screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection.			2002: there are 279 new cases of gonorrhea among women age 15-44 per 100,000 population^ 2010 target: reduce the incidence to 42 new cases per 100,000 population^
	• Human Immunodeficiency Virus (HIV), *Screening*	• Screen all adolescents and adults at increased risk for HIV infection.			1994: 17% of adults age 20-29 years have a genital herpes infection^ 2010 target: reduce proportion to 14%^
	• Syphilis, *Screening*	• Screen persons at increased risk for syphilis infection.			

Categories	*Purchaser's Guide* Recommendations	USPTSF Recommendation	HEDIS® 2007 Measures	NCQA 2006 State of Health Care Quality % of beneficiaries in the commercially-insured population who received service (2004-2005)[2]	*Healthy People 2010 Goal*
Sexually Transmitted Infections *(Continued)*	• Contraceptives, *Counseling and preventive medication*				1995: 51% of pregnancies in the U.S. are intended 2010 target: increase rate to 70%
Other	• Motor Vehicle-Related Injury Prevention, *Counseling*				2002: 8.4 per 100,000 deaths result form a motor vehicle accident (age-adjusted deaths) 2010 target: reduce rate to 8.0 deaths per 100,000^
	• Osteoporosis, *Screening and treatment*	• Screen women aged 65 and older for osteoporosis. The USPSTF recommends that routine screening begin at age 60 for women at increased risk for osteoporotic fractures	• Osteoporosis management in women who had a fracture • Osteoporosis testing in older women	• Osteoporosis management after a fracture: 20.1% (Medicare rate)	2000: 10% of adults age 50 and above have osteoporosis^ 2010 target: reduce proportion to 8%^
	• Tobacco Use Treatment, *Screening, counseling, and treatment*	• Screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco products.	• Medical assistance with smoking cessation	• Advising smokers to quit: 71.2% • Discussing cessation medications: 39.4% • Discussing quitting strategies: 39.0%	2002: 26% of adolescents in 12th grade smoke[1] 2010 target: reduce smoking rate to 16% 1999: 20% of adult females and 25% of adult males smoke[1] 2010 target: reduce adult smoking rate to 12%^
	• Tuberculosis, *Screening*	• Screen for tuberculosis infection with tuberculin skin testing among asymptomatic high-risk persons.			1998: 6.8 new cases of TB per 100,000 population^ 2010 target: reduce incidence to 1.0 new cases per 100,000 population^ 1997: 62% of contacts and other high-risk persons with latent TB complete a course of treatment 2010: Increase treatment completion to 85%

Notes:

[1] Adolescent smoking definition: an adolescent in grade 9-12 who smoked one or more cigarettes in the past 30 days. Adult smoking definition: an adult (≥18 years of age) who smoked more than 100 cigarettes in his/her lifetime and who smoked on some or all days in the past month.

[2] The NCQA Report on the State of Health Care Quality is based on 500 health plans that voluntarily report HEDIS measurements to NCQA.

Information Sources:

All information on the USPSTF recommendations was adapted from:

U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services: Pocket Guide; 2005*. [cited 2006 Jun 5]. Available from: http://www.ahrq.gov/clinic/pocketgd.htm.

All information related to the Healthy People 2010 guidelines, unless otherwise noted by * or a ^ was adapted from:

U.S. Department of Health and Human Services. *Healthy People 2010*. 2nd ed. With *Understanding and Improving Health and Objectives for Improving Health*. 2 vols. Washington. DC: U.S. Government Printing Office; November 2000.

^ U.S. Department of Health and Human Services. Healthy People 2010. Midcourse Review. Washington, DC: U.S. Department of Health and Human Services. Office of Disease Prevention and Health Promotion. [cited 2006 Jun 13]. Available from: http://www.healthypeople.gov/data/midcourse/comments/objectives.asp.

All information from NCQA was adapted from:

National Committee for Quality Assurance (NCQA). *The State of Healthcare Quality: 2006*. National Committee for Quality Assurance (NCQA); Washington, DC; 2006.

National Committee for Quality Assurance (NCQA). *The State of Healthcare Quality: 2004*. National Committee for Quality Assurance (NCQA); Washington, DC; 2004.

National Committee for Quality Assurance (NCQA). HEDIS 2007 Summary Table of Measures and Product Lines. Measure List. Washington, DC: National Committee for Quality Assurance; 2006. [cited 2006 Sept 15]. Available from: http://www.ncqa.org/Programs/HEDIS/2007/MeasuresList.pdf.

Glossary

Absenteeism: Missing days from work. In terms of health-related absenteeism, it can be attributed to general sickness, workers' compensation, short-term disability, long-term disability, sick leave, Family Medical Leave Act (FMLA), paid time off (PTO), unpaid leave, and death (premature mortality costs).[1]

Asymptomatic: Lacking symptoms of a disease or condition.

At-work productivity decline (also see **presenteeism**): Reduced normal activity and job output due to a health problem.[2]

Bed days: Number of days-of-stay in a healthcare facility (e.g., hospital) used to treat a condition or population. "Hospital bed days per thousand," for example, may describe the average number of inpatient days used in a specified period of time for every 1,000 employees.

Chemoprophylaxis: The prevention of infectious disease through the use of chemical agents[3]; such as drugs; also called preventive medication.

Clinical preventive services: A comprehensive term referring to a variety of interventions delivered to an individual (e.g., screenings, counseling, immunizations, and preventive medication) intended to detect conditions for which the individual has no symptoms of disease or to prevent escalation of an established disease or condition.

Cohort: A defined group of individuals; a group of individuals with a common statistical factor (such as birth year, age, or risk).[3]

Comorbidity: The presence of multiple diseases or conditions that are simultaneously present and not necessarily caused by one another. For example, a patient with type 2 diabetes and depression is said to have comorbid diabetes and depression. Comorbid disorders may interact to affect clinical course, severity, risk factors for other conditions, or to alter the appropriateness of tests and treatments that are normally used to manage a single condition. Comorbidity may be used as a prognostic indicator for length of hospital stay, cost factors, and outcome or survival.[5]

Complication: A side effect, secondary condition, or adverse effect related to an underlying condition. Complications may occur because of the natural course of a disease (e.g., death can be a complication of an untreated heart attack) or may occur as the result of medical procedure or treatment (e.g., post-operative infection).

Cost, indirect: Expenses associated with an illness, condition, or disorder that are not immediately related to treatment. These non-medical expenditures include lost wages, lost workdays, costs related to using replacement workers, overtime premiums, productivity losses related to unscheduled absences, and productivity losses of workers while on the job.[1]

Cost, direct: Dollars spent on health services. Direct costs include out-of-pocket payments, medical insurance benefits (e.g., medical, pharmacy, dental, mental health), disability payments, and workers' compensation losses.[1]

Cost-effective: A determination that the net cost per unit of health generated by an intervention is favorable in comparison with other health services.

Cost-effectiveness: Minimum cost for a given benefit, the maximum benefit for a given cost, or a balance of low cost and high benefit that has maximum utility.

Cost-effectiveness analysis (CEA): An economic analysis designed to compare the net cost (expense) of an intervention with the net expense of one or more other interventions. CEAs usually use a common outcome measure, such as years-of-extended life or quality-adjusted life years in which all expenditures are related to a single, common effect, usually in terms of expense per outcome achieved.

Cost-effectiveness (CE) ratio: The ratio of total investment expenditures to total accrued benefits, in terms of both dollars and benefit value. This is comparable to a Return-on-Investment (ROI) calculation.

Cost, out-of-pocket: Expenditures for a healthcare service that are not covered by a health plan or other third party and for which an individual is directly responsible.

Cost-saving: The reduction in healthcare expenses resulting from an intervention or program after accounting for the cost required to develop, implement, and maintain the given intervention or program.

Cost, total: The sum of all direct and indirect costs.

Counseling: An intervention during which a clinical provider gives information to an individual about changes in personal behavior that can reduce the risk of illness or injury.

Disability: Inability to pursue an occupation or perform job tasks because of physical or mental impairment.[3]

Direct medical expense: The economic value directly attributable to a particular clinical action, purchase, program or initiative; the amount spent for diagnosis, treatment or prevention of medical problems. Direct medical expenses include visits to physician's offices and treatment expenditures.

Evidence-based medicine: The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine integrates individual clinical expertise with the best available external clinical evidence from systematic research.[4]

Evidence-based recommendations: Require "First, good evidence that each test or procedure recommended is medically effective in reducing morbidity or mortality; second, the medical benefits must outweigh the risks; third, the cost of each test or procedure must be reasonable compared to its expected benefits; and finally, the recommended actions must be practical and feasible."[8] [*Note: The USPSTF does not consider cost as a factor in its recommendations.*]

Excess medical costs: Any medical expenditure related to a preventable disease or health condition, for example, spending for an amputation necessitated by poorly controlled diabetes or expenses related to a hospital-acquired infection.

Health economics: A branch of economics concerned with analyzing the costs and consequences of healthcare. Health economics uses mathematical models to synthesize data from biostatistics and epidemiology to support medical decision-making, both for individuals and for wider health policy.[5]

Health promotion program (also see **wellness program)**: Any prevention initiative aimed at changing lifestyle behaviors associated with greater risk of disease. These initiatives actively encourage healthy activities such as substance abuse control, weight management, smoking cessation, stress management, physical activity, or the like.

Health risk appraisal/Health risk assessment (HRA): A standardized assessment tool administered to employees (or other groups of individuals) that measures an individual's wellness and disease risk factors, interest in participating in specific programs, and readiness to change unhealthy lifestyle habits.

Health Plan Employer Data and Information Set (HEDIS®): HEDIS® is a United States program from the National Committee for Quality Assurance (NCQA) that consists of multiple, diverse measures of clinical and administrative outcomes by which the performance of a health plan can be compared to other plans, national or regional benchmarks, or the plan's performance from previous years.

Herd immunity: The immunity of a group or community. When a high proportion of a community is immunized against a particular communicable disease, the entire community (including those who are immunized) is resistant to the invasion and spread of an infectious agent because there are not enough non-immune people to transmit the disease.

High-value: An intervention that is both evidence-based and cost-effective.

Immunization (also see **vaccination**): The administration of a substance, usually by injection, oral, or nasal administration, that produces protective immunity to one or more specific diseases.

Incidence: The number of new cases of a particular illness or condition reported in a given time period (e.g., day, week, year).

Indirect medical expense: Money expenditures associated with an illness, condition, or disorder, but not immediately related to treatment of that disorder.

Life-years gained: A measure of value gained from a healthcare intervention: the average number of extra years of life resulting from treatment when compared with non-treatment. It does not include measures of quality of life or disability status (e.g., QALY, DALY).

Lost productivity: Total limitation in work experienced by an individual. It is a sum of lost workdays and productivity decline.[2]

Lost workdays: Days for which an individual reports being unable to complete normal activities due to a health condition.

Lost workday cases: Cases that involve consecutive or nonconsecutive days away from a job, on restricted activity, or both as a result of injury or illness. Counting of lost workday cases should begin following the day an injury occurs or a disease or illness commences.

Morbidity: The relative frequency and severity of a disease in a defined population; the result of experiencing illness from a disease or condition (excluding death). For example, untreated type 2 diabetes may result in morbidities such as blindness, infections, neuropathies, and other problems.

Mortality: The number of deaths in a defined population or more specifically, the number of deaths

attributable to a particular type of illness or disease.

Premature mortality: The number of deaths of people aged 0 to 74 years. Premature mortality is an important indicator of the general health of a population as a high premature mortality rate indicates poor population health status.[4]

Presenteeism: Describes an employee who is at work but not fully functioning while there. In this context, presenteeism refers to those situations whereby an employee's job performance or productivity is impaired by a health problem.[1]

Prevalence: The proportion of the general population affected by a specific illness or condition at a specific point in time or during a defined period of time.

Preventive medication: A medication taken to prevent the occurrence or delay the onset of a disease or condition.

Primary care: Clinical care provided by family physicians, pediatricians, internal medicine doctors, or obstetrician/gynecologists who treat general illnesses, provide clinical preventive services, and triage patients for specialized medical care.

Primary prevention: is aimed at preventing the onset of disease. One way of doing this is by controlling risk factors in healthy people that may lead to disease. Examples of primary prevention include 1) immunizations to prevent communicable diseases such as influenza or polio, and 2) promotion of physical activity to prevent conditions such as obesity that can lead to disease (e.g., type 2 diabetes).

Primary preventive service: Any service, procedure, medication, counseling, or immunization aimed at avoiding or delaying illness.

Productivity: The amount of output produced by a worker in a given period of time (hour or day, etc.).[2]

Recommended guidance: A recommendation or guideline that is based on the best-available information for a condition, disease, or health service, but that does not yet have the scientific research support to be considered evidence-based.

Return-on-investment (ROI): A comparison of the money earned (or lost) on an investment to the amount of money invested. For example, every $1 an employer spends on immunization produces a return of $3 in avoided healthcare costs. It is important to note that ROI is not a proxy for cost-effectiveness or vice versa. Interventions that are cost-effective or even cost-saving at the societal level do not necessarily yield a positive ROI from the business perspective, although they may provide a better value than other services.[6]

Risk, at-: Possessing a chance of succumbing to a disease or condition due to specific genetic markers, personal history, behaviors, or other factors.

Risk, high: Possessing a greater chance of succumbing to a disease or condition than the general population due to specific genetic markers, personal history, behaviors, a lack of immunity, or other factors.

Risk, low: Possessing a lesser chance of succumbing to a disease or condition than the general population due to specific genetic markers, personal history, behaviors, or other factors.

Screening: A test or examination designed to identify an individual's risk of developing an illness or condition (i.e. blood pressure measurement or cholesterol reading).

Secondary prevention: is aimed at treating a disease after its onset, but before it causes serious complications. Secondary prevention includes 1) identifying individuals with established disease, and 2) treating those individuals in a timely way so as to prevent further problems (e.g., mammography screening to detect and treat breast cancer in its earliest stages).

Spontaneous abortion (miscarriage): A sudden unplanned miscarriage of the fetus from the womb. The terms fetal death and stillborn refer to the spontaneous death of a fetus in later stages of pregnancy.

Symptomatic: Having characteristics that indicate the presence of a disease or condition.

Tertiary prevention: is aimed at treating the late or final stages of a disease so as to minimize the degree of disability caused by that disease (e.g., administering a foot check to a person with diabetes to identify infections that would require amputation if left untreated).

Test: Any technique used to determine whether a condition is present or not or to measure its level of activity or severity. Tests include, for example, maneuvers such as physical examinations, laboratory-based examinations of blood and other tissues, X-ray examinations, and questionnaires, among others.

Vaccination (also see **immunization**): The administration of a substance, usually by injection, oral, or nasal administration, that produces protective immunity to one or more specific diseases.

Wellness program (also see **health promotion program**): Any prevention initiative aimed at changing lifestyle behaviors associated with greater risk of disease. These initiatives actively encourage healthy activities such as substance abuse control, weight management, smoking cessation, stress management, physical activity, or the like.

Work loss: Time away from a job or an inability to perform normal work activities because of a health problem.

References:

1. American Academy of Occupational and Environmental Medicine. Glossary. [cited 2006 Sept 22]. Available from: http://www.acoem.org/health_productivity/terms.asp.

2. Center for Prevention and Health Services. Improving Health Improving Business: *An Employer's Guide to Clinical Preventive Services*. Washington, DC: National Business Group on Health; 2004.

3. National Library of Medicine. National Institutes of Health. Medline Plus. Medical Dictionary. [cited 2006 Sept 22]. Available from: http://www.nlm.nih.gov/medlineplus/mplusdictionary.html.

4. MedNet Online Medical Dictionary. Evidence-Based Medicine. [cited 2006 Sept 22]. Available from: http://www.medterms.com/script/main/art.asp?articlekey=33300.

5. Eddy DM. Evidence-based medicine: a unified approach. Health Affairs 2005; 24(1): 9-17.

6. Wikipedia. Return-on-investment. [cited 2006 May 11]. Available from: http://en.wikipedia.org/wiki/Return_on_investment.

Links to Cost-Calculators and Additional Resources

Cost-Calculators

Alcohol Misuse

- George Washington University Alcohol Treatment ROI Calculator, http://www.alcoholcostcalculator.org/roi/

Diabetes

- Diabetes at Work, Conducting a Diabetes Assessment. General Assessment Tool. http://www.diabetesatwork.org/diabetesatwork/assessing_gen.cfm

Obesity and Physical Activity

- American Cancer Society ROI Calculator for Obesity and Physical Activity, http://www.acsworkplacesolutions.com/obesitycalculator.asp
- Magellan Health Services Obesity Cost Calculator. http://www.magellanassist.com/customer/services/obesitycost/default.asp

Tobacco

- American Cancer Society ROI Calculator for Tobacco, http://www.acsworkplacesolutions.com/tobaccocalculator.asp
- America's Health Insurance Plans (AHIP) and Center for Health Research, Kaiser Permanente Tobacco ROI calculator, http://www.businesscaseroi.org/roi/default.aspx
- Free & Clear Employer and Health Plan ROI Calculator for Tobacco, http://www.freeclear.com/case_for_cessation/econ_impact.aspx?nav_section=2#

Additional Resources

U.S. Department of Health and Human Services (Federal)

- Advisory Committee on Immunization Practices (ACIP), http://www.cdc.gov/nip/ACIP/default.htm
  - Standards for Child and Adolescent Immunization Practices: http://www.cdc.gov/nip/publications/pink/appendices/H/standards-pediatric.pdf
  - Standards for Adult Immunization Practices: http://www.cdc.gov/nip/recs/rev_stds_adult_AJPM.pdf
- Agency for Healthcare Research and Quality (AHRQ), http://www.ahrq.gov
- Centers for Disease Control and Prevention (CDC), http://www.cdc.gov
- Healthy People 2010 Goals, http://www.healthypeople.gov/
- National Guidelines Clearinghouse, http://www.guideline.gov/
- National Healthcare Quality Report (AHRQ), http://www.qualitytools.ahrq.gov/
- National Institutes of Health (NIH), http://www.nih.gov
- Office of the U.S. Surgeon General, http://www.surgeongeneral.gov/
- Steps to a Healthier U.S., Prevention Portfolio, Department of Health and Human Services (U.S. DHHS), http://www.healthierus.gov/steps/documents.html#portfolio

- U.S. Department of Health and Human Services (USDHHS), http://www.dhhs.gov/
- U.S. Preventive Services Task Force (USPSTF), http://www.ahrq.gov/clinic/prevenix.htm
- U.S. Public Health Service (USPHS), http://www.usphs.gov

Professional Organizations

- American Academy of Family Physicians (AAFP), http://www.aafp.org
- American Academy of Pediatrics (AAP), http://www.aap.org
- American College of Obstetricians and Gynecologists (ACOG), http://www.acog.org
- American College of Occupational and Environmental Medicine (ACOEM), http://www.acoem.org/
- American College of Preventive Medicine (ACPM), http://www.acpm.org/
- American Medical Association (AMA), http://www.ama.org
- American Speech-Language-Hearing Association (ASHA), http://www.asha.org
- American College of Allergy, Asthma, & Immunology (ACAAI), http://www.acaai.org
- American College of Cardiology, http://www.acc.org/

Other

- Institute of Medicine (IOM), http://www.iom.edu
- National Committee on Quality Assurance (NCQA), http://www.ncqa.org
- HEDIS Data Set, National Committee on Quality Assurance (NCQA), http://www.ncqa.org/communications/publications/hedispub.htm

Condition/Disease Specific Resources (Federal)

- Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7), http://hyper.ahajournals.org/cgi/content/full/hypertensionaha;41/6/1178
- National Cancer Institute (NCI), http://www.nci.nih.gov
- National Cholesterol Education Program (NCEP), http://www.nhlbi.nih.gov/about/ncep/index.htm
- National Heart, Lung, and Blood Institute (NHLBI), http://www.nhlbi.nih.gov
  - *Dietary Approaches to Stop Hypertension (DASH) Eating Plan*, http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/.
  - Framingham-based risk assessment tool, http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof.
  - Healthy diet tip sheets, http://www.nhlbi.nih.gov/chd/Tipsheets/daily.htm.
  - Hypertension risk assessment tool, http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof.
  - Therapeutic lifestyle change tip sheets, http://www.nhlbi.nih.gov/chd/Tipsheets/daily.htm.
  - *Your Guide to Lowering your Cholesterol Level with Therapeutic Lifestyle Changes*, http://www.nhlbi.nih.gov/health/public/heart/chol/chol_tlc.pdf.

- National Institute of Alcohol Abuse and Alcoholism (NIAAA), http://www.niaaa.nih.gov/
- National Institute of Occupational Health and Safety (NIOSH), http://www.cdc.gov/niosh/homepage.html

Condition/Disease Specific Resources (Non-Federal)

- American Cancer Society (ACS), http://www.acs.org
- American Dental Association (ADA), http://www.ada.org
- American Diabetes Association (ADA), http://www.diabetes.org
- American Dietetics Association (ADA), http://www.eatright.org
- American Heart Association (AHA), http://www.americanheart.org
- American Lung Association (ALA), http://www.lungusa.org
- American Managed Behavioral Healthcare Association (AMBHA), http://www.ambha.org
- American Stroke Association, http://www.strokeassociation.org
- March of Dimes, http://www.marchofdimes.com
- National Mental Health Association (NHMA), http://www.nmha.org
- National Stroke Association, http://www.stroke.org

Supplemental Guides and Resources

- Agency for Healthcare Research and Quality, *The Pocket Guide to Clinical Preventive Services 2005*, http://www.ahrq.gov/clinic/pocketgd.htm
- Agency for Healthcare Research and Quality, *2005 National Healthcare Disparities Report,* http://www.ahrq.gov/qual/nhdr05/nhdr05.htm
- Centers for Disease Control and Prevention, *The CDC Guide to Breastfeeding Interventions*, http://www.cdc.gov/breastfeeding/resources/guide.htm
- Centers for Disease Control and Prevention, *The Community Guide to Preventive Services*, http://www.thecommunityguide.org/

National Business Group on Health Resources

- Improving Health, Improving Business: the Employer's Guide to Health Improvement and Preventive Services, http://www.businessgrouphealth.org/services/index.cfm
- Consumer Drive Healthcare for Children: *An Employer's Guide to Developing Child and Adolescent Benefits*, http://www.businessgrouphealth.org/prevention/et_childhealthcareconsumer.cfm
- An Employer's Guide to Behavioral Health Services: A Roadmap and Recommendations for Evaluating, Designing, and Implementing Behavioral Health Services, http://www.businessgrouphealth.org/prevention/et_behavioralhealthreport.cfm

ALPHABETICAL INDEX