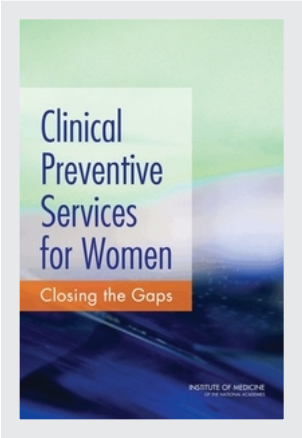

Clinical Preventive Services for Women: Closing the Gaps

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Clinical Preventive Services for Women

Closing the Gaps

Committee on Preventive Services for Women

Board on Population Health and Public Health Practice

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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We thank the following for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of the report was overseen by **Nancy E. Adler,** Professor of Medical Psychology, Departments of Psychiatry and Pediatrics, and Director, Center for Health and Community, University of California, San Francisco and **Susan J. Curry,** Dean, College of Public Health, University of Iowa. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of the report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of the report rests entirely with the author committee and the institution.

Preface

As chair of the Committee on Preventive Services for Women, I want to personally thank my fellow committee members for their willingness to serve, for their hard work, and for contributing their remarkable expertise to this study. I have been honored to contribute to this effort. Each of us works in different domains relating to preventive health services, and although the short time frame provided to perform this study presented a challenge, my esteemed colleagues who comprised the committee worked as a team with great dedication and spirit to achieve consensus. It was a pleasure to work with each and every one of them.

The diverse committee involves an impressive array of researchers and practitioners, including two members who served on the United States Preventive Services Task Force (USPSTF) and one who leads USPSTF systematic evidence reviews. Although we could not conduct a USPSTF-style systematic review for any single preventable health condition or determinant of well-being, nor were we expected to do so, I believe that our end product is a study that has important, evidence-based recommendations that provide a road map to improved preventive services for women. Throughout the process we repeatedly asked ourselves whether the disease or condition that we were addressing was of significance to women and especially whether it was more common or more serious in women than in men or whether women experienced different outcomes or benefited from different interventions than men. I believe that the preventive services that we recommend for consideration in this report readily satisfy these questions.

The Patient Protection and Affordable Care Act of 2010 has afforded

us an historic occasion. For the first time, prevention plays a central role within the scope of new health insurance plans in the United States. Also, an ongoing focus on women's preventive services is expected to be included in these efforts. Given the history of inadequate attention to women's health research and preventive services noted by many (including previous Institute of Medicine [IOM] committees), I am truly optimistic that gains in women's health and well-being will ensue. With the multiple roles that women play in society, to invest in the health and well-being of women is to invest in progress for all.

I regret that we were unable to resolve to his satisfaction the issues raised by one committee member, Anthony Lo Sasso. In his statement of dissent, he identifies his main concerns, which are with the constraints of the study's charge and subsequent process. His statement, along with the committee's response, can be found in Appendix D of the report.

I thank the IOM staff, especially our senior project officer, Karen Helsing, and also Jesse Flynn, Suzanne Landi, Chelsea Frakes, and IOM Anniversary Fellow Rebekah Gee. All went above and beyond to support the committee throughout the process. We also are indebted to Rose Marie Martinez, senior director of the Board on Population Health and Public Health Practice, for her presence throughout and her invaluable guidance and support. I am grateful as well to those who presented and attended our committee's open sessions and those who submitted comments and informed our work with their research and opinion pieces. Without their dedicated work this report would not have been possible.

Linda Rosenstock, *Chair*
Committee on Preventive Services for Women

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Summary

BACKGROUND

The Patient Protection and Affordable Care Act of 2010 (ACA) holds much promise—beyond the expansion of health care coverage—for millions of Americans. The preventive health care services and screenings specified in the legislation will be fully covered without requiring a patient copayment. These include the services with Grade A and B recommendations made by the United States Preventive Services Task Force (USPSTF), the Bright Futures recommendations for adolescents from the American Academy of Pediatrics (AAP) in cooperation with the U.S. Department of Health and Human Services (HHS), and vaccinations specified by the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP). These three sets of guidelines provide a list of preventive services, such as blood pressure measurement, diabetes and cholesterol tests, and mammography and colonoscopy screenings. As part of the ACA, the list of preventive services specific to women's health was requested to be reviewed.

CHARGE TO THE COMMITTEE

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) of HHS provided funds for the Institute of Medicine (IOM) to conduct a review of effective preventive services to ensure women's health and well-being. The charge to the committee for the project is presented in Box S-1.

BOX S-1
Statement of Task to the Committee on Preventive Services for Women

The Institute of Medicine will convene an expert committee to review what preventive services are necessary for women's health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women. The committee will also provide guidance on a process for regularly updating the preventive screenings and services to be considered. In conducting its work, the committee will: conduct a series of meetings to examine existing prevention guidelines, obtain input from stakeholders, identify gaps that may exist in recommended preventive services for USPSTF Grade A and B preventive services guidelines for women and in Bright Futures and USPSTF Grade A and B guidelines for adolescents, and highlight specific services and screenings that could supplement currently recommended preventive services for women. Specifically, the committee will consider the following questions:

- What is the scope of preventive services for women not included in those graded A and B by the USPSTF?
- What additional screenings and preventive services have been shown to be effective for women? Consideration may be given to those services shown to be effective but not well utilized among women disproportionately affected by preventable chronic illnesses.
- What services and screenings are needed to fill gaps in recommended preventive services for women?
- What models could HHS and its agencies use to coordinate regular updates of the comprehensive guidelines for preventive services and screenings for women and adolescent girls?

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) on behalf of the U.S. Department of Health and Human Services (HHS) has been charged to examine recommendations for women's preventive services. ASPE will use the information and recommendations from the committee's report to guide policy and program development related to provisions in the Affordable Care Act addressing preventive services for women.

In response, the IOM convened a committee of 16 members—including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines—to develop a set of recommendations for consideration by the ASPE of HHS.

The committee sought clarification from ASPE on a number of issues regarding its charge. In summary:

- **Preventive services were specified to be applicable to females aged 10 to 65 years;**

- **The mammography screenings specified in the ACA legislation used USPSTF guidelines from 2002, which specify that such screenings be performed every one to two years for women aged 40 years and older;**
- **The cost-effectiveness of screenings or services could not be a factor for the committee to consider in its analyses leading to its recommendations;**
- **The committee was not intended to duplicate the processes used by the USPSTF and thus should look to other bodies of evidence beyond systematic evidence-based reviews; and**
- **Preventive services were specified for clinical settings, and thus community-based prevention activities were considered beyond the scope of committee consideration.**

COMMITTEE'S APPROACH TO ITS CHARGE

The committee met five times within six months. The committee held three open information-gathering sessions at which the members heard from a diverse group of stakeholders, researchers, members of advocacy organizations, and the public. Box S-2 provides the committee definition of preventive health services.

BOX S-2
Definition of Preventive Health Services

For the purposes of this study, the Committee on Preventive Services for Women defines preventive health services to be measures—including medications, procedures, devices, tests, education and counseling—shown to improve well-being, and/or decrease the likelihood or delay the onset of a targeted disease or condition.

COMMITTEE'S METHODOLOGY

The committee's methodology to identify preventive services necessary for women's health and well-being and to identify specific services that could supplement the current list of recommended preventive services for women under the ACA follows.

The committee's first step was to review and reach an understanding of existing guidelines. The second step was to assemble and assess additional evidence, including reviews of the literature, federal health priority goals

and objectives, federal reimbursement policies, and the clinical guidelines of health care professional organizations. The committee also considered the public comments that it received. Finally, the committee formulated a list of recommendations to be considered by the Secretary of HHS in developing a comprehensive package of preventive services for women to be included under the ACA.

USPSTF Recommendations

The USPSTF process for developing recommendations is a disease-focused one. The intent of its recommendations has been to provide guidance to primary care providers. The IOM committee's approach to identifying gaps in existing services accounts for contextual issues beyond traditional research evidence used by the USPSTF. The committee looked at women's preventive service needs more broadly to account for women's health and well-being. The committee found that its interpretation of the Grade A and B recommendations was important in those cases in which ambiguity was found regarding periodicity of screenings. Furthermore, the committee compared USPSTF guidelines with those of numerous health care professional organizations to identify potential gaps.

The committee recognized that USPSTF Grade C recommendations and I statements warranted further analysis because the USPSTF did not develop and has not used these grades as support to offer or deny coverage of a preventive service. The USPSTF Grade C recommendations are made when the balance of potential benefits and harms does not strongly favor the clinician recommending the preventive service to all patients, although it may be appropriate in some cases.

The USPSTF I statements identify services for which the evidence is insufficient to suggest the effectiveness of a service because evidence is lacking, of lower quality, or conflicting. The committee notes that from a coverage perspective, the evidence supporting many clinical interventions in common use, whether in prevention or in general medical practice, is insufficient or unclear, and coverage decisions may be or have been made on the basis of other factors.

For example, although physician knowledge of the evidence of the benefits associated with a counseling service will inform a physician's decision for each patient, in many instances, it is difficult for researchers to show or conclude that outcomes are positive. Many preventive interventions that are intended to be conducted early in the life span (e.g., skin cancer prevention) require decades to demonstrate effectiveness.

Thus, each of the USPSTF Grade C and I statement recommendations and the evidence supporting them were collected and reviewed. The committee's evaluation included reviewing relevant supporting USPSTF

publications, other peer-reviewed research and clinical articles, and clinician fact sheets. Additional literature searches were conducted to identify randomized control trials published after the USPSTF recommendation was released. Furthermore, the committee compared the Grade C and I statement guidelines with guidelines from other professional organizations. The committee did not reexamine the services with Grade D recommendations, because the USPSTF recommends against providing these services.

Bright Futures Recommendations

The committee reviewed all Bright Futures guidelines and compared them with the USPSTF guidelines for adolescents. The committee noted that the methodology that Bright Futures uses is quite different from that which the USPSTF uses. Bright Futures makes decisions through a consensus-driven process; thus, expert opinion is at the core of its development of recommendations.

The committee interpreted the sample questions and advice suggested in the anticipatory guidance section of the *Bright Futures* report (AAP, 2008) to describe topics to be covered as preventive services under the ACA and addressed in an annual health care visit of sufficient length to cover age- and sex-appropriate topics in the health domain. The committee assumes that physicians will identify priorities from this section of the *Bright Futures* report on the basis of the unique circumstances of each patient.

ACIP Recommendations

The committee reviewed ACIP General Recommendations on Immunizations, which include all of the Food and Drug Administration-approved immunizations recommended for the general population of adolescent and adult women. Although literature searches were conducted to identify areas where supplemental immunization recommendations might be warranted, the committee identified little evidence to clearly indicate deficiencies in existing ACIP recommendations.

Further Committee Considerations

The committee reviewed oral and written comments submitted throughout the course of the study. The committee also invited researchers and leaders of organizations to deliver presentations in areas in which the committee believed that it could benefit from their expertise. In addition, the committee reviewed HHS documents relating to prevention priorities and reimbursement policies. It also reviewed the existing coverage practices of national, state, and private health plans. In some cases, current practice

in clinical care was also identified. Finally, the committee used the 2011 IOM report *Leading Health Indicators for Healthy People 2020* as a tool to perform horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify potential gaps (IOM, 2011).

COMMITTEE ANALYSIS

The product of these reviews was an array of potential areas where supplemental preventive measures might be warranted. Some of these areas were identified on the basis of traditional indicators, such as morbidity and mortality, whereas others were identified as being more generally supportive of a woman's well-being. The committee focused on conditions unique to women or that affected women in some specific or disproportionate way. The committee moved forward using criteria adapted from the USPSTF that considered frequency, severity, morbidity, mortality, and quality of life to bring consistency to the analyses.

For each potential supplemental preventive measure considered, the committee conducted an extensive comparison of the guidelines of professional organizations to understand the development of the guidelines and the evidence that the organizations used to reach their conclusions. The committee also performed targeted literature searches. However, it should be noted that the committee did not have adequate time or resources to conduct its own meta-analyses or comprehensive systematic review of each preventive service.

Supplemental Preventive Measures

The committee attempted to identify preventive measures that were aimed at filling the gaps that it had identified. In most cases, the committee found that measures had already been proposed in the guidelines of other professional organizations. The committee also eliminated preventive measures that, even at this early stage in the analysis, were clearly not developed, tested, or known well enough to have a measurable impact. The resulting product of this step was a series of preventive service areas with gaps in coverage and the accompanying preventive measure or measures that could be considered by HHS. The core of the committee's task was to assemble the evidence that would allow it to recommend consideration of a preventive service.

Coverage Decisions

As noted above, the USPSTF, Bright Futures, and ACIP guidelines focus on guidance for primary care providers and patients. Coverage decisions

often consider a host of other issues, such as established practice; patient and clinician preferences; availability; ethical, legal, and social issues; and availability of alternatives. Further complicating matters, special population groups such as minority populations, disabled women, recent immigrants, lesbians, prisoners, and those employed in high-risk environments, may have different health needs or benefit from different preventive services. High-risk groups, population subsets, and special populations are unevenly identified and addressed to varying degrees in current guidelines. Finally, cost-effectiveness was explicitly excluded as a factor that the committee could use in developing recommendations, and so the committee process could not evaluate preventive services on this basis.

Committee Approach

The committee developed a hybrid approach that collected relevant evidence for each measure. Four categories of evidence—posed in the form of questions—to be examined for each potential preventive measure were developed. The committee did not formally rank or assign weights to the categories, nor did it stipulate that evidence in any one category would automatically result in a recommendation for a measure or service to be considered. Instead, the queries and categories were used to consider the range of evidence and to ensure consistency in the committee's analysis and deliberations. Many of the recommendations are supported by more than one category of evidence.

Category I. Are high-quality systematic evidence reviews available indicating that the service is effective in women?

Category II. Are quality peer-reviewed studies available demonstrating effectiveness of the service in women?

Category III. Has the measure been identified as a federal priority to address in women's preventive services?

Category IV. Are there existing federal, state, or international practices, professional guidelines, or federal reimbursement policies that support the use of the measure?

RECOMMENDATIONS

Subcommittees were formed, and each subcommittee reviewed the available evidence applicable to its identified potential preventive measure(s) and assigned the evidence to one or more of the above categories. Each subcommittee then brought its analysis of the range of evidence before the full committee for deliberation. The committee then combined the burden of the condition and its potential impact on health and well-being with the array of available evidence and support to reach a consensus regarding

whether to recommend a specific preventive measure for that condition. As is true in most analytical processes in decision making, evidence and expert judgment are inextricably linked; thus, the expert judgments of the committee members also played a role in decision making.

In general, the preventive measures recommended by the committee for consideration of coverage (see Table S-1) met the following criteria:

- **The condition to be prevented affects a broad population;**
- **The condition to be prevented has a large potential impact on health and well-being; and**
- **The quality and strength of the evidence is supportive.**

Ultimately, the decision to develop a recommendation for a preventive service to be considered was made after a thoughtful review and debate of each of the subcommittee reports and when the committee found the evidence to be compelling.

TABLE S-1 Summary of the Committee's Recommendations on Preventive Services for Women

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Screening for gestational diabetes	I	The evidence provided to support a recommendation for screening for gestational diabetes is based on current federal practice policy from the U.S. Indian Health Service, the U.S. Department of Veterans Affairs, as well as current practice and clinical professional guidelines such as those set forth by the American Academy of Family Physicians and the American Congress of Obstetricians and Gynecologists.	**Recommendation 5.1** The committee recommends for consideration as a preventive service for women: screening for gestational diabetes in pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Human papillomavirus testing (HPV)	I	The evidence provided to support a recommendation to support testing for HPV is based on federal practice policy from the U.S. Department of Defense. Peer-reviewed studies demonstrate that improved testing technologies, particularly combined screening using both conventional cytology and high-risk HPV DNA testing, may significantly improve the rate of detection of cervical cancer precursors and facilitate the safe lengthening of the interval for screening.	**Recommendation 5.2** The committee recommends for consideration as a preventive service for women: the addition of high-risk human papillomavirus DNA testing in addition to cytology testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections (STIs)	I	The evidence provided to support a recommendation related to STI counseling is based on federal goals from the Centers for Disease Control and Prevention and *Healthy People 2020*, as well as recommendations from the American Medical Association and the American College of Obstetricians and Gynecologists.	**Recommendation 5.3** The committee recommends for consideration as a preventive service for women: annual counseling on sexually transmitted infections for sexually active women.

continued

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Counseling and screening for human immunodeficiency virus (HIV)	C	The evidence provided to support a recommendation for expanding screening for HIV is based on federal goals from the Centers for Disease Control and Prevention, as well as clinical professional guidelines, such as those from the American College of Physicians, the Infectious Diseases Society of America, the American Medical Association, and the American College of Obstetricians and Gynecologists.	**Recommendation 5.4** The committee recommends for consideration as a preventive service for women: counseling and screening for human immunodeficiency virus infection on an annual basis for sexually active women.
Contraceptive methods and counseling	Not Addressed	The evidence provided to support a recommendation related to unintended pregnancy is based on systematic evidence reviews and other peer-reviewed studies, which indicate that contraception and contraceptive counseling are effective at reducing unintended pregnancies. Current federal reimbursement policies provide coverage for contraception and contraceptive counseling, and most private insurers also cover contraception in their health plans. Numerous health professional associations recommend family planning services as part of preventive care for women. Furthermore, a reduction in unintended pregnancies has been identified as a specific goal in *Healthy People 2010* and *Healthy People 2020*.	**Recommendation 5.5** The committee recommends for consideration as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Breastfeeding support, supplies, and counseling	B	The evidence provided to support a recommendation regarding the inclusion of breastfeeding services is based on systematic evidence reviews, federal and international goals (such as the U.S. Surgeon General, Health Resources and Services Administration [HRSA], *Healthy People 2020*, World Health Organization and UNICEF) and clinical professional guidelines such as those set forth by the American Academy of Family Physicians, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists.	**Recommendation 5.6** The committee recommends for consideration as a preventive service for women: comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding. (The ACA ensures that breastfeeding counseling is covered; however, the committee recognizes that interpretation of this varies.)
Screening and counseling for interpersonal and domestic violence	I	The evidence provided to support a recommendation related to increasing detection of and counseling for domestic violence and abuse is based on peer-review studies and federal and international policies, in addition to clinical professional guidelines from organizations, such as the American Medical Association and the American College of Obstetricians and Gynecologists.	**Recommendation 5.7** The committee recommends for consideration as a preventive service for women: screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.

continued

TABLE S-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Well-woman visits	Not Addressed	The evidence provided to support a recommendation for including well-woman visits is based on federal and state policies (such as included in Medicaid, Medicare and the state of Massachusetts), clinical professional guidelines (such as those of the American Medical Association and the American Academy of Family Practitioners), and private health plan policies (such as those of Kaiser Permanente).	**Recommendation 5.8** The committee recommends for consideration as a preventive service for women: at least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. The committee also recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.

UPDATING GUIDELINES

Developing and maintaining a comprehensive list of covered preventive services for women is not currently under the specific purview of any HHS entity. Thus, the committee believes that it will be necessary to develop structures, accountability, and processes to ensure that preventive services meeting evidence-based standards are considered in the context of the general approach taken to identify and update preventive services for women.

The committee recommends a process supported by guiding principles that separates evidence assessment and coverage decisions.

Recommendation 6.1: The committee recommends that the process for updating the preventive services for women be:

- **Independent;**
- **Free of conflict of interest;**
- **Evidence-based;**
- **Gender-specific;**
- **Life-course oriented;**
- **Transparent;**
- **Informed by systematic surveillance and monitoring;**

- **Cognizant of the need to integrate clinical preventive services with effective interventions in public health, the community, work place, and environment; and**
- **Appropriately resourced to meet its mandate.**

Recommendation 6.2: The committee recommends that the Secretary of HHS establish a commission to recommend coverage of new preventive services for women to be covered under the ACA.

In carrying out its work the commission should:

- **Be independent of bodies conducting evidence reviews, free of conflict of interest, and transparent;**
- **Set goals for prevention (it may use available HHS reports and products or commission its own at its discretion);**
- **Design and implement a coverage decision making methodology to consider information from evidence review bodies (and other clinical guideline bodies) and coverage factors (e.g., cost, cost-effectiveness, legal, ethical);**
- **Conduct horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify new information on significant health conditions, preventive interventions, new evidence regarding efficacy, effectiveness, periodicity, and safety;**
- **Focus on the general population, but also search for conditions that may differentially affect women and high-risk subpopulations of women;**
- **Assign evidence review topics and set review priorities for the bodies reviewing clinical effectiveness;**
- **Set timetables and processes for updating clinical practice guidelines and coverage recommendations; and**
- **Submit its coverage recommendations to the Secretary of HHS.**

Recommendation 6.3: The committee recommends that the Secretary of HHS identify existing bodies or appoint new ones as needed to review the evidence and develop clinical practice guidelines to be reviewed by a preventive services coverage commission.

Bringing clinical preventive services into rational alignment with the coverage for other health care services under the ACA will be a major task. The committee notes that many of the individual components for review of the evidence are already managed within HHS but currently lack effective coordination for the purposes outlined in the ACA and that some functions are entirely new. The structure might be effectively built over time by using

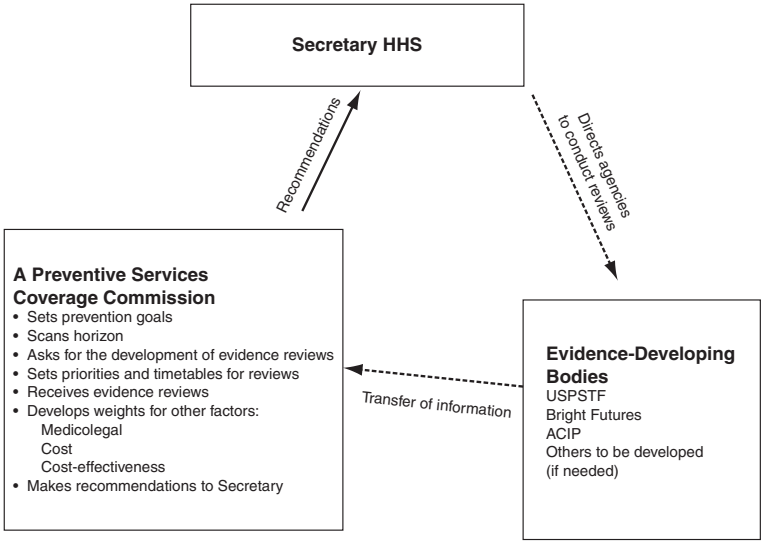

FIGURE S-1 Suggested structure for updating preventive services under the ACA.

some current bodies and adding new ones as resources permit. The committee does not believe that it has enough information to recommend which unit in HHS should implement the recommendations. Figure S-1 illustrates the committee's suggested structure.

In view of the critical importance of community-based preventive services in achieving clinical aims, the committee encourages the Secretary to consider widening the scope of authority to include public health efforts to more comprehensively address prevention. It will be critical for a preventive services coverage commission to coordinate with the new and existing committees that are charged with overseeing other elements of the ACA.

Finally, the committee notes that it would make the most sense to consider preventive services for women, men, children, and adolescents in the same way. Thus, although the committee's recommendations address women's preventive services, a parallel approach could be equally useful for determining covered preventive services for men, children, and male adolescents.

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1

Introduction

The passage of the Patient Protection and Affordable Care Act of 2010 (ACA) provides the United States with an opportunity to offer an unprecedented level of population health care coverage and dramatically reduce existing health disparities. The expansion of coverage to millions of uninsured Americans and the new standards for coverage of preventive services that are included in the ACA have the potential to increase the use of preventive health care services and screenings and in turn improve the health and well-being of individuals across the United States.

SPECIFICS OF THE LEGISLATION

The approaches to prevention and wellness offered within the Act are broad based and range from new coverage requirements and incentives to expand workplace wellness activities to new investments. Among these are prohibition of the imposition of cost-sharing requirements for recommended preventive services (an overview of the Act is provided in Box 1-1, and the preventive services are listed and described in detail in Chapter 2), the requirement to link health insurance premiums to participation in health promotion programs, public health workforce development (the ACA authorizes new training and placement programs for public health workers), and community-based prevention activities.

This report focuses on the preventive services for women specified in Section 2713 of the Public Health Service Act. These services were added by the ACA and are detailed in the last bulleted item in Box 1-1 (HHS, 2010; *Federal Register,* 2010).

BOX 1-1
Overview of Regulations in Section 2713 of the Public Health Service Act

Section 2713 of the Public Health Service Act, Coverage of Preventive Health Services, which was added by the Affordable Care Act, and the interim final regulations (26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, 45 CFR 147.130) require that group health plans and health insurance issuers offering health insurance coverage for groups or individuals provide benefits and prohibit the imposition of cost-sharing requirements for

- Medical devices or services that are evidence based and that have, in effect, a rating of Grade A or B in the current recommendations of the United States Preventive Services Task Force (USPSTF) for the individual involved.
- Immunizations for routine use in children, adolescents, and adults that have, in effect, a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) for the individual involved. A recommended ACIP immunization is considered to be "in effect" after it has been adopted by the CDC director. A recommended immunization is considered to be for routine use if it appears on the immunization schedules of the Centers for Disease Control and Prevention.
- Preventive health care and screenings for infants, children, and adolescents informed by scientific evidence and provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).
- Preventive health care and screenings for women informed by scientific evidence and provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the USPSTF). The U.S. Department of Health and Human Services is developing these guidelines and expects to issue them no later than August 1, 2011.

The complete list of recommendations and guidelines that these interim final regulations are required to cover can be found at http://www.HealthCare.gov/center/regulations/prevention.html.

ROLE OF PREVENTION IN ADDRESSING HEALTH AND WELL-BEING

Prevention is a well-recognized, effective tool in improving health and well-being and has been shown to be cost-effective in addressing many conditions early (Maciosek et al., 2010). Prevention goes beyond the use of disease prevention measures. For example, interventions to prevent injuries and binge drinking can increase positive health outcomes and reduce harm.

Historically, the many disparate components of the U.S. health care system have relied more on responding to acute problems and the urgent

needs of patients than on prevention. Although these functions are appropriate for acute and episodic health problems, a notable disparity occurs when this model of care is applied to the prevention and management of chronic conditions. The provision of preventive health care services is thus inherently different from the treatment of acute problems, but the U.S. health care system has fallen short in the provision of such services. Compared with a system that prevents avoidable conditions early, a system that responds to the acute health care needs of patients can be inefficient and costly, and a focus on response instead of prevention is a major barrier to the achievement of optimal health and well-being by Americans.

Nearly half of all deaths in the United States are caused by modifiable health behaviors (McGinnis and Foege, 1993). Maciosek and colleagues found that an increase in the use of clinical preventive services in the United States could result in the saving of more than 2 million life-years annually (Maciosek et al., 2010). Because of the numbers of diseases and conditions that are preventable, inclusion of support for prevention has become more routine during clinical health care visits (Sussman et al., 2006). When patients are systematically provided with the tools and information that they need to reduce their health risks, the likelihood that they will take steps to, for example, reduce substance use, stop using tobacco products, practice safe sex, eat healthful foods, and engage in physical activity increases (WHO, 2002). Therefore, physicians who routinely educate patients on risk-reducing behaviors may reduce the long-term burden and health care demands of chronic conditions. Stimulating the commitment and action of patients, families, and health care teams is also necessary to promote prevention and improve overall population well-being.

Evidence-based testing, diagnosis, and relief of symptoms are also hallmarks of contemporary health care, but these services are often underutilized. A well-cited reason for this underutilization is, for example, the high cost of prescription copayments, with the result being that patients do not fill their prescribed medications, resulting in the loss of lives and dollars (Shrank et al., 2010). Moreover, a recent study by The Commonwealth Fund that analyzed the responses of U.S. adults to a questionnaire indicated that U.S. adults were significantly less likely than adults in all other countries studied to have confidence in their ability to afford health care (Schoen et al., 2009).

About 51 million Americans lacked health insurance in 2009 (DeNavas-Walt et al., 2010). This is in addition to the millions of underinsured Americans who lack access to the appropriate screenings and services needed to detect and address preventable health conditions and diseases. Furthermore, health care workers have often failed to seize patient interactions as opportunities to promote health and well-being and to inform patients about disease prevention strategies (WHO, 2002). This failure to

inform patients has been found to be due to time constraints in the clinical setting, a lack of reimbursement for provision of these services, and a lack of consensus and provider knowledge about what services to prioritize for their patients. The ACA intends to mitigate these issues.

WHY WOMEN?

The ACA has the potential to transform the way in which the U.S. health care system addresses women's health issues in many ways. It expands access to coverage to millions of uninsured women, ends discriminatory practices such as gender rating in the insurance market, eliminates exclusions for preexisting conditions, and improves women's access to affordable, necessary care. The Women's Health Amendment (*Federal Register,* 2010), which was introduced by Senator Barbara Mikulski and which was added to the ACA, expands on these improvements by requiring that all private health plans cover—with no cost-sharing requirements—a newly identified set of preventive health care services for women. Defining appropriate preventive services for women and ensuring that those services can be accessed without cost sharing are important strategies to improve women's health and well-being (Bernstein et al., 2010; Blustein, 1995).

Many reasons exist for expanding the list of preventive care and screening services for women beyond those included in the guidelines of the United States Preventive Services Task Force (USPSTF) Grade A and B guidelines, the Advisory Committee on Immunization Practices (ACIP), and Bright Futures (for adolescents) stipulated in the ACA (USPSTF, ACIP, and Bright Futures and their guidelines are described in detail in Chapter 2). Even though women have longer life expectancies than men, women suffer from chronic disease and disability at rates disproportionate to those of men, with consequences for their own health and the health of their families (Wood et al., 2010). Furthermore, mounting evidence suggests that women not only have different health care needs than men (because of reproductive differences) but also manifest different symptoms and responses to treatment modalities (IOM, 2010). Behavioral factors that are shown to contribute to morbidity and mortality in women, include smoking, eating habits, physical activity, sexual risk-taking, and alcohol use (IOM, 2010). Pregnancy and childbirth also carry risks to women's health including maternal mortality (CDC, 2008). Figure 1-1 illustrates preventable mortality in women.

Health outcomes occur because of multiple factors including biology, behavior, and the social, cultural, and environmental contexts in which women live. Smoking, eating habits, physical activity, and other health-related behaviors are shaped by cultural and social contexts, including factors associated with social disadvantage. The marked differences in

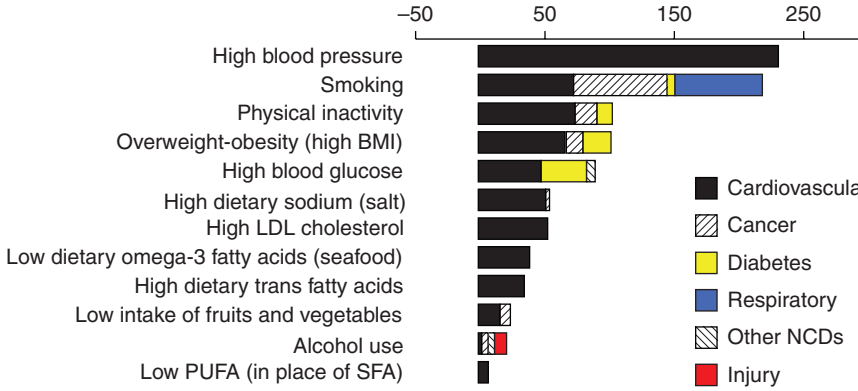

FIGURE 1-1 Deaths in women attributable to total effects of individual risk factors (in thousands), by disease.
ABBREVIATIONS: BMI, body-mass index; LDL, low-density lipoproteins; NCD, non-communicable disease; PUFA, polyunsaturated fatty acid; SFA, saturated fatty acid.
SOURCE: Danaei et al. (2009).

condition prevalence and mortality in women who experience social disadvantage are associated with minority race/ethnicity, lower education, low income, and differential exposure to stressors such as domestic violence. Such exposures are related to outcomes as varied as injury and trauma, depression, asthma, heart disease, human immunodeficiency virus (HIV) infection, and other sexually transmitted infections (Campbell et al., 2002; Coker et al., 2000; Ozer and Weinstein, 2004; Tjaden and Thoennes, 1998).

On average, women need to use more preventive care than men (Asch et al., 2006; HHS, 2001), owing to reproductive and gender-specific conditions, causing significant out-of-pocket expenditures for women (Bertakis et al., 2000; Kjerulff et al., 2007). This creates a particular challenge to women, who typically earn less than men and who disproportionately have low incomes. Indeed, women are consistently more likely than men to report a wide range of cost-related barriers to receiving or delaying medical tests and treatments and to filling prescriptions for themselves and their families (KFF, 2010). For example, women have been shown to be more likely than men to forgo preventive services such as cancer screenings and dental examinations because of cost (Rustgi et al., 2009). Studies have also shown that even moderate copayments for preventive services such as mammograms and Pap smears deter patients from receiving those services (Solanki et al., 2000; Trivedi et al., 2010). A 2010 Commonwealth Fund

survey found that 44 percent of adult women (compared with 35 percent of adult men) either reported that they had a problem paying medical bills or indicated that they were paying off medical debt over time, an increase from 38 percent in 2005 (Robertson and Collins, 2011). The same survey indicated that less than half of women are up to date with recommended preventive care screenings and services (Robertson and Collins, 2011).

Most women and men in the United States are covered by insurance obtained through the workplace. However, women with employer-based insurance are almost twice as likely as men to be covered as dependents, increasing their vulnerability to losing their insurance if they divorce, their partners lose their jobs, or they become widowed (KFF, 2010). Even though results of studies indicate that evidence-based preventive care services lower the burden of disease, are often cost-effective, increase the efficiency of health care spending, and contribute to the creation of a more productive and prosperous America, many financial barriers exist that prevent women from achieving health and well-being for themselves and their families.

PREVENTIVE SERVICES FOR WOMEN

Preventive services for women are services that prevent conditions harmful to women's health and well-being. "Conditions" are considered diseases, disabilities, injuries, behaviors, and functional states that have direct implications for women's health and well-being. These conditions may be specific to women, such as gynecologic infections and unintended pregnancy; they may be more common or more serious in women, such as autoimmune diseases and depression; they may have distinct causes or manifestations in women, such as alcohol abuse, obesity, and interpersonal violence-related posttraumatic stress disorder; or they may have different outcomes in women or different treatments, such as cardiovascular disease and diabetes (IOM, 2010). To "prevent" is to forestall the onset of a condition; detect a condition at an early stage, when it is more treatable; or slow the progress of a condition that may worsen or result in additional harm. Preventive services may therefore include the provision of immunizations, screening tests, counseling and education, Food and Drug Administration-approved medications and devices, procedures, and over-the-counter medications and devices.

COMMITTEE ON PREVENTIVE SERVICES FOR WOMEN

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services (HHS) asked the Institute of Medicine to convene a diverse committee of experts in disease prevention, women's health issues, adolescent health issues, and

evidence-based guidelines to review existing guidelines, identify existing coverage gaps, and recommend services and screenings for HHS to consider in order to fill those gaps (Box 1-2). A 16-member committee was selected to complete the statement of task.

In subsequent guidance to the committee, HHS sponsors at ASPE directed the committee to limit its focus to females between the ages of 10 and 65 years.

BOX 1-2
Statement of Task to the Committee on Preventive Services for Women

The Institute of Medicine will convene an expert committee to review what preventive services are necessary for women's health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women. The committee will also provide guidance on a process for regularly updating the preventive screenings and services to be considered. In conducting its work, the committee will: conduct a series of meetings to examine existing prevention guidelines, obtain input from stakeholders, identify gaps that may exist in recommended preventive services for USPSTF Grade A and B preventive services guidelines for women and in Bright Futures and USPSTF Grade A and B guidelines for adolescents, and highlight specific services and screenings that could supplement currently recommended preventive services for women. Specifically, the committee will consider the following questions:

- What is the scope of preventive services for women not included in those graded A and B by the USPSTF?
- What additional screenings and preventive services have been shown to be effective for women? Consideration may be given to those services shown to be effective but not well utilized among women disproportionately affected by preventable chronic illnesses.
- What services and screenings are needed to fill gaps in recommended preventive services for women?
- What models could HHS and its agencies use to coordinate regular updates of the comprehensive guidelines for preventive services and screenings for women and adolescent girls?

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) on behalf of the U.S. Department of Health and Human Services (HHS) has been charged to examine recommendations for women's preventive services. ASPE will use the information and recommendations from the committee's report to guide policy and program development related to provisions in the Affordable Care Act addressing preventive services for women.

The ACA defines the current USPSTF recommendations regarding breast cancer screening, mammography, and breast cancer prevention to be "the most current other than those issued in or around November 2009." Thus, coverage for screening mammography is guided by the 2002 USPSTF guideline, which specifies that such screenings be performed every one to two years for women aged 40 years and older.

Furthermore, for consistency in approach with the other three guidelines used by the ACA and given the time limitations for this study, the committee was restricted from considering cost-effectiveness in its process for identifying gaps in current recommendations. Finally, despite the potential health and well-being benefits to some women, abortion services were considered to be outside of the project's scope, given the restrictions contained in the ACA.

The committee received clarification from ASPE that its work was not intended to duplicate the processes used by the USPSTF or Bright Futures. Thus, the committee interpreted this guidance to indicate that evidence ranging from systematic reviews of the evidence to other bodies of evidence could be considered. This appears to be consistent with the process that led to the current preventive services within the ACA.

The committee was also directed to limit its work to identifying clinical preventive service coverage gaps and not to make recommendations regarding community-based prevention activities.

The committee recognizes that many factors that shape the health and well-being of women fall outside the realm of clinical services. These include, for example, changes to the environment and the workplace to promote health, changes in women's concept of self-efficacy to promote health, and changes in women's self-empowerment to address their own health and wellness. These factors and determinants of health are elements of models such as the Whitehead and Dahlgren (1991) determinants-of-health model and encompass biological, behavioral, and social factors. Nevertheless, evaluation of these factors and determinants of health were outside of the committee's purview.

HHS will consider the committee's recommendations as it develops guidelines to support the delivery of effective preventive services for women. If they are enacted, the recommendations from this study, along with the other coverage requirements in the ACA, will provide a comprehensive package of clinical preventive services for women.

COMMITTEE PROCESS

To meet its charge, the committee held three information-gathering meetings on preventive services for women and reviewed the relevant literature. Before the first meeting and throughout the committee's delibera-

tions, the committee gathered extensive information on numerous topics related to health and health care services for women, including chronic and mental health conditions, cancers, sexually transmitted infections, bone diseases, breastfeeding, interpersonal violence, unintended pregnancy, and a variety of behavioral health issues. During the public forums, representatives from women's health organizations, national health interest groups, health coverage providers, employer interest groups, and other experts presented statements to the committee on the latest status and developments in their respective fields (see Appendix B for the meeting agendas). Committee members questioned the speakers to address additional concerns that they did not cover in their statements. The committee also invited comments (both written and oral) from the general public and representatives from numerous organizations with interest in women's preventive services.

The committee first met in November 2010 and held its last meeting in May 2011. Within that time frame, it should be noted that the committee did not have adequate time or resources to conduct its own meta-analyses or comprehensive systematic review for each preventive service or for every special population group that may have different health needs or benefit from different preventive services, such as minority populations, disabled women, recent immigrants, lesbians, prisoners, and those employed in high-risk environments.

Box 1-3 details the committee's definition of preventive health services, which was used as a starting point for the study.

This definition of preventive health services is primarily derived from a blend of definitions from multiple health care organizations and agencies, including the USPSTF and the World Health Organization, with the text regarding well-being possessing the most original phrasing by the committee and stems from the statement of task. In addition, other key definitions are included in Box 1-4. These definitions were adapted from the Five Major Steps to Intervention of the Agency for Healthcare Research

BOX 1-3
Definition of Preventive Health Services

For the purposes of this study, the Committee on Preventive Services for Women defines preventive health services to be measures—including medications, procedures, devices, tests, education, and counseling—shown to improve well-being and/or decrease the likelihood or delay the onset of a targeted disease or condition.

BOX 1-4
Key Definitions: Preventive Interventions

Preventive interventions come in several forms: 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 use, for example, laboratory analyses and X rays and similar technologies. Screening also includes questions from clinicians. Screening may be targeted to people at increased risk because of age, gender, family or personal history, and 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. Screening is not a definitive diagnostic test, and a positive result on a screening test merely indicates that the screened individual has a higher likelihood of having the disease or condition for which the individual is being screened. Individuals who screen positive on such tests should have confirmatory diagnostic tests to ensure an accurate diagnosis.
- **Testing** refers to any process used to determine whether a condition is present or to assess the status of a condition. Testing may involve questioning patients (e.g., asking a patient about tobacco use), physical examination (e.g., mammography screening to detect potential breast cancers), or examining blood, body fluids, or tissues (e.g., to see if a cancer is present in a biopsy sample). Testing may also require the use of sophisticated technology, such as computed tomography and magnetic resonance imaging scans and other X rays, or invasive procedures, such as heart catheterization to detect blockage of coronary arteries. Tests may be used to

    1. Screen individuals who have risk factors but no indication of having the condition,
    2. Diagnose a disease or condition in individuals who have symptoms and signs but for whom a test will add certainty about the diagnosis, or
    3. 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 the 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 that they need to address their risk behaviors (e.g., the "5 A" framework for tobacco cessation: **a**sk, **a**dvise, **a**ssess, **a**ssist, **a**rrange). A special kind of counseling, informed decision making, recognizes that different people will 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

BOX 1-4 Continued

to choose from among different clinical options, such as whether to undergo genetic testing.

- **Immunization** protects an individual from a specific communicable disease (e.g., hepatitis) by exposing the individual to an antigen or a trace amount of an inactivated disease-causing agent, spurring the development of natural immunity.
- **Preventive medications** are used to prevent the onset of a disease or a condition (e.g., aspirin therapy to prevent cardiovascular events).
- **Preventive treatment** involves a procedure intended to prevent the occurrence of a disease or condition or to prevent the progression of a disease from one stage to another. Preventive treatments usually refer to the use of prescription or nonprescription (over-the-counter) medications, but they may also involve the use of prescriptions for lifestyle changes (e.g., exercise or diet change) or other interventions. Some surgical procedures may be considered preventive treatment, such as removal of polyps in the colon identified during a screening colonoscopy to prevent their progression to cancer lesions.

SOURCES: AHRQ, 2011; NBGH, 2005.

and Quality (AHRQ, 2011) and the National Business Group on Health's *Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage* (NBGH, 2005).

The report that follows is organized into seven chapters, summarized below.

- In Chapter 2, the report reviews the three existing guidelines used in the ACA to determine coverage.
- Chapter 3 details the existing practices of national, state, and selected private health plans.
- In Chapter 4, the committee discusses its framework for identifying gaps in existing preventive services and its process for selecting how to fill those gaps.
- Chapter 5 provides a description of the gaps identified through the committee's work.
- The committee's recommendations for updating guidelines for preventive services are proposed in Chapter 6.
- Chapter 7 includes committee conclusions and summarizes committee recommendations while identifying the limitations under which the committee performed its work.

- Appendix A includes a review of the conditions that the committee considered as part of its deliberations. Although no new recommendations were developed, the committee made clarifying statements or suggestions of ways to use preventive services to address these conditions.
- Appendix B provides agendas for the committee's three public meetings.
- Appendix C includes condensed biographies of committee members.
- Appendix D contains one committee member's statement of dissent and a response from all other committee members.

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2

Preventive Services Defined by the ACA

The Patient Protection and Affordable Care Act of 2010 (ACA) defined covered preventive health services for all patient populations to be those with Grade A and B recommendations made by the United States Preventive Services Task Force (USPSTF or the Task Force); for adolescents, the Bright Futures recommendations from the American Academy of Pediatrics (AAP) in cooperation with the U.S. Department of Health and Human Services (HHS), and for all patient populations, recommendations from the Advisory Committee on Immunization Practices (ACIP). The USPSTF, AAP, and ACIP are national authorities on health with defined processes for generating clinical recommendations. A summary of the methods that these entities use to arrive at recommendations and the actual recommendations follows.

UNITED STATES PREVENTIVE SERVICES TASK FORCE

The Task Force is an independent panel composed of nonfederal primary care clinicians, health behavior specialists, and methodologists. Its mission is twofold: (1) assess the benefits and harms of preventive services for people asymptomatic for the target condition on the basis of age, gender, and risk factors for disease; and (2) make recommendations about which preventive services should be incorporated into routine primary care practice. The USPSTF is now entering its 27th year of existence, and the medical community considers its methodologies and resulting recommendations to be the "gold standard" for evidence-based clinical practice in preventive services (USPSTF, 2008b).

TABLE 2-1 USPSTF Grade Definitions

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate degree of certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting; and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

SOURCE: USPSTF, 2008a.

The charge of the Task Force is limited in scope: "its recommendations address primary or secondary preventive services targeting conditions that represent a substantial burden in the United States and that are provided in primary care settings or available through primary care referral" (USPSTF, 2008b). These recommendations are intended to inform primary care providers as they care for individual patients in primary care practice. They are not intended to determine which preventive health care services health insurers should be required to cover. The methodology used in developing Task Force clinical recommendations does not take into consideration many nonclinical issues related to health care coverage (USPSTF, 2011). USPSTF uses a grade system, which is described in Table 2-1.

USPSTF Methodology

Task Force recommendations and their accompanying evidence reports are produced through the collaborative efforts of the USPSTF, the Agency

for Healthcare Research and Quality (AHRQ), Evidence-based Practice Centers (EPCs), and partner organizations. AHRQ provides methodological, technical, scientific, and administrative support to the Task Force. EPCs aid the USPSTF by developing technical reports, evidence summaries and reports, and systematic reviews that target new topics under consideration by the Task Force or that update ones addressed previously. The USPSTF uses systematic evidence reviews produced primarily by the Oregon EPC (under contract by AHRQ) and occasionally uses reviews and other analyses conducted by other groups, depending on the topic under consideration. Partner organizations consist of federal partners (examples include the Centers for Disease Control and Prevention [CDC], the U.S. Department of Defense, Centers for Medicare and Medicaid Services, and the Food and Drug Administration [FDA]) and organizations representing primary care professionals (examples include the American Academy of Family Physicians [AAFP], the American College of Obstetricians and Gynecologists [ACOG], the American Medical Association [AMA], and AAP). They contribute expertise to the evaluation process and comment on preliminary drafts of Task Force recommendation statements and the accompanying evidence reports. A step-by-step overview of the process of recommendation development, from topic selection to recommendation dissemination, follows. The average amount of time required to complete this process is 21 months (USPSTF, 2011).

1. Topic Selection—USPSTF

EPCs, Task Force members, organizations, and individuals can nominate topics through a publicly accessible website, as well as through solicitations to partner organizations and the *Federal Register.* On the basis of these submissions, the Task Force Topic Prioritization Work Group periodically updates a prioritized list of topics to be addressed either for the first time or for updating during the year.

2. Work Plan Development—AHRQ, EPCs, USPSTF

Prioritized topics are appointed to "topic teams," consisting of USPSTF "leads," AHRQ staff (including a Medical Officer), and EPC members. The topic team develops preliminary work plans from the work assignment that AHRQ has issued to the team. The work plan includes the analytic framework, key questions, the literature search strategy, and a timeline for recommendation dissemination.

3. External Work Plan Peer Review—Outside Experts

Work plans for new topics are sent to a limited number of outside experts in appropriate fields for their comments and review.

4. Approval of Work Plan—USPSTF

The topic team presents work plans for new topics to the entire Task Force. The Task Force then evaluates and requests any revisions to the work plan that it deems necessary. The work plan is then edited by the EPC in accordance with the Task Force's requests and is finalized.

5. Draft Evidence Report—EPC

The EPC next conducts a systematic evidence review addressing the key questions posed by the Task Force in the work plan, and generates a draft evidence report.

6. Peer-Review of Draft Evidence Report—USPSTF, Content Area Experts, Federal Partners

Draft evidence reports are sent to Task Force leads, content area experts, federal partners, and other partner organizations for review and comment.

7. Development of Draft Recommendation Statement—USPSTF, AHRQ

Concomitant with the draft evidence report review process, Task Force leads collaborate with the AHRQ Medical Officer to discuss and draft a preliminary recommendation statement.

8. Vote on Draft Recommendation Statement—USPSTF

The Task Force is presented with the peer-reviewed evidence report findings by the EPC and the preliminary recommendation statement by the Task Force leads at one of three annual meetings that include the USPSTF, AHRQ, the EPC, and representatives from the partner organizations. The entire Task Force, including the leads, discusses the evidence and debates the language of the recommendation statement until a consensus is reached and the statement passes a vote. The revised recommendation statement is then sent to Task Force leads for completion and editing prior to external review.

9. Final Evidence Report—EPC

The EPC revises the evidence report in response to comments from the federal partners, content area experts, and Task Force leads. The EPC then sends a summary of the comments and how the comments were addressed to AHRQ. AHRQ staff then review, approve, and finalize the revised evidence report. The EPC then prepares the finalized evidence report for submission to a peer-reviewed journal for publication. The final technical report is also made available on the AHRQ website.

10. Review of Draft Recommendation Statement—Federal and Primary Care Professional Organization Partners and the Public

The newly revised and approved recommendation statement is sent to relevant federal and primary care professional organization partners for review and comment. The statement is also posted on the AHRQ website for one month for public comment.

11. Approval of Final Recommendation Statement—USPSTF

Task Force leads edit the recommendation statement on the basis of the comments received from the federal and primary care professional organization partners and the public after discussion with the AHRQ Medical Officer.

12. Release of Recommendation Statement and Evidence Report—Peer-Reviewed Journals

Recommendation statements and the accompanying EPC evidence report-derived manuscript are often published simultaneously in the professional journals *Annals of Internal Medicine* (adult topics) or *Pediatrics* (child/adolescent topics) and must go through the respective journal's peer-review process before publication. They are occasionally published in other journals (USPSTF, 2008b).

Preventive services relevant to women that have a grade of A or B from the USPSTF are listed in Table 2-2.

TABLE 2-2 USPSTF Preventive Services Relevant to Women That Have a Grade of A or B

Topic	Description	Grade
Alcohol misuse counseling	The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.	B
Anemia screening: pregnant women	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B
Aspirin to prevent cardiovascular disease (CVD): women	The USPSTF recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.	A
Bacteriuria screening: pregnant women	The USPSTF recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.	A
Blood pressure screening	The USPSTF recommends screening for high blood pressure in adults aged 18 and older.	A
BRCA screening, counseling about	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.	B
Breast cancer preventive medication	The USPSTF recommends that clinicians discuss chemoprevention 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.	B
Breast cancer screening[a]	The USPSTF recommends screening mammography for women, with or without clinical breast examination, every 1–2 years for women aged 40 and older.	B
Breastfeeding counseling	The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.	B

TABLE 2-2 Continued

Topic	Description	Grade
Cervical cancer screening	The USPSTF strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix.	A
Chlamydial infection screening: non-pregnant women	The USPSTF recommends screening for chlamydial infection for all sexually active non-pregnant young women aged 24 and younger and for older non-pregnant women who are at increased risk.	A
Chlamydial infection screening: pregnant women	The USPSTF recommends screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk.	B
Cholesterol abnormalities screening: women 45 and older	The USPSTF strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease.	A
Cholesterol abnormalities screening: women younger than 45	The USPSTF recommends screening women aged 20 to 45 for lipid disorders if they are at increased risk for coronary heart disease.	B
Colorectal cancer screening	The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.	A
Depression screening: adolescents	The USPSTF recommends screening of adolescents (12–18 years of age) for major depressive disorder when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.	B
Depression screening: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B
Diabetes screening	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B

continued

TABLE 2-2 Continued

Topic	Description	Grade
Folic acid supplementation	The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.	A
Gonorrhea screening: women	The 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).	B
Healthy diet counseling	The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.	B
Hepatitis B screening: pregnant women	The USPSTF strongly recommends screening for hepatitis B virus infection in pregnant women at their first prenatal visit.	A
Human immunodeficiency virus (HIV) screening	The USPSTF strongly recommends that clinicians screen for HIV all adolescents and adults at increased risk for HIV infection.	A
Obesity screening and counseling: adults	The 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.	B
Osteoporosis screening: women	The USPSTF recommends screening for osteoporosis in women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors.	B
Rh incompatibility screening: first pregnancy visit	The USPSTF strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	A

TABLE 2-2 Continued

Topic	Description	Grade
Rh incompatibility screening: 24–28 weeks gestation	The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women at 24–28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.	B
Sexually transmitted infections (STIs) counseling	The USPSTF recommends high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs.	B
Tobacco use counseling and interventions: non-pregnant adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A
Tobacco use counseling: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke.	A
Syphilis screening: non-pregnant persons	The USPSTF strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A
Syphilis screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A

[a] HHS, in implementing ACA under the standard that it sets out in revised Section 2713(a)(5) of the Public Health Service Act, uses the 2002 recommendation on breast cancer screening of the USPSTF.
SOURCE: USPSTF, 2010b.

BRIGHT FUTURES—AMERICAN ACADEMY OF PEDIATRICS

The HHS Health Resources and Services Administration's Maternal and Child Health Bureau established the Bright Futures project in 1990 with the mission to "promote and improve the health, education, and well-being of infants, children, adolescents, families, and communities" (AAP, 2008). It is a "set of principles, strategies, and tools that are theory based and system oriented that can be used to improve the health and well-being of all children through culturally appropriate interventions that address the

current and emerging health promotion needs at the family, clinical practice, community, health system, and policy levels" (AAP, 2008). The most recent report, published in 2008, was developed through the collaborative efforts of four multidisciplinary panels consisting of experts in health during infancy, early childhood, middle childhood, and adolescence and was then reviewed by more than 1,000 educators, public health and health care professionals, child health advocates, and parents.

Bright Futures Methodology

The Bright Futures Steering Committee used three approaches to develop its guidance and recommendations and described these approaches as follows:

1. "Multidisciplinary Expert Panels were convened to write recommendations for Bright Futures visit priorities, the physical examination, anticipatory guidance, immunizations, and universal and selective screening topics for each age and stage of development. In carrying out this task, the Expert Panels were charged with examining the evidence for each recommendation, and evidence was an important consideration in the guidance they provided. However, lack of evidence was sometimes problematic for the physical examination (the elements of which can be considered screening interventions) and for counseling interventions. For these components, the Expert Panels relied on an indirect approach buttressed by their expertise and clinical experience" (AAP, 2008).
2. A Bright Futures Evidence Panel, composed of consultants who are experts in finding and evaluating evidence from clinical studies, was convened to examine studies and systematic evidence reviews and to develop a method of informing readers about the strength of the evidence.

   > The Evidence Panel conducted literature searches for key questions using the MEDLINE® database of the National Library of Medicine. Key themes were searched in the Medical Subject Headings (MeSH) database to determine the most appropriate search terms. Searches were limited to clinical trials, meta-analyses, and randomized controlled trials. Other limits included English language and designations for age, when appropriate. Standardized terms were used for counseling (i.e., counseling, primary prevention, health promotion, health education, and patient education) and for screening (i.e., mass screening and risk assessment). The Evidence Panel also used the systematic

> evidence reviews performed for the USPSTF and the Cochrane Collaboration [the publisher of *Cochrane Reviews* of primary research in human health care and health policy]. This approach was by no means exhaustive, but it did provide an assessment of the most relevant literature. (AAP, 2008)

3. "Throughout the Guidelines development process, the Project Advisory Committee and Expert Panels consulted with individuals and organizations with expertise and experience in a wide range of topic areas. The entire Guidelines document also underwent public review twice in 2004 and once in 2006. More than 1,000 reviewers, representing national organizations concerned with infant, child, and adolescent health and welfare, provided nearly 3,500 comments. The contributions of these reviewers provided an opportunity to refine the guidelines and strengthen the scientific base for the guidance provided" (AAP, 2008).

Bright Futures describes its guidelines as "evidence informed rather than fully evidence driven" (AAP, 2008) and takes a broader view of prevention that is less focused on specific conditions and more on general health guidance (e.g., aggregating services into health supervision visits and extensive anticipatory guidance). Like the USPSTF, Bright Futures does not directly comment on insurance coverage, but unlike the USPSTF, Bright Futures does not have categories regarding services comparable to "C" or "I" grades that do not definitively recommend for or against a particular service. Bright Futures intends to leave no gaps in its recommendations, supplementing the evidence where needed with experience and expert opinion so that clinical guidance is always provided. Figures 2-1, 2-2, and 2-3 present the Bright Futures recommendations for adolescents and outline the preventive services that are covered for adolescent women in the ACA. In addition to the information in the tables shown in Figures 2-1 to 2-3, Bright Futures also provides extensive anticipatory guidance on a range of health matters in the context of discussing health issues with adolescents. These measures do not provide action steps and are not suitable for summary in a structured format.

Physical Examination

A complete physical examination is included as part of every health supervision visit.

When performing a physical examination, the health care professional's attention is directed to the following components of the exam that are important for 11- to 14-year-olds:

- **Measure:**
  - Blood pressure
- **Measure and plot:**
  - Height
  - Weight
- **Calculate and plot:**
  - BMI
- **Skin**
  - Inspect for acne, acanthosis nigricans, atypical nevi, tattoos, piercings, and signs of abuse or self-inflicted injury
- **Spine**
  - Examine back
- **Breast**

  Female
  - Assess sexual maturity rating

  Male
  - Observe for gynecomastia
- **Genitalia**

Female
- Perform visual inspection for sexual maturity rating and observation for signs of STIs (eg, warts, vesicles, vaginal discharge)
- Perform pelvic exam, if clinically warranted, based on sexual activity (eg, for Pap smear within 3 years of onset of sexual activity) and/or specific problems (eg, pubertal aberrancy, abnormal bleeding, abdominal or pelvic pain)

Male
- Perform visual inspection for sexual maturity rating and observations for signs of STIs (ie, warts, vesicles)
- Examine testicles for hydrocele, hernias, varicocele, or masses

Screening

UNIVERSAL SCREENING	ACTION	
Vision (once in early adolescence)	Snellen test	
SELECTIVE SCREENING	**RISK ASSESSMENT***	**ACTION IF RA +**
Vision at other ages	+ on risk screening questions	Snellen test
Hearing	+ on risk screening questions	Audiometry
Anemia	+ on risk screening questions	Hemoglobin or hematocrit
Tuberculosis	+ on risk screening questions	Tuberculin skin test
Dyslipidemia	+ on risk screening questions and not previously screened with normal results	Lipid screen
STIs	Sexually active	Screen for chlamydia and gonorrhea; use tests appropriate to the patient population and clinical setting
	Sexually active and + on risk questions	Syphilis blood test HIV†
Pregnancy	Sexually active without contraception, late menses, or amenorrhea	Urine hCG
Cervical dysplasia	Sexually active, within 3 years of onset of sexual activity	Pap smear, conventional slide or liquid-based
Alcohol or drug use	+ on risk screening questions	Administer alcohol and drug screening tool

*See Rationale and Evidence chapter for the criteria on which risk screening questions are based.

†The CDC has recently recommended universal voluntary HIV screening for all sexually active people, beginning at age 13. At the time of publication, the AAP and other groups had not yet commented on the CDC recommendation, nor recommended screening criteria or techniques. The health care professional's attention is drawn to the voluntary nature of screening and that the CDC allows an opt out in communities where the HIV rate is <0.1%. The management of positives and false positives must be considered before testing.

FIGURE 2-1 Adolescence 11–14 year visits.
ABBREVIATIONS: AAP = American Academy of Pediatrics; BMI = body mass index; CDC = Centers for Disease Control and Prevention; hCG = human chorionic gonadotropin; HIV = human immunodeficiency virus; RA = risk assessment; STI = sexually transmitted infection.
SOURCE: AAP, 2008. Used with permission of the American Academy of Pediatrics, Bright Futures—Guidelines for Health Supervision of Infants, Children, and Adolescents, Third Edition, American Academy of Pediatrics, 2008.

Physical Examination

A complete physical examination is included as part of every health supervision visit.

When performing a physical examination, the health care professional's attention is directed to the following components of the exam that are important for 15- to 17-year-olds:

- **Measure:**
  - Blood pressure
- **Measure and plot:**
  - Height
  - Weight
- **Calculate and plot:**
  - BMI
- **Skin**
  - Inspect for acne, acanthosis nigricans, atypical nevi, tattoos, piercings, and signs of abuse or self-inflicted injury
- **Spine**
  - Examine back
- **Breast**

  Female
  - Assess sexual maturity rating

  Male
  - Observe for gynecomastia
- **Genitalia**

Female
- Perform visual inspection for sexual maturity rating and observation for signs of STIs (eg, warts, vesicles, vaginal discharge)
- Perform pelvic exam, if clinically warranted, based on sexual activity (eg, for Pap smear within 3 years of onset of sexual activity) and/or specific problems (eg, pubertal aberrancy, abnormal bleeding, abdominal or pelvic pain)

Male
- Perform visual inspection for sexual maturity rating and observations for signs of STIs (ie, warts, vesicles)
- Examine testicles for hydrocele, hernias, varicocele, or masses

Screening

UNIVERSAL SCREENING	ACTION	
Vision (once in middle adolescence)	Snellen test	
SELECTIVE SCREENING	**RISK ASSESSMENT***	**ACTION IF RA +**
Vision at other ages	+ on risk screening questions	Snellen test
Hearing	+ on risk screening questions	Audiometry
Anemia	+ on risk screening questions	Hemoglobin or hematocrit
Tuberculosis	+ on risk screening questions	Tuberculin skin test
Dyslipidemia	+ on risk screening questions and not previously screened with normal results	Lipid screen
STIs	Sexually active	Screen for chlamydia and gonorrhea; use tests appropriate to the patient population and clinical setting
	Sexually active and + on risk questions	Syphilis blood test HIV†
Pregnancy	Sexually active without contraception, late menses, or amenorrhea	Urine hCG
Cervical dysplasia	Sexually active, within 3 years of onset of sexual activity	Pap smear, conventional slide or liquid-based
Alcohol or drug use	+ on risk screening questions	Administer alcohol and drug screening tool

*See Rationale and Evidence chapter for the criteria on which risk screening questions are based.

†The CDC has recently recommended universal voluntary HIV screening for all sexually active people, beginning at age 13. At the time of publication, the AAP and other groups had not yet commented on the CDC recommendation, nor recommended screening criteria or techniques. The health care professional's attention is drawn to the voluntary nature of screening and that the CDC allows an opt out in communities where the HIV rate is <0.1%. The management of positives and false positives must be considered before testing.

FIGURE 2-2 Adolescence 15–17 year visits.
ABBREVIATIONS: AAP = American Academy of Pediatrics; BMI = body mass index; CDC = Centers for Disease Control and Prevention; hCG = human chorionic gonadotropin; HIV = human immunodeficiency virus; RA = risk assessment; STI = sexually transmitted infection.
SOURCE: AAP, 2008. Used with permission of the American Academy of Pediatrics, Bright Futures—Guidelines for Health Supervision of Infants, Children, and Adolescents, Third Edition, American Academy of Pediatrics, 2008.

Physical Examination

A complete physical examination is included as part of every health supervision visit.

When performing a physical examination, the health care professional's attention is directed to the following components of the exam that are important for 18- to 21-year-olds:

- **Measure:**
  - Blood pressure
- **Measure and plot:**
  - Height
  - Weight
- **Calculate and plot:**
  - BMI
- **Skin**
  - Inspect for acne, acanthosis nigricans, atypical nevi, tattoos, piercings, and signs of abuse or self-inflicted injury
- **Breast**

Female
- Clinical Breast Examination is considered routine after age 20.

- **Genitalia**

Female
- Inspect for signs of STIs (eg, warts, vesicles, vaginal discharge)
- Perform pelvic exam by age 21 or if clinically warranted, based on sexual activity (eg, for Pap smear within 3 years of onset of sexual activity) and/or specific problems (eg, pubertal aberrancy, abnormal bleeding, abdominal or pelvic pain)

Male
- Perform visual inspection for sexual maturity rating and observations for signs of STIs (ie, warts, vesicles)
- Examine testicles for hydrocele, hernias, varicocele, or masses

Screening

UNIVERSAL SCREENING	ACTION	
Vision (once in late adolescence)	Snellen test	
Dyslipidemia (once in late adolescence)	A fasting lipoprotein profile (total cholesterol, LDL choesterol, high density lipoprotein (HCL), cholesterol, and triglyceride). If the testing opportunity is non-fasting, only total cholesterol and HDL cholesterol will be usable.	
SELECTIVE SCREENING	**RISK ASSESSMENT***	**ACTION IF RA +**
Vision at other ages	+ on risk screening questions	Snellen test
Hearing	+ on risk screening questions	Audiometry
Anemia	+ on risk screening questions	Hemoglobin or hematocrit
Tuberculosis	+ on risk screening questions	Tuberculin skin test
Dyslipidemia	If not age 20, + on risk screening questions and not previously screeened with normal resaults	Lipid screen
STIs	Sexually active	Screen for chlamydia and gonorrhea; use tests appropriate to the patient population and clinical setting
	Sexually active and + on risk questions	Syphilis blood test HIV†
Pregnancy	Sexually active without contraception, late or absent menses, or heavy or irregular bleeding	Urine hCG
Cervical dysplasia	Sexually active, within 3 years of onset of sexual activity	Pap smear, conventional slide or liquid-based
Alcohol or drug use	+ on risk screening questions	Administer alcohol and drug screening tool

*See Rationale and Evidence chapter for the criteria on which risk screening questions are based.

†The CDC has recently recommended universal voluntary HIV screening for all sexually active people, beginning at age 13. At the time of publication, the AAP and other groups had not yet commented on the CDC recommendation, nor recommended screening criteria or techniques. The health care professional's attention is drawn to the voluntary nature of screening and that the CDC allows an opt out in communities where the HIV rate is <0.1%. The management of positives and false positives must be considered before testing.

FIGURE 2-3 Adolescence 18–21 year visits.
ABBREVIATIONS: AAP = American Academy of Pediatrics; BMI = body mass index; CDC = Centers for Disease Control and Prevention; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; LDL = low-density lipoprotein; RA = risk assessment; STI = sexually transmitted infection.
SOURCE: AAP, 2008. Used with permission of the American Academy of Pediatrics, Bright Futures—Guidelines for Health Supervision of Infants, Children, and Adolescents, Third Edition, American Academy of Pediatrics, 2008.

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

ACIP is the sole federal government entity that provides written recommendations for delivering vaccines to children and adults in the general population. It provides guidance and recommendations to HHS and the CDC on matters regarding the approval, administration, and safety of vaccines. Its goal is to reduce the prevalence of vaccine-preventable diseases in the United States and bolster the safe use of vaccines and other related biological products. ACIP is comprised of 15 voting immunization-related experts and 34 other representatives from liaison organizations and federal agencies that oversee national immunizations programs (CDC, 2011a).

ACIP Methodology

The ACIP General Recommendations Work Group (GRWG) revises the *General Recommendations on Immunization* every 3 to 5 years. Relevant topics are those identified by ACIP to be topics that relate to all vaccines, including timing and spacing of doses, vaccine administration procedures, and vaccine storage and handling. New topics are often added when ACIP decides that previous ACIP statements on general issues, such as combination vaccines, adolescent vaccination, and adult vaccination, should be revised and combined with the *General Recommendations on Immunization* (CDC, 2011b).

The recommendations in the 2011 GRWG report are based not only on available scientific evidence but also on expertise that comes directly from a diverse group of health care providers and public health officials. GRWG includes "professionals from academic medicine (pediatrics, family practice, and pharmacy); international (Canada), federal, and state public health professionals; and a member of the nongovernmental Immunization Action Coalition" (CDC, 2011b).

ACIP committee work groups comprising an ACIP member chair, a CDC subject-matter expert, and at least two ACIP members meet during the year to perform analyses of vaccine-related data and generate potential policy recommendations to be presented to the committee. These analyses include review of the available scientific literature on the immunizing agent, morbidity and mortality from the disease in the U.S. population, recommendation statements issued by other professional organizations, results of clinical trials with the immunizing agent, cost-effectiveness projections, and the feasibility of incorporating the vaccine into preexisting U.S. immunization programs. Draft recommendations are then subjected to further review by the FDA, CDC, ACIP members, external expert consultants, and other relevant federal agencies. Work group findings and potential recommendations are presented to ACIP at one of three annual open meetings and

are deliberated upon by the committee. Public comments are heard at the meetings and taken into consideration during the deliberations. A majority vote is then conducted to pass a recommendation that includes guidance regarding the route of administration and dosing intervals, contraindications and precautions, and target groups for immunization. Recommendations are published on the ACIP website and in *Morbidity and Mortality Weekly Report* (Smith et al., 2009).

ACIP functions in a unique position because its recommendations are relevant to the general population and to some quite specific subpopulations, but its recommendations focus on efficacy and safety for intended populations. Some of its recommendations are not intended for general clinical use (e.g., recommendations for international travelers), are not intended for the entire population (e.g., recommendations for high-risk groups such as health care workers), or require specific guidance in footnotes for special circumstances (e.g., allergies and immunosuppression).

Table 2-3 lists the FDA-Licensed Combination Vaccines, and Table 2-4 lists ACIP-recommended vaccines that are covered without cost sharing as part of the ACA.

TABLE 2-3 FDA-Licensed Combination Vaccines

Vaccine	Trade Name (Year Licensed)	Age Range	Routinely Recommended Ages
HepA-HepB	Twinrix (2001)	≥18 years	Three doses on a schedule of 0, 1, and 6 months
MMRV	ProQuad (2005)	12 months–12 years	Two doses, the first at 12–15 months, the second at 4–6 years

ABBREVIATIONS: HepA = hepatitis A; HepB = hepatitis B; MMRV = measles, mumps, rubella, and varicella.
SOURCES: AAP, 2009; CDC, 2011.

TABLE 2-4 Recommended and Minimum Ages and Intervals Between Vaccine Doses

Vaccine and Dose Number	Recommended Age for This Dose	Minimum Age for This Dose	Recommended Interval to Next Dose	Minimum Interval to Next Dose
LAIV (intranasal)[a]	2–49 years	2 years	1 month	4 weeks
MCV4-1[b]	11–12 years	2 years	5 years	8 weeks
MCV4-2	16 years	11 years (+8 weeks)		
HPV-1[c]	11–12 years	9 years	2 months	4 weeks
HPV-2	11–12 years (+2 months)	9 years (+4 weeks)	4 months	12 weeks
HPV-3[d]	11–12 years (+6 months)	9 years (+24 weeks)		
Td	11–12 years	7 years	10 years	5 years
Tdap	11–12 years	7 years		

NOTE: Combination vaccines are available. Use of licensed combination vaccines is generally preferred to separate injections of their equivalent component vaccines. When combination vaccines, the minimum age for administration is the oldest age for any of the individual components; the minimum interval between doses is equal to the greatest interval of any of the individual components. Information on traveler vaccines, including typhoid, Japanese encephalitis, and yellow fever, is available at http://www.cdc.gov/travel. Information on other vaccines that are licensed in the United States but not distributed, including anthrax and smallpox, is available at http://www.bt.cdc.gov.

ABBREVIATIONS: LAIV = live, attenuated influenza vaccine; MCV4 = quadrivalent meningococcal conjugate vaccine; HPV-1 to HPV-3 = human papillomavirus doses 1 to 3, respectively; Td = adult tetanus and diphtheria toxoids; Tdap = tetanus and reduced diphtheria toxoids and acellular pertussis vaccine (for adolescents and adults).

[a] One dose of influenza vaccine per season is recommended for most persons. Children aged < 9 years who are receiving influenza vaccine for the first time or who received only one dose the previous season (if it was their first vaccination season) should receive two doses this season.

[b] Revaccination with meningococcal vaccine is recommended for previously vaccinated persons who remain at high risk for meningococcal disease (CDC, 2009).

[c] Bivalent HPV vaccine is approved for females aged 10–25 years. Quadrivalent HPV vaccine is approved for males and females aged 9–26 years.

[d] The minimum age for HPV-3 is based on the baseline minimum age for the first dose (i.e., 108 months) and the minimum interval of 24 weeks between the first and third doses. Dose 3 need not be repeated if it is administered at least 16 weeks after the first dose.

SOURCES: AAP, 2009; CDC, 2011b.

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3

Existing Coverage Practices of National, State, and Private Health Plans

Before passage of the Patient Protection and Affordable Care Act of 2010 (ACA), little standardization of the preventive services covered by both private and public payers existed. Historically, in the private sector, the extent of coverage for the preventive services that individuals receive and their exposure to out-of-pocket spending for these services have largely depended on the type of plan in which they are enrolled and the degree of cost sharing (including copayments and deductibles) that is part of the plan design. The passage of the ACA changed this variability by expanding federal requirements for plan benefits and limits on cost sharing for certain preventive services for private plans.

On September 23, 2010, the ACA preventive services requirements, detailed in Section 2713, went into effect. This section of the law adds to and amends the Public Health Services Act and the Employee Retirement Income Security Act and, as such, has jurisdiction over plans that are sold on the individual, small-group, and large-group markets by insurers as well as self-insured plans that are funded by employers.

These new rules require that private plans cover all United States Preventive Services Task Force (USPSTF) Grade A and B recommendations, all vaccinations recommended by the Advisory Committee for Immunization Practices (ACIP) of the Centers for Disease Control and Prevention, and Bright Futures recommendations for children from the American Academy of Pediatrics (see Chapter 2) and the preventive services for women that will be informed by the deliberations of this Institute of Medicine committee and subsequently identified by the U.S. Department of Health and Human Services (HHS).

Therefore, for the first time in U.S. history, federal rules stipulate the preventive services that private plans must cover and prohibit out-of-pocket payments for individuals who obtain these covered services from in-network providers (*Federal Register,* 2010a; HHS, 2010). Only new plans or those plans that change are affected by these new requirements.[1] Private plans that do not change their benefits or cost-sharing requirements are considered to be grandfathered and are not initially subject to the new requirements for the preventive services that must be covered.

HHS estimates that 78 million people enrolled in group plans and approximately 10 million people with individual policies will be subject to the prevention provisions in the ACA (HHS, 2010). These provisions will also apply to the plans that will be offered to consumers under the new state health insurance exchanges, although these exchanges and plans will not become operational until 2014.

This chapter reviews the policies and practices of private plans and publicly sponsored programs regarding the coverage before and after the enactment of the ACA of preventive services important to women. It describes the federal and state rules that are in effect today as well as identifies the types of plans or programs that will be affected by the new rules outlined in Section 2713 of the ACA.

RULES GOVERNING COVERAGE REQUIREMENTS BEFORE AND AFTER THE ACA

The coverage of preventive care provided under the individual and group markets and through self-funded employer health plans has been highly variable, differing by employer, insurer, and plan type. The Federal Employee Retirement and Income Security Act of 1974 regulates the coverage offered by self-insured or self-funded employer health plans as well as health insurance plans. An estimated 59 percent of covered workers are enrolled in self-insured group health plans (Claxton et al., 2010).

Federal Rules and Coverage Requirements

With few exceptions, federal rules do not specify what benefits plans must cover. The exceptions are that all self-funded employer health plans and health insurance issuers must offer coverage for a 48-hour hospital stay

[1] Plans will lose their "grandfather" status if, compared to March 23, 2010, they significantly cut or reduce benefits, raise co-insurance charges or significantly raise co-payment charges or deductibles, significantly reduce employer contributions, tighten annual limits on what insurers will pay, or change insurers. Plans that make any of these changes can be deemed to lose their grandfather status and will be required to follow the ACA preventive benefit coverage rules (*Federal Register*, 2010b).

after a vaginal delivery or a 96-hour stay after a delivery by cesarean section if they cover maternity care; mental health parity, which affects mental health care benefits and benefits for the treatment of substance use disorders; and benefits for breast reconstruction after a mastectomy and treatment of surgical complications for health plans that cover mastectomies.

In addition, the Pregnancy Discrimination Act of 1978 (P.L. 95-555), which amended Title VII of the Civil Rights Act of 1964, requires that employers with 15 or more employees treat women who are pregnant or affected by pregnancy-related conditions in the same manner that employers treat other workers or applicants. It requires that "any health insurance provided by an employer must cover expenses for pregnancy-related conditions on the same basis as costs for other medical conditions." An employer is "not required to provide health insurance for expenses arising from abortion, except where the life of the mother is endangered" (95th U.S. Congress, 1978). These payments must be paid for exactly like other medical conditions; and no additional, increased, or larger deductible can be imposed. Moreover, employers must provide the same level of health benefits for spouses of male employees as they do for spouses of female employees (95th U.S. Congress, 1978).

In 2000, a ruling by Equal Employment Opportunity Commission (EEOC) found that employers that offered plans that provided coverage for drugs, devices, and preventive care but that did not include coverage for preventive contraceptives to be in violation of the Pregnancy Discrimination Act (EEOC, 2000). Although this ruling was upheld by a federal district court in the state of Washington (*Erickson v. Bartell Drug Co.*), the U.S. Court of Appeals for the 8th Circuit (No. 06-1706, 2007 WL 763842) ruled in a 2-to-1 decision that an employer may exclude contraception coverage from its health plan without violating the Pregnancy Discrimination Act because the employer also failed to cover condoms and vasectomies that affect men (2007). Despite this ruling, the EEOC finding still stands, and the vast majority of health plans cover contraceptives, and in 2002, more than 89 percent of insurance plans covered contraceptive methods (Sonfield et al., 2004). A more recent (2010) survey of employers found that 85 percent of large employers and 62 percent of small employers covered Food and Drug Administration-approved contraceptives (Claxton et al., 2010).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 permits individuals enrolled in high-deductible health plans to make tax-favored contributions to health savings accounts (HSAs). These plans may provide preventive care benefits without a deductible or with a separate deductible below the minimum plan deductible. In 2010, 93 percent of high-deductible health plans with HSAs covered preventive services without having to meet the deductible (Claxton et al., 2010). In 2004, the Internal Revenue Service (IRS) issued a bulletin that identified certain

TABLE 3-1 IRS-Defined Preventive Care Screening Services

Preventive Care Screening Service
Cancer
Breast cancer (e.g., mammogram)
Cervical cancer (e.g., Pap smear)
Colorectal cancer
Prostate cancer (e.g., prostate-specific antigen test)
Skin cancer
Oral cancer
Ovarian cancer
Testicular cancer
Thyroid cancer
Heart and Vascular Diseases
Abdominal aortic aneurysm
Carotid artery stenosis
Coronary heart disease
Hemoglobinopathies
Hypertension
Lipid disorders
Infectious Diseases
Bacteriuria
Chlamydial infection
Gonorrhea
Hepatitis B virus infection
Hepatitis C
Human immunodeficiency virus (HIV) infection
Syphilis
Tuberculosis
Mental Health Conditions and Substance Abuse
Dementia
Depression
Drug abuse
Problem drinking
Suicide risk
Family violence
Metabolic, Nutritional, and Endocrine Conditions
Anemia, iron deficiency
Dental and periodontal disease
Diabetes mellitus
Obesity in adults
Thyroid disease
Musculoskeletal Disorders
Osteoporosis
Obstetric and Gynecologic Conditions
Bacterial vaginosis in pregnancy
Gestational diabetes mellitus
Home uterine activity monitoring
Neural tube defects
Preeclampsia
Rh incompatibility
Rubella
Ultrasonography in pregnancy
Pediatric Conditions
Child developmental delay
Congenital hypothyroidism
Lead levels in childhood and pregnancy
Phenylketonuria
Scoliosis, adolescent idiopathic
Vision and hearing disorders
Glaucoma
Hearing impairment in older adults
Newborn hearing

NOTE: Services that are important to women as well as those that disproportionately or differentially affect women are indicated by boldface italic type.
SOURCE: IRS, 2004.

preventive services that are allowed to be included in these plans, which include, but are not limited to, the services listed in Table 3-1.

State Coverage Requirements

The business of insurance is regulated at the state level, and state requirements for the preventive services that health plans must cover vary

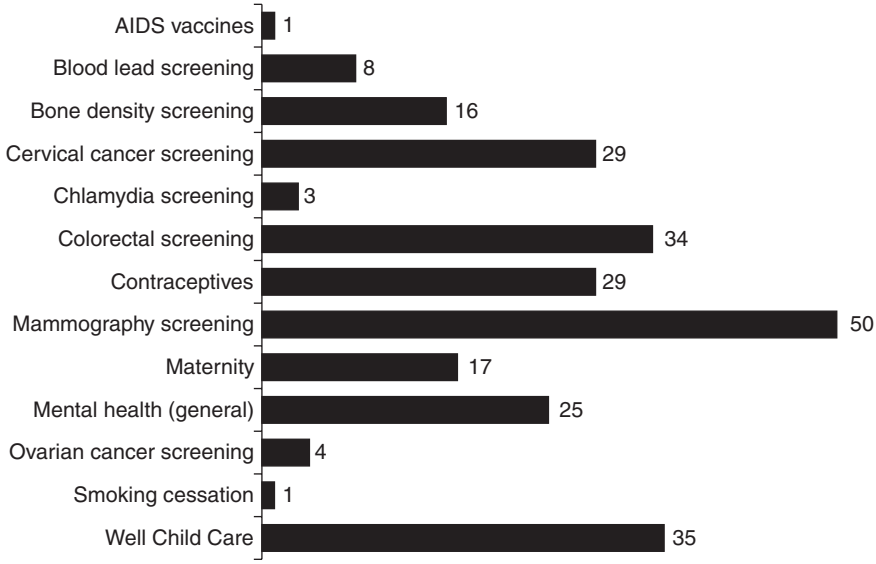

FIGURE 3-1 State-mandated preventive benefits of importance to adult women, 2010.
SOURCE: BlueCross BlueShield Association, 2010.

considerably (Figure 3-1).[2] In recent years, state lawmakers have enacted a wide range of mandates for different types of health care services. The reach of these benefit mandates is limited, however, as they apply only to insurance plans that are sold to employers and individuals in the state and do not apply to self-funded employer health plans, which are plans that provide coverage for the majority of the employer's workers and their dependents.

All states, with the exception of Utah, require plans to cover mammography screening, 29 states require coverage of cervical cancer, and 29 require coverage of contraception (Bluecross Blueshield Association, 2010). Far fewer states require bone density screening (16 states), maternity care (17 states in the case of the individual market), and screening for chlamydia infection (3 states). It also worth noting that some states require coverage for preventive services that do not yet exist, such as an AIDS vaccine and ovarian cancer screening.

[2] Many different organizations collect this information, including the BlueCross BlueShield Association, the National Association of Health Commissioners, the Council for Affordable Health Insurance, and the National Conference of State Legislatures. Figure 3-1 is presented to show the variability in coverage by state rather than an exact count of the laws that states currently have in place.

How these mandates are structured also differ substantially. For example, they can be legislated to affect the benefits that different types of insurance markets (small- or large-group plans or the individual market) must cover, what they must offer to sell (but not necessarily cover), the type of plan that is included (e.g., health maintenance organizations [HMOs]), the target populations for the service, and the periodicity of the service. Many, but not all, of these benefits are now covered under the new ACA preventive coverage rules without any cost sharing. Nevertheless, the ACA preventive care rules do not supersede state requirements. This means that for states that have coverage mandates for preventive services that are broader than the list of services required to be covered by Section 2713 of the ACA, insurance plans that sell policies in those states must still offer coverage for those services, in addition to the services required by the ACA.[3]

Although many states have coverage mandates or specific benefit requirements, 12 states have also required plans that sell on the individual and small-group markets to offer standardized benefit packages (KFF, 2009b). These standardized policies generally include a class of services and outline cost-sharing requirements. They were intended to facilitate the comparison of different plans for consumers and to make it harder for insurers to design benefit packages that are attractive to healthy individuals and avoid drawing those with health problems. In most states, insurers must offer the standardized plans but can also sell other types of plans (KFF, 2009b).

The benefit package that the commonwealth of Massachusetts requires, however, is a notable exception and does provide detailed coverage information. In 2006, the commonwealth of Massachusetts passed Chapter 58, the health reform law. This law combines the concept of individual responsibility through an individual mandate, which requires that individuals purchase health insurance that meets minimum standards developed by the state (creditable coverage). To ensure affordability, however, government subsidies are provided. This law created multiple public and private health insurance pathways and initiated a system of shared responsibility among the stakeholders in health care provision. Chapter 58 also created a health insurance exchange, known as the Commonwealth Connector, to make health coverage available to residents and to regulate the insurance products offered through the exchange to ensure that individuals have minimum creditable coverage. The reforms enacted by the commonwealth of Massachusetts served as a model for the ACA.

[3] When the federal subsidies for individuals to purchase coverage through the insurance exchanges become available, the costs of any benefits mandated by the states that exceed those specified in federal law will have to be funded by the states for those receiving subsidies. Given this new cost, it is possible that some states will eliminate these mandated benefits, at least in the individual market.

Although the overall rate of insurance coverage in Massachusetts before passage of the legislation exceeded 90 percent, since enactment, numerous subgroups of women have experienced substantial gains in coverage. In particularly, ethnic and racial minorities, low-income women, women without dependent children, and nonelderly women aged 50 to 64 years have experienced substantial gains in coverage, such that coverage is nearly universal for these subgroups of women (Long et al., 2010).

The preventive services benefits for women that plans must offer to be considered to have minimum creditable coverage are based on the recommendations for adults issued by the Massachusetts Health Quality Partners (MHQP) and other nationally recognized guidelines (Hyams and Cohen, 2010; MHQP, 2007). MHQP recommendations closely mirror those of the USPSTF but also include the coverage of preventive services such as counseling for preconception and menopause management and treatment for menopause.

According to the ACA, the new coverage rules for private plans in Massachusetts will be subject to the requirements of Section 2713, although the coverage may be broader than that included in the state law.[4] In addition, the Chapter 58 rules state that plans must cover at least three preventive visits without applying the costs for those visits to the deductible (but copayments may exist) and require that contraceptive services and supplies be covered as preventive services without cost sharing.

Private Insurance Coverage Practices

Detailed information on the coverage and benefits provided by private insurance plans and employers and on the scope of the preventive benefits that they cover is often proprietary and difficult to obtain. This information is enormously complex, and details about the coverage provided differ considerably from plan to plan and employer to employer. Although periodic surveys of employers of the health care benefits that they cover and reviews of documents that summarize the plans are performed, most surveys and reviews look at classes of services rather than the actual specific benefits provided.

In addition, research on this topic suffers from other limitations. The research is often conducted by researchers who are either funded by or who are employees of health plans or employer groups; the response rates for these surveys are usually low; and the respondents, who are typically employers, may not know the specific details about benefit coverage included

[4] Grandfathered plans, including those sold through the Commonwealth Connector, will not be subject to the new requirements unless and until they lose the grandfathered status discussed earlier.

in the plans that they have purchased. The following section highlights some of this research to provide some insights into the level of coverage and services provided by the private insurance sector but does not provide information on how plans and employers address cost sharing, copayments, and coinsurance for these specific services.

Employer-Based Health Plans

The Bureau of Labor Statistics' ongoing National Compensation Survey (DOL, 2011) surveyed approximately 3,900 employers with the aim of providing comprehensive data on employment-based health care benefits. A supplemental analysis of approximately 3,200 plan documents, including summary descriptions of the plans and other short summaries or comparison charts, was conducted to look at the extent of coverage of certain health benefits. When coverage or exclusion of a specific benefit by a plan is specifically mentioned, it is noted. For many of the benefits reviewed, coverage for particular services was mentioned one way or the other, but it is possible that the services would be covered for the workers.

The data on preventive care are limited but indicate that 56 percent of participants were in plans that identified coverage for adult immunizations and inoculations, 80 percent were in plans that covered adult physical examinations, and 77 percent were in plans that covered well-baby care. Gynecological examinations and services, such as pelvic examinations and Pap smears were covered for 60 percent of participants of employer-based health plans, usually under headings such as "well-woman exams." However, these services were often subject to plan or separate limits, and copayments were commonly required. Plans often limited the number of examinations per year and the dollar amount on the services covered during examinations.

Sterilization was not mentioned in the coverage documents for the employer-based health plans of more than 70 percent of participants. However, when it was mentioned, approximately 90 percent of participants were in plans that cover sterilization. Coverage for maternity care was also not uniformly identified by the plans. Sixty-six percent of workers were in plans that explicitly covered maternity care, and only 6 percent of the workers in those plans had these benefits in full (virtually all of the remaining third of workers were in plans that did not specifically mention coverage for maternity care).

In 2001, Mercer Human Resource Consulting Inc. conducted the National Survey of Employer-Sponsored Health Plans, which had a special supplement on preventive care. More than 2,000 employers providing benefits to their employees completed the survey. The response rate was 21 percent. The survey uncovered significant differences in the preventive services covered. These differences were related to employer size, incentives, and extent of coverage (Bondi et al., 2006). Because only one-fifth of

employers offered their workers a choice of more than one plan, examination of the rates of coverage of clinical preventive services in the employer's primary plans provides the best summary of the ranges of rates of coverage for different services: 75 percent covered physical examinations, 74 percent covered gynecological examinations, 57 percent covered cholesterol screenings, and only 37 percent covered screening for *Chlamydia* infection.

For women, primary employer-based health plans covered breast cancer and cervical cancer screening at rates of 80 and 79 percent, respectively. Lifestyle modification services were covered at much lower rates, with nutritional counseling covered by 17 percent of primary plans, weight loss and management counseling was covered by 15 percent, physical activity counseling was covered by 13 percent, alcohol problem prevention was covered by 18 percent, and any kind of tobacco cessation service was covered by 20 percent.

Approximately half of all large employers required that their plans cover clinical preventive services, whereas only 17 percent of small employers had the same requirement. Small employers were also less likely to offer coverage of clinical preventive services and lifestyle modification services, although the differences were not large.

Large employers were far more likely than small employers to offer financial incentives to employees to use clinical preventive services. However, small employers offered flexible scheduling or time off to access preventive services much more often than large employers did. Lifestyle modification services, such as physical activity counseling and weight loss management, were covered the least often, regardless of employer size.

The National Business Group on Health conducted a comprehensive analysis and synthesis of a wide range of clinical preventive services and their impacts on disease prevention and early detection of health conditions and disease according to both health and economic measures (NBGH, 2009). On the basis of their analyses, they compiled a purchaser's guide that recommends 46 clinical preventive services that should be included in employer health benefit plans. Benefits directly relevant to women are summarized in Box 3-1.

Individual Insurance Plans

As with the small- and large-group insurance markets, the individual insurance market appears to have considerable variability in coverage of preventive services. In a 2006–2007 survey of individual insurance plans conducted by American's Health Insurance Plans, the trade association for health insurers in the United States (AHIP, 2007), coverage levels were found to vary considerably by type of plan, with all HMO plans responding to the survey indicating that they covered physical examinations for adults, annual visits to an obstetrician-gynecologist, and cancer screening; but far

BOX 3-1
National Business Group on Health's Recommended Benefits Directly Relevant to Women

Breast Cancer: Breast cancer screening should include clinical breast examination and an annual mammography (for women from ages 40 to 80 years and for younger women, if it was deemed medically indicated), assessment of a woman's genetic risk for breast cancer and testing for mutations in the *BRCA* breast cancer-associated gene for women at high risk, counseling, and preventive medication and treatment (i.e., tamoxifen) for women with a high risk of breast cancer or surgical removal of the breasts or ovaries.

Cervical Cancer: The purchaser's guide recommends coverage of conventional Pap smears. Plans are to use their own discretion on coverage for newer screening methods, including liquid-based, thin-layer preparations, computer-assisted screening, and tests for human papillomavirus infection for women beginning at age 21 years or within 3 years of onset of sexual activity through age 65 years and beyond for high-risk women. The guidelines recommends coverage for screening services at least once every three years and not more than once a year.

Contraceptive Use: The guidelines recommend coverage for counseling on contraceptive use at least once a year and when emergency contraception is provided for all beneficiaries aged 13 to 55 years. They also recommend coverage of the full range of Food and Drug Administration-approved contraceptives, including all hormonal medications, contraceptive devices, and voluntary sterilization.

Osteoporosis: The guidelines recommend screening and treatment for osteoporosis starting at age 65 years for women with a normal risk. High-risk women are eligible at age 60 years or earlier, if it is medically indicated, and not more than once every two calendar years. The screening tools recommended for coverage include the Osteoporosis Risk Assessment Instrument and the Simple Calculated Osteoporosis Risk Estimation tool, dual-energy X-ray absorptiometry, peripheral dual-energy X-ray absorptiometry, peripheral quantitative computed tomography, radiographic absorptiometry, single-energy absorptiometry, and ultrasound. All Food and Drug Administration-approved treatments for osteoporosis are covered for beneficiaries age 60 years and older who meet medical necessity criteria.

Pregnancy: Pregnant women should receive screening and counseling (up to eight interventions per calendar year) for alcohol misuse during pregnancy; urine culture for asymptomatic bacteriuria at between 12 and 16 weeks of gestation and subsequently as medically indicated; structured breastfeeding education and behavioral counseling for all pregnant and lactating women (in office, in the hospital, or at home after birth), without a limit on the number of sessions, provided that care is medically necessary; folic acid counseling and supplements; screening and medication for group B streptococcal disease; screening for hepatitis B virus infection and immunizations against hepatitis B virus; screening, counseling, and preventive medication for human immunodeficiency virus; influenza immuniza-

BOX 3-1 Continued

tions; screening for preeclampsia; prenatal screening and testing for neural tube defects (for all women at elevated risk) and chromosomal abnormalities (for all women aged 35 years and older), including, but not limited to amniocentesis, chorionic villus sampling, and ultrasound; Rh (D) blood typing and antibody and immunoglobulin testing; screening for rubella and syphilis; tetanus immunization; screening and treatment (counseling) for tobacco use; and screening, counseling, and treatment for hypertension.

Sexually Transmitted Infections: The guidelines recommend coverage for counseling to prevent sexually transmitted infections for all adolescents and adults. They also recommend screening for chlamydia infection and gonorrhea for all women aged 25 years and younger (and for older women, if it is medically indicated); screening and counseling for human immunodeficiency virus infection for all people aged 13 to 64 years; and an annual screening (and screening more frequently, if needed) for syphilis for all beneficiaries at risk of infection.

SOURCE: NBGH, 2009.

fewer HMOs covered contraceptives (39 percent for HMO plans for single individuals and 59 percent for HMO plans for families).

Coverage rates were lower for preferred provider organizations (PPOs) and point-of-service (POS) plans as well as high-deductible plans with HSAs or medical savings accounts (MSAs). The rate of coverage for physical examinations for adults ranged from 66 percent for PPO or POS plans for single individuals to 75 percent of plans with HSAs or MSAs for families. The rate of coverage for annual visits to an obstetrician-gynecologist was higher, ranging from a low of 82 percent for plans with HSAs and MSAs for families to a high of 96 percent for PPOs and POS plans for single individuals. Rates of coverage for cancer screenings ranged from 81 percent for HSAs and MSAs for families to 94 percent for PPOs and POS plans for single individuals. Coverage rates for oral contraceptives were also lower, ranging from 39 percent for HMOs for single individuals to 79 percent for PPOs and POS plans for single individuals.

Federal Employees Health Benefits Program

Millions of federal workers and their dependents receive their health insurance coverage through the Federal Employee Health Benefits (FEHB) program. The FEHB program purchases health insurance coverage through private plans for federal workers and their dependents. The preventive ser-

vices covered, provider networks, and out-of-pocket spending responsibilities for these private plans vary by state. According to the ACA, plans that are offered under the FEHB program either are or will be required to offer coverage of all services that are recommended by the USPSTF, the ACIP, and Bright Futures. The plans offered under the FEHB program either are or will be required to offer coverage for preventive services for women without cost sharing if the services are obtained from an in-network provider. In addition, since 1999, almost all FEHB program plans are required to cover all Food and Drug Administration-approved contraceptive supplies and devices (OPM, 1998).

Public-Sector Programs

The federal and state governments provide health coverage to a sizable share of the U.S. population through a wide range of programs. Nearly all seniors have primary coverage through Medicare, the federal program for those aged 65 years and over and individuals with permanent disabilities. In 2010, more than 66 million low-income individuals were covered by Medicaid, the federal-state program for low-income parents, children, seniors, and people with disabilities (MACPAC, 2011). The U.S. Department of Veterans Affairs (VA) provided health care services to 5.3 million veterans and their families in 2008 (VA, 2011a); and TRICARE, the health care plan for the U.S. military, serves millions of individuals in active-duty military service and their dependents, military retirees and their families, and other beneficiaries from any of the seven services. The Indian Health Service (IHS) covers nearly 2 million American Indians and Alaska Natives (IHS, 2011).

Although the ACA contains new rules for Medicare coverage of preventive services for beneficiaries and incentives for Medicaid to cover preventive services without cost sharing, the preventive services requirements that are promulgated under Section 2713 affect only private plans. The rules in Section 2713 only amend and add to the Public Health Services Act and the Federal Employee Retirement and Income Security Act and therefore do not affect the coverage offered by military health care programs, such as TRICARE and VA program, or the IHS. It is useful, however, to understand how these different programs have handled policies for coverage of preventive services important to women. These policies are detailed in the following sections.

Medicare

Medicare provides health care coverage for about 39 million seniors and 8 million people under age 65 years with permanent disabilities (KFF, 2010). About 56 percent of Medicare beneficiaries are women (KFF, 2009a).

Sections of the ACA other than those related to Medicare make many changes to the covered preventive services that are important to female Medicare beneficiaries. Before passage of the ACA, many preventive benefits important to women's health, such as mammography, clinical breast examinations, bone density tests, Pap smears, and pelvic examinations, were covered but required a 20 percent copayment; that is, Medicare covered only 80 percent of the full cost of these tests. The ACA requires that all Medicare beneficiaries receive coverage without copayments for those services that receive Grade A or B recommendations from the USPSTF, as well as coverage for all vaccines recommended by ACIP (111th U.S. Congress, 2010). This rule became effective on January 1, 2011.

All new Medicare beneficiaries have been eligible to receive a "welcome to Medicare" visit that is similar in scope to a wellness visit. The ACA broadened this benefit for beneficiaries to include a new annual wellness examination for all beneficiaries with no copayment (111th U.S. Congress, 2010). At this visit, the medical and family health histories are reviewed, basic health measurements are taken, a screening for the preventive services required is performed, and risk factors and treatment options are identified.

Although Medicare is typically considered a program for seniors, a sizable share of Medicare beneficiaries are nonelderly and qualify on the basis of a permanent disability. In 2009, about 850,000 disabled women under age 45 years were enrolled in Medicare (CMS, 2010). Women Medicare beneficiaries in this age group have reproductive health care needs but do not get coverage for contraceptive services or devices through Medicare Part A or B. They may get coverage, however, for oral contraceptive pills through their Medicare Part D prescription drug coverage. The extent of their out-of-pocket costs and the scope of coverage for prescriptions are largely dependent on the type of Part D drug plan that they select.

A growing share of Medicare beneficiaries are enrolled in managed care arrangements through Medicare Advantage plans. These plans can be more flexible in the types of benefits that they cover. Some cover services that are not part of the traditional Medicare benefit package, such as contraceptives, although the federal government has no requirement to cover such things. Medicare does not cover sterilization when it is not part of a necessary treatment for an illness or injury, nor would any payment be made for sterilization as a preventive measure. This includes the case when a primary care provider believes that pregnancy would cause overall endangerment to a woman's health or psychological well-being (CMS, 2011).

Medicaid

Medicaid, a program for certain low-income Americans jointly financed and operated by state and federal governments, offers coverage for many preventive services. Approximately 66 million individuals were covered by

Medicaid in 2010 (MACPAC, 2011). An estimated 30 million children in the United States are insured by Medicaid (KFF, 2011b), and it provides coverage for 40 percent of all births in the United States (Wier et al., 2010). With the exception of mandatory coverage for smoking cessation with no cost sharing for pregnant women (Section 4107), the ACA does not require that Medicaid cover preventive services with or without cost sharing. Rather, it includes an incentive for states to cover the services in the form of an increased 1 percent matching federal payment for these services to states that provide the recommended preventive services without cost sharing to their beneficiaries (Section 4106) (111th U.S. Congress, 2010). Figure 3-2 shows the numbers of states offering coverage for preventive services through Medicaid.

Today, Medicaid coverage of preventive services depends on the enrollees' age and state of residence. For children under age 21 years, the scope of coverage is comprehensive as a result of the Early Periodic Screening, Diagnostic, and Treatment Program. This mandatory program requires that

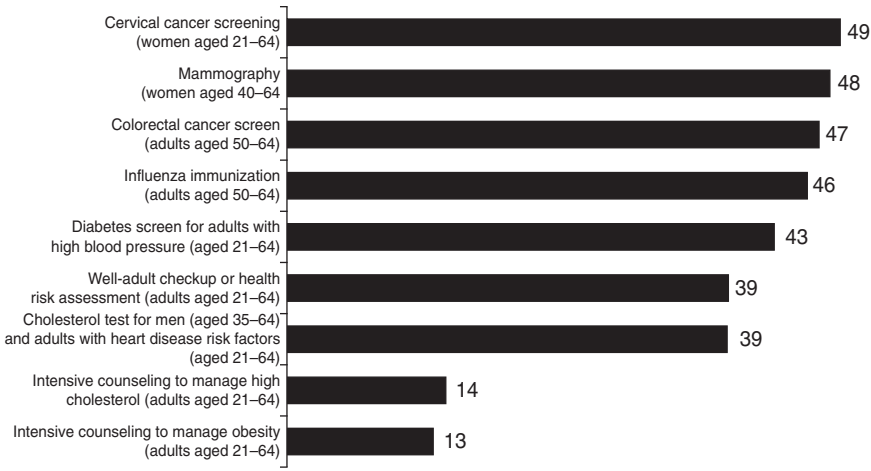

FIGURE 3-2 Number of state Medicaid programs that reported covering certain recommended preventive services for adults and health risk assessments or well-adult checkups. Although the USPSTF does not explicitly recommend well-adult checkups or health risk assessments for adults, such health care visits provide an opportunity to deliver recommended preventive services, such as blood pressure tests and obesity screenings. The data do not include the numbers for states that reported that a service is covered under the managed care program but not under the fee-for-service program.
SOURCE: Government Accountability Office analysis of survey of state Medicaid directors conducted between October 2008 and February 2009.

state Medicaid programs cover screening and diagnostic services, as well as the treatments needed to correct or improve the problems identified by the screening and diagnostic services. For children, the screening and preventive services typically include well-child visits, vision and dental screenings, and immunizations (CMS, 2005). State Medicaid programs are not permitted to charge cost sharing for services provided to children and pregnant women but may charge other eligible populations a nominal fee (SSA, 2011c).

For adults participating in Medicaid, preventive services are generally covered according to the recommendations of each state, but the preventive services for adults that the states cover vary considerably (GAO, 2009). For example, services such as cervical cancer screening and mammography were covered by nearly all state Medicaid programs, but far fewer states covered well-adult checkups or cholesterol tests (GAO, 2009). Coverage of screening and treatment for sexually transmitted infections is also typically included in almost all state Medicaid programs (Ranji et al., 2009a).

Family planning services, in contrast, are federally required for all states that participate in Medicaid. Since 1972, state Medicaid programs have been required to cover "family planning services and supplies furnished (directly or under arrangements with others) to individuals of childbearing age (including minors who can be considered to be sexually active), who are eligible under the State plan, and who desire such services and supplies" (SSA, 2011a). These services must be provided without cost sharing. In return, states receive a 90 percent federal match on the funds that they spend on these services (SSA, 2011b). All states provide coverage for family planning services and prescription contraceptive supplies, although coverage of nonprescription contraceptives, such as condoms and emergency contraceptives, and sterilization varies considerably from state to state (Ranji et al., 2009a).

Coverage of preconception counseling and other elements of preconception care are optional for state Medicaid programs and, as a result, are not as universally covered as contraceptives. Of the 44 states that responded to a 2008 Henry J. Kaiser Family Foundation survey, only 26 covered preconception counseling for women enrolled in Medicaid (Ranji et al., 2009a).

Medicaid is the largest payer of maternity services in the nation and provides coverage of a comprehensive range of pregnancy-related services for low-income women who qualify. These services, however, vary considerably from state to state. For example, in 2008, 24 out of 44 states responding to a national survey covered genetic counseling and 39 covered nutrition counseling and psychosocial counseling (Ranji et al., 2009b). Similarly, coverage of breastfeeding support services is also an optional Medicaid benefit and is more limited. Twenty-five of the 44 surveyed states covered breastfeeding education services, 15 states covered lactation con-

sultations, and 31 states covered breast pump rentals. Eight states did not cover any breastfeeding support services for women enrolled in Medicaid (Ranji et al., 2009b).

Children's Health Insurance Program

For low-income children whose family incomes exceed Medicaid eligibility levels, the Children's Health Insurance Program (CHIP) provides insurance coverage at generally affordable costs. Established in 1997, this federal block grant program to states provides state and federal funds to extend insurance coverage to low-income children. Each state may expand coverage by raising Medicaid income eligibility levels for families with children, establishing a separate state program, or designing a combination of the two approaches. In 2010, an estimated 7.7 million children and 347,000 parents and pregnant women who did not qualify for Medicaid were enrolled in CHIP at some point during the year (MACPAC, 2011).

CHIPs are prohibited from imposing cost sharing for well-baby and well-child care, including immunizations. Children who are covered through a CHIP Medicaid expansion option receive the same benefits as children who are covered through Medicaid. However, considerable variation in the scope of covered preventive services exists among the states, which operate separate programs. A 2001 review of CHIP coverage of reproductive health services conducted by the Guttmacher Institute found that of the 29 states that operated separate state programs, 16 specifically identified that family planning services and supplies were covered and most of the remaining plans covered these services through the general category "prenatal care and prepregnancy family planning services" (Gold and Sonfield, 2001). Most states also covered screening and treatment for sexually transmitted infections.

The 2008 CHIP Reauthorization Act made it easier for states to extend CHIP to cover pregnancy-related services through CHIP, and 18 states have done this either through extending eligibility to pregnant women or through a new option to extend eligibility to "unborn children" (KFF, 2011a). Like Medicaid, coverage for pregnant women under CHIP typically ends at 60 days postpartum. States that cover this group of women through the Medicaid expansion use Medicaid benefit rules.

U.S. Department of Veterans Affairs Health Care Services

The rising enlistment of women in active-duty military services has led to the growth in the numbers of women receiving care through VA. According to VA, women make up approximately 1.8 million of the nation's

23 million veterans and account for nearly 5.5 percent of veterans who use VA health care services (VA, 2011b).

The scope of care offered to women veterans is broad and includes the following preventive services important to women: health evaluation and counseling, disease prevention, nutrition counseling, weight control, smoking cessation, and substance abuse counseling and treatment, as well as gender-specific primary care, including Pap smears, mammogram, birth control, preconception counseling, human papillomavirus vaccine, and menopausal support (hormone replacement therapy). In addition, women receive coverage for "mental health, including evaluation and assistance for issues such as depression, mood, and anxiety disorders; intimate partner and domestic violence; sexual trauma; elder abuse or neglect; parenting and anger management; marital, caregiver, or family-related stress; and post-deployment adjustment or post-traumatic stress disorder (PTSD)" (VA, 2011b).

TRICARE

The U.S. Department of Defense operates TRICARE, a managed health care program for active-duty members of the military, families of active-duty service members, retirees and their families, and other beneficiaries from any of the seven services (TRICARE, 2011). Depending on their level of service, enrollees can choose from different coverage plans that have the same benefits but different provider networks and out-of-pocket spending requirements. TRICARE covers a broad range of preventive services for women enrollees, including contraceptive supplies, services, and sterilization; mammograms and physical breast examinations; counseling; maternity care; Pap smears (including human papillomavirus testing); and genetic testing.

Indian Health Service

American Indians and Alaska Natives who are members of federally recognized tribes are eligible to receive health care services without cost sharing though the IHS, which operates health care facilities on or near Indian reservations. Although a wide range of "health promotion and disease prevention services" (LII, 2010) are specified, the availability of the actual services for those using IHS services varies tremendously from region to region. Health promotion services whose provision is defined by Title 25 of the U.S. Code include smoking cessation, reduction in alcohol and drug misuse, improvement in nutrition, improvement in physical fitness, family planning, stress control, and pregnancy and infant care (including fetal alcohol syndrome prevention). The disease prevention services covered

under Title 25 include immunizations, control of high blood pressure, control of sexually transmitted diseases, prevention and control of diabetes, control of toxic agents, occupational safety and health, accident prevention, fluoridation of water, and control of infectious agents (LII, 2010). Screening mammography is also included as a covered benefit for women.

DISCUSSION

Growing attention to the importance of preventive care in both federal- and state-supported and private-sector plans has been seen in recent years. Despite this attention, coverage of preventive services in both the private and public sectors is uneven at best. Heavy reliance has been placed on the clinical guidance promulgated by the USPTSF, but adoption of the full range of services is still not the norm. Some programs and plans have provided more limited coverage, whereas others are broader in scope, providing coverage for preventive services like preconception counseling, contraceptive services and supplies, and well-woman visits, despite their absence from these recommendations. The ACA requirements will make important strides in ensuring that most Americans have coverage for the full range of recommended preventive services.

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4

Committee Methodology

This chapter outlines the methodology that the Institute of Medicine Committee on Preventive Services for Women used to identify preventive services necessary for women's health and well-being that are not included in the United States Preventive Services Task Force (USPSTF) Grade A and B recommendations, Bright Futures' recommendations, or the Advisory Committee on Immunization Practices (ACIP) guidelines and to identify specific services that could supplement the current list of preventive services recommended for women under the Patient Protection and Affordable Care Act of 2010 (ACA). The committee's first step in this process was to review and reach an understanding of the guidelines of these analytic bodies. The second step was to assemble and assess additional evidence, including reviews of the literature, federal health priority goals and objectives, federal reimbursement policies, and professional clinical guidelines. The committee also considered comments submitted by the public. Finally, the committee recommended preventive services that the Secretary of the U.S. Department of Health and Human Services (HHS) should consider in developing a comprehensive package of preventive services for women to be included under the ACA.[1]

REVIEW OF USPSTF RECOMMENDATIONS

The USPSTF process was developed to provide guidance to primary care providers. The committee's approach to identifying gaps in existing

[1] One committee member's dissenting comments regarding much of the study process are included in Appendix D.

services accounts for contextual issues beyond traditional research evidence used by the USPSTF. The committee looked at women's preventive service needs more broadly to account for women's health and well-being.

The committee found that the USPSTF Grade A and B recommendations required close examination. The specificity of several recommendations is not clear in some cases, including such details as the periodicity of screenings or how the service is to be delivered. For example, the Grade B recommendation for screening for depression could be interpreted to be universal screening, under the assumption that the primary care provider offices offering the service have adequate staff in place to support the correct delivery of the service, or the USPSTF's recommendation could be interpreted narrowly to include screening only in those practices that have a certified depression screening quality assurance program in place. Thus, after a review of the supporting evidence that led to their recommendations, the committee decided that it was important to note its interpretation of the Grade A and B recommendations in those cases in which specific aspects of the recommendation were found to be ambiguous (see Table 5-1). The committee also compared the USPSTF guidelines with the guidelines of other professional organizations to identify potential gaps.

The USPSTF Grade C and I statements (Table 4-1) also required further analysis by the committee because in neither case had the USPSTF intended its conclusions to limit or preclude consideration for coverage. The USPSTF informally refers to Grade C recommendations as close calls in which the balance of potential benefits and harms does not strongly favor the clinician recommending the preventive service to all patients, although it may be appropriate in some cases. The USPSTF makes the point that either choosing or not choosing the service with a Grade C recommendation would be within the standard of care and assumes that the service would be covered if clinically appropriate (USPSTF, 2008). The USPSTF also considers decision making to be a shared activity of the patient and the provider based on the individual circumstances of the patient.

The Grade I statement is a conclusion that the evidence is "insufficient to conclude whether the service is effective or not because evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined" (USPSTF, 2008). The I statement simply means that important outcomes have not yet been adequately evaluated by current research. The committee notes that from a coverage perspective, the evidence supporting many clinical interventions in common use, whether in prevention or in general medical practice, is insufficient or unclear, and that coverage decisions may be made or have been made on the basis of other factors. For example, although knowledge of the evidence for the benefits and harms of services and screenings informs a primary care provider's

TABLE 4-1 USPSTF Grade C Recommendations and I Statements

Topic	Description	Grade
Additional risk factors for intermediate coronary heart disease (CHD) risk: screening	The U.S. Preventive Services Task Force (USPSTF) concludes that the evidence is insufficient to assess the balance of benefits and harms of using the nontraditional risk factors discussed in this statement to screen asymptomatic men and women with no history of CHD to prevent CHD events (select "Clinical Considerations" for suggestions for practice when evidence is insufficient).	I
Avoidance of alcohol use counseling	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of routine counseling of all patients in the primary care setting to reduce driving while under the influence of alcohol or riding with drivers who are alcohol-impaired.	I
Back pain: counseling	The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of interventions to prevent low back pain in adults in primary care settings.	I
Bacterial vaginosis screening: pregnant women	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for bacterial vaginosis in asymptomatic pregnant women at high risk for preterm delivery.	I
Breast cancer screening	The USPSTF concludes that the evidence is insufficient to recommend for or against routine clinical breast examination alone to screen for breast cancer.	I
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.	I
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.	I
CHD risk assessment	The USPSTF concludes that the evidence is insufficient to assess the balance of benefits and harms of using the nontraditional risk factors discussed in this statement to screen asymptomatic men and women with no history of CHD to prevent CHD events	I
CHD screening	The USPSTF found insufficient evidence to recommend for or against routine 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 CHD events in adults at increased risk for CHD events.	I
Chlamydial infection screening: non-pregnant women	The USPSTF recommends against routinely providing screening for chlamydial infection for women aged 25 and older, whether or not they are pregnant, if they are not at increased risk.	C

continued

TABLE 4-1 Continued

Topic	Description	Grade
Cholesterol abnormalities screening	The USPSTF makes no recommendation for or against routine screening for lipid disorders in men aged 20 to 35, or in women aged 20 and older who are not at increased risk for coronary heart disease.	C
Colorectal cancer screening	The USPSTF concludes that the evidence is insufficient to assess the benefits and harms of computed tomographic colonography and fecal DNA testing as screening modalities for colorectal cancer.	I
Depression screening: adults	The USPTF recommends against routinely screening adults for depression when staff-assisted depression care supports are not in place. There may be considerations that support screening for depression in an individual patient.	C
Diabetes screening	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for type 2 diabetes in asymptomatic adults with blood pressure of 135/80 mm Hg or lower.	I
Diet 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
Drug use screening	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening adolescents, adults, and pregnant women for illicit drug use.	I
Family violence screening	The USPSTF found insufficient evidence to recommend for or against routine screening of parents or guardians for the physical abuse or neglect of children, of women for intimate partner violence, or of older adults or their caregivers for elder abuse.	I
Gestational diabetes screening	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for gestational diabetes.	I
Glaucoma screening	The USPSTF found insufficient evidence to recommend for or against screening adults for glaucoma.	I
Gonorrhea screening: pregnant women	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.	I
Hepatitis B screening	The USPSTF recommends against routinely screening the general asymptomatic population for chronic hepatitis B virus infection.	I
Hepatitis C screening	The USPSTF found insufficient evidence to recommend for or against routine screening for HCV infection in adults at high risk for infection.	I

TABLE 4-1 Continued

Topic	Description	Grade
Human immunodeficiency virus (HIV) 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	C
Lung cancer screening	The USPSTF concludes that the evidence is insufficient to recommend for or against screening asymptomatic persons for lung cancer with either low dose computerized tomography (LDCT), chest X-ray (CXR), sputum cytology, or a combination of these tests.	I
Motor vehicle restraint counseling	The USPSTF concludes that the current evidence is insufficient to assess the incremental benefit, beyond the efficacy of legislation and community-based interventions, of counseling in the primary care setting, in improving rates of proper use of motor vehicle occupant restraints (child safety seats, booster seats, and lap-and-shoulder belts).	I
Obesity screening and 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.	I
Obesity screening and 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.	I
Oral cancer screening	The USPSTF concludes that the evidence is insufficient to recommend for or against routinely screening adults for oral cancer.	I
Physical activity counseling	The USPSTF concludes that the evidence is insufficient to recommend for or against behavioral counseling in primary care settings to promote physical activity.	I
Sexually transmitted infections (STIs) counseling	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of behavioral counseling to prevent STIs in nonsexually-active adolescents and in adults not at increased risk for STIs.	I
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.	I
Skin cancer screening	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of using a whole-body skin examination by a primary care clinician or patient skin self-examination for the early detection of cutaneous melanoma, basal cell cancer, or squamous cell skin cancer in the adult general population.	I
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.	I

continued

TABLE 4-1 Continued

Topic	Description	Grade
Thyroid disease screening	The USPSTF concludes the evidence is insufficient to recommend for or against routine screening for thyroid disease in adults.	I
Vitamin supplementation for disease prevention	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	I

SOURCE: USPSTF, 2011.

decision for each patient, in many instances, research either is inconclusive or has not been conducted.

The Institute of Medicine (IOM) report on women's health research identified many areas in which research is needed (IOM, 2010). For example, the report indicated a lack of large-scale studies identifying effective gender- and age-specific interventions involving modification of lifestyle and other behaviors that affect health, such as alcohol abuse and obesity. Furthermore, determining the evidence for the value of certain services is challenging, because it is difficult to prove the effectiveness of an intervention across the life span. For example, prevention interventions that should be conducted early in the life span (e.g., skin cancer prevention) require decades to demonstrate effectiveness.

Each of the Grade C and I recommendation statements and the evidence supporting them were collected and reviewed. The committee's evaluation included reviewing relevant supporting USPSTF publications, other peer-reviewed research and clinical articles, and clinician fact sheets. The committee did not reassess the Grade D recommendations, given the evidence base driving the USPSTF to recommend against providing these services. Additional literature searches were conducted to identify randomized control trials that were conducted after the USPSTF recommendation was released for each of the Grade C and I recommendations. Furthermore, the committee compared the Grade C and I guidelines with guidelines from other professional groups.

REVIEW OF BRIGHT FUTURES RECOMMENDATIONS

The committee reviewed all Bright Futures guidelines and compared them with the USPSTF guidelines for adolescents. The committee noted that the methodology that Bright Futures uses to develop recommendations is considered "evidence informed" and includes expert opinion. Bright

Futures also uses a more comprehensive focus on health promotion and disease prevention, on the basis of its criteria for the burden of the condition (AAP, 2008).

For the committee, the principal challenge in identifying preventive services to supplement the guidance from Bright Futures was to disaggregate the health supervision visits recommended by Bright Futures and some of its anticipatory guidance into conditions and preventive measures fitting the committee's overall approach. The committee considered the sample questions and advice suggested in the anticipatory guidance section of the *Bright Futures* report to be preventive services to be covered under the ACA. According to the guidelines, these preventive services should be addressed in an annual visit of sufficient length to cover age- and sex-appropriate topics in the health domain. Thus, the topics of physical growth and development, social and academic competence, emotional well-being, risk reduction, and violence and injury prevention, as well as the sample questions and suggested guidance for both the parents and the adolescent, are expected to be addressed at each and every annual visit. The task of addressing each and every one of the suggested topics during a yearly visit seemed daunting to the committee. However, the committee assumes that primary care providers will identify priorities from this section on the basis of the unique circumstances of each patient.

REVIEW OF ACIP RECOMMENDATIONS

The committee reviewed ACIP General Recommendations on Immunization, which include all Food and Drug Administration-approved immunizations recommended for the general population of adolescent and adult women (CDC, 2011; Smith et al., 2009). In addition, to assess potential supplemental immunizations, the committee reviewed the immunizations recommended for high-risk groups and for individuals in special circumstances to determine whether some substantial subpopulation of women, clearly defined, might warrant further attention. Although literature searches were conducted to identify areas where supplemental immunization recommendations might be warranted, the committee identified little evidence to indicate clear deficiencies in existing ACIP recommendations.

FURTHER COMMITTEE CONSIDERATIONS

The committee reviewed both oral and written public comments submitted throughout the course of the study. Some of these comments were from experts, individuals expressing personal experiences with preventable conditions, and members of the U.S. Congress. All of these comments contained recommendations for the committee's consideration. Additionally,

several nongovernmental organizations submitted research studies, public statements, and recommended guidelines for preventive services for women. The committee reviewed all of this information.

The committee also invited researchers and leaders of organizations to deliver presentations in areas where the committee believed that it could benefit from their expertise. These included, for example, presentations on mental health, oral health, occupational health, and the perspectives of employers and health insurers. The committee invited speakers who requested the opportunity in addition to inviting individuals with expertise in potential gap areas or individuals identified as having a perspective that the committee should consider. Furthermore, the committee reviewed HHS documents relating to prevention priorities and reimbursement policies. It also reviewed the existing coverage practices of national, state, and private health plans (these are detailed in Chapter 3). In some cases, committee members also identified current practice in clinical care by using sources such as the British Medical Journal Best Evidence and UpToDate (BMJ Clinical Evidence, 2011; UpToDate Inc., 2011). Finally, the committee also used the 2011 IOM report *Leading Health Indicators for Healthy People 2020* as a tool to perform horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify potential gaps (IOM, 2011).

Committee Analysis

The product of these reviews was an array of areas in which supplemental preventive measures might be warranted. Some of these areas were identified on the basis of traditional indicators such as morbidity and mortality, whereas others were more generally identified to be supportive of a woman's well-being. Adhering to the definitions described in Chapter 1, the committee focused on conditions unique to women or that affect women in some specific or disproportionate way. In general, the committee used criteria adapted from the USPSTF that consider frequency, severity, morbidity, mortality, and quality of life to bring consistency to the analyses.

For each potential supplemental preventive measure considered, an extensive comparison with the guidelines of professional organizations (e.g., American Academy of Family Physicians, American College of Physicians, American College of Obstetricians and Gynecologists, American Cancer Society, American Medical Association) was conducted to understand these guidelines development processes and the evidence that the organizations use to reach their conclusions. Many of these guidelines are posted in the Agency for Healthcare Research and Quality's National Guidelines Clearinghouse. The committee also performed targeted literature searches.

Identifying Potential Supplemental Preventive Measures

The committee then attempted to identify preventive measures that were aimed at filling the gaps that it had identified. In most cases, the committee found that measures had already been proposed by the other organizations mentioned above. The committee also eliminated preventive measures that, even at this early stage in the analysis, were clearly not developed, tested, or known well enough to have a measurable impact. The resulting product of this step was a series of areas with gaps, with the accompanying preventive measure or measures that could be considered by the Secretary for HHS for inclusion in guiding policy and program development relating to the ACA.

Identifying Gap Areas and Measures with Adequate Evidence

The core of the committee's task was to assemble the evidence that would allow it to recommend consideration of a preventive service. The committee found that systematic reviews of clinical effectiveness were not available to address all the potential gaps and that a standard methodology addressing coverage of preventive services does not exist. These two issues are discussed below.

Reviews of Clinical Effectiveness

Assessment of the efficacy and effectiveness of preventive measures to provide clinical guidance was one of the topics of clinical focus that, more than 30 years ago, launched the change in the approach to health care delivery that is now called evidence-based medicine. The USPSTF and its Canadian sister organization, the Canadian Taskforce on Preventive Health Care, were active at the beginning of this movement, with a major focus being on developing the methodology. Since the 1980s, the standards for judging the effectiveness of preventive measures have matured, and the bar for determining the effectiveness of preventive measures has been set very high. Furthermore, for a number of reasons, including ethical constraints, the evidence bar is usually set higher for preventive services than for the services offered in many other areas of conventional medical care. It is generally assumed that a preventive service intended for the general population should have proven benefits and minimal harms, with the benefits clearly outweighing the harms. As noted below, the committee had neither the time and resources nor a charge to conduct its own systematic reviews, which, using the USPSTF as an example, often take 12 to 18 months for a single topic.

Methodologies with a Coverage Decision as the Goal

The USPSTF, Bright Futures, and ACIP focus on the provision of guidance to clinicians and patients, not on insurance coverage. Decision making about covering a preventive service may consider a host of other issues, such as established practice; patient and clinician preferences; availability; ethical, legal, and social issues; and availability of alternatives. Further complicating matters, special population groups, such as minority populations, recent immigrants, lesbians, prisoners, and those employed in high-risk environments, may have different health needs or benefit from different preventive services. In addition, high-risk groups, population subsets, and special populations are unevenly identified and are addressed at varying degrees in current guidelines. Finally, because cost was explicitly excluded as a factor that the committee could use in forming recommendations, the committee process could not evaluate preventive services on the basis of cost.

Against this background, the committee selected a hybrid approach that collected relevant evidence for each measure, and it determined that the question of a methodology to fully address insurance coverage was beyond its scope. Four categories of evidence—posed in the form of questions—were developed to systematically query support for each potential preventive measure. The committee neither formally ranked or assigned weights to the categories, nor did it stipulate that evidence in any one category would automatically result in a recommendation for a measure or service to be considered. Instead, the queries and categories were used to consider the range of evidence and to ensure consistency in the committee's analysis and deliberations. Many of the recommendations are supported by more than one category of evidence.

Category I. Are high-quality systematic evidence reviews available indicating that the service is effective in women?

Category II. Are quality peer-reviewed studies available demonstrating effectiveness of the service in women?

Category III. Has the measure been identified as a federal priority to address in women's preventive services?

Category IV. Are there existing federal, state, or international practices, professional guidelines, or federal reimbursement policies that support the use of the measure?

RECOMMENDATIONS ON PREVENTIVE SERVICES TO BE CONSIDERED IN DEVELOPMENT OF COMPREHENSIVE GUIDELINES

Subcommittees queried the available evidence applicable to potential preventive measures and assigned the evidence to one or more of the categories listed above. Each subcommittee then brought its analysis of the range of evidence before the full committee for deliberation. The committee combined the burden of the condition and its potential impact on health and well-being with the array of available evidence and support noted above to come to a consensus over whether to recommend that a specific preventive measure be considered by the Secretary. As is true in most analytical processes in decision making, evidence and expert judgment are inextricably linked; thus, the expert judgments of the committee members also played a role in decision making.

In general, preventive measures recommended by the committee met the following criteria:

- The condition to be prevented affects a broad population;
- The condition to be prevented has a large potential impact on health and well-being; and
- The quality and strength of the evidence is supportive.

Ultimately, the decision to develop a recommendation for a preventive measure or service was made after a thoughtful review and debate of each of the subcommittee's reports. Recommendations were made when the evidence was found compelling based on the committee's interpretation of the strength of the evidence. In Chapters 5, the committee describes the evidence that factored into its decision making for each supplemental preventive measure recommendation.

In some instances, a subcommittee's analysis resulted in the development of a clarifying statement (added to Table 5-1) on the committee's interpretation of current USPSTF guidelines. In other cases, the subcommittee's analysis suggested a service that could be considered part of a well-woman visit (Table 5-6). These are addressed in Appendix A of this report.

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5

Recommendations

This chapter describes the committee's recommendations for preventive services necessary for women's health and well-being that are not included in the United States Preventive Services Task Force (USPSTF) Grade A and B recommendations, Bright Futures, and Advisory Committee on Immunization Practices (ACIP) guidelines, and that could supplement the current list of preventive services for women recommended under the Patient Protection and Affordable Care Act of 2010 (ACA). The committee's recommendations regarding chronic diseases, sexual and reproductive health conditions, interpersonal and domestic violence, and well-woman visits follow.

The committee also provided interpretations for unclear USPSTF Grade A and B recommendations as described in Chapter 4; these are annotated in Table 5-1. Clarifying statements for osteoporosis screening and tobacco use have also been added. The rationale for including these two statements is presented in Appendix A.

DIABETES AND GESTATIONAL DIABETES

Diabetes mellitus (DM) is a syndrome characterized by either an absolute or a relative deficiency of insulin in various organ systems of the body. The inability of these organ systems to utilize glucose thus exposes all tissues of the body to chronic excess glucose in the bloodstream, or hyperglycemia (ADA, 2011a). DM has three main types: type 1, type 2, and gestational DM. Only about 5 percent of people with diabetes in the United States have type 1 diabetes, which results from the body's failure to produce insulin (ADA, 2011a). Type 2 diabetes, which accounts for about

TABLE 5-1 Grade A and B Recommendations with Committee Interpretations and Clarification Statements

Topic	USPSTF Recommendation	USPSTF Grade	IOM Committee Interpretation
Alcohol misuse counseling	The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.	B	Annual screening with approved screening instrument.
Anemia screening: pregnant women	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B	Screening in each trimester.
Blood pressure screening	The USPSTF recommends screening for high blood pressure in adults aged 18 and older.	A	Annual screening.
BRCA screening, counseling about	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.	B	Referral for genetic counseling and testing, if appropriate.
Breast cancer preventive medication	The USPSTF recommends that clinicians discuss chemoprevention 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.	B	Medication provided if indicated.
Depression screening: adolescents	The USPSTF recommends screening of adolescents (12–18 years of age) for major depressive disorder when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.	B	Annual depression screening.
Depression screening: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B	Annual depression screening.
Diabetes screening	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B	Annual screening.

TABLE 5-1 Continued

Topic	USPSTF Recommendation	USPSTF Grade	IOM Committee Interpretation
Human immunodeficiency virus HIV screening	The USPSTF strongly recommends that clinicians screen for HIV all adolescents and adults at increased risk for HIV infection.	A	Annual screening.
Obesity screening and counseling: adults	The 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.	B	Annual screening.
Osteoporosis screening: women	The USPSTF recommends that women aged 65 and older be screened routinely for osteoporosis and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has not additional risk.	B	Women with previous fractures and women with secondary causes of osteoporosis are suggested to be included (see Appendix A).
Tobacco use counseling and interventions: nonpregnant adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A	Annual screening. Counseling and Food and Drug Administration (FDA)-approved and over-the-counter medications are suggested (see Appendix A).
Tobacco use counseling: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke.	A	Discussion at each prenatal visit. It is appropriate for pregnant women who smoke to receive counseling that is tailored to their needs.
Syphilis screening: nonpregnant persons	The USPSTF strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A	Annual screening.
Syphilis screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A	Screening at first prenatal visit, and as indicated if at high risk.

90 to 95 percent of the cases of diabetes in the United States, results from the body's inability to produce sufficient amounts of insulin as well as its resistance to insulin, which means that the body does not use insulin effectively (NIDDK, 2008).

Gestational diabetes mellitus (GDM) is diabetes that arises or is diagnosed in pregnancy, typically during the second and third trimesters of pregnancy. It accounts for about 135,000 diabetic patients annually in the United States and occurs in approximately 2 to 10 percent of pregnant women (NIDDK, 2011). Although most women recover from GDM after giving birth, they have an increased risk of developing type 2 diabetes in the future (Turok et al., 2003). Furthermore, their offspring are at significantly increased risk of being overweight and insulin resistant throughout childhood (Boerschmann et al., 2010).

Prevalence/Burden

Almost 25.8 million Americans, or 8.3 percent of the population, have diabetes, which is widely recognized as one of the leading causes of death and disability in the United States (CDC, 2011c). By 2050, it is estimated that the rate of adult diabetes in the United States will triple, from 1 in 10 now to 1 in 3 (Boyle et al., 2010).

No striking gender difference in the rates of diabetes exist between men and women in the United States (ADA, 2011b). However, a gender difference in the burden of this disease does appear to exist. Narayan and colleagues (2003) found that women have a significantly higher estimated lifetime risk of developing diabetes than men (38.5 percent for females versus 32.8 percent for males born in 2000). The authors further estimated that women diagnosed with diabetes at age 40 years will lose 14.3 life-years and 22 quality-adjusted life years, whereas the length of life lost for men diagnosed with diabetes at the same age are 11.6 life-years and 18.6 quality-adjusted life-years, respectively.

The consequences of diabetes appear to be more severe for women as well. In a study to assess whether trends in mortality rates among adults with diabetes had changed, Gregg and colleagues found that between the 1971 to 1986 and 1988 to 2000 survey periods for the National Health and Nutrition Examination Survey, the all-cause mortality rate for men with diabetes decreased by 18.2 deaths per 1,000 persons annually (from 42.6 to 24.4 deaths per 1,000 persons annually), whereas for diabetic women, the all-cause mortality rate more than doubled (from 8.3 to 18.2 deaths per 1,000 persons annually) (Gregg et al., 2007).

Furthermore, recent data indicate that women with diabetes are at high risk for developing cardiovascular disease. Women with diabetes were found to be four to six times more likely to develop cardiovascular disease

than women who do not have diabetes (Rivellese et al., 2010). Women with diabetes are more than three times more likely to have a stroke as women without diabetes but no prior history of a cardiovascular event. In fact, women with diabetes have a stroke risk profile similar to that of non-diabetic women who have had a prior stroke (Ho et al., 2003).

In addition to having one of the highest diabetes rates in the world (8.3 percent), the United States has the highest rates of GDM in the world, with as many as 2 to 10 percent of pregnancies being complicated by GDM each year (Danaei et al., 2011; NIDDK, 2011). This may be in part due to increased screening conducted in the United States. Although the incidence of preexisting diabetes in pregnancy has increased over the past decade, the incidence of GDM has remained relatively stable since the late 1990s because of better recognition of the disease and more aggressive intervention, according to a Southern California Kaiser Permanente study (Lawrence et al., 2008). This suggests that the complications of GDM for both mother and infant can be reduced even further by better detection and prevention and more aggressive management of this condition (Crowther et al., 2005; Langer et al., 2005).

Many women who are first diagnosed with diabetes during pregnancy are classified as having GDM. However, it is possible that many had pre-existing or pregestational type 2 diabetes. Indeed, the majority of women with GDM seem to have β-cell dysfunction that appears on a background of chronic insulin resistance already present before pregnancy (Buchanan, 2001).

If a woman who has had GDM is not tested after delivery, the diabetes may have persisted and her next pregnancy may be incorrectly classified as recurrent GDM instead of preexisting diabetes. This distinction is important, because preexisting diabetes could be associated with more serious consequences for the fetus, including cardiac, neurological, and vascular anomalies, than diabetes that arises in the second and third trimesters of pregnancy (Jenkins et al., 2007; Ornoy, 2005; Sivan et al., 2004).

Cases of GDM increase with maternal age and occur 7 to 10 times more often among pregnant women age 24 and older than among women younger than 24 years old (Reece, 2010), suggesting that universal screening may be the most effective in the latter group (Marquette et al., 1985). GDM is itself a risk factor for type 2 diabetes. Women who have GDM during pregnancy have a seven-fold increased risk for the development of type 2 diabetes after delivery, which persists for their lifetime (Reece et al., 2009). One large, population-based study of 659,000 women found that 20 percent of women with GDM progressed to type 2 diabetes within nine years of pregnancy (Feig et al., 2008). Furthermore, the children of women with a history of GDM are at an increased risk for obesity and diabetes compared to other children (Reece, 2010).

Diabetes care costs the United States an estimated $174 billion annually, including both indirect and direct costs (ADA, 2011a). The United States spends more than half (54 percent) of the global expenditure on diabetes care and is expected to still be doing so by 2030, when it will spend an estimated $264 billion annually (Zhang et al., 2010).

Risk Factors for Diabetes

The primary risk factors for type 1 diabetes are genetics and family history (ADA, 2011a), diseases of the pancreas (Buxbaum and Eloubeidi, 2010), and infections or illnesses (Hober and Sane, 2010). The number one risk factor for type 2 diabetes is obesity (Chan et al., 1994; Colditz et al., 1995). Besides obesity, other risk factors for developing type 2 diabetes include impaired glucose tolerance or impaired fasting glucose, insulin resistance, ethnic background, high blood pressure, a history of gestational diabetes, a sedentary lifestyle, family history, polycystic ovary syndrome, and older age (ADA, 2011a).

A number of risk factors have been consistently linked to the development of GDM during pregnancy, including a history of GDM in a prior pregnancy, previously having had a large for gestational age (LGA) infant, obesity, a strong immediate family history of type 2 diabetes or GDM and a history of unexplained fetal death (Mayo Clinic, 2011).

Obesity

Obesity is an excess amount of subcutaneous body fat in proportion to lean body mass. (CDC, 2010d). The most common measure of obesity is the body mass index (BMI). If BMI is 25 to 29.9, an individual is considered overweight; a person is considered obese when his/her BMI, is greater than 30.

The rapid increase in diabetes in recent decades has closely paralleled the increase in obesity and overweight in the general population (Wang et al., 2008). The United States currently has the highest obesity rate in the world, with more than 30 percent of adults, or 77 million, considered obese. By 2030, if the secular rate of increase continues, it is estimated that nearly 90 percent of Americans will be overweight and 51 percent will be obese (Wang et al., 2008). Obesity recently passed smoking as America's greatest health threat, at least as measured by quality-adjusted life-years (QALYs) lost (Jia and Lubetkin, 2010). Obesity-related diseases account for nearly 10 percent of all medical spending in the United States (Finkelstein et al., 2009). Greater weight means a higher risk of insulin resistance, because fat interferes with the body's ability to use insulin.

Overall there are a variety of factors that play a role in obesity. This makes it a complex health issue to address. The risk factors for obesity include overeating; lack of exercise; genetics; environment; and some diseases and drugs. However, experts have concluded that the two chief causes of obesity are a sedentary lifestyle and the overconsumption of high-calorie foods (Vainio and Bianchini, 2002). Thus, most obesity interventions are directed toward modifying these two lifestyle factors.

The USPSTF recommends screening for type 2 diabetes only in asymptomatic adults with a sustained blood pressure of greater than 135/80 mm Hg and found insufficient evidence to support screening in asymptomatic adults with lower blood pressure levels. Bright Futures does not specifically address screening for diabetes.

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg. Grade B Recommendation (USPSTF, 2008b).

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for type 2 diabetes in asymptomatic adults with blood pressure of 135/80 mm Hg or lower. Grade I Statement (USPSTF, 2008b).

The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for gestational diabetes. Grade I Statement (USPSTF, 2008a).

The USPSTF recommends that all clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults. Grade B Recommendation (USPSTF, 2003).

The U.S. Department of Veterans Affairs (VA) and the U.S. Department of Defense (DOD) Clinical Practice Guidelines recommend that physicians consider screening for diabetes and encourage aerobic exercise and diet to achieve weight loss and prevent the progression of pre-diabetes to diabetes (VA, 2010). Numerous health professional associations and other organizations recommend screening for diabetes as part of preventive care for women. The American Diabetes Association, for example, recommends

that physicians consider testing for diabetes in all adults who are overweight and who have additional risk factors and all adults 45 years and older not exhibiting these conditions (Zinman et al., 2010).

Guidelines for GDM Screening

Little evidence indicates that screening for GDM improves health outcomes. For this reason, the USPSTF concluded that the evidence is insufficient to recommend for or against routine screening for gestational diabetes. However, according to the USPSTF, "clinicians should discuss screening for GDM with their patients and make case-by-case decisions. Discussions should include information about the uncertainty of benefits and harms as well as the frequency of positive screening test results." Women at increased risk include women who are obese, older than 25 years of age, have a family history of diabetes, have a history of previous GDM, or are of certain ethnic groups (Hispanic, American Indian, Asian, or African-American). There are no existing interventions to prevent GDM from occurring in pregnancy. However, some bodies have considered it important to screen pregnant women for GDM because these women are at increased risk for having infants with excessive birth weight and require operative delivery or infants with increased neonatal morbidity.

The U.S. Indian Health Service (IHS), VA, and the DOD Clinical Management Guideline for the Management of Pregnancy, for example, recommend routine screening of all pregnant women for GDM at 24 to 28 weeks of gestation (VA, 2009). While the American Academy of Family Physicians (AAFP) recognizes that more studies are needed to unequivocally support the benefit of universal screening for GDM, it also identifies that universal screening for GDM at 24 to 28 weeks of gestation is recommended by many experts. The recommendation is based on consensus, disease-oriented evidence, expert opinion, and case series (Serlin and Lash, 2009). In support of the recommendation, AAFP also notes that most obstetric practices employ this strategy. The American Congress of Obstetricians and Gynecologists (ACOG), in its Clinical Management Guidelines for Obstetrician-Gynecologists on gestational diabetes (ACOG, 2001), recommends screening for GDM at 24 to 28 weeks of gestation. Its recommendation is based on limited or inconsistent scientific evidence. Other organizations with guidelines include the National Collaborating Centre for Women's and Children's Health, the American Heart Association, the Endocrine Society, and the National Kidney Foundation.

Effective Interventions

The value of early detection of diabetes, other than type 1 diabetes, remains controversial because of the lack of an established evidence base. Randomized trials have established the benefits of interventions to prevent or delay diabetes (Knowler et al., 2002; Tuomilehto et al., 2001) and to reduce diabetes-related complications (UKPDS, 1998). However, no randomized control trial has established the benefits of early detection of diabetes. Several major studies have demonstrated that delaying and/or aggressively managing diabetes can ameliorate many of its negative consequences for women and their children.

The Diabetes Control and Complications Trial (DCCT), an almost 10-year study sponsored by the National Institutes of Health found that maintaining blood glucose levels as close to normal as possible slowed the development and progression of the eye, kidney, and nerve damage caused by diabetes (Genuth, 2006). It also found that any sustained lowering of blood glucose was beneficial. The most significant side effect of intensive treatment in the DCCT was an increase in the risk for hypoglycemia, or low blood glucose, including episodes severe enough to require additional medical assistance (Genuth, 2006).

The Diabetes Prevention Program (DPP), another intervention study, was designed to assess whether modest weight reduction through dietary changes and increased physical activity or treatment with oral diabetes medication could prevent or delay the onset of type 2 diabetes. Results from this study showed that participants who were pre-diabetic could sharply reduce their risk of developing diabetes with a modest loss of weight through dietary changes and increased physical activity (The Diabetes Prevention Program Research Group, 2000). Taking oral diabetes medication could also reduce risk, although less dramatically.

Since the conclusion of the DPP study, additional data analyses continue to provide important insights into the value of lifestyle changes in helping people prevent type 2 diabetes and its complications. One analysis found that DPP participants with specific genetic profiles had a significantly increased risk of developing diabetes and selective responses to specific interventions (Florez et al., 2007). It is possible that subgroups of individuals will not respond well to standard interventions or that some responders may respond very well to a particular treatment on the basis of their genetic profile.

Nutritional support and exercise also can have a significant impact on the incidence and severity of diabetes. The DPP found that just 30 minutes of moderate physical activity a day, coupled with a 5 to 10 percent reduction in body weight, produced a 58 percent reduction in the incidence of diabetes (Knowler et al., 2002).

The current evidence of the efficacy of obesity prevention and interven-

tions is based on a very small number of studies (Lemmens et al., 2008). Some studies showed a positive impact of the intervention on BMI or weight status, but there is too much heterogeneity in terms of study design, theoretical underpinning, and target population to be able to draw firm conclusions about which intervention approaches are more effective than others (Lemmens et al., 2008). More research is urgently needed to extend the body of evidence in this area of prevention.

The only intervention for obesity that has been shown to have great benefit for preventing other complications of obesity is surgery (Valezi et al., 2010). Gastric bypass surgery has been shown to ameliorate diabetes (Gill et al., 2011) and cardiovascular morbidity and mortality (Pontiroli and Morabito, 2011). However, this is an invasive surgical intervention, and an estimated 5 percent or more of people have serious or life-threatening complications after gastric bypass surgery (Picot et al., 2009).

Identified Gaps

The primary gaps in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) were screening for diabetes in all women and screening for gestational diabetes among pregnant women, especially those identified to be at high risk for developing gestational diabetes. The committee found insufficient evidence to support screening for diabetes in all women.

The evidence provided to support a recommendation for gestational diabetes is based on current federal practice policy from IHS and the VA as well as current practice and clinical professional guidelines such as those set forth by AAFP and ACOG.

Recommendation 5.1: The committee recommends for consideration as a preventive service for women: screening for gestational diabetes in pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.

CERVICAL CANCER

Invasive cervical neoplasia is a low-prevalence cancer with a lengthy pre-invasive phase that is amenable to screening and early detection. Current USPSTF screening recommendations do not yet address the potential role of high-risk (oncogenic) human papillomavirus (HPV) DNA testing within practice of screening for invasive cervical neoplasia (USPSTF, 2003a). High-risk HPV DNA testing detects the viral types most commonly associated with the development of cancer.

Persistent infection with 1 of 20 high-risk HPV types is the necessary precursor for the development of squamous cell carcinoma and adenocarcinoma of the uterine cervix (Plummer et al., 2007; Walboomers et al., 1999; WHO, 2005). HPV infection is highly prevalent and is sexually acquired with the onset of sexual intercourse, typically resolving within 24 months (Insinga et al., 2007; Khan et al., 2005). Progression from persistent infection to precursor lesion (high-grade squamous intraepithelial lesion or cervical intraepithelial neoplasia [CIN] grade 2 [CIN2] or CIN3) can be a lengthy process, with the 10-year risk for the development of these lesions (even for the highest-risk viral types) being approximately 17 percent (Khan et al., 2005). Even after precursor lesions, the risk of progression to invasive disease is about 31 percent in 30 years (McCredie et al., 2008). On the basis of the current understanding of the natural history or HPV infection and cervical carcinogenesis, it is recommended that adult women with a history of sexual activity undergo periodic screening as part of their routine preventive care.

Prevalence/Burden

In 2010, 12,200 cases of invasive cervical cancer were diagnosed and 4,210 deaths were estimated to have occurred in the United States (CDC, 2007a), and the incidence of cervical cancer has been steadily decreasing in the United States and Western Europe since the introduction of formal and informal cytological screening programs in the 1950s. By 2007, the rate of mortality in the United States has decreased from 10.2 and 18 per 100,000 among White and non-White women, respectively, to 2.2 and 4.3 per 100,000 for White and African-American women, respectively (CDC, 1953; NCI, 2011a). Despite these tremendous gains, women with poor access to health care services and specifically women from communities of color have lagged significantly behind and currently represent a disproportionate share of cervical cancer incidence and mortality (NCI, 2011b; Saslow et al., 2002).

Although the annual incidence of death from cervical cancer is less than that of other cancers (ACS, 2010), the fact that these deaths are almost entirely preventable through primary prevention, screening and early detection, treatment of precancerous lesions, and effective therapies for invasive disease, makes cervical cancer a high-impact public health priority. Because sexually acquired persistent high-risk HPV infection is the primary causal factor associated with the development of cervical cancer, regular screening of all adult women with a history of sexual activity has been the mainstay of prevention efforts (USPSTF, 2003a). Periodic exfoliative cervical cytology-based screening (with or without high-risk HPV DNA testing) detects pre-invasive and early-stage disease, contributing to reductions in

the rate of mortality from cervical cancer. This type of screening, in combination with prophylactic (bivalent or quadrivalent) HPV vaccination of young women and girls, has made the prevention of mortality from cervical cancer an attainable public health goal.

Healthy People 2020, which sets health goals for the United States, contains specific objectives for increasing the proportion of women who receive screening for cervical cancer (HHS, 2011a). The specific targets set for this objective are increasing the rate of screening among women aged 21 to 65 years who receive a cervical cancer screen (based on the most recent guidelines) by 10 percent so that 93 percent of women are screened.

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix. Grade A Recommendation (USPSTF, 2003a).

The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of new technologies to screen for cervical cancer. Grade I Statement (USPSTF, 2003a).

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. Grade I recommendation (USPSTF, 2003a).

Broad consensus exists about the need for periodic screening of adult women with a history of sexual activity. The American Cancer Society (ACS) and ACOG recommend the periodic screening of women beginning at 21 years of age (or three years after the onset of intercourse) (ACOG, 2005a, 2008, 2009; Saslow et al., 2002, 2007). Both entities also recommend the combined use of cytology with testing for high-risk HPV to improve detection and lengthen screening intervals in women 30 years of age and older. The discontinuation of cervical cancer screening in later life is also addressed by these recommendations, with ACS suggesting 70 years of age as the upper limit and ACOG mentioning 65 or 70 years as the upper limit. Both entities caution that discontinuation of screening should occur only when a woman has a documented history of negative screenings. Discontinuation is also recommended by both entities when a woman has had

a hysterectomy for benign disease. The DOD recently added the high-risk HPV DNA test to its list of covered preventive services (TRICARE, 2011).

The ACS and ACOG recommendations also largely agree with the 2003 recommendations of the USPSTF (USPSTF, 2003a). These call for the screening of all sexually active women with cervical cytology beginning at age 21 years or within years of the onset of sexual activity and at least every three years thereafter (Grade A). Like ACS and ACOG, the USPSTF recommends against the screening of women who have undergone hysterectomy for benign disease (Grade D), as well as women age 65 years and older in the setting of prior normal screening examinations (Grade D). In 2003, the USPSTF concluded that there was insufficient evidence to recommend for or against HPV testing in a routine screening setting.

Effective Interventions

On the basis of the summary of observational data, it can be concluded that the use of cytology for cervical cancer screening has contributed significantly to the reduction in the incidence of and rate of mortality from invasive cervical cancer. This has been accomplished on the basis of the substantial uptake of screening for cervical cancer. In 2008, more than 80 percent of women, aged 18–44, reported that they had undergone cytological screening during the previous three years (CDC, 2011a). The rate of screening utilization, however, varies substantially by race and ethnicity, level of educational attainment, and age, with significantly lower rates of screening being seen for Asian and American Indian/Alaska Native women, those with a high-school education or less, and those older than 64 years of age (CDC, 2011a). These considerations are critical, because more than half of all invasive cervical cancers occur among un- and underscreened women, while nearly a third occur among women with screening failures and the remainder are due to inadequate postscreening follow-up or misreadings (Janerich et al., 1995; Kinney et al., 1998; Leyden et al., 2005; Sung et al., 2000).

Cytology has also evolved with liquid-based cytology platforms now largely replacing conventional dry slide cytology in the United States (Irwin et al., 2006). The quality of liquid-based cytology has arguably been proposed to be superior to that of conventional dry slide cytology on the basis of lower rates of unsatisfactory results (Ronco et al., 2007; Siebers et al., 2009), although they are otherwise comparable on the basis of test performance characteristics (Arbyn et al., 2008; Davey et al., 2006). The shift to liquid-based cytology has been driven by practical considerations, including the advent of automated high-throughput processing, an aging cytotechnology workforce, and the advent of molecular testing. It is, however, the ability to perform high-risk HPV DNA testing and cytology on a

single patient specimen that may represent the most important contribution of this technology to overall cancer prevention.

The identification of HPV infection as the requisite etiologic precursor to cervical carcinoma has led to the development of clinically useful assays. The high-risk HPV DNA hybrid capture (HC2) assay (de Cremoux et al., 2003) is the most widely used assay for HPV detection. The HC2 assay is a pooled probe assay that detects 13 different high-risk HPV types and is approved by the Food and Drug Administration (FDA) for use for the triage of a cytology result indicating an atypical squamous cell of undetermined significance as well as for primary screening in combination with cytology for primary screening in women 30 years of age and older (FDA, 2009b,c). More recently, another pooled test (Cervista; Hologic, Bedford, MA) was approved for the same indication as the HC2 assay, as was a related type-specific probe for the detection of HPV types 16 and 18 (FDA, 2009a; Ronco et al., 2010). Although they are not FDA approved, a variety of commercially available and laboratory-specific molecular assays are currently in use under laboratory-specific internal validation standards.

Changing Screening Paradigms

A number of European trials have examined the usefulness of primary screening using high-risk HPV DNA testing compared with that of cervical cytology for the detection of cervical cancer and its precursors. A large randomized controlled trial conducted within the Italian national screening program compared the performance of the HC2 assay to that of conventional cytology among 35,471 women 35 years of age or older (Ronco et al., 2007). After 3.5 years of follow-up, the cumulative rates of detection of CIN3 and above (CIN3+) were 55 and 35 percent for cervical intraepithelial neoplasm grade 2 (HC2 assay) and cytology, respectively (relative risk [RR] = 1.57, 95 percent confidence interval [CI] = 1.03 to 2.4), although no differences in the number of invasive cancers detected in the two groups were detected (four in the HC2 assay arm compared with five in the cytology arm). In another large population-based European trial of 7,908 women aged 30 years and older, the HC2 assay was significantly more sensitive than cytology for the detection of CIN3+: 97 percent (95 percent CI = 83 to 99 percent) and 46 percent (95 percent CI = 31 to 62 percent), respectively (Petry et al., 2003). The magnitude of these findings is even greater at the lower, yet still clinically relevant, treatment threshold of CIN2 or greater (Bigras and de Marval, 2005; Cardenas-Turanzas et al., 2008; Cochand-Priollet et al., 2001; de Cremoux et al., 2003; Mayrand et al., 2006, 2007; Petry et al., 2003).

Taking a slightly different approach, a large Finnish randomized controlled trial compared the HC2 assay (with cytology triage of abnormal)

with cytology alone among 61,149 women in the national screening program (Kotaniemi-Talonen et al., 2008). On extended follow-up at 3.3 years, the rates of detection of CIN3+ and cancer in the HC2 testing arm (59 cases of CIN3+ and 11 invasive cancers) were significantly increased (RR = 1.77, 95 percent CI = 1.16 to 2.74) compared with those for the arm that used cytology only (33 cases of CIN3+ and 6 invasive cancers) (Anttila et al., 2010).

The impressive negative predictive value of the combination of cytology and screening for high-risk HPV was first noted in large cross-sectional studies (Cuzick et al., 2006; Kjaer et al., 2006). The combination has also subsequently been assessed in various European trials, although none used methods that reflect the current practice in the United States. In general, these trials of the combination of cytology and screening for high-risk HPV have consistently demonstrated the improved detection of cervical cancer precursors (CIN2+) over that by cytology by itself, as well as extremely high negative predictive values (Mayrand et al., 2006, 2007; Petry et al., 2003). It is this impressive predictive value of the combination of a negative cytology result and a negative result for HPV, first identified in cross-sectional studies that may permit further safe lengthening of screening intervals.

A recent U.S. study examined data from 331,818 women aged 30 and older who received care in a Kaiser Permanente Northern California from 2003 to 2005. The authors found 7.5 cervical cancers per 100,000 women/year for all women with a normal conventional cytology test, while the rate of cervical cancer was 3.8 per 100,000 woman/years for all women who were HPV-negative. The rate was lowest among women who were HPV-negative and had a normal conventional cytology result, at 3.2 per 100,000 women/year. The study also found that HPV-positive women had a 7.6 percent risk of developing a cancerous or pre-cancerous lesion over five years, while women with an abnormal conventional test result had a 4.7 percent risk. Women with a negative HPV had a lower cancer risk than women who had a normal conventional cytology test. When both cytology and HPV were positive, women had twice the risk for cancer compared to women with a positive HPV test and a normal conventional cytology test (Katki et al., 2011).

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that currently there is an absence of coverage for co-testing with cytology and high-risk HPV DNA testing among women 30 years of age and older as a strategy to increase screening intervals to every three years. Cervical cancer is

almost entirely preventable through early screening, detection, and treatment. Evidence to support high-risk HPV DNA testing is based on federal practice policy from the DOD. Peer-reviewed studies demonstrate that improved testing technologies, particularly combined screening using both conventional cytology and high-risk HPV DNA screening, may significantly improve the rate of detection of cervical cancer precursors and facilitate the safe lengthening of the interval for screening.

Recommendation 5.2: The committee recommends for consideration as a preventive service for women: the addition of high-risk HPV DNA testing to cytology testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years.

SEXUALLY TRANSMITTED INFECTIONS

Sexually transmitted infections (STIs), or sexually transmitted diseases (STDs), are diseases transmitted primarily by sexual activity. In 1997, the Institute of Medicine (IOM) labeled STDs a hidden epidemic, reflecting the knowledge that this largely unrecognized public health threat had considerable scope (IOM, 1997). The discussion that follows focuses primarily on chlamydia, gonorrhea, and syphilis.

Prevalence/Burden

For all STIs generally and for chlamydia, gonorrhea, and syphilis more specifically, the prevalence and number of reported cases are high among certain age groups, racial and ethnic groups and in certain geographic areas. Nevertheless, many STIs are asymptomatic and go undiagnosed; thus, current surveillance systems tend to underestimate the actual burden of disease. Significant short- and long-term morbidities are associated with these conditions, as is the risk for perinatal transmission, with its disease-specific attendant consequences. The services under consideration here include screening and counseling.

Women who contract STIs suffer from adverse reproductive health outcomes (Friedel and Lavoie, 2008). Infections in women, which are usually asymptomatic, can result in pelvic inflammatory disease, a major cause of infertility, ectopic pregnancy, and chronic pelvic pain. As with human immunodeficiency virus (HIV), women at risk for STIs often do not appreciate that they are at risk if they consider themselves in a monogamous relationship (Hodder et al., 2010).

In 2009, the overall rate of reported chlamydia infection among women (592 cases per 100,000 women) was almost three times higher than the

rate among men. Although the rates of reported chlamydia infections have been rising for several years, this could be due at least in part to increased screening and improvements in detection methods. The highest age-specific rates of reported cases in 2009 were among those aged 15 to 19 years.

In 2009, the rates of gonorrhea were 105.5 cases per 100,000 women and 91.9 per 100,000 men. Rates continue to be the highest among adolescents and young adults (CDC, 2009b; Workowski and Berman, 2010). In addition, epidemiological and biological studies provide strong evidence that gonococcal infections facilitate the transmission of HIV infection (Fleming and Wasserheit, 1999).

Syphilis is a genital ulcerative disease that causes significant complications if it is left untreated, including perinatal death in up to 40 percent of pregnant women, and can lead to infection of the fetus in 80 percent of cases, even if the infection is acquired during the four years before pregnancy (CDC, 2009b). Syphilis is also shown to facilitate the transmission of HIV infection (Fleming and Wasserheit, 1999). In 2009, the rate of syphilis was 7.8 cases per 100,000 men and 1.4 cases per 100,000 women. Consistent with other STIs, the rates are the highest for women aged 20 to 24 years (5.6 cases per 100,000) (Workowski and Berman, 2010).

Although the absolute risk factors for each disease may vary, in general, populations at increased risk for one STI are at increased risk for all STIs. The prevalence of gonorrhea and syphilis is highly dependent on the geographic area and sociodemographic factors, with increased rates occurring among Hispanics, African Americans, and lower socioeconomic groups. However, in general, in addition to sexual activity and age, other risk factors for STIs include a history of a prior STI; new, bisexual, or multiple sexual partners; inconsistent condom use; exchanging sex for money or drugs; and incarceration in adult correctional facilities. Sexually active adolescents are at higher risk of acquiring STIs, for a combination of developmental, behavioral, and biological reasons (Friedel and Lavoie, 2008). The risk factors for pregnant women are the same as those for nonpregnant women.

A 2008 Henry J. Kaiser Family Foundation survey found that only 38 percent of women, aged 18 to 44 years reported that they had discussed their sexual history with a doctor or nurse within the past three years. Furthermore, only 28 percent reported that they had discussed STIs with a doctor or nurse. Nevertheless, many women assume that they are tested routinely for STIs (Ranji and Salganicoff, 2011).

Existing Guidelines and Recommendations

The USPSTF recommends screening and counseling for STIs on the basis of the following risk factors listed in Table 5-2.

TABLE 5-2 Indicators of Increased Risk for STIs from USPSTF and Populations Excluded by the Guidelines

Condition/ Intervention	Indicators of Increased Risk Defined by the USPSTF	Populations Excluded
Chlamydia	Sexually active women aged 24 and younger History of STIs New or multiple sexual partners Inconsistent condom use Exchanging sex for money or drugs Incarcerated persons Military recruits Patients at public STI clinics African-American women Hispanic women	"Average risk" women older than 25
Gonorrhea	Women aged younger than 25 History of previous gonorrhea infection Other STIs New or multiple sexual partners Inconsistent condom use Commercial sex workers Drug use African-American women Individual risk depends on local epidemiology of disease	Sexually active and pregnant women not at increased risk
Syphilis	Commercial sex workers Exchanging sex for drugs Incarcerated persons	Sexually active women not at increased risk
STI counseling	Sexually active adolescents Adults/married adolescents with current STIs or infections within the past year Adults/married adolescents with multiple current sexual partners Sexually active patients in nonmonogamous relationships in a location with a high rate of STIs	Nonsexually active adolescents Sexually active women not at increased risk

SOURCES: USPSTF, 2004b, 2005a, 2007, 2008a.

The USPSTF 2008 Clinical Guidelines for counseling to prevent STIs indicate that "clinicians should also consider the communities they serve. If the practice's population has a high rate of STIs, all sexually active patients in non-monogamous relationships may be considered to be at increased risk" (Calonge et al., 2008).

The National Institute for Health and Clinical Excellence in the United Kingdom recommends identifying individuals at high risk for STIs by obtaining a sexual history and conducting one-on-one structured discussions with those at high risk of STIs. Those at risk include people who come from or who have visited areas with a high prevalence of HIV infection. Other

risk factors are misuse of alcohol or other substances, early onset of sexual activity, and unprotected sex or multiple sex partners (NICE, 2007).

The Centers for Disease Control and Prevention (CDC) recommends that all providers obtain a sexual history from each patient and engage in risk-reduction counseling. Evaluation of patients for the Five P's (partners, prevention of pregnancy, protection from STDs, practices, and past STDs) is considered an effective strategy for this purpose (Workowski and Berman, 2010). *Healthy People 2020* outlines a series of objectives for reducing STIs and STI complications, as well as addressing sexual risk behaviors (HHS, 2011a). The National Business Group on Health's (NBGH's) 2006 Evidence Statement also addresses the need for STI education and counseling (Campbell and Lantine, 2006). Furthermore, the Michigan Quality Improvement Consortium recommends that health maintenance exams include risk evaluation and counseling for STI prevention for all individuals aged 18 to 49 years (Michigan Quality Improvement Consortium, 2008). ACOG recommends counseling on STIs, including discussion of partner selection, barrier protection, and high-risk behaviors, as part of their recommended periodic assessments for women aged 13 and older (ACOG, 2007c). The American Medical Association (AMA) encourages physicians to educate their patients about STIs and condom use (AMA, 2003).

Bright Futures recommends that sexually active adolescents receive annual screenings for gonorrhea and chlamydia. In addition, Bright Futures provides anticipatory guidance for physicians to encourage adolescents to protect themselves from STIs and risky behaviors. Counseling on methods of safe sex and contraceptive use is recommended for sexually active adolescents (AAP, 2008).

Effective Interventions

Although many studies have focused primarily on behavioral interventions for prevention of HIV infection, interventions for prevention of STI and HIV infection are interdependent, because the risk-taking behaviors that result in an STI or HIV infection are similar. Short counseling interventions were shown to reduce risky behavior in patients at risk for HIV infection. Project RESPECT, a multicenter randomized control trial of 5,758 heterosexual individuals with STIs, showed that brief, individualized counseling increased the frequency of self-reported condom use through six months and reduced the rate of STI acquisition by 30 percent through six months and 20 percent through 12 months. It was also shown that counseling for those who had ever used drugs was effective and could be effective for current drug users (Kamb et al., 1998). Drug use, past and present, is a risk factor for HIV infection, gonorrhea, and potentially syphilis (Semaan et al., 2010). A study by Kelly et al. provides

some of the strongest evidence for the success of behavioral interventions in heterosexual women (Kelly et al., 1994). Rates of condom use increased from 26 to 56 percent after a cognitive behavioral intervention aimed at high-risk women.

The USPSTF currently recommends that physicians offer high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and adults at increased risk, defined by current STI status and multiple sexual partners. High-intensity interventions that were found to be effective were delivered in multiple sessions, most often in groups, with total durations being three to nine hours (USPSTF, 2008a).

In addition to a client-centered approach, the CDC recommends that comprehensive counseling includes addressing abstinence and condom use, reducing sex partners, and types of sex practiced (Friedel and Lavoie, 2008).

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA is that STI counseling is limited to adults who currently have STIs or who identify themselves as having multiple sex partners. Additionally, screening for chlamydia for women aged 25 years and older is not defined by geographic risk factors.

The evidence provided to support a recommendation related to STI counseling is based on federal goals from CDC and *Healthy People 2020* (CDC, 2010e; HHS, 2011a), as well as recommendations from AMA and ACOG. The committee found insufficient evidence to support a new recommendation related to screening for chlamydia or gonorrhea; instead, the evidence supported by federal priorities and clinical professional guidelines led to a suggestion for those screenings to be addressed during a well-woman visit.

Recommendation 5.3: The committee recommends for consideration as a preventive service for women: annual counseling on sexually transmitted infections for sexually active women.

HUMAN IMMUNODEFICIENCY VIRUS INFECTION

HIV was addressed above in the section on STIs, as HIV infection frequently coexists with other STIs and the risk factors for HIV infection and STIs are much the same. HIV is a sexually transmitted virus that causes damage to an infected person's CD4+ T cells, which are crucial for helping

the body defend itself against diseases. HIV is the virus that causes AIDS, a condition in humans in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive. HIV can develop into AIDS within just a few years if it is left untreated (CDC, 2010a). Currently, no vaccine for HIV infection/AIDS is available (Flexner, 2007). However, to date more than 30 anti-HIV drugs have been developed and licensed. In combinations of three or more, these medications have proved extremely effective in slowing the progression of HIV if it is detected and treated early (Fauci, 2011). New HIV infections in women are found at the highest rates between ages 13 and 39 years (KFF, 2011).

Prevalence/Burden

Although HIV infection/AIDS is more prevalent in men, the rate of HIV infection/AIDS in women is increasing (IOM, 2010b). From 1999 to 2003, the CDC reported a 15 percent increase in AIDS cases among women but only a 1 percent increase in men (CDC, 2006). In 1985, women accounted for 8 percent of new AIDS cases, a proportion that grew to 25 percent in 2009 (CDC, 2011b; KFF, 2011). In 2009, 9,973 women were diagnosed with HIV infection.

The majority of HIV infection and AIDS cases in women are a result of high-risk heterosexual sex (CDC, 2010b; KFF, 2011). However, many women are unknowingly infected because of the risk behavior of their partners (Hader et al., 2001; IOM, 2010b; Varghese et al., 2002). In addition, an estimated 6,000 to 7,000 HIV-positive women in the United States give birth each year (Bulterys et al., 2002; CDC, 2007c; Lee and Fleming, 2001).

Women with HIV infection often have lower socioeconomic status. Family responsibilities and a lack of access to care have been identified as barriers to women managing their HIV infection and pursuing appropriate care (Bozzette et al., 1998; Cunningham et al., 1999; Fleishman et al., 2005; Shapiro et al., 1999). Although women share with men the complication of the progression of HIV infection to AIDS, they also experience gender-specific comorbidities, such as recurrent vaginal yeast infections, severe pelvic inflammatory disease, and increased risk of precancerous changes in the cervix (NIAID, 2008). In 2007, HIV infection was the fifth leading cause of death for women (aged 25 to 44 years), but it was the third leading cause of death for black women (CDC, 2011b; KFF, 2011). HIV infection was the number one cause of death for black women aged 25 to 34 years (CDC, 2008).

Women at risk for acquisition of HIV frequently do not appreciate that they are at risk (Hodder et al., 2010). Black women, in particular, report

not knowing their sexual partner's risks, such as injection drug use, having other current sex partners, or unknown HIV status (DeCarlo and Reznick, 2009). In 2005, 80 percent of HIV-positive black woman were infected through heterosexual sex (Rose et al., 2008).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF strongly recommends that clinicians screen for human immunodeficiency virus (HIV) all adolescents and adults at increased risk for HIV infection. Grade A Recommendation (USPSTF, 2005b).

The USPSTF makes no recommendation for or against routinely screening for HIV adolescents and adults who are not at increased risk for HIV infection. Grade C Recommendation (USPSTF, 2005b).

Increased risk for HIV is defined by the following factors:

- Receives health care in a high-prevalence or high-risk clinical setting;
- Women having unprotected sex with multiple partners;
- Past or present injection drug users;
- Women who exchange sex for money or drugs or have sex partners who do;
- Individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users;
- Persons being treated for STDs;
- Persons with a history of blood transfusion between 1978 and 1985; and
- Persons who request an HIV test (USPSTF, 2005b).

The USPSTF also recommends that all pregnant women receive screening for HIV infection as part of prenatal care. Screening of adults and adolescent women who are not pregnant or who are not considered to be at increased risk for HIV infection is a USPSTF Grade C recommendation, implying that screening should not be routinely done but, rather, should be done on an individualized case-specific basis. Bright Futures recommends that all sexually active and at risk adolescents aged 11 to 21 years be screened for HIV infection annually (AAP, 2008).

The CDC, the American College of Physicians (ACP), the Infectious

Diseases Society of America (IDSA), AMA, ACOG, the American College of Nurse-Midwives, as well as the IOM recommend broader screening for HIV infection to include adolescents and sexually active adults to age 65 years (CDC, 2006; IOM, 2010a). The CDC qualifies its recommendation, stating that screening may not be warranted if the prevalence rate is <0.1 percent or the diagnostic yield is <1/1,000 screened. The CDC recommends opt-out screening and instructs physicians to offer counseling on HIV infection and test results before the patient is tested if the patient does not decline the screening. Preventive counseling regarding HIV infection is still recommended by the CDC, but the revised guidelines recommend separation of testing from screening for high-risk individuals as a way to eliminate one potential barrier to testing. For patients with a positive test result, the CDC recommends the provision of access to care, prevention counseling, and support services.

Effective Interventions

Risk-based screening has been shown in large health care networks to be an ineffective means of identifying individuals with HIV infection. Identified risk factors such as a current sexually transmitted disease or substance abuse have not been shown to be reliably used by physicians as reasons to screen, even within a health care system in which access to care is not a barrier (Gandhi et al., 2007; Owens et al., 2007). A review of Medicaid claims from 1998 revealed that of all cohort patients diagnosed with a non-blood-borne STI (gonorrhea, chlamydia, or pelvic inflammatory disease, strong risk factors for co-infection with HIV), only 10 percent were subsequently screened for HIV infection, despite the evidence that these are known risk factors for HIV infection (Rust et al., 2003). Additionally, among people who tested positive for HIV, approximately 25 percent did not report high-risk behaviors that would have led a physician to perform risk-based screening (Chou et al., 2005). As referenced earlier, many women do not believe themselves to be at risk, so it is unlikely that they will ask to be tested.

Opt-out screening was shown to be very effective in prenatal screening for HIV. In a retrospective cohort study of 12,221 pregnancies resulting in delivery, only 221 women declined the screening (Breese et al., 2004). This type of screening has been accepted by women and is now widely implemented (Schuman et al., 2004).

Early screening for HIV infection is crucial to afford patients effective treatment and also for the benefit of the patients' sexual partners. In a recent worldwide clinical trial, researchers found that HIV-infected men and women who were able to start oral antiretroviral medicines early in

the stage of HIV progression actually reduced their risk of transmitting the virus to their partners by 96 percent (NIAID, 2011).

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that current screening recommendations by the USPSTF are limited in scope; that is, they are limited to pregnant women and high-risk adolescents and adults.

The evidence provided to support a recommendation for expanding screening is based on federal goals from the CDC, as well as clinical professional guidelines, such as those from the ACP, IDSA, AMA, and ACOG.

Recommendation 5.4: The committee recommends for consideration as a preventive service for women: counseling and screening for HIV infection on an annual basis for sexually active women.

PREVENTING UNINTENDED PREGNANCY AND PROMOTING HEALTHY BIRTH SPACING

Unintended pregnancy is defined as a pregnancy that is either unwanted or mistimed at the time of conception (Finer and Henshaw, 2006) and affects women with reproductive capacity, that is, from the time of menarche to menopause. Family planning services that are provided to prevent unintended pregnancies include contraception (i.e., all FDA-approved contraceptive drugs and devices, sterilization procedures) as well as patient education and counseling.

Prevalence/Burden

Unintended pregnancy is highly prevalent in the United States. In 2001, an estimated 49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time of conception—according to the National Survey of Family Growth (Finer and Henshaw, 2006). The unintended pregnancy rate is much lower in other developed countries (Trussell and Wynn, 2008). In 2001, 42 percent of U.S. unintended pregnancies ended in abortion (Finer and Henshaw, 2006). Although 1 in 20 American women has an unintended pregnancy each year, unintended pregnancy is more likely among women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority group (Finer and Henshaw, 2006).

The consequences of an unintended pregnancy for the mother and the baby have been documented, although for some outcomes, research is limited. Because women experiencing an unintended pregnancy may not immediately be aware that they are pregnant; their entry into prenatal care may be delayed, they may not be motivated to discontinue behaviors that present risks for the developing fetus; and they may experience depression, anxiety, or other conditions. According to the IOM Committee on Unintended Pregnancy, women with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, to be depressed during pregnancy, and to experience domestic violence during pregnancy (IOM, 1995).

A more recent literature review found that U.S. children born as the result of unintended pregnancies are less likely to be breastfed or are breastfed for a shorter duration than children born as the result of intended pregnancies and that mothers who have experienced any unwanted birth report higher levels of depression and lower levels of happiness (Gipson et al., 2008). Finally, a recent systematic literature review found significantly increased odds of preterm birth and low birth weight among unintended pregnancies ending in live births compared with pregnancies that were intended (Shah et al., 2008).

The risk factors for unintended pregnancy are female gender and reproductive capacity. Although certain subgroups of women are at greater risk for unintended pregnancy than others (e.g., women aged 18 to 24 years, unmarried women, women with low incomes, women who are not high school graduates, and women who are members of a racial or ethnic minority group), all sexually active women with reproductive capacity are at risk for unintended pregnancy. In 2008, approximately 36 million U.S. women of reproductive age (usually defined as ages 15 to 44 years) were estimated to be in need of family planning services because they were sexually active, able to get pregnant, and not trying to get pregnant (Frost et al., 2010). More than 99 percent of U.S. women aged 15 to 44 years who have ever had sexual intercourse with a male have used at least one contraceptive method (Mosher and Jones, 2010).

Pregnancy spacing is important because of the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy). Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small for gestational age births (Conde-Agudelo et al., 2006; Fuentes-Afflick and Hessol, 2000; Zhu, 2005). In addition, women with certain chronic medical conditions (e.g., diabetes and obesity) may need to postpone pregnancy until appropriate weight loss or glycemic control has been achieved (ADA, 2004; Johnson et al., 2006). Finally, pregnancy may be contraindicated for women with serious medical conditions such as pulmonary hyper-

tension (etiologies can include idiopathic pulmonary arterial hypertension and others) and cyanotic heart disease, and for women with the Marfan Syndrome (Meijboom et al., 2005; Regitz-Zagrosek et al., 2008; Warnes, 2004).

Existing Guidelines and Recommendations

Numerous health care professional associations and other organizations recommend the use of family planning services as part of preventive care for women, including ACOG, AAFP, the American Academy of Pediatrics (AAP), the Society of Adolescent Medicine, the AMA, the American Public Health Association, the Association of Women's Health, Obstetric and Neonatal Nurses, and the March of Dimes. In addition, the CDC recommends family planning services as part of preventive visits for preconception health (Johnson et al., 2006).

The USPSTF does not address prevention of unintended pregnancy. Bright Futures recommends that information about contraception be offered to all sexually active adolescents and those who plan to become sexually active (AAP, 2008).

The IOM Committee on Women's Health Research recently identified unintended pregnancy to be a health condition of women for which little progress in prevention has been made, despite the availability of safe and effective preventive methods (IOM, 2010b). This report also found that progress in reducing the rate of unintended pregnancy would be possible by "making contraceptives more available, accessible, and acceptable through improved services (IOM, 2010b). Another IOM report on unintended pregnancy recommended that "all pregnancies should be intended" at the time of conception and set a goal to increase access to contraception in the United States (IOM, 1995). *Healthy People 2020* (HHS, 2011a), which sets health goals for the United States, includes a national objective of increasing the proportion of pregnancies that are intended from 51 to 56 percent. In addition, *Healthy People 2020* sets goals to increase the number of insurance plans that offer contraceptive supplies and services, to reduce the proportion of pregnancies conceived within 18 months of a previous birth, and to increase the proportion of females or their partners at risk of unintended pregnancy who used contraception during the most recent sexual intercourse (HHS, 2011a).

Effective Interventions

Family planning services are preventive services that enable women and couples to avoid an unwanted pregnancy and to space their pregnancies to promote optimal birth outcomes. A wide array of safe and highly

effective FDA-approved methods of contraception is available, including barrier methods, hormonal methods, emergency contraception, and implanted devices; sterilization is also available for women and for men (FDA, 2010). This range of methods provides options for women depending upon their life stage, sexual practices, and health status. Some methods, such as condoms, spermicides, and emergency contraceptives, are available without a prescription, whereas the more effective hormonal and long-acting reversible methods, such as oral contraceptives and intrauterine devices, are available by prescription or require insertion by a medical professional. Sterilization is a surgical procedure. For women with certain medical conditions or risk factors, some contraceptive methods may be contraindicated. These can be assessed clinically so that an appropriate method can be selected for the individual (CDC, 2010; Dragoman et al., 2010).

The effectiveness of contraceptives is determined by studying the rate of failure (i.e., having an unintended pregnancy) in the first year of use (Table 5-3). The failure rates of all FDA-approved methods in both U.S. and international populations have been well documented and are negligible with proper use (Amy and Tripathi, 2009; Hatcher et al., 2007; Kost et al., 2008; Mansour et al., 2010). Female sterilization, the intrauterine device, and the contraceptive implant have failure rates of 1 percent or less in the first 12 months of use (Fu et al., 1999; Hatcher et al., 2007). Injectable and oral contraceptives have use failure rates of seven and 9 percent, respectively, because some women miss or delay an injection or pill (Kost et al., 2008). Failure rates for both male and female condoms and other barrier methods are higher (e.g., 15 percent for the male condom) (Amy and Tripathi, 2009). These rates compare with an 85 percent chance of an unintended pregnancy within 12 months among couples using no method of contraception (Hatcher et al., 2007; Trussell and Kost, 1987).

In addition to this evidence of method effectiveness, evidence exists that greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally. Studies show that as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined (Boonstra et al., 2006). Other studies show that increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use (Santelli and Melnikas, 2010).

As with all pharmaceuticals and medical procedures, contraceptive methods have both risks and benefits. Side effects are generally considered minimal (ACOG, 2011a,b,c; Burkman et al., 2004). Death rates associated with contraceptive use are low and, except for oral contraceptive users who

TABLE 5-3 Percentage of U.S. Women Experiencing an Unintended Pregnancy During First Year of Typical Use and First Year of Perfect Use, by Contraceptive Method

Method	% Experiencing Unintended Pregnancy in First Year of	
	Typical Use[a]	Perfect Use[b]
None	85	85
Spermicides (foams, creams, gels, vaginal suppositories, and vaginal film)	29	18
Withdrawal	27	4
Fertility awareness-based methods[c]	25	
Standard days method		5
Two-day method		4
Ovulation method		3
Sponge		
Parous women	32	20
Nulliparous women	16	9
Diaphragm (with spermicidal cream or jelly)	16	6
Condom (without spermicides)		
Female	21	5
Male	15	2
Combined pill and progestin-only pill	8	0.30
Evra patch	8	0.30
NuvaRing	8	0.30
Depro-Provera	3	0.30
Intrauterine Device		
ParaGard (copper T)	0.80	0.60
Mirena (LNG-IUS)	0.20	0.20
Implanon	0.05	0.05
Female sterilization	0.50	0.50
Male sterilization	0.15	0.10

[a] Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

[b] Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

[c] The ovulation and 2-day methods are based on evaluation of cervical mucus. The standard day method avoids intercourse on cycle days 8 through 19.

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smoke, lower than the U.S. maternal mortality rate (Hatcher et al., 1998). For example, the oral contraceptive death rate per 100,000 users under the age of 35 years who are nonsmokers was 1.5 per 100,000 live births (Hatcher et al., 1998), compared with 11.2 maternal deaths per 100,000 live births in 2006 (age adjusted) (CDC, 2010c).

Contraceptive methods often have benefits separate from the ability to plan one's family and attain optimal birth spacing. For example, the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain (ACOG, 2010a). Long-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011).

Education and counseling are important components of family planning services because they provide information about the availability of contraceptive options, elucidate method-specific risks and benefits for the individual woman, and provide instruction in effective use of the chosen method (NBGH, 2005; Shulman, 2006). Research on the effectiveness of structured contraceptive counseling is limited (Halpern et al., 2006; Lopez et al., 2010b; Moos et al., 2003). However, studies show that postpartum contraceptive counseling increases contraceptive use and decreases unplanned pregnancy (Lopez et al., 2010a), that counseling increases method use among adolescents in family planning clinics (Kirby, 2007), that counseling decreases nonuse of contraception in older women of reproductive age (35 to 44 years) who do not want a future baby (Upson et al., 2010), and that counseling of adult women in primary care settings is associated with greater contraceptive use and the use of more effective methods (Lee et al., 2011; Weisman et al., 2002).

Although it is beyond the scope of the committee's consideration, it should be noted that contraception is highly cost-effective. The direct medical cost of unintended pregnancy in the United States was estimated to be nearly $5 billion in 2002, with the cost savings due to contraceptive use estimated to be $19.3 billion (Trussell, 2007). The cost-effectiveness of family planning is also documented in an evaluation of FamilyPact, California's 1115 Medicaid Family Planning Waiver Program. The unintended pregnancies averted in this program in 2002 would have cost the state $1.1 billion within two years, and $2.2 billion within five years, for public-sector health and social services that otherwise would have been needed (Amaral et al., 2007).

In a study of the cost-effectiveness of specific contraceptive methods, all contraceptive methods were found to be more cost-effective than no

method, and the most cost-effective methods were long-acting contraceptives that do not rely on user compliance (Trussell et al., 2009). The most common contraceptive methods used in the United States are the oral contraceptive pill and female sterilization. It is thought that greater use of long-acting, reversible contraceptive methods—including intrauterine devices and contraceptive implants that require less action by the woman and therefore have lower use failure rates—might help further reduce unintended pregnancy rates (Blumenthal et al., 2011). Cost barriers to use of the most effective contraceptive methods are important because long-acting, reversible contraceptive methods and sterilization have high up-front costs (Trussell et al., 2009).

Contraceptive coverage has become standard practice for most private insurance and federally funded insurance programs. For example, contraceptive services are covered for all federal employees and individuals who obtain their care through federally financed programs, such as VA, TRICARE for active-duty military and their dependents, and IHS. Federal programs provide funding for family planning services in community health centers through the Public Health Service Act, in family planning centers through Title X [Population Research and Voluntary Family Planning Programs (P.L. 91-572)], through the Maternal and Child Health Block Grant, and through the Medicaid program.

Since 1972, Medicaid, the state-federal program for certain low-income individuals, has required coverage for family planning in all state programs and has exempted family planning services and supplies from cost-sharing requirements. In addition, 26 states currently operate special Medicaid-funded family planning programs for low-income women who either no longer qualify for Medicaid or do not meet the program's categorical requirements. In Massachusetts, family planning services with no copayments will be included as part of the preventive benefits offered to members of Commonwealth Care, a program of subsidized health insurance for low- and moderate-income people (Personal communication, Stephanie Chrobak and Nancy Turnbull, Massachusetts Health Connector, May 10, 2011).

Private employers have also expanded their coverage of contraceptives as part of the basic benefits packages of most policies. This expansion has occurred in response to state and federal policies. Twenty-eight states now have regulations requiring private insurers to cover contraceptives, and 17 of these states also require that insurance cover the associated outpatient visit costs (Guttmacher Institute, 2011) (see Chapter 3). A federal court ruling issued in 2000 by the Equal Employment Opportunity Commission found an employer's failure to cover prescription contraceptive drugs and devices in a health plan that covers other drugs, devices, and preventive care to be discrimination against women in violation of Title VII of the Civil Rights Act (EEOC, 2000).

In 2007, NBGH recommended that employer-sponsored health plans include coverage of family planning services, without cost sharing, as part of a minimum set of benefits for preventive care. The Guttmacher Institute also calls comprehensive coverage of contraceptive services and supplies "the current insurance industry standard," with more than 89 percent of insurance plans covering contraceptive methods in 2002 (Camp, 2011). A more recent 2010 survey of employers found that 85 percent of large employers and 62 of small employers offered coverage of FDA-approved contraceptives (Claxton et al., 2010).

Despite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years. In fact, a review of the research on the impact of cost sharing on the use of health care services found that cost-sharing requirements, such as deductibles and copayments, can pose barriers to care and result in reduced use of preventive and primary care services, particularly for low-income populations (Hudman and O'Malley, 2003). Even small increments in cost sharing have been shown to reduce the use of preventive services, such as mammograms (Trivedi et al., 2008). The elimination of cost sharing for contraception therefore could greatly increase its use, including use of the more effective and longer-acting methods, especially among poor and low-income women most at risk for unintended pregnancy. A recent study conducted by Kaiser Permanente found that when out-of-pocket costs for contraceptives were eliminated or reduced, women were more likely to rely on more effective long-acting contraceptive methods (Postlethwaite et al., 2007).

Identified Gaps

Contraception and contraceptive counseling are not currently in the array of preventive services available to women under the ACA.

Systematic evidence reviews and other peer-reviewed studies provide evidence that contraception and contraceptive counseling are effective at reducing unintended pregnancies. Current federal reimbursement policies provide coverage for contraception and contraceptive counseling and most private insurers also cover contraception in their health plans. Numerous health professional associations recommend family planning services as part of preventive care for women. Furthermore, a reduction in unintended pregnancies has been identified as a specific goal in *Healthy People 2010* and *Healthy People 2020* (HHS, 2000, 2011a).

Recommendation 5.5: The committee recommends for consideration as a preventive service for women: the full range of Food and Drug

Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

BREASTFEEDING

Breastfeeding benefits the mother, the child, and society. The challenge is to ensure that the majority of mothers initiate breastfeeding and exclusively breastfeed their children during the first six months, with breastfeeding continuing to a year or beyond for every child (Gartner et al., 1997).

Prevalence/Burden

An AHRQ report from 2007 includes a summary of systematic reviews and meta-analyses on breastfeeding and maternal and infant health outcomes (Ip et al., 2007). The evidence is clear that breastfeeding reduces Sudden Infant Death Syndrome, gastrointestinal infections, upper and lower respiratory diseases, childhood leukemia, asthma, ear infections, childhood obesity, and diabetes mellitus type 2 risk for children, as well as rates of hospitalization (Table 5-4). They also concluded that sufficient results are available to be able to state that breastfeeding significantly lowers the maternal risk of breast and ovarian cancers (Table 5-4). Breastfeeding soon after birth may reduce the risk of maternal blood loss and enhance maternal-infant bonding (ACNM, 2004). A recent study concluded that if 90 percent of all children were exclusively breastfeed during the first six months of life, the United States would save $13 billion per year and prevent an excess of 911 deaths (Bartick and Reinhold, 2010). If only 80 percent of U.S. families complied, $10.5 billion would be saved and 741 deaths would be prevented each year.

In the United States, the majority of pregnant women plan to breastfeed (DiGirolamo et al., 2005), and yet there is a clear gap between the proportion of women who prenatally intend to breastfeed and those who actually do so by the time they are discharged after a brief hospital stay (California WIC Association and U.C. Davis Human Lactation Center, 2008; CDC, 2007b). The National Immunization Survey found that among the mothers of children born in 2007, 75 percent of mothers initiated breastfeeding, 43 percent were breastfeeding at six months, and 22 percent were breastfeeding at 12 months (CDC, 2007b). Although considerable progress has been made through overall promotion of breastfeeding in the United States, gains in breastfeeding rates have not been made equally across geographic, racial, and socioeconomic groups (Table 5-5).

Contrary to popular conception, breastfeeding appears to be a learned skill and the mother must be supported to be successful. Nevertheless,

TABLE 5-4 Impact of Breastfeeding on Infant and Maternal Health Outcomes from the Surgeon General's Call to Action to Support Breastfeeding

Outcome	Excess Risk (%) (95% CI)	Comparison Groups
Among full-term infants		
Acute ear infections (otitis media)	100 (56, 233)	EFF vs. EBF for 3 or 6 mos
Eczema (atopic dermatitis)	47 (14, 92)	EBF <3 mos vs. EBF ≥3 mos
Diarrhea and vomiting (gastrointestinal infection)	178 (144, 213)	Never BF vs. ever BF
Hospitalization for lower respiratory tract diseases in the first year	257 (85, 614)	Never BF vs. EBF ≥4 mos
Asthma, with family history	67 (22, 133)	BF <3 mos vs. ≥3 mos
Asthma, no family history	35 (9, 67)	BF <3 mos vs. ≥3 mos
Childhood obesity	32 (16, 49)	Never BF vs. ever BF
Type 2 diabetes mellitus	64 (18, 127)	Never BF vs. ever BF
Acute lymphocytic leukemia	23 (10, 41)	Never BF vs. >6 mos
Acute myelogenous leukemia	18 (2, 37)	Never BF vs. >6 mos
Sudden infant death syndrome	56 (23, 96)	Never BF vs. ever BF
Among preterm infants		
Necrotizing enterocolitis	138 (22, 2400)	Never BF vs. ever BF
Among mothers		
Breast cancer	4 (3, 6)	Never BF vs. ever BF (per year of breastfeeding)
Ovarian cancer	27 (10, 47)	Never BF vs. ever BF

ABBREVIATIONS: BF = breastfeeding; CI = confidence interval; EBF = exclusive breastfeeding; EFF = exclusive formula feeding.
SOURCE: HHS, 2011b.

a large gap exists in the area of providers discussing breastfeeding with patients prenatally and assisting with breastfeeding issues postnatally. Mothers' experiences as they receive this care have an influence on their intention to breastfeed (Howard et al., 1997), the establishment of breastfeeding (Dewey et al., 2003), and the duration of breastfeeding (DiGirolamo et al., 2003). The duration of breastfeeding is dependent on several factors. Two of these are confidence and commitment. Blyth et al. (2002) identified confidence to be a modifiable variable that may be "amenable to supportive interventions," rather than nonmodifiable demographic risk factors that are associated with feeding choices. Another review concluded that mothers often wean their babies before six months of age because of perceived difficulties with breastfeeding rather than because of choice, thus suggesting that a mother's lack of confidence in her ability to breastfeed may have a

TABLE 5-5 Provisional Breastfeeding Rates Among Children Born in 2007[a]

Sociodemographic Factor	Ever Breastfed (%)	Breastfeeding at 6 Months (%)	Breastfeeding at 12 Months (%)
United States	**75.0**	**43.0**	**22.4**
Race/ethnicity			
American Indian or Alaska Native	73.8	42.4	20.7
Asian or Pacific Islander	83.0	56.4	32.8
Hispanic or Latino	80.6	46.0	24.7
Non-Hispanic Black or African American	58.1	27.5	12.5
Non-Hispanic White	76.2	44.7	23.3
Receiving WIC			
Yes	67.5	33.7	17.5
No, but eligible	77.5	48.2	30.7
Ineligible	84.6	54.2	27.6
Maternal education			
Not a high school graduate	67.0	37.0	21.9
High school graduate	66.1	31.4	15.1
Some college	76.5	41.0	20.5
College graduate	88.3	59.9	31.1

[a] Survey limited to children aged 19–35 months at the time of data collection. The lag between birth and collection of data allows for tracking of breastfeeding initiation as well as calculating the duration of breastfeeding.

ABBREVIATION: WIC = Special Supplemental Nutrition Program for Women, Infants, and Children; U.S. Department of Agriculture.

SOURCE: From the Surgeon General's Call to Action to Support Breastfeeding (HHS, 2011b).

greater impact on breastfeeding success than her intent or desire to breastfeed (Dennis, 2002).

Mothers' experiences as patients during the maternity stay influence future feeding behaviors (Taveras et al., 2004); however, the quality of prenatal, postpartum, and pediatric medical care in the United States is inconsistent (DiGirolamo et al., 2008; Stark and Lannon, 2009). The CDC survey of Maternity Practices in Infant Nutrition and Care biannually assesses breastfeeding-related maternity practices in hospitals and birth centers across the United States. This survey discloses that policies and practices in U.S. maternity care facilities that are unsupportive and even harmful to breastfeeding, are pervasive throughout labor, delivery, and postpartum care, as well as in hospital discharge planning (CDC, 2011d).

Examples of these unsupportive policies and practices include placement of the stable, healthy, full-term newborn on an infant warmer immediately upon delivery rather than skin to skin with the mother, provision of infant formula or water to breastfed newborns without a medical indica-

tion, removal of the newborn from the mother's room at night, inadequate assurance of postdischarge follow-up for lactation support, and provision of promotional samples of infant formula from manufacturers (Bystrova et al., 2007; Chung et al., 2008; Moore et al., 2007; Rosenberg et al., 2008; Wight et al., 2009). Studies have shown that practices such as these are associated with a shorter duration of breastfeeding (DiGirolamo et al., 2008; Fairbank et al., 2000).

After being discharged from the hospital, mothers may have no means of identifying or obtaining the skilled support needed to address their concerns about lactation and breastfeeding; furthermore, barriers to reimbursement for needed lactation support and services may exist (Salem-Schatz et al., 2004). In addition, limited communication between providers across health care settings (Cherouny et al., 2005) and between providers and mothers may also make mothers less likely to comply with recommended postpartum health care visits than they were during the prenatal period (Stark and Lannon, 2009).

Several studies have found gaps between providers' intentions surrounding breastfeeding counseling and their training, experience, and practice in supporting patients with breastfeeding. Taveras and colleagues (2004) found that clinicians' perceptions of the counseling they provided on breastfeeding did not match their patients' perceptions of the counseling received. When clinicians' and patients' reports on the counseling were linked, it was found that among mothers whose prenatal clinicians stated that they always or usually discussed breastfeeding with their patients, only 16 percent of mothers indicated that breastfeeding had been discussed during their prenatal visits.

Another factor affecting the duration of breastfeeding is whether the mother works. The percentage of women in the U.S. workforce has increased dramatically over the past century, particularly in the past 50 years. One outcome of this is that working mothers, particularly those who work full time, breastfeed for a shorter duration, but it has been found that longer maternity leave and part-time work increase the rates of breastfeeding initiation and duration. A breastfeeding support program in the workplace is also important in helping to increase the breastfeeding duration. By 2009, 15 U.S. states required that employers support breastfeeding employees when they return to work (CDC, 2009a). For the continuation of breastfeeding, it is important that mothers have access to breast pumps to maintain their milk supply (Meek, 2001). Buying or renting a pump without insurance coverage is out of the economic reach of many low-income women, leaving them with few options for maintaining breastfeeding. Further, Chamberlain and colleagues (Chamberlain et al., 2006) found that providing access to breast pumps increases overall breastfeeding rates. Despite the recognition of the importance of breastfeeding in improving

women's and infant's health, coverage of breastfeeding support services differs significantly across the United States. In an analysis of state Medicaid provisions, the Henry J. Kaiser Family Foundation found that 25 states cover breastfeeding education services, 15 states cover individual lactation consultations, and 31 states cover equipment rentals, such as breast pumps (Ranji and Salganicoff, 2009).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding. Grade B recommendation (USPSTF, 2008b).

The USPSTF gives a Grade B to promoting and supporting breastfeeding, and a systematic review of the published literature on the effectiveness of primary care-based interventions encouraging breastfeeding concluded that breastfeeding interventions are more effective than usual care in increasing short- and long-term breastfeeding rates. Specifically, combined pre- and postnatal interventions and inclusion of lay support (such as peer counseling) in a multicomponent intervention are most likely to be effective (Chung et al., 2010).

The USPSTF concluded that promotion and support of breastfeeding are effective when they are integrated into systems of care that include training of clinicians and other health care team members and policy development. The Task Force noted that breastfeeding interventions should be designed and implemented in ways that do not make women feel guilty when they make an informed choice not to breastfeed (Chung et al., 2010).

The AAP Bright Futures program provides a framework for breastfeeding support that covers topics from counseling to prevention of breastfeeding problems (AAP, 2008). In January 2011, the U.S. Surgeon General, Dr. Regina Benjamin, released *The Surgeon General's Call to Action to Support Breastfeeding,* a comprehensive report that identifies specific steps that can be taken at the micro- and macrolevels to support breastfeeding mothers (HHS, 2011b). Included among these steps are ensuring that maternity care practices throughout the United States are fully supportive of breastfeeding and including basic support for breastfeeding as a standard of care for obstetricians, family physicians, and pediatricians. The steps also include accelerating the implementation of the Baby-Friendly Hospital

Initiative (WHO and UNICEF, 1999), which was established by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) in 1991 and which includes the use of evidence-based maternity practices, which are summarized in the Ten Steps to Successful Breastfeeding (Box 5-1).

The Joint Commission, the major accrediting organization for health care organizations in the United States, has identified the concept of bundles of care, such as those in the Ten Steps to Successful Breastfeeding (Box 5-1), as a promising strategy to improve the care provided to patients (Joint Commission on Accrediation of Healthcare Organizations, 2006). Researchers in California have found that hospitals that have attained a Baby-Friendly Hospital designation of Baby-Friendly Hospital Initiative do not have the disparities in the rates of exclusive breastfeeding that other hospitals in the same geographic region show (California WIC Association and U.C. Davis Human Lacation Center, 2008). Despite evidence of improved rates of breastfeeding, as of May 2011 only 110 hospitals in the United States were designated Baby-Friendly Hospitals (Kramer et al., 2001).

The Health Resources and Services Administration (HRSA) recently developed a model for implementing support for lactation and direct breastfeeding in the workplace, which is described in *The Business Case for*

BOX 5-1
Baby-Friendly Hospital Initiative Ten Steps

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within a half hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they should be separated from their infants.
6. Give newborn infants no food or drink other than breast milk, unless medically indicated.
7. Practice "rooming in"—allow mothers and infants to remain together 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

SOURCE: WHO and UNICEF, 1989.

Breastfeeding: Steps for Creating a Breastfeeding Friendly Worksite (HHS, 2008). The program components outlined in the model include flexible breaks and work schedules, a sanitary and private place to express milk, education for pregnant and lactating women, and support from supervisors and coworkers. In addition, Section 4207 of the ACA amends the Fair Labor Standards Act of 1938 by requiring employers with more than 50 employees to provide reasonable break time for a mother to express milk and to provide a place, other than a restroom, that is private and clean where she can express her milk (111th U.S. Congress, 2010).

Healthy People 2020 contains specific objectives for improving maternal, infant, and child health (HHS, 2011a). Among these objectives is increasing the proportion of infants who are breastfed. The specific targets set for this objective are increasing the proportions of infants ever breastfed to 81.9 percent, the proportions of infants breastfed at six months to 60.6 percent, and the proportions of infants breastfed at one year to 34.1 percent. It also sets targets for increasing the proportion of infants exclusively breastfed through three months to 46.2 percent and exclusively breastfed through six months to 25.5 percent (HHS, 2011a). One of the recommendations from the National Prevention Council's (NPC's) June 2011 National Prevention Strategy report includes the support of policies and programs that promote breastfeeding (National Prevention Council, 2011).

A number of professional organizations have guidance or supportive statements indicating that they find breastfeeding to be the preferred method of feeding newborns and infants. AAFP (2005) and AAP (2005) have developed guidelines and recommendations that mothers breastfeed their infants. In 2007, ACOG issued a committee opinion stating strong support for breastfeeding and urging obstetricians and gynecologists, other health care professionals, hospitals, and employers to support women in choosing to breastfeed their infants (ACOG, 2007a).

Identified Gaps

Although the ACA ensures that counseling on breastfeeding is included, the committee recognizes that interpretation of this varies. The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that comprehensive prenatal and postnatal lactation support, counseling, and supplies are not currently included.

The evidence provided to support the inclusion of these services is based on systematic evidence reviews, federal and international goals (such as the U.S. Surgeon General, HRSA, *Healthy People 2020* [HHS, 2011a], WHO and UNICEF), and clinical professional guidelines such as those set forth by AAFP, AAP, and ACOG.

Recommendation 5.6: The committee recommends for consideration as a preventive service for women: comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding. (The ACA ensures that breastfeeding counseling is covered; however, the committee recognizes that interpretation of this varies.)

INTERPERSONAL AND DOMESTIC VIOLENCE

Interpersonal and domestic violence, including intimate partner violence and childhood abuse, is a pattern of coercive behaviors that may include progressive social isolation, deprivation, intimidation, psychological abuse, childhood physical abuse, childhood sexual abuse, sexual assault, and repeated battering and injury. These behaviors are perpetrated by someone who is or was involved in a familial or intimate relationship with the victim. Women and adolescent girls of all ages experience interpersonal and domestic violence.

Prevalence/Burden

The CDC recognizes four categories of violence: physical violence, sexual violence, threat of physical or sexual violence, and psychological or emotional abuse (CDC, 2010c). Each year, as many as 1 million to 5 million women are physically, sexually, or emotionally abused by their intimate partners in the United States (Black and Breiding, 2008; The Commonwealth Fund, 1993; National Center for Injury Prevention and Control, 2003; Tjaden and Thoennes, 1998, 2000), and 39 percent of all women report intimate partner violence in their lifetimes (The Commonwealth Fund, 1999).

Prevalence rates of abuse measured in health care settings range from 4 to 44 percent within the year prior to being asked about abuse and from 21 to 55 percent over a lifetime (Abbott, 1995; Dearwater et al., 1998; Gin et al., 1991; Hamberger et al., 1992; Martins et al., 1992; Mccauley et al., 1995; Richardson et al., 2002). Approximately 20 percent of female public high school students in Massachusetts reported that they had been physically or sexually abused by a dating partner (Silverman et al., 2001). In the United States, approximately 35 percent of emergency room visits, 50 percent of all acute injuries, and 21 percent of all injuries in women requiring urgent surgery were the result of partner violence (Guth and Pachter, 2000).

The CDC estimates that intimate partner rape, stalking, and assault cost the United States more than $5.8 billion yearly, of which $4.1 billion goes to direct medical and mental health care services (National Center for Injury Prevention and Control, 2003). Women experiencing intimate partner violence have medical care costs 60 percent higher than women not experiencing abuse (Ulrich et al., 2003).

The prevalence of childhood physical and sexual abuse is not known. Prevalence estimates from population-based studies of women reporting histories of childhood physical and sexual abuse range between 20 and 38 percent (Finkelhor, 1994; Schoen et al., 1997, 1998). For adolescents, an analysis of self-reported abuse and neglect from the National Longitudinal Study of Adolescent Health indicated that 28 percent of 15,197 respondents experienced physical assault, 12 percent experienced physical neglect, 5 percent experienced contact sexual abuse, and 42 percent experienced supervision neglect (Hussey et al., 2006). Variations in estimates across studies are due to differences in the methodologies used to assess prevalence, a lack of standardized and accepted research instruments, and gaps in knowledge about how abuse victims frame and define their experiences (Hulme, 2004).

Interpersonal and domestic violence committed against adolescent girls may also meet definitions of child abuse. The 2003 Keeping Children and Families Safe Act amendment to the 1996 Federal Child Abuse Prevention and Treatment Act (CAPTA; 42 U.S.C.A. §5106g) defines "child abuse and neglect" as any recent act or failure to act on the part of a parent or caretaker which results in death, serious physical or emotional harm, sexual abuse or exploitation; or an act or failure to act which presents an imminent risk of serious harm (104th U.S. Congress, 1996; HHS, 2003, 2010). Individual states are required to define child abuse and neglect using the minimum standards in the federal law according to CAPTA; however, state definitions vary (HHS, 2009).

The immediate health consequences of interpersonal and domestic violence include injuries (Corrigan et al., 2003) and death from sexual assault (Broch, 2003), as well as sexually transmitted infections, including HIV infection (Wingood et al., 2001), pelvic inflammatory disease (Letourneau et al., 1999), pregnancy (Hathaway et al., 2000), and adverse psychological responses. Several chronic mental health conditions are related to interpersonal and domestic violence (Campbell, 2002), including posttraumatic stress disorder, depression, anxiety disorders, substance abuse, and suicide (Campbell and Lewandowski, 1997; Golding, 1999; Lehmann, 2000). Long-term physical conditions include chronic pain; neurological disorders resulting from injuries; gastrointestinal disorders, such as irritable bowel syndrome; migraine headaches; and various disabilities (Campbell and Lewandowski, 1997; Coker et al., 2000, 2002).

Although childhood sexual abuse is predominantly a prepubertal phenomenon (Finkelhor et al., 2009), the impact and consequences of this form of abuse are usually expressed in adolescence and persist into adulthood (Trickett et al., 2005). These include disability, suffering, and limitations in the quality of life that can be serious and often severe (Sickel et al., 2002). Women with childhood sexual abuse histories report more problems during pregnancy (Lukasse et al., 2009). Physical and sexual abuse in adolescence and young adulthood have been associated with poor self-esteem, alcohol and drug abuse, eating disorders, obesity, risky sexual behaviors, teen pregnancy, depression, trauma, anxiety, suicidality, and other conditions (Sickel et al., 2002; Trickett et al., 2005).

Asking women and adolescent girls about their interpersonal and domestic violence experiences could identify abuse not otherwise detected, help prevent future abuse, lessen disability, and improve future functioning and success in life (Battaglia et al., 2003; Coker et al., 2009; Martin et al., 2008; National Center for Injury Prevention, 2003; Svavarsdottir and Orlygsdottir, 2009). Women may not disclose abuse unless directly questioned under safe and respectful conditions (Dienemann et al., 2005), although there is no consensus about the most acceptable approach (Feder et al., 2009). Surveys indicate that 43 to 85 percent of female respondents consider screening for abuse acceptable, although only one-third of physicians and approximately half of emergency department nurses favored screening (Ramsay et al., 2002). Most women who have been screened for abuse report no adverse effects from the screening process (MacMillan et al., 2009; Spangaro et al., 2010).

Victims of abuse have frequent encounters with clinicians and health care services because adult victims of childhood abuse have poorer health than nonvictims and higher rates of health services utilization (Felitti, 1991; Fillingim et al., 1999; Valente, 2005). Physicians are in a unique position to identify women and adolescents experiencing abuse or neglect, and many physicians consider screening for abuse to be one of their important roles (Flaherty and Stirling, 2010). In practice, however, physicians rarely screen their patients or screen only selected patients, such as patients who have physical injuries (Bair-Merritt et al., 2004; Borowsky and Ireland, 2002; Chamberlain and Perhma-Hester, 2000, 2002; Erickson et al., 2000; Glass et al., 2001; Lapidus et al., 2002; Rodriguez et al., 2001). Barriers to screening include a lack of experience, training, time, and confidence in handling abuse cases (Bair-Merritt et al., 2004; Flaherty et al., 2006; Lane and Dubowitz, 2009; Starling et al., 2009).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF found insufficient evidence to recommend for or against routine screening of parents or guardians for the physical abuse or neglect of children, of women for intimate partner violence, or of older adults or their caregivers for elder abuse. Grade I Statement (USPSTF, 2004b).

The USPSTF recommendation applies to women without apparent injuries or symptoms of abuse and is based on the lack of evidence that screening for intimate partner violence in primary care settings reduces adverse health outcomes, including premature death (USPSTF, 2004). The Canadian Task Force on Preventive Health Care also found insufficient evidence to recommend for or against screening women for intimate partner violence (Wathen and MacMillan, 2003). A report by the Health Technology Assessment Program in the United Kingdom also concluded that evidence is insufficient to implement a screening program for partner violence against women either in health services generally or in specific clinical settings (Feder et al., 2009).

WHO states that better awareness among health workers of violence and its consequences and wider knowledge of available resources for abused women can lessen the consequences of violence (WHO, 2010). AMA recommends that physicians regularly inquire about sexual, physical, and psychological abuse when taking a medical history. Furthermore, as interpersonal abuse or violence may adversely affect a patient's health status, physicians are advised to consider abuse to be a factor in the presentation of medical complaints (AMA, 2008). ACOG recommends that physicians screen all patients for intimate partner violence and that screening should occur during routine visits and over the course of pregnancy (ACOG, 2010b). AAP also recommends screening, stating that pediatricians are in a position to recognize abused women in pediatric settings (Thackeray et al., 2010). Other groups, such as the American Nurses Association (ANA, 2000) and the Futures Without Violence (formerly the Family Violence Prevention Fund) (Family Violence Prevention Fund, 2004), also recommend that health care providers screen patients for intimate partner violence. Finally, VA covers women for health services related to intimate partner violence.

Bright Futures guidelines for adolescents include the provision of anticipatory guidance through discussions about developing healthy dating

relationships, managing conflict nonviolently, avoiding risky situations and people, and seeking help when in danger (AAP, 2008). Recommendations of other groups relevant to adolescents fall under more broadly defined statements about child abuse and neglect.

AAP advocates a prominent role for pediatricians in preventing child abuse and neglect and provides specific guidelines and information on specific risk factors and protective factors (Flaherty and Sterling, 2010). AMA recommends routine inquiry about child abuse or neglect (AMA, 2008). Other organizations do not specifically recommend universal screening but recommend that pediatricians and family practice clinicians remain alert for indications of abuse or neglect (AAFP, 2009; ENA, 2006).

All U.S. states have laws that require physicians and other health care workers, as well as other professionals who interact with children, to report suspected child abuse and neglect to Child Protective Services (CPS) (HHS, 2010b). In 2009, teachers, law enforcement and legal personnel, and social services staff made three-fifths of the reports to CPS, whereas anonymous sources, family members, friends, and neighbors made the remaining reports (HHS, 2010a). It is not clear how many reports originated from health care clinicians specifically. Some states also require physicians to report cases of adult intimate partner violence to legal authorities, and most states require reporting of injuries resulting from firearms, knives, or other weapons.

Effective Interventions

Although numerous community-based programs to safeguard victims of interpersonal and domestic violence exist, including counseling, hotlines, shelters, and advocacy groups, they are usually not directly associated with health care delivery systems. Few studies have evaluated the effectiveness of screening for abuse in health care settings by demonstrating subsequent reductions in abuse or improvement in health as a result of screening (Feder et al., 2009; Ramsay et al., 2009; Trabold, 2007; Wathen and MacMillan, 2003). Existing research has been limited by many factors, including the lack of integration of screening with services such as counseling, inadequate definitions and measurement of outcomes, loss to follow-up, insufficient study designs, patient privacy, stigma and repercussions of disclosure, and variability of individual cases, among others (Feder, 2009; MacMillan, 2006, 2009; Nelson, 2004; Rabin, 2009; Ramsay et al., 2004 Wathen and MacMillan, 2003). The 2004 IOM study *Advancing the Federal Research Agenda on Violence Against Women* reiterated the importance of strengthening the data and research infrastructure, especially the need for better prevalence and longitudinal data to determine the causes of violent victimization of women and the impact of interventions (IOM, 2004).

In the context of these issues, new research on screening and interventions for women identified with abuse in health care settings has been published since the previous 2004 USPSTF recommendation. These include evaluations of methods of identifying women who have been abused (Basile, et al. 2007; Feder et al., 2009; Rabin et al., 2009). Standardized questions and scales designed for screening purposes generally include from one to five items that may be scored in various ways to determine if abuse is present. The diagnostic accuracy of these questions varies, but five different sets of questions have been found to be suitably accurate (i.e., sensitivity and specificity >80 percent) (Chen et al., 2005 et al.; Ernst, 2004; Sohal, 2007; Thombs et al., 2007; Wathen et al., 2008; Weiss et al., 2003).

A large randomized trial compared women who were screened for abuse versus not screened in primary care and acute care settings in Canada. Results indicated improvements in rates of abuse and quality of life several months later, but there were no significant differences between screened and unscreened women (MacMillan et al., 2009). However, for ethical reasons, women randomized to the unscreened comparison group were also asked questions about abuse, received information about intimate partner violence, and were offered services if needed, reducing measureable differences between screened and unscreened women. This study also collected information on the potential harms of screening and reported no harms.

A randomized trial of counseling that included intimate partner violence as well as other health risks during pregnancy and postpartum reported less violence and better infant outcomes among women receiving counseling compared to those who did not (Kiely et al., 2010). Women in the counseling group had significantly fewer very preterm (<33 weeks) and very low birth weight (<1,500 grams) newborns, and increased gestational age (38.2 versus 36.9 weeks) (Kiely et al., 2010). Randomized trials of home visitation for new mothers at risk for abuse showed reduced measures of abuse compared to women not receiving these services (Bair-Merritt et al., 2010; Taft et al., 2011). In other trials, women reporting abuse who were randomized to counseling adopted more safety behaviors than women not receiving counseling (Gillum et al., 2009; McFarlane et al., 2002). Many additional observational and descriptive studies supporting screening and intervention have also been published, but the designs of these studies limit conclusions regarding their effectiveness.

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that interpersonal and domestic violence detection and counseling are not included.

The evidence provided to support a recommendation related to increasing detection of and counseling for interpersonal and domestic violence is based on peer-reviewed studies and federal and international policies, in addition to clinical professional guidelines from organizations, such as the AMA and ACOG.

Recommendation 5.7: The committee recommends for consideration as a preventive service for women: screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.

WELL-WOMAN PREVENTIVE VISITS

Provision of Preventive Services

The committee examined existing guidelines, available evidence, and current clinical best practices to identify effective provision of services that, when provided to women through dedicated clinical encounters, have been shown to promote optimal well-being. Primary care office visits that are dedicated to preventive care may facilitate increased access to health care services that are shown to identify chronic disease risk factors, promote well-being, and/or decrease the likelihood or delay the onset of a targeted disease or condition. Box 5-2 contains examples of terms that are commonly used to label the prevention-oriented clinical encounter; this report

BOX 5-2
Common Terms Used for Well Visits

Preventive pediatric health care visit (AAP/Bright Futures)
Well-child checkup (Early Periodic Screening, Diagnosis, and Treatment program and Medicaid)
Well-adult checkup (Medicaid)
Health risk assessment (Medicaid)
"Welcome to Medicare" visit (Medicare)
Annual wellness examination (Medicare)
Health maintenance visit (MHQP)

uses the term "well-woman preventive visit" to describe the provision of prevention services in an office visit or clinical encounter.

Target Populations

Well-woman preventive care visits apply to women of all ages (and according to the committee's charge, women from 10 through 64 years) and stages of life. Stages of womanhood are defined by age groupings, which are in general alignment with published frameworks and practice guidelines (AAP, 2008). These include adolescence (subdivided into two subgroups ages 10 to 14 years and 15 to 19 years), early adulthood (ages 20 to 24 years), middle adulthood (ages 25 to 49 years), and later adulthood (after age 50 years).

Justification of Well-Woman Visits for Provision of Preventive Services

Women's Preventive Care Is Fragmented

Although "well" visits for adults are not explicitly recommended by the USPSTF, they provide an opportunity for delivering prevention services recommended by a number of government and nongovernment health care agencies (GAO, 2009). In the U.S. health care system, for women, the tendency is to separate reproductive health care services from other components of primary care (Weisman, 1998). Because many preventive services for women are for reproductive health (e.g., screening for cervical cancer and sexually transmitted infections and contraception services), many women may see obstetrician-gynecologists for those services and a generalist physician (a family physician or a general internist) for other components of their routine health care. For example, a national survey of the U.S. female population in 1998 showed that 29 to 49 percent of women, depending of type of health plan, see both a generalist and an obstetrician-gynecologist for their regular health care (Weisman and Henderson, 2001). In another study of women aged 18 to 64 years, 58 percent of women in all stages of life saw an obstetrician-gynecologist in addition to a generalist physician (Henderson et al., 2002). In the 2008 Kaiser Women's Health Survey, 44 percent of women aged 18 to 64 years reported seeing two or more regular providers (Ranji and Salganicoff, 2011). Given these patterns of physician use, it is likely that women make more than one visit and use more than a single provider to attain needed preventive services in a given year. Thus, no single type of provider can be identified as the sole primary care provider for women.

Women have greater health care needs than men and require a broader array of health services, but not all providers are equipped or able to

provide the full range of preventive services for women. A consequence of women obtaining preventive health care from more than one provider is that women's primary care is often fragmented.

Cost as a Major Barrier to Services and Visits

Although the preventive services detailed in Table 5-6 will be covered with no cost sharing under the ACA, insurance plans are permitted to require copayments for office visits (*Federal Register,* 2010). Increased health care costs, combined with the fact that most Americans have seen too little or no gains in income in recent years, can be seen as a threat to the health and financial status of women across the country (Collins et al., 2011). Furthermore, evidence suggests that these issues are adversely affecting women disproportionately compared to men. In 2010, for example, 44 percent of women but only 35 percent of men indicated that they were experiencing difficulty paying medical bills or were paying off medical debt. Furthermore, almost a third of women stated that they did not visit a doctor or clinic when they were faced with a medical problem because of cost, whereas less than a quarter of men reported the same experience (Robertson and Collins, 2011).

Gaps in Well Visits for Women

Clinical guidelines and mandated coverage for well visits exist for children and adolescents (until age 21 years), for some adults, and into maturity (for individuals aged 65 years and older) in public-sector health plans (Medicaid and Medicare) as well as some private-sector health plans (see below and Chapter 3). However, public programs may be incomplete in providing coverage in early, middle, and later adulthood. According to a Government Accountability Office analysis of responses to a survey of state Medicaid directors conducted between October 2008 and February 2009, only 39 states cover health maintenance visits to adults under their Medicaid programs (GAO, 2009). This significant gap in coverage places a disproportionate burden on women of childbearing age, putting them at a greater risk for disease and illness in their most active reproductive years.

Existing Guidelines and Recommendations

Adolescence

Clinical preventive services guidelines for adolescents issued by governmental agencies and nonprofit medical organizations (e.g., HRSA, the Maternal and Child Health Bureau, AAP, AMA, and AAFP) have long

TABLE 5-6 List of Preventive Services to Be Obtained During Well-Woman Preventive Visits Under Recommendation 8

Topic	Description	Grade
USPSTF Grade A and B Recommended Services		
Alcohol misuse counseling	The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.	B
Anemia screening: pregnant women	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B
Bacteriuria screening: pregnant women	The USPSTF recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.	A
Blood pressure screening	The USPSTF recommends screening for high blood pressure in adults aged 18 and older.	A
BRCA screening, counseling about	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.	B
Breast cancer preventive medication	The USPSTF recommends that clinicians discuss chemoprevention 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.	B
Breast cancer screening	The USPSTF recommends screening mammography for women, with or without clinical breast examination, every 1–2 years for women aged 40 and older.	B
Breastfeeding counseling	The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.	B
Cervical cancer screening	The USPSTF strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix.	A
Chlamydial infection screening: non-pregnant women	The USPSTF recommends screening for chlamydial infection for all sexually active nonpregnant young women aged 24 and younger and for older nonpregnant women who are at increased risk.	A
Chlamydial infection screening: pregnant women	The USPSTF recommends screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk.	B
Cholesterol abnormalities screening: women 45 and older	The USPSTF strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease.	A

TABLE 5-6 Continued

Topic	Description	Grade
Cholesterol abnormalities screening: women younger than 45	The USPSTF recommends screening women aged 20 to 45 for lipid disorders if they are at increased risk for coronary heart disease.	B
Colorectal cancer screening	The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy, in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.	A
Depression screening: adolescents	The USPSTF recommends screening of adolescents (12–18 years of age) for major depressive disorder when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.	B
Depression screening: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B
Diabetes screening	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B
Folic acid supplementation	The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 μg) of folic acid.	A
Gonorrhea screening: women	The 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).	B
Healthy diet counseling	The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.	B
Hepatitis B screening: pregnant women	The USPSTF strongly recommends screening for hepatitis B virus infection in pregnant women at their first prenatal visit.	A
Human immunodeficiency virus (HIV) screening	The USPSTF strongly recommends that clinicians screen for HIV all adolescents and adults at increased risk for HIV infection.	A

continued

TABLE 5-6 Continued

Topic	Description	Grade
Obesity screening and counseling: adults	The 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.	B
Osteoporosis screening: women	The USPSTF recommends that women aged 65 and older be screened routinely for osteoporosis. The USPSTF recommends that routine screening begin at age 60 for women at increased risk for osteoporotic fractures.	B
Rh incompatibility screening: first pregnancy visit	The USPSTF strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	A
Rh incompatibility screening: 24–28 weeks gestation	The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women at 24–28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.	B
Sexually transmitted infections (STIs) counseling	The USPSTF recommends high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and for adults at increased risk for STIs.	B
Syphilis screening: non-pregnant persons	The USPSTF strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A
Syphilis screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A
Tobacco use counseling and interventions: non-pregnant adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A
Tobacco use counseling: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke.	A
Services Suggested by the Institute of Medicine[a]		
Diet and physical activity	Determine current levels of physical activity and eating behaviors in all adolescent and adult women and make referrals to appropriate services.	
Establishing pregnancy history of CVD-related conditions	Obtain a history of pregnancy complications, including preeclampsia, gestational hypertension, and gestational diabetes mellitus, from all women who have had at least one pregnancy.	
Mental health	Screen for suicide ideation and postpartum depression in women who are pregnant or who have recently given birth.	
Metabolic syndrome	Obtain a waist circumference as an essential component of screening for metabolic syndrome.	

TABLE 5-6 Continued

Topic	Description	Grade
Preconception care	Provide evidence-based tests, procedures, and screening for nonpregnant women to optimize reproductive outcomes and prevent or optimize treatment for chronic conditions, as well as topics for counseling and guidance for preconception health.	
Prenatal care	Provide evidence-based tests, procedures, and screening for pregnant women to optimize birth outcomes and future chronic conditions, as well as topics for counseling and guidance for prenatal care.	
STIs	Screen for chlamydia and gonorrhea for women above age 25 years with risk factors outlined by the USPSTF or if local rates of infections are high. High-prevalence settings are defined by the Centers for Disease Control and Prevention as those known to have a one percent or greater prevalence of infection among the patient population being served.	

[a] As suggested in Chapter 5 and Appendix A.

recommended annual well-child visits as part of a unified package of preventive health care services for children and adolescents (AAP, 1995; Elster, 1998; Elster and Kuznets, 1994).

Most recently, the Bright Futures Health Initiative, which was launched by HRSA's Maternal and Child Health Bureau in 1990, recommended a schedule of preventive services beginning in the prenatal period (for an initial history and anticipatory guidance) and running through 21 years of age for "children who are receiving competent parenting, have no manifestations of any important health problems, and are growing and developing in satisfactory fashion" (AAP, 1995, 2008). Bright Futures recommends preventive pediatric health care visits for children annually from ages 3 through age 21 years, including initial/interval medical histories, measurements, sensory screening, developmental/behavioral assessments, physical examination, age-appropriate procedures, oral health, and anticipatory guidance. Although the content of well care is tailored by gender to females and males, the recommended frequency or timing of well-care visits for girls and young women does not vary.

Under federal law, state Medicaid programs generally must cover a package of prevention services for children under age 21 years through the Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program (GAO, 2009). A key component of the EPSDT services is that it entitles

children to coverage of well-child checkups, which include a comprehensive health and developmental history, a comprehensive unclothed physical examination, appropriate immunizations and laboratory tests, and health education. The EPSDT program also covers other preventive services for children, such as height and weight measurement, nutritional assessment and counseling, immunizations, blood pressure screening, and cholesterol and other appropriate laboratory tests. State Medicaid programs must provide EPSDT program services at intervals that meet reasonable standards of medical and dental practice, as determined by the state and as medically necessary to determine the existence of a suspected illness or condition. Accordingly, either states must develop their own periodicity schedules (i.e., age-specific timetables that identify when EPSDT well-child checkups and other EPSDT services should occur), or they may adopt a nationally recognized schedule, such as that of AAP, which recommends well-child checkups once each year or more frequently, depending on age. The Omnibus Budget Reconciliation Act of 1989 (OBRA 89) required the Secretary of HHS to set annual goals for children's receipt of EPSDT services, and the Centers for Medicare and Medicaid Services (CMS) established a yearly goal that each state must provide EPSDT well-child checkups to at least 80 percent of the children enrolled in the Medicaid program in their state.

Adulthood

For adults, the USPSTF clinical preventive services recommendations do not address how, when, where, or by whom prevention services are to be provided. For adolescents and adults, ACIP recommends age-specific timing of a full array of immunizations but does not explicitly mention their preferred provision in the context of the well-care office visit. As noted in Chapter 3, states and health insurance plans in the public and private sectors vary widely in the preventive services that they cover, including the payment for designated office visits and extended coverage for specific prevention services.

For persons 65 years and older, well visits are generally covered. All new Medicare beneficiaries have been eligible to receive a welcome to Medicare visit that is similar in scope to a wellness visit (GAO, 2009). The ACA broadens this benefit for beneficiaries to include a new annual wellness examination for all beneficiaries with no copayment. At this visit, medical and family health histories are reviewed, along with the collection of basic health measurements, screening for preventive services, and the identification of risk factors and treatment options.

State Health Plan Example

In recent years, the Commonwealth of Massachusetts has been at the forefront in establishing a core set of clinical guidelines for the well care of average-risk adults 18 years of age and older from the general population (MHQP, 2007). These guidelines include health maintenance visits that were recommended annually for people age 18 to 21 years; every one to three years, depending on risk factors, from ages 22 to 49 years; and then annually for all adults 50 years of age and older. The health maintenance visit includes an individual and family history, an age-appropriate physical examination, indicated preventive screenings and counseling, and ACIP-based immunization updates. General counseling and guidance at every age include screening for alcohol and substance abuse, depression, physical activity, tobacco use, and violence or abuse in the home, as well as safety and injury and violence prevention

Statewide health care reform in Massachusetts established minimum creditable coverage regulations, which apply for purposes of the individual mandate and to all Commonwealth Care policies. These require that health plans cover at least three preventive care visits per year for an individual (six visits under a family policy) before any deductible is applied. However, preventive care visits require the normal copayment. After the enactment of the ACA, as of July 1, 2011, no copayments for preventive services, including both preventive service visits and the well office visit (Current Procedural Terminology Codes 99381 to 99397), will be charged for any patient (Personal communication, Stephanie Chrobak and Nancy Turnbull, Massachusetts Health Connector, May 10, 2011).

Private-Sector Coverage of Well-Visits

Private health maintenance plans, such as Kaiser Permanente, cover and encourage the utilization of a wide array of prevention services in the context of ongoing primary care for beneficiaries of all ages. They do not, however, promote a specific periodicity of prevention visits (Kaiser Permanente, 2011). Although detailed coverage and benefit information about the scope of preventive services covered by insurance plans is difficult to obtain, Chapter 3 addresses more examples of current private insurance practices.

Special Considerations for Reproductive Health Care

Provision of Preconception Health Care

The preconception period (before the first pregnancy) and the interconception period (between all subsequent pregnancies) have been identi-

fied as opportune times for the provision of focused well-woman preventive care visits to identify and modify biomedical, behavioral, and social risks to a woman's health and/or pregnancy outcomes. In 2006, the CDC developed recommendations for preconception care on the basis of a review of published research and the opinions of specialists from the CDC Agency for Toxic Substances and Disease Registry Preconception Care Work Group and the Select Panel on Preconception Care. The recommendations of the CDC were aimed at achieving four primary goals:

> 1) improving the knowledge and attitudes and behaviors of men and women related to preconception health; 2) assuring that all women of childbearing age in the United States receive preconception care services (i.e., evidence-based risk screening, health promotion, and interventions) that will enable them to enter pregnancy in optimal health; 3) reducing risks indicated by a previous adverse pregnancy outcome through interventions during the interconception period; and 4) reducing the racial disparities in adverse pregnancy outcomes. (Johnson et al., 2006)

However, the report did not recommend a specific suite of interventions to be included in routine preconception care. Strong evidence suggests that a number of components of preconception care are effective in improving health outcomes for women and children, in particular, screening of women who are seeking family planning services to identify and treat preconception risk conditions, the provision of nutrition services for women affected by particular metabolic conditions such as hyperphenylalanemia and diabetes, the use of dietary folate supplements by women of reproductive age who are sexually active (Korenbrot et al., 2002), and screening for depression. Furthermore, better pregnancy outcomes have been demonstrated as the result of preconception interventions for alcohol and smoking cessation (Lumley et al., 2004).

The CDC Select Panel on Preconception Care considers all women of reproductive age and potential presenting to primary care as candidates for preconception care. Its 2006 recommendations include the provision of a prepregnancy visit for couples and individuals planning a pregnancy and, as part of primary care preventive care visits, risk assessment and educational and health counseling for all women of childbearing age for improving reproductive outcomes and reducing the sequelae of future chronic diseases among women and their offspring. In 2011 the NPC issued the National Prevention Strategy. Recommendations include increasing use of preconception and prenatal care (National Prevention Council, 2011).

Prenatal Care for the Provision of Preventive Services

Another type of well-woman preventive care visit is the routine prenatal care visit for pregnant women. AAP and ACOG currently recommend

the following visit schedule for women with an uncomplicated pregnancy: a visit every 4 weeks for the first 28 weeks of pregnancy, a visit every 2 weeks until 36 weeks of pregnancy, and weekly visits thereafter (ACOG, 2007c). Women with high-risk pregnancies may need more frequent visits. The recommended content of the visit includes specific tests and procedures (e.g., blood pressure, weight, urine test, uterine size and fetal heart rate assessment, glucose tolerance testing, and screening for specific sexually transmitted infections and genetic or developmental conditions), as well as topics for counseling and guidance (e.g., tobacco avoidance and nutrition). The U.S. Public Health Service Expert Panel on the Content of Prenatal Care (USPHS, 1989) recommends less frequent visits, and some studies have supported the safety and efficacy of visits at a reduced frequency for multiparous and low-risk women. Regardless of the periodicity, pregnant women are likely to make more well-woman preventive care visits than nonpregnant women.

Additional Considerations to Assure Access to Well-Visits

Adolescence and Early Adulthood

Although an array of clinical guidelines recommend an annual well-child visit through age 21 years for the provision of preventive services, evidence on the rates of compliance with the recommendations are mixed. Only 38 percent of adolescents received a preventive care visit in the previous year, and black, Hispanic, and lower-income adolescents were the least likely to have had a preventive care visit (Irwin, 2009). Evidence of the efficacy of preventive services delivered to adolescents is stronger for increasing knowledge and awareness than for changing risky behaviors (Ozer et al., 2004).

As the ACA expands access to private and public health insurance for adolescents and young adults, it may also raise challenges for ensuring that confidential care is delivered to a newly insured segment of the adolescent and young adult population. Adolescents and young adults are likely to forgo health care when they feel that they lack access to confidential care. Time alone with the provider can enhance the client's sense of confidentiality, and it has been shown that adolescents attending a preventive care visit are more likely to have time alone with their provider than with those with a non-preventive care visit (40 and 28 percent, respectively) (Edman et al., 2010). However, the overall proportion of young people accessing confidential care remains relatively low, particularly for adolescents from low-income and ethnically diverse populations.

Other Barriers

Children enrolled in Medicaid are generally eligible for a well-child check up at least once every one to two years, but according to Medical Expenditure Panel Survey data from 2003 to 2006, an estimated 41 percent of children in Medicaid aged 2 through 20 years had not received a well-child checkup during the previous 2-year period. The estimated proportions of privately insured children who had received a well-child checkup were generally similar. CMS collects data and reports from states on the provision of EPSDT services, and reports from fiscal years 2000 through 2007 show that most states are not achieving the yearly goal of CMS that each state provide EPSDT well-child visits to at least 80 percent of the children enrolled in Medicaid in their state who should receive such care. State reports for 2007 showed that, on average, 58 percent of children enrolled in Medicaid received at least one EPSDT well-child visit for which they were eligible; the rates in individual states varied from 25 to 79 percent (GAO, 2009). As noted earlier for adults, only 39 states cover health maintenance visits to adults under Medicaid (GAO, 2009). Additional outreach to foster optimal utilization of preventive services may be necessary to overcome nonclinical barriers (e.g., transportation, literacy, and translation services).

Identified Gaps

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is lack of inclusion of well-woman preventive visits for women 21 to 64 years of age, which are used for providing recommended preventive services.

The evidence provided to support the inclusion of this service is based on federal and state policies (such as included in Medicaid, Medicare, and the Commonwealth of Massachusetts), clinical professional guidelines (such as those of AMA and AAFP), and private health plan policies (such as those of Kaiser Permanente).

Recommendation 5.8: The committee recommends for consideration as a preventive service for women: at least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. The committee also recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.

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6

Process for Regularly Updating the Recommendations

In this report, the Committee on Preventive Services for Women identifies a supplemental set of preventive health care services for women that should be considered by the U.S. Department of Health and Human Services (HHS). This task meets the first portion of the committee's charge, which was to identify services and screenings that could fill the identified gaps in women's preventive care not otherwise included in existing preventive services covered under the Patient Protection and Affordable Care Act of 2010 (ACA).

The second part of the committee's charge was to provide guidance on a process for updating the preventive services and screenings to be considered. Developing and maintaining a comprehensive list of covered preventive services for women is not currently under the specific purview of any advisory group, task force, committee, or agency within HHS. Thus, the committee believes that it will be necessary to develop structures, accountability, and processes to ensure that preventive services meeting evidence standards are considered for coverage in the context of the general approach taken to identify and update preventive services for women. Here, the committee recommends a process supported by guiding principles that separates assessment and coverage decisions. The co-mingling of evidence reviews and coverage decision making in one body could result in skewing scientific results and a decrease in transparency in the rationale for the coverage decision. Components for a comprehensive structure are discussed below.

GUIDING PRINCIPLES AND RECOMMENDATIONS

Recommendation 6.1: The committee recommends that the process for updating the preventive services for women covered under the ACA be:

- **Independent;**
- **Free of conflict of interest;**
- **Evidence-based;**
- **Gender specific;**
- **Life-course oriented;**
- **Transparent;**
- **Informed by systematic surveillance and monitoring;**
- **Cognizant of the need to integrate clinical preventive services with effective interventions in public health, the community, the workplace, and the environment; and**
- **Appropriately resourced to meet its mandate.**

A PREVENTIVE SERVICES COVERAGE COMMISSION

The committee notes that coverage decisions must take into consideration a more extensive list of factors—including medicolegal considerations, ethical considerations, patient and provider preferences, cost, and cost-effectiveness—and that these decisions must be made in the context of the coverage decisions made in other clinical domains. Existing evidence review bodies (such as the United States Preventive Services Task Force [USPSTF]) focus on clinical evidence; and other bodies that develop clinical guidelines (professional organizations) do not have the methods, the expertise, or the independence to make coverage recommendations. The committee believes that the review of the evidence and decision making about coverage are two separate activities and that there is value in preserving the separation. Thus, the committee does not recommend adding coverage decision making to the scope of work of existing evidence review bodies or bodies that develop clinical guidelines.

Recommendation 6.2: The committee recommends that the Secretary of HHS establish a commission to recommend coverage of new preventive services for women to be covered under the ACA.

In carrying out its work, the commission should:

- **Be independent from bodies conducting evidence reviews, free of conflict of interest, and transparent;**
- **Set goals for prevention (it may use available HHS reports and products or commission its own at its discretion);**

- **Design and implement a methodology for making coverage decisions that considers information from bodies that review the available clinical evidence (and other bodies that establish clinical guidelines) and coverage factors (e.g., cost, cost-effectiveness, and legal and ethical factors);**
- **Conduct horizon scanning or examine priority goals and/or persistent trends relating to women's health and well-being to identify new information on significant health conditions; preventive interventions; and new evidence on efficacy, effectiveness, periodicity, and safety;**
- **Focus on the general population but also search for conditions that may differentially affect women and high-risk subpopulations of women;**
- **Assign topics and set priorities for evidence-based reviews for the bodies reviewing clinical effectiveness;**
- **Set timetables and processes for updating clinical practice guidelines and coverage recommendations; and**
- **Submit its coverage recommendations to the Secretary of HHS.**

As noted in the guiding principles, suggested priorities are systematic surveillance and monitoring, as well as horizon scanning for new information on significant health conditions, preventive interventions, and new evidence on efficacy, effectiveness, periodicity, and safety. Similarly, setting agendas, timetables, and resources for developing the evidence reviews and guidelines will need to be recommended to the Secretary of HHS. A commission would not conduct its own systematic reviews of clinical effectiveness, relying instead on reviews completed by evidence review bodies under its direction. Recommendations will also need to be made by the commission regarding updates of evidence reviews and coverage decisions. Five years is a common benchmark for reevaluation of clinical practice guidelines and is the benchmark used by the National Guidelines Clearinghouse, but the committee notes that the process of scanning for new developments often uncovers issues that may require updates at other times.

ROLE OF EVIDENCE-BASED REVIEW BODIES

The committee believes that bodies that review the evidence, such as USPSTF, Bright Futures, and the Advisory Committee on Immunization Practices (ACIP), should continue to focus on evidence of efficacy and effectiveness. These bodies have an important role to perform and to contribute to this process in responding to direction from the Secretary of HHS and addressing topics requested. If necessary, systematic reviews will be commissioned, meeting established standards (e.g., the standards outlined in

Finding What Works in Health Care: Standards for Systematic Reviews [IOM, 2011b]). The evidence-review bodies should review the evidence with a primary focus on efficacy and effectiveness and develop clinical practice guidelines meeting established standards (e.g., the standards outlined in *Clinical Practice Guidelines We Can Trust* [IOM, 2011a]).

If the Secretary of HHS determines that existing evidence-review bodies cannot support these activities, new bodies that review the evidence should be created. Such bodies would best be populated with experts from within and outside government who are free of conflicts of interest and who represent a wide range of health and related disciplines. These experts should use standard, transparent, and accountable approaches to identify, assess, and synthesize the relevant evidence.

Recommendation 6.3. The committee recommends that the Secretary of HHS identify existing bodies or appoint new ones as needed to review the evidence and develop clinical practice guidelines to be reviewed by a preventive services coverage commission.

DISCUSSION

Bringing coverage for clinical preventive health care services into rational alignment with coverage for other health care services provided under the ACA will be a major task. The committee notes that many of the individual components are already managed within HHS but currently lack effective coordination for the purposes outlined in the ACA and that some functions are entirely new. The structure might be effectively built over time by using some current bodies and adding new ones as resources permit. The committee does not believe that it has enough information to specifically recommend which unit in HHS should implement the recommendations. Figure 6-1 illustrates the committee's suggested structure for updating preventive services under the ACA.

Additionally, the 2011 Institute of Medicine (IOM) study *Finding What Works in Health Care: Standards for Systematic Reviews* examines different grading systems in use. One review mentioned in the study found that there were more than 50 evidence-grading systems and 230 quality assessment instruments in current use. The variation, complexity, and lack of transparency in existing systems were identified (IOM, 2011b). In light of this, the Preventive Services for Women Committee chose not to identify a recommendation for HHS to consider for use in grading evidence. However, many of these models may warrant consideration.

The committee is aware that the IOM Determination of Essential Health Benefits Committee is developing recommendations regarding the criteria and methods for determining and updating the essential health

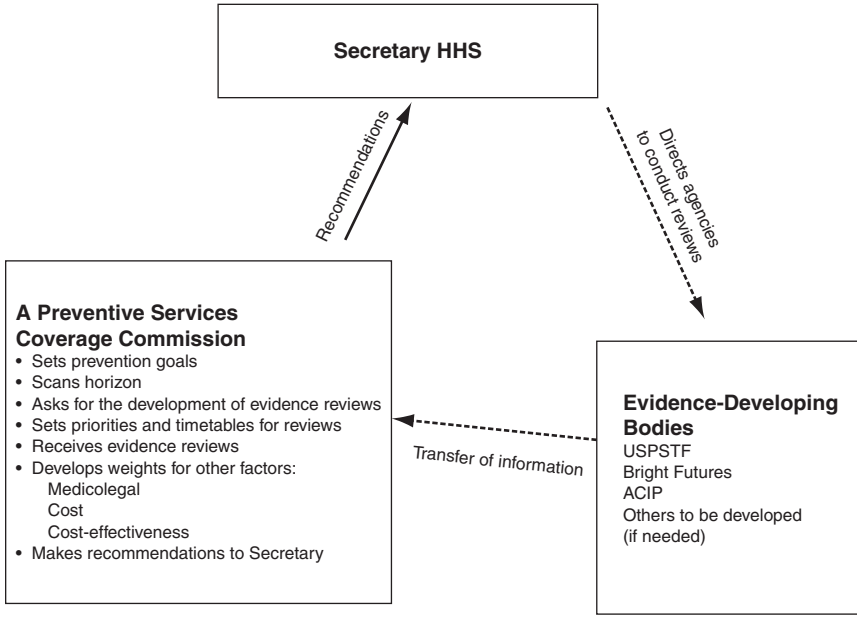

FIGURE 6-1 Suggested structure for updating preventive services under the ACA.

benefits package. That committee is reviewing how insurers determine covered benefits and medical necessity and will provide guidance on the policy principles and criteria for the Secretary to take into account when examining qualified health plans for appropriate balance among categories of care and limits on patient cost sharing. The committee's recommendations are forthcoming.

Although the ACA's preventive coverage rules are clearly directed at clinical services, the committee recognizes that in view of the critical importance of community-based preventive services and the public health system in achieving clinical aims, the committee thus encourages the Secretary to consider widening the scope of authority to include public health efforts to more comprehensively address prevention (e.g., as discussed in *Healthy People 2020: Topics & Objectives* [HHS, 2011]). It will be critical for the proposed preventive services coverage commission to coordinate with the new and existing bodies that are involved with other elements of the ACA.

Finally, the committee notes that it would make the most sense to consider preventive services for women, men, children, and adolescents in the same way. Thus, although the committee's recommendations presented here address women's preventive services, the process could be equally useful for

determining preventive services for men, children, and male adolescents that should be covered by the ACA.

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7

Findings and Recommendations for Addressing Identified Gaps in Preventive Services for Women

The Committee on Preventive Services for Women reviewed a large body of evidence on conditions that are important to women's health and well-being (see Chapters 1 and 4), including health conditions that may be specific to women, are more common or more serious in women, have distinct causes or manifestations in women, or have different outcomes or treatments in women (IOM, 2010). The committee also reviewed evidence on effective preventive measures used to address those diseases and conditions. The committee developed a list of potential preventive measures for the Secretary of the U.S. Department of Health and Human Services (HHS) to consider for coverage without cost sharing as it develops policies and programs as part of the requirements of the Patient Protection and Affordable Care Act of 2010 (ACA). Finally, Chapter 6 outlined the committee's suggested process for updating the review of preventive services for making decisions about coverage with no cost sharing by health plans governed by the ACA.

Table 7-1 summarizes the committee's recommendations for preventive services that could supplement currently recommended preventive services.

CONCLUDING OBSERVATIONS FROM THE COMMITTEE

The committee noted that a number of women's health-related research needs identified throughout the study process have been addressed more comprehensively in other Institute of Medicine (IOM) reports. Most recently, the IOM reports *Women's Health Research: Progress, Pitfalls, and Promise*, *Weight Gain During Pregnancy: Reexamining the Guidelines*,

TABLE 7-1 Summary of the Committee's Recommendations on Preventive Services for Women

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Screening for gestational diabetes	I	The evidence provided to support a recommendation for screening for gestational diabetes is based on current federal practice policy from the U.S. Indian Health Service, the U.S. Department of Veterans Affairs, as well as current practice and clinical professional guidelines such as those set forth by the American Academy of Family Physicians and the American Congress of Obstetricians and Gynecologists.	**Recommendation 5.1** The committee recommends for consideration as a preventive service for women: screening for gestational diabetes in pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.
Human papillomavirus testing (HPV)	I	The evidence provided to support a recommendation to support testing for HPV is based on federal practice policy from the U.S. Department of Defense. Peer-reviewed studies demonstrate that improved testing technologies, particularly combined screening using both conventional cytology and high-risk HPV DNA testing, may significantly improve the rate of detection of cervical cancer precursors and facilitate the safe lengthening of the interval for screening.	**Recommendation 5.2** The committee recommends for consideration as a preventive service for women: the addition of high-risk human papillomavirus DNA testing in addition to cytology testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections (STI)	I	The evidence provided to support a recommendation related to STI counseling is based on federal goals from the Centers for Disease Control and Prevention and *Healthy People 2020*, as well as recommendations from the American Medical Association and the American College of Obstetricians and Gynecologists.	**Recommendation 5.3** The committee recommends for consideration as a preventive service for women: annual counseling on sexually transmitted infections for sexually active women.

TABLE 7-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Counseling and screening for human immunodeficiency virus (HIV)	C	The evidence provided to support a recommendation for expanding screening for HIV is based on federal goals from the Centers for Disease Control and Prevention, as well as clinical professional guidelines, such as those from the American College of Physicians, the Infectious Diseases Society of America, the American Medical Association, and the American College of Obstetricians and Gynecologists.	**Recommendation 5.4** The committee recommends for consideration as a preventive service for women: counseling and screening for human immunodeficiency virus infection on an annual basis for sexually active women.
Contraceptive methods and counseling	Not Addressed	The evidence provided to support a recommendation related to unintended pregnancy is based on systematic evidence reviews and other peer-reviewed studies, which indicate that contraception and contraceptive counseling, are effective at reducing unintended pregnancies. Current federal reimbursement policies provide coverage for contraception and contraceptive counseling and most private insurers also cover contraception in their health plans. Numerous health professional associations recommend family planning services as part of preventive care for women. Furthermore, a reduction in unintended pregnancies has been identified as a specific goal in *Healthy People 2010* and *Healthy People 2020*.	**Recommendation 5.5** The committee recommends for consideration as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

continued

TABLE 7-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Breastfeeding support, supplies, and counseling	B	The evidence provided to support a recommendation regarding the inclusion of breastfeeding services is based on systematic evidence reviews, federal and international goals (such as the U.S. Surgeon General, Health Resources and Services [HRSA], *Healthy People 2020*, World Health Organization and UNICEF), and clinical professional guidelines such as those set forth by the American Academy of Family Physicians, the American Academy of Pediatrics, and the American College of Obstetricians and Gynecologists.	**Recommendation 5.6** The committee recommends for consideration as a preventive service for women: comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding. (The ACA ensures that breastfeeding counseling is covered; however, the committee recognizes that interpretation of this varies.)
Screening and counseling for interpersonal and domestic violence	I	The evidence provided to support a recommendation related to increasing detection of and counseling for domestic violence and abuse is based on peer-review studies and federal and international policies, in addition to clinical professional guidelines from organizations, such as the American Medical Association and the American College of Obstetricians and Gynecologists.	**Recommendation 5.7** The committee recommends for consideration as a preventive service for women: screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.

TABLE 7-1 Continued

Preventive Service	USPSTF Grade	Supporting Evidence	Recommendations
Well-woman visits	Not Addressed	The evidence provided to support a recommendation for including well-woman visits is based on federal and state policies (such as included in Medicaid, Medicare, and the commonwealth of Massachusetts), clinical professional guidelines (such as those of the American Medical Association and the American Academy of Family Practitioners), and private health plan policies (such as those of Kaiser Permanente).	**Recommendation 5.8** The committee recommends for consideration as a preventive service for women: at least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. The committee also recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.

and *Preterm Birth: Causes, Consequences, and Prevention* identified research priorities (IOM, 2007, 2009b, 2010). Additionally, the conditions described in Appendix A serve as examples for where additional high-quality research is needed to understand and better address preventive services specific to women.

The committee noted in its final deliberations that the United States Preventive Services Task Force (USPSTF) deserves much credit for identifying a nearly complete list of recommended preventive services for women. The USPSTF systematic evidence reviews were of great benefit during the committee's initial and follow-up examinations of the evidence. Additionally, the *Bright Futures* report (AAP, 2008) and the guidelines of the Advisory Committee on Immunization Practices filled several gaps not reviewed by the USPSTF. Although the committee started with an expansive look at a large number of diseases and conditions, the final recommendations summarized in this chapter are few.

Of note, during the course of the study process, the committee faced a number of difficult decisions. The committee decided that a strong case needed to be made regarding a disease or condition having a disproportionate effect on women. Although the committee upheld this standard, some of the recommendations made by the committee could also be considered for male populations.

Another factor that was difficult for the committee to fully ignore was the cost implications of the recommended services on the insurance market. Costs and cost-effectiveness are not easy to define or measure and differ depending upon priority perspectives—private insurer, government payer, patient, or society. The 2009 IOM study *Initial National Priorities for Comparative Effectiveness Research* examines priorities for considering cost-effectiveness in developing policy decisions (IOM, 2009a). Although the cost-effectiveness of services and examination of what the impact of new preventive health care services will have on health insurers were specifically excluded from committee's consideration, the committee notes that this sometimes made its task more difficult.

In addition, the committee deliberated on a number of interventions for reducing the incidence of diseases and conditions that were deemed effective but that were considered to be tertiary prevention, or interventions where a disease or condition had already been diagnosed. The committee determined that tertiary interventions involved treatment (and, potentially, prevention) decisions, which were outside of its scope.

Finally, questions rose as to what is common sense practice for a physician to discuss with patients. Does encouraging wearing a seat belt fall into this category? Is it the physician's responsibility to counsel patients with no clinical risk factors about healthful eating? To what extent should adolescents be afforded confidentiality? The gaps in gender analysis made this task even more difficult.

The ACA offers much promise in promoting prevention as an effective tool to improve health and well-being. When patients have health insurance coverage, a clear understanding of recommended services and screenings, and a usual source of care, it is the committee's belief that positive health outcomes will ensue. The ACA provides hope in efforts to eliminate health disparities and improve the health and well-being of women, children, and men across the United States.

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Appendixes

Appendix A

Clarifications

This appendix describes several conditions that the Committee on Preventive Services for Women examined to determine if there may be gaps in preventive services necessary for women's health and well-being that are not included in the United States Preventive Services Task Force (USPSTF) Grade A and B recommendations, Bright Futures, and Advisory Committee on Immunization Practices (ACIP) guidelines. The committee conducted a full review of the following conditions and risk factors, including those relating to cardiovascular disease, osteoporosis, breast cancer, mental health, tobacco use, and diet and physical activity. For these conditions, the committee concluded that there was insufficient evidence to develop new recommendations. At the same time, evidence supported by peer-reviewed studies, federal goals, professional clinical guidelines, and existing federal practices led the committee to suggest a clarifying statement to existing USPSTF recommendations, or led to a suggestion that specific services should be addressed within the context of the well-woman preventive care visit recommended by the committee. Several of the committee descriptions that follow serve as examples of areas in which further high-quality research is needed to understand and better address preventive services for women.

CARDIOVASCULAR DISEASE

Cardiovascular disease (CVD) is the class of diseases that involve the heart or blood vessels and includes high blood pressure, coronary heart disease (CHD), stroke, and heart failure (Bonow et al., 2011). Addressing cardiovascular disease across the life span in women, including during

adolescence, the reproductive years, and maturity, is important. It has been shown that risk factors experienced during pregnancy, such as hypertension of pregnancy, gestational diabetes, and preeclampsia, place women at risk for the development of cardiovascular disease as they age.

Prevalence/Burden

More women die annually from heart disease than men, but overall, men have a higher burden of CVD (Roger et al., 2011). Likely because of the obesity epidemic in the United States, rates of mortality from CHD (CVD affecting the coronary arteries) in women aged 35 to 54 years have increased in recent years.

CVD rates for American black females are significantly higher than those for their white counterparts (286.1/100,000 population and 205.7/100,000 population, respectively) (Mosca et al., 2011; Roger et al., 2011). The black female population also has a lower rate of awareness of heart disease than white women (Ferris et al., 2005; Kleindorfer et al., 2009; Mosca et al., 2010; Roger et al., 2011). More women die each year of stroke and stroke constitutes a higher proportion of CVD events in women, compared with a higher proportion of coronary heart disease in men. The majority of the research from which preventive care recommendations are derived is based on CHD and not stroke (Mosca et al., 2011).

Evidence shows differences in the pathology of CHD by sex, with women having a higher prevalence of disease of the small coronary vessels than men (Bairey Merz et al., 2006; Jacobs, 2006). Symptoms of CHD are more likely to be atypical, including dyspnea and epigastric discomfort (Canto et al., 2007). Lastly, premenopausal women who suffer sudden death are more likely to have pathologic findings of plaque erosion than plaque rupture, which is more common in men and postmenopausal women (Burke et al., 1998; Oparil, 1998). Older women who suffer a myocardial infarction are more likely than men to have plaque rupture with thrombus (Kruk et al., 2007). The relevance of these findings is unclear but points to biological differences in CHD in women, the full extent of which remains unknown.

Risk Factors for CVD

Most modifiable risk factors for the primary prevention of CVD, such as hypertension, hyperlipidemia, diabetes mellitus, smoking, obesity, metabolic syndrome, and physical inactivity, are similar in women and men; but the prevalence and impact of certain risk factors may differ by sex. Risk factors in which there are sex differences in prevalence and impact or in

which there are different criteria by sex are outlined below. Diabetes mellitus, obesity, smoking, and physical activity are addressed in other sections of this document.

Lipids: Elevated levels of low-density lipoprotein (LDL) present equivalent risks to women and men but a high-density lipoprotein (HDL) level of <50 mg/dL is considered a risk in women and an HDL level of <40 mg/dL is considered a risk in men (National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2002; Mosca et al., 2011). Currently, interventions to improve HDL mainly focus on lifestyle and control of traditional risk factors. No sex-specific interventions for increasing HDL levels currently exist.

Metabolic Syndrome: Metabolic syndrome is a constellation of risk factors that are associated with the development of CVD and type 2 diabetes mellitus. The diagnosis is made when three of the following five findings are present: (1) elevated waist circumference (≥40 in. [102 cm] in men and ≥35 in. [88 cm] in women), (2) elevated triglyceride levels (≥150 mg/dL [1.7 mmol/L]) or drug treatment for elevated triglyceride levels, (3) reduced HDL cholesterol levels (<40 mg/dL [1.03 mmol/L] in men and <50 mg/dL [1.3 mmol/L] in women or drug treatment for reduced HDL cholesterol levels, (4) elevated blood pressure (≥130 mm Hg systolic blood pressure or ≥85 mm Hg diastolic blood pressure) or antihypertensive drug treatment, and (5) elevated fasting glucose level of ≥100 mg/dL or drug treatment for elevated glucose levels (Grundy et al., 2005).

The prevalence of the metabolic syndrome is increasing and varies by age in women and men, with the prevalence being higher in men up to the age of 60 years, after which the rates are higher in women (51.5 percent in men versus 54.4 percent in women) (Ervin, 2009). Importantly, the rates of metabolic syndrome are significantly higher in non-Hispanic black and Mexican American women than in their male counterparts (38.8 and 25.3 percent, respectively, for non-Hispanic black women versus men and 40.6 and 33.2 percent, respectively, for Mexican American women versus men) (Ervin, 2009).

Meta-analyses of studies evaluating the metabolic syndrome showed an association of metabolic syndrome with an increased risk of developing CVD and death from CVD (relative risk = 1.78; 95 percent confidence interval = 1.58 to 2.00), with the association between metabolic syndrome and an increased risk of CVD being stronger in women than in men in the smaller number of studies that provide data by sex (relative risk = 2.63 versus 1.98, P = 0.09) (Gami et al., 2007).

Women with metabolic syndrome have a three times higher risk of dying from a heart attack or stroke than women who do not have it

(Cleveland Clinic, 2011), and they have a significantly elevated risk for developing type 2 diabetes (Lorenzo et al., 2007). Furthermore, women diagnosed with metabolic syndrome in early pregnancy have a significantly greater risk of developing gestational diabetes mellitus. An accurate measurement of the waist circumference must be obtained to make a diagnosis of metabolic syndrome.

Pregnancy-Related Risk Factors: Pregnancy-related risk factors such as preeclampsia, gestational hypertension, and gestational diabetes mellitus are specific to women and are risk factors for the development of CVD and CVD events in women as they age. These pregnancy-related disorders are highly prevalent, with approximately 5 percent of pregnancies complicated by preeclampsia. Gestational diabetes, which complicates 5 percent of pregnancies, is often seen in women who also have gestational hypertension.

Women who experience preeclampsia have twice the risk of heart disease, stroke, and venous thromboembolism as they age and are twice as likely to die of cardiovascular disease (Bellamy et al., 2007; McDonald et al., 2008; Rich-Edwards et al., 2010). In a Canadian population, women who have preeclampsia and preterm birth (<37 weeks of gestation) have been found to have an eight-fold higher risk of mortality from CVD than women who do not have preeclampsia and who give birth at term (Irgens et al., 2001).

Approximately 50 percent of the women who experience gestational diabetes mellitus will go on to develop type 2 diabetes mellitus and also experience a 70 percent increase in the risk of CVD, much of which can be attributed to the development of type 2 diabetes mellitus (Shah et al., 2008). Black women experience significantly higher rates of these pregnancy complications (Rich-Edwards et al., 2010).

Little is currently understood about the possible vascular abnormalities caused by these disorders or the time course of the increase in risk. Similarly, research on the etiology of these disorders and how best to prevent them before pregnancy, during pregnancy, or between pregnancies is lacking. Given the association of preeclampsia, gestational hypertension, and gestational diabetes with an increased risk of CVD in women as they age, the 2011 American Heart Association (AHA) guidelines for prevention of CVD in women recommends that a history of pregnancy complications be obtained as part of the evaluation of CVD risk in women (Mosca et al., 2011).

Depression: Depression is more common in women than men and disproportionately affects the outcomes of women who have experienced a myocardial infarction. Screening for depression is recommended for women with CVD, but no evidence suggests that screening affects the outcomes for these women. Research to understand the role of depression on the development of CVD and how sex and gender influence this relationship is emerging (Mosca et al., 2011).

Social Determinants of Health: Evidence shows that the risk for CVD is influenced by social determinants of health, such as socioeconomic status, geographic location, chronic stress, poverty, and racism. The intersection of race/ethnicity, gender, and economic status complicates the understanding of who is at risk for metabolic syndrome, but understanding this social patterning is important for the development of targeted interventions. In an analysis of data from the National Health and Nutrition Examination Survey III, economic status was found to have an impact on the incidence of metabolic syndrome for women but not for men. Women in the lowest economic group were more likely to be at risk than women in the highest economic group (Salsberry et al., 2007). Results such as these underscore the potential clinical significance of socioeconomic position, particularly for women (Loucks et al., 2007). Black women are at greater risk for CVD than white women of comparable socioeconomic status, and the age-adjusted rates of death from CVD for black women exceed those for white women (Hayes et al., 2006). Black women in the southern rural United States have among the highest rates of mortality from CVD, especially stroke (Casper et al., 2011).

These studies demonstrate that social determinants may have disproportionate impacts on the development of CVD in women, but more high-quality evidence is needed in this area.

High-Sensitivity C-Reactive Protein: High-sensitivity C-reactive protein is a nonspecific biomarker of increased risk for CVD. The role of the high-sensitivity C-reactive protein levels in the assessment of risk and in defining preventive strategies remains unclear. The Jupiter study, which is often cited as the rationale to use high-sensitivity C-reactive protein for screening, did not include women with low high-sensitivity C-reactive protein levels, and therefore, no definitive statement about the use of this biomarker to screen women in the general population can be made (Mosca et al., 2011; Ridker et al., 2010).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends the use of aspirin for women aged 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage. Grade A recommendation (USPSTF, 2009a).

The USPSTF recommends screening for high blood pressure in adults aged 18 and older. Grade A recommendation (USPSTF, 2007a).

The USPSTF strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease. Grade A recommendation (USPSTF, 2008).

The USPSTF recommends screening women aged 20 to 45 for lipid disorders if they are at increased risk for coronary heart disease. Grade B recommendation (USPSTF, 2008).

The USPSTF makes no recommendation for or against routine screening for lipid disorders in men aged 20 to 35 or in women aged 20 and older who are not at increased risk for CHD. Grade C recommendation (USPSTF, 2008).

The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for lipid disorders in infants, children, adolescents, or young adults (up to age 20). Grade I statement (USPSTF, 2007b).

The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Grade A recommendation (USPSTF, 2009b).

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 or adolescents. Grade I statement (USPSTF, 2003c).

Bright Futures recommends screening for high blood pressure throughout adolescence and annual screening for dyslipidemia. Otherwise, Bright Futures provides only anticipatory guidance on this subject (AAP, 2008).

Numerous organizations such as the AHA provide a wealth of expansive and specific guidelines for preventing CVD in women. The AHA alone recently published an updated list of more than 20 guidelines. These recommendations are commonly in agreement with those of the USPSTF.

The Adult Treatment Panel III from the National Cholesterol Education Program recommends that lipids be treated according to the risk stratification obtained by use of the Framingham risk score. This system stratifies patients into three basic categories by 10-year risk (the percentage probability of experiencing an event in the next 10 years): >20 percent, 10 to 20 percent, and <10 percent. However, these recommendations do not differ by sex.

Effective Interventions

A large body of evidence has been amassed to support prevention strategies for CVD in women and men. Even though CVD-related conditions are often grouped together, most evidence is based on trials that do not include stroke as the primary outcome, which is particularly important, given that stroke is more prevalent in women than men (Mosca et al., 2011). CVD is primarily prevented through adequate treatment of modifiable risk factors, including hypertension, diabetes mellitus, hyperlipidemia, and obesity, and achievement of a healthy lifestyle, including smoking cessation, physical activity, a healthy diet, and maintaining a healthy weight.

Metabolic syndrome is a significant risk factor for CVD in women, and the major focus is on preventing or treating the underlying modifiable risk factors, such as central obesity, hypertension, increased LDL and triglyceride levels, and diabetes mellitus. Lifestyle modification, including weight loss, physical activity, and a healthy diet, decreases all of the metabolic risk factors (Grundy et al., 2005). Although good data that link the modification of each risk factor that comprises metabolic syndrome to a decrease in cardiovascular risk are available, the data on preventing or treating metabolic syndrome are lacking. No data directly link screening for metabolic syndrome and prevention of CVD, although the syndrome must be recognized to accurately define women's risk.

Few data are available on effective interventions to prevent the complications of pregnancy, such as gestational hypertension and preeclampsia, which are risk factors for CVD. Achieving a healthy weight before pregnancy has been linked with decreased rates of these complications (IOM, 2009). Much remains to be learned about the mechanisms underlying these disorders, in particular, preeclampsia. Knowledge of these mechanisms might lead to effective preventive strategies (Rich-Edwards et al., 2010). Finally, identification of these disorders when a woman's medical history is obtained is important and will help to more accurately define overall risk for CVD.

Identified Gaps

The primary gaps in preventive services not already addressed by the provisions set forth in the ACA are (1) there is no comprehensive mechanism for the prevention or screening of metabolic syndrome in all women, and (2) there is no comprehensive mechanism in place to collect pregnancy complication histories to better predict the risk level of a woman for developing cardiovascular disease in the future.

The committee found insufficient evidence to support a new recommendation; instead, evidence supported by professional clinical guidelines led to committee support for the reasonableness of including screening for metabolic syndrome in women and obtaining a history of pregnancy complications within the context of the well-woman preventive visit.

BONE/SKELETAL DISEASE

The USPSTF recommends screening for osteoporosis using bone densitometry testing for women aged 65 years and older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors (USPSTF Grade B recommendation). This recommendation was based on the age and personal risk factors of average-risk women with no previous fragility fractures and does not explicitly address women with secondary causes of osteoporosis or previous fractures (USPSTF, 2011d).

Osteoporosis is a systemic skeletal condition associated with aging that is characterized by low bone density and deterioration of bone tissue that weakens bones and leads to fractures (USDHS, 2004). Osteoporosis-related fragility fractures result from forces that would not normally cause fractures, such as hip or wrist fractures from falling from standing height or a spine fracture resulting from compression of the vertebra from gravity alone. Although some types of fractures are more commonly related to osteoporosis (e.g., spine, hip, and wrist fractures), osteoporotic fractures can occur at nearly all sites.

In the absence of a fracture, osteoporosis can also be diagnosed by measuring bone density, or the thickness of bone. Results are expressed as the T-score, which is the difference between an individual's bone density measurement and normal values. The World Health Organization developed definitions for levels of bone density based on T-scores (Kanis, 1994). T-scores identify only one aspect of the condition, however. Other important components, such as rate of bone loss and quality of bone, are not currently measured in clinical practice.

Women with previous osteoporosis-related fractures are at high risk

for subsequent fractures. Although most women can accurately recall having had a previous fracture that required medical attention and fractures are usually well documented in medical records, tracking of women for follow-up care is usually difficult. As a result, evaluations for osteoporosis are often missed, drug treatments are not prescribed, and rates of subsequent fractures are high. Fractures that do not require immediate medical attention are often not recognized, such as spine fractures with mild or no symptoms. Nonetheless, asymptomatic spine fractures are also important in establishing the diagnosis of osteoporosis and determining needs for drug therapy.

Osteoporosis may occur without a known cause (primary osteoporosis) or occur as the result of another condition (secondary osteoporosis). Common secondary causes include dietary deficiencies in calcium or vitamin D; use of certain medications (aluminum antacids, anticoagulants, anticonvulsants, aromatize inhibitors, barbiturates, cancer chemotherapeutic drugs, depo-medroxyprogesterone, glucocorticoids, gonadotropin-releasing hormone agonists, lithium, and others); and the presence of health conditions (rheumatoid arthritis, diabetes, hyperparathyroidism, gastric bypass and other gastrointestinal surgery, malabsorption, inflammatory bowel disease, hemophilia, lupus, rheumatoid arthritis, kidney disease, depression, multiple sclerosis, emphysema, and others).

Several additional risk factors for osteoporosis and fractures have been determined from large population studies. Risk factors that cannot be modified include age, menopause, low body mass index, and a family history of osteoporosis and fractures. Modifiable risk factors include immobility, falls, tobacco use, and excessive alcohol intake (three or more drinks daily).

Prevalence/Burden

Low bone density, osteoporosis, and related fragility fractures are common in older adults. Estimates indicate that as many as 50 percent of Americans over age 50 years, or 14 million individuals by 2020, will be at risk for osteoporotic fractures during their lifetimes (USDHS, 2004). Fracture rates are higher and ages of incidence are younger for women than for men. Rates are highest in whites than in other racial groups, although osteoporosis is common in all groups (George et al., 2003; Looker et al., 1997; Nelson et al., 1995). Older individuals have much higher fracture rates than younger individuals with the same bone density because of increasing risks from other important contributors, such as falling (Heaney, 1998). All types of fractures are associated with higher rates of death (Bliuc et al., 2009; Center et al., 1999; Leibson et al., 2002). Nonfatal fractures at any site can impair function and quality of life, cause chronic pain and

disability, and result in high costs for health care and lost productivity (HHS, 2004).

Bone densitometry measures the mass of bone and can be used to predict the risk of future fractures, although it is an imperfect measure. Among bone measurement tests at various sites, the result of dual-energy X-ray absorptiometry (DXA) of the hip is the strongest predictor of hip fracture (Marshall et al., 1996). Several peripheral bone measurement tests have also been developed, including quantitative ultrasound (QUS) of the calcaneus (heel), which can predict fractures, as well as DXA, although variation exists across studies (Nelson et al., 2010b). QUS measures bone qualities differently from DXA, and correlates only modestly. Therefore, it is not clear how the results of QUS can be used clinically to select individuals who should receive drug therapies that were proven effective in clinical trials on the basis of DXA criteria.

Measurement of the bone density of appropriate candidates is essential before initiation of drug therapy because all of the drugs approved by the Food and Drug Administration (FDA) to treat low bone density and osteoporosis work by increasing bone density. Obtaining a bone density measure before therapy also provides an opportunity to monitor a response to the drug, if needed.

Identification of secondary causes and modifiable risk factors can lead to decisions to treat the underlying cause or risk factor specifically; to monitor bone density and treat osteoporosis if bone density is low or a fracture occurs; or to treat osteoporosis, in addition to the secondary cause or risk factor. Actual management depends on the secondary cause or risk factor, the severity of osteoporosis, additional health considerations, and patient preferences.

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends screening for osteoporosis in women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors. Grade B recommendation (USPSTF, 2011c).

Clinical guidelines from the National Osteoporosis Foundation recommend bone density testing for individuals with osteoporosis-related fractures

or secondary causes of osteoporosis, all women aged 65 years and older, and younger postmenopausal women with key risk factors (NOF, 2010).

Despite the increased awareness of osteoporosis and recommendations for screening and treatment from multiple groups, osteoporosis is underdetected and inappropriately treated in the United States (Kiebzak, 2002; Wilkins and Goldfeder, 2004). The reasons for this are unclear, although the different recommendations for identifying candidates for testing and treatment and confusion in interpreting the results of testing may be contributors (Morris et al., 2004). In addition, current medical practice in the United States is commonly fragmented for individuals experiencing osteoporosis-related fractures. The fracture itself is usually treated by an acute care team in hospital emergency departments and orthopedic services, whereas screening, prevention, and treatment are addressed in other contexts.

Effective Interventions

Primary prevention of osteoporosis and fractures begins early in life, while bone undergoes development. Attainment of peak bone mass and its maintenance require optimal nutrition and physical activity throughout the life span and avoidance of tobacco, alcohol, and other exposures that contribute to osteoporosis. All women require adequate calcium (1,200 mg daily) and vitamin D (800 to 1,000 international units daily) intake to avoid deficiencies and prevent osteoporosis and fractures (Standing Committee, 1997). Those with secondary causes of osteoporosis may require treatment of their specific underlying conditions to reduce their risks for osteoporosis and fractures. Women using medications causing osteoporosis may require adjustments in their medications and serial measures of bone densitometry to monitor effects on their bones.

The FDA has approved several drugs for prevention or treatment of osteoporosis (FDA, 2011) that reduce the risk for osteoporosis-related fractures by increasing bone density. Women with the lowest levels of bone density or with previous osteoporosis-related fractures are the most likely to benefit (Cummings et al., 1998). These drugs differ by their mechanisms of action, effectiveness in reducing fractures, routes of administration, and adverse effects.

Drugs for prevention are intended for individuals who have no previous fractures and whose bone density levels are not in the osteoporotic range (i.e., T-score ≥–2.5). For women, these include four bisphosphonate drugs, alendronate (Fosamax), ibandronate (Boniva), risedronate (Actonel, Actonel with calcium), and zoledronic acid (Reclast); several forms of estrogen with or without a progestin hormone; and raloxifene (Evista). For

some of the drugs, such as alendronate, prevention doses are smaller than treatment doses. Alendronate, raloxifene, and estrogen significantly reduced the incidence of spine fractures in clinical trials of women without previous fractures (Nelson et al., 2010a,b).

Drugs approved for treatment purposes are intended for individuals who have had previous osteoporosis-related fractures or whose T-scores are low (≤–2.5). For women, these include four bisphosphonate drugs, alendronate (Fosamax, Fosamax Plus D), ibandronate (Boniva), risedronate (Actonel, Actonel with calcium), and zoledronic acid (Reclast); calcitonin (Fortical, Miacalcin); denosumab (Prolia); raloxifene (Evista); and teriparatide (Forteo). In clinical trials of women with previous fractures, all of these drugs significantly reduced spine fractures, and all except calcitonin and raloxifene reduced fractures at other sites (MacLean et al., 2008; Nelson et al., 2010b). Trials evaluating the effectiveness of non-drug interventions alone and in combination with drugs would be clinically useful but are lacking. These interventions include functional assessment and improvement, safety evaluations, vision examinations, and nutritional analyses, among others.

Identified Gap

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is the lack of bone densitometry testing explicitly for women below the age of 65 at high risk for osteoporosis, such as those with previous fractures and secondary causes of osteoporosis. Evidence supported by systematic evidence reviews and the National Osteoporosis Foundation guidelines support a clarification statement to the USPSTF recommendation.

Clarification Statement

The committee interprets the current USPSTF recommendation regarding osteoporosis screening for women to include screening women with previous fractures and with secondary causes of osteoporosis.

BREAST CANCER

Women at high risk for breast cancer may require additional screening and surveillance services that are not included in the USPSTF screening recommendations and current legislation intended for average-risk women (*Federal Register*, 2010; USPSTF, 2009f). Issues surrounding the prevention of breast cancer in high-risk women are technical in nature because of the complexity of the condition.

Although several factors are associated with increased risk for breast cancer, few increase a woman's risk to levels that are clinically significant for screening purposes. Women at high risk include those with known mutations in breast cancer susceptibility genes one and two (*BRCA1* and *BRCA2*), with unknown mutation status but have a first-degree relative (parent, brother, sister, or child) with a *BRCA1* or *BRCA2* gene mutation, or have a family history of breast and related cancers regardless of mutation status. Also at increased risk are women who received radiation therapy to the chest, such as for treatment of Hodgkin's disease (Wahner-Roedler et al., 2003); have abnormal pathology results on a previous breast biopsy (Arpino et al., 2005); or have extremely dense breasts when viewed on mammography (Kerlikowske et al., 2010).

Prevalence/Burden

Breast cancer is the most frequently diagnosed cancer after skin cancer and the second leading cause of cancer deaths after lung cancer among women in the United States (ACS, 2010). In 2010, an estimated 207,090 cases of invasive breast cancer and 54,010 cases of noninvasive breast cancer were diagnosed, and an estimated 39,840 women died of breast cancer (ACS, 2010). Periodic mammography screening detects early stages of breast cancer and reduces the rate of mortality from breast cancer in clinical trials, although the extent of these benefits varies by age (Nelson et al., 2009a). Because most women with breast cancer have no major risk factors and are considered to be at average risk, mammography screening is recommended for women at all levels of risk (Smith et al., 2003a; USPSTF, 2009f). However, several individual characteristics are associated with an increased risk for breast cancer in epidemiological studies. Identifying women with risk factors most strongly associated with breast cancer can lead to the use of additional screening measures to improve early breast cancer detection and reduce the burden of disease for these women.

Clinically significant *BRCA* mutations are associated with an approximately 60 percent lifetime risk of breast cancer and a 15–40 percent lifetime risk of ovarian cancer. The prevalence of deleterious *BRCA* mutations is estimated to be between 1 in 400 to 1 in 800 in the general population (Anglian Breast Cancer Study Group, 2000; Ford and Easton, 1995; Whittemore et al., 2004), although specific *BRCA* mutations are clustered among certain ethnic groups such as Ashkenazi Jews (1 in 40) (Struewing et al., 1997). Rare disease syndromes related to deleterious mutations located on different genes also increase breast cancer risk to high levels (Garber and Offit, 2005).

Women with high risk for breast cancer can also be identified by risk

assessment instruments used in genetic counseling that are based mainly on family history information (Amir et al., 2003; Claus et al., 1994; Domchek et al., 2003; Gail et al., 1989; Tyrer et al., 2004). Approximately 10 percent of women have a first-degree relative (i.e., mother, sister, or daughter) with breast cancer, which doubles their risk of having breast cancer themselves (Collaborative Group, 2001; Pharoah et al., 1997). Risks are higher if more than one relative is affected and if breast cancer in relatives was diagnosed at younger ages, especially below age 50 years (Collaborative Group, 2001; Pharoah et al., 1997). Risk assessment considers all of these factors to provide an estimate of an individual's breast cancer risk.

Most women previously treated for breast cancer are closely monitored after treatment, and this type of surveillance generally falls outside of screening recommendations. Women who had previous biopsies that indicated abnormal lesions that were not cancer often re-enter screening programs after their biopsies. Some of these abnormal lesions can increase the breast cancer risk 4 to 10 times above average, depending on the type of lesion (Arpino et al., 2005). Approximately 16 biopsies are obtained for every 1,000 women undergoing mammography screening in the United States (Weaver et al., 2006). Of these biopsies, approximately 1 of the 16 has an abnormal lesion that increases the risk for breast cancer.

Women with extremely dense breasts when viewed by mammography have twice the five-year risk for breast cancer than women with normal breast density (Kerlikowske et al., 2010). Women with unevenly dense breasts also have elevated risks, but to a lesser degree (Kerlikowske et al., 2010). High breast density compromises the accuracy of mammography and increases susceptibility to breast cancer (Boyd et al., 2007; Kerlikowske et al., 1996; van Gils et al., 1998a,b). Women with extremely dense breasts, particularly younger women, are more likely to be diagnosed with advanced-stage disease than women with average breast density (Kerlikowske et al., 2010). A national study of mammography screening found that approximately 9 percent of women have extremely dense breasts and 37 percent have unevenly dense breasts, with the highest rates among younger women (Kerlikowske et al., 2010). The use of breast density as a risk factor in screening is currently limited, however, because it is not routinely provided with mammography results and interpretations vary widely in practice (Kerlikowske et al., 1998).

Determination of a woman's risk of breast cancer provides important clinical information to guide appropriate screening and prevention decisions. Women with family history information indicating high risk could adopt more intensive screening regimens that begin at younger ages that are more frequent and include additional clinical examinations and imaging technologies than women at average risk (Burke et al., 1997; Kriege et

al., 2004; Lee et al., 2010; Saslow et al., 2007; Warner et al., 2004). Those with family histories suspicious for deleterious *BRCA* mutations could undergo genetic testing and inform their relatives of their status to benefit them as well. Women at high risk of breast cancer could consider the use of medications (i.e., tamoxifen or raloxifene) or surgeries (i.e., mastectomy or oophorectomy, or both) to reduce their risks (Nelson et al., 2005, 2009b). Conversely, women often overestimate their risk of breast cancer (Bowen et al., 1998; Lerman et al., 1991, 1996). Women initially suspected to be at high risk but determined to be at average risk after further evaluation could be spared unnecessary evaluations, procedures, and worry if they had that information available.

Screening recommendations target primary care practice as the appropriate context for initial identification of women at high risk for breast cancer; however, methods for accurately stratifying women into high-risk and average-risk groups in this setting have not been adequately demonstrated (Nelson et al., 2005, 2009c). The accuracy of family cancer history information is variable, although a report of breast cancer in a first-degree relative was reasonably accurate in one study (sensitivity = 82 percent, specificity = 91 percent) (Murff et al., 2004). The accuracy of information for a first-degree relative was better than for a second-degree relative.

Health maintenance organizations, professional organizations, cancer programs, and state and national health programs have developed referral guidelines to assist primary care clinicians with identifying women at potentially increased risk (Nelson et al., 2005). Although specific items vary, most include questions about personal and family histories of *BRCA* mutations and breast and ovarian cancer, age of diagnosis, bilateral breast cancer, and Ashkenazi Jewish heritage. Most guidelines are intended to lead to a referral for more extensive genetic evaluation and counseling. No consensus or gold standard about the use of guidelines currently exists, and the effectiveness of this approach has not been evaluated. Concerns about inappropriate referrals in current practice include not only too few referrals of high-risk women but also too many referrals of average-risk women (White et al., 2008).

Genetic counseling provides an assessment of risk using established risk calculation instruments and is an essential step in determining if a woman is at increased risk and requires enhanced screening and prevention services. Genetic counseling to determine cancer risk status for women without breast cancer is a new concept in practice. No study has yet determined how genetic counseling modifies cancer screening behaviors or if doing so improves early detection and mortality. Information to guide effective integration of shared decision making into this process is also lacking. Although enhanced screening is recommended by expert groups (Burke et al.,

1997) and is based on favorable results of programs designed for women with familial risk (Brekelmans et al., 2001; Burke et al., 1997; Gui et al., 2001; Kollias et al., 1998; Warner et al., 2004), no trials of its effectiveness have been conducted.

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. Grade B recommendation (USPSTF, 2009e).

The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms. Grade C recommendation (USPSTF, 2009e).

The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older. Grade I Statement (USPSTF, 2009e).

The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older. Grade I statement (USPSTF, 2009e).

The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer. Grade I statement (USPSTF, 2009e).

The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing. Grade B recommendation (USPSTF, 2005a).

The USPSTF recommends that clinicians discuss chemoprevention 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. Grade B recommendation (USPSTF, 2002b).

The American Cancer Society recommends yearly magnetic resonance imaging (MRI) screening, in addition to mammography screening, and that clinicians consider starting screening at age 30 years for women with lifetime risks for breast cancer of >20 percent (ACS, 2011; Saslow et al., 2007). Expert groups also advise that women with *BRCA* mutations or with

strong family histories of early age of breast cancer onset begin screening at younger ages (e.g., five years younger than the age of diagnosis) (Burke et al., 1997). The Society of Breast Imaging and the American College of Radiology recently published guidelines on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer, recommending for women at high risk earlier screening and additional technologies that vary depending on the risk factor (Lee et al., 2010).

Assessment of breast cancer risk status and use of enhanced screening services are highly variable in practice. Ideally, an initial risk assessment based on personal characteristics and family cancer history would occur for all women as part of routine prevention in primary care. Currently, referrals to risk and genetic counseling for women without existing breast cancer are most commonly offered to relatives of women diagnosed with cancer and with strong family histories. As a result, enhanced screening is being provided to only some women who have been appropriately identified to be at high risk, as well as to others whose risk status may have been inadequately determined.

Effective Interventions

The efficacy of MRI in detecting breast cancer for screening purposes was demonstrated in a study of women with either deleterious *BRCA* mutations or a family history of breast cancer indicting a lifetime risk of 15 percent or greater (Kriege et al., 2004). Women were screened every six months by clinical breast examination and yearly by mammography and MRI. The sensitivity and specificity for detecting invasive breast cancer were 18 and 98 percent, respectively, for clinical breast examination; 33 and 95 percent, respectively, for mammography; and 79.5 and 90 percent, respectively, for MRI. The results were compared with those for two age-matched control groups undergoing usual screening (yearly mammography and clinical breast examination). One control group had a lifetime risk of 15 percent or greater, and the other had average risk. Women screened with clinical breast examination, mammography, and MRI had significantly smaller tumors at diagnosis and fewer cases of cancer spreading beyond the breast than women in either control group. Use of MRI also led to twice as many unneeded additional examinations as mammography and three times as many unneeded biopsies.

A comparison of four intensive screening approaches in *BRCA* mutation carriers included yearly MRI, mammography, and ultrasound and clinical breast examinations provided every 6 months (Warner et al., 2004). MRI was more sensitive in detecting breast cancers (sensitivity = 77 percent, specificity = 95 percent) than mammography (sensitivity = 36 percent, specificity = 99.8 percent), ultrasound (sensitivity = 33 percent, specificity = 96 percent), or clinical breast examination alone (sensitivity = 9 percent, speci-

ficity = 99 percent). Use of MRI, ultrasound, clinical breast examination, and mammography together had a sensitivity of 95 percent. In this study, 14 percent of women had a biopsy that proved to be benign. Additional clinical outcomes, including mortality, were not reported in either study.

Identified Gap

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is the lack of enhanced breast cancer screening services for high-risk women who may require earlier and/or more frequent examinations and imaging, as well as additional imaging technologies beyond mammography.

The committee believes that the evidence is insufficient to recommend coverage for additional breast cancer screening services for high-risk women at this time. The committee recognizes the complexity of appropriately identifying women with high levels of breast cancer risk to determine eligibility for services and the limitations of research on the potential benefits of the services. Considerations for increasing use of screening services are coupled with the acknowledgment of the harms that can also occur, including increasing the rates of false-positive results and benign biopsies and the adverse impact these experiences have on women. Nonetheless, the committee feels that with rapidly evolving scientific inquiry, such consideration should be reevaluated given evidence that may alter this assessment.

MENTAL HEALTH

Depression is a widespread mental disorder that affects approximately 121 million people worldwide and has been identified to be one of the top 10 leading causes of disease burden (Lopez et al., 2006; WHO, 2011). Symptoms include depressed mood, loss of interest or pleasure, feelings of guilt or low self-worth, fatigue, insomnia, and disturbed appetite. Depression may also lead to suicidal ideation and actions (NIMH, 2011b; WHO, 2011). In addition, postpartum depression is a condition specific to new mothers. Depression can occur throughout the life course, from childhood to late in life.

Prevalence/Burden

Adolescence is perhaps the most critical time period for recognizing mental health issues. Half of all mental disorders diagnosed in adulthood develop in puberty, by age 14 years (Merikangas et al., 2010). Data from the Behavioral Risk Factor Surveillance System (BRFSS) survey from 2008 revealed that young adults aged 18 to 24 years experienced the highest rates of current depression at 10.9 percent. The 45- to 64-year-old adult age

group experienced the next highest rates at 10 percent (CDC, 2010a). Adolescents and young adults also have high rates of suicide, which accounts for 12.2 percent of deaths among 15- to 24-year-olds annually (CDC, 2010b). In 2009, one in seven U.S. high school students reported that he/she had seriously considered attempting suicide over the past 12 months, and 6.3 percent reported that they had made at least one attempt during this time period. Suicide rates in women are highest over the age range of 45 to 54 years (CDC, 2010b). Across the life course, women may develop depression more often or more prominently around the time of certain reproductive events, such as menstruation, pregnancy, loss of a baby, birth of a baby, infertility, and menopause (ACOG, 2008).

Women are consistently rated as a high-risk group for depression (Kessler, 2003; Kessler et al., 2003) because depression is significantly more prevalent in women than in men at almost twice the rate. According to data from the BRFSS survey from 2008, 4 percent of women currently fit the criteria for major depression, whereas the rate was 2.7 percent among the surveyed men (CDC, 2010a). This disproportionate ratio emerges in adolescence, between ages 10 and 15 years (Angold et al., 1998). A lifetime experience of abuse, which women experience at higher rates, contributes to the development of depression, as well as suicide ideation and suicide (NIMH, 2011a,b; Tjaden and Thoennes, 1998).

Although death rates by suicide are higher among men, women attempt suicide two to three times more often (WHO, 2002). Existing mental disorders, particularly mood disorders like depression, are often seen as a precursor to a suicide attempt (Bertolote et al., 2003; Henriksson et al., 1993; Mann et al., 2005; Robins et al., 1959). Data from psychological autopsy studies have revealed that diagnoses of clinical mental disorders were found in nearly all suicide victims. The most prevalent disorders were depression and alcohol dependence or abuse. A diagnosis of major depression was documented in 46 percent of female suicide victims (of 26 percent of male suicide victims) (Henriksson et al., 1993). Minority sexual orientation and disclosure of sexuality are associated with various rates of suicidal ideation in women. In a U.S. survey of women, lesbians and bisexual women who were not "out" were more likely to have attempted suicide than heterosexual women (Koh and Ross, 2006).

Between 10 and 20 percent of mothers experience postpartum depression within the first year after giving birth, which has significant consequences for both the child's development and the mother's well-being (Chaudron et al., 2004; Freeman et al., 2005; Mishina and Takayama, 2009). Although it is common for new mothers to experience feelings of sadness, anxiety, and mood swings after giving birth, these "baby blues" last for a short period of time and are not severe. Postpartum depression symptoms are markedly more severe, last longer than two weeks, and require treatment from a trained professional (womenshealth.gov). Women

with postpartum depression are at risk for future depression, including recurrent postpartum depression. Like other instances of depression, postpartum depression can lead to suicidal ideation. One in five postpartum maternal deaths is a result of suicide (Lindahl et al., 2005). Mothers with postpartum depression may have difficulty with mother-infant bonding or have thoughts of harming their infant. They may also have impaired attention to pediatric preventive practices, like the use of care safety seats and pediatric health care utilization (Chaudron et al., 2004).

Diagnosis of postpartum depression is challenging for a number of reasons. Women who did not receive their pregnancy care from a family physician may be confused about who to turn to, if they are not scheduled to visit their obstetrician-gynecologist until a year later or if they view their pediatrician as purely their child's doctor. Symptoms of postpartum depression such as sleep disturbance, loss of energy, weight loss, and diminished concentration may be seen as normal sequelae of childbirth and not recognized as a marker of illness (Epperson, 1999).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up. Grade B recommendation (USPSTF, 2009g).

The USPSTF recommends against routinely screening adults for depression when staff-assisted depression care supports are not in place. There may be considerations that support screening for depression in an individual patient. Grade C recommendation (USPSTF, 2009g).

The USPSTF recommends screening of adolescents (12–18 years of age) for major depressive disorder (MDD) when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up. Grade B recommendation (USPSTF, 2009d).

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening of children (7–11 years of age). Grade I statement (USPSTF, 2009d).

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. Grade I Statement (USPSTF, 2004).

Bright Futures identifies emotional well-being and mental health to be priority screening areas for adolescents from ages 11 to 21 years and directs physicians to screen for depression and suicidal thoughts through the use of sample questions and anticipatory guidance. Bright Futures also recommends that mothers be screened for postpartum depression during the first- and second-month infant visits (AAP, 2008).

To help bring awareness to and combat the high rates of depression, the Institute of Medicine's (IOM's) report *Leading Health Indicators* recommended that *Healthy People 2020* (HHS, 2011) adopt a reduction in the proportion of people who experience major depressive episodes as one of its objectives (IOM, 2011). *Healthy People 2020* has already set a goal of increasing rates of screening for depression in primary care (HHS, 2011). In 1999, the U.S. Surgeon General identified suicide to be a major public health issue in the report *Call to Action to Prevent Suicide,* and current *Healthy People 2020* goals are to reduce the suicide rate overall, particularly for adolescents (HHS, 1999, 2011).

Professional organizations have also published guidelines on screening for suicide and postpartum depression, in addition to the depression screening that is already recommended by the USPSTF. The American College of Obstetricians and Gynecologists (ACOG) recommends a psychosocial evaluation that includes asking about suicide and depressive symptoms in patients aged 13 through 18 years (ACOG, 2007b). The American Medical Association (AMA) advises physicians with adolescent patients to ask about behaviors or emotions that indicate severe depression or suicidal thoughts on an annual basis (AMA, 1997). ACOG recommends that women be counseled about postpartum depression during the third trimester of pregnancy and that obstetricians-gynecologists consult with their patients about their risk of psychiatric illness during the postpartum period (ACOG, 2007a). ACOG also recommends that postpartum counseling take place as part of preconception care (ACOG, 2007b). In recognition of the underdiagnosis of postpartum depression, the U.S. Department of Veterans Affairs (VA) Clinical Practice Guideline for the Management of Major Depressive Disorder states that women receiving care through the VA be screened for depression at first contact with health care services in the antenatal and postnatal periods, separate from its guidelines on screening for depression in the general patient population (VA, 2009).

Effective Interventions

Depression is a condition commonly encountered in primary care because people with major depression utilize health care at high rates. A review of the evidence of rates of primary care and mental health specialist contact rates in select developed countries revealed that 45 percent

of suicide victims visit their primary care provider within one month of the suicide (Luoma et al., 2002). Moreover, increased rates of physician education and recognition of depression in primary care are associated with a reduction in the accompanying suicide rates (Mann et al., 2005). This evidence points to the utility of screening for depression in a primary care setting as a method of suicide prevention. However, the most recent systematic review of the evidence by the USPSTF, which was in 2004, found insufficient evidence to routinely screen for suicide risk in the general population (Gaynes et al., 2004).

Postpartum depression can be screened for and detected in the context of a well-child visit, as Bright Futures already recommends (AAP, 2008; Chaudron et al., 2004; Freeman et al., 2005; Mishina and Takayama, 2009). Six states (Illinois, Iowa, Kentucky, Pennsylvania, Louisiana, and Massachusetts) have implemented projects funded by the Health Resources and Services Administration to increase rates of screening for postpartum depression by increasing awareness, assessment, and treatment and joining the maternal and infant health care systems (Shade et al., 2011). The USPSTF recommendation for screening for depression does not address postpartum depression or denotes new mothers to be a high-risk group.

Mental health issues are increasingly becoming a part of primary care, in part because of increased physician education (Kessler et al., 2007). Although the numbers of patients who receive outpatient treatment for depression have increased, most individuals with depression receive inadequate care for their symptoms (Olfson et al., 2002). Among those receiving mental health services, more than one-fifth of patients received their treatment from a general medical provider (Wang et al., 2005). Psychotherapy treatment has decreased, whereas prescriptions for antidepressants have increased, including in children and adolescents, in part because of managed care plan support of pharmaceuticals over specialty care and also the challenges of providing psychotherapy in a physician's office, including but not limited to time constraints (Ma et al., 2005; Olfson et al., 2002; Pignone et al., 2002). Under the Mental Health Parity and Addiction Equity Act of 2008, group health plans and health insurance issuers must not place dollar limits on mental health benefits that are any lower than limits for medical and surgical benefits (DOL, 2011). Mental health benefits for depression would include ongoing psychotherapy and pharmacotherapy treatments.

Identified Gap

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that the current

recommendation for depression screening and follow-up does not address suicide and postpartum depression as related conditions to be evaluated. The committee found insufficient evidence to support a new recommendation; instead, evidence supported by systematic reviews, federal agendas from *Healthy People 2020* (HHS, 2011), and the U.S. Surgeon General, as well as clinical professional guidelines and federal practice guidelines support the reasonableness of including screening for suicide ideation and postpartum depression in women who are pregnant and/or who have recently given birth during the context of a well-woman visit.

TOBACCO USE

Tobacco use in the form of cigarette smoking is the leading cause of preventable morbidity and mortality in the United States. Quitting smoking with the help of cessation aids such as counseling and pharmacotherapy greatly improves a woman's health and well-being. Women of all ages should be encouraged and aided in their efforts to quit smoking, although pharmacotherapy is currently approved only for those over 18 years.

Prevalence/Burden

From 2000 to 2004, there were approximately 270,000 smoking-attributable deaths annually among males and approximately 174,000 smoking-attributable deaths annually among females (CDC, 2008a). Approximately 90 percent of lung cancer deaths are due to smoking (Stewart et al., 2008). Almost all tobacco use in women consists of cigarette smoking (SAMHSA, 2004). Although trends in the prevalence of smoking show that it is lower among women than men, between 1955 and 1995 the prevalence of smoking decreased more rapidly among men (Chilcoat, 2009). After 1995, a gradual decrease in the incidence of cigarette smoking occurred for both men and women. Data from the 2009 National Health Interview Survey show that in 1997, 27.6 percent of men and 22.1 percent of women reported being current smokers (CDC, 1999), whereas in 2009, 23.5 percent of men and 17.9 percent of women reported being current smokers (CDC, 2010c). Although the gap in smoking prevalence between men and women has narrowed considerably over time, these trends differ across levels of educational attainment. Women with less education appear to be a group at particularly high risk (Chilcoat, 2009).

In addition to lung cancer, smoking increases women's risk of developing uterine, cervix, and other cancers, including cancers of the head and neck, pancreas, kidney, and bladder. Smoking doubles a woman's risk of developing coronary heart disease (HHS, 2001). Women who smoke and

concurrently use oral contraceptives are at a 30-fold increased risk for myocardial infarction and a 3-fold increased risk of stroke compared with nonsmokers (Burkman et al., 2004). Postmenopausal women who smoke have lower bone density than women who never smoked, and they have an increased risk for hip fracture than woman who never smoked (HHS, 2001; Law et al., 1997). Cigarette smoking also increases the risk for infertility, and smoking during pregnancy may result in negative reproductive and developmental effects, including premature birth, stillbirth, low birth weight, intrauterine growth retardation, and sudden infant death syndrome (Ashford et al., 2010; Behm et al., 2011; IOM, 2011; Khader et al., 2011; Ye et al., 2010).

Smoking cessation may be more difficult for women for a number of reasons. Women metabolize nicotine faster than men, and oral contraceptives lead to an even faster rate of metabolization of nicotine (Benowitz, 2008; Benowitz et al., 2006). The faster rate of metabolism found in women may contribute to a higher level of nicotine addiction. In addition, smoking and depression are strongly linked, and women suffer higher rates of depression, which may make quitting smoking more difficult (Smith et al., 2003b). Women may be motivated to quit for different reasons than men, such as improving fertility and reproductive health, pregnancy outcomes, physical appearance, and health problems that occur predominantly in women, such as osteoporosis (Smith et al., 2003b).

Most cases of tobacco dependence begin during childhood and adolescence (Fiore et al., 2008). The younger that a person is when he or she starts smoking, the more likely it is that the person will become dependent on nicotine and the more difficult it will be to quit (IOM, 1994). Only about 4 percent of young smokers are successful in quitting each year. Between 1991 and 2009, the prevalence rates of current cigarette smoking in high school students were similar in males and females and have shown a gradual decline over the past decade (Latimer and Zur, 2010). During this period, the prevalence of smoking decreased from 27.3 to 19.1 percent in females and from 27.6 to 19.8 percent in males (Garrett et al., 2011). Among adolescents 12 to 17 years of age, the prevalence of tobacco use is 11.4 percent (CDC, 2010e), and it has been found that tobacco use during adolescence is associated with risky sexual behavior and use of alcohol and other drugs (Latimer and Zur, 2010).

Existing Guidelines and Recommendations

USPSTF Recommendations

The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. Grade A recommendation (USPSTF, 2009b).

The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke. Grade A recommendation (USPSTF, 2009b).

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 or adolescents. Grade I statement (USPSTF, 2003c).

The 2008 Public Health Service Guideline Update Panel (Fiore et al., 2008) made 10 recommendations regarding effective interventions delivered in health care settings. The updated guidelines were sponsored by eight federal government and private nonprofit organizations, including the Adolescent Health Research Program, the Centers for Disease Control and Prevention (CDC), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Drug Abuse (NIDA), the American Legacy Foundation, the Robert Wood Johnson Foundation, and the University of Wisconsin Center for Tobacco Research and Intervention. These recommendations go beyond those of the USPSTF, in that they provide in detail the specific types of behavioral interventions and pharmacological treatments that clinicians can recommend to patients. The guideline panel noted that providing coverage for these treatments increased quit rates, and it recommended that all insurance plans include coverage for the strategies that it identified to be effective. The Partnership for Prevention supports the more detailed recommendations of the panel on the tobacco cessation services that should be covered by health insurance, including recognition that quitting often requires multiple or repeated interventions (Richland, 2011).

The panel emphasized that tobacco cessation interventions be interpreted to include both counseling and FDA-approved and over-the-counter medications. These recommendations have been echoed by numerous federal agencies and national medical and health associations and are consistent with the mandates of the Affordable Care Act (ACA) and the Centers

for Medicare and Medicaid Services to provide expanded coverage for tobacco screening and cessation services delivered in health care settings (Morris et al., 2011).

A number of organizations have made recommendations regarding screening for and counseling about tobacco use in adolescents (ACOG, 2010; Binns et al., 2009; Fiore et al., 2008; Gostin et al., 1997; Marwick, 1997). The 2008 guideline panel made specific recommendations for children and adolescents. It recommended that clinicians (1) ask their pediatric and adolescent patients about tobacco use and provide a strong message about abstaining from tobacco use (strength of evidence C); (2) provide counseling interventions to facilitate cessation (strength of evidence B); and (3) ask parents about tobacco use and offer cessation advice and assistance to quit (strength of evidence B).

Effective Interventions

A number of intervention strategies, including behavioral counseling and pharmacotherapies, have been shown to be effective for tobacco cessation when they are delivered in a primary care setting to nonpregnant adults aged 18 years and over (USPSTF, 2009c). The USPSTF concluded that a dose-response relation between quit rates and the intensity of counseling exists. Providing more sessions or increasing the length of sessions increased quit rates. Components of counseling strategies that were effective included instruction in problem solving and coping techniques, goal setting, developing a plan for quitting, motivational interviewing, telephone quit lines, and referrals. Combining counseling with pharmacotherapy was more effective than either approach alone. Although women appear to benefit from the same interventions as men, the data are inconsistent as to whether they benefit as much and what types of interventions are the most effective for women (Fiore et al., 2008; Munafo et al., 2004; Perkins and Scott, 2008). One meta-analysis found that the efficacy of nicotine replacement therapy was less effective in women than in men (Perkins and Scott, 2008); however, other meta-analyses have shown equivalent benefits in men and women (Baker et al., 2011; Killen et al., 2002). Behavioral interventions, such as tailored educational messages and self-help materials, were found to increase abstinence from smoking during pregnancy, but the USPSTF found inadequate evidence to evaluate the safety or efficacy of pharmacotherapy during pregnancy (USPSTF, 2009c).

In a systematic review conducted by the National Commission on Prevention Priorities for the Partnership for Prevention, screening for tobacco use and brief intervention counseling with an offer of pharmacotherapy ranked third of 25 clinical preventive services in terms of the most beneficial services to offer patients (Maciosek et al., 2009, 2010). The percent-

age of adult smokers who visited a clinician within the past year and who reported that they received advice to quit was about 68 percent, but only about 35 percent of smokers received brief counseling in which medication and cessation strategies recommended by the USPSTF were discussed (CDC, 2003; NCQA, 2005). Likewise, identifying and counseling adolescent smokers are estimated to occur in only 33 to 42 percent of physician visits and about 20 percent of dental visits (Alfano et al., 2002; Shelley et al., 2005).

Most behavior change intervention studies of smoking cessation and prevention in youth and adolescents have been conducted in school or community settings. Scant data on intervention strategies delivered in clinical settings are available, and the existing data are inconsistent (Fiore et al., 2008; Grimshaw and Stanton, 2006). In an analysis of seven studies comparing counseling with usual care or no treatment, the long-term abstinence rate doubled for the groups receiving counseling; however, the absolute abstinence rate was low (Fiore et al., 2008). Effective strategies varied in content, format, and intensity and included brief advice, educational pamphlets, self-help materials, and/or referrals. No data were available on whether these strategies were equally effective in boys and girls when they were offered in clinical settings. An update of the Surgeon General's report on preventing tobacco use among young people is expected to be released by December 2011 (in press).

Identified Gap

The primary gap in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) is that while tobacco cessation aids and counseling are recommended, the potential need for multiple interventions defined by the Public Health Service Guidelines, which include pharmacotherapy, in helping women to quit smoking are not addressed. The committee found insufficient evidence to develop a new recommendation; instead, the evidence supported by high-quality systematic reviews, supportive systematic reviews, federal agendas from the CDC, NCI, NHLBI, and NIDA, as well as clinical professional guidelines, led to a clarifying statement, which was added to the USPSTF recommendation.

Clarification Statement

In recognizing that women may need more than one type of intervention for successful tobacco cessation, the committee interprets the current USPSTF recommendation regarding tobacco use screening and cessation to consider including both counseling and FDA-approved and over-the-

counter medications. Additionally, it is appropriate for pregnant women who smoke to receive counseling that is tailored to their needs.

DIET/PHYSICAL ACTIVITY

An unhealthy diet and physical inactivity are associated with the leading causes of morbidity and mortality among women in the United States. Counseling patients in a clinical setting offers an opportunity to motivate women to adopt healthy dietary and physical activity behaviors. The target populations for diet and physical activity counseling are adult women 18 years of age and older, pregnant women of any age, and adolescent females.

Prevalence/Burden

Physical inactivity is associated with increased risk of all-cause mortality, coronary heart disease, high blood pressure, stroke, type 2 diabetes, metabolic syndrome, colon cancer, breast cancer, osteoporotic fractures, falls, and depression. Regular physical activity during pregnancy may reduce the risk of preterm birth, low birth weight, early pregnancy loss, and chronic health problems in the offspring; and moderate-intensity physical activity may increase cardiorespiratory and metabolic fitness (Physical Activity Guidelines Advisory Committee, 2008).

The benefits of physical activity in children and adolescents have been less studied; however, data support the findings that important health and fitness benefits accrue to children and adolescents who participate in 60 or more minutes of moderate to vigorous physical activity daily. Regular exercise helps control weight and build and maintain strong bones and confers positive psychological benefits (CDC, 2008b; Physical Activity Guidelines Advisory Committee, 2008).

Data from the 2008 National Health Interview Survey show that women are less likely than men to be highly active and are more likely to be insufficiently active and inactive (Carlson et al., 2010). Every year from 1998 through 2008, women were less likely to be aerobically active, according to *Healthy People 2010* criteria (Carlson et al., 2010; HHS, 2011). In 2008, 33 percent of men but only 24 percent of women were highly active. Data from the BRFSS also show that women are less active than men for every measure of physical activity (e.g., recommended physical activity, insufficient physical activity, inactivity, and no leisure-time physical activity), and this pattern was consistent from 2001 through 2008 (CDC, 2008c).

As the prevalence of physical activity has decreased, the prevalence of

unhealthy eating behaviors has increased, contributing to an epidemic of obesity in the United States. Men and women appear to be equally at risk for obesity. In the 2009 BRFSS survey, 27.4 percent of men and 26 percent of women were obese, as measured from the body mass index (CDC, 2010d). Data from the first National Health and Nutrition Examination Survey (NHANES I) for the period from 1971 to 1975 compared with data from the 2005 and 2006 NHANES show that the percentage of overweight and obese men and women has increased substantially. For women, the proportion who were overweight or obese increased from 40.7 to 61.5 percent; for men, the increase was from 52.9 to 73.6 percent (Austin et al., 2011).

In contrast to the male-female differences in physical activity, women are more likely than men to report that they eat a healthier diet. In the 2009 BRFSS survey, 36.1 percent of women and 28.7 percent of men reported eating fruit two or more times a day (2010). Women were also more likely than men to report eating vegetables three or more times a day: 30.9 and 21.4 percent for women and men, respectively. This pattern has been consistent since 1996 (CDC, 1996; Serdula et al., 2004). Despite these differences, the average intake of carbohydrates, protein, total fat, and saturated fat as a percentage of total kilocalories was similar for men and women (Wright and Wang, 2010).

Healthy diet and physical activity during pregnancy have health benefits for the woman and her child (Physical Activity Guidelines Advisory Committee, 2008). Moreover, 20 percent of women are obese when they become pregnant (Van Horn, 2010), indicating that they may not be receiving appropriate nutrients or maintaining a healthy diet. Many women put on excess weight during pregnancy and have difficulty losing it afterwards, but during the postpartum period, physical activity alone will not produce weight loss unless it is coupled with dietary changes. The importance of proper nutritional intake and proper eating behavior during pregnancy was underscored by the 2010 Dietary Guidelines Advisory Committee, which recommended that future reports include dietary recommendations from birth (Van Horn, 2010).

Similar to the pattern for adult females, data from the Youth Risk Behavioral Surveillance System show that the self-reported prevalence of physical activity is substantially lower in girls than in boys and remained so from 1993 to 2009 (CDC, 2011). During that period, there was a marked decrease in the percentage of adolescents who met the recommended physical activity levels. In 1993, 75 percent of boys and 56 percent of girls met the recommended levels. In 2009, only 46 percent of boys and 28 percent of girls met the recommended activity levels (CDC, 2011).

Existing Guidelines and Recommendations

USPSTF Recommendations

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. Grade I statement (USPSTF, 2003a).

The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians. Grade B recommendation (USPSTF, 2003a).

The USPSTF concludes that the evidence is insufficient to recommend for or against behavioral counseling in primary care settings to promote physical activity. Grade I statement (USPSTF, 2002a).

The USPSTF is in the process of updating its 2002 recommendation on behavioral counseling to promote physical activity (Berg et al., 2002) and its 2003 recommendation on behavioral counseling to promote a healthy diet in adults (USPSTF, 2003b). The earlier systematic reviews found insufficient evidence to recommend for or against behavioral counseling in primary care settings to promote either physical activity or healthy dietary behaviors in adults without preexisting cardiovascular disease or its risk factors (2003; Berg et al., 2002). An updated draft recommendation statement was available for comment from February 22 to March 22, 2011 (USPSTF, 2011b). This recommendation (Lin et al., 2010) will replace the USPSTF's previous separate recommendations on behavioral counseling to promote a healthful diet (USPSTF, 2003b) and physical activity (Berg et al., 2002).

Although the 2003 recommendation on dietary counseling included a positive recommendation for counseling adults with risk factors for cardiovascular disease (Grade B recommendation) (USPSTF, 2003b), the updated statement does not include a recommendation for this subgroup (Lin et al., 2010). On the basis of the updated systematic review, the USPSTF concluded that "the average benefit of primary care behavioral counseling interventions to promote a healthful diet and/or physical activity for cardiovascular disease prevention is small. Clinicians may consider selectively providing or referring individual patients for medium- or high-intensity behavioral counseling interventions" (Grade C recommendation) (USPSTF, 2011b).

Bright Futures recommends that physicians calculate the body mass

index for patients ages 10 to 21 years and discuss healthy diet and physical activity through the provision of anticipatory guidance (AAP, 2008). The AMA also advises physicians to provide adolescents with annual guidance about healthy dietary habits and the benefits of engaging in physical activity on a regular basis (Copperman, 1997).

Effective Interventions

Counseling about diet and physical activity in the primary care setting provides an opportunity to mitigate the negative health outcomes associated with poor dietary behaviors and physical inactivity. The systematic review conducted for the USPSTF (Lin et al., 2010) identified 66 trials of counseling to promote physical activity, a healthy diet, or both. The outcomes measured in these trials included morbidity and mortality related to cardiovascular disease, risk factors for cardiovascular disease, and self-reported dietary and physical activity behaviors. High-intensity counseling about a healthy diet with or without counseling about physical activity resulted in positive changes in body mass index (adiposity), systolic and diastolic blood pressure, and total and low-density lipoprotein cholesterol levels. Medium- and high-intensity physical activity counseling interventions resulted in small increases in physical activity levels, although data for low-intensity interventions were inconsistent. Reductions in self-reported fat intake were observed at all levels of intervention intensity, but high-intensity interventions resulted in larger reductions. Increased fruit and vegetable consumption was observed at all levels of intervention intensity. Very few trials had periods of follow-up beyond 12 months, thus the long-term effects of the counseling interventions about dietary patterns is unknown.

Although all of the trials were conducted in health care settings or recruited participants from health care settings, the role of the primary care provider was minimal in some of the studies.

Virtually all of the trials included women; however, very few provided gender-specific comparisons of the impact of the interventions on health-related outcomes, and very few studies included women during pregnancy or the postpartum period (Lin et al., 2010). An earlier review examined diet and physical activity interventions delivered in health care settings only to women (Wilcox et al., 2001). Findings from these earlier studies were consistent with the positive results of the USPSTF review for body mass index; systolic and diastolic blood pressure; and total cholesterol, low-density lipoprotein cholesterol, dietary fat, and physical activity levels. Although effect size estimates, as measured by the mean correlation coefficient, were small, they were statistically significant. Results for dietary fiber, energy in-

take, general dietary factors, and high-density lipoprotein cholesterol were not statistically significant (Wilcox et al., 2001).

The AHA recently reviewed interventions to promote physical activity and dietary changes and issued recommendations for counseling people to increase their levels of physical activity and make healthy dietary changes. Although the review was not limited to interventions delivered in a clinical setting, the group made recommendations about strategies that clinicians could use in primary care settings to assist adults in adopting and maintaining health dietary and physical activity behaviors, including the use of cognitive-behavioral strategies and modifying interventions to be appropriate to the patient's social and cultural context (Artinian et al., 2010).

Most intervention studies to promote a healthy diet or physical activity in children and adolescents have been conducted in school or community settings. Interventions conducted in clinical settings have targeted overweight and obese children (Summerbell et al., 2003; Whitlock et al., 2010). A 2006 report of the USPSTF on screening and interventions that targeted overweight children and adolescents found insufficient evidence for the effectiveness of behavioral counseling or other preventive interventions that could be conducted in primary care settings or to which primary care clinicians could make referrals. However, some reviews of interventions for preventing obesity in children and adolescents have been conducted (Summerbell et al., 2003; Whitlock et al., 2010).

Identified Gaps

The primary gaps in preventive services not already addressed by the provisions set forth in the ACA (reviewed in this section) are the lack of interventions in primary care practice that address healthy diet and physical activity. The committee found insufficient evidence to develop a new recommendation; instead, the evidence supported by high-quality systematic evidence reviews and clinical practice guidelines, as well as the draft recommendation statement from the USPSTF (indicating that medium- to high-intensity interventions for diet and physical activity led to small benefits toward prevention of cardiovascular disease), led to support for the reasonableness of including diet and physical activity counseling during a well-woman visit.

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Appendix B

Agendas of Public Meetings Held by the Committee on Preventive Services for Women

FIRST MEETING
November 16, 2010
The Dupont Circle Hotel
Washington, DC

Welcome and Overview
Linda Rosenstock, M.D., M.P.H.
Committee Chair

Presentation of the Charge
Mona Shah, J.D., M.P.H.
Professional Staff Member
Office of Senator Barbara Mikulski (MD)
Senate Committee on Health, Education, Labor, and Pensions

Sherry Glied, Ph.D.
Assistant Secretary for Planning and Evaluation
Department of Health and Human Services

Mary Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration

Committee Discussion

Groups Interested in Women's Issues

Judy Waxman, J.D.
Vice President of Health and Reproductive Rights
National Women's Law Center

Cynthia Pearson
National Women's Health Network
Women's Voices Are Raising Women's Voices for the Health Care We Need

Carolyn Westhoff, M.D., M.Sc.
Planned Parenthood Federation of America
Board Member and Immediate Past Chair of the National Medical Advisory Committee

Eleanor Hinton Hoytt
Women of Color United for Health Reform

Esta Soler
President and Founder of the Family Violence Prevention Fund

Adolescent Issues

Sarah S. Brown
Cofounder and Chief Executive Officer
The National Campaign to Prevent Teen and Unplanned Pregnancy

John Santelli, M.D., M.P.H.
Mailman School of Public Health
Columbia University
and Society for Adolescent Medicine

Methodological Approaches

Mary Barton, M.D., M.P.P.
Scientific Director of the United States Preventive Services Task Force (USPSTF).
Agency for Healthcare Research and Quality

Ned Calonge, M.D., M.P.H. (via phone)
Chair, USPSTF

Joseph Hagan, M.D.
Paula Duncan, M.D. (via phone)
Authors
Bright Futures for Infants, Children, and Adolescents

Sarah Scholle, Dr.P.H., M.P.H.
Assistant Vice President of Research and Analysis
National Committee on Quality Assurance
Quality for Well-Woman Care

Committee Discussion

Opportunity for Attendees to Comment

SECOND MEETING
January 12, 2011
National Academies Keck Center
Washington, DC

Welcome and Overview
Linda Rosenstock, M.D., M.P.H.
Committee Chair

Women's Health Organizations
Sharon Camp, M.A., Ph.D.
President and Chief Executive Officer
The Guttmacher Institute

Hal Lawrence, M.D., F.A.C.O.G.
Incoming Executive Vice President
Vice President of Practice Activities
American Congress of Obstetricians and Gynecologists

Catherine Ruhl, C.N.M., M.S.
The Association of Women's Health, Obstetric and Neonatal Nurses

National Health Interest Groups
Sharon Moffatt, R.N., B.S.N., M.S.
Chief of Health Promotion and Disease Prevention
Association of State and Territorial Health Officials

Jud Richland, M.P.H.
President and Chief Executive Officer
Partnership for Prevention

Margaret Blythe, M.D. F.A.A.P.
Chair, Committee on Adolescence
American Academy of Pediatrics

Provider and Employer Perspectives
George Isham, M.D., M.S.
Medical Director and Chief Health Officer
HealthPartners

Joanne Armstrong, M.D., M.P.H. (via phone)
Senior Medical Director and Head of Women's Health
Aetna

Helen Darling, M.A.
President
National Business Group on Health

Wayne Burton, M.D.
Global Corporate Medical Director
American Express Corporation

Opportunity for Attendees to Comment

THIRD MEETING
March 9, 2011
National Academy of Public Administration
Washington, DC

Welcome and Overview
Linda Rosenstock, M.D., M.P.H.
Committee Chair

Guidelines Development and Use
Doug Campos-Outcalt, M.D., M.P.A.
AAFP Liaison to United States Preventive Services Task Force and Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention

Melissa Starkey, Ph.D.
Clinical Guidelines Administrator
American College of Physicians

David Rind, M.D. (via phone)
Co-Executive Editor
UpToDate
GRADE Working Group

Coverage Design and Decision Making

Sara Rosenbaum, J.D.
Hirsh Professor and Chair
Department of Health Policy
School of Public Health and Health Services
The George Washington University Medical Center

Other Preventive Health Issues

Gwen Keita, Ph.D.
Director, Women's Programs Office and Associate Executive Director
Public Interest Directorate
American Psychological Association

Lauren Patton, D.D.S.
Professor and Chair
Department of Dental Ecology and Program Director
General Practice Residency
School of Dentistry
University of North Carolina, Chapel Hill

Melissa A. McDiarmid, M.D., M.P.H., D.A.B.T.
Professor
Departments of Medicine and Epidemiology and Public Health and Director
Occupational Health Program
University of Maryland School of Medicine

Opportunity for Attendees to Comment

Appendix C

Committee Biographies

Linda Rosenstock, M.D., M.P.H. (elected to the Institute of Medicine [IOM] in 1995), is dean of the School of Public Health, University of California at Los Angeles (UCLA). She is a recognized authority in occupational and environmental health as well as global public health and science policy. Prior to going to UCLA in 2000, Dr. Rosenstock served for seven years as the director of the National Institute for Occupational Safety and Health, where she led a staff of 1,500 at the only federal agency mandated to undertake research and prevention activities in occupational safety and health. In recognition of her efforts, Dr. Rosenstock received the Presidential Distinguished Executive Rank Award, the highest executive service award in the federal government. In 2003 she cochaired the IOM committee addressing public health workforce needs that authored the report *Who Will Keep the Public Healthy? Educating Public Health Professionals for the 21st Century*. Dr. Rosenstock is immediate past chair of the Association of Schools of Public Health and immediate past president of the Society of Medical Administrators.

Alfred O. Berg, M.D., M.P.H., is professor in the Department of Family Medicine at the University of Washington School of Medicine, Seattle. Dr. Berg received his professional education in family medicine and in general preventive medicine and public health at Washington University in St. Louis, Missouri; the University of Missouri; and the University of Washington and is a member of the Institute of Medicine. Dr. Berg's research has focused on clinical epidemiology in primary care settings. He has been active on many expert panels using evidence-based methods to develop

clinical guidelines, including chair of the United States Preventive Services Task Force, cochair of the otitis media panel convened by the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality), chair and moderator of the STD Treatment Guidelines panel of the Centers for Disease Control and Prevention (CDC), member of the American Medical Association-CDC panel producing Guidelines for Adolescent Preventive Services, and chair of the CDC's Evaluation of Genetic Applications in Practice and Prevention working group. He has served on the Institute of Medicine's Immunization Safety Review Committee (member), the Committee on the Treatment of Post Traumatic Stress Disorder (chair), and the Committee on Standards for Systematic Reviews of Clinical Effectiveness Research (chair).

Claire D. Brindis, Dr.P.H., M.P.H., is professor of pediatrics and health policy in the Department of Pediatrics and Department of Obstetrics, Gynecology, and Reproductive Health Sciences at the University of California, San Francisco. Dr. Brindis is director of the Philip R. Lee Institute for Health Policy Studies, executive director of National Adolescent Health Information and Innovation Center, and director of the Bixby Center for Global Reproductive Health. Dr. Brindis's research interests are in the area of developing and evaluating innovative, community-based, comprehensive, integrated services for children, youth, and women and in combining qualitative and quantitative approaches to program evaluation. Her research focuses on child and adolescent health policy and women's health, with a special focus on Latina health. Dr. Brindis's educational background includes a doctoral degree in public health and behavioral sciences from the University of California at Berkeley and a master's degree in public health from the University of California at Los Angeles.

Angela Diaz, M.D., M.P.H., is the Jean C. and James W. Crystal Professor of Pediatrics and Community Medicine at Mount Sinai School of Medicine. After earning her medical degree in 1981 at the Columbia University College of Physicians and Surgeons, she completed her postdoctoral training at the Mount Sinai School of Medicine in 1985 and subsequently received a master's in public health from Harvard University. Dr. Diaz is the director of the Mount Sinai Adolescent Health Center, a unique program that provides comprehensive, integrated, interdisciplinary primary care, sexual and reproductive health, mental health, and health education services to teens. She has been a White House Fellow, a member of the Food and Drug Administration Pediatric Advisory Committee, and a member of the National Institutes of Health State of the Science Conference on Preventing Violence and Related Health Risk Social Behaviors in Adolescents. She serves on an advisory panel for the National Institutes of Health Reproductive Sciences

Branch. She is a frequent speaker at conferences throughout the country and around the world.

Francisco Garcia, M.D., M.P.H., is the director of the University of Arizona Center of Excellence in Women's Health. Dr. Garcia is the Distinguished Professor of Public Health, Obstetrics and Gynecology, Pharmacy and Mexican-American Studies at the University of Arizona and Chair of Family and Child Health of the Mel and Enid Zuckerman College of Public Health. He also serves as the codirector of the Cancer Disparities Institute of the Arizona Cancer Center. He is the past director of the Arizona Hispanic Center of Excellence (until 2007), as well as former director of the Division of Gynecology (until 2006). Dr. Garcia has served as a consultant to and collaborator on a variety of domestic and international agencies and nongovernmental organizations concerned with cervical cancer prevention, including the Department of Health of the State of Sonora, Population Council, the Pan-American Health Organization, the Instituto Nacional de Enfermedades Neoplasicas (Peruvian National Cancer Institute), IMSS-Solidaridad, Programa de Salud Reproductiva (the Mexican Social Security Institute-Reproductive Health Program), JHPIEGO, and PATH.

Kimberly Gregory, M.D., M.P.H., is vice chair of Women's Healthcare Quality and Performance Improvement, Department of Obstetrics and Gynecology at Cedars-Sinai Medical Center. She also serves as professor at the David Geffen School of Medicine at the University of California at Los Angeles (UCLA) and the UCLA School of Public Health. Dr. Gregory is board certified in obstetrics and gynecology and maternal-fetal medicine. Her research interests include obstetrical health care utilization, rates of delivery by cesarean section, and the management of complications of labor and delivery as it relates to patient safety and health care quality. Dr. Gregory served on the U.S. Public Health Service's Prevention Task Force (2006 to 2010). Dr. Gregory received her bachelor's degree from UCLA and her medical degree from the Charles Drew University School of Medicine and Science. She completed her internship and residency in obstetrics and gynecology at Beth Israel Hospital in Boston and her fellowship in maternal-fetal medicine at Los Angeles County, University of Southern California Medical Center. Dr. Gregory received her master's of public health from the Harvard University School of Public Health in 1991.

Paula A. Johnson, M.D., M.P.H., an internationally recognized cardiologist, is the executive director of the Connors Center for Women's Health and Gender Biology and chief of the Division of Women's Health at Brigham and Women's Hospital, and associate professor of Medicine at Harvard Medical School. Dr. Johnson brings a broad range of experience as a phy-

sician, researcher, and expert in public health and health policy to bear in the effort to transform the health of women. Central to the Connors Center's mission is discovering how disease is expressed differently in women and men, integrating leading-edge research about women's health into the delivery of care, influencing health policy, addressing the health of women globally, and training the next generation of leadership in the field. Dr. Johnson is a graduate of Harvard and Radcliffe Colleges, and received her M.D. and M.P.H. from Harvard. Dr. Johnson has been recognized with many awards for her contributions in women's and minority health and public health and is featured as a national leader in medicine by the National Library of Medicine.

Anthony Lo Sasso, Ph.D., is a professor and senior research scientist in the Division of Health Policy and Administration at the University of Illinois at Chicago School of Public Health and the Institute of Government and Public Affairs at the University of Illinois. He joined the University of Illinois at Chicago faculty in 2004. Dr. Lo Sasso is an economist whose research spans several dimensions of health economics and health services research. Dr. Lo Sasso is keenly interested in how government policies affect private-sector decisions. Dr. Lo Sasso has studied the impact of the State Children's Health Insurance Program on uninsurance among children and the extent to which public coverage crowded out private coverage. In addition, he has examined how community rating provisions affected non-group health insurance coverage and uninsurance. Dr. Lo Sasso also studies the effects of health savings accounts and other high-deductible health insurance products on service use and spending. He is currently working with the Upstate Health Research Network in New York to calculate usual and customary reimbursement rates for the health insurance industry. Dr. Lo Sasso received his doctorate in economics in 1996 from Indiana University, Bloomington.

Jeanette H. Magnus, M.D., Ph.D., is Cecile Usdin Professor in Women's Health; professor of public health and chair of the Department of Community Health Sciences at the Tulane University School of Public Health and Tropical Medicine; and a clinical professor in the Department of Medicine, Tulane University School of Medicine. She is also the director of the Tulane Xavier National Center of Excellence in Women's Health and the Mary Amelia Douglas-Whited Community Women's Health Education Center. Dr. Magnus's work bridges clinical medicine and science, epidemiology, public health, and community research. She has extensive experience in rheumatology and internal medicine. She developed and established the Tulane University Total Woman Health Care Clinic in 2000, providing primary and specialty care to women across the life span. Her research interests are in gender and race disparity in health and disease;

the association between health behaviors, self-evaluated health or mental health, and chronic disease; cardiovascular disease; and osteoporosis. Dr. Magnus has more than 130 publications and extensive experience in network building and coordination of projects that involve research scientists and practitioners with different backgrounds. She is the associate editor for the Epidemiology and Population Health Section for *Gender Medicine* and a member of the editorial boards of the B*iology of Sex Differences* and the *Journal of Women's Health*. Dr. Magnus earned both her M.D. and Ph.D. from University of Tromsø in Norway.

Heidi D. Nelson M.D., M.P.H., is a research professor of medical informatics and clinical epidemiology and medicine at the Oregon Health & Science University and medical director for cancer prevention and screening at Providence Health and Services, Portland, Oregon. Dr. Nelson received her M.D. and M.P.H. at the University of Minnesota and completed her internal medicine residency at the Oregon Health & Science University and fellowship in clinical epidemiology at the University of California, San Francisco. Since 1998, Dr. Nelson has conducted systematic evidence reviews and comparative effectiveness reviews for the United States Preventive Services Task Force, National Institutes of Health, Agency for Healthcare Research and Quality Effective Healthcare Program, and Drug Effectiveness Review Project, among others, at the Oregon Evidence-Based Practice Center. Her work has been used in developing clinical recommendations, practice guidelines, and consensus statements primarily in areas of women's health. At Providence, a not-for-profit, community-based, integrated health system in the western United States, she has developed patient data registries for quality improvement and research purposes, including a breast cancer screening and treatment registry. She has also led planning, implementation, and evaluation of health care programs and practices across the state to improve health care for women.

Roberta B. Ness, M.D., M.P.H., is dean, M. David Low Chair in Public Health, and professor in epidemiology at The University of Texas School of Public Health. Dr. Ness was formerly chair of the Department of Epidemiology at the University of Pittsburgh Graduate School of Public Health and served as interim dean in 2005 and 2006. Dr. Ness received her M.D. from Cornell University and her M.P.H. from Columbia University. Dr. Ness was one of the first to propose the research paradigm now termed "gender-based biology" in her book titled *Health and Disease Among Women* (1999). Dr. Ness is also known for her work on teaching innovation. She recently authored *Innovation Generation*, an instructional program for innovative thinking (to be published in 2012 by Oxford University Press). Dr. Ness is a fellow of the American College of Physicians; member of the Academy

of Medicine, Engineering, and Science of Texas; and member of the Institute of Medicine of the National Academies. She is president-elect of the American Epidemiologic Society and past president of the American College of Epidemiology. She is an elected member of the prestigious American Society for Clinical Investigation, Delta Omega Honorary Society, and the American Epidemiologic Society. She was selected by the Society for General Internal Medicine to be the 2008 Distinguished Professor of Women's Health. In 2011 she was named a U.S. presidential appointee to the Mickey Leland Center for Environmental Air Toxicant Research.

Magda G. Peck, Sc.D., professor of public health and pediatric at the University of Nebraska Medical Center (UNMC), in Omaha, is a national leader in maternal and child health. Dr. Peck's specific areas of expertise include prevention and public health for women and children, translating science into effective programs and policies, and leadership and workforce development. She received master's and doctoral degrees (1983, 1986) from the Harvard University School of Public Health, specializing in maternal and child health and social policy. For more than two decades, Dr. Peck has worked to build public health capacity to make a measurable difference for women and children. In 1988, Dr. Peck founded CityMatCH (www.citymatch.org), which has become the leading national public health organization dedicated to improving the health and well-being of women, children, and families in America's urban communities. While serving as CityMatCH's chief executive officer (until 2007), she lead the design and dissemination of innovative approaches to improving local understanding and action to address mother-to-baby transmission of human immunodeficiency virus and AIDS, reduce health disparities, and improve women and infant's health, including the perinatal periods of risk approach. She served as a member of the Select Panel for Preconception Care with the Centers for Disease Control and Prevention to shape national recommendations on the care of women prior to pregnancy, and co-led the Public Health Work Group of the National Preconception Health Steering Committee. Dr. Peck has been a pioneer for academic public health in Nebraska. She was founding director of the state's only master of public health program and helped establish the Great Plains Public Health Leadership Institute, which she has directed since 2005. As the new associate dean for community engagement and public health practice of the new UNMC College of Public Health, she ensures a dynamic, mutually beneficial interface between academe and community.

E. Albert Reece, M.D., Ph.D., M.B.A., is currently vice president, University of Maryland, and dean of the School of Medicine. Previously, he was vice chancellor and dean of the University of Arkansas College of Medi-

cine. Dr. Reece received his undergraduate degree (B.S., magna cum laude) from Long Island University, his M.D. degree from New York University, his Ph.D. degree in biochemistry from the University of the West Indies, Kingston, Jamaica, and his M.B.A. degree from the Fox School of Business and Management of Temple University. He completed a residency in obstetrics and gynecology at Columbia University Medical Center and a fellowship in maternal-fetal medicine at Yale University School of Medicine. He served on the faculty at Yale for almost 10 years and was the Abraham Roth Professor and chair of the Department of Obstetrics, Gynecology, and Reproductive Sciences at Temple University. Dr. Reece has published more than 500 journal articles, book chapters, and abstracts, and 9 textbooks, with revisions. He is an associate editor for the *Journal of Maternal-Fetal Medicine* and a reviewer for several scientific journals. He directs a National Institutes of Health-funded laboratory studying the biomolecular mechanisms of diabetes-induced birth defects. Dr. Reece is a member of the Institute of Medicine.

Alina Salganicoff, Ph.D., is vice president and director of Women's Health Policy at the Henry J. Kaiser Family Foundation. She directs the foundation's work on health coverage and access to care for women, with an emphasis on challenges facing underserved women. She also directs KaiserEDU.org, the foundation's educational website. Dr. Salganicoff has written and spoken extensively on a broad range of health policy concerns facing women, ranging from health disparities to long-term care. She was also an associate director of the Kaiser Commission on Medicaid and the Uninsured, specializing on the access challenges facing low-income families, Medicaid managed care, and state health reform. Prior to joining Kaiser, she worked on the program staff of the Pew Charitable Trusts. She has served on numerous federal, state, and nonprofit advisory committees, including the Institute of Medicine's Committee on Women's Health Research. Dr. Salganicoff received a B.S. from the Pennsylvania State University and holds a Ph.D. in health policy from The Johns Hopkins University School of Hygiene and Public Health.

Sally W. Vernon, Ph.D., is director of the Division of Health Promotion and Behavioral Sciences, Blair Justice Professor in Mind-Body Medicine and Public Health, and professor of epidemiology and behavioral sciences at the University of Texas-Houston School of Public Health (UTSPH) and the Center for Health Promotion and Prevention Research. Dr. Vernon's training is in epidemiology and behavioral sciences. She received her B.A. in Spanish from the University of Oklahoma, her M.A. in sociology from New York University, and her Ph.D. in community health sciences from UTSPH. Dr. Vernon conducts interdisciplinary research in cancer prevention and control, with

an emphasis on breast, cervical, and colorectal cancers. Her work has been conducted in community, work-site, and medical care settings, where she has developed and tested interventions to promote cancer screening behaviors. Dr. Vernon has published more than 150 scientific articles and book chapters and is currently a member of several editorial boards including those of the *Journal of National Cancer Institute*, *Cancer Epidemiology*, *Biomarkers & Prevention*, *Preventive Medicine*, and *Cancer Causes and Control*. She is a fellow and past president of the American College of Epidemiology.

Carol S. Weisman, Ph.D., is distinguished professor of public health sciences and obstetrics and gynecology at the Pennsylvania State University College of Medicine, with a joint appointment in the Department of Health Policy and Administration, and associate dean for faculty affairs. Dr. Weisman is a sociologist and health services researcher with a principal interest in women's health care and policy. Her research focuses on improving access and quality in women's primary care and on how health care and health risks affect women's health. She is director of the Central Pennsylvania Center of Excellence for Research on Pregnancy Outcomes and of the Central Pennsylvania Women's Health Study (CePAWHS); Principal Investigator of the Penn State BIRCWH (Building Interdisciplinary Research Careers in Women's Health) K-12 Program; and Associate Editor of *Women's Health Issues*. She received her B.A. from Wellesley College with a major in sociology and anthropology and her Ph.D. in social relations (sociology) from the Johns Hopkins University.

Appendix D

Dissent and Response

This appendix has two parts. The first is a dissent statement from committee member Anthony Lo Sasso, and the second is a response from the chair and the other 14 members of the Committee on Preventive Services for Women.

DISSENTING OPINION

Anthony Lo Sasso

Summary

Given the combination of the unacceptably short time frame for the PSW committee to conduct or solicit meaningful reviews of the evidence associated with the preventive nature of the services considered, this dissent advocates that no additional preventive services beyond those explicitly stated in the Affordable Care Act (ACA) be recommended for consideration by the Secretary for first dollar coverage until such time as the evidence can be objectively and systematically evaluated and an appropriate framework can be developed. The long-run risks associated with making poorly informed decisions, and their likely irreversibility once codified, outweigh the ACA-mandated rapidity with which the committee was confronted.

Rationale

The ACA provided the impetus for the IOM to form a panel to make recommendations about screening and preventive services that "have been shown to be effective for women" that in turn will be considered by the Secretary for coverage on a first-dollar basis by all new private plans in operation in 2014. However, a remarkably short time frame was provided for the task of reviewing all evidence for preventive services beyond the services encompassed by the USPSTF, Bright Futures and ACIP: the final report from the committee was needed barely six months from the time the group was empanelled.

As the Report acknowledges, the lack of time prevented a serious and systematic review of evidence for preventive services. This should in no way reflect poorly on the tireless work of the committee and staff; it instead merely reflects the fact that the process set forth in the law was unrealistic in the time allocated to such an important and time-intensive undertaking. Where I believe the committee erred was with their zeal to recommend something despite the time constraints and a far from perfect methodology.

The Report posits four categories as the basis for the recommendations ranging from "high quality systematic evidence reviews" (Category I) to potentially self-serving guidelines put forth by professional organizations (Category IV). The categories alone on their face provide little basis to exclude many preventive services. For example, Category II asks whether there are any "quality" supportive peer-reviewed studies, but there is no clear benchmark for what quality means in this context; many studies published in peer-reviewed journals (even very well respected journals) are of low quality and are not generalizable. The problematic nature of the categories aside, the relative weights applied to each category vis-à-vis the recommendations were not specified, making it impossible to discern what factors were most important in the decision to recommend one service versus another. The categories were combined with expert judgment from members of the committee and supplemented with committee debate to arrive at the recommendations put forth in the Report. Readers of the Report should be clear on the fact that the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered. Put differently, evidence that use of the services in question leads to lower rates of disability or disease and increased rates of well-being is generally absent.

The view of this dissent is that the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy. An abiding principle in the evaluation of the evidence and the

recommendations put forth as a consequence should be transparency and strict objectivity, but the committee failed to demonstrate these principles in the Report. This dissent views the evidence evaluation process as a fatal flaw of the Report particularly in light of the importance of the recommendations for public policy and the number of individuals, both men and women, that will be affected.

Other Considerations

Another concerning aspect of the Report is the lack of a coherent framework to evaluate coverage apart from the evidence regarding clinical efficacy. Although coverage determinations were not explicitly part of the committee's charge, it is nevertheless difficult to ignore the fact that the committee's recommendations will have important implications for coverage considerations. Thus while the lack of a theoretical or conceptual framework to examine coverage decisions can perhaps be forgiven, it is clear that the "life course" model put forth in the Report does not lend itself to the consideration of coverage decisions. I describe one potential framework below that could inform such thinking around coverage determinations.

The ACA law requires coverage by private insurers of all USPSTF A and B recommendations. The USPSTF process of evidence review represents a "gold standard" based on a critical and scholarly review of all extant literature and therefore is the bar the committee should have aspired to in basing its recommendations to the Secretary. That said, the clinical recommendations from the USPSTF were never intended to provide a basis for insurance coverage determinations; they are intended as guides to physician practice. Given the previous role of the USPSTF it is worth noting that basing coverage decisions categorically on USPSTF recommendations has the potential to jeopardize the objectivity and scientific integrity of the USPSTF review process.

In contrast, while Bright Futures is a body aimed at influencing clinical practice, the evidence bar for its recommendations is considerably lower than that of the USPSTF. Recommendations are considered "evidence-informed" and rely heavily on expert opinion rather than systemic, critical reviews of the literature. This is troubling given the important public policy consequences that will now result from Bright Futures recommendations.

Additions to the Update Recommendations

There are reasons to support the framework for future evaluation of preventive services in the Report (Chapter 6). The proposed framework crucially recognizes the importance of separating the scientific objective

of establishing the effectiveness and potentially the cost effectiveness of preventive services from the policy decision regarding coverage of services. This dissent advocates for a more concrete structure based on sound public policy principles to frame both the evidence review and coverage decision for specific preventive services for women.

A highly regarded framework to examine coverage decisions of preventive services in an insurance context was developed more than twenty years ago by Pauly and Held (1990). The authors consider coverage decisions for a hypothetical preventive service that is presumed to reduce the probability of a covered and potential costly healthcare treatment episode (for example, inpatient treatment of a preventable disease outcome). More formally, if one assumes a preventive service, *S*, that costs *P* is available that when administered changes the probability from p_n to p_y of experiencing an inpatient event with cost *E*, the following can be observed:

1. If $p_n > p_y$ the service is effective in prevention as the treatment *S* reduces the probability of experiencing the negative outcome; this represents the minimum necessary threshold for which "preventive" needs to be defined.
2. If $(p_n - p_y)E > P$ the service is "cost effective"[1] in that the cost associated with the relative reduction in the probability of the negative outcome exceeds the cost of the treatment S; this is a potentially high bar but an important one for a preventive service.

However, it is important to understand that point (1) and even point (2) do not necessarily imply that first-dollar coverage of preventive services leads to an overall reduction in insurer payments (and hence insurance premiums) as many might assume. Whether coverage of preventive service leads to a reduction in healthcare expenditure depends on the fraction of enrollees using the service before the service becomes covered and the magnitude of the response among enrollees who experience the reduction in out-of-pocket price. This latter point is what Pauly and Held term "benign moral hazard" and it points to a critical parameter of interest as the elasticity or responsiveness of preventive service utilization to the user price for the service. Knowing how elastic patient demand is to preventive services is a critical element to a coverage decision even if one already has good estimates of the effectiveness and cost-effectiveness. This is self-evidently a useful parameter to know for any preventive service because it highlights

[1] It is important to note that the statute rules out cost as a consideration by the committee. Cost is included in the example only to demonstrate that the hypothetical preventive service meets a high bar beyond effectiveness.

the impact that first-dollar coverage of the service will have, perhaps in relation to other forms of outreach.

More recently, Pauly and Blavin (2008) incorporate some additional considerations in the wake of research on so-called value-based health insurance designs. First dollar coverage can be justified if enrollees lack information about the benefits of preventive services in order to make correct (or at least fully informed) decisions. Such a determination, however, would depend on the relative efficacy of information provision about the benefits of preventive services versus reducing (or eliminating) cost sharing.

REFERENCES

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RESPONSE TO DISSENTING STATEMENT

Linda Rosenstock (Chair), Alfred O. Berg, Claire D. Brindis, Angela Diaz, Francisco Garcia, Kimberly Gregory, Paula A. Johnson, Jeanette H. Magnus, Heidi D. Nelson, Roberta B. Ness, Magda G. Peck, E. Albert Reece, Alina Salganicoff, Sally W. Vernon, and Carol S. Weisman

The dissenting committee member wanted more time and the opportunity to incorporate cost-benefit analysis. At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions. The dissent also includes inaccurate statements regarding the committee process and its approach to the committee charge. The committee members' expertise is diverse and while many have different perspectives, no other member shares the opinion that report recommendations were not soundly evidence based.