



The Institute of Medicine Committee
On Preventive Services for Women

Testimony of
Hal C. Lawrence, III, MD, FACOG
Vice President for Practice Activities
American Congress of Obstetricians and Gynecologists

January 12, 2011
Washington DC

Thank you, Dr. Rosenstock and panel members, for giving me the opportunity to provide our views to the Institute of Medicine (IOM) Committee on Preventive Services for Women on this important topic of women's preventive health care. I am Dr. Hal C. Lawrence, Vice President for Practice Activities at the American Congress of Ob-Gyns. ACOG represents 54,000 board-certified ob-gyns and partners in women's health. Coverage of preventive health care services at no cost to patients is a very important element of the Affordable Care Act, and this panel has a very important job to do in defining this care for millions of American women.

ACOG is committed to developing guidance for women's health care providers, based on the best evidence available, and we encourage you to look to already-established and well-respected guidance, including ACOG's, on preventive service in women's health. We've previously provided to the panel a number of ACOG documents detailing the specialty's approach to preventive health care for women.

My comments focus first on the methodology the IOM committee should adopt and then outline recommendations regarding the preventive health care services that should be provided to women.

Methodology

This Committee has been charged with rapidly assessing the evidence and developing guidelines for women's preventive services. How the Committee chooses to do this can help or hinder its ability to fulfill its charge. We offer the Committee recommendations related to process and making decisions when faced with conflicting guidelines.

Process Recommendations

Recommendation 1: ACOG has extensive experience in developing our own guidelines and a thorough understanding of the process used by the U.S. Preventive Services Task Force

(USPSTF) to develop its guidelines. We encourage you to learn from the Task Force's 25 years of experience in developing recommendations for preventive services, and recommend the Task Force's procedure manual as an excellent overview of its methods (<http://www.uspreventiveservicestaskforce.org/uspstf08/methods/procmanual.htm>).

However, the USPSTF labors under a number of characteristics that markedly limit its ability to fully address women's preventive health care needs, making much of the Task Force's methodology poorly suited to this Committee's unique needs and timeframe. The Task Force's work requires vast resources, including contracts with multiple Evidence-Based Practice Centers and a major staff commitment from the Agency for Healthcare Research and Quality (AHRQ). The USPSTF process requires years of work to develop and publish a single Recommendation Statement that may not even offer clear guidance for practice, as when a preventive service is given a "C" or "I" recommendation.

In addition, the USPSTF only makes recommendations for individual, not bundled, preventive services. Although single-service recommendations are helpful in educating primary care clinicians—the original charge of the USPSTF—they are seriously inadequate as a means of determining which preventive health care services insurance companies should cover without cost-sharing—a new role outlined in the Affordable Care Act for USPSTF recommendations graded "A" or "B." Preventive services are not typically delivered piecemeal, but as a part of a preventive services visit. A physician may screen a patient for high blood pressure and obesity and perform a Pap test, all as part of a preventive visit. The physician does not bill for each screening service separately, rather these components are billed as part of the visit.

Recommendation 2: To address this limitation, we urge the Committee to mirror the processes used in the Bright Futures framework for well-child care and the new Medicare annual wellness visit benefit enacted in the Affordable Care Act, which recognize the importance of and include payment for both a preventive service visit and specific recommended services which may be provided during the annual preventive visit.

Recommendation 3: It is equally important that IOM recognize that prevention does not stop at the office door, but often requires ongoing access to preventive medications and treatment. IOM must recommend coverage without cost-sharing of both counseling regarding a preventive intervention and the intervention itself. It does not benefit a woman's health if smoking cessation counseling is covered, but not the nicotine-replacement therapies her physician recommends. Medications and other interventions used for primary prevention, such as aspirin, vaccines, and contraceptive drugs and devices (including condoms, emergency contraception, and permanent contraception), must be covered with no cost-sharing.

This approach to prevention is consistent with the draft National Prevention and Health Promotion Strategy developed by the National Prevention, Health Promotion and Public Health Council, which calls for increasing “use of the most effective and highest impact/priority evidence-based clinical preventive services and medications, such as the preventive use of aspirin; screening and treatment for high blood pressure and cholesterol; cancer screening; screening and treatment for HIV [(human immunodeficiency virus)], chronic viral hepatitis, and [sexually transmitted diseases]; and immunizations, among others.”

(http://www.healthcare.gov/center/councils/nphpphc/draftframework_.pdf)

Only by covering preventive services and visits, as well as medications and devices for primary prevention, can all of a woman's prevention needs be covered.

Recommendation 4: IOM can best complete its work on schedule and make recommendations that reflect the most current knowledge in the field by adopting recommendations, as appropriate, that have already been developed by the American College of Obstetricians and Gynecologists, other professional medical associations and organizations, and certain federal agencies. There are good precedents for this approach. The Bright Futures program of services, included in the Affordable Care Act, is based on recommendations from the American Academy of Pediatrics. The USPSTF has a history of deferring to the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC)

on immunization recommendations and has recently considered deferring to others as well—even if the Task Force is not in complete agreement with the other agency’s methodology.

The College’s clinical guidelines, previously shared with you, offer an excellent resource for the IOM committee and encompass the entire field of women’s preventive care. Our guidance is based on the best available evidence and is developed by committees with expertise reflecting the breadth of women’s health care and subject to a rigorous conflict of interest policy. All clinical guidance documents developed by College committees are reviewed, revised, and approved by two other bodies, including the College’s Executive Board. Approved guidelines are published in the College’s journal *Obstetrics & Gynecology*, where they can be accessed by clinicians and researchers through literature search engines such as PubMed. All clinical guidance documents are reviewed at least every 18–24 months to ensure that they are current and accurate.

Recommendation 5: All recommendations developed by the IOM committee must be similarly reviewed and revised as necessary on a regular basis. The College recognizes that while it has made the commitment to ongoing maintenance of our recommendations, doing so presents challenges for IOM. With a mission of serving as “adviser to the Nation on health,” the IOM’s duties are broad. While the need for updated recommendations for women’s preventive health care services will persist after the IOM delivers its recommendations to the Health Resources and Services Administration (HRSA), IOM will be required to move on to other topics. Deferring to existing recommendations from the College and other professional medical associations will ensure that clinicians can continue to rely on current, accurate guidance in the future.

Recommendation 6: Finally, it must be noted that regardless of the preventive services guidelines ultimately accepted by the Department of Health and Human Services, no guideline will fit every woman. This is the downside of evidence-based medicine. In order to be appropriately powered, clinical trials typically look at large, relatively homogeneous groups of women; in looking at a forest, it is easy to miss the trees. The IOM’s recommendations must address subpopulations, including lesbian, gay, bisexual, and transgendered individuals, when

evidence is available and encourage flexibility in coverage to meet women's individual needs, and we urge you to explicitly state in your guidelines that there must be flexibility for coverage, with no cost-sharing, of additional preventive services that are required by an individual woman because of her unique health history and characteristics. Insurance companies need to understand that recommendations in clinical guidelines may not address all subpopulations and may not adequately address the preventive health needs of a particular woman. With the current emphasis on personalized medicine, coverage of smaller subpopulations is only likely to grow. Providing preventive services to specific women who can benefit is a smart use of health care dollars.

Conflicting Guidelines

In the Affordable Care Act, Congress assigned responsibility for prevention to these organizations and preventive service guidelines: the USPSTF, Bright Futures, and HRSA. As the IOM committee completes the work commissioned by HRSA, it will quickly identify existing recommendations that are in conflict. Sometimes these conflicts even occur within recommendations issued by agencies of the Department of Health and Human Services.

Screening for HIV in women who are at average risk of infection is an example. The USPSTF makes no recommendation for or against screening in this population, but the CDC recommends that women be routinely screened. Conflicting advice from two such preeminent organizations must be managed, and the solution appears straightforward: the organizations must improve their cooperation, one must defer to the other, or both must refer to clinical guidelines developed by relevant professional organizations, as described above. By including federal and professional medical association partners in its work, the USPSTF has shown its willingness to work collaboratively, and we recommend that IOM advocate that this cooperation be enhanced.

Recommendation 7: ACOG urges the IOM to adopt the following strategy for resolving conflict between recommendations of the USPSTF and recommendations of federal agencies or professional medical associations:

- Preventive services recommended by the USPSTF (“A” or “B” ratings) should be covered without cost-sharing, as intended in the Affordable Care Act. Agencies and

organizations that believe these services should not be routinely provided should provide evidence for their position to the Task Force for consideration under its usual processes.

IOM should not recommend services given a “D” rating by the USPSTF. Agencies and organizations that advocate coverage of services given a “D” rating should share their evidence and recommendations with the Task Force.

IOM should recommend coverage of services given a “C” rating by the USPSTF if they are supported by other organizations’ evidence-based guidelines.

- The USPSTF “I” recommendations --“current evidence is inadequate to assess the balance of the benefits and harms of the service” -- represent a broad area of conflict. In cases where other organizations have conducted evidence-based assessments that result in their recommendation of the service, the IOM should recommend coverage with no cost-sharing.

Many groups offering comments at the first meeting of this IOM committee urged coverage of screening for intimate partner violence—a service that the USPSTF has rated “I.” We share these groups’ beliefs in the appropriateness of screening for intimate partner violence, continue to recommend this service, and urge the IOM committee to include it in its final recommendations.

Recommended Preventive Services

Recommendation 8: Before this panel can make recommendations for preventive services that ought to be covered with no cost-sharing, it must agree on how it will define prevention. We recommend adoption of the commonly accepted definition from the World Health Organization (WHO), unchanged since 1948: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” (Preamble to the Constitution of the World Health Organization; <http://www.who.int/about/definition/en/print.html>.)

The role of preventive services in achieving health for women must promote women's overall well-being and not merely keep them from developing a disease state or becoming injured.

The USPSTF uses similar criteria, found in their Procedure Manual: "The Task Force's scope is specific: 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. Primary preventive measures in a clinical setting are those provided to individuals to prevent the onset of a targeted condition (for example, the routine immunization of healthy children)." The Task Force's view of prevention is consistent with the WHO's view of health as constituting more than the absence of disease.

Recommendation 9: At its first meeting, the IOM committee heard that women's health and well-being often depends on their receiving care not addressed by USPSTF recommendations, including those below. We urge the IOM to recommend coverage of the following services and products without cost-sharing:

- a. Well-woman visits
- b. Preconception care visits
- c. Counseling about and provision of family planning services
- d. HIV screening for women at average risk
- e. Screening for intimate partner violence
- f. Testing for human papillomavirus (HPV) as a part of cervical cancer screening

Well-Woman Visits

Well-woman visits are the foundation on which women's preventive care is built. They include not only specific screening tests, but also a medical history, physical examination, evaluation and counseling, and, as indicated, vaccinations. Over the past 20 years, it has become clear that "one size does not fit all" when it comes to prevention. Although a 30-year-old woman without risk factors for cervical cancer may only need a Pap test every 3 years, the same woman would need

an annual Pap test if she were infected with HIV or had a history of cervical cancer precursors. It is only after taking a medical history, performing a physical examination, and evaluating and counseling a patient that a physician can make patient-specific recommendations for screening tests, vaccinations, preventive medications, and other preventive services.

Recommendation 9a: The IOM should recommend coverage without cost-sharing of an annual well-woman examination visit in addition to specific preventive services delivered at the visit, to reflect how health care services are actually reimbursed in this country. Covering the well-woman visit without cost-sharing would be consistent with Congress' other actions in the Affordable Care Act. By including the Bright Futures well-child visits and the Medicare annual wellness visit in the Affordable Care Act, Congress has demonstrated that it values the preventive visit itself as well as specific services delivered at the visit.

Greater use of preventive services could save over 2 million life-years annually and save more than \$3.7 billion in health care costs (Maciosek MV et al. Greater use of preventive services in U.S. health care could save lives at little or no cost. *Health Aff* 2010;29:1656–1660.). Covering the well-woman visit is our best hope of increasing the proportion of women who receive all recommended preventive services, and it is vital that IOM recommend that it be covered annually with no cost-sharing.

Preconception Care Visits

The College encourages its members to work with their patients to formulate a reproductive health plan and to discuss the plan with patients at each visit. Such a plan would address the woman's desire for a child or children (or desire not to have children); the optimal number, spacing, and timing of children in the family; and age-related changes in fertility (The importance of preconception care in the continuum of women's health care. ACOG Committee Opinion No. 313. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2005;106:665-6.).

For women who are contemplating pregnancy, the reproductive health plan leads to preconception care. Improving a woman's health before she becomes pregnant helps improve reproductive health outcomes. The College recommends that preconception care include counseling on appropriate medical care and behavior to optimize both a woman's health and pregnancy outcomes (ACOG Committee Opinion #313, AAP, ACOG. Guidelines for perinatal care. 6th ed., 2007.)

Recommendation 9b: In 2006, CDC issued 10 recommendations for improving preconception care and health through changes in consumer knowledge, clinical practice, public health programs, health-care financing, and data and research activities (Johnson K et al. Recommendations to improve preconception health and health care—United States. MMWR 2006;55(RR-06):1–23.). Three of the CDC's ten recommendations specifically call for a preconception visit and identify specific services that should be provided. This major work is a tremendous resource to those, such as the IOM committee, who are making recommendations on preventive health care for women. ACOG urges the IOM committee to adopt the recommendations in this guideline and advocate for coverage of a preconception visit with no cost-sharing.

Women often face significant barriers to receiving this important care. Often, insurers cover one well-woman, preventive visit each year. A woman who returns later that year for preconception care counseling may not have her visit covered. The preconception visit should not be viewed as just another well-woman visit. Specific and different counseling and interventions are provided at this visit which are not routinely a part of the well-woman examination.

Even the USPSTF framework for coverage of preventive services leaves significant gaps for coverage of preconception care, as it rarely addresses the preconception care needs of subpopulations. The recommendation of the IOM committee will be vital to giving women access to this valuable service.

Counseling About and Provision of Family Planning Services

Family planning is an essential part of basic preventive health care for women, especially for the two-thirds of American women of reproductive age who wish to avoid or postpone pregnancy. Access to family planning counseling and a full array of family planning services—including permanent contraception—is vital for women’s health and well-being.

By helping women control the timing, number, and spacing of births, family planning has many benefits for a woman and children she may have in the future. Planned pregnancies—which for most women require contraception—benefit women by allowing them to take steps to optimize their own health before pregnancy and childbirth. An unintended pregnancy may have significant implications for a woman’s health, sometimes worsening a preexisting health condition such as diabetes, hypertension, or coronary artery disease. Planned pregnancies improve the health of children as well, as adequate birth spacing lowers the risk of low birth weight, preterm birth, and small-for-gestational age.

The United States has the highest rate of unintended pregnancy in the developed world; approximately half of all pregnancies are unintended. In addition to the health impacts noted above, unintended pregnancies can also result in tremendous individual and societal consequences including family upheaval, nonattainment of educational goals, and financial burdens.

Recommendation 9c: To support women’s well-being and efforts to achieve their individual reproductive health plans and have a meaningful impact on unintended pregnancy rates, both contraceptive counseling and services must be provided without cost-sharing—neither alone is sufficient. The most effective contraceptive methods have the highest up-front costs, and cost is certainly a barrier to women using these effective methods. A full array of contraceptive drugs and devices, including those for permanent contraception, must be covered without cost-sharing. It is equally essential that women have access to counseling that supports them in choosing a contraceptive method that is best for them and in using that method effectively.

HIV Screening for Women at Average Risk

Recommendation 9d: As noted previously, the USPSTF “C” recommendation for HIV screening in women at average risk conflicts with the CDC’s recommendation that this service be provided. It is essential that the IOM committee recommend this screening. According to CDC, the approximately 21% of HIV-infected individuals who are unaware of their HIV infection account for 54% of new infection transmissions.(Campsmith ML, et al. Undiagnosed HIV prevalence among adults and adolescents in the United States at the end of 2006. J Acquir Immune Defic Syndr 2010; 53:619–24.)

Because HIV testing is an important and effective HIV prevention strategy, the College recommends routine HIV screening of women aged 19–64 years and targeted screening for women with risk factors outside of that age range.

Screening for Intimate Partner Violence

Approximately 90% of female patients in a primary care practice believe that physicians can help with problems related to abuse (Friedman LS, et al. Inquiry about victimization experiences. A survey of patient preferences and physician practices. Arch Intern Med 1992;152:1186-90.). However, more than 70% of abused women have never discussed abuse with their physicians, so screening to identify the presence of abuse is critical. Yet, the 2004 recommendation of the USPSTF is that evidence is insufficient to recommend this service.

Recommendation 9e: This type of service is commonly not a high priority for the Task Force, and given its capacity issues, it may be some time before the Task Force takes up this topic again. It is time to revisit the evidence supporting the benefit of screening women for intimate partner violence, and we urge the IOM committee to do so.

Testing for HPV as a part of cervical cancer screening

Similarly, the current recommendation of the USPSTF indicates insufficient evidence to recommend HPV testing as a part of cervical cancer screening. This recommendation, too, needs to be revised and the Task Force’s revision may take a year or more.

Recommendation 9f: The College and the American Cancer Society have already updated our recommendations to reflect the current evidence on this issue, and until the UPSTF updates its own guidance, there is conflict and confusion among providers and insurers regarding the recommendations. We urge the IOM committee to recommend this service. Details regarding appropriate candidates for HPV testing plus Pap testing are included in the College guidelines previously sent to the IOM committee (Cervical Cytology Screening. ACOG Practice Bulletin No. 109. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009; 114:1409–20.)

Summary

Thank you again, Dr. Rosenstock and panel members, for taking on this important task and for the work that you'll do here to improve the health of women for years to come. I appreciate the opportunity to provide you with our expertise and recommendations and we look forward to working with you as your work continues.