FINAL REPORT

WPSI

Women's Preventive Services Initiative

Recommendations for Preventive Services for Women
Final Report to the U.S. Department of Health and Human Services, Health Resources & Services Administration
December 2016

This project was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number UHOMC29940, Bright Futures for Women's Health: Standard Practice Guidelines for Well Women Care. This information or content and conclusions are those of the author and should not be construed as the official position nor policy of, nor should any endorsements be inferred by HRSA, HHS, or the U.S. Government.

COPYRIGHT

Recommendations for Preventive Services for Women was developed by the Multidisciplinary Steering Committee of the Women's Preventive Services Initiative. The information in *Recommendations for Preventive Services for Women* should not be viewed as a rigid body of rules. The recommendations are general and intended to be adapted to many different situations, taking into account the needs and resources particular to the locality, the institution, or the type of practice. Variations and innovations that improve the quality of patient care are encouraged rather than restricted. The purpose of these guidelines will be well served if they provide a firm basis on which local norms may be built.

Library of Congress Cataloging-in-Publication Data

Names: Women's Preventive Services Initiative (U.S.). Multidisciplinary Steering Committee, author. | American College of Obstetricians and Gynecologists, issuing body. | United States. Health Resources and Services Administration, sponsoring body.
Title: Recommendations for preventive services for women : final report to the U.S. Department of Health and Human Services, Health Resources & Services Administration / developed by the Multidisciplinary Steering Committee of the Women's Preventive Services Initiative.
Other titles: Final report to the U.S. Department of Health and Human Services, Health Resources & Services Administration
Description: Washington, DC : American College of Obstetricians and Gynecologists, [2017] | "December 2016." | Includes bibliographical references and index. | Supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number UHOMC29940.
Identifiers: LCCN 2017022228 | ISBN 9781934984703 (alk. paper)
Subjects: | MESH: Preventive Health Services | Women's Health | Women's Health Services | Health Planning Guidelines | United States
Classification: LCC RA564.85 | NLM WA 309 AA1 | DDC 362.1082--dc23
LC record available at https://lccn.loc.gov/2017022228

Evidence Summaries are used with permission from Oregon Health & Science University.

12345/10987

TABLE OF CONTENTS

STATEMENTS OF SUPPORT

Members of the Advisory Panel support the Women's Preventive Services Initiative:

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

NPWH
NURSE PRACTITIONERS IN WOMEN'S HEALTH
Caring for Women

ACP
American College of Physicians
Leading Internal Medicine, Improving Lives

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

The organizations comprising the Multidisciplinary Steering Committee endorse the collaborative and consensus process of the Women's Preventive Services Initiative:

ACADEMY OF WOMEN'S HEALTH
best practices for better outcomes

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

AAPA

American Cancer Society®

AMERICAN COLLEGE of NURSE-MIDWIVES
With women, for a lifetime®

ACPM
American College of Preventive Medicine
physicians dedicated to prevention

AOA®
AMERICAN OSTEOPATHIC ASSOCIATION
TREATING OUR FAMILY AND YOURS

AMERICAN PSYCHIATRIC ASSOCIATION
Medical leadership for mind, brain and body.

AMCHP
ASSOCIATION OF MATERNAL & CHILD HEALTH PROGRAMS

Association of Reproductive Health Professionals

AWHONN
PROMOTING THE HEALTH OF WOMEN AND NEWBORNS

NCCN National Comprehensive Cancer Network®

NMA National Medical Association
Since 1895

national partnership for women & families

NATIONAL WOMEN'S LAW CENTER
EXPANDING THE POSSIBILITIES

AGS Geriatrics Healthcare Professionals
Leading Change. Improving Care for Older Adults.

Conflict of Interest Disclosures

The following Advisory Panel and Multidisciplinary Steering Committee members reported no financial relationships or potential conflicts of interest to disclose: Jeanne Conry, MD, PhD; Pelin Batur, MD, FACP, NCMP, CCD; Therese Bevers, MD; Gale R. Burstein, MD, MPH, FAAP, FSAHM; Octavia Cannon, DO; David Chelmow, MD; Stamatia Destounis, MD, FACR, FSBI; Susan C. Dimock, PhD; Jennifer Frost, MD; Janel George, JD; Kimberly D. Gregory, MD, MPH; Linda Humphrey, MD, MPH; Susan M. Kendig, JD, WHNP-BC; Jeanette Kowalik, PhD, MPH, MCHES; Melissa McNeil, MD, MPH; Edith P. Mitchell, MD, FACP; Susan Peck, RNC, MSN, APN; Maureen Phipps, MD, MPH; Amir Qaseem, MD, PhD, MHA, FACP; Alina Salganicoff, PhD; Maureen Sayres Van Niel, MD; Robert Smith, PhD; James Stevermer, MD, MSPH, FAAFP; Annamarie Streilein, MHS, PA-C; Jessi Leigh Swenson, JD and Stacy Tessler Lindau, MD, MAPP, FACOG.

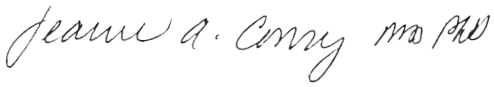
Michelle Collins, PhD, CNM, FACNM in 2015, served as an expert witness for a law firm that represents Bayer pharmaceuticals in the class action suit against Bayer re: Mirena IUDs. She may be called upon again for testimony, though there is doubt that it will go to trial. Susan Hoffstetter, PhD, WHNP-BC, FAANP is a Nexplanon Trainer. Rachel Urrutia, MD receives salary support from KNDR Healthcare management group. KNDR Healthcare management group works to improve access to fertility awareness methods of family planning.

FOREWORD

The American College of Obstetricians and Gynecologists is pleased to submit our report "Recommendations for Preventive Services for Women" to the U.S. Department of Health and Human Services Administration. The Women's Preventive Services Initiative is a collaborative effort between health professional societies and consumer organizations that are experts in women's health. This report is the first in a 5-year effort to develop, review, update, and disseminate recommendations for women's preventive health care services and identifies needs across a woman's life span, from adolescence through adulthood into maturity. The goal of the Women's Preventive Services Initiative is to promote health over the course of a woman's lifetime through disease prevention and preventive health care.

In order to ensure that women of all ages receive appropriate preventive health screenings, both health care providers and patients need uniform, established guidelines. The Women's Preventive Services Initiative recognizes that women may seek guidance for preventive services from a diverse set of experts in women's health, including family physicians and internists, obstetrician–gynecologists, physician assistants, nurse practitioners, certified nurse-midwives, and certified midwives. It will take the collaborative effort of the Women's Preventive Services Initiative, with its broad membership of specialty societies providing women's health care, to share guidelines and to hold all accountable for optimizing the health and well-being of women. Efficient, effective guidelines established with evidence-based processes and vetted by women's health experts will optimize health care delivery and outcomes.

The American College of Obstetricians and Gynecologists thanks the Health Resources and Services Administration for the opportunity to undertake this rewarding and satisfying project. We represent more than 58,000 obstetrician–gynecologists and, more importantly, the women we serve. Over the next 4 years, we look forward to the prospect of identifying and developing more topic-specific recommendations and building an implementation strategy so that the health of all women is improved in this generation and generations to come!



Jeanne Ann Conry, MD, PhD, FACOG
ACOG Past President
Chairperson, Women's Preventive Services Initiative

EXECUTIVE SUMMARY

On March 1, 2016, the American College of Obstetricians and Gynecologists (ACOG) launched the Women's Preventive Services Initiative (WPSI), a close collaboration of national health professional societies and consumer organizations, all with important contributions to improving women's health. Through a 5-year cooperative agreement with the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), ACOG will coordinate the WPSI effort to develop, review, update, and disseminate recommendations for women's preventive health care services.

The WPSI Advisory Panel provides oversight to the Initiative and is made up of representatives from ACOG and three other major professional organizations representing the majority of women's health care providers: the American Academy of Family Physicians, the American College of Physicians, and the National Association of Nurse Practitioners in Women's Health. The Multidisciplinary Steering Committee, which develops the preventive health care recommendations, includes representatives from medical specialty societies that oversee the majority of women's primary care services and chronic disease management care, public health professionals, and patients and consumers (**see the box**).

2016 Multidisciplinary Steering Committee Participating Organizations

American Academy of Family Physicians

American College of Obstetricians and Gynecologists

American College of Physicians

National Association of Nurse Practitioners in Women's Health

Academy of Women's Health

American Academy of Pediatrics

American Academy of Physician Assistants

American Cancer Society

American College of Nurse–Midwives

American College of Preventive Medicine

American College of Radiology

American Osteopathic Association

American Psychiatric Association

American Geriatrics Society

Association of Reproductive Health Professionals

Association of Women's Health, Obstetric and Neonatal Nurses

National Comprehensive Cancer Network

National Medical Association

Association of Maternal & Child Health Programs

National Partnership for Women & Families

National Women's Law Center

Patient Representative

Federal Partners

Centers for Disease Control and Prevention

Health Resources and Services Administration

Office of Health Reform

Office of Minority Health

Office of Population Affairs

Office on Women's Health

In addition, the WPSI incorporates a strong evidence-based structure that follows the criteria specified by the Institute of Medicine (IOM, now the National Academies of Sciences, Engineering, and Medicine) for trustworthy guidelines[1] combined with the in-depth knowledge and expertise of the WPSI members. The recommendations will help ensure that women receive a comprehensive set of preventive services. In its first year, the WPSI updated eight topics addressed by the 2011 IOM report, *Clinical Preventive Services for Women: Closing the Gap*.[2] Because of the confusion caused by contradictory recommendations around breast cancer screening, the WPSI also addressed breast cancer screening for women at average risk. Additional topics will be determined by WPSI members with input from the public and addressed in subsequent years.

The benefits to women of preventive health services throughout the life course are well documented in the literature. Evidence-based preventive health care has been shown to identify risk factors for disease and to promote early detection of disease and infection, allowing more effective management and prevention of further complications.[3] Preventive care—including reproductive life planning, optimization of nutrition and exercise, screening for and management of chronic diseases, immunizations, management of infectious diseases, and attention to psychological and behavioral health—contributes to women's overall health.

To ensure women of all ages receive appropriate preventive health screenings, health care providers and patients need uniform, established guidelines for recommended preventive services for women. The availability of various and sometimes inconsistent guidelines fuels provider uncertainty and patient confusion. Efficient and effective guidelines established by the WPSI's strong evidence-based process and vetted by experts in women's health will impact patient preventive care delivery, patient safety, and quality of care by increasing the consistency of behavior and replacing individual preferences with best practices. Because the WPSI recommendations represent the consensus of the members, the participating organizations will work together to adopt and widely promote the recommendations to help ensure that all women receive a comprehensive set of preventive services.

The WPSI partnered with physician scientists from the Pacific Northwest Evidence-based Practice Center (EPC) at Oregon Health & Science University to review and update the evidence for each topic under consideration. The WPSI methodology and process were designed to promote thorough consideration of the best available evidence, ensure transparency, minimize the impact of individual bias and conflicts of interest, and drive members to reach consensus on recommendations. The process allows for public input and periodic updating of recommendations. When evidence was lacking, the WPSI also took into account members' clinical expertise and judgment as well as current best practices and patient perspectives.

Overall, the recommendations presented here (see page 23) apply to the general population of U.S. women at average risk for the conditions addressed. The final WPSI preventive services recommendations are presented in a single website, WomensPreventiveHealth.org, that is easily accessible by both health care providers and their patients. The recommendations contained in this report represent the conclusions of the WPSI and are not necessarily endorsed by individual organizations that participated in the Multidisciplinary Steering Committee that created them.

These WPSI recommendations are the culmination of a multidisciplinary effort to identify needed services and to improve the uptake of women's preventive services that will contribute to overall improved health. These recommendations take into account the most current evidence available, yet research gaps remain. In particular, more research is needed to address the preventive health needs of racial and ethnic minority women and underserved populations.

With the WPSI recommendations approved by HRSA, the WPSI will convene stakeholders with broad national networks for outreach and proven success in reaching their targeted audiences to promote the recommendations and increase consumer awareness of the need for and benefits of preventive care. As a result, more women will get the services they need and avoid unnecessary services as well. As the IOM stated, "Trustworthy guidelines hold the promise of improving health care quality and outcomes."[3] At the same time, ensuring that more women have access to recommended preventive health services will improve the health of women, their families, and their communities.

References

[1] Institute of Medicine. Clinical Practice Guidelines We Can Trust. Washington, DC: National Academies Press; 2011.

[2] Institute of Medicine. Clinical Preventive Services for Women: Closing the Gaps. Washington, DC: National Academies Press; 2013.

[3] Maciosek MV. Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost. Health Aff (Millwood) 2010;29(9):1656–60.

Introduction

On March 1, 2016, the American College of Obstetricians and Gynecologists (ACOG) launched the Women's Preventive Services Initiative (WPSI). The WPSI is a close collaboration of national health professional societies and consumer organizations that recognizes important contributions of these stakeholders to improved women's healthcare. Through a 5-year cooperative agreement with the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), ACOG will coordinate the WPSI effort to develop, review, update, and disseminate recommendations for women's preventive health care services, including the HRSA-sponsored Women's Preventive Services Guidelines.

The WPSI incorporates a strong evidence-based structure aligned with Institute of Medicine (IOM, now National Academics of Sciences, Engineering, and Medicine)-specified criteria for trustworthy guidelines, combined with the women's health expertise of the WPSI's members. Because the WPSI recommendations represent the consensus of the members, these participating organizations will work together to adopt and to widely promote the recommendations to help ensure that all women receive a comprehensive set of preventive services. ACOG has a track record of coalition-building and recommendation development, with notable success in synthesizing a wide range of information and opinions and arriving at strong consensus-based outcomes accepted across broad audiences nationwide.

In its first year, in keeping with HRSA priorities, the WPSI focused on updating eight topics addressed by the IOM in its 2001 report, *Clinical Preventive Services for Women: Closing the Gap.*[1] Because of the confusion caused by contradictory recommendations from multiple entities around breast cancer screening, the WPSI also addressed breast cancer screening for women at average risk. Additional topics will be determined by WPSI members with input from the public and addressed in subsequent years.

This document presents the following recommendations from the WPSI:

- Breast cancer screening for average-risk women
- Breastfeeding services and supplies
- Screening for cervical cancer
- Contraception
- Screening for gestational diabetes mellitus
- Screening for human immunodeficiency virus
- Screening for interpersonal and domestic violence
- Counseling for sexually transmitted infections
- Well-woman preventive visits

Preventive Health Care Improves Health

The benefits to women of preventive health visits throughout the life course are well documented in the literature. Evidence-based preventive health care has been shown to identify risk factors for disease and to promote early detection of disease and infection, allowing more effective management and prevention of further complications.[2] Preventive care—including reproductive life planning, optimization of nutrition and exercise, screening for and management of chronic diseases, immunizations, management of infectious diseases, and attention to psychological and behavioral health—contributes to women's overall health.

The role of preventive health care services, particularly in conjunction with early treatment of symptoms that may lead to worsening conditions, is the foundation of well-woman care.[3] In its Fifth Annual Report to Congress, *High-Priority Evidence Gaps for Clinical Preventive Services: Improving the Health of Women Through Research*, the U.S. Preventive Services Task Force (USPSTF) acknowledged the larger impact of preventive interventions that improve the health and well-being of women and girls. It noted that "the experience of disease and disability among women has unique transgenerational implications not only for themselves but for their children, their parents, their spouses, and even their communities."[4]

Uniform Guidelines Needed

To ensure women of all ages receive appropriate preventive health screenings, health care providers and patients need uniform, established guidelines for recommended preventive services for women. The development, updating, and maintenance of recommendations for women's preventive health services across the lifespan are not the purview of any one entity or institution. Governmental organizations and agencies may conduct high-quality, systematic reviews of existing evidence and develop recommendations. At the same time, clinical specialty societies create clinical practice guidelines, sometimes with contributions from organizations with disease-specific or population-specific interests. The availability of various guidelines, which may be inconsistent or even contradictory, leads to provider uncertainty and patient confusion about needed preventive services.

In addition, clinicians may not know that guidelines exist, may find them complex with unclear or difficult to implement recommendations, or lack the time and resources to fully adhere to recommended practice. Health care providers are more likely to use preventive health guidelines if they are evidenced-based. Therefore, efficient and effective guidelines established by a strong evidence-based process, vetted by experts in women's health, will impact patient preventive care delivery, patient safety, and quality by increasing the consistency of behavior and replacing individual preferences with best practices.

Women must also be engaged partners in the effort to follow consistent, well-vetted recommendations on prevention. In addition, guidelines need to be updated regularly to reflect the latest scientific evidence available and address any inconsistencies between medical and specialty organizations so that providers can give women clear messages on which to base informed decision making.

The development of consistent, evidence-based guidelines is sometimes hampered by limitations of supporting evidence. For the nine topics addressed in its first year, the WPSI found insufficient evidence for use in tailoring recommendations for preventive services for underserved or special populations of women, such as racial and ethnic minorities and those at high risk to certain conditions. These populations may have different needs for routine preventive health screening and intervention, and the WPSI fully supports development of additional data and resources to clarify these needs. When evidence was lacking, the WPSI also took into account its Multidisciplinary Steering Committee members' clinical expertise and judgment as well as current best practices and patient perspectives. Overall, the recommendations presented here apply to the general population of U.S. women at average risk for the conditions addressed; where relevant data were available, the recommendations address women at increased risk.

Overcoming Barriers to Preventive Care Uptake

More must be done by those working in preventive women's health to improve awareness and adoption of preventive measures. Providers need to be aware of and endorse evidenced-based guidelines and implement them in their practices. The Patient Protection and Affordable Care Act (ACA) provides expanded access to and coverage for preventive services for all women; an estimated 55.6 million women have received no-cost coverage for preventive services since the policy went into effect.[5] For both insured and uninsured women, affordability of care remains a significant concern.[6] Despite clear recognition of the benefits of preventive health services—such as improved long-term health outcomes and more efficient utilization of health services—disparities persist in the use of screening procedures among racial and ethnic minorities, those with lower health literacy, and the poor.[7,8] Coordination of care among providers is also required. High-quality care for women throughout the lifespan depends on use of consistent evidence-based guidelines across specialties, open communication and transparency, and patient education.

Collaborative, Multidisciplinary Approach

The WPSI is a collaboration among national professional societies and consumer organizations all with important contributions to improved women's health. The WPSI provides a forum for reviewing evidence and reaching consensus on recommendations for preventive women's care. The specific aims of the WPSI are as follows:

1. Establish a process for developing and regularly recommending updates to guidelines for women's preventive service.
2. Obtain participation from health professional organizations in developing recommended guidelines for women's preventive services.
3. Review and synthesize existing guidelines and new scientific evidence for women's preventive services.
4. Develop recommended guidelines for women's preventive services.
5. Disseminate HRSA-supported comprehensive guidelines for use in clinical practice.

The WPSI consists of an Advisory Panel made up of representatives from ACOG and three other major professional organizations representing the majority of women's health care providers: the American Academy of Family Physicians, the American College of Physicians, and the National Association of Nurse Practitioners in Women's Health. In addition, three individuals who were members of the IOM's 2011 Committee on Preventive Services for Women serve as Advisory Panel members.

The Advisory Panel oversees two standing committees—the Multidisciplinary Steering Committee (MSC) and the Implementation Steering Committee—and any future work groups formed. The WPSI instituted a strong evidence-based structure, tailored to the IOM standards for trustworthy guidelines, to create widely accepted recommendations that apply nationwide to women at various life stages. The methodology is detailed below.

The WPSI is chaired by Jeanne A. Conry, MD, PhD, Past President of ACOG. The Advisory Panel is chaired by Maureen Phipps, MD, MPH. Members of the MSC include representatives from medical specialty societies that oversee the majority of women's primary care services and chronic disease management care, public health professionals, and patients and consumers (see the box). The MSC also includes federal agency liaisons. In years 2–5, the MSC membership will be adjusted also to include expertise relevant to a specific topic selected. The WPSI partnered with physician scientists from the Pacific Northwest Evidence-based Practice Center (EPC) at Oregon Health & Science University to conduct reviews and updates of the evidence for each topic under consideration. Additional methodological, clinical, policy, and academic expertise came from three members of the 2011 IOM Clinical Preventive Services for Women panel. The WPSI is coordinated by ACOG staff members. Appendix 1 lists the WPSI members and staff.

2016 Multidisciplinary Steering Committee Participating Organizations

American Academy of Family Physicians

American College of Obstetricians and Gynecologists

American College of Physicians

National Association of Nurse Practitioners in Women's Health

Academy of Women's Health

American Academy of Pediatrics

American Academy of Physician Assistants

American Cancer Society

American College of Nurse–Midwives

American College of Preventive Medicine

American College of Radiology

American Osteopathic Association

American Psychiatric Association

American Geriatrics Society

Association of Reproductive Health Professionals

Association of Women's Health, Obstetric and Neonatal Nurses

National Comprehensive Cancer Network

National Medical Association

Association of Maternal & Child Health Programs

National Partnership for Women & Families

National Women's Law Center

Patient Representative

Federal Partners

Centers for Disease Control and Prevention

Health Resources and Services Administration

Office of Health Reform

Office of Minority Health

Office of Population Affairs

Office on Women's Health

METHODOLOGY

The IOM's July 2011 report, *Clinical Practice Guidelines We Can Trust*, noted a perceived lack of transparency in the derivation of some clinical practice recommendations and in managing conflicts of interest.[9] It cites variations in guidelines development processes as one fundamental cause of a lack of consistent guidelines across specialties and groups, which contributes to provider uncertainty and patient confusion about needed preventive services. The WPSI methodology is predicated on the belief that a strong evidence-based process will improve compliance with preventive service guidelines. The WPSI process was designed to ensure a strong evidence foundation, transparency, and to minimize the impact of individual bias and conflicts of interest.

In keeping with its aim to review and synthesize existing guidelines and new scientific evidence as it develops new recommendations, the WPSI avoids duplicating or contradicting recommendations of the USPSTF; the American Academy of Pediatrics (AAP) Bright Futures Initiative for infants, children, and adolescents; and the CDC's Advisory Committee on Immunization Practices. These sources reflect comprehensive reviews

of evidence conducted in a rigorous, transparent way. Topics considered by the WPSI require targeted systematic reviews that focus on specific evidence gaps not covered by existing recommendations from these bodies and new recommendations not addressed by these groups.

The methodology for the WPSI recommendations is based on the criteria for evidence-based clinical practice guideline development articulated in the IOM report, *Clinical Practice Guidelines We Can Trust*. These criteria are intended to support the accuracy, integrity, and clinical relevance of the recommendations, and they provide the framework for their development.

Ensuring Transparency

The MSC is made up of health care professionals from national organizations involved in the provision of women's preventive health services across the lifespan. This broad representation of experienced clinicians and experts increases transparency to the public by ensuring that multiple perspectives and approaches are included. It also minimizes the impact of individual biases and opinions on the recommendations.

The MSC also includes members representing patient and consumer perspectives. These members serve as full MSC committee and subcommittee members and are involved in all aspects of recommendation development, including topic selection, defining the scope of the recommendation, reviewing the evidence provided by the EPC, and participating in the development and dissemination of the HRSA-supported recommendations. These members serve an important role in ensuring that the recommendations are made with patients' perspectives in mind. Patient and consumer members will also be involved in dissemination efforts, including development of patient education materials, in future years.

In addition, the WPSI provided opportunity for broad public input through a public comment period that increased transparency of the process and improved balance, comprehensiveness, and quality. The dispensation of public comment responses, including changes to the recommendation or no action, was documented and retained by WPSI project staff.

Mitigating Conflict of Interest

All WPSI participants and project staff followed ACOG's formal Conflict of Interest Policy and submitted the standard organizational disclosure form prior to appointment to the initiative and will do so annually thereafter. Any disclosures were shared with the MSC at each meeting. Members of the Advisory Panel, the WPSI Chair, Subcommittee Chairs, and project staff were not permitted to have any financial conflicts of interest. All disclosed conflicts of interest are listed in Appendix I.

Broad Range of Perspectives and Experience

Members of the MSC are multispecialty, multidisciplinary representatives from national health professional organizations with expertise in women's health care across the lifespan, including obstetricians and gynecologists, family physicians, internal medicine physicians, nurse practitioners, nurse–midwives, women's health nurses, women's health researchers, public health professionals, and patient representatives. They are experts in the fields of women's health, primary care, chronic disease management, mental health, and gerontology, among others. Members were assigned to subcommittees based on clinical and methodological expertise. In coming years, subcommittees will be tasked with developing recommendations on one to two new topics each year.

Rigorous, Thorough Evidence Review

Physician scientists from the EPC at Oregon Health & Science University with extensive experience in systematic review methodology and clinical guideline development conducted reviews and updates of the evidence for each topic under consideration. Focused updates of evidence reviewed for the nine topics considered for revision included overviews of recent systematic reviews for the USPSTF published since the last recommendations were issued by the IOM Committee in 2011, as well as summaries of additional relevant studies published since the systematic reviews.

MSC members provided input to the EPC to refine the scope of the update based on criteria from the Populations, Interventions, Comparators, Outcomes, Timing, and Setting/Study Design (PICOTS) format, a well-established protocol for clearly articulating the topic of interest. In future years, key questions will be developed for each new topic based on the PICOTS format, and the EPC will work with the MSC to refine inclusion and exclusion criteria for the literature searches.

For the updates to the IOM's 2011 recommendations presented in this report, a research librarian conducted searches in Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews through August 2016 for all topics. For topics on counseling for sexual transmitted infections, interpersonal and domestic violence, and well-woman visits, searches were also conducted in PsycINFO through March 2016. Investigators also manually reviewed reference lists of relevant articles.

A best evidence approach was applied when reviewing abstracts and selecting studies to include for the updates that involves using the most relevant studies with the strongest methodologies.[10,11,12] For most topics, systematic reviews and key studies published since the most recent systematic review for the USPSTF were included. For well-woman visits and contraceptive methods and counseling, there are no USPSTF reviews or recommendations. Therefore, other systematic reviews and studies published since the 2011 IOM recommendations for these topics were included.

Randomized, controlled trials and large (ie, more than 100 subjects) prospective cohort studies were included if they provided relevant information for a specific topic. Other study designs, such as case-control and modeling studies, were included when evidence was lacking or when they demonstrated new findings. Studies conducted in settings

applicable to the United States were particularly targeted. Findings relevant to population subgroups were specifically included when available. The focus of each review was on gaps identified in the 2011 IOM recommendations and any new evidence that could change or additionally inform the recommendations where evidence was not previously available. Selection criteria specific to each topic were developed to address issues specific to the WPSI.

Applicability is defined as the extent to which the effects observed in published studies are likely to reflect the expected results when an intervention is applied to the population of interest under "real-world" conditions.[12] It is an indicator of the extent to which research included in a review might be useful for informing clinical decisions in specific situations. Factors important for understanding the applicability of studies were considered, including differences in the interventions and comparators, populations, and settings.

No new or revised statistical meta-analyses were conducted. Studies were qualitatively synthesized according to interventions, populations, and outcomes measured. Studies and their findings were summarized in a narrative, descriptive format to provide an overview of the new evidence for each topic.

Establishing the Strength of Recommendations

As recommendations were developed by the MSC members, EPC investigators created evidence maps to provide a descriptive summary of supporting evidence for each component of the recommendation. Evidence maps for the WPSI updates were adapted from methods of the 2011 IOM panel. Current systematic reviews and research studies, epidemiologic data, USPSTF and AAP Bright Futures recommendations, clinical best practices, and other relevant sources were included. In addition, like the 2011 IOM Panel, the MSC considered multiple levels of evidence when developing recommendations and permitted recommendations to be based on varying levels of evidence, expert consensus, or standard best practices.

Reaching Consensus Around Evidence-Based Recommendations

A summary of the evidence for each topic was presented to the full MSC and served as the basis for recommendation development. A subcommittee of the MSC considered the evidence in depth and formulated a draft recommendation. Draft recommendations were presented and discussed by the full MSC and revised as needed. To build consensus, the foundation for the recommendation must be transparent and clearly articulated to provide an understanding of the volume and quality of the supporting evidence and an accurate assessment of the benefits and harms for each topic. Although the recommendations were based on the evidence reviewed, some components lacked sufficient evidence. In such cases, recommendations were supplemented with the expert consensus of the over 20 multidisciplinary women's health experts of the MSC, taking into consideration standards of best practice, risk-benefit analysis, and expert opinion.

Once the MSC discussion concluded, the proposed draft recommendation was put forth for a vote by the full MSC. Votes were taken by hand, without secret ballots, and recorded as "approve," "do not approve," or "abstain." The MSC is required to reach at least 75% agreement from voting members for the recommendation

to be adopted. If 75% agreement was not reached after one round of voting, further discussion was permitted, and an email vote outside of the meeting was permitted if additional time was needed. Although not required for these first nine topics, if after discussion and a second round of voting 75% agreement was not reached, the recommendation would have been returned to the subcommittee for reconsideration, at the discretion of the MSC chair. The subcommittee would then determine whether the recommendation should be reconsidered after a reevaluation of the supporting evidence and information. These steps will be considered for future topics that require additional discussion to reach consensus agreement.

Inviting Public Comment and External Review

A draft of each recommendation was released online for public comment for a one-month period, based on a process mirroring that of AAP Bright Futures. Input during the public comment period was solicited from all interested organizations and individuals. Commenters represented a broad array of perspectives and expertise on women's preventive health care. All comments were reviewed and summarized by project staff and provided to the MSC. Comments were reviewed and addressed by the corresponding subcommittee or full MSC as needed. For future recommendations, a process for in-person public comment addressed directly to the MSC will be considered as time permits.

Continual Updating of Recommendations

Recommendations will be reviewed for currency and accuracy at least every 24 months after submission to and adoption by HRSA. For each recommendation, the literature search dates, along with the proposed date for review, will be reported. The EPC and ACOG project staff will scan the horizon continuously to identify emerging evidence, assess current validity of each recommendation, and identify or clarify associated benefits and harms. Recommendations identified for updates will be included on the list of next topics to be addressed by the MSC.

WPSI RECOMMENDATIONS

Each WPSI recommendation is made up of clinical considerations and implementation considerations. The clinical considerations describe the overarching clinical recommendation based on the best available evidence and clinical expertise. The implementation considerations address clinical and practical aspects of applying the recommendation for patient care.

The WPSI recommendations recognize that decisions about preventive health services should be based on a periodic shared decision-making process involving the woman and her health care provider. The shared decision-making process assists women in making an informed decision and includes, but is not limited to, a discussion about benefits and harms, an assessment of the woman's values and preferences, and consideration of factors such as life expectancy, comorbidities, and health status.

ADDITIONAL CONSIDERATIONS

These WPSI recommendations are the culmination of a multidisciplinary effort to identify needed services and to improve the uptake of women's preventive services that will contribute to overall improved health. These recommendations take into account the most current evidence available, yet research gaps remain. In particular, more research is needed to address the preventive health needs of racial and ethnic minority women and underserved populations. For example, current evidence does not sufficiently address screening strategies to eliminate disparities in breast cancer detection, treatment, and mortality for minority women.

Although access to preventive health services has expanded, coverage of important preventive services differs across payers and may be incomplete. The implementation considerations included in each WPSI

recommendation not only address practical aspects of implementation but also offer guidance to payers about what is included in preventive services based on the best interpretation of evidence.

The process established by the WPSI for developing and updating recommendations seeks to address the shortcomings noted by the IOM by ensuring transparency, mitigating conflicts of interest, incorporating multiple perspectives, and relying on evidence. However, the WPSI has opportunities to improve:

Needs of Minority Women: Some have been critical of the WPSI for the extent to which the needs of minority women were considered. As part of the commitment to ensuring broad representation of providers, patient representative organizations, and consumers, the MSC included individuals from ethnic and minority groups. Despite the diversity of perspective, the WPSI acknowledges the lack of sufficient scientific evidence for tailoring many of the recommendations to specific needs of racial and ethnic minority women. The WPSI recognizes the importance of addressing the needs of these often underserved women and will continue to seek relevant information to develop recommendations that are tailored to diverse populations. As the WPSI progresses in years 2–5, it will work with HRSA to determine high-priority new topics based on the availability of evidence, the identified gaps in preventive services for women, and the likelihood of impact on a broad population of women.

Public Participation: Although highly desirable, the timeframe for the WPSI's first year did not allow for in-person public input into topic refinement or recommendations. The WPSI will work with HRSA to ensure that staff can plan and promote public comment opportunities with broad and meaningful outreach. These opportunities are vital to ensure transparency in the guideline development process and to give the public an opportunity to voice issues they would like the MSC to consider when developing new or updating recommendations. For future recommendations, a process for in-person public comment addressed directly to the MSC will be incorporated as time permits.

NEXT STEPS

With the WPSI recommendations approved by HRSA, stakeholders with broad national networks for outreach and proven success in reaching their targeted audiences will be convened. The second standing committee, the Implementation Steering Committee, will be convened in year 2 by engaging supporting partners from the MSC and other groups active in community and provider outreach and patient awareness activities with capabilities to reach a wide audience of women, including adolescents; reproductive-aged, mature, and older women; and those from underserved communities. The Implementation Steering Committee will work to promote the recommendations from the MSC and increase consumer awareness of the need for and benefits of preventive care.

The final WPSI preventive services recommendations are presented in a single website, WomensPreventiveHealth.org, that is easily accessible by both health care providers and their patients. All messaging surrounding the WPSI's outreach will involve directing patients and providers to the website for consistent, up-to-date information, interactive tools, and resources for provider recommendations and patient preventive care awareness.

CONCLUSION

The WPSI is a unique collaboration of experts and advocates representing national organizations whose constituencies reflect the full spectrum of the health and well-being of adolescents and adult women in the United States. These recommendations are the result of a rigorous, transparent, and well-structured process informed by clinical and patient perspectives. They are based on the best available current evidence. The MSC members dedicated numerous hours to discussion, debate, evidence review, and draft revisions to develop recommendations that represent a consensus among clinical experts in women's health, patient and consumer health advocates, and public health policymakers. As such, they represent the kind of reliable and trustworthy recommendations the IOM called for in its 2011 report, *Clinical Practice Guidelines We Can Trust*. Implementing uniform recommendations such as these for preventive services will provide clarity for clinicians and their patients. As a result, more women will get the services they need and avoid unnecessary services as well. As the IOM stated, "Trustworthy guidelines hold the promise of improving health care quality and outcomes."[1] At the same time, ensuring that more women have access to recommended preventive health services will improve the health of women, their families, and their communities.

References

[1]Institute of Medicine. Clinical Preventive Services for Women: Closing the Gaps. Washington, DC: National Academies Press; 2013.

[2] Maciosek MV. Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost. Health Aff (Millwood) 2010;29(9):1656–60.

[3]Conry JA. Every Woman, Every Time. Obstet Gynecol 2013;122:3–6.

[4]U.S. Preventive Services Task Force. Fifth Annual Report to Congress. High-Priority Evidence Gaps For Clinical Preventive Services: Improving the Health of Women Through Research. https://www.uspreventiveservicestaskforce.org/Page/Name/fifth-annual-report-to-congress-on-high-priority-evidence-gaps-for-clinical-preventive-services. November 2015. Accessed November 28, 2016.

[5]Henry J. Kaiser Family Foundation. Preventive Services Covered by Private Health Plans under the Affordable Care Act. http://kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/. August 4, 2015. Accessed November 28, 2016.

[6]Henry J. Kaiser Family Foundation. Women's Health Insurance Coverage. http://kff.org/womens-health-policy/fact-sheet/womens-health-insurance-coverage-fact-sheet/. October 21, 2016. Accessed November 28, 2016.

[7]Partnership for Prevention. Preventive Care: A National Profile on Use, Disparities and Health Benefits. Washington, DC: Partnership for Prevention; 2007. http://www.rwjf.org/en/library/research/2007/08/preventive-care-national-profile-on-use.html. Accessed January 3, 2016.

[8]Bennett I, Chen J, Sourou JS, White S. The Contribution of Health Literacy to Disparities in Self Rated Health Status and Preventive Health Behaviors in Older Adults. Ann Fam Med 2009;7(3):204–211.

[9]Institute of Medicine. Clinical Practice Guidelines We Can Trust. Washington, DC: National Academies Press; 2011.

[10]Institute of Medicine. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: National Academies Press; 2011.

[11]Nelson HD. Systematic Reviews to Answer Health Care Questions. Philadelphia, PA: Lippincott Williams & Wilkins; 2014.

[12]Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication Number 10(14)-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality; January 2014.

Final Recommendations: Preventive Services for Women
Women's Preventive Services Initiative Multidisciplinary Steering Committee*
December 2016

Breast Cancer Screening for Average-Risk Women

Clinical Recommendations

The Women's Preventive Services Initiative recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

Implementation Considerations

The Women's Preventive Services Initiative recommends, as a preventive service, that women initiate mammography screening no earlier than age 40 and no later than age 50 and continue through at least age 74. Screening mammography should occur at least biennially and as frequently as annually.

Decisions regarding when to initiate screening, how often to screen, and when to stop screening should be based on a periodic shared decision-making process involving the woman and her health care provider. The shared decision-making process assists women in making an informed decision and includes, but is not limited to, a discussion about the benefits and harms of screening, an assessment of the woman's values and preferences, and consideration of factors such as life expectancy, comorbidities, and health status.

Breastfeeding Services and Supplies

Clinical Recommendations

The Women's Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.

Implementation Considerations

Lactation support services include counseling, education, and breastfeeding equipment and supplies. A lactation care provider should deliver lactation support and provide services across the antenatal, perinatal, and postpartum periods to ensure successful preparation, initiation, and continuation of breastfeeding. Lactation care providers include, but are not limited to, lactation consultants, breastfeeding counselors, certified

midwives, certified nurse-midwives, certified professional midwives, nurses, advanced practice providers (eg, physician assistants and nurse practitioners), and physicians. Breastfeeding equipment and supplies, as agreed upon by the woman and her lactation care provider, include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be based on optimization of breastfeeding, and not predicated on prior failure of a manual pump.

Screening for Cervical Cancer

Clinical Recommendations

The Women's Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service, cervical cancer screening for average-risk women aged 21 to 65 years. For average-risk women aged 30 to 65 years, informed shared decision-making between the patient and her clinician regarding the preferred screening strategy is recommended.

Women who have received the human papillomavirus vaccine should be screened according to the same guidelines as women who have not received the vaccine.

These recommendations are for routine screening in average-risk women and do not apply to women infected with human immunodeficiency virus, women who are immunocompromised because of another etiology (such as those who have received solid organ transplantation), women exposed to diethylstilbestrol in utero, or women treated for cervical intraepithelial neoplasia grade 2 or higher within the past 20 years. Screening strategies for high-risk women are outside the scope of these recommendations.

Cervical cancer screening is not recommended for women younger than 21 years or those older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer. Adequate prior negative screening is defined as documentation (or a reliable patient report) of three consecutive negative cytology results or two consecutive negative cotest results within the previous 10 years with the most recent test within the past 5 years. Cervical cancer screening is also not recommended for women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesions (eg, cervical intraepithelial neoplasia grade 2 or grade 3 or cervical cancer within the past 20 years).

Contraception

Clinical Recommendations

The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (eg, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.

The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), 8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service, access to and provision of the full range of female-controlled U.S. Food and Drug Administration-identified contraceptive methods. This includes access to contraceptive counseling, initiation of contraceptive use, and follow-up care (eg, management, evaluation, as well as changes to and removal or discontinuation of the contraceptive method) by a health care provider or appropriately trained individual. Additionally, effective family planning practices, and patient-specific services or U.S. Food and Drug Administration-approved methods that may be required based on individual women's needs are recommended as part of contraceptive preventive services.

The Women's Preventive Services Initiative recommends accommodation of an alternative form of contraception when a particular drug or device (generic or brand name) is medically inappropriate for a patient as determined by the individual's health care provider. Research indicates that delayed initiation or disruption of contraceptive use increases the risk of unintended pregnancy; therefore, the Women's Preventive Services Initiative recommends timely authorization of contraceptives.

The Women's Preventive Services Initiative also recommends as a preventive service counseling that emphasizes patient-centered decision-making and allows for discussion of the full range of contaceptive options.

For some women, more than one visit may be needed to achieve effective contraception. More than one visit may also be necessary to identify the appropriate contraceptive methods to optimize compliance and effectiveness as determined by a woman and her health care provider, based on shared decision making.

Screening for Gestational Diabetes Mellitus

Clinical Recommendations

The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity.

The Women's Preventive Services Initiative suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.

Implementation Considerations

Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation to prevent adverse birth outcomes. Risk factors for diabetes mellitus that may help identify women for early screening include, but are not limited to, those identified by the Institutes of Medicine (now National Academies of Science, Engineering, and Medicine). The optimal test for screening

prior to 24 weeks of gestation is not known. However, acceptable modalities may include a 50-g oral glucose challenge test, a 2-hour 75-g oral glucose tolerance test, a hemoglobin A1c test, a random plasma glucose test, or a fasting plasma glucose test. If early screening is normal, screening with a 50-g oral glucose challenge test should be conducted at 24 to 28 weeks of gestation as described above.

Screening for Human Immunodeficiency Virus Infection

Clinical Recommendations

The Women's Preventive Services Initiative recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan. All women should be tested for HIV at least once during their lifetime. Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection.

Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service for women, prevention education and risk assessment for HIV infection in adolescents and women at least annually throughout the lifespan. More frequent screening for high-risk women, as determined by clinical judgment, is also recommended as a preventive service. Annual or more frequent HIV testing may be needed and is recommended as a preventive service for women who are identified or self-identify as high risk.

This recommendation refers to routine HIV screening, which is different from incident-based or exposure-based HIV testing. Risk factors for HIV infection in women include, but are not limited to, being an active injection drug user; having unprotected vaginal or anal intercourse; having multiple sexual partners; initiating a new sexual relationship; having sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; being a victim of sex trafficking; being incarcerated (currently or previously); and having other sexually transmitted infections.

Approximately 20–26% of infected patients are not identified by risk-based screening. Early detection and treatment improves outcomes for patients and reduces transmission; therefore, based on clinical best practice, screening annually or more frequently may be reasonable.

Screening for Interpersonal and Domestic Violence

Clinical Recommendations

The Women's Preventive Services Initiative recommends screening adolescents and women for interpersonal and domestic violence, at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service, screening adolescents and women for interpersonal and domestic violence. Factors associated with increased risk include, but are not limited to, pregnancy; younger and older age; increased stress; lesbian, gay, bisexual, transgender, and queer (or questioning) status; dependency; drug and alcohol misuse; former or current military service; and living in an institutional setting. There are multiple screening tools that have shown adequate sensitivity and specificity for identifying intimate partner violence and domestic violence in specific populations of women. Minimum screening intervals are unknown; however, based on the prevalence of interpersonal and domestic violence as well as evidence demonstrating that many cases are not reported, it is reasonable to conduct screening at least annually although the frequency and intensity of screening may vary depending on a particular patient's situation.

Counseling for Sexually Transmitted Infections

Clinical Recommendations

The Women's Preventive Services Initiative recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

The Women's Preventive Services Initiative recommends that health care providers use a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgement.

Implementation Considerations

The Women's Preventive Services Initiative recommends as preventive service for women at increased risk for STIs, directed behavioral counseling that includes, but is not limited to, longer duration or multiple counseling sessions, motivational interviewing techniques, and goal setting.

The Women's Preventive Services Initiative recommends as a preventive service, STI counseling regardless of whether or not STI screening takes place during the same visit and regardless of the type of sexual activity or the partners' gender.

Well-Woman Preventive Visits

Clinical Recommendations

The Women's Preventive Services Initiative recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services, including preconception and many services necessary for prenatal and interconception care, are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service for women, that women receive at least one preventive care visit per year. Additional well-woman visits may be needed to obtain all necessary services depending on a woman's age, health status, reproductive health needs, pregnancy status, and risk factors. Visits should allow sufficient time to address and coordinate services, and a team-based approach may facilitate delivery of services.

Well-woman preventive services may include, but are not limited to, assessment of physical and psychosocial function, primary and secondary prevention and screening, risk factor assessments, immunizations, counseling, education, preconception care, and many services necessary for prenatal, and interconception care. Recommended services are evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force, immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved, with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration, and with respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

*These are the recommendations of the WPSI and not necessarily of any individual participating organization.

Breast Cancer Screening for Average-Risk Women

Clinical Recommendations

The Women's Preventive Services Initiative recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

Implementation Considerations

The Women's Preventive Services Initiative recommends, as a preventive service, that women initiate mammography screening no earlier than age 40 and no later than age 50 and continue through at least age 74. Screening mammography should occur at least biennially and as frequently as annually. Decisions regarding when to initiate screening, how often to screen, and when to stop screening should be based on a periodic shared decision-making process involving the woman and her health care provider. The shared decision-making process assists women in making an informed decision and includes, but is not limited to, a discussion about the benefits and harms of screening, an assessment of the woman's values and preferences, and consideration of factors such as life expectancy, comorbidities, and health status.

EVIDENCE MAP

- Average-risk women should initiate mammography screening no earlier than age 40 and no later than age 50.
- Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

Systematic Reviews	Additional Studies	USPSTF[1]
USPSTF 2016 review[2]: • Meta-analyses of screening RCTs indicate statistically significant breast cancer mortality reductions with screening for ages 50-59 and 60-69 years; but not 39-49 and 70-74 years. Estimates for age >70 are limited by small sample sizes. • Meta-analysis of screening RCTs indicate no reductions in advanced breast cancer with screening for age 39 to 49 years; but reduced risk with screening for age 50 years and older.	Observational studies of screening indicate reduced breast cancer mortality for ages 50-69; studies of younger and older women are lacking or inconsistent.	• Age 40-49: Biennial screening mammography should be based on individual factors including the patient's values regarding specific benefits and harms (Level C; 2016). • Age 50-74: Biennial screening mammography (Level B; 2016). • Age 75 and older: Evidence is insufficient to assess the additional benefits and harms of screening mammography (2016).

Screening mammography should occur at least biennially and as frequently as annually.

Systematic Reviews	Additional Studies	USPSTF[1]
USPSTF 2016 review[2]: Screening trials do not compare screening intervals; observational studies are inconsistent and biases limit interpretation.	CISNET modeling study[3]: Biennial screening intervals provide the most benefit while minimizing potential harms.	Age 50-74: Biennial screening mammography (Level B; 2016).

Decisions regarding when to initiate screening, how often to screen, and when to stop screening should be based on a periodic shared decision-making process involving the woman and her health care provider.

Systematic Reviews	Additional Studies	USPSTF[1]
None	None	Suggests informed decision making, however, no studies have evaluated the effectiveness of this approach (2016).

Abbreviations: CISNET=Cancer Intervention and Surveillance Modeling Network; RCTs=randomized controlled trials; USPSTF=U.S. Preventive Services Task Force

SUMMARY OF EVIDENCE

Introduction

Breast cancer commonly includes an asymptomatic phase that can be identified with mammography. The rationale for screening is to improve survival by identifying treatable cancer at localized stages, although screening may not reduce mortality for some aggressive cancer types,[4] and has less impact on slowly progressive types.[5,6] Screening for women at average risk for breast cancer (i.e., without risk factors indicating high risk) is conducted using periodic mammography. Digital mammography has generally replaced film in the United States, and newer technologies, such as digital tomosynthesis, are rapidly disseminating. Rates of screening mammography in the United States are generally high and have remained relatively stable for the past decade. Mammography screening between 2009 and 2011 was performed by 71% of eligible women covered by commercial plans, 69% for Medicare plans, and 51% for Medicaid plans.[7]

While there is general consensus that mammography screening is beneficial for many women, conflicting screening recommendations have led to practice variability. Issues lacking consensus include the optimal ages to begin and end routine screening; optimal screening intervals; defining and balancing the benefits of screening with potential harms; appropriate use of various imaging modalities including supplemental technologies; values and preferences of women regarding screening; and how all of these considerations vary depending on a woman's risk for breast cancer.

Current Recommendations and Coverage of Services

The previous Institute of Medicine panel did not address breast cancer screening coverage[8] because a specific clause in the Affordable Care Act indicated that annual mammography screening would be covered for women age 40 years and older without a co-pay or deductible.[9] This coverage applies to the annual screening mammogram only, and subsequent related services are not similarly covered.

In 2016, the U.S. Preventive Services Task Force (USPSTF) updated its recommendation for breast cancer screening for asymptomatic, average-risk women.[1,7,10] The new recommendation is similar to the previous recommendation issued in 2009.[11] The USPSTF recommends biennial screening mammography for women ages 50 to 74 years, and determined that 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.

The USPSTF concluded that evidence was insufficient to assess the additional benefits and harms of screening mammography in women age 75 years or older. In addition, they determined that evidence was insufficient to support digital breast tomosynthesis (DBT) as a primary screening method, and adjunctive screening for breast cancer using breast ultrasonography, magnetic resonance imaging (MRI), DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram.

Background

Breast cancer is the second most common cancer in women in the United States after non-melanoma skin cancer, and is the second leading cause of cancer death after lung cancer.[12] In 2016, an estimated 246,660 women in the United States will be diagnosed with breast cancer and 40,450 will die, representing 14.6% of all new cancer cases and 6.8% of all cancer deaths.[12] The overall 5-year relative survival rate for breast cancer from 2006 to 2012 was 89.7%, and approximately 3 million women were living with breast cancer in the United States in 2013.[12]

Although many risk factors have been associated with breast cancer in epidemiologic studies, most relationships are weak or inconsistent.[13] Most women who develop breast cancer have no identifiable risk factors beyond sex and age. However, a small number of clinically significant risk factors are associated with high risks for breast cancer and can be used to identify women who may be eligible for screening outside routine screening recommendations. These include women with deleterious BRCA mutations and their untested first-degree relatives; other hereditary genetic syndromes; previously diagnosed high-risk breast lesions;[14] and history of high-dose radiation therapy to the chest between the ages of 10 to 30 years, such as for treatment of Hodgkin lymphoma.

Family history of breast cancer, particularly among first-degree relatives, is also an important risk factor. Approximately 5 to 10% of women with breast cancer have a mother or sister with breast cancer, and up to 20% have either a first-degree or a second-degree relative with breast cancer.[15] The degree of risk associated with family history varies according to familial patterns of disease. Estimates of lifetime risk of breast cancer determined by kindred analysis of over 15 or 20% are considered high.

Breast density is a radiographic measure of breast tissue that is associated with increased risk for breast cancer and reduced mammography sensitivity. Breast density is currently described by four categories: almost entirely fat, scattered fibroglandular densities, heterogeneously dense, and extremely dense.[16] Approximately 37% of women had dense breasts in a recent U.S. study; however, there was a wide variation in density assessment across radiologists.[17] Increased breast density is more common among younger women.[18] Compared with women with scattered fibroglandular densities, hazard ratios for breast cancer are 1.6 for premenopausal women with heterogeneously dense breasts and 2.0 for those with extremely dense breasts.[19]

Models that incorporate several of these risk factors have been developed to predict breast cancer risk for individual women. All of the models include age and number of first-degree relatives with breast cancer into their calculations, but vary in their complexity. Studies of their diagnostic accuracy indicate that the models are poor predictors of an individual's risk[20] and their effectiveness in selecting candidates for breast cancer screening remains unproven.

Current practice guidelines vary across professional organizations (**Table 1**).

Table 1. Recommendations of Professional Organizations

American College of Obstetricians and Gynecologists (ACOG)[21]	Mammography screening should be offered annually to women beginning at age 40.
American Academy of Family Physicians (AAFP)[22]	The decision to conduct screening mammography prior to age 50 should be individualized and take into consideration the patient's context and risk factors. For women between ages 50 and 74, the AAFP recommends biennial screening.
American Cancer Society[23]	Women with an average risk of breast cancer should undergo regular screening mammography starting at age 45 years; women aged 45 to 54 years should be screened annually; women 55 years and older should transition to biennial screening or have the opportunity to continue screening annually. Women should have the opportunity to begin annual screening between the ages of 40 and 44 years and should continue screening mammography as long as their overall health is good and they have a life expectancy of 10 years or longer.
American College of Radiology (ACR)[24]	Annual screening mammography for asymptomatic women 40 years of age and older. The decision as to when to stop routine mammography screening should be made on an individual basis by each woman and her physician based on a woman's overall health.
National Comprehensive Cancer Network (NCCN)[25]	Annual screening mammography, clinical breast exam, and breast awareness for asymptomatic, average risk women age 40 years and older.

UPDATE OF EVIDENCE

The WPSI update focuses on three issues: optimal ages to begin and discontinue regular screening mammography, and optimal screening intervals for women screened at any age. Several comprehensive evidence reviews on breast cancer screening were recently conducted, including reviews from the Pacific Northwest Evidence-based Practice Center for the USPSTF published in February 2016.[2,26] Results relevant to the three issues covered in this update are summarized below. Literature searches used for the USPSTF reviews were repeated in August 2016 to identify new evidence, however, no new studies relevant to the update met inclusion criteria.

Effectiveness of Screening at Different Ages

Reducing breast cancer mortality

Meta-analyses of randomized controlled trials (RCTs) of breast cancer screening with updated data from the Canadian, Swedish Two-County Study, and Age trials indicated statistically significant breast cancer mortality reductions with screening for ages 50 to 59 years and 60 to 69 years, but not for age 39 to 49 years and 70 to 74 years (**Table 2**).[2] Estimates for women age 70 and older were limited by low numbers of events from trials that had smaller sample sizes of women in this age group.

Observational studies of the effectiveness of population-based mammography screening on breast cancer mortality reported a wide range of reductions in breast cancer death. Most studies were conducted in Europe or the United Kingdom and included women age 50 to 69 years. Meta-analyses from recent reviews from the EUROSCREEN Working Group indicated 25 to 31% mortality reduction for women invited to screening in the screening programs. This compares to 19 to 22% reduction for women age 50 to 69 years in the USPSTF meta-analysis of screening RCTs.[2]

Table 2. Age-specific Rates of Breast Cancer Mortality Reduction with Screening[2] Number of deaths prevented if 10,000 women were followed for 10 years

Age, yrs	Number of trials	Mortality rate in the control group per 100,000 person-years (95% CI)*	Breast cancer mortality reduction RR (95% CI)†	Deaths prevented with screening over 10 years (95% CI)
39-49	9	39-49	0.88 (0.73 to 1.003)	4.1 (-0.1 to 9.3)
50-59	7	50-59	0.86 (0.68 to 0.97)	7.7 (1.6 to 17.2)
60-69	5	60-69	0.67 (0.54 to 0.83)	21.3 (10.7 to 31.7)
70-74	3	70-74	0.80 (0.51 to 1.28)	12.5 (-17.2 to 32.1)

*Based on trials of screening included in the meta-analysis.
†From meta-analysis of screening trials using the longest follow-up time available.
CI=confidence interval; RR=relative risk.

The only U.S observational study of breast cancer mortality reduction is a record review that indicated no differences in breast cancer deaths between screened versus non-screened women older than age 80 years.[27] A large study of the Mammography Screening of Young Women Cohort in Sweden indicated reduced risk for breast cancer deaths for women age 40 to 49 years invited to screening compared with women not invited (RR 0.74; 95% CI, 0.66 to 0.83).[28] An observational study of Canadian women age 40 to 79 comparing screening program participants versus nonparticipants indicated 40% reduced breast cancer mortality among participants.[29] However, observational studies were susceptible to important methodologic biases limiting these conclusions, particularly regarding important fundamental differences between participants and nonparticipants of screening programs.

Reducing all-cause mortality

All-cause mortality did not differ between randomized groups in meta-analyses of the screening RCTs, regardless of whether trials were analyzed in combined or separate age groups

Reducing advanced breast cancer

The RCTs of mammography screening provided several measures of intermediate breast cancer outcomes. However, most comparisons between screening and control groups using these categories provided differences

between the two groups in relatively early stages of disease, rather than advanced stages. When thresholds were defined by the most severe disease categories available from the trials (Stage III + IV disease, size ≥50 mm, 4+ positive lymph nodes), meta-analysis indicated no reductions in advanced breast cancer with screening for age 39 to 49 years (RR 0.98; 95% CI 0.74 to 1.37); but reduced risk with screening for age 50 years and older (RR, 0.62; 95% CI 0.46 to 0.83). The majority of cases from screening were ductal carcinoma in situ (DCIS) and early stage, and screening resulted in more mastectomies (RR 1.20 [95% CI 1.11 to 1.30]; 5 trials) and radiation (RR 1.32 [95% CI 1.16 to 1.50]; 2 trials).

Several observational studies describe differences between screened and unscreened women, but report various definitions of advanced breast cancer.[2] Six observational studies compared advanced breast cancer outcomes between women in populations participating in screening versus nonparticipating. Of these, two studies indicated statistically significantly more Stage III and IV breast cancer among unscreened women; three reported more lymph node positive disease; and three reported more tumors greater than 20 mm in size. Four case series studies indicated less extensive surgery, such as fewer total mastectomies and more breast conservation therapies, and less chemotherapy among women who had previously had screening mammography compared with those who did not, but these studies included women with DCIS and early stage cancer as well as advanced cancer.

An analysis of data from the Breast Cancer Surveillance Consortium (BCSC) indicated a lower proportion of Stage III + IV disease among women age 40 to 49 years screened annually versus biennially, but not for women age 50 to 59 years. A second analysis of BCSC data indicated that women age 40 to 49 years with extremely dense breasts had increased risks for advanced stage cancer (IIB+) and large-size tumors (>20 mm) with biennial compared with annual screening. Differences were not significantly different for positive lymph nodes, other density categories, other age groups, or between biennial and triennial screening.

Effectiveness of Screening Using Different Intervals

There are no head-to-head trials of the effectiveness of different screening intervals, and existing trials do not provide enough information to determine the specific effects of screening intervals. Two observational studies of screening intervals indicated no breast cancer mortality differences between annual and biennial screening for women 50 years or older, or between annual and triennial screening among women age 40 to 49 years. No RCTs evaluated the incidence of advanced breast cancer outcomes and treatment on the basis of screening intervals.

Because of the lack of studies addressing the effectiveness of different screening intervals, the USPSTF commissioned a modeling study from the CISNET modeling group.[3] Results indicated that biennial screening intervals provided the most benefit while minimizing potential harms.

Harms of Screening

The USPSTF weighs the benefits of screening against potential harms, including false-positive results leading to additional imaging and biopsies, false-negative results, overdiagnosis, anxiety and distress with screening, pain, and radiation exposure.

False-Positive and False-Negative Mammography Results, Recommendations for Additional Imaging, and Recommendations for Biopsies

Data from the BCSC for regularly screened women using digital mammography based on results from a single screening round indicated that false-positive mammography rates were highest among women age 40 to 49 years (121.2 per 1,000 women; 95% CI 105.6 to 138.7) and declined with age; rates of false-negative results tended to increase with age, but were not statistically significantly different across age groups (**Table 3**).[30] Rates of recommendations for additional imaging were highest among women age 40 to 49 years (124.9 per 1,000 women; 95% CI 109.3 to 142.3) and decreased with age, while rates of recommendations for biopsy did not differ between age groups. For every case of invasive breast cancer detected by mammography screening in women age 40 to 49 years, 464 women had screening mammography, 58 were recommended for additional imaging, and 10 were recommended for biopsies. These estimates declined with age. These results did not differ by time since last mammography screening regardless of whether broad or narrow estimates of one versus two years were used.

When these outcomes were evaluated by breast cancer risk factors, family history of breast cancer, high breast density, and previous benign breast biopsy were associated with higher rates of false-positive and false-negative results and recommendations for additional imaging and biopsy across most age groups. Premenopausal status, use of menopausal hormone therapy, and lower BMI were associated with some of the outcomes for specific age groups only. Rates for all outcomes were lowest for women with almost entirely fat breasts, and highest for women with heterogeneously dense breasts or for those in the combined category of heterogeneous and extreme density.

Published data from the BCSC using film and digital mammography provided 10-year cumulative rates of false-positive results and biopsies.[31,32] Rates of false-positive mammography results were 61% for annual and 41% for biennial screening, while rates of false-positive biopsy were 7 to 9% for annual and 5 to 6% for biennial screening. Women older than age 50 years had higher false-positive biopsy rates. Rates of false-positive mammography results and biopsy were highest among women receiving annual mammography, those with heterogeneously dense or extremely dense breasts, and those either 40 to 49 years old or who used combination hormone therapy.

Overdiagnosis

Overdiagnosis refers to breast cancer cases that are detected by screening that would not become clinically important to the patient in the absence of screening. A meta-analysis of three RCTs, a systematic review of 13 observational studies, and 18 individual studies of overdiagnosis were identified for the USPSTF update.[33]

Studies of overdiagnosis were primarily based on screening trials, screening programs and registries, or modeled data. Studies differed by their characteristics, methods, and measures. These differences influenced their estimates of overdiagnosis, limited comparisons, and prohibited combined estimates.

Estimates from RCTs indicate overdiagnosis rates of 10.7 to 19.0%. Unadjusted estimates from 13 observational studies included in the EUROSCREEN review indicated overdiagnosis rates ranging from 0 to 54%. For six studies that adjusted overdiagnosis estimates for breast cancer risk and lead time, rates varied from 1 to 10%. Additional observational studies not included in the EUROSCREEN review reported overdiagnosis estimates of 3 to 50%, with most between 14 to 25%. Although several statistical models of overdiagnosis have been published, these studies have been less acceptable to guideline development groups because of the many assumptions that were used to construct them. Models indicated estimates ranging from 0.4 to 50%.

Table 3. Age-Specific Rates of False-Positive and False-Negative Digital Mammography Results and Recommendations for Additional Imaging and Biopsies From a Single Screening Round in the BCSC[3]

	Age, y					Difference
	40–49	50–59	60–69	70–79	80–89	(P-value)*
Women screened, n	113,770	127,958	94,507	50,204	18,752	
Invasive breast cancer cases, n	349	574	651	427	154	
DCIS cases, n	191	246	208	120	43	
***Outcomes, n per 1,000 women screened* (95% CI)**						
False-positive mammography result	121.2 (105.6 to 138.7)	93.2 (82.8 to 104.7)	80.8 (72.9 to 89.4)	69.6 (62.6 to 77.3)	65.2 (58.8 to 72.2)	<0.001
False-negative mammography result	1.0 (0.9 to 1.2)	1.1 (0.9 to 1.3)	1.2 (0.9 to 1.5)	1.5 (1.1 to 1.9)	1.3 (0.9 to 1.9)	0.32
Additional imaging recommended†	124.9 (109.3 to 142.3)	98.5 (88.0 to 110.1)	88.7 (80.6 to 97.4)	79.0 (71.9 to 86.9)	74.4 (67.4 to 82.2)	<0.001
Biopsy recommended†	16.4 (13.2 to 20.3)	15.9 (12.7 to 19.7)	16.5 (14.3 to 19.1)	17.5 (15.2 to 20.2)	15.6 (13.4 to 18.2)	0.12
Screen-detected invasive cancer	2.2 (1.8 to 2.6)	3.5 (3.1 to 4.0)	5.8 (5.3 to 6.4)	7.2 (6.4 to 8.1)	7.1 (5.9 to 8.5)	<0.001
Screen-detected DCIS	1.6 (1.3 to 1.9)	1.8 (1.5 to 2.2)	2.1 (1.7 to 2.5)	2.3 (1.7 to 3.0)	2.1 (1.5 to 3.0)	0.05

*2-sided P-values and 95% confidence intervals from a logistic regression model that accounts for clustering by radiology facility using generalized estimating equations.
†After positive mammography result.
Abbreviations: CI=confidence interval; DCIS=ductal carcinoma in situ.

Anxiety, Distress, and Other Psychological Responses

Systematic reviews including over 100 descriptive studies of anxiety, distress, and other psychological responses to mammography screening have been published, but provide mixed results.[33-37] In general, women with false-positive results had more anxiety, psychological distress, and breast cancer specific worry after screening compared with those with normal screening results in most studies. Anxiety improved over time for most women, but persisted for over 2 years for some. Two studies reported that women with false-positive results were less likely to return for their next mammogram; two other studies reported no differences; however, when women were given letters tailored to their last screening result they were more likely to re-attend.

Pain during Procedures

A review of 22 descriptive studies indicated that many women experience pain during mammography (1% to 77%), but the proportion of those experiencing pain who do not attend future screening varies (11% to 46%).[38]

Radiation Exposure

Published models calculate the number of deaths due to radiation induced cancer using estimates for digital mammography is between 2 per 100,000 in women age 50 to 59 years screened biennially, and up to 11 per 100,000 in women ages 40 to 59 years screened annually.[39] A new model for the USPSTF reported similar findings.[39]

CONCLUSIONS

Results of trials comparing mammography screening to no screening indicate reduced breast cancer deaths with screening for women ages 50 to 69 years, but not for women in their 40s or age 70 and older. Individual factors that increase risk for breast cancer, such as family history of breast cancer, previous biopsies, increased breast density, and others, have not been evaluated in screening trials. Models indicate that women with some of these factors may benefit from screening beginning in their 40s. Given the reduction in mortality and years of life extended by screening women starting at age 40, it is appropriate to begin offering screening starting at age 40 using shared decision-making involving a discussion of the anticipated benefits and adverse consequences. Given that the benefit-to-harm ratio improves with age, women who have not chosen to initiate mammography in their 40s should be recommended to do so at age 50.

Estimates for women age 70 and older are limited by the low numbers of older women in the trials. Deaths from all causes are not reduced with screening; while advanced breast cancer is reduced for women age 50 and older, but not younger women. False-positive results are common and are higher with annual screening, for younger women, and for women with dense breasts. Although overdiagnosis, anxiety, pain, and radiation exposure may cause harm, their effects on individual women are difficult to estimate and vary widely. No trials provide information regarding optimal screening intervals. Estimates based on models indicate that biennial screening intervals provide the most benefit while minimizing potential harms. No studies have evaluated the effectiveness of shared decision making in determining whether to undergo mammography screening.

REFERENCES

[1]Siu AL, Force USPST. Screening for Breast Cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2016;164(4):279-96. doi: 10.7326/M15-2886. PMID: 26757170.

[2]Nelson HD, Fu R, Cantor A, et al. Effectiveness of breast cancer screening: Systematic review and meta-analysis to update the 2009 U.S. Preventive Services Task Force recommendation. Ann Intern Med. 2016;164(4):244-55. doi: 10.7326/M15-0969. PMID: 26756588.

[3]Mandelblatt JS, Stout NK, Schechter CB, et al. Collaborative modeling of the benefits and harms associated with different U.S. breast cancer screening strategies. Ann Intern Med. 2016;164(4):215-25. doi: 10.7326/M15-1536. PMID: 26756606.

[4]Esserman LJ, Thompson IM, Reid B, et al. Addressing overdiagnosis and overtreatment in cancer: a prescription for change. Lancet Oncol. 2014;15(6):e234-42. doi: 10.1016/s1470-2045(13)70598-9. PMID: 24807866.

[5]Berry DA, Cronin KA, Plevritis SK, et al. Effect of screening and adjuvant therapy on mortality from breast cancer. N Engl J Med. 2005;353(17):1784-92. doi: 10.1056/NEJMoa050518. PMID: 16251534.

[6]Kalager M, Zelen M, Langmark F, et al. Effect of screening mammography on breast-cancer mortality in Norway. N Engl J Med. 2010;363(13):1203-10. doi: 10.1056/NEJMoa1000727. PMID: 20860502.

[7]Nelson H, Cantor A, Humphrey L, et al. Screening for breast sancer: A systematic review to update the 2009 U.S. Preventive Services Task Force recommendation. Evidence Synthesis No. 124. AHRQ Publication No. 14-05201-EF-1. Rockville, MD: Agency for Healthcare Research and Quality: 2016. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breast-cancer-screening1?ds=1&s=Breast%20cancer. Accessed November 30, 2016.

[8]IOM (Institute of Medicine). Clinical Preventive Services for Women: Closing the gaps. Washington DC: National Academies Press; 2011.

[9]U.S. Department of Health and Human Services. Affordable Care Act: About the law. Washington DC: U.S. Department of Health and Human Services; 2015. https://www.hhs.gov/healthcare/about-the-law/index.html#. Accessed October 14 2016.

[10]Melnikow J, Fenton J, Whitlock E, et al. Supplemental screening for breast cancer in women with dense breasts: A systematic review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 126. AHRQ Publication No. 14-05201-EF-3. Rockville, MD: Agency for Healthcare Research and Quality: 2016. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breast-cancer-screening1?ds=1&s=Breast%20cancer. Accessed November 30, 2016.

[11]Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2009;151(10):716-26, w-236. doi: 10.7326/0003-4819-151-10-200911170-00008. PMID: 19920272.

[12]National Cancer Institute. SEER Stat fact sheets: Female breast cancer. Bethesda MD: National Institutes of Health; 2016. http://seer.cancer.gov/statfacts/html/breast.html. Accessed October 14 2016.

[13]Nelson HD, Zakher B, Cantor A, et al. Risk factors for breast cancer for women aged 40 to 49 years: a systematic review and meta-analysis. Ann Intern Med. 2012;156(9):635-48. doi: 10.7326/0003-4819-156-9-201205010-00006. PMID: 22547473.

[14]Coopey SB, Mazzola E, Buckley JM, et al. The role of chemoprevention in modifying the risk of breast cancer in women with atypical breast lesions. Breast Cancer Res Treat. 2012;136(3):627-33. doi: 10.1007/s10549-012-2318-8. PMID: 23117858.

[15]Pharoah PD, Day NE, Duffy S, et al. Family history and the risk of breast cancer: a systematic review and meta-analysis. Int J Cancer. 1997;71(5):800-9. PMID: 9180149.

[16]D'Orsi CJ, Sickles EA, Mendelson EB, et al. ACR BI-RADS® Atlas, Breast imaging reporting and data system. Reston VA: American College of Radiology; 2013.

[17]Sprague BL, Conant EF, Onega T, et al. Variation in mammographic breast density assessments among radiologists in clinical practice: A multicenter observational study. Ann Intern Med. 2016;165(7):457-64. doi: 10.7326/m15-2934. PMID: 27428568.

[18]Sprague BL, Gangnon RE, Burt V, et al. Prevalence of mammographically dense breasts in the United States. J Natl Cancer Inst. 2014;106(10)doi: 10.1093/jnci/dju255. PMID: 25217577.

[19]Kerlikowske K, Cook AJ, Buist DS, et al. Breast cancer risk by breast density, menopause, and postmenopausal hormone therapy use. J Clin Oncol. 2010;28(24):3830-7. doi: 10.1200/jco.2009.26.4770. PMID: 20644098.

[20]Nelson HD, Smith ME, Griffin JC, et al. Use of medications to reduce risk for primary breast cancer: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2013;158(8):604-14. doi: 10.7326/0003-4819-158-8-201304160-00005. PMID: 23588749.

[21]Practice bulletin no. 122: Breast cancer screening. Obstet Gynecol. 2011;118(2 Pt 1):372-82. doi: 10.1097/AOG.0b013e31822c98e5. PMID: 21775869.

[22]American Academy of Family Physicians. Clinical preventive service recommendation: breast cancer. 2016. http://www.aafp.org/patient-care/clinical-recommendations/all/breast-cancer.html. Accessed October 14, 2016.

[23]Oeffinger KC, Fontham ET, Etzioni R, et al. Breast cancer screening for women at average risk: 2015 guideline update from the American Cancer Society. JAMA. 2015;314(15):1599-614. doi: 10.1001/jama.2015.12783. PMID: 26501536.

[24]Lee CH, Dershaw DD, Kopans D, et al. Breast cancer screening with imaging: recommendations from the Society of Breast Imaging and the ACR on the use of mammography, breast MRI, breast ultrasound, and other technologies for the detection of clinically occult breast cancer. J Am Coll Radiol. 2010;7(1):18-27. doi: 10.1016/j.jacr.2009.09.022. PMID: 20129267.

[25]Breast cancer screening and diagnosis. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); 2016. https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf. Accessed Decemember 7, 2016.

[26]Miglioretti DL, Lange J, van den Broek JJ, et al. Radiation-induced breast cancer incidence and mortality from digital mammography screening: A modeling study. Ann Intern Med. 2016;164(4):205-14. doi: 10.7326/m15-1241. PMID: 26756460.

[27]Schonberg MA, Silliman RA, Marcantonio ER. Weighing the benefits and burdens of mammography screening among women age 80 years or older. J Clin Oncol. 2009;27(11):1774-80. doi: 10.1200/jco.2008.19.9877. PMID: 19255318.

[28]Hellquist BN, Duffy SW, Abdsaleh S, et al. Effectiveness of population-based service screening with mammography for women ages 40 to 49 years: evaluation of the Swedish Mammography Screening in Young Women (SCRY) cohort. Cancer. 2011;117(4):714-22. doi: 10.1002/cncr.25650. PMID: 20882563.

[29]Coldman A, Phillips N, Wilson C, et al. Pan-Canadian study of mammography screening and mortality from breast cancer. J Natl Cancer Inst. 2014;106(11)doi: 10.1093/jnci/dju261. PMID: 25274578.

[30]Nelson HD, O'Meara ES, Kerlikowske K, et al. Factors associated with rates of false-positive and false-negative results from digital mammography screening: An analysis of registry data. Ann Intern Med. 2016;164(4):226-35. doi: 10.7326/M15-0971. PMID: 26756902.

[31]Hubbard RA, Kerlikowske K, Flowers CI, et al. Cumulative probability of false-positive recall or biopsy recommendation after 10 years of screening mammography: a cohort study. Ann Intern Med. 2011;155(8):481-92. doi: 10.7326/0003-4819-155-8-201110180-00004. PMID: 22007042.

[32]Kerlikowske K, Zhu W, Hubbard RA, et al. Outcomes of screening mammography by frequency, breast density, and postmenopausal hormone therapy. JAMA Intern Med. 2013;173(9):807-16. doi: 10.1001/jamainternmed.2013.307. PMID: 23552817.

[33]Nelson HD, Pappas M, Cantor A, et al. Harms of breast cancer screening: Systematic review to update the 2009 U.S. Preventive Services Task Force recommendation. Ann Intern Med. 2016;164(4):256-67. doi: 10.7326/M15-0970. PMID: 26756737.

[34]Brett J, Bankhead C, Henderson B, et al. The psychological impact of mammographic screening. A systematic review. Psychooncology. 2005;14(11):917-38. doi: 10.1002/pon.904. PMID: 15786514.

[35]Brewer NT, Salz T, Lillie SE. Systematic review: the long-term effects of false-positive mammograms. Ann Intern Med. 2007;146(7):502-10. PMID: 17404352.

[36]Bond M, Pavey T, Welch K, et al. Psychological consequences of false-positive screening mammograms in the UK. Evid Based Med. 2013;18(2):54-61. doi: 10.1136/eb-2012-100608. PMID: 22859786.

[37]Hafslund B, Nortvedt MW. Mammography screening from the perspective of quality of life: a review of the literature. Scand J Caring Sci. 2009;23(3):539-48. doi: 10.1111/j.1471-6712.2008.00634.x. PMID: 19170959.

[38]Armstrong K, Moye E, Williams S, et al. Screening mammography in women 40 to 49 years of age: a systematic review for the American College of Physicians. Ann Intern Med. 2007 Apr 3;146(7):516-26. PMID: 17404354.

[39]Miglioretti D, Lange J, van Ravesteyn N, et al. Radiation-induced breast cancer and breast cancer death from mammography screening. AHRQ Publication No. 14-05201-EF-5. 2015.

Breastfeeding Services and Supplies

Clinical Recommendations

The Women's Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.

Implementation Considerations

Lactation support services include counseling, education, and breastfeeding equipment and supplies. A lactation care provider should deliver lactation support and provide services across the antenatal, perinatal, and postpartum periods to ensure successful preparation, initiation, and continuation of breastfeeding. Lactation care providers include, but are not limited to, lactation consultants, breastfeeding counselors, certified midwives, certified nurse-midwives, certified professional midwives, nurses, advanced practice providers (e.g., physician assistants and nurse practitioners), and physicians. Breastfeeding equipment and supplies, as agreed upon by the woman and her lactation care provider, include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be based on optimization of breastfeeding, and not predicated on prior failure of a manual pump.

EVIDENCE MAP

Comprehensive lactation support services, including counseling, education, and breastfeeding equipment and supplies.		
Systematic Reviews	**Additional Studies**	**USPSTF[1]**
2016 USPSTF review of 52 studies reported increased rates of any and exclusive breastfeeding at <3 months and at 3-6 months, and exclusive breastfeeding at 6 months for women enrolled in individual-level breastfeeding interventions versus usual care.[2]	None	For pregnant women, new mothers, and their children, the USPSTF recommends providing interventions during pregnancy and after birth to support breastfeeding (Level B; 2016)
A lactation care provider should deliver lactation support and provide services across the antenatal, perinatal, and postpartum periods to ensure successful preparation, initiation, and continuation of breastfeeding.		
Systematic Reviews	**Additional Studies**	**USPSTF[1]**
2016 USPSTF review of studies evaluating the timing of breastfeeding interventions (intervention during only one period [prenatal, perinatal, or postpartum] vs. across multiple periods). Results indicated increased breastfeeding when interventions occurred across multiple periods.	Two good-quality trials of effective breast feeding interventions in the U.S. included 5 in-person visits with a lactation consultant (two during prenatal clinic visits, one in the hospital, and one or two voluntary postpartum home visits).[3] These were supplemented by phone calls and EHR alerts.	For pregnant women, new mothers, and their children, the USPSTF recommends providing interventions during pregnancy and after birth to support breastfeeding (Level B; 2016)
Efficiency of double electric pumps.		
Systematic Reviews	**Additional Studies**	**USPSTF[1]**
Compared to other methods, double electric breast pumps more closely mimic the sucking actions of an infant, result in a greater volume of expressed milk, and come the closest to matching the milk removal efficiency of a healthy infant (85% of milk removed in 15 minutes versus 80% of milk removed in 5 minutes).[4]	None	Not addressed

Abbreviations: EHR=electronic health record; USPSTF=U.S. Preventive Services Task Force

SUMMARY OF EVIDENCE

Introduction

Breastfeeding is the process of feeding infants with human milk from a woman's breast, either directly from the breast or by expressing (pumping) the milk from the breast and bottle-feeding.[5] Breastfeeding counseling and support includes maternity care practices, such as discussions with healthcare professionals about breastfeeding; structured breastfeeding education, such as information and resources provided during the prenatal and intrapartum periods; employee benefits and services, such as designated private space and time for breastfeeding or expressing milk (now included under a provision of the ACA);[6] peer support, such as individual counseling and mother-to-mother support groups; professional support, such as lactation consultations; and marketing initiatives.[7]

Current Recommendations and Coverage of Service

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 previously identified by the Institute of Medicine (IOM) Committee was that comprehensive prenatal and postnatal lactation support, counseling, and supplies were not included.[8] Health insurance plans are now required to provide breastfeeding support, counseling, and equipment for the duration of breastfeeding including the purchase or rental cost of breast pumps (**Table 1**).[9] The IOM recommendation includes an explicit description of a more comprehensive set of services than the U.S. Preventive Services Task Force (USPSTF).

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

IOM Committee[8]	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.
USPSTF[10]	Provide interventions during pregnancy and after birth to support breastfeeding (Level B; 2016). Interventions may include more than one component and be delivered over prenatal, perinatal, and postpartum periods.

Abbreviations: IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

Background

Breastfeeding is associated with several health benefits for infants including reduced risk of acute otitis media, non-specific gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma (young children), obesity, type 1 and 2 diabetes, childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing enterocolitis.[11] Breastfeeding is not recommended in specific situations involving mothers who have been infected with human immunodeficiency virus (HIV) or human T-cell lymphotropic virus type I or type II; who are prescribed cancer chemotherapy agents, taking antiretroviral therapy or drugs, undergoing radiation therapies; using or dependent upon illicit drugs; or have untreated, active tuberculosis.[12]

The Surgeon General's call to action to support breastfeeding identified several barriers to breastfeeding in the United States.[13] These include lack of knowledge, social norms, poor family and social support, embarrassment, lactation problems, employment and child care issues, and lack of access to health services.

The Centers for Disease Control and Prevention (CDC) reported in 2012 that 80.0% of newborn infants started breastfeeding at birth, 51.4% were still breastfeeding at 6 months, and 29.2% at 12 months; 43.3% were exclusively breastfeeding at 3 months and 21.9% exclusively breastfeeding at 6 months.[14] These rates are close to the goals set by Healthy People 2020[15] (**Table 2**).

Breastfeeding rates vary greatly and are higher with increasing maternal age, education, and income, and among mothers who do not receive supplemental nutrition assistance (WIC).[16] Rates differ across racial/ethnic groups, with 83.2% of Asian/Pacific Islanders reporting initiating breastfeeding in 2012, 83.0% of whites, 82.4% of Hispanics, 71.5% of American Indian/Alaska Natives, and 66.4% of blacks. These differences are most apparent in the southern United States, with differences between whites and blacks ranging from 9% in Florida to 32 in Alabama.

Table 2. Rates and Goals of Breastfeeding Practices in the United States

Breastfeeding practice	Prevalence in 2012[14]	Healthy People 2020 goals[15]
Initiation	80.0%	81.9%
At 6 months	51.4%	60.6%
At 12 months	29.2%	34.1%
Exclusively at 3 months	43.3%	46.2%
Exclusively at 6 months	21.9%	25.5%

The American Congress of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Nurse-Midwives (ACNM), and the World Health Organization (WHO) all recommend exclusive breastfeeding for the first 6 months, with continued breastfeeding along with appropriate complementary foods up to age 2 years or beyond. Most groups emphasize breastfeeding through the first year of life and then continuing as long as mutually desired (**Table 3**).

Table 3. Recommendations of Professional Organizations

Organization	Recommendation
American Academy of Family Physicians (AAFP)[17,18]	All babies, with rare exceptions, be breastfed and/or receive expressed human milk exclusively for the first 6 months of life. Breastfeeding should continue with the addition of complementary foods throughout the second half of the first year.
American Congress of Obstetricians and Gynecologists (ACOG)[19]	Exclusive breastfeeding is recommended for the first 6 months of a baby's life. Breastfeeding should continue up to the baby's first birthday as new foods are introduced. Continue breastfeeding after the baby's first birthday for as long as mother and baby would like.
American Academy of Pediatricians (AAP)[20]	Exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant. Medical contraindications to breastfeeding are rare.
American College of Nurse-Midwives (ACNM)[21]	Exclusive breastfeeding for the first 6 months provides complete nutrition for growth and development, and ideally breastfeeding should continue throughout the first year of life.
American College of Nurse-Midwives (ACNM)[21]	Exclusive breastfeeding for the first 6 months provides complete nutrition for growth and development, and ideally breastfeeding should continue throughout the first year of life.
The World Health Organization (WHO)[22]	Exclusive breastfeeding is recommended up to 6 months of age, with continued breastfeeding along with appropriate complementary foods up to 2 years of age or beyond.

Recommendations provide additional guidance on how to promote and support breastfeeding. Several recommendations suggest the adoption of the WHO/The United Nations Children's Emergency Fund (UNICEF) Ten Steps to Successful Breastfeeding (**Table 4**).[23]

Table 4. The 10 Steps to Successful Breastfeeding[23]

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in the skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within one hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.
6. Give 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 pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

UPDATE OF EVIDENCE

Interventions to Support Breastfeeding Initiation and Duration

A systematic review[2,24] was recently published to support the 2016 USPSTF recommendation[1] on breastfeeding. The review is an update of a prior review published in 2008, and includes new studies and re-evaluation of studies included in the prior review.

The review includes 52 studies assessing the effectiveness of breastfeeding support interventions in increasing initiation of breastfeeding and prolonging breastfeeding, either exclusively or with supplementation. The review included only randomized controlled trials (RCTs) for individual-level interventions, and controlled before and after studies and prospective cohort studies for system-level interventions. Studies were conducted in either the prenatal, peripartum, or postpartum phase, or a combination of phases.

Of the 52 studies, 43 provided data about individual level interventions,[3,25-71] while the other nine studies provided data on system level interventions.[72-80] Individual-level interventions include professional support (one-to-one support during hospital stay or outpatient visits, home visits, or telephone support from health professionals); peer support (counseling or social support from peers or lay persons); and formal or structured education (structured education sessions or classes directed at mothers or other family members, typically provided in group sessions). System-level interventions include policies, programs, and staff training (Baby-Friendly Hospital Initiative [BFHI], implementation of a new policy or protocol, or training of health professionals); and other maternity care practices (encouragement of skin-to-skin contact, rooming-in, restricted pacifier use, or distribution of breast pumps).

Individual-Level Interventions

Meta-analyses of trials of individual-level interventions to promote and support breastfeeding reported in the 2016 USPSTF review indicate statistically significantly higher rates of any breastfeeding at less than 3 months (RR 1.07; 95% CI, 1.03 to 1.11; 26 trials) and at 3 to 6 months (RR 1.11; 95% CI, 1.04 to 1.18; 23 trials), but not on initiation of breastfeeding or breastfeeding at 6 months (Table 5).[2] The review also reported statistically significantly higher rates of exclusive breastfeeding at less than 3 months (RR 1.21; 95% CI, 1.11 to 1.33; 22 trials), 3 to 6 months (RR 1.20; 95% CI, 1.05 to 1.38; 18 trials), and at 6 months (RR 1.20; 95% CI, 1.05 to 1.38; 17 trials).

Table 5. Summary of Results of Meta-analysis of Trials of Individual-level Interventions to Promote and Support Breastfeeding[2]

Breastfeeding practice	Time Point (months)	Studies, n	Mothers, n	RR (95% CI)	I^2 (%)
Any	Initiation	14	9,428	1.00 (0.99 to 1.02)	22.8
	<3	26	11,588	1.07 (1.03 to 1.11)	72.0
	3 to <6	23	8,942	1.11 (1.04 to 1.18)	46.5
	6	20	9,715	1.07 (0.98 to 1.16)	57.5
Exclusive	<3	22	8,246	1.21 (1.11 to 1.33)	52.4
	3 to <6	18	7,027	1.20 (1.05 to 1.38)	44.6
	6	17	7,690	1.16 (1.02 to 1.32)	14.3

Number of Individual-level Intervention Sessions. The USPSTF review did not specifically assess the optimal number of sessions required for successful breastfeeding.[2] Results from individual studies are mixed, although higher numbers of professional intervention sessions generally increased breastfeeding rates at less than 3 months, 3 to 6 months, and 6 months. For example, among seven studies of single-session interventions, none showed statistically significant effects on breastfeeding rates at less than 3 months. In comparison, in six studies of 2 to 10 intervention sessions, the intervention was consistently associated with higher rates of breastfeeding, although only three studies reported statistically significant differences. Results were similar for 10 or more intervention sessions, based on 3 studies.

Providing breastfeeding interventions during the prenatal, peri-, and postpartum time points was more effective than interventions provided at one or two time points. Of 10 studies of interventions provided at all three time points, all found higher rates or breastfeeding relative to control at <3, 3 to <6 and 6 month measures, although for three of these studies the risk estimate was not statistically significant.

A best evidence approach that examines the most effective and most relevant studies provides an estimate of the number of intervention visits needed for effective breastfeeding in the United States. Of the eight studies conducted in the U.S.,[3,27,31,48,60,67] only three studies reported statistically significantly increased breastfeeding rates at any of the follow-up time points,[3,27] and one[48] reported rates with borderline statistical significance at one time point (**Table 6**). The Bonuck 2014 studies (two trials reported in one publication) are among the largest studies, and the only U.S. studies with statistically significant results that met criteria for good study quality. Results showed consistently increased rates of breastfeeding at less than 3, 3 to 6, and 6 month follow-up times. Although the interventions in both trials required 20 sessions, only 5 of these sessions were in-person visits with a lactation consultant (two during prenatal clinic visits, one in the hospital, and one or two voluntary postpartum home visits). The prenatal visits averaged 1 hour, hospital visits 40 to 50 minutes, and postpartum

contacts greater than 1 hour. The other sessions included prompts in the EMR at prenatal visits or regular phone calls postpartum. In comparison, the fair-quality Bonuck 2006 trial included 4 intervention sessions, and achieved statistically significant rates at <3 and 3 to 6 months, but not at 6 months follow-up.

Table 6. U.S. Based Studies of Individual-level Interventions to Promote and Support Breastfeeding – Effectiveness According to Number of Sessions[2]

Author, year N; Quality	Number of sessions	Timing of intervention	Intervention type	Risk estimate (RR; 95% CI) Intervention vs. Control
Outcome: any breastfeeding, <3 months				
Bonuck 2014a[3] N=666; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.26 (1.03 to 1.54)
Bonuck 2014b[3] N=275; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.23 (1.08 to 1.40)
Bonuck 2006[27] N=382; *Fair*	4	Pre; Peri; Post	Lactation support	1.32 (1.10 to 1.57)
Pollard 2011[67] N=86; *Good*	4	Peri; Post	Self-monitoring	1.21 (0.89 to 1.64)
Paul 2012[48] N=1154; *Fair*	2	Peri	Home visits	1.09 (1.00 to 1.18)
Hopkinson 2009[60] N=552; *Good*	1	Post	Lactation support	0.99 (0.93 to 1.05)
Outcome: any breastfeeding, 3 to 6 months				
Edwards 2013[31] N=248; *Fair*	23	Pre; Peri; Post	Lactation support	1.88 (0.65 to 1.20)
Bonuck 2014a[3] N=666; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.49 (1.09 to 2.03)
Bonuck 2014b[3] N=275; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.37 (1.07 to 1.73)
Pollard 2011[67] N=86; *Good*	4	Peri; Post	Self-monitoring	1.11 (0.65 to 1.90)
Outcome: any breastfeeding, 6 months				
Bonuck 2014a[3] N=666; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.28 (0.85 to 1.94)
Bonuck 2014b[3] N=275; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.48 (1.01 to 2.17)
Bonuck 2006[27] N=382; *Fair*	4	Pre; Peri; Post	Lactation support	1.34 (0.98 to 1.84)
Pollard 2011[67] N=86; *Good*	4	Peri; Post	Self-monitoring	1.12 (0.62 to 2.03)

Subgroup Differences. Seven trials provided direct comparisons of the effect of the intervention based on characteristics of the mother (age, education, insurance status, country of origin, primary language spoken, delivery type, parity, prior breastfeeding experience, and breastfeeding intentions). Maternal country of origin and language spoken were the only significant findings. Breastfeeding rates were lower among women in the U.S.-born control groups than in the U.S.-born intervention group and all foreign-born participants[28] at 13 and 52 weeks; and Spanish-speaking women at 4, 12, and 26 weeks, but not English-speaking women at 4 weeks.[68]

Adolescents and Young Adults. Four trials[31,44,49,69] were limited to adolescents or young adults. The three U.S. trials reported statistically significant differences between intervention and usual care groups, while the trial conducted in Australia showed no effect.[49] A U.S. trial[81] provided mothers with support by a community doula during the prenatal, peripartum, and postpartum phases. Mothers in the intervention group were more likely to initiate breastfeeding than the usual care group (63.9% vs. 49.6%; p=0.02) and to breastfeed for at least 6 weeks (28.7% vs. 16.8%; p=0.04), but there was no difference in breastfeeding between groups at 16 weeks (8.3% vs. 4.4%). Another U.S. trial[69] of mothers receiving group prenatal education and given electric breast pumps beginning in the second trimester and through postpartum reported higher rates of breastfeeding initiation compared with usual care (79% vs. 63%) and longer median duration of any breastfeeding (177 days vs. 61 days). The third U.S. trial[44] provided mothers with postpartum peer telephone support, and reported statistically significant longer durations of exclusive breastfeeding than those receiving usual care (median 35 days vs. 10 days; p=0.004).

System-Level Interventions

Three good-quality studies[74,79,80] reported the effects of hospital policies or BFHI accreditation on breastfeeding rates. One study found that women with lower education (≤12 years) who delivered at a BFHI accredited hospital had higher rates of exclusive breastfeeding at 4 weeks or more by 4.5 percentage points compared with women who delivered at non-BFHI accredited hospitals (effect estimate 0.045; 95% CI, 0.01 to 0.08; p=0.02).[79] No effects were found in other studies.

Three fair-quality trials[72,73,78] of the effects of maintaining mother and baby contact following delivery reported mixed results with only one trial demonstrating an effect. The trial included women scheduled for cesarean section deliveries who were randomized to either a new protocol for minimizing maternal-infant separation following birth or usual peripartum care (infants were removed immediately from the operating room and transferred to the obstetric recovery room with brief or no physical contact with their mother).[78] Women in the intervention group reported higher rates of breastfeeding at hospital discharge (76.0% vs. 52.0%) and at 4 weeks (72.7% vs. 33.3%) compared with usual care (unadjusted RR 2.18; 95% CI, 1.17 to 4.06). Three good-quality trials[75-77] reported no differences in breastfeeding rates between mothers instructed to delay or restrict pacifier use and those not given these instructions.

Efficiency of Different Breast Pumps

Over 80% of mothers need to express breast milk during the first 4 months postpartum.[82] Breast milk can be expressed by hand or through the use of a breast pump. Breast pumps fall into three general categories: manual, battery-operated, and electric. In addition, breast pumps can be single (expressing milk from one breast at a time) or double (expressing milk from both breasts simultaneously) action pumps. Manual and battery-operated breast pumps tend to be single action while electric pumps can be either single or double action.[83]

Reviews of breast milk expression methods have found little direct evidence on which type of breast pump is ideal, and have concluded that the best method of milk expression is likely dependent on individual factors.[84,85] For example, a recent Cochrane review of breast milk expression methods found few differences between breast pump type and maternal satisfaction, adverse events (including milk contamination and breast pain or damage), or volume of milk expressed.[85] The milk expressed by both hand expression and electric pumps had a higher protein content than that expressed by battery-operated pumps, but there were no differences between pump type and other nutrient levels. Only one study included in the review compared electric and manual pumps and the effect on time spent pumping, finding that woman using an electric breast pump spent 20 minutes less per day pumping milk compared to manual pump users.[86] The studies included in the review were heterogeneous in terms of population (both mothers and babies) and the review ultimately concluded that the best method of breast milk expression may be dependent on individual circumstances.

A more recent review evaluated aspects of different methods of breast milk expression.[4] Using the human infant as the "gold standard" for milk expression, electric breast pumps more closely mimicked the sucking actions of an infant and were more efficient at expressing milk when compared with hand expression. The use of double electric breast pumps, particularly in situations where the breast pump is acting as a replacement for an infant unable to breastfeed, resulted in a greater volume of expressed milk.[4] In addition to volume of breast milk expressed, double electric breast pumps come the closest to matching the milk removal efficiency of a healthy infant (85% of milk removed in 15 minutes versus 80% of milk removed in 5 minutes).[4] The efficiency of milk expression is an important factor in breast pump choice for working mothers who may have limited time to pump or mothers of infants unable to breastfeed (e.g. neonatal intensive care unit infants) who must pump many times a day.

Related to breast pump volume and efficiency, is the mother's level of dependence on milk expression. For women who are completely dependent on a breast pump to regulate their lactation level, the review concluded that hospital-grade electric pumps are the best choice because of their efficiency and convenience.[4]

For mothers unable to breastfeed during the first days postpartum, electric breast pumps are also important in order to avoid subsequent lactation failure, and their use remains important once lactation has been established.[4] For mothers of healthy breastfeeding infants with established lactation, who are partially or minimally dependent on breast pumps, convenience may be the most important factor in pump choice. Electric pumps may be the best choice for these women.

Harms of Interventions to Promote or Support Breastfeeding

Two trials[29,33] reported harms related to breastfeeding. In one trial,[29] mothers in the intervention group expressed feelings of anxiety, decreased confidence, or concerns about confidentiality, while the other trial[33] reported no statistically significant differences between the intervention and usual care groups on the State-Trait Anxiety Inventory at 2 weeks.

Relevant Studies Published Since the USPSTF Draft Systematic Review

Other Reviews

A recent systematic review included observational studies as well as trials of interventions to improve breastfeeding outcomes (initiation of breastfeeding, exclusive breastfeeding, continued breastfeeding, and any breastfeeding) and reported similar pooled results as the USPSTF report (**Table 7**).[87]

Table 7. Meta-analysis of Trials and Observational Studies[87]

Breastfeeding practice	Studies, n	OR (95% CI)	I^2
Initiation	49	1.25 (1.19 to 1.32)	90.6
Exclusive up to 6 months	130	1.44 (1.38 to 1.51)	91.0
Continued past 6 months	18	1.61 (1.17 to 2.20)	92.0
Any breastfeeding	118	1.30 (1.23 to 1.37)	92.1

Abbreviations: CI=confidence interval; OR=odds ratio

Ongoing Studies

Ten randomized controlled trials of interventions to promote or support breastfeeding initiation and prolong breastfeeding are currently in progress.2 Three trials include telephone support; two focus on earlier versus later (usual care) timing of the intervention; one assesses lay person support; one targets low-income mothers; and another targets populations at risk for childhood obesity. Two Cochrane systematic reviews of interventions for promoting and supporting breastfeeding among overweight or obese women[88] or among women with multiple pregnancies[89] are currently in progress.

CONCLUSIONS

Breastfeeding is associated with health benefits, and clinical guidelines encourage women to breastfeed exclusively for 6 months and breastfeed with solid food supplementation up to 1 year. However, multiple barriers discourage breastfeeding including lack of knowledge, inadequate support, lactation problems, constraints of employment, and limited access to appropriate health services and lactation supplies. Randomized controlled trials of individual-level interventions administered by professionals, peers, or lay persons, provided during prenatal, peripartum, or postpartum phases indicate higher rates of breastfeeding initiation and duration than women not receiving interventions. This includes increased rates of any and exclusive breastfeeding at less than 3 months and at 3 to 6 months, and exclusive breastfeeding at 6 months.

Trials evaluating the timing of breastfeeding interventions (intervention during only one period [prenatal, perinatal, or postpartum] versus across multiple periods) indicate increased breastfeeding when interventions occurred across multiple periods. Two good-quality trials of effective breast feeding interventions in the United States included five in-person visits with a lactation consultant (two during prenatal clinic visits, one in the hospital, and one or two voluntary postpartum home visits). These were supplemented by phone calls and alerts in the electronic health record. A review of breast pump methods indicates that double electric breast pumps more closely mimic the sucking actions of an infant, result in a greater volume of expressed milk, and come the closest to matching the milk removal efficiency of a healthy infant.

REFERENCES

[1]U.S. Preventive Services Task Force, Bibbins-Domingo K, Grossman DC, et al. Primary care interventions to support breastfeeding: US Preventive Services Task Force recommendation statement. JAMA. 2016;316(16):1688-93. doi: doi: 10.1001/jama.2016.14697.

[2]Patnode CD, Henninger ML, Senger CA, et al. Primary care interventions to support breastfeeding: updated systematic review for the U.S. Preventive Services Task Force Agency for Healthcare Research and Quality. Rockville MD: 2016.

[3]Bonuck K, Stuebe A, Barnett J, et al. Effect of primary care intervention on breastfeeding duration and intensity. American journal of public health. 2014;104(1)

[4]Meier PP, Patel AL, Hoban R, et al. Which breast pump for which mother: an evidence-based approach to individualizing breast pump technology. J Perinatol. 2016;36(7):493-9. doi: 10.1038/jp.2016.14. PMID: 26914013.

[5]National Institute of Child Health and Human Development. Breastfeeding and breast milk: condition information. 2013. https://www.nichd.nih.gov/health/topics/breastfeeding/conditioninfo/Pages/default.aspx. Accessed May 12, 2016.

[6]Raju TNK. Reasonable break time for nursing mothers: a provision enacted through the Affordable Care Act. Pediatrics. 2014;134(3):423-4. doi: 10.1542/peds.2014-0762.

[7]Shealy KR, Li R, Benton-Davis S, et al. The CDC guide to breastfeeding interventions. Atlanta: U.S. Department of Health and Human Services, Center for Disease Control and Prevention; 2005.

[8]IOM (institute of Medicine). Clinical preventive services for women: closing the gaps. Washington, DC: National Academies Press; 2011.

[9]Healthcare.gov. Breastfeeding benefits. Baltimore, MD: USA.gov. https://www.healthcare.gov/coverage/breast-feeding-benefits/. Accessed May 12, 2016.

[10]U.S. Preventive Services Task Force. Primary care interventions to promote breastfeeding: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2008;149(8):560-4. PMID: 18936503.

[11]Ip S, Chung M, Raman G, et al. Breastfeeding and maternal and infant health outcomes in developed countries. Evid Rep Technol Assess (Full Rep). 2007;(153):1-186. PMID: 17764214.

[12]Centers for Disease Control and Prevention. When should a mother avoid breastfeeding? Atlanta, GA: U.S. Department of Health & Human Services; 2015. http://www.cdc.gov/breastfeeding/disease/index.htm. Accessed May 12, 2016.

[13]Office of the Surgeon General (US), Centers for Disease Control and Prevention (US), Office on Women's Health (US). The Surgeon General's call to action to support breastfeeding. Rockville, MD: Office of the Surgeon General (US); 2011.

[14]Centers for Disease Control and Prevention. National Immunization Survey (NIS). Atlanta, GA: U.S. Department of Health and Human Services; 2015. http://www.cdc.gov/breastfeeding/data/nis_data/index.htm. Accessed May 12, 2016.

[15]Office of Disease Prevention and Health Promotion. Maternal, infant, and child health. Washington, DC: U.S. Department of Health and Human Services; 2014. https://www.healthypeople.gov/2020/topics-objectives/topic/maternal-infant-and-child-health/objectives. Accessed May 12, 2016.

[16]Centers for Disease Control and Prevention. Racial and ethnic differences in breastfeeding initiation and duration, by state --- National Immunization Survey, United States, 2004--2008. Atlanta, GA: USA.gov; 2010. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5911a2.htm#tab1. Accessed May 12, 2016.

[17]American Academy of Family Physicians. Breastfeeding (Policy Statement). 2016. http://www.aafp.org/about/policies/all/breastfeeding.html. Accessed May 12, 2016.

[18]American Academy of Family Physicians. Breastfeeding, family physicians supporting (Position Paper). 2014. http://www.aafp.org/about/policies/all/breastfeeding-support.html. Accessed May 12, 2016.

[19]The American Congress of Obstetricians and Gynecologists. Optimizing support for breastfeeding as part of obstetric practice. Washington DC; 2016. http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Optimizing-Support-for-Breastfeeding-as-Part-of-Obstetric-Practice. Accessed May 12, 2016.

[20]Johnston M, Landers S, Noble L, et al. Breastfeeding and the use of human milk. Pediatrics. 2012;129(3):e827-41. doi: 10.1542/peds.2011-3552. PMID: 22371471.

[21]American College of Nurse-Midwives. Position statement: breastfeeding. 2011. http://www.midwife.org/ACNM/files/ACNMLibraryData/UPLOADFILENAME/000000000248/Breastfeeding%20statement%20May%202011.pdf. Accessed May 14, 2016.

[22]World Health Organization. Breastfeeding. 2016. http://www.who.int/topics/breastfeeding/en/. Accessed May 12, 2016.

[23]Baby-Friendly USA. The Ten Steps to Successful Breastfeeding. 2012. http://www.babyfriendlyusa.org/about-us/baby-friendly-hospital-initiative/the-ten-steps. Accessed May 12, 2016.

[24]USPSTF. Primary care interventions to support breastfeeding: U.S. Preventive Services Task Force recommendation statement. JAMA. 2016;316(16):1688-93. doi: 10.1001/jama.2016.14697.

[25]Abbass-Dick J, Stern SB, Nelson LE, et al. Coparenting breastfeeding support and exclusive breastfeeding: a randomized controlled trial. Pediatrics. 2015;135(1):102-10. doi: 10.1542/peds.2014-1416. PMID: 25452653.

[26]Anderson AK, Damio G, Young S, et al. A randomized trial assessing the efficacy of peer counseling on exclusive breastfeeding in a predominantly Latina low-income community. Arch Pediatr Adolesc Med. 2005;159(9):836-41. doi: 10.1001/archpedi.159.9.836. PMID: 16143742.

[27]Bonuck KA, Freeman K, Trombley M. Randomized controlled trial of a prenatal and postnatal lactation consultant intervention on infant health care use. Arch Pediatr Adolesc Med. 2006;160(9):953-60. doi: 10.1001/archpedi.160.9.953. PMID: 16953019.

[28]Bonuck KA, Trombley M, Freeman K, et al. Randomized, controlled trial of a prenatal and postnatal lactation consultant intervention on duration and intensity of breastfeeding up to 12 months. Pediatrics. 2005;116(6):1413-26 doi: 10.1542/peds.2005-0435. PMID: 16322166.

[29]Dennis CL, Hodnett E, Gallop R, et al. The effect of peer support on breast-feeding duration among primiparous women: a randomized controlled trial. CMAJ. 2002;166(1):21-8. PMID: 11800243.

[30]Di Napoli A, Di Lallo D, Fortes C, et al. Home breastfeeding support by health professionals: findings of a randomized controlled trial in a population of Italian women. Acta Paediatr. 2004;93(8):1108-14. PMID: 15456204.

[31]Edwards RC, Thullen MJ, Korfmacher J, et al. Breastfeeding and complementary food: Randomized trial of community doula home visiting. Pediatrics. 2013;132(SUPPL.2):S160-S6.

[32]Forster D, McLachlan H, Lumley J, et al. Two mid-pregnancy interventions to increase the initiation and duration of breastfeeding: a randomized controlled trial. Birth. 2004;31(3):176-82. doi: 10.1111/j.0730-7659.2004.00302.x. PMID: 15330879.

[33]Gagnon AJ, Dougherty G, Jimenez V, et al. Randomized trial of postpartum care after hospital discharge. Pediatrics. 2002;109(6):1074-80. PMID: 12042545.

[34]Gijsbers B, Mesters I, Knottnerus JA, et al. The success of an educational program to promote exclusive breastfeeding for 6 months in families with a history of asthma: A randomized controlled trial. Pediatr Asthma Allergy Immunol. 2006;19(4):214-22. doi: 10.1089/pai.2006.19.214.

[35]Graffy J, Taylor J, Williams A, et al. Randomised controlled trial of support from volunteer counsellors for mothers considering breast feeding. BMJ. 2004;328(7430):26. doi: 10.1136/bmj.328.7430.26. PMID: 14703543.

[36]Henderson A, Stamp G, Pincombe J. Postpartum positioning and attachment education for increasing breastfeeding: a randomized trial. Birth. 2001;28(4):236-42. PMID: 11903211.

[37]Howell EA, Balbierz A, Wang J, et al. Reducing postpartum depressive symptoms among black and Latina mothers: a randomized controlled trial. Obstet Gynecol. 2012;119(5):942-9. doi: 10.1097/AOG.0b013e318250ba48. PMID: 22488220.

[38]Jolly K, Ingram L, Freemantle N, et al. Effect of a peer support service on breast-feeding continuation in the UK: a randomised controlled trial. Midwifery. 2012;28(6):740-5. doi: 10.1016/j.midw.2011.08.005. PMID: 21944571.

[39]Kools EJ, Thijs C, Kester AD, et al. A breast-feeding promotion and support program a randomized trial in The Netherlands. Prev Med. 2005;40(1):60-70. doi: 10.1016/j.ypmed.2004.05.013. PMID: 15530582.

[40]Labarere J, Bellin V, Fourny M, et al. Assessment of a structured in-hospital educational intervention addressing breastfeeding: a prospective randomised open trial. BJOG. 2003;110(9):847-52. PMID: 14511968.

[41]Labarere J, Gelbert-Baudino N, Ayral AS, et al. Efficacy of breastfeeding support provided by trained clinicians during an early, routine, preventive visit: a prospective, randomized, open trial of 226 mother-infant pairs. Pediatrics. 2005;115(2):e139-46. doi: 10.1542/peds.2004-1362. PMID: 15687421.

[42]Lavender T, Baker L, Smyth R, et al. Breastfeeding expectations versus reality: a cluster randomised controlled trial. BJOG. 2005;112(8):1047-53. doi: 10.1111/j.1471-0528.2005.00644.x. PMID: 16045516.

[43]Mattar CN, Chong YS, Chan YS, et al. Simple antenatal preparation to improve breastfeeding practice: a randomized controlled trial. Obstet Gynecol. 2007;109(1):73-80. doi: 10.1097/01.aog.0000249613.15466.26. PMID: 17197590.

[44]Meglio GD, McDermott MP, Klein JD. A randomized controlled trial of telephone peer support's influence on breastfeeding duration in adolescent mothers. Breastfeed Med. 2010;5(1):41-7. doi: 10.1089/bfm.2009.0016. PMID: 20043705.

[45]Muirhead PE, Butcher G, Rankin J, et al. The effect of a programme of organised and supervised peer support on the initiation and duration of breastfeeding: a randomised trial. Br J Gen Pract. 2006;56(524):191-7. PMID: 16536959.

[46]Noel-Weiss J, Bassett V, Cragg B. Developing a prenatal breastfeeding workshop to support maternal breastfeeding self-efficacy. J Obstet Gynecol Neonatal Nurs. 2006;35(3):349-57. doi: 10.1111/j.1552-6909.2006.00053.x. PMID: 16700684.

[47]Noel-Weiss J, Rupp A, Cragg B, et al. Randomized controlled trial to determine effects of prenatal breastfeeding workshop on maternal breastfeeding self-efficacy and breastfeeding duration. J Obstet Gynecol Neonatal Nurs. 2006;35(5):616-24. doi: 10.1111/j.1552-6909.2006.00077.x. PMID: 16958717.

[48]Paul IM, Beiler JS, Schaefer EW, et al. A randomized trial of single home nursing visits vs office-based care after nursery/maternity discharge: the Nurses for Infants Through Teaching and Assessment After the Nursery (NITTANY) Study. Arch Pediatr Adolesc Med. 2012;166(3):263-70. doi: 10.1001/archpediatrics.2011.198. PMID: 22064874.

[49]Quinlivan JA, Box H, Evans SF. Postnatal home visits in teenage mothers: a randomised controlled trial. Lancet. 2003;361(9361):893-900. doi: 10.1016/s0140-6736(03)12770-5. PMID: 12648967.

[50]Stockdale J, Sinclair M, Kernohan WG, et al. Feasibility study to test designer breastfeeding™: A randomised controlled trial. Evidence Based Midwifery. 2008;6(3):76-82.

[51]Su LL, Chong YS, Chan YH, et al. Antenatal education and postnatal support strategies for improving rates of exclusive breast feeding: randomised controlled trial. BMJ. 2007;335(7620):596. doi: 10.1136/bmj.39279.656343.55. PMID: 17670909.

[52]Wallace LM, Dunn OM, Alder EM, et al. A randomised-controlled trial in England of a postnatal midwifery intervention on breast-feeding duration. Midwifery. 2006;22(3):262-73. doi: 10.1016/j.midw.2005.06.004. PMID: 16380197.

[53]Wen LM, Baur LA, Rissel C, et al. Early intervention of multiple home visits to prevent childhood obesity in a disadvantaged population: a home-based randomised controlled trial (Healthy Beginnings Trial). BMC Public Health. 2007;7:76. doi: 10.1186/1471-2458-7-76. PMID: 17490492.

[54]Wong KL, Fong DY, Lee IL, et al. Antenatal education to increase exclusive breastfeeding: a randomized controlled trial. Obstet Gynecol. 2014;124(5):961-8. doi: 10.1097/a0g.0000000000000481. PMID: 25437725.

[55]Bunik M, Shobe P, O'Connor ME, et al. Are 2 weeks of daily breastfeeding support insufficient to overcome the influences of formula? Academic pediatrics. 2010;10(1):21-8. doi: http://dx.doi.org/10.1016/j.acap.2009.09.014. PMID: 20129478.

[56]Carlsen EM, Kyhnaeb A, Renault KM, et al. Telephone-based support prolongs breastfeeding duration in obese women: a randomized trial. American Journal of Clinical Nutrition. 2013;98(5):1226-32. doi: http://dx.doi.org/10.3945/ajcn.113.059600. PMID: 24004897.

[57]Chapman DJ, Morel K, Bermudez-Millan A, et al. Breastfeeding education and support trial for overweight and obese women: a randomized trial. Pediatrics. 2013;131(1):e162-70. doi: http://dx.doi.org/10.1542/peds.2012-0688. PMID: 23209111.

[58]Elliott-Rudder M, Pilotto L, McIntyre E, et al. Motivational interviewing improves exclusive breastfeeding in an Australian randomised controlled trial. Acta Paediatrica. 2014;103(1):e11-6. doi: http://dx.doi.org/10.1111/apa.12434. PMID: 24117857.

[59]Fu IC, Fong DY, Heys M, et al. Professional breastfeeding support for first-time mothers: a multicentre cluster randomised controlled trial. BJOG. 2014;121(13):1673-83. doi: http://dx.doi.org/10.1111/1471-0528.12884. PMID: 24861802.

[60]Hopkinson J, Konefal Gallagher M. Assignment to a hospital-based breastfeeding clinic and exclusive breastfeeding among immigrant Hispanic mothers: a randomized, controlled trial. Journal of Human Lactation. 2009;25(3):287-96. doi: http://dx.doi.org/10.1177/0890334409335482. PMID: 19436060.

[61]Howell EA, Bodnar-Deren S, Balbierz A, et al. An intervention to extend breastfeeding among black and Latina mothers after delivery. American Journal of Obstetrics & Gynecology. 2014;210(3):239.e1-5. doi: http://dx.doi.org/10.1016/j.ajog.2013.11.028. PMID: 24262719.

[62]Kronborg H, Maimburg RD, Vaeth M. Antenatal training to improve breast feeding: a randomised trial. Midwifery. 2012;28(6):784-90. doi: http://dx.doi.org/10.1016/j.midw.2011.08.016. PMID: 22018394.

[63]MacArthur C, Jolly K, Ingram L, et al. Antenatal peer support workers and initiation of breast feeding: cluster randomised controlled trial. BMJ. 2009;338:b131. doi: http://dx.doi.org/10.1136/bmj.b131. PMID: 19181730.

[64]McDonald SJ, Henderson JJ, Faulkner S, et al. Effect of an extended midwifery postnatal support programme on the duration of breast feeding: a randomised controlled trial. Midwifery. 2010;26(1):88-100. doi: http://dx.doi.org/10.1016/j.midw.2008.03.001. PMID: 18486287.

[65]McQueen KA, Dennis CL, Stremler R, et al. A pilot randomized controlled trial of a breastfeeding self-efficacy intervention with primiparous mothers. J Obstet Gynecol Neonatal Nurs. 2011;40(1):35-46. doi: http://dx.doi.org/10.1111/j.1552-6909.2010.01210.x. PMID: 21244493.

[66]Mesters I, Gijsbers B, Bartholomew K, et al. Social cognitive changes resulting from an effective breastfeeding education program. Breastfeed Med. 2013;8(1):23-30. doi: http://dx.doi.org/10.1089/bfm.2012.0011. PMID: 23186384.

[67]Pollard DL. Impact of a feeding log on breastfeeding duration and exclusivity. Maternal & Child Health Journal. 2011;15(3):395-400. doi: http://dx.doi.org/10.1007/s10995-010-0583-x. PMID: 20177755.

[68]Reeder JA, Joyce T, Sibley K, et al. Telephone peer counseling of breastfeeding among WIC participants: a randomized controlled trial. Pediatrics. 2014;134(3):e700-9. doi: http://dx.doi.org/10.1542/peds.2013-4146. PMID: 25092936.

[69]Wambach KA, Aaronson L, Breedlove G, et al. A randomized controlled trial of breastfeeding support and education for adolescent mothers. Western Journal of Nursing Research. 2011;33(4):486-505. doi: http://dx.doi.org/10.1177/0193945910380408. PMID: 20876551.

[70]Wen LM, Baur LA, Simpson JM, et al. Effectiveness of an early intervention on infant feeding practices and "tummy time": a randomized controlled trial. Archives of Pediatrics & Adolescent Medicine. 2011;165(8):701-7. doi: http://dx.doi.org/10.1001/archpediatrics.2011.115. PMID: 21810633.

[71]Kellams AL, Gurka KK, Hornsby PP, et al. The Impact of a Prenatal Education Video on Rates of Breastfeeding Initiation and Exclusivity during the Newborn Hospital Stay in a Low-income Population. J Hum Lact. 2016;32(1):152-9. doi: 10.1177/0890334415599402. PMID: 26289058.

[72]Carfoot S, Williamson P, Dickson R. A randomised controlled trial in the north of England examining the effects of skin-to-skin care on breast feeding. Midwifery. 2005;21(1):71-9. doi: 10.1016/j.midw.2004.09.002. PMID: 15740818.

[73]Gouchon S, Gregori D, Picotto A, et al. Skin-to-skin contact after cesarean delivery: an experimental study. Nurs Res. 2010;59(2):78-84. doi: 10.1097/NNR.0b013e3181d1a8bc. PMID: 20179657.

[74]Hawkins SS, Stern AD, Baum CF, et al. Evaluating the impact of the Baby-Friendly Hospital Initiative on breast-feeding rates: a multi-state analysis. Public Health Nutr. 2015;18(2):189-97. doi: 10.1017/s1368980014000238. PMID: 24625787.

[75]Howard CR, Howard FM, Lanphear B, et al. Randomized clinical trial of pacifier use and bottle-feeding or cupfeeding and their effect on breastfeeding. Pediatrics. 2003;111(3):511-8. PMID: 12612229.

[76]Jenik AG, Vain NE, Gorestein AN, et al. Does the recommendation to use a pacifier influence the prevalence of breastfeeding? J Pediatr. 2009;155(3):350-4.e1. doi: 10.1016/j.jpeds.2009.03.038. PMID: 19464025.

[77]Kramer MS, Barr RG, Dagenais S, et al. Pacifier use, early weaning, and cry/fuss behavior: a randomized controlled trial. JAMA. 2001;286(3):322-6. PMID: 11466098.

[78]Nolan A, Lawrence C. A pilot study of a nursing intervention protocol to minimize maternal-infant separation after Cesarean birth. J Obstet Gynecol Neonatal Nurs. 2009;38(4):430-42. doi: 10.1111/j.1552-6909.2009.01039.x. PMID: 19614878.

[79]Hawkins SS, Stern AD, Baum CF, et al. Compliance with the Baby-Friendly Hospital Initiative and impact on breastfeeding rates. Archives of Disease in Childhood Fetal & Neonatal Edition. 2014;99(2):F138-43. doi: http://dx.doi.org/10.1136/archdischild-2013-304842. PMID: 24277661.

[80]Hoddinott P, Britten J, Prescott GJ, et al. Effectiveness of policy to provide breastfeeding groups (BIG) for pregnant and breastfeeding mothers in primary care: cluster randomised controlled trial. BMJ. 2009;338:a3026. doi: http://dx.doi.org/10.1136/bmj.a3026. PMID: 19181729.

[81]Edwards RA, Bickmore T, Jenkins L, et al. Use of an interactive computer agent to support breastfeeding. Maternal & Child Health Journal. 2013;17(10):1961-8. doi: http://dx.doi.org/10.1007/s10995-013-1222-0. PMID: 23329167.

[82]Eglash A, Malloy ML. Breastmilk expression and breast pump technology. Clinical Obstetrics & Gynecology. 2015;58(4):855-67. doi: http://dx.doi.org/10.1097/GRF.0000000000000141. PMID: 26398296.

[83]U.S. Food and Drug Administration. Breast pumps. Silver Spring MD: U.S. Food and Drug Administration; 2016. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BreastPumps/ucm061584.htm. Accessed October 19 2016.

[84]Flaherman VJ, Lee HC. "Breastfeeding" by feeding expressed mother's milk. Pediatr Clin North Am. 2013;60(1):227-46. doi: 10.1016/j.pcl.2012.10.003. PMID: 23178067.

[85]Becker GE, Smith HA, Cooney F. Methods of milk expression for lactating women. Cochrane Database of Systematic Reviews. 2015;2:CD006170. doi: http://dx.doi.org/10.1002/14651858.CD006170.pub4. PMID: 25722103.

[86]Fewtrell MS, Lucas P, Collier S, et al. Randomized trial comparing the efficacy of a novel manual breast pump with a standard electric breast pump in mothers who delivered preterm infants. Pediatrics. 2001;107(6):1291-7. PMID: 11389245.

[87]Sinha B, Chowdhury R, Sankar MJ, et al. Interventions to improve breastfeeding outcomes: a systematic review and meta-analysis. Acta Paediatrica. 2015;104(467):114-34. doi: http://dx.doi.org/10.1111/apa.13127. PMID: 26183031.

[88]Soltani H, Fair FJ. Interventions for supporting the initiation and continuation of breastfeeding among women who are overweight or obese. Cochrane Database of Systematic Reviews. 2016(2) PMID: 00075320-100000000-10499.

[89]Whitford HM, Wallis SK, Dowswell T, et al. Breastfeeding education and support for women with multiple pregnancies. Cochrane Database of Systematic Reviews. 2015(12) PMID: 00075320-100000000-10410.

Screening for Cervical Cancer

Clinical Recommendations

The Women's Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Co-testing with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service, cervical cancer screening for average-risk women aged 21 to 65 years. For average-risk women aged 30 to 65 years, informed shared decision-making between the patient and her clinician regarding the preferred screening strategy is recommended. Women who are at average risk should not be screened more than once every 3 years.

Women who have received the human papillomavirus vaccine should be screened according to the same guidelines as women who have not received the vaccine.

These recommendations are for routine screening in average-risk women and do not apply to women infected with human immunodeficiency virus, women who are immunocompromised because of another etiology (such as those who have received solid organ transplantation), women exposed to diethylstilbestrol in utero, or women treated for cervical intraepithelial neoplasia grade 2 or higher within the past 20 years. Screening strategies for high-risk women are outside the scope of these recommendations.

Cervical cancer screening is not recommended for women younger than 21 years or those older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer. Adequate prior negative screening is defined as documentation (or a reliable patient report) of three consecutive negative cytology results or two consecutive negative co-test results within the previous 10 years with the most recent test within the past 5 years. Cervical cancer screening is also not recommended for women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesions (e.g., cervical intraepithelial neoplasia grade 2 or grade 3 or cervical cancer within the past 20 years).

EVIDENCE MAP

- Cervical cancer screening for average-risk women aged 21 to 65 years.
- For women aged 21 to 29 years, screening using cervical cytology (Pap test) every 3 years.
- Co-testing with cytology and human papillomavirus testing is not recommended for women younger than 30 years.

Systematic Reviews	Additional Studies	USPSTF[1]
Cytology alone in younger women supported by: • USPSTF review of epidemiologic and observational study data.[1] • USPSTF modeling study.[2]	Co-testing not recommended in younger women supported by: • One diagnostic accuracy study.[3] • One RCT.[4] • USPSTF modeling study.[2]	USPSTF[5]: The USPSTF recommends screening for cervical cancer in women age 21-65 years with cytology (Pap smear) every 3 years or, for women age 30-65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years.

Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years.

Systematic Reviews	Additional Studies	USPSTF[1]
Similar or greater detection of CIN2/3+ and cancer for co-testing versus cytology supported by: • 2011 USPSTF review of 4 RCTs.[1,6] Updated meta-analysis of 4 RCTs from • 2014 USPSTF review.[7]	• Similar or greater detection of CIN2/3+ and cancer for co-testing versus cytology supported by: USPSTF modeling study;[2] 4 RCTs updated from USPSTF review;8 1 observational study.[9] • Improved detection of adenocarcinoma using co-testing versus cytology demonstrated in 4 RCTs updated from USPSTF review.[8] • Negative HPV test is more predictive of normal results in future screening rounds than negative cytology, supporting extended screening intervals with co-testing, supported by follow-up of 1 RCT[10] and 1 observational study.[9,11]	USPSTF: see above

Evidence map continued on page 61.

Cervical cancer screening is not recommended for women younger than 21 years or those older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer.		
Systematic Reviews	**Additional Studies**	**USPSTF[1]**
Start and stop ages for cervical cancer screening: • 2011 USPSTF review based on SEER and observational study data[1] supports starting age. • Stop age was not systematically reviewed in 2012 USPSTF review, but recommendation was based on 12 observational[12-22] studies from 2002 USPSTF review 23 and epidemiologic and observational study data identified during the 2012 USPSTF review that supported prior findings. • Screening in women with a hysterectomy: USPSTF recommendation was based on 2 observational studies[24,25] from the 2002 USPSTF review.[23]	• USPSTF modeling study.[2] • 4 observational studies.[11,26-28]	USPSTF: see page 70.
Women who have received the HPV vaccine should be screened according to the same guidelines as women who have not been vaccinated.		
Systematic Reviews	**Additional Studies**	**USPSTF[1]**
None	None	USPSTF[5]: Clinical considerations note that current trials do not provide data on long-term efficacy; therefore, the possibility that vaccination might reduce the need for screening with cytology alone or in combination with HPV testing is not established. Given these uncertainties, women who have been vaccinated should continue to be screened.

Abbreviations: ACA=Affordable Care Act, HPV=human papilloma virus, USPSTF=U.S. Preventive Services Task Force.

SUMMARY OF EVIDENCE

Introduction

Invasive cervical neoplasia is caused by persistent infection with high-risk strains of human papilloma virus (HPV) that lead to the development of squamous cell carcinoma and adenocarcinoma of the uterine cervix.[29,30] HPV is the most common sexually transmitted infection in the United States with approximately 79 million currently infected individuals.[31] Each year, an estimated 14 million individuals are newly infected.[31] HPV infections are typically self-limited,[32] asymptomatic, and not diagnosed.[33] The 10-year risk for development of cancer precursor lesions ranges from 13% to 17%,[34] while the risk of progression from precancerous lesions to invasive disease is 31% over 30 years.[35]

Periodic screening of sexually active women with cytology-based techniques has long been the standard of care for early cancer detection. In recent years, the introduction of testing for high-risk HPV DNA has allowed the detection of viral strains most commonly associated with the development of cancer even when cytology results are negative.[9,30,34,36,37]

Current Recommendations and Coverage of Service

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) Committee was the absence of coverage for co-testing with cytology and high-risk HPV DNA testing among women age 30 years and older (**Table 1**). In 2012, the U.S. Preventive Services Task Force (USPSTF) issued new recommendations for women age 30 to 65 years that included screening with a combination of cytology and HPV testing every 5 years. The USPSTF is currently updating this recommendation including an evaluation of the effectiveness and harms of HPV testing with or without cytology as a primary screening strategy.

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

IOM Committee[38]	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.
USPSTF[5]	Screening for cervical cancer in women age 21 to 65 years with cytology every 3 years or, for women age 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and HPV testing every 5 years (Level A 2012). Recommends against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women age <30 years; screening women age <21 years; screening women age >65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer; screening women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer (Level D 2012). Clinical considerations: Current trials do not provide data on long-term efficacy; therefore, the possibility that vaccination might reduce the need for screening with cytology alone or in combination with HPV testing is not established. Given these uncertainties, women who have been vaccinated should continue to be screened

Abbreviations: CIN=cervical intraepithelial neoplasia; HPV=human papilloma virus; IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

Background

In 2012, cervical cancer was diagnosed in 12,042 women and caused 4,074 deaths in the United States.[39] Cervical cancer diagnosis was most frequent in women age 35 to 44 years (median 49 years) and deaths were most common among those age 45 to 54 years (median 57 years).[40] Although mortality from cervical cancer has generally declined since the introduction of screening programs in the 1950s, women with poor access to care and women of color continue to share a disproportionate burden of incidence and mortality. Among new cervical cancer cases in 2012, black and Hispanic[31] women experienced incidence rates of 9.0 and 9.5 per 100,000, respectively, compared with 7.1 per 100,000 among white women;[39] death rates were 3.7 and 2.7 versus 2.1 per 100,000.[39]

Although deaths from cervical cancer are less common than deaths from other types of cancer,[41] they are mostly preventable through primary prevention, screening, and treatment.[42] In 2010, the overall cervical cancer screening rate among American women was 83%,[43] although rates were lower among Asians (75%), American Indians/Alaska Natives (79%), and Hispanics (79%), as well as women without access to health care (64%). More than half of cervical cancer cases occur among women who had no cytology testing during the months preceding diagnosis, with the remainder attributed to failure of detection and follow-up.[44,45] Healthy People 2020 contains objectives for increasing the proportion of women in the United States age 21 to 65 years who receive cervical cancer screening by 10% so that 93% of women are screened.[46]

Traditionally, screening used cytology-based methods alone including either conventional dry slide or liquid-based platforms. In the United States, liquid-based cytology accounts for more than 90% of cytology testing,[47] offering improved sample quality compared with conventional cytology, though test characteristics are generally comparable.[6,48-52] The most notable advantage of liquid-based cytology is that it allows both cytology and high-risk HPV testing on a single patient specimen. There are currently two U.S. Food and Drug Administration (FDA) approved liquid-based platforms for cervical cancer screening: the SurePath Pap and the ThinPrep Pap Test.

Co-testing for high-risk HPV types is an option for women between ages 30 and 65 years who wish to extend their screening interval from 3 to 5 years. FDA-approved HPV tests include the Digene HC2, the Cervista, the cobas 4800 HPV test,[53] and the APTIMA HPV Assay. In 2012, a survey by the College of American Pathologists found that 60% of U.S. laboratories were performing co-testing.[54] In 2014, the FDA approved the cobas HPV test to be used as a primary screening tool for cervical cancer in addition to its use in co-testing with cytology.[55,56] This decision was based on findings from a large U.S. study[57] that found the HPV test to have equivalent or superior effectiveness compared with cytology for primary cervical cancer screening.[56]

The HPV vaccine is an effective method for preventing infection with HPV. Two HPV vaccines are licensed in the United States.[53] HPV4 is a quadrivalent vaccine (HPV 16, 18, 6, 11) licensed for use in males and females and HPV2 (HPV 16, 18) is a bivalent vaccine licensed for use in females. These vaccines are composed of virus-like particles prepared from a capsid protein of targeted HPV strains. Vaccines are prophylactic and do not have any therapeutic effect on HPV-related disease or disease progression in those already infected with HPV. The HPV

vaccination is covered in the ACA under a separate recommendation for immunizations.[58] Currently, practice standards recommend screening women who have had an HPV vaccine under the same guidelines as women who have not been vaccinated.

Current practice recommendations from professional organizations are similar to the USPSTF and advise cytology alone or co-testing (**Table 2**).

Table 2. Recommendations of Professional Organization

American College of Obstetricians and Gynecologists (ACOG) 2012,[59] American Cancer Society (ACS) 2012, American Society for Clinical Pathology (ASCP) 2012, and American Society for Colposcopy and Cervical Pathology (ASCCP) 2012[60], American College of Physicians (ACP), National Comprehensive Cancer Network (NCCN)[61,62]	
Start and Stop	Age 21 to 65 years of age*
Cytology	Age 21 to 65 years every 3 years
Cytology and HPV test together	Age 30 to 65 years every 5 years is preferred (ACP does not specify preference); HPV testing not recommended in women age < 30 years
Post-hysterectomy	Recommend against screening in women with a hysterectomy for benign disease that included removal of the cervix
HPV vaccinated women	Follow age-specific recommendations (same as unvaccinated women)

*Discontinuation of screening is based on an adequate screening history in women who are not otherwise at high risk for cervical cancer. Adequate screening history is defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years before cessation of screening, with the most recent test occurring within 5 years.
Abbreviations: HPV=human papilloma virus

Expert representatives from multiple advisory groups, including ACOG, ACS, ASCCP, and the ASCP recently convened to provide interim guidance on the use of HPV testing alone for cervical cancer screening. Based on a study that demonstrated equivalent or superior performance of primary HPV screening for detecting lesions compared with cytology alone, the interim advisory panel suggested that HPV alone could be considered as an alternative to current U.S.-based cervical cancer screening methods.[63] However, this option has not been incorporated into current recommendations.

UPDATE OF EVIDENCE

The 2012 USPSTF recommendation was based on a systematic review of the evidence of liquid-based cytology and high-risk HPV screening. This review included studies meeting criteria for fair and good-quality and focused on routine screening in populations in developed countries.[1,6] In addition, the USPSTF commissioned a decision analysis modeling study to evaluate optimal ages at which to begin and end screening, optimal screening intervals, and benefits and harms of different screening strategies.

Ages to Start and Stop Screening; Screening Intervals

USPSTF systematic review and decision analysis

Data are lacking regarding the effectiveness of screening at specific ages and intervals. Indirect evidence includes data on the incidence, prevalence, and mortality of cervical cancer. Based on Surveillance, Epidemiology, and End Results Program (SEER) data from 2009 to 2013, 0.1% of all incident cervical cancer occurred in women younger than age 20 years[40] and there were no reported deaths in this age group. Five observational studies[64-69] from the United Kingdom, United States, and Iceland suggested that high-risk HPV infections and cytological abnormalities were common and self-limited in women under age 20 years, whereas CIN3+ was less common in this group compared with women older than 25 years. Generally, in these studies, screening in younger women resulted in lower detection rates and higher false positive rates than screening in older women, and did not result in decreased incidence of cervical cancer.

Modeling studies demonstrated no advantage to screening prior to age 21 years,[2] with women in this age group experiencing the largest number of false positive test results (960 at age 20 years to 1003 at age 15 years with annual screening), and the lowest number of expected cancer cases (<3 per 1000 women). With each successive year that screening was delayed beyond age 21 years, the number of false positive test results declined and expected cancer cases increased. In modeling studies, screening every 5 years from age 21 years was associated with a difference in cancer mortality of 2.4 per 1000 women and cancer incidence of 10.2 per 1000 women compared with screening every year. Screening each year was associated with almost four times the number of colposcopies compared with screening every 5 years. Strategies that screen women every 3 to 5 years starting in their 20s were more efficient than annual screening during the teen years. A strategy of screening beginning at age 21 and repeated every 3 years was identified as particularly efficient.[2]

The age to stop screening was not systematically addressed by the 2012 USPSTF review because a prior review undertaken in 2002 found limited evidence based on 12 observational studies[12-22] regarding the benefits of screening women older than age 65 years.[23] In particular, the 2002 systematic review noted that the incidence and prevalence of CIN tends to decrease with age, cervical cancer in older women is not more aggressive or progressive than in younger women, and that rates of high-grade intraepithelial lesions (HSIL) are low among older women who have been screened. Though not systematically addressed, evidence from the 2012 USPSTF systematic review confirmed reduced rates of abnormal cytology and detection of CIN3+ cases as women age and with subsequent screening.[65,66,70,71]

In addition, the recommended age to stop screening was supported by epidemiological data and modeling studies. SEER data from 2009 to 2013 indicate that the median age at diagnosis of cervical cancer was 49 years[40] and incidence declined during the fourth decade. Modeling studies showed that in women with adequate screening histories, changing the age at which to end screening from 65 to 95 years by 5-year intervals resulted in less than 1 life-year improvement after age 65 years, but substantially increased harms related to false positive tests and increased number of colposcopies and cervical biopsies.[2] An adequate screening history was defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years prior to stopping screening, with the most recent test being within 5 years. However, in women who have never

been screened or have had inadequate screening, screening past age 65 years was shown to have a mortality advantage. In modeling studies, strategies that involved screening women who had never been screened every 2 to 5 years starting at age 65 years and ending at age 70 to 75 years demonstrated a balanced tradeoff between benefits and harms.[2]

Overall, the USPSTF-commissioned modeling study found that a strategy of screening with cytology every 3 years prior to age 30 and then co-testing every 5 years was associated with fewer colposcopies (575 vs. 1083 per 1000), cancers (7.44 vs. 8.50 per 1000), and cancer deaths (1.35 vs. 1.55 per 1000) compared with cytology screening every 3 years from age 21 years.[2] In this model, data were limited to HPV DNA testing using one HPV testing platform (HC2) and the effect of vaccination was not accounted for.

Relevant studies published since the USPSTF systematic review

A large U.S. cohort study of health plan enrollees (Kaiser Permanente Northern California cohort) that estimated the 5-year risk of CIN3+ results in women age 21 to 24 years found very low risks of cervical cancer.[72] In addition, a positive cytology test result predicted low CIN3+ risk except in 0.6% of results that were high grade.[72] The more common HPV positive/ASC-US and low-grade squamous intraepithelial lesion (LSIL) results in women age 21 to 24 years in this study predicted CIN3+ risks similar to ASC-US in women age 30 to 64 years, for which a 6- to 12-month return visit is recommended. Further, the 5-year risk (4.4%) of these women did not reach the 5.2% implicit threshold for colposcopy, supporting repeat testing. In those with HPV-negative/ASC-US and Pap-negative results, CIN3+ risks were similar to cytology alone in women age 30 to 64 years, for which a 3-year return visit is recommended.

Similarly, an observational study used national screening data from England and Wales to compare 3-yearly screening in 100,000 women starting at age 20 versus 25 years. Results indicated that starting at age 20 would lead to an estimated excess of 119,000 screens, 20,000 non-negative test results, over 8,000 referrals to colposcopy, and nearly 3,000 women treated with potentially 1.3 additional cancers detected per 100,000 women.[26] Based on these data, between 12,500 and 40,000 additional women would be screened, and between 300 and 900 treated for CIN to prevent one invasive cancer.

Studies of screening older women are based on observational studies of screened versus unscreened or inadequately screened women. A review of screening histories of Kaiser Permanente Northern California enrollees aged 65 years and older who were diagnosed with cervical cancer found few cancers in this age group, and most cancers were diagnosed in women who were inadequately screened previously (i.e., not meeting criteria of 3 consecutive negative cytology tests or a single co-test).[27] In a case-control study conducted in the United Kingdom, women with adequate negative screening at age 65 years had the lowest risk of cervical cancer (8 cancers per 10,000 women 20-year risk) compared with those not screened at age 50 to 64 years (49 cancers per 10 000 women 20-year risk).[28] Screening at least every 5.5 years between the ages of 50 to 64 years was associated with a 75% lower risk of cervical cancer between ages 65 to 79 years compared with not screening. In this study, adequate screening was defined as at least three tests at age 50 to 64 years with at least one between ages 60 to 64 years, the last three of which were negative, and no HSIL or worse since age of 50 years. Regular

screening was associated with low risk of cervical cancer until age 75 years, and by age 80 years, the risk in adequately screened women was half that of unscreened women.

A case-control study from two U.S. health plans that investigated the screening histories of women age 55 to 79 years who had died from cervical cancer found that cytology screening 5 to 7 years prior to diagnosis was associated with a 74% reduction in cervical cancer death (odds ratio 0.26; 95% CI, 0.10 to 0.63) after adjustment for covariates (smoking, marital status, race/ethnicity).[73] This study estimated that 630 deaths would be averted annually by screening all women age 55 to 79 years in the United States, though estimates were based on small numbers of cases. A second study of the same two U.S. health plans that included women age 55 to 79 years who were diagnosed with invasive cervical cancer found that cytological screening approximately 1 year prior to the occult invasive phase of cervical cancer was associated with a 75% to 77% reduction in the risk of invasive cervical cancer.[74] In this study, incidence remained low for several years following a negative screen, returning to the incidence of unscreened women after 5 to 7 years.

HPV Testing in Combination with Cytology

USPSTF systematic review and decision analysis

Four fair-quality randomized controlled trials comparing combination HPV (co-testing) versus cytology alone were included in the USPSTF review.[1,6] Trials included women from national screening programs in Italy (NTCC Phase 1),[4] the United Kingdom (ARTISTIC),[75] Sweden (Swedescreen),[76] and the Netherlands (POBASCAM)[77] enrolling more than 127, 000 women age 20 to 64 years. Colposcopy referral thresholds, follow-up duration, and completeness varied between trials, limiting data on harms and complete ascertainment of outcomes.

Among women age 30 years or older, round-specific screening resulted in relatively more CIN2+ lesions detected with co-testing compared with cytology alone after round 1, less CIN3+ detected after round 2, and fewer cancer cases in the co-testing compared with the cytology group. Cumulative CIN3+ detection was similar between co-testing and cytology alone after two screening rounds in all trials. Cumulative invasive cancer detection was similar, or just slightly higher, for cytology alone versus co-testing in three of four trials.[4,76,77] Only the NTCC trial found a relative increase in any cumulative CIN measure after co-testing, with increased CIN2+ and CIN3+ detection after one screening round and cumulative detection of CIN2+ overall.[4] However, this trial used a lower threshold for colposcopy referral, increasing sensitivity of the primary test.

An observational study of the Kaiser Permanente Northern California cohort compared co-testing to cytology alone among 330,000 women and found that cumulative 5-year incidence of cervical cancer was lower in the HPV-negative and cytology-negative group versus the cytology-negative group alone (3.2 per 100,000 vs. 7.5 per 100,000).[9] Detection of CIN3+ was also higher in earlier screening rounds with co-testing versus cytology alone in this study.

Modeling studies supported similar benefits of co-testing every 5 years or cytology every 3 years (7.44 vs. 8.50

cancer cases and 1.35 vs. 1.55 deaths, respectively), though the preferred strategy would incorporate 3-yearly cytology screening under age 30 and then co-testing after age 30 to limit the number of colposcopies.[2]

In a trial of co-testing (NTCC Phase 1)[4] that included younger women, CIN2+ detection was increased in a substantial number of women under the age of 35 years during the first round and cumulatively. However, younger women who tested positive in this study were not referred to immediate colposcopy like their older counterparts and were instead retested. This difference in testing protocol led to differential loss to follow-up between the study arms. Also, no cumulative data on colposcopy were provided by the study.

Harms of co-testing were difficult to assess because of incomplete reporting of outcomes and varying approaches to abnormal results in studies. However, approaches to management of abnormal screening results in these studies generally differed from U.S. recommendations, limiting their clinical applicability. In four diagnostic accuracy studies,[3,78-80] co-testing was generally more sensitive, but less specific than cytology alone, though these data were limited by different thresholds for positivity across studies.

In study of test performance for co-testing in younger women,[3] co-testing (64.0%) was less sensitive for CIN3+ than HPV (92.5%) but not cytology (65.4%) testing alone. Specificity was higher with co-testing (87.6%) than with cytology (81.5%) and HPV testing alone (70.1%).

Relevant studies published since the USPSTF systematic review

A meta-analysis of four European randomized controlled trials included in the USPSTF review that compared co-testing with cytology alone for the detection of high grade CIN lesions and cancer (ARTISTIC, NTCC Phase 1, POBASCAM, Swedescreen) found that co-testing at baseline was associated with significantly higher detection of CIN2+ (RR 1.41, 95% confidence interval [CI] 1.12 to 1.76) and non-significantly higher detection of CIN3+ (RR 1.15, 95% CI 0.99 to 1.33).[7] At the second round, co-testing was associated with significantly lower detection rates of both CIN 2+ and CIN3+ (RR 0.77, 95% CI 0.63 to 0.96; RR 0.68, 95%, CI 0.55 to 0.85; respectively). Overall detection rates did not differ between testing strategies for CIN2+ or CIN3+.

A follow-up study of the four European trials that followed more than 176,000 women age 20 to 64 years over a median of 6.5 years indicated reduced invasive cancer (rate ratio 0.60, 95% CI 0.40 to 0.89).[8] Detection was similar between screening strategies for the first 2.5 years, but was lower among women who had subsequent co-testing (RR 0.45, 95% CI 0.25 to 0.81). Also, the cumulative incidence of invasive cervical cancer was lower with negative entry tests among those who were co-tested compared with cytology alone (4.6 per 100,000 vs. 7.9 at 3.5 years; 8.7 per 100,000 vs. 36.0 at 5.5 years). Rate ratios were generally lower for adenocarcinoma than squamous-cell carcinoma and lowest among women age 30 to 34 years.

An extended follow-up study of the ARTISTIC trial found that a negative HPV test was significantly more predictive of normal results than a negative cytology result over 3 rounds, adding support to extended screening intervals with co-testing.[10] The Kaiser Northern California cohort study reported similar results that indicated the 5-year CIN3+ risk for women with HPV-negative/cytology-negative results was 0.08% (95% CI 0.07% to 0.09%), which is less than the 3-year CIN3+ risk for cytology-negative results of 0.16% in this population.[11]

HPV Testing Compared with Cytology

USPSTF Systematic Review and Decision Analysis

The USPSTF review[1,6] included six[3,78-82] fair- and good-quality diagnostic accuracy studies that found 1-time HPV testing was more sensitive, but less specific than cytology, with HPV testing sensitivity ranging from 86% to 97% for CIN3+ outcomes and 63% to 98% for CIN2+ outcomes versus 46% to 50% and 38% to 65%, respectively for cytology. Specificity for these outcomes was 3 to 5 percentage points less using HPV testing compared with cytology. One large fair-quality Italian randomized controlled trial (NTCC Phase 2)[83] that compared first round screening with HPV to cytology found increased detection of CIN3+ cancer in women screened with HPV alone compared with cytology, and equivalent numbers of invasive cancers detected in both arms. When invasive cancer cases from HPV testing alone were combined with cases from HPV co-testing strategies from an earlier trial, the cumulative incidence of invasive cancer was lower compared with cytology in women age 35 years and older. However, this finding is based on pooling non-comparable screening strategies.

Assessment of harms from trial data was limited because women with positive HPV results or ASC-US on cytology were immediately referred to colposcopy, resulting in more colposcopies among women screened with the more sensitive HPV test compared with cytology (5.8% vs. 2.5%). This strategy would not be applicable to U.S. women who would have been referred for repeat testing prior to colposcopy. Also, determination of harms was generally limited by incomplete reporting, use of different screening strategies in different rounds of the trial (cytology alone was done in both arms of round 2), and differing referral criteria. Four fair-quality observational studies[84-87] found that women who tested positive for HPV had increased immediate anxiety and distress compared with women who tested negative, but this difference had resolved by 6 months.

In women younger than 30 or 35 years, results were similar to those in older women, but they had higher rates of colposcopy referrals after HPV testing.[4,75,83,88-99] One study that provided test characteristics of HPV and cytology testing in younger women showed that HPV test sensitivity for CIN3+ and CIN2+ was 23% to 27% higher than cytology, but specificity of HPV testing was reduced to a much greater degree in younger women compared with older women (about 11%).[3]

Relevant studies published since the USPSTF systematic review

In April 2014, the FDA approved the cobas HPV test for primary cervical cancer screening on the basis of findings from a large U.S. study (ATHENA)[57] that found it to have equivalent or superior performance for detecting lesions compared with cytology alone. The ATHENA study enrolled 42,000 women age 25 years and older who had cytology and HPV testing. Women without CIN2+ findings were entered into a 3-year follow-up phase to compare three screening strategies: cytology with HPV testing only for ASC-US (cytology); cytology in women under age 30 years followed by co-testing in women 30 years and older (hybrid); and HPV testing in women 25 years and older (HPV primary).

At follow-up, the 3-year cumulative incidence rate of CIN3+ cases in cytology negative women was 0.8% (95% CI, 0.5% to 1.1%) compared with 0.3% (95% CI, 0.1% to 0.7%) in HPV-negative women, and 0.3% (95% CI, 0.1% to 0.6%) in women who were negative for both tests. Cytology was less sensitive (47.8%) for the detection

of CIN3+ cases versus HPV primary testing (76.1%) and the hybrid strategy (61.7%), but was more specific (specificity of 97.1%, 94.6%, and 93.5% for cytology, hybrid strategy, and HPV primary testing, respectively). Overall, the HPV primary screening strategy resulted in increased detection of CIN3+ cases compared with other strategies, but also resulted in more colposcopies, though the number of colposcopies needed to detect a single case of CIN3+ was similar to that for the hybrid strategy.

A follow-up study from the Kaiser cohort[9] evaluated the effectiveness of primary HPV testing every 3 years compared with primary Pap testing every 3 years or concurrent Pap and HPV testing (co-testing) every 5 years.[100] This study included data from 1,037,021 women age 30 to 64 who underwent screening at approximately 3-year intervals using co-testing with Pap and high risk HPV testing. Estimation of 3-year risks of cancer and CIN3+ or worse following a negative HPV result were lower than 3-year risks following a negative Pap result (CIN3+=0.069% vs 0.19%, P<0.0001; cancer=0.011% vs 0.020%, P<0.0001) and 5-year risks following an HPV negative/Pap negative co-test (CIN3+=0.069% vs 0.11%, P<0.0001; cancer=0.011% vs 0.014%, P=0.21).

CONCLUSIONS

Pap tests are effective in identifying abnormal cervical cytology for women age 21 to 29 years, and co-testing with HPV DNA tests in conjunction with cervical cytology are effective for women age 30 to 65. Research supports preferred screening intervals of 3 years for women age 21 to 65 years using cytology alone (Pap test); and every 5 years for women age 30 to 65 years using cytology and HPV DNA testing (co-testing). Data are lacking on the effectiveness of primary HPV testing. Further research is needed to clearly define the optimal screening interval and most effective combination of tests for screening for cervical cancer, as well as the effectiveness of screening using high risk HPV testing alone.

REFERENCES

[1]Vesco K, Whitlock E, Eder M, et al. Screening for cervical cancer: A systematic evidence review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 86. AHRQ Publication No. 11-05156-EF-1. Rockville, MD: Agency for Healthcare Research and Quality: May 2011. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/cervical-cancer-screening?ds=1&s=cervical%20cancer. Accessed November 30, 2016.

[2]Kulasingam SL, Havrilesky LJ, Ghebre R, et al. Screening for cervical cancer: a modeling study for the US Preventive Services Task Force. J Low Genit Tract Dis. 2013;17(2):193-202. doi: 10.1097/LGT.0b013e3182616241. PMID: 23519288.

[3]Kulasingam SL, Hughes JP, Kiviat NB, et al. Evaluation of human papillomavirus testing in primary screening for cervical abnormalities: comparison of sensitivity, specificity, and frequency of referral. JAMA. 2002;288(14):1749-57. PMID: 12365959.

[4]Ronco G, Segnan N, Giorgi-Rossi P, et al. Human papillomavirus testing and liquid-based cytology: results at recruitment from the new technologies for cervical cancer randomized controlled trial. J Natl Cancer Inst. 2006;98(11):765-74. doi: 10.1093/jnci/djj209. PMID: 16757701.

[5]Moyer VA. Screening for cervical cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2012;156(12):880-91, w312. doi: 10.7326/0003-4819-156-12-201206190-00424. PMID: 22711081.

[6]Whitlock EP, Vesco KK, Eder M, et al. Liquid-based cytology and human papillomavirus testing to screen for cervical cancer: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2011;155(10):687-97, w214-5. doi: 10.7326/0003-4819-155-10-201111150-00376. PMID: 22006930.

[7]Bouchard-Fortier G, Hajifathalian K, McKnight MD, et al. Co-testing for detection of high-grade cervical intraepithelial neoplasia and cancer compared with cytology alone: a meta-analysis of randomized controlled trials. J Public Health. 2014 Mar;36(1):46-55. doi: http://dx.doi.org/10.1093/pubmed/fdt057. PMID: 23735961.

[8]Ronco G, Dillner J, Elfstrom KM, et al. Efficacy of HPV-based screening for prevention of invasive cervical cancer: Follow-up of four European randomised controlled trials. Lancet. 2014;383(9916):524-32. PMID: CN-00983853 UPDATE.

[9]Katki HA, Kinney WK, Fetterman B, et al. Cervical cancer risk for women undergoing concurrent testing for human papillomavirus and cervical cytology: a population-based study in routine clinical practice. Lancet Oncol. 2011;12(7):663-72. doi: 10.1016/s1470-2045(11)70145-0.

[10]Kitchener HC, Gilham C, Sargent A, et al. A comparison of HPV DNA testing and liquid based cytology over three rounds of primary cervical screening: extended follow up in the ARTISTIC trial. Eur J Cancer. 2011;47(6):864-71. doi: http://dx.doi.org/10.1016/j.ejca.2011.01.008. PMID: 21334200.

[11]Katki HA, Schiffman M, Castle PE, et al. Benchmarking CIN 3+ risk as the basis for incorporating HPV and Pap cotesting into cervical screening and management guidelines. J Low Genit Tract Dis. 2013;17(5 Suppl 1):S28-35. doi: 10.1097/LGT.0b013e318285423c. PMID: 23519302.

[12]Cecchini S, Ciatto S, Zappa M, et al. Trends in the prevalence of cervical intraepithelial neoplasia grade 3 in the district of Florence, Italy. Tumori. 1995;81(5):330-3. PMID: 8804448.

[13]Gustafsson L, Sparen P, Gustafsson M, et al. Efficiency of organised and opportunistic cytological screening for cancer in situ of the cervix. Br J Cancer. 1995;72(2):498-505. PMID: 7640239.

[14]Kainz C, Gitsch G, Heinzl H, et al. Incidence of cervical smears indicating dysplasia among Austrian women during the 1980s. Br J Obstet Gynaecol. 1995;102(7):541-4. PMID: 7647055.

[15]Forsmo S, Jacobsen BK, Stalsberg H. Cervical neoplasia in pap smears: risk of cervical intra-epithelial neoplasia (CIN) after negative or no prior smears in a population without a mass screening programme. Int J Epidemiol. 1996;25(1):53-8. PMID: 8666505.

[16]Mitchell H, Medley G, Higgins V. An audit of the women who died during 1994 from cancer of the cervix in Victoria, Australia. Aust N Z J Obstet Gynaecol. 1996;36(1):73-6. PMID: 8775257.

[17]Cruickshank ME, Angus V, Kelly M, et al. The case for stopping cervical screening at age 50. Br J Obstet Gynaecol. 1997;104(5):586-9. PMID: 9166202.

[18]Gram IT, Macaluso M, Stalsberg H. Incidence of cervical intraepithelial neoplasia grade III, and cancer of the cervix uteri following a negative Pap-smear in an opportunistic screening. Acta Obstet Gynecol Scand. 1998;77(2):228-32. PMID: 9512333.

[19]Lawson HW, Lee NC, Thames SF, et al. Cervical cancer screening among low-income women: results of a national screening program, 1991-1995. Obstet Gynecol. 1998;92(5):745-52. PMID: 9794662.

[20]Sigurdsson K. Trends in cervical intra-epithelial neoplasia in Iceland through 1995: evaluation of targeted age groups and screening intervals. Acta Obstet Gynecol Scand. 1999;78(6):486-92. PMID: 10376857.

[21]Sawaya GF, Kerlikowske K, Lee NC, et al. Frequency of cervical smear abnormalities within 3 years of normal cytology. Obstet Gynecol. 2000;96(2):219-23. PMID: 10908766.

[22]Sawaya G, Kerlikowske K, lee NC. When can cervical cancer screening intervals be lengthened? Outcomes following 1, 2, and 3 or more normal cervical smears. (unpublished data).

[23]Hartmann K, Hall S, Nanda K, et al. Screening for Cervical Cancer [Internet]. Rockvillle (MD): Agency for Healthcare Research and Quality (US); 2002. (Systematic Evidence Reviews, No. 25). 2002. http://www.ncbi.nlm.nih.gov/books/NBK42831/. Accessed August 11, 2016.

[24]Fox J, Remington P, Layde P, et al. The effect of hysterectomy on the risk of an abnormal screening Papanicolaou test result. Am J Obstet Gynecol. 1999;180(5):1104-9. PMID: 10329862.

[25]Pearce KF, Haefner HK, Sarwar SF, et al. Cytopathological findings on vaginal Papanicolaou smears after hysterectomy for benign gynecologic disease. N Engl J Med. 1996;335(21):1559-62. doi: 10.1056/nejm199611213352103. PMID: 8900088.

[26]Landy R, Birke H, Castanon A, et al. Benefits and harms of cervical screening from age 20 years compared with screening from age 25 years. Br J Cancer. 2014;110(7):1841-6. doi: http://dx.doi.org/10.1038/bjc.2014.65. PMID: 24518600.

[27]Dinkelspiel H, Fetterman B, Poitras N, et al. Screening history preceding a diagnosis of cervical cancer in women age 65 and older. Gynecol Oncol. 2012;126(2):203-6. doi: 10.1016/j.ygyno.2012.04.037. PMID: 22561038.

[28]Castanon A, Landy R, Cuzick J, et al. Cervical screening at age 50-64 years and the risk of cervical cancer at age 65 years and older: population-based case control study. PLOS Med. 2014;11(1):e1001585. doi: http://dx.doi.org/10.1371/journal.pmed.1001585. PMID: 24453946.

[29]Human papillomaviruses. IARC Monogr Eval Carcinog Risks Hum. 2007;90:1-636. PMID: 18354839.

[30]Walboomers JM, Jacobs MV, Manos MM, et al. Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. J Pathol. 1999 Sep;189(1):12-9. doi: 10.1002/(sici)1096-9896(199909)189:1<12::aid-path431>3.0.co;2-f. PMID: 10451482.

[31]Centers for Disease Control and Prevention. Genital HPV Infection – CDC Fact Sheet. http://www.cdc.gov/std/hpv/stdfact-hpv.htm. Accessed May 12, 2016.

[32]Plummer M, Schiffman M, Castle PE, et al. A 2-year prospective study of human papillomavirus persistence among women with a cytological diagnosis of atypical squamous cells of undetermined significance or low-grade squamous intraepithelial lesion. J Infect Dis. 2007;195(11):1582-9. doi: 10.1086/516784. PMID: 17471427.

[33]Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep. 2015;64(Rr-03):1-137. PMID: 26042815.

[34]Khan MJ, Castle PE, Lorincz AT, et al. The elevated 10-year risk of cervical precancer and cancer in women with human papillomavirus (HPV) type 16 or 18 and the possible utility of type-specific HPV testing in clinical practice. J Natl Cancer Inst. 2005;97(14):1072-9. doi: 10.1093/jnci/dji187. PMID: 16030305.

[35]McCredie MRE, Sharples KJ, Paul C, et al. Natural history of cervical neoplasia and risk of invasive cancer in women with cervical intraepithelial neoplasia 3: a retrospective cohort study. Lancet Oncol. 2008;9(5):425-34. doi: 10.1016/s1470-2045(08)70103-7.

[36]Cuzick J, Clavel C, Petry KU, et al. Overview of the European and North American studies on HPV testing in primary cervical cancer screening. Int J Cancer. 2006;119(5):1095-101. doi: 10.1002/ijc.21955. PMID: 16586444.

[37]Wright TC, Jr., Stoler MH, Sharma A, et al. Evaluation of HPV-16 and HPV-18 genotyping for the triage of women with high-risk HPV+ cytology-negative results. Am J Clin Pathol. 2011;136(4):578-86. doi: 10.1309/AJCPTUS5EXAS6DKZ. PMID: 21917680.

[38]IOM (institute of Medicine). Clinical preventive services for women: Closing the gaps. Washington, DC: National Academies Press; 2011.

[39]U.S. Cancer Statistics Working Group. United States cancer statistics: 1999–2012 incidence and mortality web-based report. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2015. https://nccd.cdc.gov/uscs/. Accessed May 12, 2016.

[40]SEER cancer statistics factsheets: Cervix uteri cancer. National Cancer Institute. Bethesda, MD. http://seer.cancer.gov/statfacts/html/cervix.html. Accessed May 12, 2016.

[41]American Cancer Society. Cancer facts & figures 2016 American Cancer Society. Atlanta: 2016. http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/. Accessed November 30, 2016.

[42]Peto J, Gilham C, Fletcher O, et al. The cervical cancer epidemic that screening has prevented in the UK. Lancet. 2004;364(9430):249-56. doi: 10.1016/s0140-6736(04)16674-9.

[43]Cancer screening - United States, 2010. MMWR Morb Mortal Wkly Rep. 2012;61(3):41-5. PMID: 22278157.

[44]Sung HY, Kearney KA, Miller M, et al. Papanicolaou smear history and diagnosis of invasive cervical carcinoma among members of a large prepaid health plan. Cancer. 2000;88(10):2283-9. PMID: 10820350.

[45]Leyden WA, Manos MM, Geiger AM, et al. Cervical cancer in women with comprehensive health care access: attributable factors in the screening process. J Natl Cancer Inst. 2005;97(9):675-83. doi: 10.1093/jnci/dji115. PMID: 15870438.

[46]Healthy People 2020. Washington, DC: U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. https://www.healthypeople.gov/2020/topics-objectives/topic/cancer/objectives. Accessed May 12, 2016.

[47]Gibb RK. The use of liquid-based cytology in cervical cancer screening. Rev Obstet Gynecol. 2011;4(Suppl 1):S1. PMID: 21617784.

[48]Arbyn M, Bergeron C, Klinkhamer P, et al. Liquid compared with conventional cervical cytology: a systematic review and meta-analysis. Obstet Gynecol. 2008;111(1):167-77. doi: 10.1097/01.AOG.0000296488.85807.b3. PMID: 18165406.

[49]Davey E, Barratt A, Irwig L, et al. Effect of study design and quality on unsatisfactory rates, cytology classifications, and accuracy in liquid-based versus conventional cervical cytology: a systematic review. Lancet. 2006;367(9505):122-32. doi: 10.1016/s0140-6736(06)67961-0.

[50]Ronco G, Cuzick J, Pierotti P, et al. Accuracy of liquid based versus conventional cytology: overall results of new technologies for cervical cancer screening: randomised controlled trial. BMJ. 2007;335(7609):28. doi: 10.1136/bmj.39196.740995.BE. PMID: 17517761.

[51]Davey E, d'Assuncao J, Irwig L, et al. Accuracy of reading liquid based cytology slides using the ThinPrep Imager compared with conventional cytology: prospective study. BMJ. 2007;335(7609):31. doi: 10.1136/bmj.39219.645475.55. PMID: 17604301.

[52]Beerman H, van Dorst EB, Kuenen-Boumeester V, et al. Superior performance of liquid-based versus conventional cytology in a population-based cervical cancer screening program. Gynecol Oncol. 2009;112(3):572-6. doi: 10.1016/j.ygyno.2008.12.012. PMID: 19150573.

[53]Centers for Disease Control and Prevention. Manual for the Surveillance of Vaccine-Preventable Diseases. http://www.cdc.gov/vaccines/pubs/surv-manual/index.html. Accessed May 13, 2016.

[54]Zhao C, Moriarty AT, Ghofrani M, et al. Human papillomavirus testing and reporting rates in 2012: results of a College of American Pathologists national survey. Arch Pathol Lab Med. 2015;139(6):757-61. doi: 10.5858/arpa.2014-0393-CP. PMID: 25436905.

[55]U.S. Food and Drug Administration. FDA approves first human papillomavirus test for primary cervical cancer screening. 2014. http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm394773.htm. Accessed May 13, 2016.

[56]2014 meeting materials of the Food and Drug Administration (FDA) microbiology devices panel. 2014. http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MicrobiologyDevicesPanel/ucm388531.htm. Accessed November 30, 2016.

[57]Wright TC, Stoler MH, Behrens CM, et al. Primary cervical cancer screening with human papillomavirus: end of study results from the ATHENA study using HPV as the first-line screening test. Gynecol Oncol. 2015;136(2):189-97. doi: 10.1016/j.ygyno.2014.11.076. PMID: 25579108.

[58]U.S. Department of Health & Human Services. The Affordable Care Act and Immunization. 2010. http://www.hhs.gov/healthcare/facts-and-features/fact-sheets/aca-and-immunization/index.html. Accessed May 16, 2016.

[59]Practice Bulletin No. 157: Cervical cancer screening and prevention. Obstet Gynecol. 2016;127(1):e1-e20. doi: 10.1097/aog.0000000000001263. PMID: 26695583.

[60]Saslow D, Solomon D, Lawson HW, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. J Low Genit Tract Dis. 2012;16(3):175-204. PMID: 22418039.

[61]Sawaya GF, Kulasingam S, Denberg TD, et al. Cervical cancer screening in average-risk women: Best practice advice from the clinical guidelines committee of the American College of Physicians. Ann Intern Med. 2015;162(12):851-9. doi: 10.7326/M14-2426.

[62]Partridge EE, Abu-Rustum N, Campos SM, et al. NCCN Guidelines Version 2.2012 Panel Members Cervical Cancer Screening. National Comprehensive Cancer Network; 2012. https://www.tri-kobe.org/nccn/guideline/gynecological/english/cervical_screening.pdf. Accessed July 5, 2016.

[63]Huh WK, Ault KA, Chelmow D, et al. Use of primary high-risk human papillomavirus testing for cervical cancer screening: interim clinical guidance. Gynecol Oncol. 2015;136(2):178-82. doi: 10.1016/j.ygyno.2014.12.022. PMID: 25579107.

[64]Sasieni P, Castanon A, Cuzick J. Effectiveness of cervical screening with age: population based case-control study of prospectively recorded data. BMJ. 2009;339:b2968. doi: 10.1136/bmj.b2968. PMID: 19638651.

[65]Peto J, Gilham C, Deacon J, et al. Cervical HPV infection and neoplasia in a large population-based prospective study: the Manchester cohort. Br J Cancer. 2004;91(5):942-53. doi: 10.1038/sj.bjc.6602049. PMID: 15292939.

[66]Insinga RP, Glass AG, Rush BB. Diagnoses and outcomes in cervical cancer screening: a population-based study. Am J Obstet Gynecol. 2004;191(1):105-13. doi: 10.1016/j.ajog.2004.01.043. PMID: 15295350.

[67]Sigurdsson K, Sigvaldason H. Is it rational to start population-based cervical cancer screening at or soon after age 20? Analysis of time trends in preinvasive and invasive diseases. Eur J Cancer. 2007;43(4):769-74. doi: 10.1016/j.ejca.2006.11.017. PMID: 17236755.

[68]Woodman CB, Collins S, Winter H, et al. Natural history of cervical human papillomavirus infection in young women: a longitudinal cohort study. Lancet. 2001;357(9271):1831-6. doi: 10.1016/s0140-6736(00)04956-4. PMID: 11410191.

[69]Sigurdsson K. Cervical cancer: cytological cervical screening in Iceland and implications of HPV vaccines. Cytopathology. 2010;21(4):213-22. doi: 10.1111/j.1365-2303.2010.00783.x. PMID: 20646020.

[70]Benard VB, Eheman CR, Lawson HW, et al. Cervical screening in the National Breast and Cervical Cancer Early Detection Program, 1995-2001. Obstet Gynecol. 2004;103(3):564-71. doi: 10.1097/01.AOG.0000115510.81613.f0. PMID: 14990422.

[71]Rebolj M, van Ballegooijen M, Lynge E, et al. Incidence of cervical cancer after several negative smear results by age 50: prospective observational study. BMJ. 2009;338:b1354. doi: 10.1136/bmj.b1354. PMID: 19395420.

[72]Katki HA, Schiffman M, Castle PE, et al. Estimating 5-year risk of CIN 3+ to guide the management of women aged 21-24. J Low Genit Tract Dis. 2013;17(5 Suppl 1):S64-8. doi: http://dx.doi.org/10.1097/LGT.0b013e3182854399. PMID: 23519307.

[73]Rustagi AS, Kamineni A, Weinmann S, et al. Cervical screening and cervical cancer death among older women: a population-based, case-control study. Am J Epidemiol. 2014;179(9):1107-14. doi: http://dx.doi.org/10.1093/aje/kwu035. PMID: 24685531.

[74]Kamineni A, Weinmann S, Shy KK, et al. Efficacy of screening in preventing cervical cancer among older women. Cancer Causes Control. 2013;24(9):1653-60. doi: http://dx.doi.org/10.1007/s10552-013-0239-4. PMID: 23744043.

[75]Kitchener HC, Almonte M, Thomson C, et al. HPV testing in combination with liquid-based cytology in primary cervical screening (ARTISTIC): a randomised controlled trial. Lancet Oncol. 2009;10(7):672-82. doi: 10.1016/s1470-2045(09)70156-1. PMID: 19540162.

[76]Naucler P, Ryd W, Tornberg S, et al. Human papillomavirus and Papanicolaou tests to screen for cervical cancer. N Engl J Med. 2007;357(16):1589-97. doi: 10.1056/NEJMoa073204. PMID: 17942872.

[77]Bulkmans NW, Berkhof J, Rozendaal L, et al. Human papillomavirus DNA testing for the detection of cervical intraepithelial neoplasia grade 3 and cancer: 5-year follow-up of a randomised controlled implementation trial. Lancet. 2007;370(9601):1764-72. doi: 10.1016/s0140-6736(07)61450-0. PMID: 17919718.

[78]Coste J, Cochand-Priollet B, de Cremoux P, et al. Cross sectional study of conventional cervical smear, monolayer cytology, and human papillomavirus DNA testing for cervical cancer screening. BMJ. 2003;326(7392):733. doi: 10.1136/bmj.326.7392.733. PMID: 12676841.

[79]Mayrand MH, Duarte-Franco E, Rodrigues I, et al. Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. N Engl J Med. 2007;357(16):1579-88. doi: 10.1056/NEJMoa071430. PMID: 17942871.

[80]Petry KU, Menton S, Menton M, et al. Inclusion of HPV testing in routine cervical cancer screening for women above 29 years in Germany: results for 8466 patients. Br J Cancer. 2003;88(10):1570-7. doi: 10.1038/sj.bjc.6600918. PMID: 12771924.

[81]Cardenas-Turanzas M, Nogueras-Gonzalez GM, Scheurer ME, et al. The performance of human papillomavirus high-risk DNA testing in the screening and diagnostic settings. Cancer Epidemiol Biomarkers Prev. 2008;17(10):2865-71. doi: 10.1158/1055-9965.epi-08-0137. PMID: 18843032.

[82]Bigras G, de Marval F. The probability for a Pap test to be abnormal is directly proportional to HPV viral load: results from a Swiss study comparing HPV testing and liquid-based cytology to detect cervical cancer precursors in 13,842 women. Br J Cancer. 2005;93(5):575-81. doi: 10.1038/sj.bjc.6602728. PMID: 16136031.

[83]Ronco G, Giorgi-Rossi P, Carozzi F, et al. Efficacy of human papillomavirus testing for the detection of invasive cervical cancers and cervical intraepithelial neoplasia: a randomised controlled trial. Lancet Oncol. 2010;11(3):249-57. doi: http://dx.doi.org/10.1016/S1470-2045(09)70360-2. PMID: 20089449.

[84]McCaffery K, Waller J, Forrest S, et al. Testing positive for human papillomavirus in routine cervical screening: examination of psychosocial impact. BJOG. 2004;111(12):1437-43. PMID: 15663132.

[85]Kitchener HC, Fletcher I, Roberts C, et al. The psychosocial impact of human papillomavirus testing in primary cervical screening-a study within a randomized trial. Int J Gynecol Cancer. 2008;18(4):743-8. doi: 10.1111/j.1525-1438.2007.01113.x. PMID: 17944916.

[86]McCaffery KJ, Irwig L, Turner R, et al. Psychosocial outcomes of three triage methods for the management of borderline abnormal cervical smears: an open randomised trial. BMJ. 2010;340:b4491. doi: http://dx.doi.org/10.1136/bmj.b4491. PMID: 20179125.

[87]Maissi E, Marteau TM, Hankins M, et al. Psychological impact of human papillomavirus testing in women with borderline or mildly dyskaryotic cervical smear test results: cross sectional questionnaire study. BMJ. 2004;328(7451):1293. doi: 10.1136/bmj.328.7451.1293. PMID: 15166066.

[88]Kotaniemi-Talonen L, Anttila A, Malila N, et al. Screening with a primary human papillomavirus test does not increase detection of cervical cancer and intraepithelial neoplasia 3. Eur J Cancer. 2008;44(4):565-71. doi: 10.1016/j.ejca.2007.12.002. PMID: 18248809.

[89]Leinonen M, Nieminen P, Kotaniemi-Talonen L, et al. Age-specific evaluation of primary human papillomavirus screening vs conventional cytology in a randomized setting. J Natl Cancer Inst. 2009;101(23):1612-23. doi: 10.1093/jnci/djp367. PMID: 19903804.

[90]Anttila A, Kotaniemi-Talonen L, Leinonen M, et al. Rate of cervical cancer, severe intraepithelial neoplasia, and adenocarcinoma in situ in primary HPV DNA screening with cytology triage: randomised study within organised screening programme. BMJ. 2010;340:c1804. doi: http://dx.doi.org/10.1136/bmj.c1804. PMID: 20423964.

[91]Kitchener HC, Almonte M, Gilham C, et al. ARTISTIC: a randomised trial of human papillomavirus (HPV) testing in primary cervical screening. Health Technol Assess. 2009;13(51):1-150, iii-iv. doi: 10.3310/hta13510. PMID: 19891902.

[92]Ronco G, Giorgi-Rossi P, Carozzi F, et al. Results at recruitment from a randomized controlled trial comparing human papillomavirus testing alone with conventional cytology as the primary cervical cancer screening test. J Natl Cancer Inst. 2008;100(7):492-501. doi: 10.1093/jnci/djn065. PMID: 18364502.

[93]Ronco G, Cuzick J, Segnan N, et al. HPV triage for low grade (L-SIL) cytology is appropriate for women over 35 in mass cervical cancer screening using liquid based cytology. Eur J Cancer. 2007;43(3):476-80. doi: 10.1016/j.ejca.2006.11.013. PMID: 17223540.

[94]Ronco G, Brezzi S, Carozzi F, et al. The New Technologies for Cervical Cancer Screening randomised controlled trial. An overview of results during the first phase of recruitment. Gynecol Oncol. 2007;107(1 Suppl 1):S230-2. doi: 10.1016/j.ygyno.2007.07.021. PMID: 17822751.

[95]Anttila A, Hakama M, Kotaniemi-Talonen L, et al. Alternative technologies in cervical cancer screening: a randomised evaluation trial. BMC Public Health. 2006;6:252. doi: 10.1186/1471-2458-6-252. PMID: 17042938.

[96]Kotaniemi-Talonen L, Nieminen P, Anttila A, et al. Routine cervical screening with primary HPV testing and cytology triage protocol in a randomised setting. Br J Cancer. 2005;93(8):862-7. doi: 10.1038/sj.bjc.6602799. PMID: 16189520.

[97]Kitchener HC, Almonte M, Wheeler P, et al. HPV testing in routine cervical screening: cross sectional data from the ARTISTIC trial. Br J Cancer. 2006;95(1):56-61. doi: 10.1038/sj.bjc.6603210. PMID: 16773068.

[98]Sargent A, Bailey A, Turner A, et al. Optimal threshold for a positive hybrid capture 2 test for detection of human papillomavirus: data from the ARTISTIC trial. J Clin Microbiol. 2010;48(2):554-8. doi: 10.1128/jcm.00896-09. PMID: 20007387.

[99]Sargent A, Bailey A, Almonte M, et al. Prevalence of type-specific HPV infection by age and grade of cervical cytology: data from the ARTISTIC trial. Br J Cancer. 2008;98(10):1704-9. doi: 10.1038/sj.bjc.6604324. PMID: 18392052.

[100]Gage JC, Schiffman M, Katki HA, et al. Reassurance against future risk of precancer and cancer conferred by a negative human papillomavirus test. Journal of the National Cancer Institute. 2014;106(8)doi: http://dx.doi.org/10.1093/jnci/dju153. PMID: 25038467.

Contraception

Clinical Recommendations

The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.

The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), 8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel); and (18) emergency contraception (ulipristal acetate); and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service, access to and provision of the full range of female-controlled U.S. Food and Drug Administration-identified contraceptive methods. This includes access to contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, evaluation, as well as changes to and removal or discontinuation of the contraceptive method) by a health care provider or appropriately trained individual. Additionally, effective family planning practices, and patient-specific services or U.S. Food and Drug Administration-approved methods that may be required based on individual women's needs are recommended as part of contraceptive preventive services.

The Women's Preventive Services Initiative recommends accommodation of an alternative form of contraception when a particular drug or device (generic or brand name) is medically inappropriate for a patient as determined by the individual's health care provider. Research indicates that delayed initiation or disruption of contraceptive use increases the risk of unintended pregnancy; therefore, the Women's Preventive Services Initiative recommends timely authorization of contraceptives.

The Women's Preventive Services Initiative also recommends as a preventive service counseling that emphasizes patient-centered decision-making and allows for discussion of the full range of contraceptive options.

Recommendations continued on page 82.

For some women, more than one visit may be needed to achieve effective contraception. More than one visit may also be necessary to identify the appropriate contraceptive methods to optimize compliance and effectiveness as determined by a woman and her health care provider, based on shared decision making.

EVIDENCE MAP

- Adolescent and adult women should have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes.
- The full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures should be available as part of contraceptive care.

Systematic Reviews	Additional Studies	USPSTF[1]
None	• Contraceptive efficacy is well established and supported in an observational study and review of population data.[1] • LARC uptake is associated with lower rates of abortion, repeat abortion, and teenage births compared to regional and national rates ($p<0.001$).[2] • Counseling about and access to the full range of contraceptive methods is associated with increased contraceptive use and decreased unintended pregnancy rates.[2,3]	• USPSTF: No recommendation • Bright Futures[4]: Recommends a developmentally targeted sexual history, assessment of STI and pregnancy risk, and provision of appropriate screening, counseling, and, if needed, contraceptives.

Evidence map continued on page 83.

Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).		
Systematic Reviews	**Additional Studies**	**USPSTF[1]**
2013 Cochrane review supports the effectiveness of counseling on contraceptive adherence and continuation for oral contraceptives and injectables.[5]	• Counseling about and access to the full range of contraceptive methods is associated with increased contraceptive use and decreased unintended pregnancy rates.[2,3] • Higher continuation rates are associated with increased supply of oral contraceptives at initiation (1 RCT)[6,7] • Providing an increased supply of contraceptive pill packages is associated with decreased unintended pregnancies.[7,8]	• USPSTF: No recommendation • Bright Futures: See page 92.

Abbreviations: ACA=Affordable Care Act, LARC=long acting reversible contraceptive, USPSTF=U.S. Preventive Services Task Force

SUMMARY OF EVIDENCE

Introduction

The goal of primary prevention of unintended pregnancy is to aid women in the achievement of their pregnancy intentions and to improve maternal, child, and family outcomes by increasing the likelihood that every pregnancy is one that is both desired and planned.[9] Contraceptive methods enable women to actively prevent unintended pregnancy and control the timing of a desired pregnancy. When choosing a contraceptive method, women may consider efficacy, side effects, convenience, prevention of sexually transmitted infections, and non-contraceptive benefits. Most of these methods are female controlled and can be discussed in the context of routine clinical care or with specific counseling.

Contraceptive counseling offers an opportunity to discuss reproductive health goals, educate about the various methods, clarify or dispel myths or misinformation, and facilitate the provision of a method that will be successful for individual women. Comprehensive counseling may facilitate effective use and increase the provision of methods with the highest efficacy, especially in high risk populations, while taking into account the woman's preferences, her time frame for pregnancy, contraceptive efficacy, safety, and side effects.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) Committee was the absence of coverage for contraception[10] (**Table 1**).

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

IOM Committee[11]	Includes the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity to prevent unintended pregnancy and promote healthy birth spacing.
USPSTF	Not addressed
Bright Futures[4]	Recommends a developmentally targeted sexual history, assessment of STI and pregnancy risk, and provide appropriate screening, counseling, and, if needed, contraceptives.

Abbreviations: IOM=Institute of Medicine; STI=sexually transmitted infection; USPSTF=U.S. Preventive Services Task Force

Contraceptive coverage under the ACA requires that all plans in the Health Insurance Marketplace cover contraceptive methods and counseling for all women, as prescribed by a health care provider without charging copayment or coinsurance when provided by an in-network provider regardless of whether the deductible has been met.[12] Private companies are increasingly challenging the contraception provisions in the ACA,[13] and employed women may have plans that are exempt from contraceptive coverage.[14] Nonetheless, as a result of the ACA's contraceptive coverage requirement, more than 55 million women currently have access to birth control without copayments.[15]

Data from a 2016 study evaluating the impact of contraceptive coverage under the ACA demonstrated a 70% decrease in mean total out-of-pocket expenses for U.S. Food and Drug Administration (FDA) approved contraceptives for commercially insured women from 2011 to 2013.[16] The study reviewed contraceptive claims for nearly 2.5 million women ages 15 to 44 years in a commercial claims database who were using contraceptives and compared out of pocket costs for pre-implementation versus post-implementation of the ACA contraceptive and family planning mandate.

Title X of the Public Health Service Act, a federal grant program established in 1970 and administered by the Department of Health and Human Services, provides reproductive healthcare and contraceptive services to low-income U.S. women and men.[17] Title X serves approximately 1 million teens each year and provides family planning and related preventive health services for low-income persons.

Background

Family planning services are at the cornerstone of effective prevention in reproductive health and include contraception, patient education, and counseling. In the United States, nearly half of the pregnancies that occur annually are unintended.[18,19] Unintended pregnancy is defined as a pregnancy that is either mistimed (27% of all pregnancies) or unwanted (18% of all pregnancies).[19,20] Between 2008 and 2011, the overall unintended pregnancy rate in the United States decreased substantially among women ages 15 to 44 years from 54 per 1,000 to 45 in 2011, a decline of 18% and the lowest rate of unintended pregnancy in at least 30 years.[19,20] Despite the availability of effective forms of contraception, disparities exist in contraceptive use and rates of unintended pregnancy.[21] Unintended pregnancies disproportionately occur in women age 18 to 24 years, especially among those with low incomes or from racial/ethnic minorities.[22]

Long acting reversible contraception (LARC) has been recommended to effectively reduce unintended pregnancy,[23] although these methods are less frequently used in the United States compared with other developed countries.[24] Access to effective forms of contraception is an important step in preventing unintended pregnancies, but it is not enough to address disparities in unplanned pregnancy. A comprehensive approach includes access to preconception care, fertility planning, health care counseling, and reproductive health education and promotion.[25]

The Healthy People 2020[26] goals specify the importance of promoting healthy pregnancy outcomes by preventing unintended conception[26,27] and recognize this as a challenge in the United States. These goals are further defined by increasing the proportion of intended pregnancies from 51% to 56%[26] because births resulting from unintended or closely spaced pregnancies are associated with adverse maternal and child health outcomes. These include delayed prenatal care, premature birth, and negative physical and mental health effects for children.[28-30]

Other harms include increased risk of delaying prenatal care, maternal depression, or experiencing physical violence during pregnancy,[31-34] in addition to the impact on health behaviors such as breastfeeding and birth outcomes. Secondary benefits of access to contraception include promoting pregnancy spacing, or healthy pregnancy intervals, which is associated with reduction of repeated unintended pregnancy and improved health outcomes for both the mother and the infant. In spite of advances in contraceptive technology and its effectiveness, rates of unintended pregnancy in the United States remain high.

Primary prevention is aimed at preventing the onset of a specific condition.[35] As recently as 2016, a committee assembled by the Centers for Disease Control and Prevention (CDC) released guidelines on health care system measures to advance preconception care[36] and to consider this as a quality metric for prevention. Preconception interventions, such as an evaluation of every woman's current pregnancy intentions, may be incorporated as an aspect of women's primary care since data suggest that healthier pregnancies occur in women who are healthy prior to conception.[37] A preconception visit can optimize the chances of a healthy pregnancy by screening for conditions that adversely affect pregnancy, reducing the use of teratogenic medications, and promoting the use folic acid daily to prevent birth defects.[38]

Contraception as primary prevention enables the routine screening of pregnancy intention. Primary prevention of unintended pregnancy also includes an evaluation of a patient's satisfaction with her contraceptive method at subsequent visits to reduce discontinued or interrupted use. A recent study found that at subsequent visits after a birth control method was started, providers were less likely to discuss method satisfaction, consistent and correct use, or take a subsequent sexual history than at initial family planning visits.[39] Over a 1-year period, as many as a one fourth of all women experience a gap in contraceptive use and approximately two out of five women may use their oral contraceptives inconsistently, contributing significantly to the risk for unintended pregnancy.[40]

Contraceptive efficacy is well established (**Table 2**),[1,41] non-contraceptive benefits of hormonal contraception are recognized,[42] and risk factors for unintended pregnancy are known.[11] Effectiveness is primarily related to contraceptive accessibility and access, especially amongst vulnerable or higher risk populations, including adolescents. Barriers to contraceptive access include policy provisions for privately insured women, immediate access to emergency contraception, and patient protections in the case of provider refusal, including pharmacists, all of which may vary by state.[43]

From 2006 to 2010, the National Survey of Family Growth reported that 78.6% of sexually experienced females ages 15 to 44 years received reproductive health services in the previous 12 months.[18] The Healthy people 2020 target for this health indicator is 86.5%.[45] In 2010, 11.5 million visits were made to primary care offices for family planning counseling or contraception.[46] In the same year, 62% of reproductive aged women used contraception.[47] The most frequently used methods of contraception in the United States continue to be oral contraceptives and sterilization (**Table 3**), despite an increase in the availability of more effective methods.[48]

The use of LARC among women at risk for unintended pregnancy is increasing in the United States, but was only 8.5% in 2009,[24] compared with much higher rates in other developed countries.[24] National data show that, contrary to the evidence-based CDC recommendations on medical eligibility criteria for contraceptive use,[49] only 38% of physicians providing contraception in the United States offer intrauterine devices (IUDs) to adolescents, 53% to nulliparous women, and 25% immediately after abortion.[50,51] Women who do not use any form of contraception represent 10% of women at risk for unintended pregnancies, yet account for over half of the unintended pregnancies that occur annually.[1] Notably, the annual risk of pregnancy associated with nonuse of contraception is 85%.

Table 2. Contraceptive Effectiveness, Proportion Pregnant Over 1 Year of Use[1,44]

Contraceptive method	**Prefect use** (%)	**Typical use** (%)
Implant	0.05	0.05
Vasectomy	0.10	0.15
IUD, levonorgesterol-releasing	0.2	0.2
IUD, Copper-T	0.6	0.8
Tubal sterilization	0.5	0.5
Injectable	0.2	6
Pill	0.3	9
Vaginal ring	0.3	9
Patch	0.3	9
Diaphragm	6	12
Sponge*	9/20	12/24
Male condom	2	18
Withdrawal	4	22
Fertility awareness methods†	0.4-5	24
Spermicides	18	28
Emergency contraception‡	NA	NA
No method	85	85

*For sponge, first figure is for women who have not previously given birth and second is for women who have.
†Includes cervical mucus methods, body temperature methods, and periodic abstinence.
‡Effectiveness of emergency contraception is not measured on a 1-year basis like other methods; it is estimated to reduce the incidence of pregnancy by approximately 90% when used to prevent pregnancy after 1 instance of unprotected sex.
Abbreviations: IUD = intrauterine device

Table 3. Contraceptive Method Choice, U.S. Women 2012*

Method	Users, N	Women age 15-45 years (%)	Women at risk of unintended pregnancy (%)	Contraceptive user (%)
Pill	9,720,000	16.0	23.3	25.9
Tubal (female) sterilization	9,443,000	15.5	22.6	25.1
Male condom	5,739,000	9.4	13.7	15.3
IUD	3,884,000	6.4	9.3	10.3
Vasectomy	3,084,000	5.1	7.4	8.2
Withdrawl	1,817,000	3.0	4.4	4.8
Injectable	1,697,000	2.8	4.1	4.5
Fertility awareness-based methods	509,000	0.8	1.2	1.4
Implant	492,000	0.8	1.2	1.3
Patch	217,000	0.4	0.5	0.6
Emergency Contraception	91,000	0.2	0.2	0.2
Other methods†	133,000	0.2	0.3	0.4
No method, at risk of unintended‡ pregnancy	4,175,000	6.9	10.0	NA
No method, not at risk	19,126,000	31.4	NA	NA
Total	60,887,000	100.0	100.0	100.0

*Most effective method used in the past month by U.S. women.
†Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream, and other methods.
‡At risk refers to women who are sexually active; not pregnant, seeking to become pregnant, or postpartum; and not non-contraceptive sterile.
Abbreviations: IUD=intrauterine device; N=sample size.

Several national and professional organizations have issued recommendations for contraception use (**Table 4**). The United States Medical Eligibility Criteria for Contraceptive Use, 2016 (US MEC),[49,52] is adapted from the World Health Organization (WHO) medical eligibility criteria (MEC) 5th edition[53] and provides recommendations for contraceptive method safety and efficacy based on updated scientific evidence for women with a wide range of medical conditions.[49] These provide clinicians with comprehensive safety and prescribing guidelines for patients with comorbidities and potential contraindications to particular contraceptive methods.

The U.S. Selected Practice Recommendations for Contraceptive Use 2016 (U.S. SPR),[52] comprises recommendations that address a select group of common, yet sometimes controversial or complex issues regarding initiation and use of specific contraceptive methods, serve as a supplement to the MEC, and are specific to U.S. family planning practices.[54] The document offers guidance related to the use of contraceptives, including initiation, choice of method, follow-up criteria and testing prior to initiation of methods, with additional guidance on problems that may arise during use such as missed pills or unscheduled bleeding.[54]

The CDC recommendations for Providing Quality Family Planning Services (QFP) provide additional guidance on contraceptive counseling and provision for the full range of contraceptive methods,[55] with specific guidance for offering comprehensive contraceptive services. Some organizations, including the CDC, now recommend increasing access to LARC to reduce unintended pregnancy because of its high level of effectiveness.[23] The American Academy of Pediatrics (AAP) updated its policy statement in 2014 to emphasize that the first-line contraceptive choice for adolescents who choose not to be abstinent is a LARC method, specifically an intrauterine device or a subdermal implant.[56] In 2015, the American College of Obstetricians and Gynecologists (ACOG) strengthened its LARC recommendations to underscore LARC as the most effective reversible contraceptive option for most women, including nulliparous women and adolescents who are sexually active.[57]

Table 4. Recommendations of Professional Organizations[58]

American College of Obstetricians and Gynecologists (ACOG)[59]	Counseling on contraceptive options to prevent unwanted pregnancy, including emergency contraception, for women 13-39 years.
American Academy of Family Physicians (AAFP)[60]	Counseling for men and women to decrease the number of unwanted pregnancies, including abstinence information and prescriptions for routine contraception and emergency contraception.
American Academy of Pediatrics (AAP)[61]	Routine contraception and counseling for all adolescents regardless of sexual activity.
American Medical Association (AMA)[62]	Reducing unintended pregnancy through family planning and education, and discussing emergency contraception during routine contraceptive counseling.
Centers for Disease Control, U.S Office of Population affairs (CDC)[55]	Recommends contraceptive services to delay or prevent pregnancy. These include a full range of FDA-approved contraceptive methods, a brief assessment to identify the methods that are safe for the client, contraceptive counseling to help a client choose a method of contraception and use it correctly and consistently, and provision of one or more selected contraceptive method(s), preferably on site, but by referral if necessary. Education is an integral component of the contraceptive counseling process that helps clients to make informed decisions and obtain the information they need to use contraceptive methods correctly.

UPDATE OF EVIDENCE

Contraception is effective in preventing unintended pregnancy[1] and LARC methods have the highest efficacy in all patient populations. Data from California demonstrate a 47% reduction in the rate of adolescent pregnancy between 1992 and 2005, crediting accurate sexual education and increased access to family planning.[63] A statistical model estimating the number of women at risk for unintended pregnancy in Oregon if a similar approach to family planning were adopted determined that numbers would drop from >58,000 to <6,000.[64]

Contraceptive counseling provides an effective opportunity to discuss contraceptive options and emphasize patient-centered decision making.[2,3,65] A recent cluster randomized trial evaluating the effectiveness of a "contraceptive vital sign" in primary care demonstrated that primary care providers who routinely incorporated an evaluation of patients' contraceptive use or pregnancy intentions improved prescribing practices and were more likely to document effective contraceptive use when prescribing potentially teratogenic medication.[66] Contraceptive counseling in primary care may increase the uptake of hormonal methods and LARC,[67] although data on structured counseling in specialized reproductive health settings demonstrated no such effect.[2,3,65,68,69]

A randomized controlled trial conducted in California demonstrated higher continuation rates of oral contraceptives for patients who received a 7-month supply compared with a 3-month supply of oral pill packs (51% vs. 35%; OR 1.9, 95% CI 1.3 to 2.7). Continuation rates were also higher among participants receiving pill packs compared with those receiving a prescription (OR 1.5, 95% CI 1.1 to 2.4) regardless of age, education, parity, or insurance status.[6] An observational study, also from California, of data from publicly funded reproductive health programs found an association between women receiving a 1-year supply of oral contraceptive pill packages and a decrease in both unintended pregnancies and abortions[6,8] compared with women who received 3 or 1 cycle of pills. Improved continuation rates are also associated with use of LARC versus oral contraceptives[70] due to ease of use and efficacy.

A 2013 Cochrane review of strategies to improve contraceptive adherence and acceptability identified three trials demonstrating effectiveness of contraceptive adherence and continuation, while six other trials did not.[5] Two of three trials showing counseling effectiveness were conducted in the United States. Studies focused on oral contraceptives or injectables (DMPA), and, while hormonal contraceptives are the most popular forms of reversible contraception, patterns of typical use result in lower effectiveness compared to the high theoretical effectiveness of this method. Effective counseling methods to improve adherence were limited to the trials that combined intensive counseling and multiple contacts or reminders. Limitations of the review included variation in counseling strategies, small sample sizes, high loss to follow-up, and limited contraceptive types, as none examined counseling for users of the vaginal ring, implant, IUD, or levonorgestrel intrauterine system (LNG IUS).

The CHOICE project was a large scale U.S. study aimed at reducing unintended pregnancies by providing no-cost contraception and promoting the use of LARC methods. Notably there was no randomization or control group, but findings demonstrated a teenage birth rate of 6.3 per 1,000 among study participants compared with the national average of 34.3 per 1,000 over the same period. Among 9,256 adolescents and women ages 14

to 45 years at risk for unintended pregnancy who were offered no-cost contraception of any type, there was a significant reduction in the rate of abortion, repeat abortion, and teenage birth rates compared with regional and national rates ($p<0.001$).[2] Population based outcomes of teenage birth and repeat abortion were used as proxies for unintended pregnancies.

A cluster randomized trial across 40 clinics in the United States[71] investigated whether a clinic-level intervention could improve access to LARCs and reduce pregnancy rates among women age 18 to 25. Results demonstrated a lower pregnancy rate in the family planning intervention group who received counselling on IUDs or implants (565 [71%] of 797 vs 271 [39%] of 693, odds ratio 3.8, 95% CI 2.8 to 5.2) and more selecting LARC methods during the clinic visit (224 [28%] vs 117 [17%], 1.9, 1.3 to 2.8). There was a significant intervention effect on pregnancy rates in women attending family planning visits (hazard ratio 0.54, 95% CI 0.34 to 0.85).

CONCLUSIONS

The effectiveness of the full range of FDA-approved contraceptive methods for preventing or delaying pregnancy is well established. Effective comprehensive contraceptive care includes counseling, initiation, and follow-up. Contraceptive counseling and access to contraceptive methods is associated with increased contraceptive use and decreased unintended pregnancy rates. Long acting reversible contraceptive (LARC) methods are the most effective reversible contraceptive option for most women, including nulliparous women and adolescents who are sexually active. Counseling on LARC methods is associated with lower pregnancy rates and lower rates of abortion and repeat abortion. Providing an increased supply of oral contraceptives at initiation is associated with higher continuation rates and lower unintended pregnancy rates. Further research is needed to evaluate counseling approaches that promote uptake of the most effective contraceptive methods, reducing costs for women seeking contraception, and reducing barriers to access, especially among those at highest risk for unintended pregnancy.

REFERENCES

[1]Trussell J. Contraceptive failure in the United States. Contraception. 2011;83(5):397-404. doi: http://dx.doi.org/10.1016/j.contraception.2011.01.021. PMID: 21477680.

[2]Peipert JF, Madden T, Allsworth JE, et al. Preventing unintended pregnancies by providing no-cost contraception. Obstet Gynecol. 2012;120(6):1291-7. doi: http://dx.doi.org/10.1097/AOG.0b013e318273eb56. PMID: 23168752.

[3]Harper CC, Rocca CH, Thompson KM, et al. Reductions in pregnancy rates in the USA with long-acting reversible contraception: a cluster randomised trial. Lancet. 2015;386(9993):562-8. doi: http://dx.doi.org/10.1016/S0140-6736(14)62460-0. PMID: 26091743.

[4]Hagan JF, Shaw JS, Duncan PM. Bright Futures: Guidelines for health supervision of infants, children and adolescents, 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics: 2008. https://brightfutures.aap.org/bright%20Futures%20Documents/BF3%20pocket%20guide_final.pdf.

[5]Halpern V, Lopez LM, Grimes DA, et al. Strategies to improve adherence and acceptability of hormonal methods of contraception. Cochrane Database of Systematic Reviews. 2013;10:CD004317. doi: http://dx.doi.org/10.1002/14651858.CD004317.pub4. PMID: 24163097.

[6]O'Connell White K, Roca C, Westhoff CL. The impact of pack supply on oral contraceptive continuation: a randomized controlled trial. Contraception. 2010;82(2):185-6. doi: 10.1016/j.contraception.2010.04.034.

[7]Steenland MW, Rodriguez MI, Marchbanks PA, et al. How does the number of oral contraceptive pill packs dispensed or prescribed affect continuation and other measures of consistent and correct use? A systematic review. Contraception. 2013;87(5):605-10. doi: 10.1016/j.contraception.2012.08.004. PMID: 23040121.

[8]Foster DG, Hulett D, Bradsberry M, et al. Number of oral contraceptive pill packages dispensed and subsequent unintended pregnancies. Obstet Gynecol. 2011;117(3):566-72. doi: 10.1097/AOG.0b013e3182056309. PMID: 00006250-201103000-00008.

[9]Taylor D, James EA. An evidence-based guideline for unintended pregnancy prevention. JOGNN. 201;40(6):782-93. doi: http://dx.doi.org/10.1111/j.1552-6909.2011.01296.x. PMID: 22092349.

[10]Adler N, Adashi E, Aguilar-Gaxiola S, et al. Women's health research: progress, pitfalls, and promise Institute of Medicine's (IOM) committee on women's health research. The National Academies Press: Washington, D.C.: 2010. http://www.nationalacademies.org/hmd/Reports/2010/Womens-Health-Research-Progress-Pitfalls-and-Promise.aspx.

[11]IOM (institute of Medicine). Clinical preventive services for women: closing the gaps. Washington, DC: National Academies Press; 2011.

[12]U.S. Centers for Medicare & Medicaide Services. Birth control benefits. https://www.healthcare.gov/coverage/birth-control-benefits/. Accessed May 15, 2016.

[13]Zubik v. Burwell, No. 14–1418, 578 U.S. ___, slip op. at 3, 5 (2016) (per curiam).

[14]Tanne JH. Companies increasingly challenge health act's contraception provisions. BMJ. 2013;346:f281. doi: http://dx.doi.org/10.1136/bmj.f281. PMID: 23319581.

[15]Department of Health & Human Services. The Affordable Care Act is improving access to preventive services for millions of Americans. 2015. https://aspe.hhs.gov/sites/default/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf. Accessed May 11, 2016.

[16]Law A, Wen L, Lin J, et al. Are women benefiting from the Affordable Care Act? A real-world evaluation of the impact of the Affordable Care Act on out-of-pocket costs for contraceptives. Contraception. 2016;93(5):392-7. doi: http://dx.doi.org/10.1016/j.contraception.2016.01.008.

[17]Office of Population Affairs. Program requirements for Title X funded family planning projects. 2014. https://www.hhs.gov/opa/sites/default/files/program-requirements-for-title-x-funded-family-planning-projects.pdf. November 30, 2016.

[18]Mosher WD, Jones J, Abma JC. Intended and unintended births in the United States: 1982-2010. Natl Health Stat Report. 2012. (55):1-28. PMID: 23115878.

[19]Guttmacher Institute. Unintended pregnancy in the United States. 2016. https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states. Accessed May 15, 2016.

[20]Finer LB, Zolna MR. Declines in unintended pregnancy in the United States, 2008-2011. N Engl J Med. 2016;374(9):843-52. doi: 10.1056/NEJMsa1506575. PMID: 26962904.

[21]Finer LB, Henshaw SK. Disparities in rates of unintended pregnancy in the United States, 1994 and 2001. Perspect Sex Reprod Health. 2006;38(2):90-6. doi: 10.1363/psrh.38.090.06. PMID: 16772190.

[22]Finer LB, Zolna MR. Shifts in intended and unintended pregnancies in the United States, 2001-2008. Am J Public Health. 2014;104 Suppl 1:S43-8. doi: 10.2105/ajph.2013.301416. PMID: 24354819.

[23]Centers for Disease Control and Prevention. Unintended pregnancy prevention. 2015. http://www.cdc.gov/reproductivehealth/unintendedpregnancy/. Accessed May 15, 2015.

[24]Finer LB, Jerman J, Kavanaugh ML. Changes in use of long-acting contraceptive methods in the United States, 2007-2009. Fertil Steril. 2012;98(4):893-7. doi: 10.1016/j.fertnstert.2012.06.027. PMID: 22795639.

[25]Levi A, Dau KQ. Meeting the national health goal to reduce unintended pregnancy. JOGNN. 2011;40(6):775-81. doi: http://dx.doi.org/10.1111/j.1552-6909.2011.01292.x. PMID: 22092984.

[26]Office of Disease Prevention and Health Promotion. Family planning. 2010. https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning/objectives#4425. Accessed May 17, 2016.

[27]Johnson K, Posner SF, Biermann J, et al. Recommendations to improve preconception health and health care--United States. A report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. MMWR Recomm Rep. 2006;55(Rr-6):1-23. PMID: 16617292.

[28]Mayer JP. Unintended childbearing, maternal beliefs, and delay of prenatal care. Birth. 1997;24(4):247-52. PMID: 9460316.

[29]Orr ST, Miller CA, James SA, et al. Unintended pregnancy and preterm birth. Paediatr Perinat Epidemiol. 2000;14(4):309-13. PMID: 11101017.

[30]Barber JS, Axinn WG, Thornton A. Unwanted childbearing, health, and mother-child relationships. J Health Soc Behav. 1999;40(3):231-57. PMID: 10513146.

[31]Hellerstedt WL, Pirie PL, Lando HA, et al. Differences in preconceptional and prenatal behaviors in women with intended and unintended pregnancies. Am J Public Health. 1998;88(4):663-6. PMID: 9551015.

[32]Joyce TJ, Kaestner R, Korenman S. The effect of pregnancy intention on child development. Demography. 2000;37(1):83-94. PMID: 10748991.

[33]Gazmararian JA, Adams MM, Saltzman LE, et al. The relationship between pregnancy intendedness and physical violence in mothers of newborns. The PRAMS Working Group. Obstet Gynecol. 1995;85(6):1031-8. PMID: 7770250.

[34]Goodwin MM, Gazmararian JA, Johnson CH, et al. Pregnancy intendedness and physical abuse around the time of pregnancy: findings from the pregnancy risk assessment monitoring system, 1996-1997. PRAMS Working Group. Pregnancy Risk Assessment Monitoring System. Matern Child Health J. 2000;4(2):85-92. PMID: 10994576.

[35]Oberg E. Preventive services update. Integr Med (Encinitas). 2010;9(4):22-6.

[36]Frayne DJ, Verbiest S, Chelmow D, et al. Health care system measures to advance preconception wellness: consensus recommendations of the clinical workgroup of the National Preconception Health and Health Care Initiative. Obstet Gynecol. 2016;127(5):863-72. doi: 10.1097/aog.0000000000001379. PMID: 27054935.

[37]Moos MK. Preconceptional wellness as a routine objective for women's health care: an integrative strategy. J Obstet Gynecol Neonatal Nurs. 2003;32(4):550-6. PMID: 12903706.

[38]Wolff T, Witkop CT, Miller T, et al. U.S. Preventive Services Task Force evidence syntheses, formerly systematic evidence reviews. folic acid supplementation for the prevention of neural tube defects: an update of the evidence for the U.S. Preventive Services Task Force. 2009. PMID: 20722169.

[39]Landry DJ, Wei J, Frost JJ. Public and private providers' involvement in improving their patients' contraceptive use. Contraception. 2008;78(1):42-51. doi: 10.1016/j.contraception.2008.03.009. PMID: 18555817.

[40]Guttmacher Institute. Improving Contraceptive Use in the United States. 2008. https://www.guttmacher.org/report/improving-contraceptive-use-united-states. Accessed May 17, 2016.

[41]Hatcher RA. Contraceptive technology, 20th ed. [New York, N.Y.]: Ardent Media; 2011.

[42]Schindler AE. Non-contraceptive benefits of oral hormonal contraceptives. Int J Endocrinol Metab. 2013;11(1):41-7. doi: 10.5812/ijem.4158. PMID: 23853619.

[43]National Women's Law Center. The past and future in women's health: a ten-year review and the promise of the Affordable Care Act and other federal initiatives. Washington, DC; 2010. http://hrc.nwlc.org/past-and-future. Accessed May 17, 2016.

[44]Trussell J. Contraceptive efficacy. In: Hatcher R, Trussell J, Stewart F, et al., eds. Contraceptive technology eighteenth revised edition. New York: Ardent Media, 2004.

[45]Office of Disease Prevention and Health Promotion. Family Planning. 2010. https://www.healthypeople gov/2020/data-search/Search-the-Data?&f%5b0%5d=field_topic_area%3A3521. Accessed May 15, 2016.

[46]Centers for Disease Control and Prevention. National Ambulatory Medical Care Survey: 2010 Summary Tables. http://www.cdc.gov/nchs/data/ahcd/namcs_summary/2010_namcs_web_tables.pdf. Accessed November 30, 2016.

[47]Jones J, Mosher W, Daniels K. Current contraceptive use in the United States, 2006-2010, and changes in patterns of use since 1995. Natl Health Stat Report. 2012 (60):1-25. PMID: 24988814.

[48]Mosher WD, Jones J. Use of contraception in the United States: 1982-2008. Vital Health Stat 23. 2010 (29):1-44. PMID: 20939159.

[49]Centers for Disease Control and Prevention. United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2010. http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm. Accessed May 15, 2016.

[50]Harper CC, Henderson JT, Raine TR, et al. Evidence-based IUD practice: family physicians and obstetrician-gynecologists. Fam Med. 2012;44(9):637-45. PMID: 23027156.

[51]Harper CC, Stratton L, Raine TR, et al. Counseling and provision of long-acting reversible contraception in the US: national survey of nurse practitioners. Prev Med. 2013;57(6):883-8. doi: 10.1016/j.ypmed.2013.10.005. PMID: 24128950.

[52]Curtis K, Jatlaoui T, Tepper N, et al. U.S. selected practice recommendations for contraceptive use, 2016 (U.S. SPR). MMWR Recomm Rep. 2016;65(4):1-66. doi: http://dx.doi.org/10.15585/mmwr.rr6504a1.

[53]World Health Organization. Medical eligibility criteria for contraceptive use -- 4th ed. 2009. https://books.google.com/books?hl=en&lr=&id=pouTfH33wF8C&oi=fnd&pg=PP2&dq=Medical+Eligibility+Criteria+for+Contraceptive+Use+---+4th+ed.&ots=8W-UGSRozR&sig=fZOWvmPOKvpyIEJ-NujtrS6PjmJg#v=onepage&q=Medical%20Eligibility%20Criteria%20for%20Contraceptive%20Use%20--%204th%20ed.&f=false. November 30, 2016.

[54]U.S. Selected Practice Recommendations for Contraceptive Use, 2013: adapted from the World Health Organization selected practice recommendations for contraceptive use, 2nd edition. MMWR Recomm Rep. 2013;62(Rr-05):1-60. PMID: 23784109.

[55]Gavin L, Pazol K. Update: providing quality family planning services — recommendations from CDC and the U.S. Office of Population Affairs. MMWR Morb Mortal Wkly Rep. 2015;65:231-4. doi: http://dx.doi.org/10.15585/mmwr.mm6509a3.

[56]Ott MA, Sucato GS, Committee on Adolescence. Contraception for adolescents. Pediatrics. 2014;134(4):e1257-81. doi: http://dx.doi.org/10.1542/peds.2014-2300. PMID: 25266435.

[57]Committee Opinion No. 642: Increasing access to contraceptive implants and intrauterine devices to reduce unintended pregnancy. Obstet Gynecol. 2015;126(4):e44-8. doi: 10.1097/aog.0000000000001106. PMID: 26393458.

[58]Pickle S, Wu J, Burbank-Schmitt E. Prevention of unintended pregnancy: a focus on long-acting reversible contraception. Primary Care; Clinics in Office Practice. 2014;41(2):239-60. doi: http://dx.doi.org/10.1016/j.pop.2014.02.004. PMID: 24830607.

[59]American College of Obstetricians and Gynecologists. Well-woman care: assessments & recommendations. 2013. https://www.acog.org/-/media/Departments/Annual-Womens-Health-Care/Primary-and-Preventive-Care-ONLINE.pdf?dmc=1&ts=20160316T1529528590. November 30, 2016.

[60]American Academy of Family Physicians. Contraceptive advice. 2014. http://www.aafp.org/about/policies/all/contraceptive.html. Accessed May 15, 2016.

[61]American Academy of Pediatrics Committee on Adolescence, Blythe MJ, Diaz A. Contraception and adolescents. Pediatrics. 2007;120(5):1135-48. PMID: 17974753.

[62]AMA Women Physicians Congress. Policy compendium on issues relation to women physicians and women's health. Chicago: American Medical Association: 2013.

[63]Boonstra HD. Winning campaign: California's concerted effort to reduce its teen pregnancy rate. Guttmacher Policy Review. 2010;13(2):18-24.

[64]Burlone S, Edelman A, Dantas S, et al. Estimated cost savings with providing universal contraception in the state of Oregon. Contraception. 2010;82(2):190-1. doi: http://dx.doi.org/10.1016/j.contraception.2010.04.053.

[65]Dehlendorf C, Henderson JT, Vittinghoff E, et al. Association of the quality of interpersonal care during family planning counseling with contraceptive use. Am J Obstet Gynecol. 2016;215(1):78.e1-9. doi: 10.1016/j.ajog.2016.01.173. PMID: 26827879.

66Schwarz EB, Parisi SM, Williams SL, et al. Promoting safe prescribing in primary care with a contraceptive vital sign: a cluster-randomized controlled trial. Annals of family medicine. 2012;10(6):516-22. PMID: CN-00853650 UPDATE.

[67]Lee JK, Parisi SM, Akers AY, et al. The impact of contraceptive counseling in primary care on contraceptive use.[Erratum appears in J Gen Intern Med. 2011;26(7):822 Note: Borrerro, Sonya [corrected to Borrero, Sonya]]. Journal of General Internal Medicine. 2011;26(7):731-6. doi: http://dx.doi.org/10.1007/s11606-011-1647-3. PMID: 21301983.

[68]Simmons KB, Edelman AB, Li H, et al. Personalized contraceptive assistance and uptake of long-acting, reversible contraceptives by postpartum women: a randomized, controlled trial. Contraception. 2013;88(1):45-51. doi: http://dx.doi.org/10.1016/j.contraception.2012.10.037. PMID: 23218851.

[69]Langston AM, Rosario L, Westhoff CL. Structured contraceptive counseling--a randomized controlled trial. Patient Educ Couns. 2010;81(3):362-7. PMID: CN-00779150 UPDATE.

[70]Speidel JJ, Harper CC, Shields WC. The potential of long-acting reversible contraception to decrease unintended pregnancy. Contraception. 2008;78(3):197-200. doi: 10.1016/j.contraception.2008.06.001. PMID: 18692608.

[71]Harper CC, Rocca CH, Thompson KM, et al. Reductions in pregnancy rates in the USA with long-acting reversible contraception: a cluster randomised trial. The Lancet. 2015;386(9993):562-8. doi: 10.1016/S0140-6736(14)62460-0.

Screening for Gestational Diabetes Mellitus

Clinical Recommendations

The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity.

The Women's Preventive Services Initiative suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.

Implementation Considerations

The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation to prevent adverse birth outcomes. Risk factors for diabetes mellitus that may help identify women for early screening include, but are not limited to, those identified by the Institutes of Medicine (now National Academies of Sciences, Engineering, and Medicine). The optimal test for screening prior to 24 weeks of gestation is not known. However, acceptable modalities may include a 50-g oral glucose challenge test, a 2-hour 75-g oral glucose tolerance test, a hemoglobin A1c test, a random plasma glucose test, or a fasting plasma glucose test. If early screening is normal, screening with a 50-g oral glucose challenge test should be conducted at 24 to 28 weeks of gestation as described above.

EVIDENCE MAP

Screen pregnant women for gestational diabetes mellitus (GDM) after 24 weeks of gestation, preferably between 24 and 28 weeks of gestation, in order to prevent adverse birth outcomes.

Systematic Reviews	Additional Studies	USPSTF
2013 USPSTF review of 5 RCTs and 6 cohort studies compared diet modification, glucose monitoring, and insulin as needed with no treatment.[1] Treatment of GDM reduced shoulder dystocia, macrosomia, and preeclampsia.	None	USPSTF[2]: screening for gestational diabetes mellitus (GDM) in asymptomatic pregnant women after 24 weeks of gestation. (Level B; 2014)

Screening with the 50-g oral glucose challenge test (OCT), followed by the 3-hour 100-g oral glucose tolerance test (OGTT) for women with abnormal results on the initial OCT, is preferred because of its high sensitivity and specificity.

Systematic Reviews	Additional Studies	USPSTF
2013 USPSTF review of 51 cohort studies of screening tests for GDM (50 g OGCT, fasting glucose, HbA1c) indicated highest sensitivity and specificity for the 50 g OGCT at either the 130 mg/dL or 140 mg/dL threshold).[3]	None	USPSTF: not specifically addressed in recommendation.

Women with risk factors for diabetes mellitus should be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit.

Systematic Reviews	Additional Studies	USPSTF
None	None; studies are ongoing.	USPSTF[2]: Current evidence is insufficient to assess the balance of benefits and harms of screening for GDM in asymptomatic pregnant women before 24 weeks of gestation. (Level I; 2014)

Evidence map continued on page 99.

The optimal test for screening prior to 24 weeks of gestation is not known; acceptable modalities may include a 50-g oral glucose challenge test, a 2-hour 75-g oral glucose tolerance test, a hemoglobin A1c test, a random plasma glucose test, or a fasting plasma glucose test.		
Systematic Reviews	**Additional Studies**	**USPSTF**
None	None	Not addressed
Appropriate diabetes care (e.g., diet modification, glucose monitoring, counseling, education, and medication) for women diagnosed with diabetes mellitus or gestational diabetes mellitus are necessary to achieve optimal outcomes for both the mother and infant.		
Systematic Reviews	**Additional Studies**	**USPSTF**
2013 USPSTF review of 5 RCTs and 6 cohort studies compared diet modification, glucose monitoring, and insulin as needed with no treatment.[1] Treatment of GDM reduced shoulder dystocia, macrosomia, and preeclampsia.	Postprandial glucose levels are predictive for adverse fetal outcomes.[4] Adherence with insulin therapy is higher for patients enrolled in insurance plans with reduced or no co-payments for insulin.[5,6]	USPSTF: not specifically addressed in recommendation.

Abbreviations: ACA=Affordable Care Act, AAFP=American Academy of Family Physicians, AAP=American Academy of Pediatrics, ADA=American Diabetes Association, ACOG=American College of Obstetricians and Gynecologists, BMI=body mass index, GDM=gestational diabetes mellitus, HbA1c=hemoglobin A1c, IADPSG=International Association of the Diabetes and Pregnancy Study Groups, IOM=Institute of Medicine, OGCT=oral glucose challenge test, OGTT=oral glucose tolerance test, USPSTF=U.S. Preventive Services Task Force

SUMMARY OF EVIDENCE

Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance detected during pregnancy. GDM increases risk for maternal and fetal complications including preeclampsia,[7] fetal macrosomia causing shoulder dystocia and birth injury, and neonatal hypoglycemia.[8] Women diagnosed with GDM have increased risk for developing type 2 diabetes mellitus after pregnancy.[9] Screening for GDM is a long-established part of prenatal care that typically involves an oral glucose test administered after 24 weeks gestation.[10]

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 previously identified by the Institute of Medicine (IOM) Committee was that screening for GDM was not included.[11] In 2014, the U.S. Preventive Services Task Force (USPSTF) issued recommendations for screening for GDM in asymptomatic women after 24 weeks of gestation, but determined that evidence was insufficient to support screening earlier in pregnancy (**Table 1**).[2]

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

IOM Committee[11]	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.*
USPSTF[2]	Screening for gestational diabetes mellitus in asymptomatic pregnant women after 24 weeks of gestation (B recommendation; 2014).

*The IOM report described risk factors that have been associated with the development of GDM during pregnancy including history of GDM in a prior pregnancy, previous delivery of a large for gestational age infant, obesity, strong immediate family history of type 2 diabetes or GDM, and a history of unexplained fetal death.[11]
Abbreviations: IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

Background

In 2010, the prevalence of GDM in the United States was reported as 4.6% on birth certificates, 8.7% on the Pregnancy Risk Assessment Monitoring System (PRAMS) questionnaire, and 9.2% by either source.[12] Prevalence is higher among certain racial/ethnic groups including black, Asian, Hispanic, and Native American women compared with white women. Risk factors for GDM include older maternal age, history of GDM in a prior pregnancy, previous delivery of a large for gestational age infant, obesity, strong immediate family history of type 2 diabetes or GDM, and a history of unexplained fetal death.[11]

GDM is associated with adverse health effects for pregnant women as well as their infants. GDM increases risk for gestational hypertension, preeclampsia, and cesarean delivery;7 and for developing diabetes later in life.[9] Approximately 15% to 60% of women with GDM develop type 2 diabetes within 5 to 15 years of delivery.[13] Effects of GDM on infants include macrosomia causing shoulder dystocia and birth trauma, and neonatal hypoglycemia.[8]

Screening for GDM has been an established part of prenatal care in the United States since the 1970s and is commonly performed at 24 to 28 weeks gestation. Several professional organizations have issued screening recommendations (**Table 2**).

Table 2. Recommendations of Professional Organizations

American College of Obstetricians and Gynecologists (ACOG)[10]	All pregnant patients should be screened for GDM, whether by the patient's medical history, clinical risk factors, or laboratory screening test results to determine blood glucose levels. Screening is generally performed at 24-28 weeks of gestation. Early pregnancy screening is also suggested in women with risk factors (previous GDM, known impaired glucose metabolism, BMI ≥30); if GDM is not diagnosed, testing should be repeated at 24-28 weeks of gestation.
American Academy of Family Physicians (AAFP)[14]	Pregnant women without known diabetes mellitus should be screened for GDM after 24 weeks of gestation.
American Diabetes Association (ADA)[15]	Screening is recommended at 24-28 weeks in women who were not previously diagnosed with overt diabetes.
Endocrine Society[16]	Recommends universal testing for diabetes with a fasting plasma glucose, HbA1c, or an untimed random plasma glucose at the first prenatal visit (before 13 weeks gestation or as soon as possible thereafter) for women not known to already have diabetes.

Abbreviations: BMI=body mass index; GDM=gestational diabetes mellitus; HbA1c=hemoglobin A1c; USPSTF=U.S. Preventive Services Task Force

The two-step approach to testing is most commonly used and is endorsed by the American College of Obstetricians and Gynecologists (ACOG).[10] This involves the administration of 50 g of an oral glucose solution followed by a 1-hour venous glucose test. Women meeting or exceeding the screening threshold (130-140 mg/dL) then undergo a 100 g 3-hour diagnostic oral glucose tolerance test. Although the two-step method uses a standard protocol, results are variable because diagnostic thresholds differ. The one-step method proposed by the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) uses a 75 g 2-hour oral glucose tolerance test. The diagnosis of GDM is determined when various threshold values are met.[17] While this method has been endorsed by the American Diabetes Association, a higher proportion of women are diagnosed with GDM using the one-step compared with the two-step method, and the effectiveness of treatment based on one-step diagnostic criteria is not known.

Treatment for GDM includes nutrition therapy, exercise, and glucose monitoring supplemented by pharmacologic therapy when glucose levels exceed targets. While preprandial glucose levels are monitored in nonpregnant adults with diabetes, postprandial levels are obtained in pregnant women with GDM because they are more predictive for adverse fetal outcomes.[4] Threshold levels of 140 mg/dL at 1 hour postprandial or 120 mg/dL at 2 hours postprandial are recommended.[18] Insulin, which does not cross the placenta, is the standard

pharmacologic treatment for GDM. Although oral hypoglycemic medications have demonstrated effective glycemic control in women with GDM, they are not approved by the U.S. Food and Drug Administration (FDA) for this purpose.

UPDATE OF EVIDENCE

A systematic review of screening and treatment for GDM was conducted for a National Institutes of Health Consensus Development Conference on Diagnosis of Gestational Diabetes Mellitus in 2013 and was used to update the USPSTF's clinical recommendations in 2014.[1,3]

Performance of Screening Tests

Data from 51 cohort studies were used to calculate the performance characteristics of screening tests including the 50 g oral glucose challenge test (OGCT), fasting plasma glucose levels, and hemoglobin A1c (HbA1c).[3] Studies used various screening thresholds for the initial test and various criteria for the diagnostic oral glucose tolerance test. Diagnostic criteria included the American Diabetes Association (ADA), Carpenter-Coustan (CC), Canadian Diabetes Association (CDA), IADPSG, National Diabetes Data Group (NDDG), and World Health Organization (WHO). Results indicated the highest sensitivity and specificity values for the 50 g OGCT at either the 130 mg/dL or 140 mg/dL threshold, which is the current standard of care in the United States (**Table 3**). Sensitivity and specificity values varied across diagnostic criteria, although the numbers of studies for each set of criteria also varied. Results for the fasting plasma glucose test indicated more variability in sensitivity and specificity than the OGCT, while HbA1c levels had poorer test characteristics than either OGCT or fasting plasma glucose.

Table 3. Summary of Studies of Test Characteristics of Screening Tests for GDM

Screening Test	Threshold	Diagnostic critera	Studies, N	Sensitivity; specificity (%)
50 g OGCT	130 mg/dL	CC	6	99; 77
		NDDG	3	88; 66
	140 mg/dL	CC	9	85; 86
		ADA	3	88; 84
		NDDG	7	85; 83
		CDA	1	81; 69
		WHO	3	70; 89
Fasting glucose	85 mg/dL	CC	4	87; 52
	90 mg/dL	CC	4	77; 76
	92 mg/dL	CC	3	76; 92
	95 mg/dL	CC	5	54; 93
HbA1c	5.0%	CC	1	92; 28
	5.3%	IADPSG	1	12; 97
	5.5%	ADA	1	86; 61
	7.5%	ADA	1	82; 21

Abbreviations: ADA=American Diabetes Association; CC=Carpenter-Coustan; CDA=Canadian Diabetes Association; IADPSG=International Association of the Diabetes and Pregnancy Study Groups; HbA1c=hemoglobin A1c; n=sample size; NDDG=National Diabetes Data Group; OGCT=oral glucose challenge test; WHO=World Health Organization

Benefits and Harms of Treating GDM

Five randomized trials and six cohort studies compared diet modification, glucose monitoring, and insulin as needed with no treatment.[1] Only three outcomes associated with GDM were reduced with treatment. These included shoulder dystocia (risk ratio [RR] 0.42, 95% confidence interval [CI] 0.23 to 0.77, 3 trials); macrosomia (birthweight >4000 g) (RR 0.50, 95% CI 0.35 to 0.71, 5 trials); and preeclampsia (RR 0.62, 95% CI 0.43 to 0.89, 3 trials). No differences were found for neonatal hypoglycemia, cesarean delivery, small-for-gestational-age neonates, induction of labor, or admission to a neonatal intensive care unit, although studies were limited for most outcomes. Evidence was insufficient for maternal weight gain, birth injury, and long-term metabolic outcomes among offspring. No studies evaluated screening earlier than 24 weeks gestation or among high-risk women specifically.

Although there is limited evidence for GDM screening at less than 24 weeks' gestation, there is clinical justification for early screening in women at high risk for overt diabetes. The highest increase in prevalence of

diabetes has occurred in women of reproductive age 69, and the highest perinatal mortality rates of all forms of maternal diabetes occur in women with overt diabetes diagnosed during pregnancy[70].

Adherence to Treatment

A systematic review of factors affecting adherence to insulin therapy included 17 studies of patients with diabetes mellitus.[19] None of the studies specifically enrolled women with GDM, although treatment is similar regardless of pregnancy status. Results indicated that adherence to insulin therapy is generally poor, especially for women. Adherence was higher for patients using a pen devise rather than vial/syringe method of insulin administration. In two studies conducted in the U.S., adherence improved when patients were enrolled in insurance plans with reduced or no co-payments for insulin.[5,6] These findings are consistent with results from another review of 66 studies from Canada and the U.S. indicating that increasing the patient share of medication costs for a number of medical conditions was associated with lower adherence.[20]

CONCLUSIONS

Gestational diabetes mellitus increases risk for maternal and fetal complications including preeclampsia, fetal macrosomia causing shoulder dystocia and birth injury, and neonatal hypoglycemia. Women with GDM can be identified through screening. A comprehensive review of screening tests for GDM (50 g OGCT, fasting glucose, HbA1c) indicates highest sensitivity and specificity for the 50 g OGCT at either the 130 mg/dL or 140 mg/dL threshold. Treatment of GDM with diet modification, glucose monitoring, and insulin reduces shoulder dystocia, macrosomia, and preeclampsia compared to no treatment in RCTs and cohort studies. Available studies focus exclusively on screening and treatment for GCM after 24 weeks gestation and the effectiveness of screening earlier in pregnancy is not clear.

REFERENCES

[1]Hartling L, Dryden DM, Guthrie A, et al. Benefits and harms of treating gestational diabetes mellitus: a systematic review and meta-analysis for the U.S. Preventive Services Task Force and the National Institutes of Health Office of Medical Applications of Research. Ann Intern Med. 2013;159(2):123-9. doi: 10.7326/0003-4819-159-2-201307160-00661. PMID: 23712381.

[2]Moyer VA. Screening for gestational diabetes mellitus: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2014;160(6):414-20. doi: 10.7326/m13-2905. PMID: 24424622.

[3]Donovan L, Hartling L, Muise M, et al. Screening tests for gestational diabetes: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2013;159(2):115-22. doi: 10.7326/0003-4819-159-2-201307160-00657. PMID: 23712349.

[4]de Veciana M, Major CA, Morgan MA, et al. Postprandial versus preprandial blood glucose monitoring in women with gestational diabetes mellitus requiring insulin therapy. N Engl J Med. 1995;333(19):1237-41. doi: 10.1056/nejm199511093331901. PMID: 7565999.

[5]Nair KV, Miller K, Saseen J, et al. Prescription copay reduction program for diabetic employees: impact on medication compliance and healthcare costs and utilization. Am Health Drug Benefits. 2009;2(1):14-24. PMID: 25126268.

[6]Chang A, Liberman J, Coulen C, et al. Value-based insurance design and antidiabetic medication adherence. Am J Pharm Benefits. 2010;2(6).

[7]Yogev Y, Xenakis EM, Langer O. The association between preeclampsia and the severity of gestational diabetes: the impact of glycemic control. Am J Obstet Gynecol. 2004;191(5):1655-60. doi: 10.1016/j.ajog.2004.03.074. PMID: 15547538.

[8]Metzger BE, Lowe LP, Dyer AR, et al. Hyperglycemia and adverse pregnancy outcomes. N Engl J Med. 2008;358(19):1991-2002. doi: 10.1056/NEJMoa0707943. PMID: 18463375.

[9]England LJ, Dietz PM, Njoroge T, et al. Preventing type 2 diabetes: public health implications for women with a history of gestational diabetes mellitus. Am J Obstet Gynecol. 2009;200(4):365.e1-8. doi: 10.1016/j.ajog.2008.06.031. PMID: 18691691.

[10]Committee on Practice Bulletins-Obstetrics. Practice Bulletin No. 137: Gestational diabetes mellitus. Obstetrics & Gynecology. 2013;122(2 Pt 1):406-16. doi: http://dx.doi.org/10.1097/01.AOG.0000433006.09219.f1. PMID: 23969827.

[11]IOM (institute of Medicine). Clinical preventive services for women: Closing the gaps. Washington, DC: National Academies Press; 2011.

[12]DeSisto CL, Kim SY, Sharma AJ. Prevalence estimates of gestational diabetes mellitus in the United States, Pregnancy Risk Assessment Monitoring System (PRAMS), 2007-2010. Prev Chronic Dis. 2014;11:E104. doi: 10.5888/pcd11.130415. PMID: 24945238.

[13]Kim C, Newton KM, Knopp RH. Gestational diabetes and the incidence of type 2 diabetes: a systematic review. Diabetes Care. 2002;25(10):1862-8. PMID: 12351492.

[14]Garrison A. Screening, diagnosis, and management of gestational diabetes mellitus. Am Fam Physician. 2015;91(7):460-7. PMID: 25884746.

[15]American Diabetes Association. Standards of medical care in diabetes—2016. Diabetes Care. 2016;39 (Suppl 1):S1-S106.

[16]Blumer I, Hadar E, Hadden DR, et al. Diabetes and pregnancy: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2013;98(11):4227-49. doi: 10.1210/jc.2013-2465. PMID: 24194617.

[17]Metzger BE, Gabbe SG, Persson B, et al. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care. 2010;33(3):676-82. doi: 10.2337/dc09-1848. PMID: 20190296.

[18]Basevi V, Di Mario S, Morciano C, et al. Comment on: American Diabetes Association. standards of medical care in diabetes--2011. Diabetes Care 2011;34(Suppl. 1):S11-S61. Diabetes Care. 2011;34(5):e53; author reply e4. doi: 10.2337/dc11-0174. PMID: 21525493.

[19]Davies MJ, Gagliardino JJ, Gray LJ, et al. Real-world factors affecting adherence to insulin therapy in patients with type 1 or type 2 diabetes mellitus: a systematic review. Diabet Med. 2013;30(5):512-24. doi: 10.1111/dme.12128. PMID: 23323988.

[20]Eaddy MT, Cook CL, O'Day K, et al. How patient cost-sharing trends affect adherence and outcomes: a literature review. P t. 2012;37(1):45-55. PMID: 22346336.

Screening for Human Immunodeficiency Virus Infection

Clinical Recommendations

The Women's Preventive Services Initiative recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan. All women should be tested for HIV at least once during their lifetime. Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection.

Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service for women, prevention education and risk assessment for HIV infection in adolescents and women at least annually throughout the lifespan. More frequent screening for high-risk women, as determined by clinical judgment, is also recommended as a preventive service. Annual or more frequent HIV testing may be needed and is recommended as a preventive service for women who are identified or self-identify as high risk.

This recommendation refers to routine HIV screening, which is different from incident-based or exposure-based HIV testing. Risk factors for HIV infection in women include, but are not limited to, being an active injection drug user; having unprotected vaginal or anal intercourse; having multiple sexual partners; initiating a new sexual relationship; having sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; being a victim of sex trafficking; being incarcerated (currently or previously); and having other sexually transmitted infections.

Approximately 20–26% of infected patients are not identified by risk-based screening. Early detection and treatment improves outcomes for patients and reduces transmission; therefore, based on clinical best practice, screening annually or more frequently may be reasonable.

EVIDENCE MAP

Prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan.

Systematic Reviews	Additional Studies	USPSTF; Bright Futures
• 2013 USPSTF review on HIV[1]: no studies evaluated the effect of counseling interventions on transmission risk for HIV. • 2014 USPSTF review of 31 trials[2]: counseling was effective for promoting safer sexual practices and reducing STIs in general. • Systematic review of 13 meta-analyses and systematic reviews[3]: behavioral counseling was effective for promoting safer sexual practices and reducing STIs in general. • Systematic review of 31 trials[4]: brief sexuality communication showed some effect for promoting safer sexual practices and reducing STIs in general.	No studies specific to HIV: • Reduced sexual risk taking behaviors after various behavioral interventions in adolescents was reported in 2 RCTs.[5-7] • A brief sexuality intervention had no effect on safer sexual practices and reducing STIs versus a brief general health intervention in one RCT.[8] No studies on optimal intervals for prevention education and risk assessment for HIV infection.	• USPSTF[9]: The USPSTF recommends high-intensity behavioral counseling to prevent STIs for all sexually active adolescents and for adults at increased risk for infection. HIV counseling is included in this general recommendation. (Level B; 2013) • Bright Futures[10]: Risk reduction for STIs should be discussed in adolescent visits as part of routine health supervision. Anticipatory guidance should include discussions about sexuality and healthy sexual development and provide an opportunity for risk screening, health promotion, counseling, and sex education.

All women should be tested for HIV at least once during their lifetime.

Systematic Reviews	Additional Studies	USPSTF; Bright Futures
2013 USPSTF review[1]: • No studies comparing screening versus no screening reported clinical outcomes. • No studies compared different screening strategies (e.g. risk-based screening versus routine screening). *Continued on page 119*	One RCT found initiation of treatment for HIV infection at CD4 counts of >0.500 x 109 cells/L reduced risk of a composite endpoint that included death and serious AIDS-related and serious non-AIDS-related events (HR 0.43, 95% CI 0.30 to 0.62) compared with initiation of treatment at CD4 counts of 0.350 x 109 cells/L.[11]	• USPSTF[9]: Screen for HIV infection in adolescents and adults aged 15-65 years. Younger adolescents and older adults who are at increased risk should also be screened. (Level A; 2013) • Bright Futures[10]: Screen all sexually active high-risk teens for HIV at least once a year. High-risk teens include, but are not limited to, STI clinic patients, youth in detention centers, and injection drug users.

Evidence map continued on page 109.

Systematic Reviews	Additional Studies	USPSTF; Bright Futures
• 1 RCT and 6 observational studies found a significant reduction in risk of HIV transmission with early treatment compared with delayed treatment. 2 RCTs and 5 observational studies consistently found early treatment of HIV infection significantly reduced risk of death/AIDS-related morbidity compared with delayed treatment.		
Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection.		
Systematic Reviews	**Additional Studies**	**USPSTF; Bright Futures**
2013 USPSTF review1: no studies compared the yield of repeated HIV screening with one-time screening.	None	USPSTF9: Evidence is insufficient to determine optimum time intervals for HIV screening. A reasonable approach may be to rescreen groups at very high risk (e.g., injection drug users) for new HIV infection at least annually and individuals at increased risk at somewhat longer intervals (for example, 3-5 years). Routine rescreening may not be necessary for individuals not at increased risk since they were found to be HIV-negative.

Evidence map continued on page 110.

Risk factors for HIV infection in women include, but are not limited to, being an active injection drug user; having unprotected vaginal or anal intercourse; having multiple sexual partners; initiating a new sexual relationship; having sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; being a victim of sex trafficking; being incarcerated (currently or previously); and having other sexually transmitted infections.

Systematic Reviews	Additional Studies	USPSTF; Bright Futures
None	Risk factors based on CDC surveillance reports.[12]	• USPSTF[9]: High risk includes active injection drug use; having unprotected vaginal or anal intercourse; having sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; acquiring or requesting testing for other sexually transmitted infections (STIs). • Bright Futures[10]: High-risk teens include, but are not limited to, STI clinic patients, youth in detention centers, and injection drug users.

Abbreviations: ACA=Affordable Care Act, AIDS=acquired immunodeficiency syndrome, CD4=cluster of differentiation 4 glycoprotein, CDC=Centers for Disease Control and Prevention, CI=confidence interval, HIV=human immunodeficiency virus, HR=hazard ratio, IOM=Institute of Medicine, L=liter, RCT=randomized controlled trial, STI=sexually transmitted infection, USPSTF=U.S. Preventive Services Task Force

SUMMARY OF EVIDENCE

This summary of evidence does not include screening for pregnant women, which is covered under previous recommendations of the U.S. Preventive Services Task Force (USPSTF).

Introduction

Human immunodeficiency virus (HIV) causes infection leading to acquired immunodeficiency syndrome (AIDS) if untreated. AIDS is characterized by progressive failure of the immune system resulting in life-threatening infections and cancer. HIV cannot be cured, but can be controlled with antiretroviral therapy which can prolong life and reduce transmission to others, particularly when used during early stages of infection. Screening for HIV infection detects individuals who are unaware of their infection and would otherwise miss the opportunity to benefit from early therapy.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) Committee was that screening was limited

to pregnant women and high-risk adolescents and adults. The IOM Committee recommended expanding this scope to annual counseling and screening for HIV infection for all sexually active women (**Table 1**).[13]

In 2013, the USPSTF updated its recommendation for HIV screening to include all adolescents and adults aged 15 to 65 years; and younger adolescents and older adults who are at increased risk.[9] Individuals at increased risk include men who have sex with men; active injection drug users; those with sexually transmitted infections; having unprotected vaginal or anal intercourse; having sexual partners who are HIV-infected, bisexual, or injection drug users; and exchanging sex for drugs or money. Screening for pregnant women is also included under this USPSTF recommendation. An update began in late 2016.

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

IOM Committee[13]	Annual counseling and screening for HIV infection for sexually active women. HIV counseling is also included under a separate recommendation for STI counseling.
USPSTF[1,9]	• HIV screening for adolescents and adults aged 15 to 65 years and younger adolescents and older adults who are at increased risk (Level A; 2013). • HIV screening for all pregnant women, including those who present in labor who are untested and whose HIV status is unknown (Level A; 2013).
Bright Futures[10]	Screening all sexually active high-risk teens for HIV at least once a year. High-risk teens include, but are not limited to, STI clinic patients, youth in detention centers, men who have sex with men, and injection drug users.

Abbreviations: HIV=human immunodeficiency virus; IOM=Institute of Medicine; STI=sexually transmitted infection; USPSTF=U.S. Preventive Services Task Force

Background

An estimated 1.2 million individuals age 13 years and older were living with HIV infection in the United States in 2012, including 156,300 (12.8%) whose infections had not been diagnosed.[14] In 2014, the estimated number of new HIV diagnoses in the United States was 44,073. These included an estimated 35,571 diagnoses among adult and adolescent males (13 years or older), 8,328 among adult and adolescent females, and 174 among children younger than 13 years.[15] Among women with HIV infection, 74% of infections are attributed to heterosexual contact and the reminder to injection drug use.[9,16] Adults age 20 to 29 years accounted for the most new cases of infection (15,738) among different age groups. Blacks accounted for the most (44%) new cases among racial/ethnic groups, with whites accounting for 27% and Hispanics 23%. HIV infection among men who have sex with men accounted for 63% of new HIV diagnoses.[12]

Risk factors for HIV infection in women include active injection drug use; unprotected vaginal or anal intercourse; sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; and having other sexually transmitted infections. However, women may not be aware of their sexual partner's HIV risk. Primary prevention involves behavioral counseling to prevent STIs and condom use.

Several tests are approved for screening including the conventional serum test (reactive immunoassay followed by confirmatory Western blot or immunofluorescent assay); rapid HIV test using blood or oral fluid specimens; combination tests (p24 antigen and HIV antibodies); and qualitative HIV-1 RNA. Tests are highly sensitive and specific. Clinical progression and disease transmission can be reduced with effective combined antiretroviral therapy using three or more antiretroviral agents, immunizations, and prophylaxis for opportunistic infections.

Several professional organizations have issued recommendations for screening (**Table 2**).

Table 2. Recommendations of Professional Organizations

American College of Obstetricians and Gynecologists (ACOG)[17]	Females age 13 to 64 years be tested at least once in their lifetime and annually thereafter based on factors related to risk. Obstetrician–gynecologists should annually review patients' risk factors for HIV and assess the need for retesting. Repeat HIV testing should be offered at least annually to women who are injection drug users or sex partners of injection-drug users; exchange sex for money or drugs; are sex partners of HIV-infected persons; have had sex with men who have sex with men since the most recent HIV test; have had more than one sex partner since their most recent HIV test.
American Academy of Family Physicians (AAFP)[18]	Screen adolescents and adults ages 18 to 65 years for HIV infection. Younger adolescents and older adults who are at increased risk should also be screened. Screen all pregnant women for HIV, including those who present in labor whose HIV status is unknown.
American College of Physicians (ACP)[19]	Clinicians adopt routine screening for HIV and encourage patients to be tested; clinicians determine the need for repeat screening on an individual basis.
Centers for Disease Control and Prevention (CDC)[20]	Diagnostic HIV testing and opt-out HIV screening as a part of routine clinical care in all health-care settings for women age 13 to 64 years, while also preserving the patient's option to decline HIV testing and ensuring a provider-patient relationship conducive to optimal clinical and preventive care. The guidelines address HIV testing in health-care settings only; they do not modify existing guidelines concerning HIV counseling, testing, and referral for persons at high risk for HIV who seek or receive HIV testing in nonclinical settings.

Abbreviations: HIV=human immunodeficiency virus

Update of Evidence

A systematic review of screening for HIV was used to update the USPSTF's clinical recommendations in 2013.[1,9] This review focused on the effectiveness universal versus targeted HIV screening; the yield of repeated versus one-time screening; the effectiveness of antiretroviral therapy (ART) on clinical outcomes for individuals with early infections and on sexual transmission of HIV; and harms of ART. Clinical outcomes of interest included HIV transmission, AIDS-related events, mortality; and risk of cardiovascular harms associated with long-term (≥2 years) ART use. The updated literature search for the WPSI identified one RCT published since the 2013

USPSTF review that is relevant to screening.[11] Studies of behavioral counseling to prevent STIs in general (i.e., that are not specific to HIV) are described in the Counseling for Sexually Transmitted Infections Evidence Summary.

Effectiveness of Screening

The 2013 USPSTF review found no studies comparing clinical outcomes between adults and adolescents that were screened versus not screened for HIV infection or comparing the yield of repeated HIV screening with one-time screening.

Effectiveness of Counseling on Transmission Risk

The 2013 USPSTF review found no studies that evaluated the effects of counseling interventions on transmission risk.

Effectiveness of ART in Reducing Sexual Transmission

One RCT (n=1,763 primarily heterosexual, married couples) found that immediate ART in persons with a baseline CD4 count of 0.350 to 0.550 x 109 cells/L was associated with substantially lower risk for HIV transmission than delaying therapy until CD4 count was less than 0.250 x 109 cells/L (hazard ratio [HR] 0.04, 95% CI 0.01 to 0.27).[21] Pooled results from six observational studies were consistent with the RCT (pooled HR 0.16, 95% CI 0.07 to 0.35.)

Effectiveness of ART in Early Infections

The 2013 USPSTF review included one randomized controlled trial (RCT) and a subgroup analysis from another RCT that found that initiating ART at CD4 counts less than 0.250 x 109 cells/L was associated with higher risk for death or AIDS events than initiation at CD4 counts greater than 0.350 x 109 cells/L (HR 1.7, 95% CI 1.1 to 2.5 and HR 5.3, 95% CI 1.3 to 9.6.)[16] Four large observational studies also found that initiating ART at CD4 counts between 0.350 and 0.500 x 109 cells/L was associated with significantly lower risk for death than deferred or no ART, and a fifth observational study reported similar results, although the reduction in risk was not statistically significant. Four studies on initiation of ART at CD4 counts greater than 0.500 x 109 cells/L did not consistently demonstrate clinical benefits.

One RCT published since the 2013 USPSTF review (n=4,685) compared initiation of ART at CD4 counts greater than 0.500 x 109 cells/L with delayed initiation at CD4 counts of 0.350 x 109 cells/L.[11] The study found early initiation with ART significantly reduced risk of serious AIDS-related events (HR 0.28, 95% CI 0.15 to 0.50) and risk of a composite endpoint that included death, serious AIDS-related and serious non-AIDS-related events (HR 0.43, 95% CI 0.30 to 0.62.) All-cause mortality was also reduced, although the number of deaths in both groups was small (0.5% versus 0.9%) and the risk estimate was not statistically significant (HR 0.58, 95% CI 0.28 to 1.17.)

Harms of ART

Additional follow-up from a large cohort study found that some protease inhibitors were associated with increased risk for myocardial infarction (RR 1.1 to 1.2 per year of exposure).[22] No clear association was shown between other antiretrovirals and increased risk for cardiovascular events, and the newer antiretrovirals are believed to not be associated with the cardiometabolic effects of the older regimens.

CONCLUSIONS

Screening for HIV infection detects individuals who are unaware of their infection and would otherwise miss the opportunity to benefit from early therapy. New studies of antiretroviral therapy indicate significantly reduced risks of serious AIDS-related events and death, as well as disease transmission, when treatment is initiated early in the infection. In addition, there are fewer adverse effects with the newer antiretroviral medications. This research strengthens the rationale for population screening.

REFERENCES

[1]Chou R, Selph S, Dana T, et al. Screening for HIV: systematic review to update the U.S. Preventive Services Task Force recommendation. Evidence Synthesis No. 95. AHRQ Publication No. 12-05173-EF-1. Rockville, MD: Agency for Healthcare Research and Quality: November 2012. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/human-immunodeficiency-virus-hiv-infection-screening?ds=1&s=HIV. Accessed November 30, 2016.

[2]O'Connor E, Lin JS, Burda BU, et al. Behavioral sexual risk reduction counseling in primary care to prevent sexually transmitted infections: an updated systematic evidence review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 114. AHRQ Publication No. 13-05180-EF-1. Rockville, MD: Agency for Healthcare Research and Quality: 2014. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/sexually-transmitted-infections-behavioral-counseling1?ds=1&s=sexually Accessed November 30, 2016. PMID: 25356447.

[3]von Sadovszky V, Draudt B, Boch S. A systematic review of reviews of behavioral interventions to promote condom use. Worldviews on Evidence-Based Nursing. 2014;11(2):107-17. doi: http://dx.doi.org/10.1111/wvn.12017. PMID: 24119245.

[4]Cooper B, Toskin I, Kulier R, et al. Brief sexuality communication--a behavioural intervention to advance sexually transmitted infection/HIV prevention: a systematic review. BJOG: An International Journal of Obstetrics & Gynaecology. 2014; 121 Suppl 5:92-103. doi: http://dx.doi.org/10.1111/1471-0528.12877. PMID: 25335846.

[5]Morrison-Beedy D, Crean HF, Passmore D, et al. Risk reduction strategies used by urban adolescent girls in an HIV prevention trial. Current HIV Research. 2013;11(7):559-69. PMID: 24476350.

[6]DiClemente RJ, Wingood GM, Rose ES, et al. Efficacy of sexually transmitted disease/human immunodeficiency virus sexual risk-reduction intervention for african american adolescent females seeking sexual health services: a randomized controlled trial. Arch Pediatr Adolesc Med. 2009;163(12):1112-21. doi: 10.1001/archpediatrics.2009.205. PMID: 19996048.

[7]DiClemente RJ, Bradley E, Davis TL, et al. Adoption and implementation of a computer-delivered HIV/STD risk-reduction intervention for African American adolescent females seeking services at county health departments: implementation optimization is urgently needed. Journal of Acquired Immune Deficiency Syndromes: JAIDS. 2013;63 Suppl 1:S66-71. doi: http://dx.doi.org/10.1097/QAI.0b013e318292014f. PMID: 23673891.

[8]Carey MP, Senn TE, Walsh JL, et al. Evaluating a brief, video-based sexual risk reduction intervention and assessment reactivity with STI clinic patients: results from a randomized controlled trial. AIDS & Behavior. 2015;19(7):1228-46. doi: http://dx.doi.org/10.1007/s10461-014-0960-3. PMID: 25433653.

[9]Moyer VA. Screening for HIV: U.S. Preventive Services Task Force tecommendation statement. Ann Intern Med. 2013;159(1):51-60. doi: 10.7326/0003-4819-159-1-201307020-00645. PMID: 23698354.

[10]Hagan JF, Shaw JS, Duncan PM. Bright Futures: Guidelines for health supervision of infants, children and adolescents, 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics: 2008. https://brightfutures.aap.org/bright%20Futures%20Documents/BF3%20pocket%20guide_final.pdf. Accessed November 30, 2016.

[11]Lundgren JD, Babiker AG, Gordin F, et al. Initiation of antiretroviral therapy in early asymptomatic HIV infection. N Engl J Med. 2015;373(9):795-807. doi: 10.1056/NEJMoa1506816. PMID: 26192873.

[12]Centers for Disease Control and Prevention. HIV Among Gay and Bisexual Men. 2015. http://www.cdc.gov/hiv/group/msm/. Accessed May 18, 2016.

[13]IOM (institute of Medicine). Clinical preventive services for women: Closing the gaps. Washington, DC: National Academies Press; 2011.

[14]Hall HI, An Q, Tang T, et al. Prevalence of diagnosed and undiagnosed HIV infection--United States, 2008-2012. MMWR Morb Mortal Wkly Rep. 2015;64(24):657-62. PMID: 26110835.

[15]Centers for Disease Control and Prevention. HIV surveillance report, 2014. 2015. http://www.cdc.gov/hiv/library/reports/surveillance/. Accessed November 30, 2016.

[16]Chou R, Selph S, Dana T, et al. Screening for HIV: systematic review to update the 2005 U.S. Preventive Services Task Force recommendation. Ann Intern Med. 2012;157(10):706-18. doi: 10.7326/0003-4819-157-10-201211200-00007. PMID: 23165662.

[17]ACOG Committee Opinion no 596: Committee on gynecologic practice: routine human immunodeficiency virus screening. Obstet Gynecol. 2014;123(5):1137-9. doi: 10.1097/01.aog.0000446828.64137.50. PMID: 24785878.

[18]American Academy of Family Physicians. Clinical preventive service recommendation: human immunodeficiency virus (HIV). http://www.aafp.org/patient-care/clinical-recommendations/all/hiv.html. Accessed May 18, 2016.

[19]Graham L. ACP releases guidance statement on screening for HIV. American Family Physician. 2009;80(4):405-7.

[20]Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR Recomm Rep. 2006;55(Rr-14):1-17; quiz CE1-4. PMID: 16988643.

[21]ACOG Committee Opinion No. 389, December 2007. Human immunodeficiency virus. Obstet Gynecol. 2007;110(6):1473-8. doi: 10.1097/01.AOG.0000291572.09193.7f. PMID: 18055751.

[22]Worm SW, Sabin C, Weber R, et al. Risk of myocardial infarction in patients with HIV infection exposed to specific individual antiretroviral drugs from the 3 major drug classes: the data collection on adverse events of anti-HIV drugs (D:A:D) study. J Infect Dis. 2010;201(3):318-30. doi: 10.1086/649897. PMID: 20039804.

Screening for Interpersonal and Domestic Violence

Clinical Recommendations

The Women's Preventive Services Initiative recommends screening adolescents and women for interpersonal and domestic violence, at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service, screening adolescents and women for interpersonal and domestic violence. There are multiple screening tools that have shown adequate sensitivity and specificity for identifying intimate partner violence and domestic violence in specific populations of women. Minimum screening intervals are unknown; however, based on the prevalence of interpersonal and domestic violence as well as evidence demonstrating that many cases are not reported, it is reasonable to conduct screening at least annually although the frequency and intensity of screening may vary depending on a particular patient's situation.

EVIDENCE MAP

Screen adolescents and women for interpersonal and domestic violence.

Systematic Reviews	Additional Studies	USPSTF; Bright Futures (covered by ACA)
Screening effectiveness (health outcomes): • 2012 USPSTF review1:[1] cluster RCT indicated no differences between screened versus non screened women[2]. • Cochrane review[3]: included an additional RCT indicating no differences between screened versus non-screened women[4]. Screening harms: • 2013 USPSTF review[1]: included 1 cluster RCT indicating no harms[2]. Accuracy of screening instruments: • 2012 USPSTF review[1]: included 7 studies of 5 instruments[5-11] with fair to high diagnostic accuracy in detecting current or recent IPV; 1 study[12] of the PVS accurately predicted future IPV; 1 study[13] identified past childhood abuse; and 2 studies[14,15] of mothers in pediatric settings reported low sensitivity/high specificity in predicting IPV	1 new study of 80 VA women reported accuracy of the HITS instrument[16].	• USPSTF[17]: Women of childbearing age: Screen women of childbearing age for intimate partner violence (IPV). (Level B; 2013; update in progress) Elderly or vulnerable adults: Insufficient evidence to assess the balance of benefits and harms of screening all elderly or vulnerable adults (physically or mentally dysfunctional) for abuse and neglect. • Bright Futures[18]: Discuss intimate partner violence at the prenatal, newborn, 1-month, 9-month, and 4-year visits and discuss interpersonal and dating violence at the middle and late adolescence health supervision visits. Consider screening mothers at child health supervision visits when signs or symptoms raise concerns, or if the mother has a new intimate partner. Consider screening adolescents if they have a new intimate partner, when signs or symptoms raise concerns, or during prenatal visits.

Evidence map continued on page 119.

When needed, provide or refer for intervention services.

Systematic Reviews	Additional Studies	USPSTF; Bright Futures (covered by ACA)
Studies of interventions with IPV outcomes: • 2012 USPSTF review[1]: included 6 RCTs[19-26] reporting IPV outcomes; 2 reported reduced recurrent IPV episodes during pregnancy and postpartum for the intervention groups (counseling and mentor support) versus usual care;[19,20,23,26] 1 study of home visitation[21] reported lower rates of IPV; 1 study of counseling[25] reported decreased pregnancy coercion; use of a wallet-size referral card in 1 study[24] showed no differences. • Cochrane review[27] of education or skill-based interventions reported no differences. • Cochrane review of advocacy versus usual care (10 RCTs)[28] found no differences in incidence of abuse. • Cochrane review of any intervention versus usual care in pregnant women (10 RCTs)[29] reported decreased partner abuse. Harms: • 2012 USPSTF review1: included 2 RCTs[21,24] and 11 descriptive studies[30-40] reporting harms; 1 trial reported no harms while another reported increased verbal victimization following home visitations; descriptive studies reported low rates of harms, but some women voiced concerns.	• 1 review of advocacy interventions versus usual care (12 RCTs)[41] reported decreased incidence of physical and psychological abuse. • 1 review of counseling techniques (12 RCTs)[41] reported mixed results. • 1 review of home visitation versus usual care (6 studies)[42] reported mixed results. • 2 reviews of any intervention versus usual care: a review of studies of pregnant women (9 RCTs)[43] reported decreased partner abuse; a review of women seen in multiple settings (17 studies)[44] indicated that 13 out of 17 studies reported ≥1 benefit. • 3 RCTs,[45-47] 2 of motivational interviewing and 1 of case manager versus computer driven interventions, found no differences in outcomes.	• USPSTF[17]: Women of childbearing age, clinicians provide or refer women who screen positive to intervention services. (Clinical Considerations provide more information on effective interventions.) (Level B; 2013; update in progress) • Bright Futures[18]: No recommendation regarding intervention services.

Abbreviations: ACA=Affordable Care Act, USPSTF=U.S. Preventive Services Task Force, VA=Veteran's Administration

SUMMARY OF EVIDENCE

Introduction

Interpersonal violence includes and domestic violence and, including intimate partner violence (IPV). IPV refers to physical, sexual, or psychological harm by a current or former partner or spouse.[48] Women and adolescents of all ages experience intimate partner violence. It can occur among heterosexual and same-sex couples and does not require sexual intimacy. The Centers for Disease Control and Prevention (CDC) identifies four main types of IPV (**Table 1**):[49]

Table 1. Types of IPV

IPV Type	CDC Definition[49]
Physical violence	The intentional use of physical force with the potential for causing death, disability, injury, or harm. May include (but not limited to): scratching; pushing; shoving; throwing; grabbing; biting; choking; shaking; aggressive hair pulling; slapping; punching; hitting; burning; use of a weapon; and use of restraints or one's body, size, or strength against another person. Also includes coercing other people to commit any of the above acts.
Sexual violence	Attempted or completed: • Rape or penetration of victim • Victim was made to penetrate someone else • Non-physically pressured unwanted penetration • Unwanted sexual contact • Non-contact unwanted sexual experiences (unwanted sexual events that are not of a physical nature that occur without the victim's consent) All of these acts occur without the victim's consent, including cases in which the victim is unable to consent due to being too intoxicated (e.g., incapacitation, lack of consciousness, or lack of awareness) through their voluntary or involuntary use of alcohol or drugs.
Stalking	A pattern of repeated, unwanted, attention and contact that causes fear or concern for one's own safety or the safety of someone else (e.g., family member or friend).
Psychological aggression	The use of verbal and non-verbal communication with the intent to harm another person mentally or emotionally, and/or to exert control over another person.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 previously identified by the Institute of Medicine (IOM) Committee was that interpersonal and domestic violence screening and counseling were not included. In 2013, the U.S. Preventive Services Task Force (USPSTF) issued new recommendations for screening for intimate partner violence and providing or referring women who screen positive to intervention services[17] (**Table 2**). Recommendations regarding screening for violence apply to women and adolescents who do not have signs or symptoms of abuse, and generally involve clinicians asking a series of questions.

Table 2. Summary of Recommendations Currently Covered under the Affordable Care Act

IOM Committee[50]	Coverage for screening and counseling for interpersonal and domestic violence. This involves 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.
USPSTF[17]	Screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services (Level B 2013).
Bright Futures[18]	Discuss intimate partner violence at the prenatal, newborn, 1-month, 9-month, and 4-year visits and discuss interpersonal and dating violence at the middle and late adolescence health supervision visits. Consider screening mothers at child health supervision visits when signs or symptoms raise concerns, or if the mother has a new intimate partner. Consider screening adolescents if they have a new intimate partner, when signs or symptoms raise concerns, or during prenatal visits.

Abbreviations: IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

Background

A survey by the CDC in 2011 indicated that 32% of women experienced physical violence in their lifetimes, and 22% reported severe physical violence by an intimate partner. In addition, 47% experienced psychological aggression, including expressive aggression (i.e., name calling, insults, and/or humiliation) and coercive control (i.e., behaviors intended to monitor, control, or threaten).[51] Also, 19% of women experienced rape and 44% experienced sexual violence besides rape. Of those raped, 45% were raped by an intimate partner.

Health effects of intimate partner violence include death and nonfatal traumatic injuries including contusions, fractures, and traumatic brain injury that can result in chronic health conditions.[52] Sexual violence may cause sexually transmitted infections, sexual dysfunction, unintended pregnancy, pregnancy complications including preterm delivery, delayed prenatal care, and pelvic inflammatory disease. Chronic health effects include

exacerbation of asthma, urinary tract infections, cardiovascular disease, fibromyalgia, irritable bowel syndrome, and chronic pain syndromes including headaches.[53]

Associated psychological conditions include anxiety, depression, posttraumatic stress disorder, antisocial behavior, suicidal ideation and behaviors, low self-esteem, fear of intimacy, emotional detachment, sleep disturbances, and inability to trust others.[52,54-57] Social repercussions may include restricted access to services, strained relationships with health providers and employers, isolation from social networks, and homelessness.[56-58]

Screening methods to identify women exposed to IPV have been developed for administration in a variety of healthcare settings (e.g., obstetrics visits, primary-care settings, emergency department) (**Table 3**). Some instruments demonstrated high sensitivity (>80%) in accurately detecting IPV in studies, however results differed across studies and populations.[1]

Table 3. Clinical Screening Instruments for IPV Evaluated in Studies[1,5]

Measure	Components	Sensitivity; specificity
HITS	4 item (hurt, insult, threaten, scream), 5-point Likert scale, self-report or clinician administered survey; score ranges from 4-20 points, ≥11 indicates abuse.	86%; 99%
PSQ	3 items (physically hurt or threatened, afraid, order for protection), dichotomous scale; score ranges from 0-3.	19%; 93%
OVAT	4 item (threaten, beaten, would like to kill you, no respect), dichotomous scale; score ranges from 0-4.	86-93%; 83-86%
SAFE-T	5 items (secure at home, accepted by partner, family likes partner, even disposition of partner, talks with partner to resolve differences), dichotomous scale; score ranges from 0-5.	54%; 81%
PVS	3 items (past physical violence, perceived personal safety), dichotomous scale, clinician administered; score ranges from 0-3, with ≥1 indicates IPV.	49%; 94%
WAST	8 item (physical, sexual, and emotional abuse), 3-point response (0=never, 1=sometimes, 2=often) scale; scores range from 0-16; ≥4 indicates exposure to IPV. Short form includes 2 questions about tension in the relationship and how arguments are resolved.	47-88%; 89-96%
STaT	3 item (pushed or slapped, threatened with violence, partner has thrown, broken, or punched things), dichotomous, self-report scale; score ranges from 0-3.	96%; 75%

Table 3 continued on page 123.

Measure	Components	Sensitivity; specificity
AAS	5 item (sexual coercion, lifetime abuse, current abuse, abuse during pregnancy), dichotomous scale, clinician administered survey; scores range from 0-5, with any positive response considered a positive screen.	32-93%; 55-99%
HARK	4 item (humiliation, afraid, rape, kick, dichotomous scale, self-report survey, adapted from AAS; scoring ranges from 0-4.	81%; 95%
Modified CTQ-SF	28 item (abuse and neglect in childhood), 8-point Likert scale, self-report survey; positive response (anything other than never) indicates exposure to IPV.	85%; 88%
OAS	5 item (threaten, beaten, would like to kill you, no respect), dichotomous scale; scores range from 0-5.	60%; 90%

Abbreviations: AAS=Abuse Assessment Screen; CTQ-SF=Conflict Tactics Scale-Revised Short Form; E-HITS=Extended Hurt/Insult/Threaten/Scream tool; HARK=Humiliation, Afraid, Rape, Kick tool; HITS=Hurt/Insult/Threaten/Scream tool; OAS=Ongoing Abuse Screen; OVAT=Ongoing Violence Assessment Tool; PSQ=Parent Screening Questionnaire; PVS=Partner Violence Screen; SAFE-T=Secure, Accepted, Family, Even, Talk measure; STaT=Slapped, Threatened, and Throw measure; WAST=Woman Abuse Screening Tool.

Women exposed to IPV may benefit from interventions aimed at reducing exposure to IPV and its negative health effects. Interventions generally include advocacy and safety planning, education, and counseling. Several professional organizations recommend screening for IPV (**Table 4**).

Table 4. Recommendations of Professional Organizations

Organization	Recommendation
American College of Obstetricians and Gynecologists (ACOG)[60]	Screen all women for intimate partner violence at periodic intervals, such as annual examinations and new patient visits. Screening during obstetric care should occur at the first prenatal visit, at least once per trimester, and at the postpartum checkup.
American Medical Association (AMA)[61]	Questions to assess risk for family violence should be included within the context of taking a routine social history, past medical history, history of present illness, and review of systems as part of emergency, diagnostic, preventive, and chronic care management.
American Academy of Family Physicians (AAFP)[62]	Screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services.
American College of Emergency Physicians (ACEP)[63]	Assess patients for family violence in all its forms, including that directed toward children, elders, intimate partners, and other family members.
Emergency Nurses Association (ENA)[64]	Routinely screen patients for intimate partner violence.
American Academy of Pediatricians (AAP)[65]	Remain alert to the signs and symptoms of exposure to intimate partner violence in caregivers and children and consider attempts to identify evidence of intimate partner violence either by targeted screening of high-risk families or universal screening.

UPDATE OF EVIDENCE

The 2013 USPSTF recommendation was based on a systematic review of evidence of effectiveness of IPV screening in reducing subsequent IPV and adverse health outcomes; diagnostic accuracy of screening instruments; and effectiveness of interventions to reduce IVP.1

Effectiveness of Screening on Subsequent IPV and Health Outcomes

Trials were limited by heterogeneity, lack of true control groups, high loss to follow-up, self-reported measures, and lack of accepted reference standards.

USPSTF systematic review

A large (n=6,743) cluster randomized controlled trial (RCT) in Canada assessed outcomes of abuse and quality

of life measures at 18 months for women randomized to either screening or non-screening groups.[2] Clinicians, at their discretion, discussed positive findings from the screening instrument (Woman Abuse Screening Tool) with patients, and provided them with referrals and/or treatment as they saw necessary. During follow-up, no statistically significant differences were found between screened and non-screened groups in the numbers of women accessing additional health care services; with reduced IPV recurrence, posttraumatic stress disorder symptoms, or alcohol problems; and on scores for quality of life, depression, or mental health.

This trial has several methodological limitations. Women with positive screenings were not offered a specific intervention, and few women who had positive screening results actually participated in discussions about IPV with their clinicians during their clinic visits. Women who were randomly assigned to the nonscreening group were provided with information cards of locally available resources for women with IPV, which constitutes an intervention in other studies. Women in the nonscreening group had extensive questioning about IPV over the 18 months of the trial which could increase their self-awareness of IPV, affect their utilization of services, and influence outcomes of the trial by creating a substantial Hawthorne effect (i.e., the phenomenon that study participants change their behavior as a result of being involved in the study).

Relevant studies published since the USPSTF systematic review

A Cochrane review[3] identified two RCTs reporting outcomes of reduced IPV after screening including the Canadian trial[2] and a trial conducted in Japan that also found no statistically significant differences in IPV 3 months after screening.[4]

Diagnostic Accuracy of Screening Instruments

USPSTF systematic review

Seven studies of five screening instruments[5-11] demonstrated fair to high diagnostic accuracy in detecting current or recent IPV (summarized in Table 3 above). A study evaluating risk for future IPV reported that positive responses on the Partner Violence Screen predicted verbal aggression (risk ratio [RR] 7.3; 95% confidence interval [CI], 3.2 to 16.2) and violence (RR 11.3; 95% CI 4.8 to 26.3) during the 4 months after screening.[12] A study of the modified Childhood Trauma Questionnaire-Short Form to identify adult women who had past childhood physical or sexual abuse reported high diagnostic accuracy (sensitivity 85%; specificity 88%).[13] Two studies evaluated mothers in pediatric settings screened with either the Parent Screening Questionnaire[14] or five questions asked by clinicians.[15] Both methods had low sensitivity, but high specificity in predicting IPV (sensitivity: 19% to 29% and 40%, respectively; specificity: 91% to 93% and 91%, respectively).

Relevant studies published since the USPSTF systematic review

A study of 80 women veterans compared the diagnostic accuracy of the 4-item Hurt/Insult/Threaten/Scream (HITS) instrument and an extended HITS (E-HITS) version that included a sexual IPV item with the Revised Conflict Tactics Scale (CTS-2), which was the reference standard.[16] Using a cutoff score of 6 on the HITS and 7 on the E-HITS resulted in the best balance of sensitivity (75% for both) and specificity (83% for HITS and 82% for E-HITS).

Effectiveness of Interventions

Studies of the effectiveness of interventions were generally limited by their heterogeneity, lack of true control groups, high loss to follow-up, use of self-reported measures, and lack of accepted reference standards. Results need to be interpreted with these limitations in mind.

USPSTF systematic review

Six RCTs[19-26] reported outcomes after interventions to reduce IPV; three trials targeted pregnant and postpartum women and three trials included primary care patients. Two trials[19,20,23,26] reported statistically significant differences between women receiving interventions (counseling, mentor support) versus usual care for the number of recurrent episodes of IPV during pregnancy and postpartum, birth outcomes (fewer very preterm infants, lower rates of very low birth weight infants, and increased mean gestational age), reduced abuse scores, and odds of experiencing violence at follow-up.

A trial of home visitations for women who recently gave birth to an infant at risk for maltreatment[21] reported lower rates of IPV victimization and IPV perpetration, although results were of borderline statistical significance. A cluster RCT[25] indicated that women receiving counseling who reported IPV at baseline had decreased pregnancy coercion at follow-up, and all women in the intervention group, regardless of recent IPV status, were more likely to discontinue unhealthy or unsafe relationships compared with women receiving usual care. A RCT[24] of a wallet-size referral card compared with a nurse management protocol showed no differences at 2-year follow-up, although both groups had fewer threats of abuse, assaults, danger risks for homicide, and events of work harassment.

Relevant studies published since the USPSTF systematic review

Seven reviews of the effectiveness of interventions in reducing exposure to IPV included advocacy,[28,41] cognitive behavioral therapy (CBT),[41] home visiting,[42] educational or skill-based interventions,[27] or any type of intervention.[29,43,44] Many studies included in these reviews did not meet inclusion criteria for the USPSTF review for various reasons including lack of comparison groups, no IPV or health outcomes, and low relevance to clinical settings.

The two reviews comparing the effectiveness of advocacy interventions with usual care included seven of the same trials. One review included ten RCTs in the analysis, but was unable to pool most of the studies due to clinical and methodological heterogeneity.[28] The review found no significant differences between the intervention and usual care groups in the reduction of physical abuse (standard mean difference [SMD] 0.00; 95% CI -0.17 to 0.16; 3 trials) or sexual abuse (SMD -0.12; 95% CI -0.37 to 0.14; 2 trials). The review reported a significantly decreased risk of developing depression for those receiving a brief advocacy intervention compared with usual care (odds ratio [OR] 0.31; 95% CI 0.15 to 0.65; 2 trials). However, there were no differences in reduced depression at 12 months (mean difference -0.14; 95% CI -0.33 to 0.05; 3 trials) or 2 years (SMD -0.12; 95% CI -0.36 to 0.12; 1 trial) after an intensive advocacy intervention compared with usual care. The other review included six RCTs in the analysis and reported decreased incidence of physical abuse (SMD -0.13; 95% CI -0.25 to -0.00; 5 trials) and psychological abuse (SMD -0.19; 95% CI - 0.32 to -0.05; 4 trials) after an

advocacy intervention compared with usual care.[41] There were no differences in incidence of sexual abuse (SMD -0.20; 95% CI -0.43 to 0.02; 2 trials) or any IPV (SMD -0.32; 95% CI -0.69 to 0.04; 1 trial).

Trials comparing cognitive behavioral therapy with usual care indicated decreased incidence of physical abuse (SMD -0.79; 95% CI -1.26 to -0.33; 2 trials) and psychological abuse (SMD -0.80; 95% CI -1.25 to -0.36; 2 trials), but not sexual abuse (SMD -0.35; 95% CI -1.73 to 1.03; 1 trial) or any type of IPV (SMD 0.09; 95% CI -0.05 to 0.23; 1 trial).[41]

A review assessed home visitation interventions compared with usual care in six trials and reported mixed results.[42] Three trials reported statistically significant reductions in IPV for mothers in the short-term, but the other three trials showed no benefit for the intervention group.

A Cochrane review assessed the effectiveness of education or skill-based interventions aimed at preventing dating or relationship violence in adolescents (12-18 years) or young adults (19-25 years) in any setting.[27] The review found no differences between intervention and usual care groups in reducing episodes of relationship violence (RR 0.77; 95% CI 0.53 to 1.13; 8 trials).

Three reviews assessed the effectiveness of any intervention for preventing or reducing IPV; two exclusively in pregnant women[29,43] and one in women seen in multiple settings.[44] Both reviews of pregnant women included predominantly the same studies and found limited evidence for reduced IPV exposure. One of the reviews included five studies reporting statistically significant decreases in physical, sexual, and/or psychological partner violence (ORs from 0.47 to 0.92).[43] The other review reported fewer episodes of partner violence during pregnancy in the intervention group in one trial (RR 0.62; 95% CI 0.43 to 0.88).[29] The third review of any type of intervention included 17 trials.[44] The review reported that 13 studies demonstrated more than one intervention-related benefit. Six of the 11 studies measuring IPV persistence found reductions in future violence; two of five studies measuring safety-promoting behaviors found increases; and six of ten studies measuring IPV/community resource referrals found enhanced use. Some studies also documented health improvements.

Three RCTs that were not included in the reviews reported effectiveness of interventions to reduce exposure to IPV; two involved motivational interviewing[45,46] and one compared a case manager driven intervention with a computerized intervention.[47] Neither study of motivational interviewing reported significant differences between groups at either 4 or 12 months follow-up in depressive symptoms, self-efficacy, abuse, or heavy drinking. The study comparing the case manager driven intervention with a computerized intervention also found no differences between groups from baseline to 3-month follow-up for identification of IPV or improvement in receipt of IPV services, social support, IPV self-efficacy, and abstinence from drug use.

Harms of Screening or Interventions

USPSTF systematic review

Three trials[2,21,24] and 11 descriptive studies[30-40] reported outcomes related to harms of IVP screening or interventions. Two trials found no harms,[2,24] while another trial indicated increased verbal abuse victimization and perpetration over long-term follow-up among women assigned to home visitations because their infants were considered at risk for maltreatment.[21] The descriptive studies generally reported low levels of harms that included discomfort with screening, particularly among those with prior IPV; infringement of privacy; worries about increasing abuse by disclosing IPV; feelings of sadness and depression; and general concerns with IPV screening.[59] Only a minority of respondents voiced these concerns. No new studies reported adverse effects of IVP screening or interventions.

CONCLUSIONS

Two trials evaluating screening for IPV in clinical settings and its effects on health outcomes are inconclusive. Several brief screening instruments to identify women exposed to IPV in healthcare settings (obstetrics visits, primary-care settings, emergency department) have high sensitivity (>80%), although results vary across studies and populations. Studies of interventions focus primarily on pregnant women or women seeking obstetric care. Results indicate generally beneficial outcomes, but studies are heterogeneous and most enrolled small numbers of women limiting applicability.

REFERENCES

[1]Nelson HD, Bougatsos C, Blazina I. Screening women for intimate partner violence: a systematic review to update the U.S. Preventive Services Task Force recommendation. Ann Intern Med. 2012;156(11):796-808, w-279, w-80, w-81, w-82. doi: 10.7326/0003-4819-156-11-201206050-00447. PMID: 22565034.

[2]MacMillan HL, Wathen CN, Jamieson E, et al. Screening for intimate partner violence in health care settings: a randomized trial. JAMA. 2009;302(5):493-501. doi: 10.1001/jama.2009.1089. PMID: 19654384.

[3]O'Doherty L, Hegarty K, Ramsay J, et al. Screening women for intimate partner violence in healthcare settings. Cochrane Database Syst Rev. 2015;7:CD007007. doi: http://dx.doi.org/10.1002/14651858.CD007007.pub3. PMID: 26200817.

[4]Koziol-McLain J, Garrett N, Fanslow J, et al. A randomized controlled trial of a brief emergency department intimate partner violence screening intervention. Ann Emerg Med. 2010;56(4):413-23.e1. doi: 10.1016/j.annemergmed.2010.05.001. PMID: 20538369.

[5]Chen PH, Rovi S, Vega M, et al. Screening for domestic violence in a predominantly Hispanic clinical setting. Fam Pract. 2005;22(6):617-23. doi: 10.1093/fampra/cmi075. PMID: 16055473.

[6]Weiss SJ, Ernst AA, Cham E, et al. Development of a screen for ongoing intimate partner violence. Violence Vict. 2003;18(2):131-41. PMID: 12816400.

[7]Paranjape A, Liebschutz J. STaT: a three-question screen for intimate partner violence. J Womens Health (Larchmt). 2003;12(3):233-9. doi: 10.1089/154099903321667573. PMID: 12804354.

[8]Paranjape A, Rask K, Liebschutz J. Utility of STaT for the identification of recent intimate partner violence. J Natl Med Assoc. 2006;98(10):1663-9. PMID: 17052059.

[9]Sohal H, Eldridge S, Feder G. The sensitivity and specificity of four questions (HARK) to identify intimate partner violence: a diagnostic accuracy study in general practice. BMC Fam Pract. 2007;8:49. doi: 10.1186/1471-2296-8-49. PMID: 17727730.

[10]Wathen CN, Jamieson E, MacMillan HL. Who is identified by screening for intimate partner violence? Womens Health Issues. 2008;18(6):423-32. doi: 10.1016/j.whi.2008.08.003. PMID: 19041594.

[11]MacMillan HL, Wathen CN, Jamieson E, et al. Approaches to screening for intimate partner violence in health care settings: a randomized trial. JAMA. 2006;296(5):530-6. doi: 10.1001/jama.296.5.530. PMID: 16882959.

[12]Houry D, Feldhaus K, Peery B, et al. A positive domestic violence screen predicts future domestic violence. J Interpers Violence. 2004;19(9):955-66. doi: 10.1177/0886260504267999. PMID: 15296611.

[13]Thombs BD, Bernstein DP, Ziegelstein RC, et al. A brief two-item screener for detecting a history of physical or sexual abuse in childhood. Gen Hosp Psychiatry. 2007;29(1):8-13. doi: 10.1016/j.genhosppsych.2006.10.013. PMID: 17189738.

[14]Dubowitz H, Prescott L, Feigelman S, et al. Screening for intimate partner violence in a pediatric primary care clinic. Pediatrics. 2008;121(1):e85-91. doi: 10.1542/peds.2007-0904. PMID: 18166548.

[15]Zink T, Levin L, Putnam F, et al. Accuracy of five domestic violence screening questions with nongraphic language. Clin Pediatr (Phila). 2007;46(2):127-34. doi: 10.1177/0009922806290029. PMID: 17325085.

[16]Iverson KM, King MW, Gerber MR, et al. Accuracy of an intimate partner violence screening tool for female VHA patients: A replication and extension. J Trauma Stress. 2015;28(1):79-82. doi: http://dx.doi.org/10.1002/jts.21985. PMID: 2015-03496-001.

[17]Moyer VA. Screening for intimate partner violence and abuse of elderly and vulnerable adults: U.S. preventive services task force recommendation statement. Ann Intern Med. 2013;158(6):478-86. doi: 10.7326/0003-4819-158-6-201303190-00588. PMID: 23338828.

[18]American Academy of Pediatrics. Performing preventive services: a Bright Futures handbook. Pediatrics. 2010.

[19]El-Mohandes AA, Kiely M, Gantz MG, et al. Very preterm birth is reduced in women receiving an integrated behavioral intervention: a randomized controlled trial. Matern Child Health J. 2011;15(1):19-28. doi: 10.1007/s10995-009-0557-z. PMID: 20082130.

[20]Kiely M, El-Mohandes AA, El-Khorazaty MN, et al. An integrated intervention to reduce intimate partner violence in pregnancy: a randomized controlled trial. Obstet Gynecol. 2010;115(2 Pt 1):273-83. doi: 10.1097/AOG.0b013e3181cbd482. PMID: 20093899.

[21]Bair-Merritt MH, Jennings JM, Chen R, et al. Reducing maternal intimate partner violence after the birth of a child: a randomized controlled trial of the Hawaii Healthy Start Home Visitation Program. Arch Pediatr Adolesc Med. 2010;164(1):16-23. doi: 10.1001/archpediatrics.2009.237. PMID: 20048237.

[22]Curry MA, Durham L, Bullock L, et al. Nurse case management for pregnant women experiencing or at risk for abuse. J Obstet Gynecol Neonatal Nurs. 2006;35(2):181-92. doi: 10.1111/j.1552-6909.2006.00027.x. PMID: 16620243.

[23]El-Mohandes AA, Kiely M, Joseph JG, et al. An intervention to improve postpartum outcomes in African-American mothers: a randomized controlled trial. Obstet Gynecol. 2008;112(3):611-20. doi: 10.1097/AOG.0b013e3181834b10. PMID: 18757660.

[24]McFarlane JM, Groff JY, O'Brien JA, et al. Secondary prevention of intimate partner violence: a randomized controlled trial. Nurs Res. 2006;55(1):52-61. PMID: 16439929.

[25]Miller E, Decker MR, McCauley HL, et al. A family planning clinic partner violence intervention to reduce risk associated with reproductive coercion. Contraception. 2011;83(3):274-80.

[26]Taft AJ, Small R, Hegarty KL, et al. MOthers' AdvocateS In the Community (MOSAIC)--non-professional mentor support to reduce intimate partner violence and depression in mothers: a cluster randomised trial in primary care. BMC Public Health. 2011;11(178) PMID: CN-00786278 UPDATE.

[27]Fellmeth LTG, Heffernan C, Nurse J, et al. Educational and skills-based interventions for preventing relationship and dating violence in adolescents and young adults. Cochrane Database Syst Rev. 2013(6) PMID: 00075320-100000000-03463.

[28]Rivas C, Ramsay J, Sadowski L, et al. Advocacy interventions to reduce or eliminate violence and promote the physical and psychosocial well-being of women who experience intimate partner abuse. Cochrane Database Syst Rev. 2015(12) PMID: 00075320-100000000-03938.

[29]Jahanfar S, Howard LM, Medley N. Interventions for preventing or reducing domestic violence against pregnant women. Cochrane Database Syst Rev. 2014(11) PMID: 00075320-100000000-07817.

[30]Chang JC, Decker M, Moracco KE, et al. What happens when health care providers ask about intimate partner violence? A description of consequences from the perspectives of female survivors. J Am Med Womens Assoc. 2003;58(2):76-81. PMID: 12744419.

[31]Houry D, Kaslow NJ, Kemball RS, et al. Does screening in the emergency department hurt or help victims of intimate partner violence? Ann Emerg Med. 2008;51(4):433-42, 42.e1-7. doi: 10.1016/j.annemergmed.2007.11.019. PMID: 18313800.

[32]Spangaro JM, Zwi AB, Poulos RG, et al. Six months after routine screening for intimate partner violence: attitude change, useful and adverse effects. Women Health. 2010;50(2):125-43. doi: 10.1080/03630241003705060. PMID: 20437301.

[33]Koziol-McLain J, Giddings L, Rameka M, et al. Intimate partner violence screening and brief intervention: experiences of women in two New Zealand Health Care Settings. J Midwifery Womens Health. 2008;53(6):504-10. doi: 10.1016/j.jmwh.2008.06.002. PMID: 18984506.

[34]Liebschutz J, Battaglia T, Finley E, et al. Disclosing intimate partner violence to health care clinicians - what a difference the setting makes: a qualitative study. BMC Public Health. 2008;8:229. doi: 10.1186/1471-2458-8-229. PMID: 18601725.

[35]Renker PR, Tonkin P. Women's views of prenatal violence screening: acceptability and confidentiality issues. Obstet Gynecol. 2006;107(2 Pt 1):348-54. doi: 10.1097/01.AOG.0000195356.90589.c5. PMID: 16449123.

[36]Sethi D, Watts S, Zwi A, et al. Experience of domestic violence by women attending an inner city accident and emergency department. Emerg Med J. 2004;21(2):180-4. PMID: 14988343.

[37]Weinsheimer RL, Schermer CR, Malcoe LH, et al. Severe intimate partner violence and alcohol use among female trauma patients. J Trauma. 2005;58(1):22-9. PMID: 15674145.

[38]Zeitler MS, Paine AD, Breitbart V, et al. Attitudes about intimate partner violence screening among an ethnically diverse sample of young women. J Adolesc Health. 2006;39(1):119.e1-8. doi: 10.1016/j.jadohealth.2005.09.004. PMID: 16781970.

[39]Hurley KF, Brown-Maher T, Campbell SG, et al. Emergency department patients' opinions of screening for intimate partner violence among women. Emerg Med J. 2005;22(2):97-8. doi: 10.1136/emj.2002.002626. PMID: 15662056.

[40]Spangaro JM, Zwi AB, Poulos RG. "Persist. persist.": A qualitative study of women's decisions to disclose and their perceptions of the impact of routine screening for intimate partner violence. Psychol Violence. 2011;1(2):150-62.

[41]Tirado-Munoz J, Gilchrist G, Farre M, et al. The efficacy of cognitive behavioural therapy and advocacy interventions for women who have experienced intimate partner violence: a systematic review and meta-analysis. Ann Med. 2014;46(8):567-86. doi: http://dx.doi.org/10.3109/07853890.2014.941918. PMID: 25211469.

[42]Prosman GJ, Lo Fo Wong SH, van der Wouden JC, et al. Effectiveness of home visiting in reducing partner violence for families experiencing abuse: a systematic review. Fam Pract. 2015;32(3):247-56. doi: http://dx.doi.org/10.1093/fampra/cmu091. PMID: 25947931.

[43]Van Parys AS, Verhamme A, Temmerman M, et al. Intimate partner violence and pregnancy: a systematic review of interventions. PLoS ONE [Electronic Resource]. 2014;9(1):e85084. doi: http://dx.doi.org/10.1371/journal.pone.0085084. PMID: 24482679.

[44]Bair-Merritt MH, Lewis-O'Connor A, Goel S, et al. Primary care-based interventions for intimate partner violence: a systematic review. Am J Prev Med. 2014;46(2):188-94. doi: http://dx.doi.org/10.1016/j.amepre.2013.10.001. PMID: 24439354.

[45]Rhodes KV, Rodgers M, Sommers M, et al. Brief motivational intervention for intimate partner violence and heavy drinking in the emergency department: a randomized clinical trial. JAMA. 2015;314(5):466-77. doi: http://dx.doi.org/10.1001/jama.2015.8369. PMID: 26241598.

[46]Saftlas AF, Harland KK, Wallis AB, et al. Motivational interviewing and intimate partner violence: a randomized trial. Ann Epidemiol. 2014;24(2):144-50. doi: http://dx.doi.org/10.1016/j.annepidem.2013.10.006. PMID: 24252714.

[47]Gilbert L, Shaw SA, Goddard-Eckrich D, et al. Project WINGS (Women Initiating New Goals of Safety): A randomised controlled trial of a screening, brief intervention and referral to treatment (SBIRT) service to identify and address intimate partner violence victimisation among substance-using women receiving community supervision. Crim Behav Ment Health. 2015;25(4):314-29. doi: http://dx.doi.org/10.1002/cbm.1979. PMID: 26482019.

[48]Centers for Disease Control and Prevention. Intimate Partner Violence. 2016. http://www.cdc.gov/violenceprevention/intimatepartnerviolence/. Accessed May 14, 2016.

[49]Breiding M, Basile K, Smith S, et al. Intimate partner violence surveillance: uniform definitions and recommended data elements, version 2.0. Atlanta (GA): 2015. https://www.cdc.gov/violenceprevention/pdf/intimatepartnerviolence.pdf Accessed August 10, 2016.

[50]IOM (institute of Medicine). Clinical preventive services for women: closing the gaps. Washington, DC: National Academies Press; 2011.

[51]Breiding MJ, Smith SG, Basile KC, et al. Prevalence and characteristics of sexual violence, stalking, and intimate partner violence victimization--national intimate partner and sexual violence survey, United States, 2011. MMWR Surveill Summ. 2014;63(8):1-18. PMID: 25188037.

[52]Black MC. Intimate partner violence and adverse health consequences: implications for clinicians. Am J Lifestyle Med. 2011:428-39.

[53]Centers for Disease Control and Prevention. Intimate Partner Violence: Consequences. 2015. http://www.cdc.gov/violenceprevention/intimatepartnerviolence/consequences.html. Accessed May 14, 2016.

[54]Coker AL, Davis KE, Arias I, et al. Physical and mental health effects of intimate partner violence for men and women. Am J Prev Med. 2002;23(4):260-8. PMID: 12406480.

[55]Roberts TA, Klein JD, Fisher S. Longitudinal effect of intimate partner abuse on high-risk behavior among adolescents. Arch Pediatr Adolesc Med. 2003;157(9):875-81. doi: 10.1001/archpedi.157.9.875. PMID: 12963592.

[56]Warshaw C BB, Gil J. Mental health consequences of intimate partner violence. In: Mitchell C, Anglin D, eds. Intimate partner violence: a health- based perspective. New York: Oxford University Press; 2009:147-71.

[57]Heise L, Garcia-Moreno C. Violence by intimate partners. In: Krug E, Dahlberg LL, Mercy JA, et al., eds. World report on violence and health. geneva, Switzerland: World Health Organization. . Geneva (Switzerland): World Health Organization; 2002:87-121.

[58]Plichta SB. Intimate partner violence and physical health consequences: policy and practice implications. J Interpers Violence. 2004;19(11):1296-323. doi: 10.1177/0886260504269685. PMID: 15534333.

[59]Nelson H, Bougatsos C, Blazina I. Screening women for intimate partner violence and elderly and vulnerable adults for abuse: systematic review to update the 2004 U.S. Preventive Services Task Force recommendation. Evidence Synthesis No. 92. AHRQ Publication No. 12-05167-EF-1. Rockville, MD: Agency for Healthcare Research and Quality: 2012. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/intimate-partner-violence-and-abuse-of-elderly-and-vulnerable-adults-screening?ds=1&s=violence. Accessed November 30, 2016.

[60]ACOG Committee Opinion No. 518: Intimate partner violence. Obstet Gynecol. 2012;119(2 Pt 1):412-7. doi: 10.1097/AOG.0b013e318249ff74. PMID: 22270317.

[61]American Medical Association. H-515.965 Family and Intimate Partner Violence. 2015. https://searchpf.ama-assn.org/SearchML/searchDetails.action?uri=%2FAMADoc%2FHOD.xml-0-4662.xml. Accessed May 14, 2016.

[62]American Academy of Family Physicians. Clinical preventive service recommendation: intimate partner violence and abuse of vunerable adults. 2013. http://www.aafp.org/patient-care/clinical-recommendations/all/domestic-violence.html. Accessed May 14, 2016.

[63]American College of Emergency Physicians. Domestic family violence. 2013. https://www.acep.org/Clinical---Practice-Management/Domestic-Family-Violence/. Accessed May 14, 2016.

[64]Emergency Nurses Association. Intimate partner violence. 2013. https://www.ena.org/SiteCollectionDocuments/Position%20Statements/Joint/IPV.pdf. Accessed May 14, 2016.

[65]Thackeray JD, Hibbard R, Dowd MD. Intimate partner violence: the role of the pediatrician. Pediatrics. 2010;125(5):1094-100. doi: 10.1542/peds.2010-0451. PMID: 20421260.

Counseling for Sexually Transmitted Infections

Clinical Recommendations

The Women's Preventive Services Initiative recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

The Women's Preventive Services Initiative recommends that health care providers use a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgement.

Implementation Considerations

The Women's Preventive Services Initiative recommends as preventive service for women at increased risk for STIs, directed behavioral counseling that includes, but is not limited to, longer duration or multiple counseling sessions, motivational interviewing techniques, and goal setting.

The Women's Preventive Services Initiative recommends as a preventive service, STI counseling regardless of whether or not STI screening takes place during the same visit and regardless of the type of sexual activity or the partners' gender.

EVIDENCE MAP

Behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at increased risk for sexually transmitted infections (STIs).

Systematic Reviews	Additional Studies	USPSTF; Bright Futures
• 2014 USPSTF review of 31 trials[1]: intensive counseling is most effective for promoting safer sexual practices and reducing STIs, although less intense approaches are also effective in some studies. • Systematic review of 13 meta-analyses and systematic reviews[2]: behavioral counseling is effective for promoting safer sexual practices and reducing STIs. • Systematic review of 31 trials[3]: brief sexuality communication showed some effect for promoting safer sexual practices and reducing STIs.	• Reduced sexual risk taking behaviors after various behavioral interventions in adolescents reported in 2 RCTs.[4-6] • A brief sexuality intervention had no effect on safer sexual practices and reducing STIs versus brief general health intervention in one RCT.[7]	• USPSTF[8]: Recommends intensive behavioral counseling for all sexually active adolescents and for adults who are at increased risk for sexually transmitted infections (STIs). At-risk adults include those with current STIs or infections within the past year; have multiple sex partners; or who do not consistently use condoms. Clinicians should also be aware of populations with a high prevalence of STIs. (Level B; 2014) • Bright Futures[9]: Risk reduction for STIs should be discussed in adolescent visits as part of routine health supervision. Anticipatory guidance should include discussions about sexuality and healthy sexual development and provide an opportunity for risk screening, health promotion, counseling, and sex education.

Abbreviations: RCT=randomized controlled trial, STI=sexually transmitted infection, USPSTF=U.S. Preventive Services Task Force

SUMMARY OF EVIDENCE

Introduction

Sexually transmitted infections (STIs) are a broad category of infectious diseases that are transmitted primarily through sexual activity including chlamydia, gonorrhea, hepatitis B, genital herpes, human immunodeficiency virus (HIV), and syphilis. Counseling to prevent STIs includes any intervention that may reduce the likelihood of an individual acquiring a STI. Interventions range in intensity, delivery, structure, and content, though the focus of this discussion is on interventions that can be delivered by health care providers in a clinical setting.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) Committee was the limitation of STI counseling to adults who have current or recent STIs or who identify as having multiple sex partners.[10] The IOM Committee recommended expanding this scope to annual counseling for STIs for all sexually active women (**Table 1**). The U.S. Preventive Services Task Force (USPSTF) updated its recommendation in 2014, however, the updated recommendation is limited to at-risk adults[8] as opposed to all sexually active adults.

Table 1. Summary of Recommendations Currently Covered under the Affordable Care Act

IOM Committee[10]	Annual counseling on STIs for sexually active women. HIV counseling is also included under a separate recommendation for HIV screening.
USPSTF[8]	Intensive behavioral counseling for all sexually active adolescents and for adults who are at increased risk for STIs. At-risk adults include those with current STIs or infections within the past year; have multiple sex partners; or who do not consistently use condoms. Clinicians should also be aware of populations with a high prevalence of STIs (e.g. African Americans, men who have sex with men, persons with low incomes in urban settings, current or former inmates, military recruits, persons who exchange sex for money or drugs, persons with mental illness or disability, current or former intravenous drug users, persons with a history of sexual abuse, and patients at public STI clinics). Intensive behavioral interventions range in duration from 30 minutes to 2 or more hours. Interventions vary in their components and delivery methods but are intended to be provided by primary care clinicians or through referral to trained counselors. (Level B; 2014)
Bright Futures[9]	Risk reduction for STIs should be discussed in adolescent visits as part of routine health supervision. Anticipatory guidance should include discussions about sexuality and healthy sexual development and provide an opportunity for risk screening, health promotion, counseling, and sex education.

Abbreviations: HIV=human immunodeficiency virus; IOM=Institute of Medicine; STIs=sexually transmitted infections; USPSTF=U.S. Preventive Services Task Force

Background

The Centers for Disease Control and Prevention (CDC) provides information about rates and trends of chlamydia, gonorrhea, and syphilis infections in U.S. populations. According to the CDC there were 1,441,789 cases of chlamydia reported in 2014 (546.1 cases per 100,000 population), an increase of 2.8% from previous year.[11] Rates in women as a group increased between 2013 and 2014. However, rates decreased by 4.2% in adolescent women 15 to 19 years, continuing a decline in rates of infection among this group since 2011. Compared with men, the rate of chlamydia infection in women was nearly double (278.4 vs. 672.2 cases per 100,000), reflecting the greater number of women screened for chlamydia. Although overall rates of infection

in men are lower than women, they increased by 22% from 2010-2014, compared with a 6% increase for women during the same period. Racial disparities for chlamydia also exist. The highest rates are among blacks, with rates 6 times that of whites, and American Indians/Alaska Natives with infection rates nearly 4 times that of whites.

From 2009 to 2012 the rate of gonorrhea infection increased annually to 106.7 cases per 100,000 population.[11] The increased rate of gonorrhea infection from 2013 to 2014 occurred primarily among men. The burden of infection varied by race with the highest rate of infection among blacks (405.4 cases per 100,000), which was almost 11 times the rate among whites (38.3 cases per 100,000 population). However, while rates of gonorrhea have been declining among blacks since 2010, they have increased in all other racial/ethnic groups. Notably, among American Indian/Alaska Natives, rates have increased 104% over the same period.

Rates of primary and secondary syphilis have increased almost every year since 2000. In 2014, there were a total of 19,999 cases reported to the CDC and the national rate increased to 6.3 cases per 100,000 population, the highest rate reported since 1994.[11] The increased rate of syphilis infection from 2000 to 2014 is largely attributed to an increase among men, specifically, among men who have sex with men. However, during 2013 to 2014, overall rates of infection increased for both women (22.7%) and men (14.4%). In 2014, 91% of all cases of primary and secondary syphilis were in men. During the same period, overall rates of infection increased among men and women in all age categories between 15 and 44, in every region, and in every race/ethnicity other than Native Hawaiians/Pacific Islanders. As with gonorrhea and chlamydia infections, the rate of primary and secondary syphilis infection affect different racial groups disproportionally. The 2014 infection rate among blacks was 5.4 times that of whites and the infection rates among black and American Indian/Alaska Native women were 9 to 10 times higher than that of white women.

STIs in women can result in long term reproductive consequences including pelvic inflammatory disease and subsequent infertility, ectopic pregnancy, and chronic pelvic pain. Perinatal transmission is also a concern. Unfortunately many women are not adequately screened and counselled for STIs. A recent Kaiser Family Foundation survey-based study found that counseling about STIs is not routine among women age 15 to 44 years.[12] Specifically, only 50% of women reported a recent conversation about sexual history with a health provider, 34% reported discussing HIV, and 30% reported discussing STIs. Many women are under the impression that HIV and STI testing are a routine part of the gynecological exam, and about half of women who reported being tested for HIV/STIs in the past two years mistakenly believed that the testing was done as a routine part of an examination.[12] Consequently, actual screening rates are likely lower than reported rates.

Several professional organizations have issued practice recommendations regarding counseling for STI prevention (**Table 2**).

Table 2. Recommendations of Professional Organizations

American College of Obstetricians and Gynecologists (ACOG)[13-15]	STIs should be discussed at the initial reproductive health visit for adolescent patients and when patients transition from pediatric to adult health care. The annual well-woman visit is an opportunity to counsel women about STI risk and provide information on risk reduction strategies, as well as screening and immunizations for STIs based on age and risk factors.
American Academy of Family Physicians (AAFP)[16]	Intensive behavioral counseling for all sexually active adolescents and for adults at increased risk for STIs.
Centers for Disease Control and Prevention (CDC)[17]	All providers should routinely obtain sexual histories from their patients and encourage risk reduction strategies through prevention counseling. Prevention counseling should be provided to all sexually active adolescents and adults with an STD diagnosis, a history of an STD in the past year, or those with multiple sex partners.

Abbreviations: STD=sexually transmitted disease; STI=sexually transmitted infection

UPDATE OF EVIDENCE

USPSTF systematic review

A 2014 USPSTF systematic review addressed the effectiveness of behavioral sexual risk-reduction counseling in primary care for prevention of STIs. This review included 31 fair-to good-quality trials.[18-48] Trials focused on persons at increased risk for STIs based on demographics, risky sexual behavior, or history of an STI; and included mostly women and nonwhite or minority populations.[1,49]

Although interventions varied, several elements were similar. All interventions aimed to minimize high-risk sexual behaviors and provided basic information about STIs. Interventions often included communication of basic information about STIs, risk assessment, skills training in condom use, safe sex communication, problem solving, and decision making. Some interventions included additional components such as HIV counseling, and many interventions were culturally tailored to a target group. Intervention implementation varied and included face-to-face counseling, videos, computer, and phone support. Most high-intensity (>2 hours) interventions included group sessions with extensive educational and behavioral change components; moderate-intensity programs generally involved one or two individual meetings; and low-intensity programs involved brief individual meetings with providers or were limited to modalities other than face-to-face contact. Interventions were commonly delivered in the setting of a primary care clinic or an STI clinic.

Among adolescents, high intensity interventions significantly reduced STI incidence (odds ratio [OR], 0.38; 95% confidence interval [CI] 0.24 to 0.60, 5 studies).[18,31,34,36,46] Two moderate intensity intervention groups showed reductions of 33% to 47% in the odds of having an STI, though only one result was statistically significant.[36,37] One low intensity intervention trial demonstrated non-significant group differences.[23] Four trials[23,31,34,37] conducted in primary care settings reported reductions of 33% or more in the odds of contracting

an STI, though not all effects were statistically significant. Six trials that reported sexual behavior outcomes in adolescents found a beneficial effect for some outcomes, most commonly for condom use or unprotected sex.

As with adolescents, high intensity interventions significantly reduced STI incidence among adults (OR 0.70, 95% CI 0.56 to 0.87; 9 studies).[20,21,24,25,35,36,38,45,46] Three high-intensity trials[20,35,38] conducted in primary care settings had ORs ranged from 0.48 (95% CI 0.24 to 0.97) to 0.82 (95% CI 0.46 to 1.45). The pooled effects for low- and moderate-intensity trials did not demonstrate reductions in the odds of contracting an STI,[49] though some individual low- and moderate-trials demonstrated effectiveness.[29,35,40,47] Nine of twelve high intensity interventions that reported behavioral outcomes found a benefit for at least one outcome. Four trials reported increased use of condoms (reduction in OR 24% to 42%). Studies of moderate intensity interventions had mixed results, with odds ratio for condom use and unprotected sex ranging from 0.98 to 2.2. Low-intensity interventions generally showed no group differences in behavioral outcomes.

Three trials that reported adverse events found no harms related to counseling interventions.[19,26,38] No statistically significant increases in STI incidence were noted in any of the studies, and no consistent evidence demonstrated that interventions increased sexual activity in adolescents.[49]

Most included trials were conducted in populations with high STI incidence, particularly blacks and/or Hispanic women, and found interventions to be effective in reducing STI incidence. Aside from the increased likelihood of benefit in adolescents compared with adults, there was no clear evidence that any interventions were more or less likely to be effective in any given subgroup evaluated by intervention trials, though some subpopulations were underrepresented in trials. Subgroup results were generally consistent with overall results.

Intervention intensity was the only characteristic that appeared to influence outcomes in trials.[49] There were no clear relationships between other aspects, such as cultural tailoring, group versus individual format, counselor characteristics, setting, or number of sessions and outcomes, although these effects were difficult to isolate.

The results from the USPSTF review were limited in their generalizability since low-risk populations were underrepresented in all studies. Also, there were few studies meeting criteria for good-quality. Methodological shortcomings included high attrition and lack of information on allocation concealment and randomization. The use of self-reported behaviors also affected data reliability.

Relevant studies published since the USPSTF systematic review

Since the USPSTF review, a systematic review that included 31 trials and observational studies (23 in the United States) focused on brief sexuality communication (10 to 60 minute interventions that include some type of communication on sexual health).[3] Interventions included audio/visual materials, risk assessment, didactic sessions, skill building/motivational interviewing, and providing resource lists. Overall, results indicated that STIs and HIV were less commonly reported in intervention groups compared with control groups. Condom use was also higher, and numbers of sexual partners and unprotected sexual intercourse were lower in the

intervention compared with control groups. This review did not provide data based on age or subpopulations and not all trials showed differences.[7]

Another systematic review included 13 meta-analyses or systematic reviews (representing 248 studies) of behavioral interventions to promote condom use.[2] Results indicated that behavioral interventions were effective in promoting condom use and reducing STIs, as well as delaying intercourse, decreasing the frequency of intercourse and number of partners, increasing STD/HIV knowledge, and reducing unprotected sex. Most interventions were delivered face-to-face, but their components were heterogeneous and included individual counseling, coping strategies, risk reduction counseling, skills training, and provision of resources. This review found that tailoring interventions to the characteristics of the population and including skills building exercises were aspects of successful interventions. The included reviews varied by geography, population, gender, ethnicity, and age sampling, and the primary outcomes were based on self-report.

Two randomized controlled trials of adolescents reported reduced sexual risk taking behaviors after various behavioral interventions. A trial of 738 U.S. urban adolescent females (69% black) randomized participants to a theory-based, sexual risk reduction intervention or a health promotion control group.[4] Girls in both groups increased their use of risk reduction strategies post-intervention, but those in the intervention group used risk reduction strategies at a faster rate than those in the control group. Both groups were exposed to motivational interviewing techniques and group and booster sessions.

A trial of 715 African American adolescent females age 15 to 21 years recruited from U.S. clinics providing sexual health services randomized participants to intervention or usual care groups.[5] The intervention included two 4-hour group sessions and 4 telephone contacts over 12 months that focused on personal, relational, sociocultural, and structural factors associated with adolescent STI/HIV risk (HORIZONS). The enhanced usual care arm consisted of 1-hour group sessions that included an STI prevention video, question and answer session, and group discussion. Over the 12-month follow-up period, fewer adolescents in the intervention arm had chlamydial infections (42 vs. 67; RR 0.65, 95% CI 0.42 to 0.98) or recurrent chlamydial infections (4 vs. 14; RR 0.25, 95% CI 0.08 to 0.83). Participants in the intervention arm also had higher numbers of condom-protected sex acts (mean difference 10.84, 95% CI 5.57 to 16.42). They were also more likely to report consistent condom use (RR 1.41, 95% CI 1.09 to 1.80) during the 60 days prior to assessment, as well as condom use at last intercourse (RR 1.30, 95% CI 1.09 to 1.54).

To assess persistence of risk reduction behavior following the HORIZONS intervention, a trial of 701 adolescent African American girls from U.S. sexual health clinics compared the HORIZONS intervention that also included a prevention maintenance intervention against a prevention maintenance intervention that focused on general health.[50] The intervention included phone contact every 8 weeks for 36 months to reinforce prevention messages. Results indicated that fewer participants in the prevention specific group had incident chlamydial infection compared with the general health group (94 vs. 105; RR 0.95, 95% CI 0.90 to 1.00) at 36-month follow-up. Participants in the prevention specific group reported more condom use in the 90 days (mean difference

0.08; 95% CI, 0.06 to 0.11) and 6 months (mean difference -0.61, 95% CI -0.98 to -0.24) prior to assessment, fewer episodes of sexual acts while on drugs and/or alcohol, and fewer vaginal sex partners in the prior 6 months.

In addition, a retrospective cohort study based on chart review of 274 sexually active girls aged 15 to 19 years who were seen in an adolescent clinic and diagnosed with gonorrhea, chlamydia, or trichomonas infection found that girls who were had been seen by a health educator for a 20 minute session focused on STI acquisition, treatment adherence, and prevention of future STIs had lower rates of recurrent STIs at 3, 6, and 12 months compared with girls receiving usual care that included standardized counseling by a health care provider or triage nurse (29% vs. 57%, 42% vs. 65%, and 57% vs. 76%, respectively; $p< 0.05$ for all comparisons), as well as longer time to STI recurrence. Although girls in the control group were more likely to engage in high-risk behaviors including substance use and no-condom use versus girls in the intervention group, the reduced risk among those receiving health education counseling persisted after adjusting for clinical presentation, past history of STIs, drug use, condom use, numbers of retest, age of first intercourse, and numbers of sex partners (hazard ratio 0.38, 95% CI 0.19 to 0.74). Also, in the final multivariate model, health education counseling was found to be protective against subsequent STIs (hazard ratio 0.39, 95% CI 0.22 to 0.72).[51]

CONCLUSIONS

Behavioral counseling interventions are effective in reducing high risk STI behaviors for both adolescents and adults. In studies, the effectiveness of interventions generally varies by intensity, with higher intensity interventions more consistently improving outcomes across studies (increased condom use, reduced unprotected sex acts, reduced STI incidence). Interventions targeting adolescents are particularly effective, even at lower intensities. Although a wide variety of counseling interventions have been studied, characteristics defining the most effective methods are not clear. However, most efficacious interventions provide basic STI information, risk assessment, and training in relevant skills such as condom use. Low-risk populations are not well represented in studies, limiting generalizability of conclusions. Also, there is a lack of data regarding the appropriate frequency of interventions, although one study of adolescents demonstrated sustained effects over 36 months with phone contacts every 8 weeks. In the future, new methods of delivery such as text messaging may improve the accessibility, acceptability, and effectiveness of less intense counseling interventions.

REFERENCES

[1]O'Connor E, Lin JS, Burda BU, et al. Behavioral sexual risk reduction counseling in primary care to prevent sexually transmitted infections: an updated systematic evidence review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 114. AHRQ Publication No. 13-05180-EF-1. Rockville, MD: Agency for Healthcare Research and Quality: 2014. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/sexually-transmitted-infections-behavioral-counseling1?ds=1&s=sexually Accessed November 30, 2016. PMID: 25356447.

[2]von Sadovszky V, Draudt B, Boch S. A systematic review of reviews of behavioral interventions to promote condom use. Worldviews on Evidence-Based Nursing. 2014;11(2):107-17. doi: http://dx.doi.org/10.1111/wvn.12017. PMID: 24119245.

[3]Cooper B, Toskin I, Kulier R, et al. Brief sexuality communication--a behavioural intervention to advance sexually transmitted infection/HIV prevention: a systematic review. BJOG: An International Journal of Obstetrics & Gynaecology. 2014;121 Suppl 5:92-103. doi: http://dx.doi.org/10.1111/1471-0528.12877. PMID: 25335846.

[4]Morrison-Beedy D, Crean HF, Passmore D, et al. Risk reduction strategies used by urban adolescent girls in an HIV prevention trial. Current HIV Research. 2013;11(7):559-69. PMID: 24476350.

[5]DiClemente RJ, Wingood GM, Rose ES, et al. Efficacy of sexually transmitted disease/human immunodeficiency virus sexual risk-reduction intervention for african american adolescent females seeking sexual health services: a randomized controlled trial. Arch Pediatr Adolesc Med. 2009;163(12):1112-21. doi: 10.1001/archpediatrics.2009.205. PMID: 19996048.

[6]DiClemente RJ, Bradley E, Davis TL, et al. Adoption and implementation of a computer-delivered HIV/STD risk-reduction intervention for African American adolescent females seeking services at county health departments: implementation optimization is urgently needed. Journal of Acquired Immune Deficiency Syndromes: JAIDS. 2013;63 Suppl 1:S66-71. doi: http://dx.doi.org/10.1097/QAI.0b013e318292014f. PMID: 23673891.

[7]Carey MP, Senn TE, Walsh JL, et al. Evaluating a brief, video-based sexual risk reduction intervention and assessment reactivity with STI clinic patients: results from a randomized controlled trial. AIDS & Behavior. 2015;19(7):1228-46. doi: http://dx.doi.org/10.1007/s10461-014-0960-3. PMID: 25433653.

[8]LeFevre ML. Behavioral counseling interventions to prevent sexually transmitted infections: U.S. PreventiveServices Task Force recommendation statement. Ann Intern Med. 2014;161(12):894-901. doi: 10.7326/m14-1965. PMID: 25244227.

[9]American Academy of Pediatrics. Bright Futures: Guidelines for health supervision of infants, children and adolescents, 3rd ed. American Academy of Pediatrics: Elk Grove Village, IL. 2008.

[10]IOM (institute of Medicine). Clinical preventive services for women: Closing the gaps. Washington, DC: National Academies Press; 2011.

[11]Centers for Disease Control and Prevention. Sexually transmitted disease surveillance 2014 U.S. Department of Health and Human Services. Atlanta: 2015. http://www.cdc.gov/std/stats. Accessed November 30, 2016.

[12]Salganicoff A, Ranji U, Beamesderfer A, et al. Women and health care in the early years of the ACA: Key findings from the 2013 Kaiser Women's Health Survey. Menlo Park (CA): The Henry J. Kaiser Family Foundation. 2014.

[13]Committee opinion no. 626: the transition from pediatric to adult health care: preventive care for young women aged 18-26 years. Obstet Gynecol. 2015;125(3):752-4. doi: 10.1097/01.AOG.0000461764.54910.a8. PMID: 25730254.

[14]ACOG Committee Opinion no. 598: Committee on Adolescent Health Care: The initial reproductive health visit. Obstet Gynecol. 2014;123(5):1143-7. doi: 10.1097/01.AOG.0000446826.46833.c0. PMID: 24785880.

[15]Committee opinion No. 534: well-woman visit. Obstet Gynecol. 2012;120(2 Pt 1):421-4. doi: 10.1097/AOG.0b013e3182680517. PMID: 22825111.

[16]American Academy of Family Physicians. Clinical preventive service recommendation: sexually transmitted infections. http://www.aafp.org/patient-care/clinical-recommendations/all/stis.html. Accessed May 15, 2016.

[17]Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep. 2015;64(Rr-03):1-137. PMID: 26042815.

[18]Champion JD, Collins JL. Comparison of a theory-based (AIDS Risk Reduction Model) cognitive behavioral intervention versus enhanced counseling for abused ethnic minority adolescent women on infection with sexually transmitted infection: results of a randomized controlled trial. International journal of nursing studies. 2012;49(2):138-50.

[19]Metsch LR, Feaster DJ, Gooden L, et al. Effect of risk-reduction counseling with rapid HIV testing on risk of acquiring sexually transmitted infections: the AWARE randomized clinical trial. JAMA. 2013;310(16):1701-10. doi: http://dx.doi.org/10.1001/jama.2013.280034. PMID: 24150466.

[20]Wingood GM, Diclemente RJ, Robinson-Simpson L, et al. Efficacy of an HIV intervention in reducing high-risk human papillomavirus, nonviral sexually transmitted infections, and concurrency among African American women: a randomized-controlled trial. Journal of Acquired Immune Deficiency Syndromes: JAIDS. 2013;63 Suppl 1:S36-43. doi: http://dx.doi.org/10.1097/QAI.0b013e3182920031. PMID: 23673884.

[21]Berenson AB, Rahman M. A randomized controlled study of two educational interventions on adherence with oral contraceptives and condoms. Contraception. 2012;86(6):716-24. doi: 10.1016/j.contraception.2012.06.007.

[22]Berkman A, Pilowsky DJ, Zybert PA, et al. HIV prevention with severely mentally ill men: A randomised controlled trial. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV. 2007;19(5):579-88. doi: 10.1080/09540120701213989.

[23]Boekeloo BO, Schamus LA, Simmens SJ, et al. A STD/HIV prevention trial among adolescents in managed care. Pediatrics. 1999;103(1):107-15. doi: 10.1542/peds.103.1.107.

[24]Boyer CB, Barrett DC, Peterman TA, et al. Sexually transmitted disease (STD) and HIV risk in heterosexual adults attending a public STD clinic: Evaluation of a randomized controlled behavioral risk-reduction intervention trial. AIDS. 1997;11(3):359-67. doi: 10.1097/00002030-199703110-00014.

[25]Carey MP, Carey KB, Maisto SA, et al. Reducing HIV-Risk Behavior among Adults Receiving Outpatient Psychiatric Treatment: Results from a Randomized Controlled Trial. Journal of Consulting and Clinical Psychology. 2004;72(2):252-68. doi: 10.1037/0022-006X.72.2.252.

[26]Carey MP, Senn TE, Vanable PA, et al. Brief and intensive behavioral interventions to promote sexual risk reduction among STD clinic patients: Results from a randomized controlled trial. AIDS and Behavior. 2010;14(3):504-17. doi: 10.1007/s10461-009-9587-1.

[27]Cianelli R, Ferrer L, Norr KF, et al. Mano a Mano-Mujer: An Effective HIV prevention intervention for Chilean women. Health Care for Women International. 2012;33(4):321-41. doi: 10.1080/07399332.2012.655388.

[28]Cortes-Bordoy J, Vidart JA, Coll-Capdevila C, et al. Usefulness of an educational leaflet to modify sexual risk behaviour in women with external genital warts. European Journal of Dermatology. 2010;20(3):339-44. doi: 10.1684/ejd.2010.0898.

[29]Crosby R, DiClemente RJ, Charnigo R, et al. A brief, clinic-based, safer sex intervention for heterosexual African American men newly diagnosed with an STD: a randomized controlled trial. American journal of public health. 2009;99 Suppl 1:S96-103. doi: 10.2105/AJPH.2007.123893.

[30]Danielson R, Marcy S, Plunkett A, et al. Reproductive health counseling for young men: What does it do? Family Planning Perspectives. 1990;22(3):115-21. doi: 10.2307/2135642.

[31]DiClemente RJ, Wingood GM, Harrington KF, et al. Efficacy of an HIV prevention intervention for African American adolescent girls: A randomized controlled trial. Journal of the American Medical Association. 2004;292(2):171-9. doi: 10.1001/jama.292.2.171.

[32]Ehrhardt AA, Exner TM, Hoffman S, et al. A gender-specific HIV/STD risk reduction intervention for women in a health care setting: Short- and long-term results of a randomized clinical trial. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV. 2002;14(2):147-61. doi: 10.1080/09540120220104677.

[33]Guilamo-Ramos V, Bouris A, Jaccard J, et al. A parent-based intervention to reduce sexual risk behavior in early adolescence: Building alliances between physicians, social workers, and parents. Journal of Adolescent Health. 2011;48(2):159-63. doi: 10.1016/j.jadohealth.2010.06.007.

[34]Jemmott Iii JB, Jemmott LS, Braverman PK, et al. HIV/STD risk reduction interventions for African American and Latino adolescent girls at an adolescent medicine clinic: A randomized controlled trial. Archives of Pediatrics and Adolescent Medicine. 2005;159(5):440-9. doi: 10.1001/archpedi.159.5.440.

[35]Jemmott LS, Jemmott Iii JB, O'Leary A. Effects on sexual risk behavior and STD rate of brief HIV/STD prevention interventions for African American women in primary care settings. American Journal of Public Health. 2007;97(6):1034-40. doi: 10.2105/AJPH.2003.020271.

[36]Kamb ML, Fishbein M, Douglas Jr JM, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases. A randomized controlled trial. Journal of the American Medical Association. 1998;280(13):1161-7. doi: 10.1001/jama.280.13.1161.

[37]Kershaw TS, Magriples U, Westdahl C, et al. Pregnancy as a window of opportunity for HIV prevention: Effects of an HIV intervention delivered within prenatal care. American Journal of Public Health. 2009;99(11):2079-86. doi: 10.2105/AJPH.2008.154476.

[38]Marion LN, Finnegan L, Campbell RT, et al. The well woman program: A community-based randomized trial to prevent sexually transmitted infections in low-income African American women. Research in Nursing and Health. 2009;32(3):274-85. doi: 10.1002/nur.20326.

[39]Marrazzo JM, Thomas KK, Ringwood K. A behavioural intervention to reduce persistence of bacterial vaginosis among women who report sex with women: Results of a randomised trial. Sexually Transmitted Infections. 2011;87(5):399-405. doi: 10.1136/sti.2011.049213.

[40]Neumann MS, O'Donnell L, Doval AS, et al. Effectiveness of the VOICES/VOCES sexually transmitted disease/human immunodeficiency virus prevention intervention when administered by health department staff: Does it work in the "real world"? Sexually Transmitted Diseases. 2011;38(2):133-9. doi: 10.1097/OLQ.0b013e3181f0c051.

[41]Peipert JF, Redding CA, Blume JD, et al. Tailored intervention to increase dual-contraceptive method use: a randomized trial to reduce unintended pregnancies and sexually transmitted infections. Am J Obstet Gynecol. 2008;198(6):630.e1-.e8. doi: 10.1016/j.ajog.2008.01.038.

[42]Petersen R, Albright J, Garrett JM, et al. Pregnancy and STD prevention counseling using an adaptation of motivational interviewing: A randomized controlled trial. Perspectives on Sexual and Reproductive Health. 2007;39(1):21-8. doi: 10.1363/3902107.

[43]Proude EM, D'Este C, Ward JE. Randomized trial in family practice of a brief intervention to reduce STI risk in young adults. Family Practice. 2004;21(5):537-44. doi: 10.1093/fampra/cmh510.

[44]Scholes D, McBride CM, Grothaus L, et al. A tailored minimal self-help intervention to promote condom use in young women: Results from a randomized trial. AIDS. 2003;17(10):1547-56. doi: 10.1097/00002030-200307040-00016.

[45]Shain RN, Piper JM, Holden AEC, et al. Prevention of gonorrhea and chlamydia through behavioral intervention: Results of a two-year controlled randomized trial in minority women. Sexually Transmitted Diseases. 2004;31(7):401-8. doi: 10.1097/01.olq.0000135301.97350.84.

[46]Shain RN, Piper JM, Newton ER, et al. A randomized, controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. NEJM. 1999;340(2):93-100. doi: 10.1056/NEJM199901143400203.

[47]Warner L, Klausner JD, Rietmeijer CA, et al. Effect of a brief video intervention on incident infection among patients attending sexually transmitted disease clinics. PLoS Medicine. 2008;5(6):0919-21. doi: 10.1371/journal.pmed.0050135.

[48]Wenger NS, Greenberg JM, Hilborne LH, et al. Effect of HIV antibody testing and AIDS education on communication about HIV risk and sexual behavior. A randomized, controlled trial in college students. Ann Intern Med. 1992;117(11):905-11.

[49]O'Connor EA, Lin JS, Burda BU, et al. Behavioral sexual risk-reduction counseling in primary care to prevent sexually transmitted infections: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2014;161(12):874-83. doi: 10.7326/m14-0475. PMID: 25243895.

[50]DiClemente RJ, Wingood GM, Sales JM, et al. Efficacy of a telephone-delivered sexually transmitted infection/human immunodeficiency virus prevention maintenance intervention for adolescents: a randomized clinical trial. JAMA Pediatrics. 2014;168(10):938-46. doi: http://dx.doi.org/10.1001/jamapediatrics.2014.1436. PMID: 25155070.

[51]In-Iw S, Braverman PK, Bates JR, et al. The impact of health education counseling on rate of recurrent sexually transmitted infections in adolescents. J Pediatr Adolesc Gynecol. 2015;28(6):481-5. doi: http://dx.doi.org/10.1016/j.jpag.2015.02.001. PMID: 26220351.

Well-Woman Preventive Visits

Clinical Recommendations

The Women's Preventive Services Initiative recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services, including preconception and many services necessary for prenatal and interconception care, are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service for women, that women receive at least one preventive care visit per year. Additional well-woman visits may be needed to obtain all necessary services depending on a woman's age, health status, reproductive health needs, pregnancy status, and risk factors. Visits should allow sufficient time to address and coordinate services, and a team based approach may facilitate delivery of services.

Well-woman preventive services may include, but are not limited to, assessment of physical and psychosocial function, primary and secondary prevention and screening, risk factor assessments, immunizations, counseling, education, and preconception, prenatal, and interconception care. Recommended services are evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force, immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved, with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration, and with respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.

EVIDENCE MAP

WPSI recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services are obtained.

Systematic Reviews	Additional Studies	USPSTF; Bright Futures
2012 Cochrane review[1]: no reductions in morbidity or mortality (overall, cardiovascular, or cancer related), but increases in the numbers of new diagnoses with annual health checks.	No studies evaluate the effectiveness of well-woman preventive visits; 3 observational studies of the effectiveness of the periodic health exam concern specific components of the visit rather than the visit itself.[1-3]	• USPSTF: No recommendation • Bright Futures[4]: Preventive pediatric health care visits for children annually from ages 3 through 21 years, including initial/interval medical histories, measurements, sensory screening, developmental/ behavioral assessments, physical examination, age-appropriate procedures, oral health, and anticipatory guidance.

The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

Systematic Reviews	Additional Studies	USPSTF; Bright Futures
None	None	• USPSTF: Individual age-appropriate preventive services are supported by separate USPSTF recommendations.[5] • Bright Futures: see above

Abbreviations: ACA=Affordable Care Act, USPSTF=U.S. Preventive Services Task Force

SUMMARY OF EVIDENCE

Introduction

A well-woman preventive visit is a clinical encounter that addresses issues of general wellness and provides screening, immunizations, counseling, and other prevention services for a variety of health conditions. Visits facilitate access to health care services, identify risk factors, and reduce the likelihood or delay the onset of disease. Well-woman visits apply to women of all ages and stages of life, and are individualized for delivery of appropriate screening recommendations and prevention services.

Current Recommendations and Coverage of Services

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 (ACA) previously identified by the Institute of Medicine (IOM) was the absence of coverage for well-woman preventive care visits for women ages 21 to 64 years.[6] Support of these visits was based on current policies (Medicaid, Medicare), professional guidelines, and private health plan policies that included mandated

coverage for preventive visits for children and adolescents up to age 21 and for some adults age 65 and older. The IOM committee recognized this gap in coverage, further emphasizing a disproportionate burden on women of childbearing age.

The U.S. Department of Health and Human Services (HHS) adopted the IOM Committee's recommendation[6] for at least one annual well-woman preventive visit (**Table 1**). These visits include a full evaluation, separate from any other visit for sickness or injury, and focus on preventive care that may include immunizations, screening tests, education, and counseling. In order to obtain all of the recommended services, several visits may be necessary for some women depending on age, health status, health needs, and risk factors.[7] Under the ACA, at least 15 preventive services and one wellness visit are covered on Major Medical Plans sold after 2014 without copays and coinsurance, regardless of meeting deductibles.[8-10]

Clinical preventive services for adolescents are based on a package of preventive services[11] through the Bright Futures health initiative, a nationally recognized pediatric periodicity schedule that recommends preventive health care visits annually for children ages 3 through 21 years.[4] Federal standards require the provision of prevention services for children under 21 through the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program, which provides comprehensive and preventive health care services for children under age 21 who are enrolled in Medicaid.[12] Medicare covers annual wellness visits for adults over age 65 years.[13]

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

IOM Committee[6]	At least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. 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.
USPSTF	Not addressed.
Bright Futures[11]	Preventive pediatric health care visits for children annually from ages 3 through 21 years, including initial/interval medical histories, measurements, sensory screening, developmental/behavioral assessments, physical examination, age-appropriate procedures, oral health, and anticipatory guidance.

Abbreviations: IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

Background

Preventive health care improves health and is a major component of medical practice in the United States.[14,15] Well-woman preventive visits are important to women of all ages, including adolescents, and its goals vary by age, risk factors, and comorbidities.[4,6,16]

There are no standard definitions for the well-woman preventive visit, and various other terms have been used

to describe these types of visits including the periodic health exam, annual physical, and health maintenance visit. Few studies have been done to determine the effectiveness of the visit in improving health outcomes,[3] although the effectiveness of many services that would be delivered in this setting is well supported, including A and B Level recommendations from the USPSTF.[5] Routine visits have been associated with subsequent use of increased preventive care and cancer screening.[3] They may serve as entry points to additional prevention care, as well as opportunities to reach marginalized individuals who would not otherwise seek regular health care.[17]

A well-woman preventive visit consists of various components that often vary among medical specialties.[18,19] In addition, the scope of services may vary by provider,[20,21] as well was by the perceived value of routine exams by both physicians[22-24] and the public.[25] In a survey of primary care physicians, 65% agreed that a periodic health exam was necessary for asymptomatic adults.[22] Despite variation, several professional groups recommend periodic preventive health visits (**Table 2**).

Several models of care may improve delivery of these services. The concept of the patient centered medical home has been proposed as a model for streamlining women's health care as it emphasizes care coordination, continuity, evidence-based practice, enhanced access, and payment reform.[26] In early 2008, the National Committee for Quality Assurance (NCQA), in collaboration with four medical specialty societies (AAFP, ACP, AAP, and the AOA) and the Patient Centered Primary Care Collaborative, further refined the concept of the patient centered medical home by defining specific practice standards and reporting measures.[27] Another potential model of focused preventive visits is the Medicare Annual Wellness visit, which is a tailored, evidence-based approach to an annual exam that includes a medical history, recommended immunizations and screenings with further tests depending on health and medical history. In this case, compliance with the visit may affect coverage or reimbursement.

Table 2. Recommendations of Professional Organizations

American College of Obstetricians and Gynecologists (ACOG)[18]	Annual health assessments and routine annual exams for women ages 13 and above as an opportunity to counsel patients about preventive care and to provide or refer for recommended services. These assessments should include screening, laboratory and other tests, counseling, and immunizations based on age and risk factors. The interval for individual services varies.
American Academy of Family Physicians (AAFP)[28]	Policy recommendations for a number of clinical preventive services for general and specific populations, but no specific recommendation for or against a well-woman exam or routine physical.
Centers for Disease Control and Prevention (CDC)[29]	See a doctor or nurse for a well-woman visit every year. These visits include a full checkup, separate from any other visit for sickness or injury, and focus on preventive care for women. Recommended for women under 65.

Based on 2015 data from the DHHS, 137 million Americans now have insurance coverage for preventive services without cost sharing under the ACA, including over 55 million women.[30] A study of the impact of coverage for young adults, age 18 to 26 years, after the implementation of the ACA demonstrated higher rates for receiving routine examinations (47.8% vs 44.1%, P<0.05) and preventive services from 2009 to 2011.[31] While implementation of the ACA has provided women access to well-woman preventive visits, many women are unaware of the benefit and providers may not be sure what is covered despite consumer and provider oriented materials[32] to help them understand and access services.

UPDATE OF EVIDENCE

Most studies of the effectiveness of the periodic health exam concern specific components of the visit rather than the visit itself.[1-3,33]

A 2012 Cochrane systematic review quantified the benefits and harms of general health checks, or preventive health exams, focusing on morbidity and mortality outcomes. Data from 14 randomized trials comparing health checks versus no health checks (182,880 patients) found no reduction in morbidity or mortality (overall, cardiovascular, or cancer related), but an increase in the number of new diagnoses. Harmful outcomes were infrequently studied or reported.[1] However, the clinical applicability of these studies to U.S. population is low. Eleven of the studies included in the Cochrane review were conducted in Europe, where health care delivery and coverage differ greatly from the United States. In addition, most patients in the Cochrane studies had regular contact with primary care physicians. The three U.S. studies were conducted between 1964 and 1980, before the wide-spread implementation of routine, evidence-based screening.

The effectiveness of routine well-woman physical exams has not been supported by studies. Traditionally, these exams were tied to screening, such as for cervical and breast cancer, that are themselves effective health services. However, more recent studies[34] demonstrate the limited utility of routine pelvic exams outside of cervical cancer screening.[35]

CONCLUSIONS

A well-woman preventive visit is a clinical encounter that addresses issues of general wellness and provides screening, immunizations, counseling, and other prevention services for a variety of health conditions. These visits also serve to facilitate access to health care services. Few studies have been done to determine the effectiveness of the visit in improving health outcomes, although the effectiveness of many services that would be delivered in this setting is well supported. These include A and B Level recommendations from the USPSTF such as screening for different types of cancer (e.g. cervical, breast, colon) and sexually transmitted infections, risk assessment for chronic diseases (e.g., cardiovascular disease, osteoporosis), and counseling for healthy behavior changes (e.g., smoking cessation).

REFERENCES

[1]Krogsboll LT, Jorgensen KJ, Gronhoj Larsen C, et al. General health checks in adults for reducing morbidity and mortality from disease. Cochrane Database Syst Rev. 2012;10doi: 10.1002/14651858.CD009009.pub2. PMID: 23076952.

[2]Bloomfield HE, Wilt TJ, Ensrud K, et al. Evidence brief: role of the annual comprehensive physical examination in the asymptomatic adult. 2011.

[3]Boulware LE, Marinopoulos S, Phillips KA, et al. Systematic review: the value of the periodic health evaluation. Ann Intern Med. 2007;146(4):289-300. PMID: 17310053.

[4]Hagan JF, Shaw JS, Duncan PM. Bright Futures: Guidelines for health supervision of infants, children and adolescents, 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics: 2008. https://brightfutures.aap.org/bright%20Futures%20Documents/BF3%20pocket%20guide_final.pdf. Accessed November 30, 2016.

[5]U.S. Preventive Services Task Force. Published Recommendations. Rockville MD; 2016. https://www.uspreventiveservicestaskforce.org/BrowseRec/Index. Accessed October 6 2016.

[6]IOM (institute of Medicine). Clinical preventive services for women: Closing the gaps. Washington, DC: National Academies Press; 2011.

[7]Centers for Medicare & Medicaid Services. Affordable Care Act implementation FAQs - set 12. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html. Accessed May 12, 2016.

[8]U.S. Department of Health and Human Resources. Affordable Care Act expands prevention coverage for women's health and well-being. http://www.hrsa.gov/womensguidelines/. Accessed May 14, 2016.

[9]Centers for Medicare & Medicaid Services. Preventive care benefits for women. https://www.healthcare.gov/preventive-care-women/. Accessed May 14, 2016.

[10]Centers for Medicare & Medicaid Services. Healthcare.gov. https://www.healthcare.gov/. Accessed May 14, 2016.

[11]Recommendations for preventive pediatric health care. Committee on Practice and Ambulatory Medicine. Pediatrics. 1995;96(2 Pt 1):373-4. PMID: 7630705.

[12]Government Accountability Office. Medicaid preventive services: Concerted efforts needed to ensure beneficiaries receive services. Washington, DC: Government Accountability Office: 2009. http://www.gao.gov/products/GAO-09-578. Accessed November 30, 2016.

[13]Centers for Medicare & Medicaid Services. Preventive visit & yearly wellness exams. https://www.medicare.gov/coverage/preventive-visit-and-yearly-wellness-exams.html. Accessed May 14, 2016.

[14]Centers for Disease Control and Prevention (CDC). Ten great public health achievements--United States, 1900-1999. MMWR Morb Mortal Wkly Rep. 1999;48(12):241-3. PMID: 10220250.

[15]LaVeist TA, Rolley NC, Diala C. Prevalence and patterns of discrimination among U.S. health care consumers. Int J Health Serv. 2003;33(2):331-44. PMID: 12800890.

[16]The American College of Obstetricians and Gynecologists. Annual Well-Woman examination. Top reasons why you should have an annual well-woman examination. 2015. https://www.acog.org/-/media/For-Patients/Annual-Well-Woman-Exam-Infographic-lg.pdf?la=en. Accessed April 14, 2016.

[17]Duerksen A, Dubey V, Iglar K. Annual adult health checkup: update on the Preventive Care Checklist Form((c)). Can Fam Physician. 2012;58(1):43-7. PMID: 22267619.

[18]The American College of Obstetricians and Gynecologists. Committee opinion No. 534: well-woman visit. Obstet Gynecol. 2012;120(2 Pt 1):421-4. doi: 10.1097/AOG.0b013e3182680517. PMID: 22825111.

[19]Qaseem A, Humphrey LL, Harris R, et al. Screening pelvic examination in adult women: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2014;161(1):67-72. doi: 10.7326/m14-0701. PMID: 24979451.

[20]Mehrotra A, Zaslavsky AM, Ayanian JZ. Preventive health examinations and preventive gynecological examinations in the United States. Arch Intern Med. 2007;167(17):1876-83. doi: 10.1001/archinte.167.17.1876. PMID: 17893309.

[21]Weisman CS, Henderson JT. Managed care and women's health: access, preventive services, and satisfaction. Womens Health Issues. 2001;11(3):201-15. PMID: 11336861.

[22]Prochazka AV, Lundahl K, Pearson W, et al. Support of evidence-based guidelines for the annual physical examination: a survey of primary care providers. Arch Intern Med. 2005;165(12):1347-52. doi: 10.1001/archinte.165.12.1347. PMID: 15983282.

[23]The periodic health examination. Canadian Task Force on the Periodic Health Examination. Can Med Assoc J. 1979;121(9):1193-254. PMID: 115569.

[24]The Guide to Clinical Preventive Services 2014: Recommendations of the U.S. Preventive Services Task Force Agency for Healthcare Research and Quality (US). Rockville (MD): 2014. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/index.html Accessed November 30, 2016. PMID: 25144048.

[25]Oboler SK, Prochazka AV, Gonzales R, et al. Public expectations and attitudes for annual physical examinations and testing. Ann Intern Med. 2002;136(9):652-9. PMID: 11992300.

[26]The American Congress of Obstetricians and Gynecologists. Medical home answers to some questions. Washington DC: American Congress of Obstetricians and Gynecologists; 2016. http://www.acog.org/About-ACOG/ACOG-Departments/Practice-Management-and-Managed-Care/Medical-Home----Answers-to-Some-Questions. Accessed May 12, 2016.

[27]The National Committee of Quality Assurance. Evidence showing effectiveness of NCQA recognition. 2015. http://www.ncqa.org/Portals/0/Programs/Recognition/PCMHEvidenceReportJune2015_Web.pdf?ver=2016-02-24-143948-347. Accessed November 30, 2016.

[28]American Academy of Family Physicians. Summary of recommendations for clinical preventive services. 2016. http://www.aafp.org/dam/AAFP/documents/patient_care/clinical_recommendations/cps-recommendations.pdf. Accessed November 30, 2016.

[29]Office of Disease Prevention and Health Promotion. Get your well-woman visit every year. 2015. http://healthfinder.gov/HealthTopics/Category/everyday-healthy-living/sexual-health/get-your-well-woman-visit-every-year. Accessed May 18, 2016.

[30]Department of Health & Human Services. The Affordable Care Act is improving access to preventive services for millions of Americans. 2015. https://aspe.hhs.gov/sites/default/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf. Accessed May 11, 2016.

[31]Lau JS, Adams SH, Park MJ, et al. Improvement in preventive care of young adults after the affordable care act: the affordable care act is helping. JAMA Pediatrics. 2014;168(12):1101-6. doi: http://dx.doi.org/10.1001/jamapediatrics.2014.1691. PMID: 25347766.

[32]Fitzgerald T, Glynn A, Davenport K, et al. Well-woman visits: Guidance and monitoring are key in this turning point for women's health. Women's Health Issues. 2015;25(2):89-90. doi: http://dx.doi.org/10.1016/j.whi.2015.01.001. PMID: 2015-10012-003.

[33]United States Preventive Services Task Force. Guide to clinical preventive services: an assessment of the effectiveness of 169 interventions: Williams and Wilkins; 1989.

[34]Bloomfield HE, Olson A, Greer N, et al. Screening pelvic examinations in asymptomatic, average-risk adult women: an evidence report for a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2014;161(1):46-53. doi: 10.7326/m13-2881. PMID: 24979449.

[35]Pascale A, Beal MW, Fitzgerald T. Rethinking the well woman visit: A scoping review to identify eight priority areas for well woman care in the era of the affordable care act. Women's Health Issues. 2016;26(2):135-46. doi: http://dx.doi.org/10.1016/j.whi.2015.11.003. PMID: 2016-09732-002.

WOMEN'S PREVENTIVE SERVICES INITIATIVE ROSTER

Women's Preventive Services Initiative Chairperson

American College of Obstetricians and Gynecologists
Jeanne Conry, MD, PhD

Women's Preventive Services Initiative Advisory Panel

American Academy of Family Physicians
Jennifer L. Frost, MD, FAAFP

American College of Obstetricians and Gynecologists
Jeanne Conry, MD, PhD

American College of Obstetricians and Gynecologists and Multidisciplinary Steering Committee Chairperson
Maureen G. Phipps, MD, MPH

American College of Physicians
Amir Qaseem, MD, PhD, MHA, FACP

Member of the IOM 2011 Committee on Preventive Services for Women
Kimberly D. Gregory, MD, MPH

Member of the IOM 2011 Committee on Preventive Services for Women
Alina Salganicoff, PhD

Member of the IOM 2011 Committee on Preventive Services for Women
Heidi D. Nelson, MD, MPH, MACP

National Association of Nurse Practitioners in Women's Health
Susan Kendig, JD, WHNP-BC, FAAN

Women's Preventive Services Initiative Multidisciplinary Steering Committee

Academy of Women's Health
Melissa McNeil, MD, MPH, MACP

American Academy of Family Physicians
James J. Stevermer, MD, MSPH, FAAFP

American Academy of Pediatrics
Gale R. Burstein, MD, MPH, FAAP

American Academy of Physician Assistants
Annamarie F. Streilein, MHS, PA-C

American Cancer Society
Robert Smith, PhD

American College of Nurse-Midwives
Michelle Collins, PhD, CNM, FACNM, FAAN

American College of Obstetricians and Gynecologists
David Chelmow, MD

American College of Physicians
Linda L. Humphrey, MD, MPH, MACP

American College of Preventive Medicine
Rachel Peragallo Urrutia, MD, MS

American College of Radiology
Stamatia Destounis MD, FACR, FSBI

American Geriatrics Society
Stacy Tessler Lindau, MD, MAPP

American Osteopathic Association
Octavia Cannon, DO, FACOOG

American Psychiatric Association
Maureen Sayres Van Niel, MD

Association of Maternal and Child Health Programs
Jeanette Kowalik, PhD, MPH, MCHES

Association of Reproductive Health Professionals
Pelin Batur, MD, FACP, NCMP

Association of Women's Health, Obstetric and Neonatal Nurses
Susan Peck, RN, MSN WHNP

National Comprehensive Cancer Network
Therese B. Bevers, MD

National Medical Association
Edith Peterson Mitchell, MD, FACP, FCPP

National Partnership for Women & Families
Jessi Leigh Swenson, JD

National Association of Nurse Practitioners in Women's Health
Susan Hoffstetter, PhD, WHNP

National Women's Law Center
Janel A. George, JD

Patient Representative
Susan C. Dimock, PhD

Pacific Northwest Evidence-based Practice Center Oregon Health & Science University/WPSI Project Team

Principal Investigator
Heidi D. Nelson, MD, MPH, MACP

Co-investigators
Amy Cantor, MD, MPH
Bernadette Zakher, MBBS

Project Managers
Miranda Pappas, MA
Tracy Dana, MLS

Librarian
Andrew Hamilton, MLS, MS

Project Staff
Spencer Dandy
Sara Grusing
Liev Miller

Federal Partners

Health Resources and Services Administration Maternal and Child Health Bureau
Michael Lu, MD, MS, MPH
Hani Atrash, MD, MPH
Kimberly Sherman, MPH, MPP
Vanessa Lee, MPH
CDR Johannie Escarne, MPH
Lee Wilson

Centers for Disease Control and Prevention
Kathryn M. Curtis, PhD

Office of Health Reform
Kristi L. Martin

Office of Minority Health
Aracely Macias, MPH

Office of Population Affairs
Susan B. Moskosky, MS, WHNP-BC

Office on Women's Health
Nancy C. Lee, MD
Sayeedha Uddin, MD, MPH

American College of Obstetricians and Gynecologists/Women's Preventive Services Initiative Staff

Vice President of Practice Activities
Christopher M. Zahn, MD, Col (Ret), USAF, MC

Senior Director of Gynecologic Practice
Nancy O'Reilly, MHS

WPSI Program Director
Sarah Son, MPH

WPSI Program Manager
Ariste Sallas-Brookwell, MSW

WPSI Program Specialist
Katie Ogden
Rebecca Kauma

LIST OF ABBREVIATIONS

Abbreviation	Definition
AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatricians
AAS	Abuse Assessment Screen
AAS	Abuse Assessment Screen
ACA	Patient Protection and Affordable Care Act of 2010
ACEP	American College of Emergency Physicians
ACOG	American College of Obstetricians and Gynecologists
ACS	American Cancer Society
ADA	American Diabetes Association
AMA	American Medical Association
ART	antiretroviral therapy
ARTISTIC	A Randomized Trial in Screening to Improve Cytology
ASCCP	American Society for Colposcopy and Cervical Pathology
ASCP	American Society for Clinical Pathology
ASC-US	atypical cells of undetermined significance
ATHENA	Addressing the Need for Advanced HPV Diagnostics study
CBT	cognitive behavioral therapy
CC	Carpenter-Coustan
CCRCT	Cochrane Central Register of Controlled Trials
CDA	Canadian Diabetes Association
CDC	Centers for Disease Control and Prevention
CDSR	Cochrane Database of Systematic Reviews
CI	confidence interval
CIN	cervical intraepithelial neoplasia
CTS-2	Revised Conflict Tactics Scale
DMPA	depot medroxyprogesterone acetate

Table continued on page 158.

LIST OF ABBREVIATIONS CONTINUED

Abbreviation	Definition
DNA	deoxyribonucleic acid
E-HITS	Extended Hurt/Insult/Threaten/Scream tool
ENA	Emergency Nurses Association
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
FDA	U.S. Food and Drug Administration
GDM	gestational diabetes mellitus
HARK	Humiliation, Afraid, Rape, Kick tool
HbA1c	hemoglobin A1c
HHS	U.S. Department of Health and Human Services
HITS	Hurt/Insult/Threaten/Scream tool
HIV	human immunodeficiency virus
HIV	human immunodeficiency virus
HPV	human papilloma virus
HR	hazard ratio
HSIL	high-grade squamous intraepithelial lesion
IADPSG	International Association of the Diabetes and Pregnancy Study Groups
IOM	Institute of Medicine
IPV	intimate partner violence
LARC	Long acting reversible contraception
LNG IUS	levonorgestrel intrauterine system
LSIL	low-grade squamous intraepithelial lesion
MEC	medical eligibility criteria
Modified CTQ-SF	Conflict Tactics Scale-Revised Short Form
N	sample size
NCQA	National Committee for Quality Assurance
NDDG	National Diabetes Data Group
NTCC	New Technologies for Cervical Cancer screening study

Table continued on page 159.

LIST OF ABBREVIATIONS CONTINUED

Abbreviation	Definition
OAS	Ongoing Abuse Screen
OGCT	oral glucose challenge test
OR	odds ratio
OVAT	Ongoing Violence Assessment Tool
POBASCAM	Population Based Screening Study Amsterdam Program
PRAMS	Pregnancy Risk Assessment Monitoring System
PSQ	Parent Screening Questionnaire
PVS	Partner Violence Screen
RCT	randomized controlled trial
RR	risk ratio
SAFE-T	Secure, Accepted, Family, Even, Talk measure
SEER	Surveillance, Epidemiology, and End Results Program
SGIM	Society of General Internal Medicine
SIDs	sudden infant death syndrome
SMD	standard mean difference
STaT	Slapped, Threatened, and Throw measure
STD	sexually transmitted disease
STI	sexually transmitted infection
U.S. SPR	US Selected Practice Recommendations for Contraceptive Use 2013
U.K.	United Kingdom
UNICEF	United Nations Children's Emergency Fund
U.S.	United States
USPSTF	U.S. Preventive Services Task Force
vs.	versus
WAST	Woman Abuse Screening Tool
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

CHAPTER 1: INTRODUCTION

Focused updates of evidence reviewed for the nine topics considered for revision under the Women's Prevention Services Initiative were conducted by the Pacific Northwest Evidence-based Practice Center at Oregon Health & Science University beginning in March 2016. Methods for the evidence reviews are based on standards in the field.[1-3] Summaries for each topic provide overviews of recent systematic reviews for the U.S. Preventive Services Task Force (USPSTF) published since the last recommendations were issued by the Institute of Medicine (IOM) Committee in 2011,[4] as well as summaries of additional relevant studies published since the systematic reviews. The focus of each review was on gaps identified in the 2011 IOM recommendations and any new evidence that could change or additionally inform the recommendations where evidence was not previously available. Included topics are described in the table below.

Topics Included in Update

IOM Panel Recommendations 2011	USPSTF Recommendation 2011	Current USPSTF Recommendation	Gaps	Key Questions for Update
Breast cancer screening was not addressed	C age 40-49; B age 50-75; I age >75	C age 40-49; B age 50-75; I age >75 (average risk; 2016)	Screening for women who determine that benefits outweigh harms at an individual level	What is the new evidence of optimal screening ages and intervals?
Breastfeeding, support, supplies, and counseling (comprehensive lactation support and counseling and costs of renting equipment)	B (counseling only)	B (breastfeeding interventions during pregnancy and after birth; 2016)	Inclusion of comprehensive lactation support, counseling, and costs (not limited to renting)	What is the new evidence of the effectiveness of counseling and support for breastfeeding?
Cervical cancer screening: HPV testing (addition of HPV testing to cytology testing beginning at age 30 and no more frequently than every 3 years)	I	A (cytology and HPV combination age 30-65 every 5 years; 2012). Review in progress on HPV testing alone +/- cytology (2018)	• Ending screening age >65 • 3-year versus 5-year screening intervals for co-testing	What is the new evidence of the effectiveness of cervical cancer screening, including ages to end screening and screening intervals?

Table continued on page 161.

IOM Panel Recommendations 2011	USPSTF Recommendation 2011	Current USPSTF Recommendation	Gaps	Key Questions for Update
Contraceptive methods and counseling	Not addressed	Not addressed	Not covered by USPSTF	What is the new evidence of the effectiveness of contraceptives and access to them?
Gestational diabetes screening (24-26 weeks gestation and first prenatal visit for women at high risk for diabetes)	I	B (asymptomatic women after 24 weeks gestation; 2012)	• Earlier screening for women at high risk for diabetes • Screening between 24 to 26 weeks versus after 24 weeks	What is the new evidence of the effectiveness of screening for gestational diabetes in average-risk and high-risk women?
HIV counseling and testing (annual counseling and testing for sexually active nonpregnant women)	C	A (age 15-65; pregnant women; others at increased risk; 2013)	• Screening all sexually active women versus all women • Inclusion of adolescents • Annual coverage versus non-specified screening intervals	What is the new evidence of the effectiveness of HIV counseling and screening?
Interpersonal and domestic violence screening and counseling (includes current and past violence)	I	B (screen women of childbearing age; 2013)	• All ages versus child bearing age • Effects of past as well as current violence • Includes counseling	What is the new evidence of the effectiveness of screening and counseling for interpersonal and domestic violence?
STI counseling (annual counseling for sexually active nonpregnant women)	I	B (all sexually active adolescents; adults at increased risk; 2014)	• Screening all sexually active women versus women at increased risk • Annual versus non-specified screening intervals	What is the new evidence of the effectiveness of counseling for STIs in average versus high-risk women?

Table continued on page 162.

IOM Panel Recommendations 2011	USPSTF Recommendation 2011	Current USPSTF Recommendation	Gaps	Key Questions for Update
Well-woman visits	Not addressed	Not addressed	Not covered by USPSTF	What is the new evidence of the effectiveness of well-women visits to improve health?

Key to USPSTF codes: A=Recommend; substantial net benefit; B=Recommend; at least moderate net benefit; C=Provide selectively; D=Do not recommend; I=Insufficient evidence
Current USPSTF recommendations http://www.uspreventiveservicestaskforce.org/BrowseRec/Search?s
Abbreviations: HIV=human immunodeficiency virus; HPV= human papilloma virus; IOM=Institute of Medicine; STI=sexually transmitted infection; USPSTF=U.S. Preventive Services Task Force

REFERENCES

[1]Institute of Medicine Committee on Standards for Systematic Reviews of Comparative Effectiveness R. In: Eden J, Levit L, Berg A, Morton S, eds. Finding What Works in Health Care: Standards for Systematic Reviews. Washington (DC): National Academies Press (US) Copyright 2011 by the National Academy of Sciences. All rights reserved.; 2011.

[2]Nelson HD. Systematic Reviews to Answer Health Care Questions: Lippincott Williams & Wilkins; 2014.

[3]Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication Number 10(14)-EHC062-EF. Rockville, MD: Agency for Healthcare Research and Quality: January 2014. www.effectivehealthcare.ahrq.gov Accessed May 15, 2016. PMID: 21433403.

[4]IOM (institute of Medicine). Clinical preventive services for women: Closing the gaps. Washington, DC: National Academies Press; 2011.

CHAPTER 2: LITERATURE SEARCHES

A research librarian conducted electronic database searches in Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews through August 2016 for all topics. For topics on counseling for sexual transmitted infections (STIs), interpersonal and domestic violence, and well-woman visits, searches were also conducted in PsycINFO through March 2016. Search strategies for each topic are provided below. Investigators also manually reviewed reference lists of relevant systematic reviews and articles.

BREAST CANCER SCREENING

Database: Ovid MEDLINE(R) without Revisions

1 exp breast neoplasms/
2 exp Mass Screening/
3 1 and 2
4 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
5 exp biomarkers/
6 mammogra*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
7 4 or 5 or 6
8 exp breast neoplasms/di
9 exp mammography/
10 7 and 8
11 3 or 9 or 10
12 (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
13 11 or 12
14 limit 13 to (english language and humans)
15 exp "Sensitivity and Specificity"/
16 exp Diagnostic Errors/
17 exp Diagnosis, Differential/
18 exp "Outcome and Process Assessment (Health Care)"/
19 exp "Costs and Cost Analysis"/
20 15 or 16 or 17 or 18 or 19
21 14 and 20
22 limit 21 to yr="2015 -Current"
23 limit 14 to yr="2015 -Current"
24 limit 23 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
25 exp Epidemiologic Studies/
26 23 and 25
27 26 not (22 or 24)

Database: Ovid MEDLINE(R) without Revisions

1 exp breast neoplasms/
2 exp Mass Screening/
3 1 and 2
4 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
5 exp biomarkers/

6 mammogra*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
7 4 or 5 or 6
8 exp breast neoplasms/di
9 exp mammography/
10 7 and 8
11 3 or 9 or 10
12 (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
13 11 or 12
14 limit 13 to (english language and humans)
15 exp "Sensitivity and Specificity"/
16 exp Diagnostic Errors/
17 exp Diagnosis, Differential/
18 exp "Outcome and Process Assessment (Health Care)"/
19 exp "Costs and Cost Analysis"/
20 15 or 16 or 17 or 18 or 19
21 14 and 20
22 limit 21 to yr="2015 -Current"
23 limit 14 to yr="2015 -Current"
24 l
imit 23 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
25 exp Epidemiologic Studies/
26 23 and 25
27 26 not (22 or 24)
28 22 not 24

Database: Ovid MEDLINE(R) without Revisions

1 exp breast neoplasms/
2 exp Mass Screening/
3 1 and 2
4 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier
5 exp biomarkers/
6 mammogra*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
7 4 or 5 or 6
8 exp breast neoplasms/di
9 exp mammography/
10 7 and 8
11 3 or 9 or 10

12 (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
13 11 or 12
14 limit 13 to (english language and humans)
15 exp "Sensitivity and Specificity"/
16 exp Diagnostic Errors/
17 exp Diagnosis, Differential/
18 exp "Outcome and Process Assessment (Health Care)"/
19 exp "Costs and Cost Analysis"/
20 15 or 16 or 17 or 18 or 19
21 14 and 20
22 limit 21 to yr="2015 -Current"
23 limit 14 to yr="2015 -Current"
24 limit 23 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
25 exp Epidemiologic Studies/
26 23 and 25
27 26 not (22 or 24)
28 22 not 24

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2 ((sensitiv* or specific*) adj3 (diagnos* or detect* or test*) adj7 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
3 ((Diagnos* or detect* or mammogra*) adj5 (accura* or error* or erroneous* or mistak* or miss* or wrong* or fals*) adj7 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
4 ((((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*)))) or mammogra*) adj7 (death* or dead or mortal* or surviv*)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
5 ((((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*)))) or mammogra*) adj7 ((outcom* or success* or fail* or impact* or treat* or therap* or effect* or regimen* or interven* or chemother* or pharmcother* or radiother*) adj5 (measur* or judg* or assess* or quantif* or determin* or compar* or estimat* or calculat*))).mp.
6 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*)))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
7 mammogra*.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (1327)
8 1 or 2 or 3 or 4 or 5 or 6 or 7
9 limit 8 to yr="2015 -Current"

Database: EBM Reviews - Cochrane Database of Systematic Reviews

1 (predict* adj3 ((breast* or mammar*) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, abstract, full text, keywords, caption text]
2 ((sensitiv* or specific*) adj3 (diagnos* or detect* or test*) adj7 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*))).mp. [mp=title, abstract, full text, keywords, caption text]
3 ((Diagnos* or detect* or mammogra*) adj5 (accura* or error* or erroneous* or mistak* or miss* or wrong* or fals*) adj7 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*))).mp. [mp=title, abstract, full text, keywords, caption text]
4 ((((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*)))) or mammogra*) adj7 (death* or dead or mortal* or surviv*)).mp. [mp=title, abstract, full text, keywords, caption text]
5 ((((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*)))) or mammogra*) adj7 ((outcom* or success* or fail* or impact* or treat* or therap* or effect* or regimen* or interven* or chemother* or pharmcother* or radiother*) adj5 (measur* or judg* or assess* or quantif* or determin* or compar* or estimat* or calculat*))).mp.
6 ((breast* or mammar*) adj3 (cancer* or carcinom* or neoplas* or tumor* or tumour* or malig*) adj7 (biomarker* or screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*)))).mp. [mp=title, abstract, full text, keywords, caption text]
7 mammogra*.mp. [mp=title, abstract, full text, keywords, caption text]
8 1 or 2 or 3 or 4 or 5 or 6 or 7
9 (2015* or 2016*).up.
10 8 and 9

BREASTFEEDING SUPPORT, SUPPLIES, AND COUNSELING

Database: Ovid MEDLINE(R) without Revisions

1 exp Breast Feeding/
2 exp Counseling/
3 exp Health Promotion/
4 exp Health Education/
5 exp Physician-Patient Relations/
6 exp Attitude to Health/
7 (counsel* or guid* or promot* or instruct* or teach* or learn* or taught).mp.
8 6 and 7
9 2 or 3 or 4 or 5 or 8
10 1 and 9
11 limit 10 to english language
12 limit 11 to yr="2008 -Current"
13 limit 12 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
14 exp "Quality of Life"/
15 exp "Quality of Health Care"/
16 exp "Costs and Cost Analysis"/
17 14 or 15 or 16
18 12 and 17

19 18 not 13
20 exp Epidemiologic Studies/
21 12 and 20
22 21 not (13 or 18)

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 ((counsel* or guid* or promot* or instruct* or teach* or learn* or taught) adj7 (breastfeed* or breastfed or (breast* adj2 (feed or fed)))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

Database: EBM Reviews - Cochrane Database of Systematic Reviews

1 ((counsel* or guid* or promot* or instruct* or teach* or learn* or taught) adj7 (breastfeed* or breastfed or (breast* adj2 (feed or fed)))).mp. [mp=title, abstract, full text, keywords, caption text]

CERVICAL CANCER SCREENING: HUMAN PAPILLOMAVIRUS DNA TESTING

Database: Ovid MEDLINE(R) without Revisions

1 exp cervical neoplasms/
2 exp Papillomavirus Infections/
3 exp Mass Screening/
4 1 and 3
5 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6 exp biomarkers/
7 5 or 6
8 exp cervical neoplasms/di
9 7 and 8
10 4 or 9
11 (predict* adj3 ((cervical or cervix) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
12 10 or 11
13 limit 12 to (english language and humans)
14 exp "Sensitivity and Specificity"/
15 exp Diagnostic Errors/
16 exp Diagnosis, Differential/
17 exp "Outcome and Process Assessment (Health Care)"/
18 exp "Costs and Cost Analysis"/
19 14 or 15 or 16 or 17 or 18
20 13 and 19
21 limit 20 to yr="2010 -Current" (635)
22 limit 13 to yr="2010 -Current" (2642)
23 limit 22 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
24 exp Epidemiologic Studies/

25 22 and 24
26 25 not (21 or 23)

Database: Ovid MEDLINE(R) without Revisions

1 exp cervical neoplasms/
2 exp Papillomavirus Infections/
3 exp Mass Screening/
4 1 and 3
5 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6 exp biomarkers/
7 5 or 6
8 exp cervical neoplasms/di
9 7 and 8
10 4 or 9
11 (predict* adj3 ((cervical or cervix) adj2 (cancer* or tumor* or tumour* or malig* or neoplas*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
12 10 or 11
13 limit 12 to (english language and humans)
14 exp "Sensitivity and Specificity"/
15 exp Diagnostic Errors/
16 exp Diagnosis, Differential/
17 exp "Outcome and Process Assessment (Health Care)"/
18 exp "Costs and Cost Analysis"/
19 14 or 15 or 16 or 17 or 18
20 13 and 19
21 limit 20 to yr="2010 -Current"
22 limit 13 to yr="2010 -Current"
23 limit 22 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
24 exp Epidemiologic Studies/
25 22 and 24
26 21 not 23

Database: EBM Reviews - Cochrane Database of Systematic Reviews

1 ((screen* or biomarker* or (gene* adj3 (risk* or predispos*)) or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or test* or assay* or identif*))) adj7 (hpv or human papilloma virus* or human papillomavir* or ((cervical or cervix) adj3 (cancer* or neoplas* or tumor* or tumour* or malig* or carcino*)))).mp.

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 ((screen* or biomarker* or (gene* adj3 (risk* or predispos*)) or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or test* or assay* or identif*))) adj7 (hpv or human papilloma virus* or human papillomavir* or ((cervical or cervix) adj3 (cancer* or neoplas* or tumor* or tumour* or malig* or carcino*)))).mp.

CONTRACEPTION

Database: Ovid MEDLINE(R) without Revisions

1 exp Contraception/
2 exp Contraceptive Devices/
3 exp Contraception Behavior/
4 exp Family Planning Services/
5 exp preconception care/
6 1 or 2 or 3 or 4
7 limit 6 to female
8 limit 6 to male
9 8 not 7
10 6 not 9
11 limit 10 to english language
12 exp Primary Health Care/
13 women's health services/
14 exp women's health/
15 Physicians, Family/
16 exp General Practice/
17 exp General Practitioners/
18 exp Counseling/
19 12 or 13 or 14 or 15 or 16 or 17 or 18
20 11 and 19
21 limit 20 to english language
22 limit 21 to "review articles"
23 limit 21 to (meta analysis or systematic reviews)
24 22 or 23
25 limit 24 to yr="2011 -Current"
26 exp "Outcome and Process Assessment (Health Care)"/
27 exp "Sensitivity and Specificity"/
28 mo.fs.
29 exp vital statistics/
30 28 or 29
31 exp "Quality of Life"/
32 exp Attitude to Health/
33 exp health behavior/
34 (aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
35 exp health services accessibility/

36 26 or 27 or 30 or 31 or 32 or 33 or 34 or 35
37 21 and 36
38 limit 37 to yr="2011 -Current"
39 limit 11 to (meta analysis or systematic reviews)
40 limit 11 to "review articles"
41 39 or 40
42 exp united states/
43 41 and 42
44 limit 43 to humans
45 44 not 25
46 11 and 36
47 limit 46 to yr="2011 -Current"
48 42 and 47
49 48 not 38

Database: Ovid MEDLINE(R) without Revision

1 exp Contraception/
2 exp Contraceptive Devices/
3 exp Contraception Behavior/
4 exp Family Planning Services/
5 exp preconception care/
6 1 or 2 or 3 or 4
7 limit 6 to female
8 limit 6 to male
9 8 not 7
10 6 not 9
11 limit 10 to english language
12 exp Primary Health Care/
13 women's health services/
14 exp women's health/
15 Physicians, Family/
16 exp General Practice/
17 exp General Practitioners/
18 exp Counseling/
19 12 or 13 or 14 or 15 or 16 or 17 or 18
20 11 and 19
21 limit 20 to english language
22 limit 21 to "review articles"
23 limit 21 to (meta analysis or systematic reviews)
24 22 or 23
25 limit 24 to yr="2011 -Current"
26 exp "Outcome and Process Assessment (Health Care)"/
27 exp "Sensitivity and Specificity"/
28 mo.fs.

29 exp vital statistics/
30 28 or 29
31 exp "Quality of Life"/
32 exp Attitude to Health/
33 exp health behavior/
34 (aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
35 exp health services accessibility/
36 26 or 27 or 30 or 31 or 32 or 33 or 34 or 35
37 21 and 36
38 limit 37 to yr="2011 -Current"
39 limit 11 to (meta analysis or systematic reviews)
40 limit 11 to "review articles"
41 39 or 40
42 exp united states/
43 41 and 42
44 limit 43 to humans
45 44 not 25
46 11 and 36
47 limit 46 to yr="2011 -Current"
48 42 and 47
49 48 not 38

Database: Ovid MEDLINE(R) without Revisions

1 exp Contraception/
2 exp Contraceptive Devices/
3 exp Contraception Behavior/
4 exp Family Planning Services/
5 exp preconception care/
6 1 or 2 or 3 or 4
7 limit 6 to female
8 limit 6 to male
9 8 not 7
10 6 not 9
11 limit 10 to english language
12 exp Primary Health Care/
13 women's health services/
14 exp women's health/
15 Physicians, Family/
16 exp General Practice/
17 exp General Practitioners/
18 exp Counseling/
19 12 or 13 or 14 or 15 or 16 or 17 or 18

20 11 and 19
21 limit 20 to english language
22 limit 21 to "review articles"
23 limit 21 to (meta analysis or systematic reviews)
24 22 or 23
25 limit 24 to yr="2011 -Current"
26 exp "Outcome and Process Assessment (Health Care)"/
27 exp "Sensitivity and Specificity"/
28 mo.fs.
29 exp vital statistics/
30 28 or 29
31 exp "Quality of Life"/
32 exp Attitude to Health/
33 exp health behavior/
34 (aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
35 exp health services accessibility/
36 26 or 27 or 30 or 31 or 32 or 33 or 34 or 35
37 21 and 36
38 limit 37 to yr="2011 -Current"
39 limit 6 to english language
40 limit 11 to (meta analysis or systematic reviews)
41 limit 11 to "review articles"
42 40 or 41
43 exp united states/
44 42 and 43
45 limit 44 to humans
46 45 not 25
47 11 and 36
48 limit 47 to yr="2011 -Current"
49 43 and 48
50 49 not 38

Database: Ovid MEDLINE(R) without Revisions

1 exp Contraception/
2 exp Contraceptive Devices/
3 exp Contraception Behavior/
4 exp Family Planning Services/
5 exp preconception care/
6 1 or 2 or 3 or 4
7 limit 6 to female
8 limit 6 to male
9 8 not 7
10 6 not 9

11 limit 10 to english language
12 exp Primary Health Care/
13 women's health services/
14 exp women's health/
15 Physicians, Family/
16 exp General Practice/
17 exp General Practitioners/
18 exp Counseling/
19 12 or 13 or 14 or 15 or 16 or 17 or 18
20 11 and 19
21 limit 20 to english language
22 limit 21 to "review articles"
23 limit 21 to (meta analysis or systematic reviews)
24 22 or 23
25 limit 24 to yr="2011 -Current"
26 exp "Outcome and Process Assessment (Health Care)"/
27 exp "Sensitivity and Specificity"/
28 mo.fs.
29 exp vital statistics/
30 28 or 29
31 exp "Quality of Life"/
32 exp Attitude to Health/
33 exp health behavior/
34 (aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
35 exp health services accessibility/
36 26 or 27 or 30 or 31 or 32 or 33 or 34 or 35
37 21 and 36
38 limit 37 to yr="2011 -Current"
39 limit 11 to (meta analysis or systematic reviews)
40 limit 11 to "review articles"
41 39 or 40
42 exp united states/
43 41 and 42
44 limit 43 to humans
45 44 not 25
46 11 and 36
47 limit 46 to yr="2011 -Current"
48 42 and 47
49 48 not 38

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 ((counsel* or advis* or advice or advocat*) adj7 (contracept* or (birth* adj control*) or condom* or iud* or (intrauterin* adj devic*) or (family adj plan*) or vasectom* or (tub* adj2 (ligat* or tie or tied)))).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]

Database: EBM Reviews - Cochrane Database of Systematic Reviews

1 ((counsel* or advis* or advice or advocat*) adj7 (contracept* or (birth* adj control*) or condom* or iud* or (intrauterin* adj devic*) or (family adj plan*) or vasectom* or (tub* adj2 (ligat* or tie or tied)))).ti,ab,kw.
2 ((effectiv* or strateg* or interven* or outcom* or success* or ((primar* or family) adj2 (physician* or care)) or (general adj practi*) or (family adj medicin*)) adj10 ((counsel* or advis* or advice or advocat* or educat* or instruct*) adj7 (contracept* or (birth* adj control*) or condom* or iud* or (intrauterin* adj devic*) or (family adj plan*) or vasectom* or (tub* adj2 (ligat* or tie or tied))))).mp.
3 1 or 2

GESTATIONAL DIABETES SCREENING

Database: Ovid MEDLINE(R) without Revisions

1 exp Diabetes, Gestational/
2 exp Mass Screening/
3 1 and 2
4 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp.
5 exp biomarkers/
6 4 or 5
7 exp Diabetes, Gestational/di
8 6 and 7
9 3 or 8
10 (predict* adj3 (gestation* adj2 diabet*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
11 9 or 10
12 limit 11 to (english language and humans)
13 exp "Sensitivity and Specificity"/
14 exp Diagnostic Errors/
15 exp Diagnosis, Differential/
16 exp "Outcome and Process Assessment (Health Care)"/
17 exp "Costs and Cost Analysis"/
18 13 or 14 or 15 or 16 or 17
19 12 and 18
20 limit 19 to yr="2012 -Current"
21 limit 12 to yr="2012 -Current"
22 limit 21 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
23 exp Epidemiologic Studies/
24 21 and 23
25 22 or 24
26 20 or 25

Database: EBM Reviews - Cochrane Database of Systematic Reviews

1 ((screen* or biomarker* or (gene* adj3 (risk* or predispos*)) or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or test* or assay* or identif*)) or predict*) adj7 (gestat* adj3 diabet*)).mp.

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 ((screen* or biomarker* or (gene* adj3 (risk* or predispos*)) or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or test* or assay* or identif*)) or predict*) adj7 (gestat* adj3 diabet*)).mp.

HUMAN IMMUNODEFICIENCY VIRUS SCREENING AND COUNSELING

Database: Ovid MEDLINE(R) without Revisions

1 exp hiv/
2 exp hiv Infections/
3 exp Mass Screening/
4 1 and 3
5 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6 exp biomarkers/
7 5 or 6
8 exp hiv infections/di
9 7 and 8
10 4 or 9
11 limit 10 to (english language and humans)
12 exp "Sensitivity and Specificity"/
13 exp Diagnostic Errors/
14 exp Diagnosis, Differential/
15 exp "Outcome and Process Assessment (Health Care)"/
16 exp "Costs and Cost Analysis"/
17 12 or 13 or 14 or 15 or 16
18 11 and 17
19 limit 18 to yr="2012 -Current"
20 limit 11 to yr="2012 -Current"
21 limit 20 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
22 exp Epidemiologic Studies/
23 20 and 22
24 23 not (19 or 21)

Database: Ovid MEDLINE(R) without Revisions

1 exp hiv/
2 exp hiv Infections/
3 exp Mass Screening/
4 1 and 3
5 (screen* or ((earl* or routin*) adj2 (diagnos* or detect* or discover* or identif*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6 exp biomarkers/
7 5 or 6

8 exp hiv infections/di
9 7 and 8
10 4 or 9
11 limit 10 to (english language and humans)
12 exp "Sensitivity and Specificity"/
13 exp Diagnostic Errors/
14 exp Diagnosis, Differential/
15 exp "Outcome and Process Assessment (Health Care)"/
16 exp "Costs and Cost Analysis"/
17 12 or 13 or 14 or 15 or 16
18 11 and 17
19 limit 18 to yr="2012 -Current"
20 limit 11 to yr="2012 -Current"
21 limit 20 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
22 exp Epidemiologic Studies/
23 20 and 22
24 23 not (19 or 21)
25 19 not 21

Database: EBM Reviews - Cochrane Database of Systematic Reviews

1 ((effectiv* or strateg* or interven* or outcom* or success* or ((primar* or family) adj2 (physician* or care)) or (general adj practi*) or (family adj medicin*)) adj10 ((screen* or (routin* or periodic*)) adj3 (test* or detect* or diagnos* or assay*) adj7 (aids or hiv or acquired immunodefic*))).mp.
2 ((screen* or ((routin* or periodic*) adj3 (test* or detect* or diagnos* or assay*))) adj7 (hiv or acquired immunodefic*)).mp.
3 ((effectiv* or strateg* or interven* or outcom* or success* or ((primar* or family) adj2 (physician* or care)) or (general adj practi*) or (family adj medicin*)) adj10 ((counsel* or advis* or advice or advocat* or educat* or instruct*) adj7 (hiv or acquired immunodefic*))).mp.
4 (counsel* adj7 (hiv or acquired immunodefic*)).mp
5 1 or 2 or 3 or 4

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 ((effectiv* or strateg* or interven* or outcom* or success* or ((primar* or family) adj2 (physician* or care)) or (general adj practi*) or (family adj medicin*)) adj10 ((screen* or (routin* or periodic*)) adj3 (test* or detect* or diagnos* or assay*) adj7 (aids or hiv or acquired immunodefic*))).mp.
2 ((screen* or ((routin* or periodic*) adj3 (test* or detect* or diagnos* or assay*))) adj7 (hiv or acquired immunodefic*)).mp
3 ((counsel* or advis* or advice or advoc*) adj7 (hiv or acquired immunodefic*)).mp
4 ((effectiv* or strateg* or interven* or outcom* or success* or ((primar* or family) adj2 (physician* or care)) or (general adj practi*) or (family adj medicin*)) adj10 ((counsel* or advis* or advice or advocat* or educat* or instruct*) adj7 (hiv or acquired immunodefic*))).mp.
5 1 or 2 or 3 or 4

INTERPERSONAL AND DOMESTIC VIOLENCE SCREENING AND COUNSELING

Database: Ovid MEDLINE(R) without Revisions

1 exp intimate partner violence/
2 ((((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal)).mp.
3 1 or 2
4 exp Counseling/
5 exp Health Promotion/
6 exp Health Education/
7 exp Physician-Patient Relations/
8 exp Attitude to Health/
9 ((counsel* or guid* or promot* or instruct* or persuad*) adj3 (test* or screen*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
10 8 and 9
11 4 or 5 or 6 or 10
12 3 and 11
13 limit 12 to english language
14 limit 13 to female
15 limit 14 to yr="2012 -Current"
16 limit 15 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
17 limit 3 to yr="2012 -Current"
18 limit 17 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
19 limit 18 to female
20 limit 18 to male
21 20 not 19
22 18 not 21
23 19 or 22
24 15 or 23

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 exp intimate partner violence/
2 ((((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal)).mp.
3 1 or 2
4 exp Counseling/
5 exp Health Promotion/
6 exp Health Education/
7 exp Physician-Patient Relations/
8 exp Attitude to Health/
9 ((counsel* or guid* or promot* or instruct* or persuad*) adj3 (test* or screen*)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (1936)

10 8 and 9
11 4 or 5 or 6 or 10
12 3 and 11
13 limit 12 to english language
14 ((counsel* or screen* or detect* or measur* or disclos* or interview* or survey* or questionnair* or assess* or advis* or advocat* or diagnos* or determin* or identif* or interven* or prevent* or reduc*) adj7 ((((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal))).mp.
15 12 or 14

Database: EBM Reviews - Cochrane Database of Systematic Reviews

1 ((((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal)).ti,ab,kw.
2 ((counsel* or screen* or detect* or measur* or disclos* or interview* or survey* or questionnair* or assess* or advis* or advocat* or diagnos* or determin* or identif* or interven* or prevent* or reduc*) adj7 ((((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal))).mp.
3 1 or 2

Database: PsycINFO

1 exp intimate partner violence/
2 exp domestic violence/
3 ((((intimat* or domestic* or romantic* or dating) adj3 partner*) or spous* or husband* or wife or wives or common law) adj5 (violen* or abus* or assault* or attack* or intimidat* or harass* or crime* or criminal)).mp.
4 1 or 2 or 3
5 exp screening/
6 exp screening tests/
7 screen*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
8 5 or 6 or 7
9 4 and 8
10 exp Counseling/
11 exp Health Promotion/
12 exp Health Education/
13 exp health attitudes/
14 ((counsel* or guid* or promot* or instruct* or persuad*) adj3 (test* or screen*)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
15 13 and 14
16 10 or 11 or 12 or 15
17 4 and 16
18 9 or 17
19 limit 18 to english language
20 limit 19 to female

SEXUALLY TRANSMITTED INFECTION COUNSELING

Database: Ovid MEDLINE(R) without Revisions

1 exp sexually transmitted infections/di, pc
2 exp sexually transmitted infections/
3 exp hiv/
4 exp Treponema pallidum/
5 exp Neisseria gonorrhoeae/
6 exp Chlamydia trachomatis/
7 2 or 3 or 4 or 5 or 6
8 exp mass screening/ or screen*.mp. or test*.mp.
9 7 and 8
10 1 or 9
11 exp Counseling/
12 exp Health Promotion/
13 exp Health Education/
14 exp Physician-Patient Relations/
15 exp Attitude to Health/
16 ((counsel* or guid* or promot* or instruct* or persuad*) adj3 (test* or screen*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
17 15 and 16
18 11 or 12 or 13 or 17
19 10 and 18
20 limit 19 to english language
21 limit 20 to female
22 limit 21 to yr="2013 -Current"
23 limit 22 to (comparative study or controlled clinical trial or guideline or meta analysis or randomized controlled trial or systematic reviews)
24 exp "Quality of Life"/
25 exp "Quality of Health Care"/
26 exp "Costs and Cost Analysis"/
27 24 or 25 or 26
28 22 and 27
29 28 not 23
30 exp Epidemiologic Studies/
31 22 and 30

Database: EBM Reviews - Cochrane Database of Systematic Reviews

1 ((counsel* or advis* or advice or advocat*) adj7 (sti or stis or syphilli* or gonorrh* or chlamyd* or (genital* adj2 herp*) or (sex* adj2 transmi* adj5 (infect* or diseas*)))).mp.

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 ((counsel* or advis* or advice or advocat*) adj7 (sti or stis or syphilli* or gonorrh* or chlamyd* or (genital* adj2 herp*) or (sex* adj2 transmi* adj5 (infect* or diseas*)))).mp. (130)
2 limit 1 to yr="2011 -Current"

Database: PsycINFO

1 exp sexually transmitted diseases/
2 (hiv or acquired immunodefic*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
3 (Treponema or syphili*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
4 gonorrh*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
5 Chlamydia*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
6 1 or 2 or 3 or 4 or 5
7 exp screening/ or exp screening tests/ or screen*.mp. or test*.mp.
8 6 and 7
9 exp Counseling/
10 exp Health Promotion/
11 exp Health Education/
12 exp Health Attitudes/
13 ((counsel* or guid* or promot* or instruct* or persuad*) adj3 (test* or screen*)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
14 12 and 13
15 9 or 10 or 11 or 14
16 8 and 15
17 limit 16 to english language
18 limit 17 to female

WELL-WOMAN VISITS

Database: Ovid MEDLINE(R)

1 (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
2 (wellness adj2 (physical or exam* or appointment* or visit*)).mp [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
3 (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
4 ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*)).mp.
5 3 or 4
6 1 or 2 or 5
7 Female/
8 Male/
9 8 not 7
10 6 not 9
11 limit 10 to english language

12 limit 11 to (meta analysis or "review" or systematic reviews)
13 limit 12 to yr="2011 -Current"
14 exp "Outcome and Process Assessment (Health Care)"/
15 exp "Sensitivity and Specificity"/
16 mo.fs.
17 exp vital statistics/
18 16 or 17
19 exp "Quality of Life"/
20 exp Attitude to Health/
21 exp health behavior/
22 14 or 15 or 18 or 19 or 20 or 21
23 11 and 22
24 limit 23 to yr="2011 -Current"
25 limit 24 to english language
26 (aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
27 10 and 26
28 13 and 22

Database: Ovid MEDLINE(R)

1 (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
2 (wellness adj2 (physical or exam* or appointment* or visit*)).mp [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
3 (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
4 ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*)).mp.
5 3 or 4
6 1 or 2 or 5
7 Female/
8 Male/
9 8 not 7
10 6 not 9
11 limit 10 to english language
12 limit 11 to (meta analysis or "review" or systematic reviews)
13 limit 12 to yr="2011 -Current"
14 exp "Outcome and Process Assessment (Health Care)"/
15 exp "Sensitivity and Specificity"/
16 mo.fs.
17 exp vital statistics/

18 16 or 17
19 exp "Quality of Life"/
20 exp Attitude to Health/
21 exp health behavior/
22 14 or 15 or 18 or 19 or 20 or 21
23 11 and 22
24 limit 23 to yr="2011 -Current"
25 limit 24 to english language
26 (aca or affordable care act).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
27 10 and 26
28 13 and 22
29 1 or 2 or 24 or 27
30 limit 29 to english language
31 limit 30 to yr="2011 -Current"
32 31 not 28
33 exp United States/
34 32 and 33

Database: EBM Reviews - Cochrane Database of Systematic Reviews

1 (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, abstract, full text, keywords, caption text]
2 (wellness adj2 (physical or exam* or appointment* or visit*) adj5 (woman or women or female* or mother*)).mp.
3 1 or 2
4 ((woman or women or female* or mother*) adj7 (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)))).mp.
5 ((woman or women or female* or mother*) adj5 ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*))).mp.
6 4 or 5
7 6 not 3

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword]
2 (wellness adj2 (physical or exam* or appointment* or visit*) adj5 (woman or women or female* or mother*)).mp.
3 1 or 2
4 ((woman or women or female* or mother*) adj7 (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)))).mp.
5 ((woman or women or female* or mother*) adj5 ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*))).mp.
6 4 or 5
7 6 not 3

Database: PsycINFO

1 (well* adj2 (woman or women) adj5 (visit* or appointment* or check-up or checkup)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
2 (wellness adj2 (physical or exam* or appointment* or visit*) adj5 (woman or women or female* or mother*)).mp.
3 1 or 2
4 (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*))).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
5 ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*)).mp.
6 4 or 5
7 exp Human Females/
8 6 and 7
9 ((woman or women or female* or mother*) adj7 (((regular* adj2 schedul*) or routine* or periodic* or annual* or yearly or year) adj5 ((doctor* or physician* or practitioner* or health* or medical* or wellness or prevent* or screen*) adj3 (assess* or checkup* or check-up* or physical or physicals or exam* or appointment* or visit*)))).mp.
10 ((woman or women or female* or mother*) adj5 ((routine* or annual* or yearly or (health* adj maint*)) adj2 (physical or exam* or appointment* or visit*))).mp.
11 9 or 10
12 8 or 11
13 12 not 3
14 exp health promotion/
15 exp prevention/
16 exp Early Intervention/
17 exp Public Health/
18 14 or 15 or 16 or 17
19 13 and 18

CHAPTER 3: STUDY SELECTION

A best evidence approach was applied when reviewing abstracts and selecting studies to include for this review that involves using the most relevant studies with the strongest methodologies.[1-3] The results of searches are described in the table below. For most topics, systematic reviews and key studies published since the most recent systematic review for the USPSTF were included. For well-woman visits and contraceptive methods and counseling, there are no USPSTF reviews or recommendations, therefore, other systematic reviews and studies published since the 2011 IOM recommendations for these topics were included.

Randomized controlled trials and large (>100) prospective cohort studies were included if they provided relevant information for a specific topic. Other study designs, such as case-control and modeling studies, were included when evidence was lacking or when they demonstrated new findings. Studies conducted in settings applicable to the United States were particularly applicable. Findings related to population subgroups were specifically included when available. The focus of each review was on gaps identified in the 2011 IOM recommendations and any new evidence that could change or additionally inform the recommendations where evidence was not previously available. Selection criteria specific to each topic include the following:

Breast Cancer Screening for Average-risk Women

Comprehensive evidence reviews on breast cancer screening were recently conducted by the EPC for the USPSTF and published in February 2016. These reviews served as the main source documents for the evidence summary. Literature searches used for the USPSTF reviews were repeated to identify new evidence relevant to optimal ages to start and stop screening and screening intervals. However, no new studies met inclusion criteria.

Breastfeeding Services and Supplies

Abstracts that described interventions to promote or support breastfeeding in developed countries were reviewed. The population of interest was pregnant women or women who recently gave birth. Studies that focused on effectiveness of interventions and included outcomes related to breastfeeding practices (initiation and duration of breastfeeding) were included. A systematic review of breastfeeding support published in 2016 that was used to update the USPSTF's clinical recommendations served as the main source document.

Screening for Cervical Cancer

Abstracts that described screening for cervical cancer in average-risk women in developed countries were reviewed. Studies that focused on the efficacy of screening or addressed screening intervals, age to start screening, and age to stop screening were targeted. Since most cytological screening in the U.S. is done with liquid-based techniques, the comparison between conventional and liquid-based platforms was not reviewed. Studies that evaluated screening with a combination of cytology and high-risk HPV testing (co-testing) were included. An in-depth review of the performance of screening tests was not undertaken and different triage protocols were not evaluated. Modeling and case-control studies were included when information was lacking or when new findings were presented.

Contraception

Abstracts that described the effectiveness of providing contraception were reviewed, including counseling interventions and access. Studies that focused on counseling, health disparities, contraceptive access, and provision of contraception were targeted. Studies of contraceptive efficacy and risks for unintended pregnancy were not reviewed because contraceptive efficacy is well established and risk factors for unintended pregnancy are known. Non-contraceptive benefits of hormonal contraception were outside the scope of this report and not included. Studies that addressed the impact of coverage and contraceptive access and reproductive planning were included. Modeling and observational studies were included when randomized trials were lacking or when relevant population data were provided.

Screening for Gestational Diabetes Mellitus

Abstracts of studies of the benefits and harms of screening for gestational diabetes mellitus (GDM) among average-risk or high-risk women that were applicable to U.S. medical practice were reviewed. Studies addressing evidence gaps, such as screening at early or later stages of pregnancy; risk-based screening; comparisons of screening and diagnostic strategies; and comparisons of treatment effects were particularly targeted. A systematic review of screening and treatment for GDM for a National Institutes of Health Consensus Development Conference on Diagnosis of Gestational Diabetes Mellitus in 2013, and used to update the USPSTF's clinical recommendations in 2014, served as the main source document.

Screening for Human Immunodeficiency Virus Infection (HIV)

Abstracts of studies of the benefits and harms of screening and counseling for HIV among average-risk or high-risk women that were applicable to U.S. medical practice were reviewed. Studies addressing evidence gaps, such as screening at early versus later stages of infection; risk-based screening; comparisons between universal versus selective strategies, including screening intervals; and comparisons of treatment effects on health outcomes and transmission were particularly targeted. A systematic review of screening and treatment for HIV that was used to update the USPSTF's clinical recommendations in 2013 served as the main source document.

Screening for Interpersonal and Domestic Violence

Abstracts that described screening and interventions for interpersonal and domestic violence were reviewed. The population of interest was asymptomatic women presenting to settings applicable to the U.S. Studies that focused on diagnostic accuracy of screening instruments or trials of interventions aimed at reducing exposure to intimate partner violence were targeted. Studies that reported infant or maternal health outcomes from screening, accuracy of screening instruments, and reduced exposure to interpersonal and domestic violence were included.

Counseling for Sexually Transmitted Infections (STI)

Abstracts that described counseling interventions applicable to clinical settings intended to prevent any type of STI were reviewed. Studies about interventions that focused on reducing STIs in general or chlamydia, gonorrhea, and syphilis specifically were targeted. Articles that described outcomes of STI incidence or behavioral changes such as condom use were included.

Well-Woman Visit

Currently there is not a standard definition for the well-woman exam or the periodic health exam. A conceptual framework was developed to define this visit and its potential benefits and harms, and searches were based on key terms that could be used to describe a well-woman visit. Abstracts that described annual, well woman, or routine physical exam or visit were reviewed. Existing guidelines were reviewed and studies were included using a best evidence approach, prioritizing systematic reviews and clinical best practices to identify which services or group of services may promote well-being.

Yield of Updated Literature Searches

Topic	Database searched Dates searched	Citations reviewed	Full-text reviewed	Included
Breast Cancer Screening	Medline, CDSR, CCRCT 2015-2016	1,116	107	Four USPSTF reviews (97 studies)
Breastfeeding Support and Counseling	Medline, CDSR, CCRCT 2015-2016	1,238	59	USPSTF review (52 studies); 6 other reviews
Gestational Diabetes Screening	Medline, CDSR, Medline, CDSR, CCRCT 2011-2016 2015-2016	307	52	USPSTF review (62 studies); 4 other studies
HIV Screening and Counseling	Medline, CDSR, CCRCT 2012-2016	1,474	101	USPSTF review (22 studies)
Cervical Cancer Screening	Medline, CDSR, CCRCT 2010-2016	1,763	189	USPSTF review (35 studies); 1 modeling study; 11 other studies
Interpersonal Domestic Violence Screening and Counseling	Medline, CDSR, CCRCT, PsycINFO 2012-2016	1,011	122	USPSTF review (35 studies); 4 Cochrane reviews of 74 trials;* 4 SRs of 51 studies;* 4 other studies
Contraceptive Methods and Counseling	Medline, CDSR, CCRCT 2009-2016	1,642	258	Cochrane review of 9 trials; 11 other studies
STI Counseling	Medline, CDSR, CCRCT, PsycINFO 2010-2016	1,181	72	USPSTF review (31 studies); 1 SR of 31 studies; 1 SR of 13 SRs or meta-analyses; 3 other studies

Table continued on page 187.

Topic	Database searched Dates searched	Citations reviewed	Full-text reviewed	Included
Well-Woman Visit	Medline, CDSR, CCRCT, PsycINFO 2011-2016	562	55	Cochrane review of 14 trials; 3 other studies

*Studies may overlap between systematic reviews

Abbreviations: CDSR=Cochrane Database of Systematic Reviews; CCRCT=Cochrane Central Register of Controlled Trials; HIV=human immunodeficiency virus; SR=systematic review; STI=sexually transmitted infection; USPSTF=U.S. Preventive Services Task Force

REFERENCES

[1]Institute of Medicine Committee on Standards for Systematic Reviews of Comparative Effectiveness R. In: Eden J, Levit L, Berg A, Morton S, eds. Finding What Works in Health Care: Standards for Systematic Reviews. Washington (DC): National Academies Press (US) Copyright 2011 by the National Academy of Sciences. All rights reserved.; 2011.

[2]Nelson HD. Systematic Reviews to Answer Health Care Questions: Lippincott Williams & Wilkins; 2014.

[3]Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication Number 10(14)-EHC062-EF. Rockville, MD: Agency for Healthcare Research and Quality: January 2014. www.effectivehealthcare.ahrq.gov Accessed May 15, 2016. PMID: 21433403.

CHAPTER 4: SYNTHESIS

Data Management and Analysis

No new or revised statistical meta-analyses were conducted. Studies were qualitatively synthesized according to interventions, populations, and outcomes measured. Studies and their findings are described in a narrative, descriptive format to provide an overview of the new evidence for each topic.

Assessing Applicability

Applicability is defined as the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under "real-world" conditions.[1] It is an indicator of the extent to which research included in a review might be useful for informing clinical decisions in specific situations. Factors important for understanding the applicability of studies were considered including differences in the interventions, comparators, populations, and settings.

Establishing the Strength of Recommendations

Investigators created evidence maps to provide a descriptive summary of supporting evidence for each component of the recommendations. Evidence maps for the update were adapted from methods of the 2011 IOM panel. Results of key systematic reviews and research studies, epidemiologic data, USPSTF and AAP Bright Futures recommendations, clinical best practices, and other relevant sources were included in the evidence maps.

REFERENCES

[1]Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication Number 10(14)-EHC062-EF. Rockville, MD: Agency for Healthcare Research and Quality: January 2014. www.effectivehealthcare.ahrq.gov Accessed May 15, 2016. PMID: 21433403.

Women's Preventive Services Initiative

wpsi@acog.org | www.womenspreventivehealth.org