CECA
Coalition to Expand Contraceptive Access

Issue Brief #2:
Expanding Contraceptive Access Through Clinical and Programmatic Guidelines

October 2019

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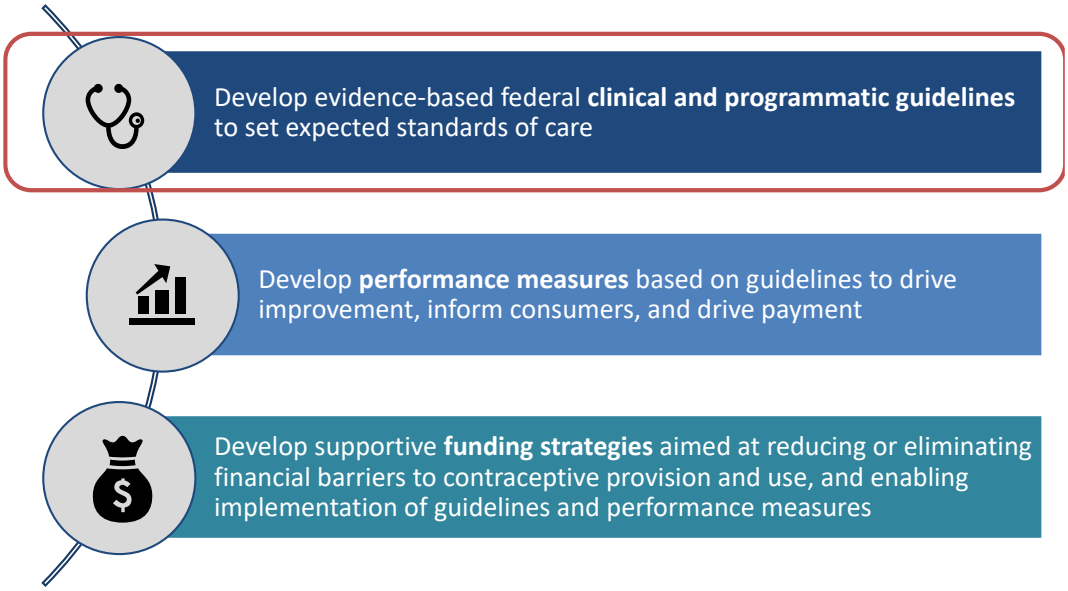
Introduction

Reproductive health outcomes, including access to contraception, are directly impacted by the systems within which individuals receive care, as well as the care that is delivered. Major changes are happening in the way health care is delivered, including changes that reflect new technologies as well as preferences for how health care is accessed. Guidelines that incorporate new ways of providing care, as well as new health care issues will require guidelines that incorporate these as well as other evolving considerations.

Exhibit 1. Federal Processes to Improve Contraceptive Access: Clinical and Programmatic Guidelines



This briefing document provides an overview of federal clinical and programmatic guidelines for contraception, with particular attention toward currently identified challenges and future directions for improvement. Sources include published scientific literature, when available, as well as gray literature (i.e., expert white papers from research and advocacy organizations and public-facing government and non-government organization documents, including websites).

The Context

Clinical and Programmatic Guidelines: What, Why, and How

Clinical and programmatic guidelines that are rigorously developed and consistently adopted, implemented, and evaluated have the potential to improve both the quality and process of care and patient outcomes. As highlighted in **Exhibit 2**, while the population level may be different, the purpose of guidelines, whether clinical or programmatic, is to help providers, policymakers, recipients of health care, and other stakeholders make informed decisions based on comprehensive and objective assessments of available evidence.[1]

[1] World Health Organization, *WHO Handbook for Guideline Development*, 2014, http://apps.who.int/iris/bitstream/10665/145714/1/9789241548960_eng.pdf.

Exhibit 2. Clinical and Programmatic Guidelines

Clinical Practice Guidelines	Programmatic Guidelines
Clinical practice guidelines are systematically developed statements that help providers and patients make informed decisions about appropriate clinical care.	**Programmatic and public health guidelines** identify interventions that are applied at a group, community, or other population level to impact health or a particular aspect of health.
Both types of guidelines are used to establish benchmarks and monitor progress over time, help stakeholders make informed decisions, and ensure care remains current with the latest science and new health care delivery innovations.	

Federal agencies within the U.S. Department of Health and Human Services (HHS) play an important role in developing both programmatic and clinical guidelines that set expected standards for care that greatly impact the quality and content of care that is delivered across the U.S. The Centers for Disease Control and Prevention (CDC), Agency for Healthcare Quality and Research (AHRQ), Centers for Medicare and Medicaid Services (CMS), Office of Population Affairs (OPA), and Office of Disease Prevention and Health Promotion (ODPHP) are all examples of agencies that have developed guidelines that impact the delivery of health care and access to specific services, including contraceptive services.

Clinical Guidelines

Clinical practice guidelines are statements that include recommendations designed to optimize patient care. According to the Institute of Medicine (IOM), "they are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[2] A detailed discussion of several clinical guidelines developed by agencies within HHS to address contraception are detailed in the "Potential Solutions" section beginning on page 6.

Institute of Medicine (IOM)

At the request of Congress, in 2008, the IOM undertook a study on the best methods for developing clinical practice guidelines. The IOM convened a committee of experts to inform the process so that approaches were objective, scientifically valid, and consistent. Highlighted in **Exhibit 3**, the study articulated the characteristics of trustworthy guidelines and identified eight "standards" for developing trustworthy guidelines.[2]

[2] Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, *Clinical Practice Guidelines We Can Trust*, ed. Robin Graham et al. (Washington (DC): National Academies Press (US), 2011), http://www.ncbi.nlm.nih.gov/books/NBK209539/.

Exhibit 3. IOM Recommendations for Developing Trustworthy Guidelines

Characteristics	Standards
• Be based on a systematic review of existing evidence • Be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups • Consider important patient subgroups and patient preferences, as appropriate • Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest • Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations • Be reconsidered and revised as appropriate when new evidence warrants modifications of recommendations	1. Establishing transparency 2. Management of conflict of interest 3. Guideline development group composition 4. Clinical practice guideline-systematic review intersection 5. Establishing evidence foundations for and rating strength of recommendations 6. Articulation of recommendations 7. External review 8. Updating

The World Health Organization (WHO)

WHO similarly identifies steps in the guidelines development process and emphasizes the importance of planning and scoping guidelines as essential preparatory steps before delving into the process of guideline development. WHO's *Handbook for Guideline Development* provides guidance on systematic reviews and the importance of properly identifying questions that need to be addressed and that will direct the evidence search and grading process. Specific recommendations include the use of:

- **PICO** (Population, Intervention, Comparator, and Outcomes) elements in formulating questions that should govern the systematic search for evidence.
- **GRADE** (Grading of Recommendations, Assessment, Development, and Evaluation), a widely adopted and internationally accepted approach to assess the quality of evidence, develop and present evidence transparently, and make recommendations. The four levels of evidence are high, moderate, low or very low, with evidence from randomized controlled trials starting at high quality, and evidence based on observational data generally rated as low quality.[3]

U.S. Preventive Services Task Force (USPSTF)

USPSTF makes recommendations about clinical preventive services—such as screenings, counseling, and preventive medications—based on rigorous reviews of existing peer-reviewed evidence. Comprised of a 16-member volunteer panel, who come from the fields of preventive medicine and primary care, each member is appointed by the Director of AHRQ. They review and assess existing research and assign recommendations a letter grade of A, B, C, D, or I based on the strength of the evidence and on the balance of benefits and harms of the preventive service (**Exhibit 4**).[4]

[3] Reed Siemieniuk and Gordon Guyatt, "What Is GRADE? | BMJ Best Practice," accessed September 3, 2019, https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade/.
[4] US Preventive Services Task Force, "Grade Definitions," October 2018, https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions.

USPSTF GRADE Definitions and Suggestions for Practice

GRADE	Definition	Suggestions for Practice
A	Recommends service – high certainty that net benefit is substantial	Offer or provide service
B	Benefits outweigh harms – high certainty that net benefit is moderate to substantial	Offer or provide service
C	Offer or provide based on professional judgment and patient preference – moderate certainty that net benefit is small	Offer or provide to selected patients depending on individual circumstances
D	Recommends against service – moderate or high certainty that service has no net benefit or that harms outweigh benefits	Discourage use of service
I	Current evidence is insufficient to assess balance of benefits and harms – evidence is lacking, of poor quality, or conflicting, and balance of benefits and harms cannot be assessed	If service is offered, patients should understand the uncertainty about the balance of benefits and harms

The USPSTF also publishes the "Levels of Certainty Regarding the Net Benefit" of each recommendation (High, Moderate, or Low). USPSTF documents the methods and process they use to develop recommendations in a detailed procedure manual in an effort to be transparent.[5]

Programmatic Guidelines

Programmatic and public health guidelines identify interventions that are applied at a group, community, or other population level to impact health or a particular aspect of health. Inherent to both programmatic and clinical guidelines is the critical role they play in establishing benchmarks and monitoring progress over time and ensuring care remains current with the latest science and new innovations in health care delivery. They are also often intended to encourage and facilitate collaborations across communities and sectors. Examples of programmatic guidelines include:

- The set of science-based, 10-year national objectives set by **the Healthy People Initiative**, coordinated by ODPHP.[6]
- **The Guide to Community Preventive Services**, a collection of evidence-based findings of the Community Preventive Services Task Force, coordinated by CDC. The "Community Guide" includes interventions and approaches to more than 22 health topics that are applicable to groups, communities, or other populations. The identified interventions are directed at improving health directly; preventing or reducing risky behaviors, disease, injuries, complications, or detrimental environmental or social factors; or promoting healthy behaviors and environments.[7]
- **The Women's Preventive Services Guidelines**, a set of evidence-based recommendations outlining specific preventive services to help keep women healthy.[8]

[5] US Preventive Services Task Force, "Methods and Processes," June 2019, https://www.uspreventiveservicestaskforce.org/Page/Name/methods-and-processes.
[6] Office of Disease Prevention and Health Promotion, "Healthy People 2020," September 3, 2019, https://www.healthypeople.gov/.
[7] The Community Guide, "The Guide to Community Preventive Services," accessed September 3, 2019, https://www.thecommunityguide.org/.
[8] Health Resources & Services Administration, "Women's Preventive Services Guidelines," Text, September 2018, https://www.hrsa.gov/womens-guidelines/index.html.

The Affordable Care Act—the health insurance reform legislation passed by Congress and signed into law on March 23, 2010—helped make prevention affordable and accessible by requiring health plans to cover preventive services, such as those outlined in the Women's Preventive Services Guidelines. The Health Resources and Services Administration (HRSA) was charged with the responsibility for updating the guidelines and awarded a 5-year cooperative agreement to American College of Obstetricians and Gynecologists (ACOG) for the Women's Preventive Services Initiative (WPSI). In December 2016, HRSA updated the list of Women's Preventive Services, and it included provision and counseling for all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education for all women with reproductive capacity.

An important step forward in increasing access to contraception occurred when the IOM issued a set of **Women's Preventive Services Guidelines** in 2011, as part of the Affordable Care Act, that included access to contraception as a preventive health service that was to be covered by all non-grandfathered health plans without cost sharing.

The Challenges

While great strides have been made in the development of clinical guidelines that have helped to increase access to contraception and evidence-based, quality care, many of those efforts have stalled in recent years. To keep pace with changes, guidelines for practice that help providers implement self-management strategies through new service delivery platforms, including telemedicine and new contraceptive delivery mechanisms, will require up-to-date research upon which to base practice. Developing evidence-based recommendations requires leadership, time, effort, dedication, will, and resources. It is unfortunate that during some periods of time, contraception and access to services and providers that support it become unnecessarily politicized. This makes it more difficult to access care and also creates barriers to keeping related recommendations current because there is concern that recommendations may be biased or not based on sound scientific evidence.

Additionally, while currently there are guidelines in place for individual client care related to contraceptive access and care, there are no national recommendations for providing access to contraception as a basic, clinical preventive service. This reinforces the perception that contraceptive care is "exceptional" and not a service that can help prevent an outcome that is not desired.

The Potential Solutions

Previous Efforts to Expand Contraceptive Access Through Federal Guidelines

Three sets of recommendations have helped set the "gold standard of care" for all providers or potential providers of family planning services. This includes providers working in service delivery sites that are dedicated to family planning service delivery as well as private and public providers of more comprehensive primary care, such as Federally Qualified Health Centers (FQHCs) or private Medicaid providers. As closely as possible, CDC and OPA sought to use IOM's rigorous standards for developing trustworthy clinical guidelines, as described previously in the "Clinical Guidelines" section on page 3.

CDC's Medical Eligibility for Contraceptive Use (US MEC)

The US MEC was first published by CDC in 2010 and was most recently updated in 2017. It provides evidence-based guidance for the safe use of various contraceptive methods among U.S. women with specific characteristics or medical conditions. It is adapted to the U.S. context from global guidance from WHO and is updated date based on continual reviews of published literature.[9]

CDC's Selected Practice Recommendations for Contraceptive Use (US SPR)

The U.S. Selected Practice Recommendations for Contraceptive Use (US SPR) was also adapted from global guidance provided by WHO; it was first published in 2013 and revised in 2016. The US SPR provides guidance on how to address specific contraceptive management issues, including initiation of methods and some of the more complex and/or controversial contraception management issues.[10]

CDC/OPA's Quality Family Planning Recommendations (QFP)

A detailed description of the development of QFP follows as an example or "case study" of federal processes involved in developing clinical guidelines or recommendations. Published in 2014, the QFP recommendations built on the MEC and SPR recommendations to develop a comprehensive recommendation for 'how' to provide quality family planning services. QFP defined the set of services that comprise family planning for women and men and described how to provide contraceptive and other clinical services, serve adolescents, and incorporate quality improvement into family planning care.[11] The QFP also encouraged providing selected women's preventive health services as part the family planning visit in accordance with the set of recommendations issued by IOM and adopted by HHS as part of the Affordable Care Act.[12] A central premise of the recommendations was that improving the quality of family planning services would lead to improved reproductive health outcomes.

Until 2014, when CDC and OPA released **Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs**, or "QFP," no comprehensive national, professional recommendations existed for "how" to provide quality planning services.

As closely as possible, CDC and OPA endeavored to implement IOM's standards for "trustworthy guidelines" and tried to ensure that the recommendations were as evidence-based as possible and decisions were made in a transparent manner. A comprehensive description of the development of QFP was published in a journal supplement of the *American Journal of Preventive Medicine* (AJPM); a summary of the process and timeline is illustrated in **Exhibit 5**.[13]

[9] Centers for Disease Control and Prevention, "US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016," November 2, 2018, https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html.
[10] Kathryn M. Curtis et al., "U.S. Selected Practice Recommendations for Contraceptive Use, 2016," *MMWR. Recommendations and Reports* 65 (2016), https://doi.org/10.15585/mmwr.rr6504a1.
[11] Loretta Gavin et al., "Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs," *MMWR Recommendations and Reports* 63, no. RR-4 (April 25, 2014), https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf.
[12] Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps* (Washington, DC: The National Academies Press, 2011), https://doi.org/10.17226/13181.
[13] Loretta E. Gavin, Susan B. Moskosky, and Wanda D. Barfield, "Introduction to the Supplement: Development of Federal Recommendations for Family Planning Services," *American Journal of Preventive Medicine* 49, no. 2 Suppl 1 (August 2015): S1-5, https://doi.org/10.1016/j.amepre.2015.03.028.

Exhibit 4. Key Steps in Developing Recommendations for Providing Quality Family Planning Services

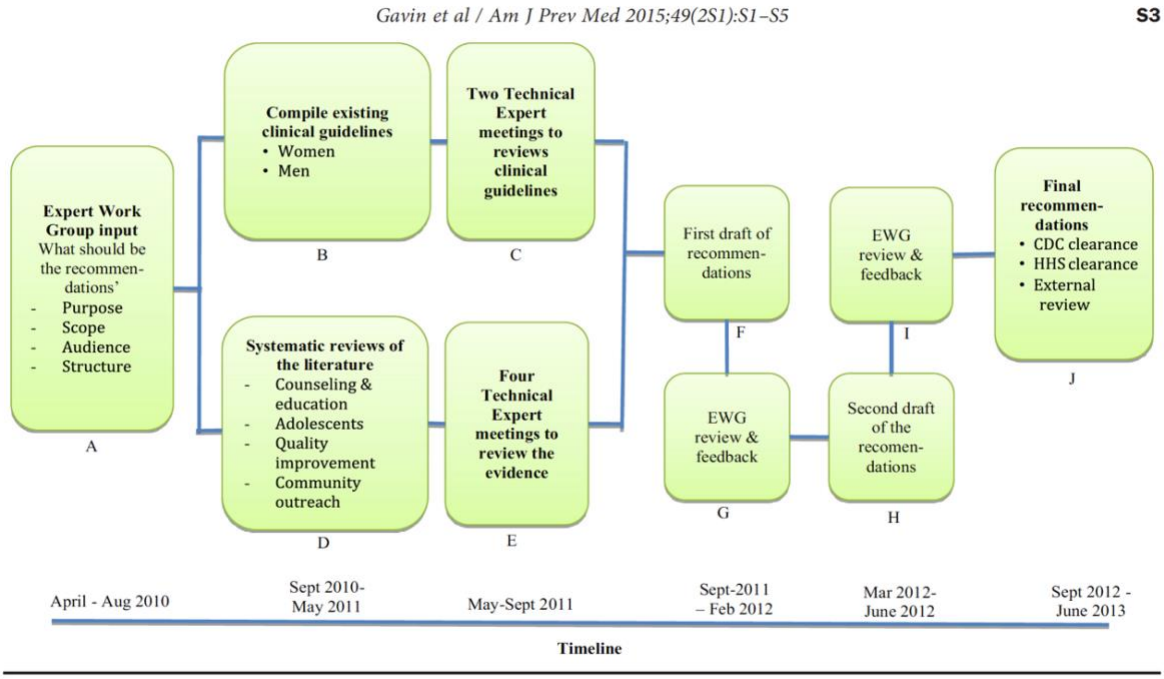


Figure 1. Key steps in developing recommendations for providing quality family planning services.
EWG, expert working group.

Expert Work Group (EWG)

CDC and OPA convened an EWG, consistent with IOM's recommendation to form a guideline development group. The group consisted of representatives from a range of relevant groups, including clinical providers, relevant medical and professional groups, federal agencies, and program administrators. The EWG provided feedback to CDC and OPA throughout the 4-year process, advising on the overall structure and content as well as feasibility and relevancy of the recommendations.

Systematic Reviews

Four priority areas of family planning service delivery were identified as key areas for systematic reviews: 1) counseling and education, 2) serving adolescents, 3) quality improvement, and 4) community engagement. Existing evidence and information were gathered for each of the priority areas, and federal and professional recommendations and guidelines for relevant clinical services for women and for men were compiled. Technical panels of subject matter experts were then convened to consider the quality of the evidence and make suggestions for recommendations that would be supported by the evidence. Technical panels were convened to provide advice about existing clinical guidelines and how they should best be incorporated into the QFP.

Recommendations and Additional Reviews

OPA and CDC drafted recommendations based on all these considerations and presented them in draft to the EWG, who provided feedback on the feasibility and appropriateness of the recommendations. EWG input was provided using an adapted form of the GRADE methodology, taking into consideration: quality of the evidence;

positive and negative consequences of implementing the recommendations on health outcomes, costs or cost saving and implementation challenges; and relative importance of consequences.[14]

Extensive scientific and other reviews of the document were conducted by objective experts who were not involved in the development of the recommendations. These experts were from different divisions within CDC and other agencies throughout HHS. In addition, external peer review was conducted in accordance with CDC's policy governing "Influential Scientific Information (ISI);" this included additional reviews by experts in reproductive health policy, pediatrics, family medicine, men's health, and women's preventive services. After a very long process of review within HHS, the recommendations were ultimately published as a CDC MMWR "Recommendations and Reports" in April 2014.

Updates

One of the key standards of trustworthy guidelines noted by the IOM is the need to continuously monitor, update, and revise recommendations when new evidence suggests the need for modification of a clinical recommendation.[15] To that end, CDC and OPA collaborated to publish two updates to QFP, one in March 2016[16] and one in December 2017[17], that summarized updated clinical recommendations and references published in the interim. CDC and OPA intended to update the systematic reviews of the four previously identified priority areas every 3-4 years and conduct systematic reviews in additional topic areas. Those systematic review updates were published in a journal supplement in 2018.[16] CDC and OPA also intended to undertake "complete revisions" of QFP periodically and although an "expanded" EWG was convened in 2016 as part of planning for a prospective full revision to QFP, no further actions have been taken to comprehensively revise QFP.

Future Directions

Although guidelines must be available to be incorporated into practice or policy, strategic dissemination and facilitating implementation or adoption of those guidelines are other huge endeavors. Appropriately identifying the audience(s), working with organizations that can help support widespread dissemination and implementation, and creating tools to make it easier for providers to implement new guidelines are all parts of the puzzle.

National Recommendations for Contraception as a Clinical Preventive Service

While progress has been made in establishing guidelines for individual women's access to contraceptive methods and related care (e.g., through the Women's Preventive Services Initiative), there is no national, programmatic recommendation establishing contraception as a basic, clinical preventive service, such as a USPSTF recommendation This reinforces the perception that contraception is different, and not a basic preventive service that helps to prevent an outcome that is not desired.

[14] Siemieniuk and Guyatt, "What Is GRADE?"
[15] Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, *Clinical Practice Guidelines We Can Trust*.
[16] Loretta Gavin and Karen Pazol, "Update: Providing Quality Family Planning Services - Recommendations from CDC and the U.S. Office of Population Affairs, 2015," *MMWR. Morbidity and Mortality Weekly Report* 65, no. 9 (March 11, 2016): 231–34, https://doi.org/10.15585/mmwr.mm6509a3.
[17] Loretta Gavin, Karen Pazol, and Katherine Ahrens, "Update: Providing Quality Family Planning Services - Recommendations from CDC and the U.S. Office of Population Affairs, 2017," *MMWR. Morbidity and Mortality Weekly Report* 66, no. 50 (December 22, 2017): 1383–85, https://doi.org/10.15585/mmwr.mm6650a4.

Dissemination and Implementation Research

An entire field has emerged in recent years around dissemination and implementation research—with the focus on helping to ensure that evidence-based practices, interventions, and policies are effectively translated and incorporated into practice. During the past five years, NIH has awarded a number of grants to study dissemination and implementation of evidence-based interventions, and it will be an area to continue monitoring going forward.[18]

Performance Measures

Performance measures that are based on evidence-based guidelines are key implementation tools that can be used to guide quality improvement, quality assurance, and pay for performance. This emphasizes the need for using the most rigorous standards for the development of guidelines and ensuring that the methods to develop guidelines are based on the best available science.

The Call to Action

As described earlier in this document, clinical and programmatic guidelines that are rigorously developed and consistently adopted, implemented, and evaluated have the potential to improve both the quality and the process of care and patient outcomes. The federal government, specifically agencies within HHS, play an important role in setting expected standards for care that greatly impact the quality and content of care that is provided across the U.S. **Exhibit 6** outlines several potential actions that can be taken to facilitate development of guidelines and recommendations that will lead to expanded contraceptive access. This work will set the stage for subsequent recommendations that can be made to the Federal Executive Branch.

Exhibit 5. Potential Actions to Support Guidelines that Will Expand Contraceptive Access

Outline the plan for a fully revised QFP and encourage continued support for revisions to MEC and SPR

Steps might include:

- Conduct a mock expert work group.
- Identify essential groups that should be represented on an actual expert work group.
- Outline a possible/suggested structure for a revised QFP.
- Identify topic areas for new systematic reviews and identify a process for getting them completed.
- Identify additional conditions that should be considered for inclusion in MEC and/or new methods that need to be considered.
- Identify new or additional complex contraceptive management issues that should be addressed in the SPR.

[18] Ross C. Brownson, Graham A. Colditz, and Enola K. Proctor, eds., *Dissemination and Implementation Research in Health: Translating Science to Practice*, Second Edition, New to this Edition: (Oxford, New York: Oxford University Press, 2017).

Support work leading to a USPSTF recommendation for contraception counseling and provision

Currently, there is no USPSTF recommendation for contraception as a basic, clinical preventive service. This reinforces the perception that contraceptive care is "exceptional" and not a service that can help prevent an outcome that is not desired.

Very preliminary work is currently happening that could possibly lay the groundwork for a USPSTF recommendation for contraception—an "A" or "B" USPSTF recommendation would further ensure access to contraception as a preventive service that would be covered by insurance plans (currently those without religious or moral objections) without cost sharing.

Assess the possibility of seeking a recommendation from The Community Preventive Guide on community-wide access to contraception

Work has been undertaken in several states to support statewide access to contraception. Assessing whether The Community Guide could be a venue for disseminating community-wide strategies for contraceptive access that work in improving specific aspects of community health should be considered.

Identify other guidelines that might be needed to support expanded access to contraception

For example, a technical panel might be convened to identify innovative or emerging strategies, such as telemedicine or other service delivery platforms for expanding contraceptive access that would possibly require new guidelines to be developed or could be incorporated into QFP.

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