



AGENCY FOR HEALTHCARE RESEARCH AND QUALITY



Overview of USPSTF Methods for Establishing I Statements and Determining and Disseminating Evidence Gaps in Clinical Preventive Services

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AGENDA

- Key Points
- Background
- Methods
- Dissemination
- Evidence Gaps – Real World Examples
- Summary Thoughts

Key Points

The USPSTF:

- Mission is to develop and disseminate recommendations on clinical preventive services
- Uses rigorous methods to develop its recommendations, including the types of evidence it considers
- Identifies gaps in evidence in all recommendation statements and evidence reviews
- Looks to partner organizations and agencies to play key role in helping fill evidence gaps and supporting dissemination and implementation
- Hopes taxonomy can provide immediate and long-term solutions for the various stakeholders

BACKGROUND

USPSTF Overview



- Makes recommendations based on rigorous review of existing peer-reviewed evidence
 - ▶ Does not conduct the research studies, but reviews & assesses the research
 - ▶ Evaluates benefits & harms of each service
 - ▶ Makes population-based recommendations for primary care clinicians for adults & children with no signs or symptoms (or unrecognized signs and symptoms)

Who is the USPSTF?



- Created in 1984
- Independent panel of volunteer, non-Federal experts in prevention & evidenced-based medicine
- Experts in primary care, prevention, research methods
- AHRQ provides scientific, technical, administrative, dissemination support (since 1998)
- Systematic Evidence Review support from Evidence-based Practice Centers (EPCs) with funding from AHRQ

METHODS

USPSTF Recommendation Development Process



- Rigorous 4-stage recommendation development process:
 - ▶ Topic nomination
 - ▶ Draft and final research plans
 - ▶ Draft evidence review and recommendation statement
 - ▶ Final evidence review and recommendation statement
- 4-week public comment period on all draft materials
- The Task Force works with AHRQ EPCs to develop research plans and review evidence
- Subject matter experts are consulted throughout the recommendation development process
- Procedure Manual available under Methods and Processes at: www.uspreventiveservicestaskforce.org

USPSTF Partners



Partners Who Support Primary Care Delivery

- American Academy of Family Physicians (AAFP)
- American Association of Nurse Practitioners (AANP)
- American Academy of Pediatrics (AAP)
- American Academy of Physician Assistants (AAPA)
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Physicians (ACP)
- American College of Preventive Medicine (ACPM)
- American Medical Association (AMA)
- American Osteopathic Association (AOA)
- American Psychological Association (APA)
- National Association of Pediatric Nurse Practitioners (NAPNAP)

Partners Focused on Healthcare Utilization, Coverage, and Quality

- America's Health Insurance Plans (AHIP)
- AARP
- Business Group on Health (BGH)
- National Committee for Quality Assurance (NCQA)
- Patient-Centered Outcomes Research Institute (PCORI)

Partners Who Develop Recommendations on Prevention

- Canadian Task Force on Preventive Health Care (CTFPHC)
- Community Preventive Services Task Force (CPSTF)

Federal Partners

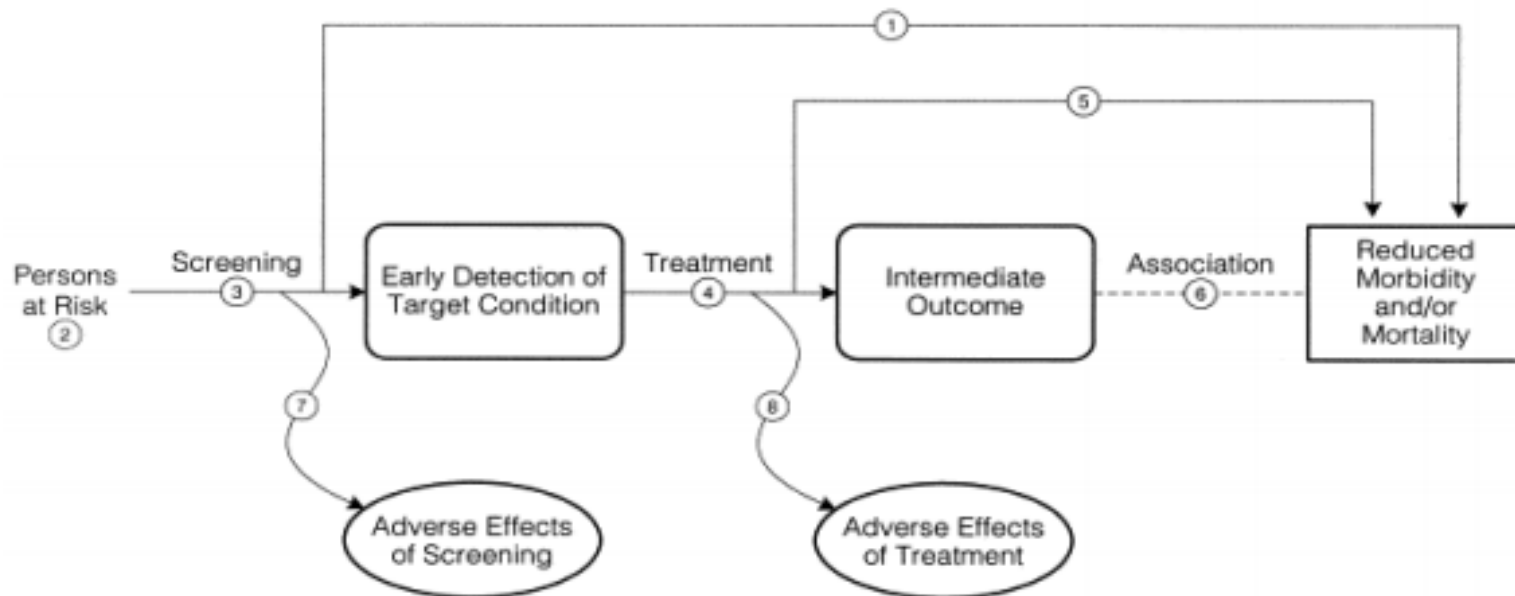
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Department of Defense (DOD) Military Health System
- Department of Veterans Affairs (VA) Center for Health Promotion & Disease Prevention
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Cancer Institute (NCI)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion (ODPHP)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- U.S. Food and Drug Administration (FDA)

Recommendation Grades

Letter grades are assigned to each recommendation statement. These grades are based on the strength of the evidence on the harms and benefits of a specific preventive service. <https://www.uspreventiveservicestaskforce.org/uspstf/grade-definitions>

Grade	Definition
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Sample Template for USPSTF Analytic Framework



Hierarchy of Research Designs



- Properly powered and conducted RCT; well-conducted systematic review or meta-analysis of homogeneous RCTs
- Well-designed controlled trial without randomization
- Well-designed cohort or case-control analysis study
- Multiple time-series, with or without the intervention; results from uncontrolled studies that yield results of large magnitude

Read More: USPSTF Procedure Manual:

<https://www.uspreventiveservicestaskforce.org/uspstf/procedure-manual>

Criteria for RCTs and Cohort Studies



- Initial assembly of comparable groups
- Maintenance of comparable groups
- Differential loss to followup or overall high loss to followup
- Measurements: equal, reliable, and valid
- Clear definition of interventions
- All important outcomes considered
- Analysis:
 - ▶ Adjustment for potential confounders for cohort studies or intention-to-treat analysis for RCTs

Read More: USPSTF Procedure Manual:

<https://www.uspreventiveservicestaskforce.org/uspstf/procedure-manual>

Criteria for Diagnostic Accuracy Studies



- Screening test relevant, available for primary care, and adequately described
- Credible reference standard, performed regardless of test results
- Reference standard interpreted independently of screening test
- Indeterminate results handled in a reasonable manner
- Spectrum of patients included in study
- Sample size
- Reliable screening test

Read More: USPSTF Procedure Manual:

<https://www.uspreventiveservicestaskforce.org/uspstf/procedure-manual>

Modeling

- USPSTF uses modeling to inform the recommendation process
 - ▶ When there is direct evidence of the benefit of a preventive service on health outcomes or when there is evidence for each of the linkages in the analytic framework
- Decision models can be critical to the USPSTF when more information is needed to determine:
 - ▶ When to start and how long to continue delivering a clinical preventive service
 - ▶ How frequently to repeat the service
 - ▶ The best or equally appropriate choices among different ways of delivering the service

Read More: USPSTF Procedure Manual:

<https://www.uspreventiveservicestaskforce.org/uspstf/procedure-manual>

USPSTF Recommendation Dissemination Efforts



- **Partnership with JAMA**, which publishes the recommendation statements, podcasts, and other materials
- **Prevention TaskForce** (formerly ePSS) (<https://www.uspreventiveservicestaskforce.org/apps/>), a Web site and mobile app that allows clinicians to identify which preventive services are right for their patients
- **Healthfinder Web site** (<http://healthfinder.gov>) a tool for patients to learn more about prevention and find the right preventive services for them
- **Email list notifications** to alert subscribers to topic activity as well as general Task Force updates
- **News bulletins** to summarize recommendations for the media
- **Plain language summaries** of Task Force draft recommendations to help individuals understand the recommendation before submitting comments
- **Clinician summaries** of the recommendations for clinicians; embedded as a table within the recommendation statement and available as a separate document on the website

Efforts to Improve Communication of Recommendations and Evidence Gaps

Table. Contents of the Revised US Preventive Services Task Force (USPSTF) Recommendation Statement

Section	Description
Summary of recommendation	The recommendation, including the letter grade; the “bottom line” of the USPSTF statement
Clinician summary	Table that summarizes the recommendation and what clinicians may need to do to carry out the recommendation
Importance	Why this health issue matters; a brief description of the condition, the prevalence, and major consequences
Assessment of magnitude of net benefit	USPSTF’s reasoning or rationale for its recommendation, including an overall assessment of the evidence
Practice considerations	Information clinicians need to know to carry out the recommendation in practice, including population, assessment of risk, screening tests or interventions, and additional tools and resources
Update of previous USPSTF recommendation	Overall changes from the prior recommendation (if applicable)
Supporting evidence	Summary of the evidence the USPSTF used to inform its recommendation, and the USPSTF’s interpretation of the evidence that justifies the recommendations made
Research needs and gaps	Key research that is still needed on this topic
Recommendation of others	Summary of recommendations from related organizations and agencies
Supplemental materials and end matter	<i>Tables of what the USPSTF grades mean and levels of certainty of the evidence</i>
	<i>USPSTF statement of principles, orients readers to the intention and proposed usage of USPSTF recommendations</i>
	<i>References, provide a small sample of the important literature on this topic and citations from the evidence review</i>
	<i>Other related information, including conflict of interest disclosures</i>

Epling JW, Borsky AE, Gerteis J. Improvements to the US Preventive Services Task Force Recommendation Statement. JAMA. 2019 Sep 24;322(12):1143-1144. doi: 10.1001/jama.2019.11311. PMID: 31550039.

EVIDENCE GAPS

Ways USPSTF Highlights Evidence Gaps



- **Issuing an “I statement”**
 - ▶ USPSTF issues “I statements” when the current evidence is lacking, of poor quality, or conflicting
 - ▶ When the evidence is insufficient, the USPSTF is unable to assess the balance of benefits and harms of the preventive service
 - ▶ 54 I statements
- **Including within the Recommendations and Evidence Reviews**
 - ▶ In all recommendation statements, the USPSTF points out where gaps in the evidence remain in a section called “Research Needs and Gaps”
 - 85 recommendation statements, with 136 specific recommendation grades
 - ▶ All evidence reviews examine whether there are populations that have a higher prevalence or experience greater morbidity or mortality from the condition of interest

I Statements Examples

- I statements may pertain:
 - ▶ To an entire recommendation, such as Screening for Celiac Disease (2017)
 - ▶ To a subset of the recommendation, such as Aspirin Use to Prevent Cardiovascular Disease and Colorectal Cancer (2016)
 - I statements for adults aged 50 and younger and over age 70
 - B for adults aged 50 to 59 years with a $\geq 10\%$ 10-year CVD risk
 - C for adults aged 60 to 69 years with a $\geq 10\%$ 10-year CVD risk

Health Equity

- USPSTF needs quality evidence about the benefits and harms of the service and about the ways **specific population groups** are affected
- Examples include:
 - ▶ Age groups, including children and older adults
 - ▶ Racial and ethnic groups, such as Black, Hispanic/Latino, American Indian or Alaska Native, and Asian American and Pacific Islander
 - ▶ People who do not identify as heterosexual
 - ▶ Those disproportionately affected by social risk factors, such as financial strain or lack of access to affordable and nutritious food

Disparities Example



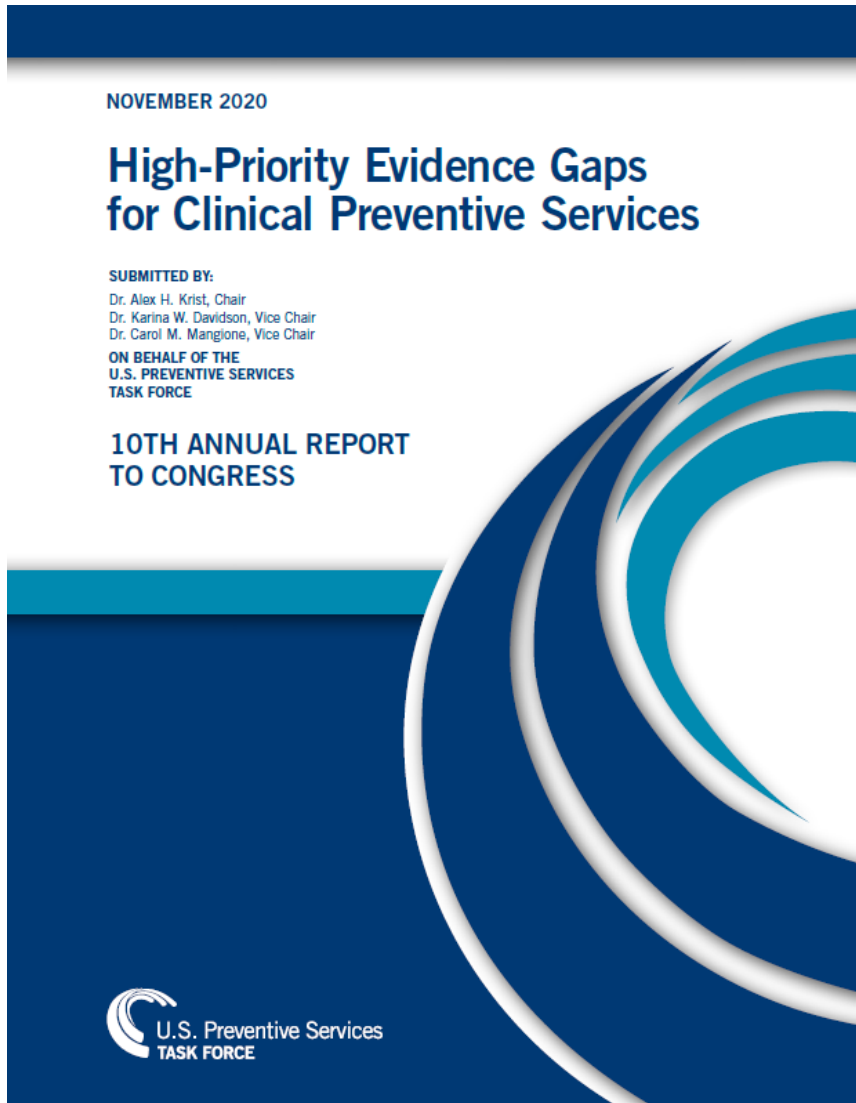
- The evidence reviews include identifying populations that have a higher prevalence or experience greater morbidity or mortality from the condition
- Evidence is often times lacking to inform recommendations that can address gaps identified for groups, such as Blacks or LatinX who are disproportionately impacted by the condition
- Example, Screening for Lung Cancer and Screening for Colorectal Cancer (2020 Draft Recommendations)

Read More: Bibbins-Domingo K, Whitlock E, Wolff T, et al. Developing Recommendations for Evidence-Based Clinical Preventive Services for Diverse Populations: Methods of the U.S. Preventive Services Task Force. *Ann Intern Med.* 2017;166(8):565-571.




Research Needs and Gaps Example

- Screening for Lung Cancer (2020 Draft Recommendation): B Grade
- Research Needs and Gaps:
 - ▶ Implementation research to address how to increase the uptake of lung cancer screening discussions in clinical practice is needed, particularly among minority and vulnerable populations.
 - ▶ Research is needed to evaluate whether, as lung cancer screening is implemented in diverse community settings, including among racial/ethnic minorities, among socioeconomically disadvantaged populations (where smoking prevalence and lung cancer incidence is higher), and in settings that screen greater numbers of women, the balance of benefits and harms differs from that found in RCTs.
 - ▶ Research to identify biomarkers that identify high risk persons is needed.
 - ▶ Research to identify technologies that more accurately discriminate between benign and malignant lung nodules is needed.
 - ▶ Research is needed on the benefits and harms of using risk prediction models to select patients for lung cancer screening, including whether use of risk prediction models creates a barrier to wider implementation of lung cancer screening in primary care.

Annual Report on Evidence Gaps



- Focus on Child and Adolescent Health and Health Inequities

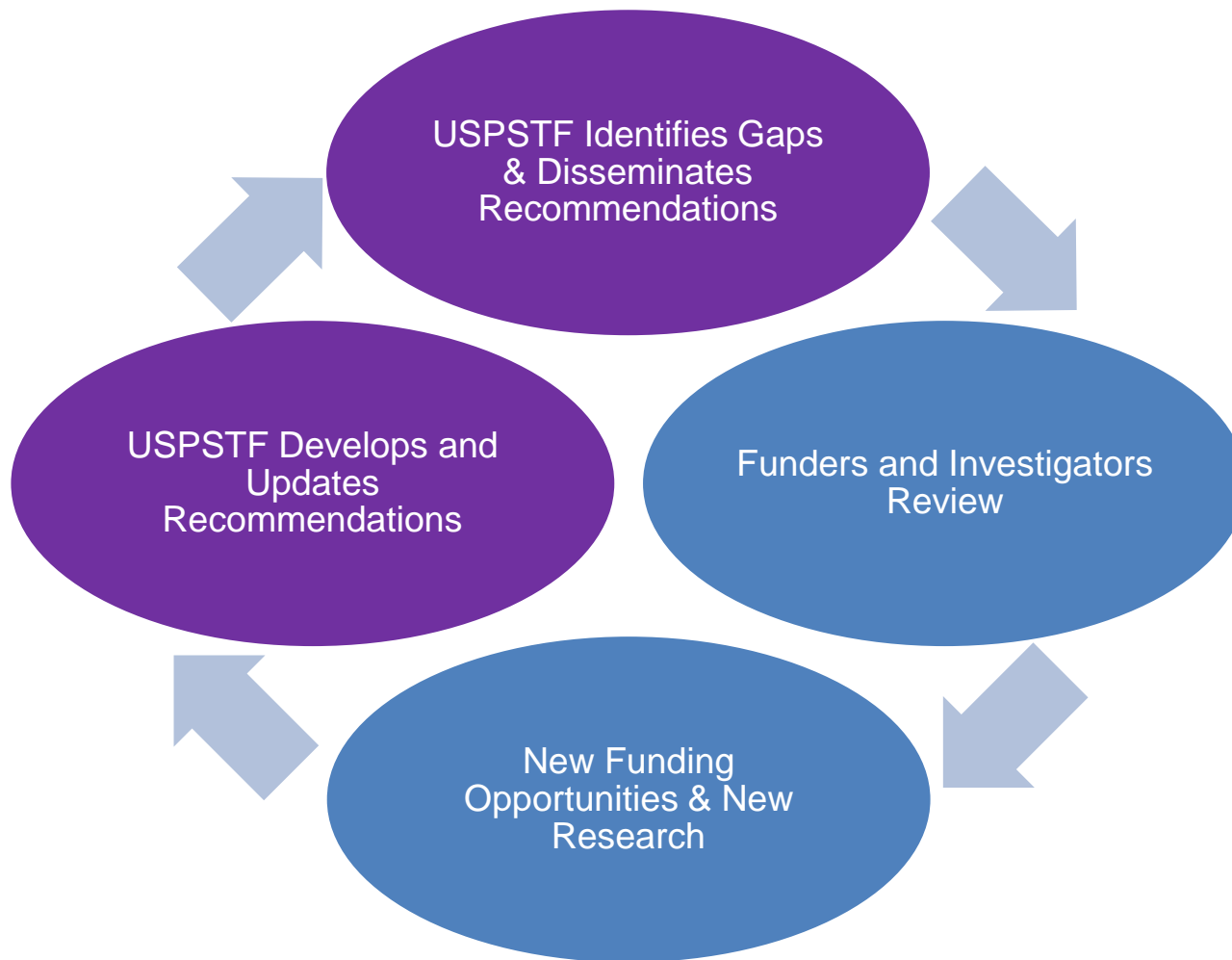
-  Mental and Behavioral Health
-  Substance Use
-  Obesity

General Guidance on What's Needed to Fill Gaps



- Examine preventive services conducted in the **primary care setting** or that are referable from primary care
- Include **populations most affected by the condition of interest**
- Include populations **without obvious signs or symptoms** of the condition
- Adopt a **rigorous study design** appropriate for the question, such as a randomized, controlled trial or a high-quality observational study
 - ▶ USPSTF may also commission modeling
- Compare outcomes for a **screened versus unscreened** population
- Be **free of potential sources of bias**, such as high dropout rates among participants or biased assessment of outcomes

Research Gaps Process



SUMMARY THOUGHTS

AHRQ Perspective: Recap Project Goals



- Goals of the evidence gaps taxonomy are to provide immediate and long-term solutions that will help:
 - ▶ Organizations that develop preventive services recommendations, such as the USPSTF, to more clearly communicate evidence gaps
 - ▶ Funding agencies, including the NIH, to understand, assess the relative importance of, and use evidence gaps from preventive services recommendations in order to ultimately support research to fill the gaps
 - ▶ Members of the research community to focus their research on high priority areas that have evidence gaps
 - ▶ All stakeholders, including patients, to bridge the translation of evidence gaps into funding opportunities and other initiatives that ultimately use innovative methods to close evidence gaps related to clinical preventive services

Challenges

Communication challenges:

- Describing gaps in a way that is clear but flexible for the various approaches that could be used to fill the gaps
- Multiple organizations play a role in filling evidence gaps
 - ▶ Mission of USPSTF is to develop the recommendations

Evidence challenges:

- Balancing innovation with replication in studies
- Examining health outcomes or connecting intermediate outcomes with health outcomes

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