The USPSTF's Framework for Making Cancer Screening Recommendations

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Disclaimer

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134 Recommendations on 84 Topics

Recommendations For 2019

Draft Research Plan

- Aspirin to Prevent Preeclampsia
- Interventions to Prevent Opioid Use Disorder
- Prevention of Dental Caries in Children
- Screening for Carotid Artery Stenosis
- Screening for Colorectal Cancer
- Screening for Chlamydia & Gonorrhea
- Screening for Gestational Diabetes Mellitus
- Screening for Hearing Loss in Older Adults
- Screening for Hepatitis B in Adolescents & Adults
- Screening for Vitamin D Deficiency
- Vitamin Supplementation to Prevent CVD & Cancer

Final Research Plan

- Aspirin to Prevent Preeclampsia
- Screening for Abnormal Blood Glucose & Type 2 Diabetes Mellitus
- Screening for Colorectal Cancer
- Screening for Chlamydia & Gonorrhea
- Screening for Gestational Diabetes Mellitus
- Screening for Hearing Loss in Older Adults
- Screening for Hepatitis B in Adolescents & Adults
- Screening for High Blood Pressure in Adults
- Screening for High Blood Pressure in Children & Adolescents
- Screening for Vitamin D Deficiency
- Vitamin Supplementation to Prevent CVD & Cancer

Draft Recommendation

- Interventions for Prevention and Cessation of Tobacco Use in Children & Adolescents
- Interventions to Prevent Drug Use in Children, Adolescents & Young Adults
- Medication Use to Reduce Risk of Breast Cancer
- PrEP for HIV Prevention
- Prevention of *BRCA*-Related Cancer
- Screening for Abdominal Aortic Aneurysm
- Screening for Asymptomatic Bacteriuria in Adults
- Screening for Cognitive Impairment in Older Adults
- Screening for Illicit Drug Use
- Screening for Hepatitis B in Pregnant Women
- Screening for Hepatitis C in Adolescents & Adults
- Screening for HIV
- Screening for Lead in Children & Pregnant Women

Final Recommendation

- Interventions to Prevent Child Maltreatment
- Interventions to Prevent Perinatal Depression
- Medication Use to Reduce Risk of Breast Cancer
- Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum
- PrEP for HIV Prevention
- Prevention of *BRCA*-Related Cancer
- Prevention of Unhealthy Alcohol Use
- Screening for Asymptomatic Bacteriuria in Adults
- Screening for Hepatitis B in Pregnant Women
- Screening for HIV
- Screening for Intimate Partner Violence & Elder Abuse
- Screening for Lead in Children & Pregnant Women
- Screening for Pancreatic Cancer

Preventive services are done for people without signs or symptoms – i.e. healthy people.

Most people won't get the cancer we are screening for and won't directly benefit, but they are at risk for the harms.

We need to hold preventive services to a high bar before recommending them.

Key Principles for Cancer Screening Recommendations

- Systematic
- Evidence-based
- Based on health outcomes
- Incorporates benefits and harms
- Reproducible
- Transparent
- Free from conflict of interest
- Clear and actionable
- Respects patient values and preferences
- Grounded in ethical principles

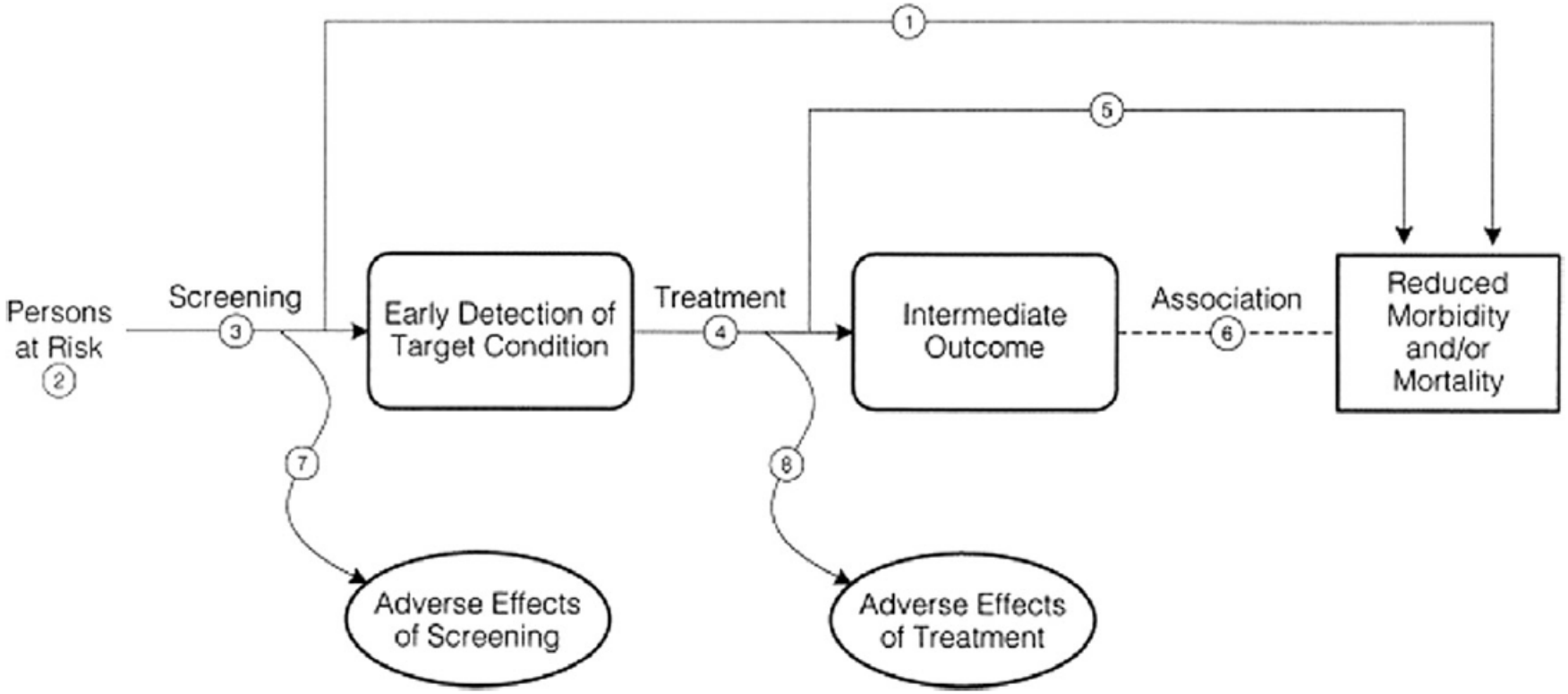
Overview of USPSTF

- Independent panel of volunteer experts in prevention & evidence-based medicine
- Makes evidence-based recommendations about clinical preventive services, including screening, counseling, and preventive medications
  - Recommendations address only services offered in the primary care setting or services referred by a primary care clinician
  - Recommendations apply to adults & children with no signs or symptoms (or unrecognized signs and symptoms)

Overview of USPSTF

- 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 based on factors such as age & sex
- Systematically solicits input from topical experts throughout the process

Generic Analytic Framework



Define Included Study Characteristics (PICOTS)

	Include	Exclude
Populations	Age ≥40 years, average-risk or unselected populations; screening populations (i.e., asymptomatic)	Populations selected for personal or family history of colorectal cancer, known genetic susceptibility syndromes (e.g., Lynch syndrome, familial adenomatous polyposis), or personal history of inflammatory bowel disease; nonscreening populations (e.g., persons who are symptomatic, screen positive, have iron deficiency anemia, or are under surveillance for a previous colorectal lesion)
Settings	Settings representative of community practice for flexible sigmoidoscopy and colonoscopy studies; developed countries (i.e., rated "very high" on the Human Development Index)	Primarily research-based settings (or select academic settings that would not be applicable to most practice settings) for endoscopy studies (e.g., small studies aimed at evaluating new endoscopy technologies, studies with operator or resource characteristics not applicable to community practice); developing countries
Screening Tests	**KQ 1:** Any program of colorectal screening, including endoscopy, imaging, and fecal or blood testing **KQs 2–3:** Colonoscopy; flexible sigmoidoscopy; CT colonography; fecal screening tests, such as gFOBT (e.g., Hemoccult SENSA®), FIT (quantitative and qualitative testing), and fecal DNA test; blood screening tests (i.e., mSEPT9)	**KQs 2–3:** Hemoccult II (review of test performance and harms limited to high-sensitivity gFOBT); stool testing using in-office digital rectal examination; double contrast barium enema; capsule endoscopy (e.g., PillCam®); magnetic resonance colonography
Comparisons	**KQ 1:** No screening or alternate screening strategy **KQ 2:** Diagnostic accuracy studies that use colonoscopy as a reference standard **KQ 3:** No comparator necessary	

Define Included Study Characteristics (PICOTS)

Comparisons	**KQ 1:** No screening or alternate screening strategy **KQ 2:** Diagnostic accuracy studies that use colonoscopy as a reference standard **KQ 3:** No comparator necessary	
Outcomes	**KQ 1:** Colorectal cancer incidence (by stage), interval colorectal cancer; colorectal cancer–specific or all-cause mortality **KQ 2:** Test performance, including sensitivity and specificity (per person); positive and negative predictive value (per person); yield and miss rates (per lesion) for structural examinations (i.e., colonoscopy, flexible sigmoidoscopy, CT colonography) For detection of colorectal cancer, advanced adenoma (high-grade dysplasia, villous histology, and/or measuring ≥10 mm), and/or adenomatous polyps by size (i.e., measuring ≤5 mm, 6–9 mm, ≥10 mm) By location in colon (e.g., proximal versus distal) **KQ 3:** Serious adverse events requiring unexpected or unwanted medical attention and/or resulting in death (e.g., requiring hospitalization), including but not limited to perforation, major bleeding, severe abdominal symptoms, and cardiovascular events; extra-colonic findings and subsequent diagnostic workup and adverse events from diagnostic testing for incidental findings on CT colonography; radiation exposure per CT colonography examination	**KQ 1:** Incidence of adenomas or advanced neoplasia (composite outcome of advanced adenomas and colorectal cancer) **KQ 3:** Minor adverse events defined as those not necessarily needing or resulting in medical attention (e.g., patient dissatisfaction, anxiety/worry, minor gastrointestinal complaints)
Study Design	Fair- to good-quality studies; studies published between January 1, 2008 and May 31, 2014 (bridge searches will be conducted as required to keep review current at time of publication) **KQ 1:** Systematic reviews (of included study designs); randomized, controlled trials; selected well-designed controlled clinical trials; cohort studies; or case-control studies	Poor-quality studies with a fatal flaw; studies with a publication date outside of review window **KQ 1:** Decision analyses **KQ 2:** Diagnostic accuracy studies without colonoscopy as a reference standard, diagnostic accuracy studies without representation of a full spectrum of disease

Evaluate Evidence for Each Key Question and Across Framework

Critical Appraisal Questions

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of sufficient quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population of interest to the intervention and situation? (i.e., what is the applicability?)
4. How many and how large are the studies that address the key question(s)? Are the results precise?
5. How consistent are the results of the studies?
6. Are there additional factors that assist us in drawing conclusions (e.g., fit within a biologic model)?

USPSTF Steps: Brief and Generic

The USPSTF assesses the evidence across the analytic framework:

- Judges the ***certainty*** of the estimates of the potential benefits and harms
- Judges the ***magnitude*** of the potential benefits and harms
- The ultimate goal is to judge the ***balance*** of the benefits and harms, or the ***magnitude of the net benefit*** of the preventive service
- When evidence is insufficient (low certainty), the USPSTF *does not* use “expert opinion”

Basic USPSTF Methods for Developing Recommendations: The Letter Grades

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	I—insufficient evidence			

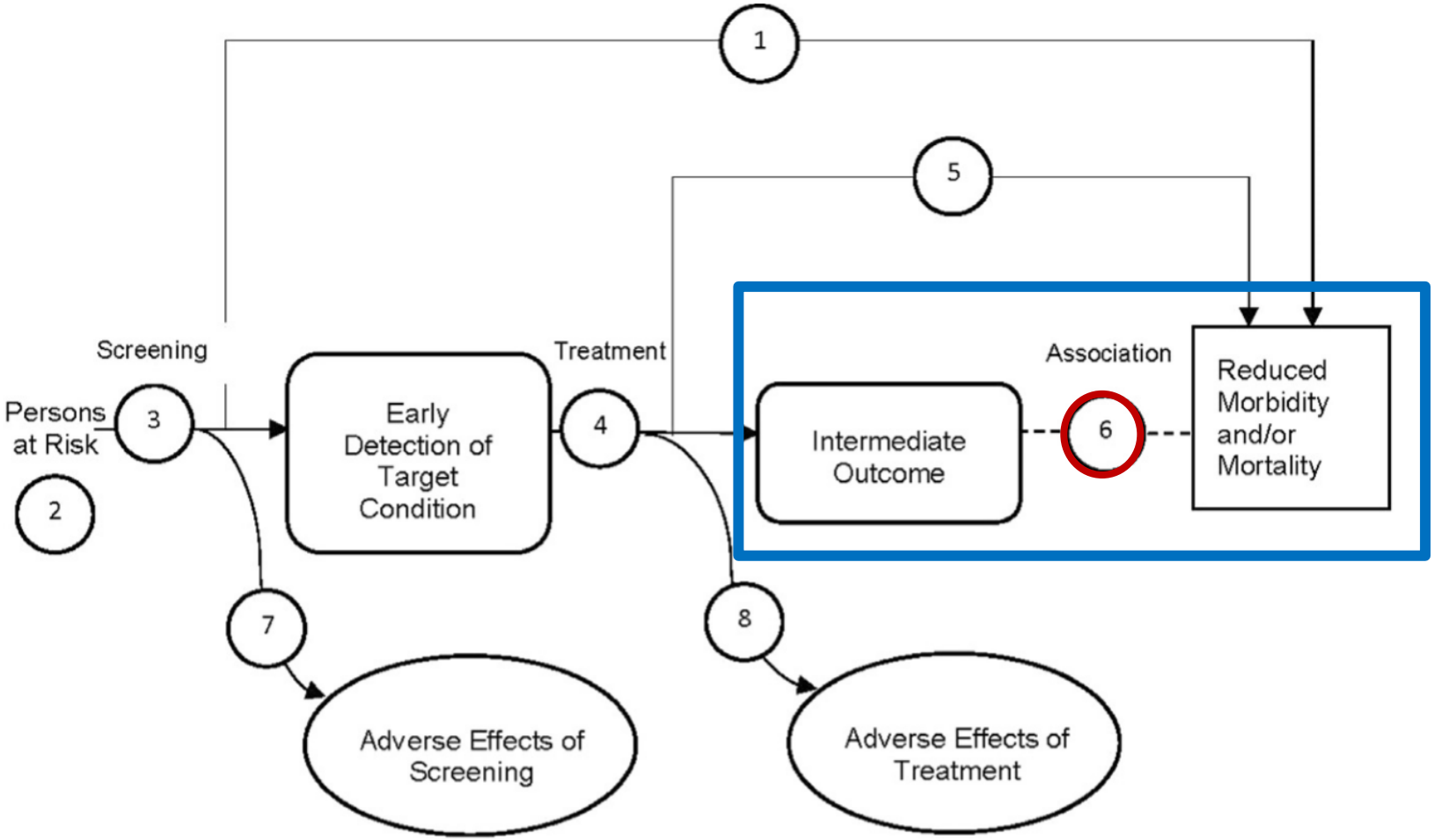
What Grades Suggest for Practice

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
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.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Health Outcome vs. Intermediate Outcome

- Health outcome – outcomes that patients can experience or feel and affect how long a patient lives or the quality of life or both
- Intermediate outcome – outcomes that may be influenced by a preventive service, but are not health outcomes in and of themselves; they are pathologic, physiologic, psychologic, social, or behavioral measures
  - Examples include blood pressure, serum cholesterol, vitamin levels, viral levels, physical activity measures, ***cancer diagnosis, stage shift***
  - The USPSTF requires evidence demonstrate an effect on health outcomes not just intermediate outcomes

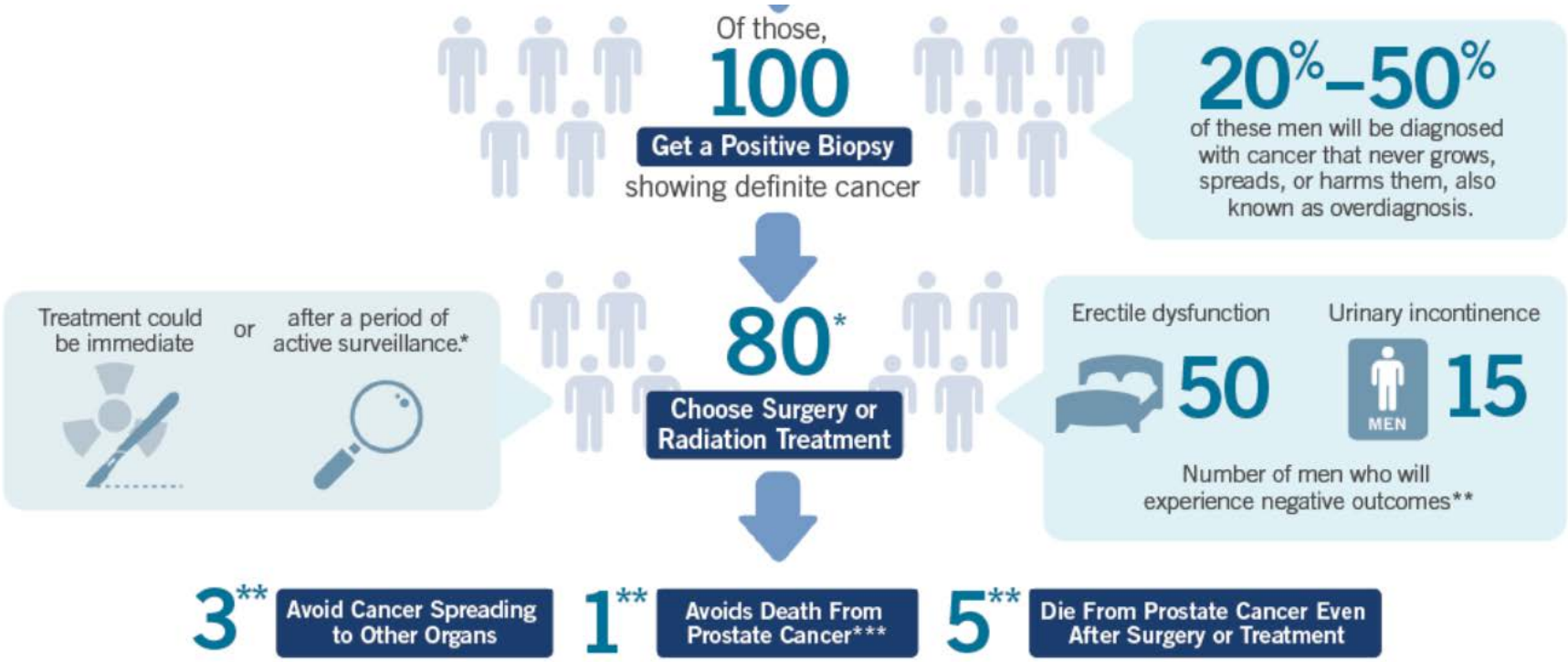
IO-HO Linkage in Analytic Framework



Never Relied on IO-HO to Make a Cancer Screening Recommendation

- (A, 2015) Smoking Cessation Counseling – IO of quitting smoking
- (A, 2018) Ocular Prophylaxis for Gonococcal Ophthalmia – IO of reduced gonococcal infection
- (B, 2018) Primary Care Interventions to Promote Breastfeeding – IO of increased breastfeeding
- (C, 2019) Screening for Hepatitis C – IO of sustained virologic response

How Do You Weigh Benefits vs Harms? (Prostate Cancer Screening Example)



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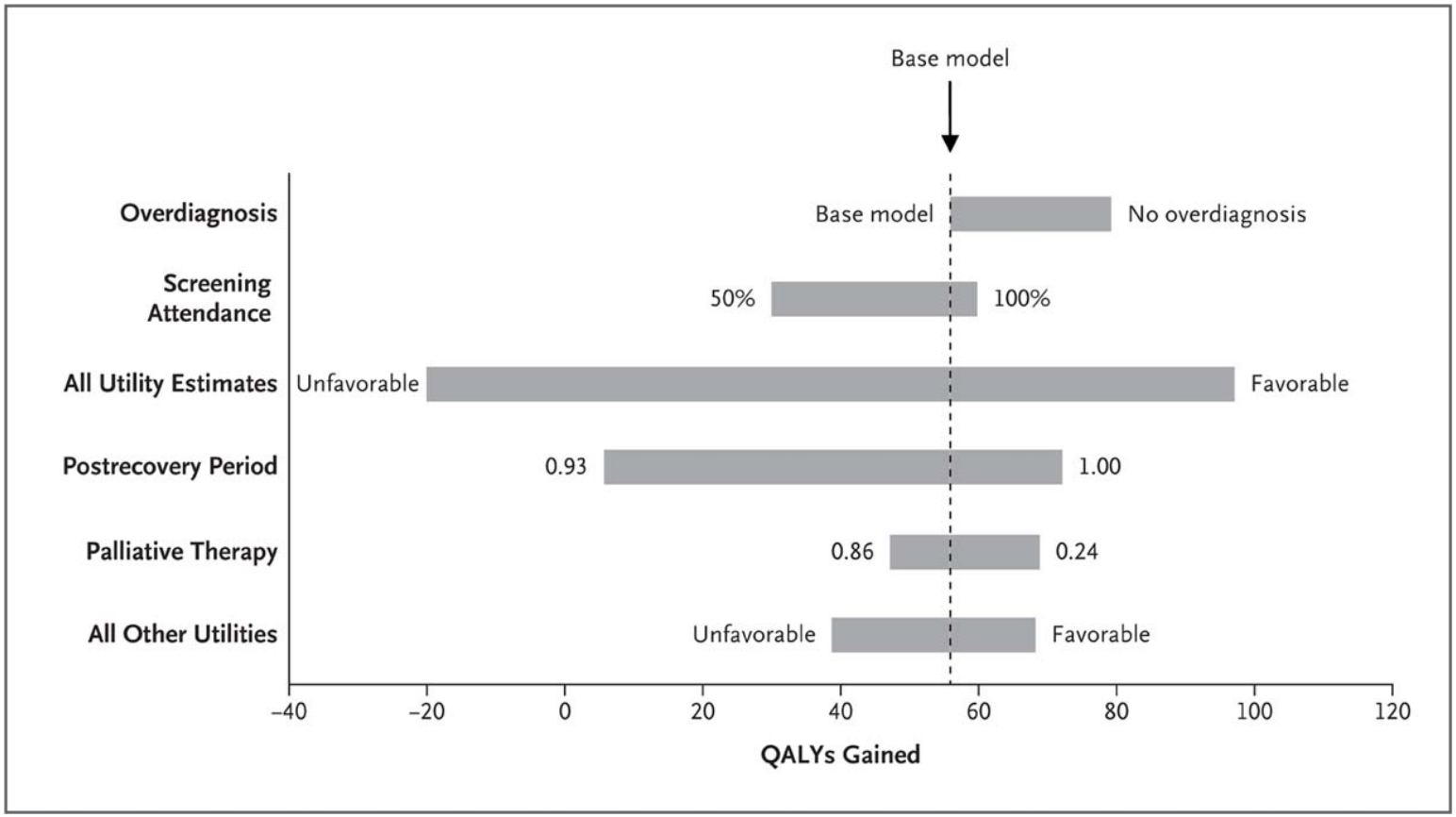
Benefit Depends on Patient's Values (Modeling Net Benefit – QALYs)



Heijnsdijk et al. New Engl J Med. 2012;367;659-668.

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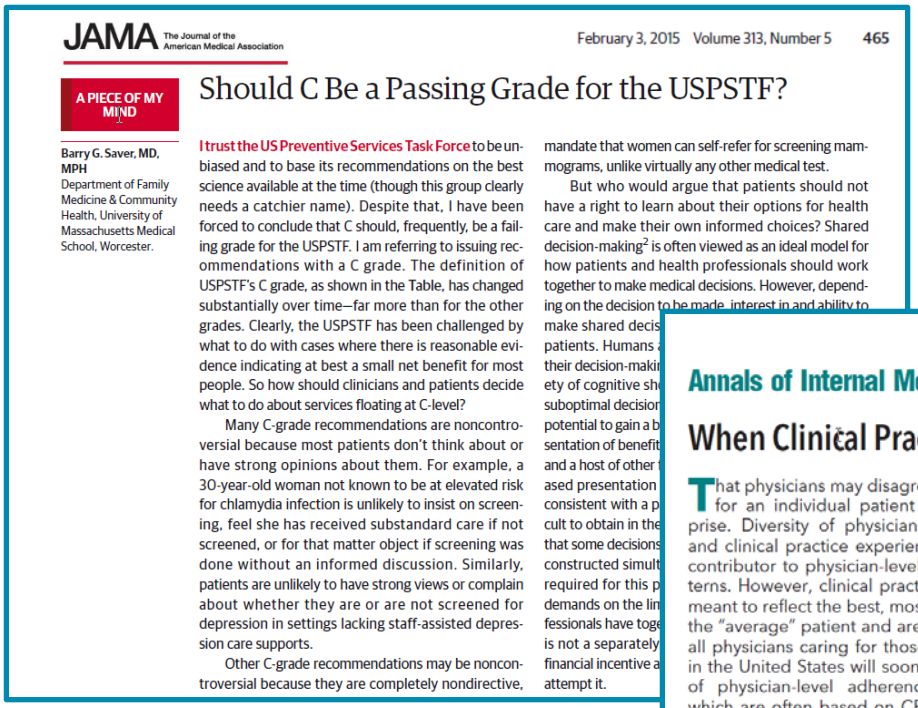
THE USPSTF RECOMMENDATIONS DEVELOPMENT PROCESS

1. TOPIC NOMINATION
2. DRAFT AND FINAL RESEARCH PLANS
3. DRAFT EVIDENCE REVIEW AND DRAFT RECOMMENDATION STATEMENT
4. FINAL EVIDENCE REVIEW AND FINAL RECOMMENDATION STATEMENT

Transparent Process for Public Input

- Anyone can nominate a topic for the USPSTF to consider via the web site
  - http://www.uspreventiveservicestaskforce.org/tftopicnon.htm
- Anyone can comment on:
  - Posted Draft Research Plans
  - Posted Draft Evidence Reports and Recommendation Statements.
- We read every nomination and comment

Everyone Wants One Answer – Do It / Don't Do It



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A PIECE OF MY MIND

Should C Be a Passing Grade for the USPSTF?

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I trust the US Preventive Services Task Force to be unbiased and to base its recommendations on the best science available at the time (though this group clearly needs a catchier name). Despite that, I have been forced to conclude that C should, frequently, be a failing grade for the USPSTF. I am referring to issuing recommendations with a C grade. The definition of USPSTF's C grade, as shown in the Table, has changed substantially over time—far more than for the other grades. Clearly, the USPSTF has been challenged by what to do with cases where there is reasonable evidence indicating at best a small net benefit for most people. So how should clinicians and patients decide what to do about services floating at C-level?

Many C-grade recommendations are noncontroversial because most patients don't think about or have strong opinions about them. For example, a 30-year-old woman not known to be at elevated risk for chlamydia infection is unlikely to insist on screening, feel she has received substandard care if not screened, or for that matter object if screening was done without an informed discussion. Similarly, patients are unlikely to have strong views or complain about whether they are or are not screened for depression in settings lacking staff-assisted depression care supports.

Other C-grade recommendations may be noncontroversial because they are completely nondirective, mandate that women can self-refer for screening mammograms, unlike virtually any other medical test.

But who would argue that patients should not have a right to learn about their options for health care and make their own informed choices? Shared decision-making[2] is often viewed as an ideal model for how patients and health professionals should work together to make medical decisions. However, depending on the decision to be made, interest in and ability to make shared decis
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Annals of Internal Medicine

Sheldon Greenfield, MD
Sherrie H. Kaplan, PhD, MPH
Ann Intern Med. 2017;167:677-678.

EDITORIAL

When Clinical Practice Guidelines Collide: Finding a Way Forward

That physicians may disagree about appropriate care for an individual patient should come as no surprise. Diversity of physicians' backgrounds, training, and clinical practice experience is a well-documented contributor to physician-level variation in practice patterns. However, clinical practice guidelines (CPGs) are meant to reflect the best, most evidence-based care for the "average" patient and are meant to be followed by all physicians caring for those patients. Compensation in the United States will soon be adjusted on the basis of physician-level adherence to quality measures, which are often based on CPGs, and insurance coverage is increasingly based on CPG recommendations. Therefore, a high degree of consensus should be expected in CPGs for a given clinical situation.

Unfortunately, conflict is not atypical among evidence-based CPGs that are developed by different entities for the same clinical situation in the same target patient population and are to be used by the same group of physicians caring for those patients. Incongruity between CPGs generates confusion for providers, patients, payers, and policymakers. One noteworthy ex-

though the evidence will never support CPGs for individual patients, segmenting CPGs into relevant patient risk subgroups, with modified content as appropriate, would be a step forward. Yet, even with such segmenting, would consensus inherently follow? Probably not. Despite ample evidence for a specific subgroup, there are 2 reasons why different guideline developers might make different recommendations. First, they may disagree about the appropriate constituents of the relevant subgroups. Second, potential conflicts of interest, whether financial or intellectual, can influence different persons to draw different conclusions from the same evidence (6).

The ADA, the VA/DoD, and the AACE have identified several important variables, including race/ethnicity and comorbidity, for defining subgroups of patients for whom glycemic targets should vary from those for the average patient. Ideally, important subgroups should be empirically identified by observational studies or large, well-designed randomized controlled trials of clinical effectiveness with prespecified subgroup analyses. However, amassing such a body of evidence

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Need to Know What We Know and Don't Know

Other Considerations

For all recommendations…

Research Needs and Gaps

Research has focused on screening and diagnostic tools and treatment for symptomatic children, especially those who are severely affected. Good-quality studies are needed to better understand the intermediate and long-term health outcomes of screening for ASD among children without obvious signs and symptoms and whether earlier identification through universal screening is associated with clinically important improvements in health outcomes. These studies are especially needed in populations with low socioeconomic status and minority populations, where access to care may be more limited. A number of different study designs could greatly improve the understanding of the potential of screening. Large, good-quality, randomized clinical trials (RCTs) of treatment that enroll young children with ASD identified through screening and that report patient-centered outcomes are critical to understanding the effects of screening.

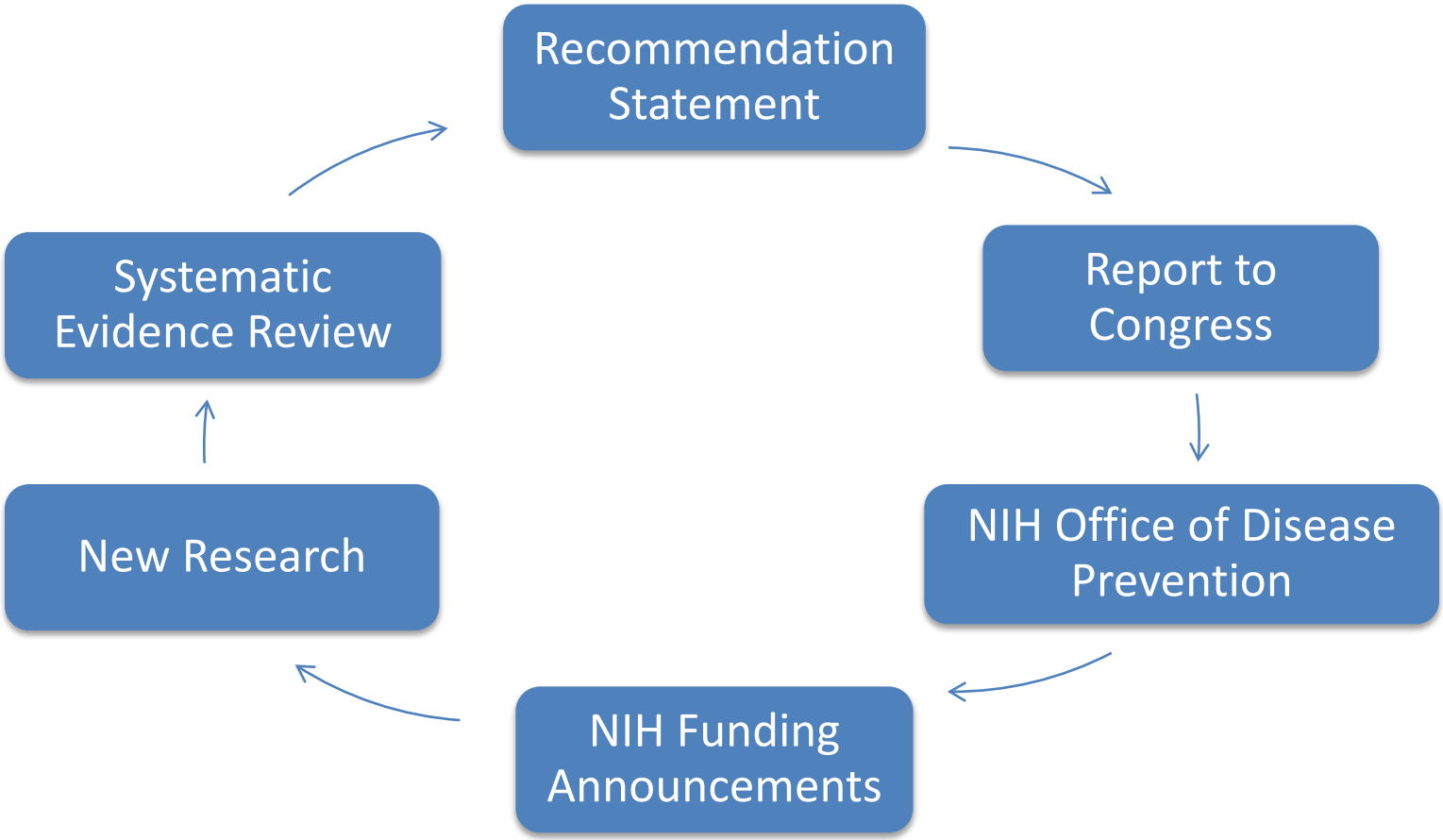
For I statements…

Suggestions for Practice Regarding the I Statement

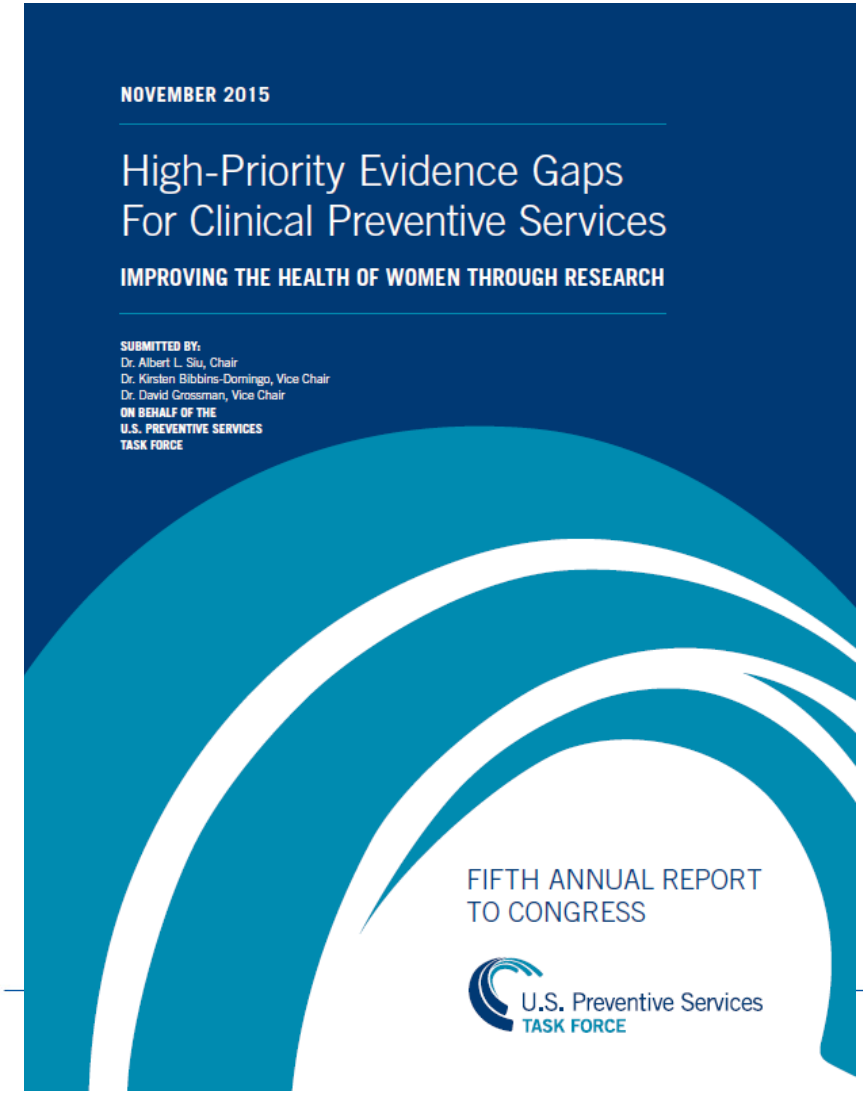
Potential Preventable Burden

Autism spectrum disorder can cause significant social, communication, and behavioral challenges for affected children and place substantial strain on family members and other caregivers. Treatment and maturation may reduce the effects of the core symptoms of ASD for some children, but others may experience long-term effects on education, employment, and ability to live independently.[2] It is important that clinicians listen carefully to parents when concerns are raised by the parents or during an examination and make prompt use of validated tools to assess the need for further diagnostic testing and services. Disparities have been observed in the frequency and age at which ASD is diagnosed among children by race/ethnicity, socioeconomic status, and language of origin, creating concern that certain groups of children with ASD may be systematically underdiagnosed.[3] It is important to note that an "I" statement is not a recommendation for or against screening. In the absence of evidence about the balance of benefits and harms, clinicians should use their clinical judgment to decide if screening in children without overt signs and symptoms is appropriate for the population in their care.

Addressing Gaps

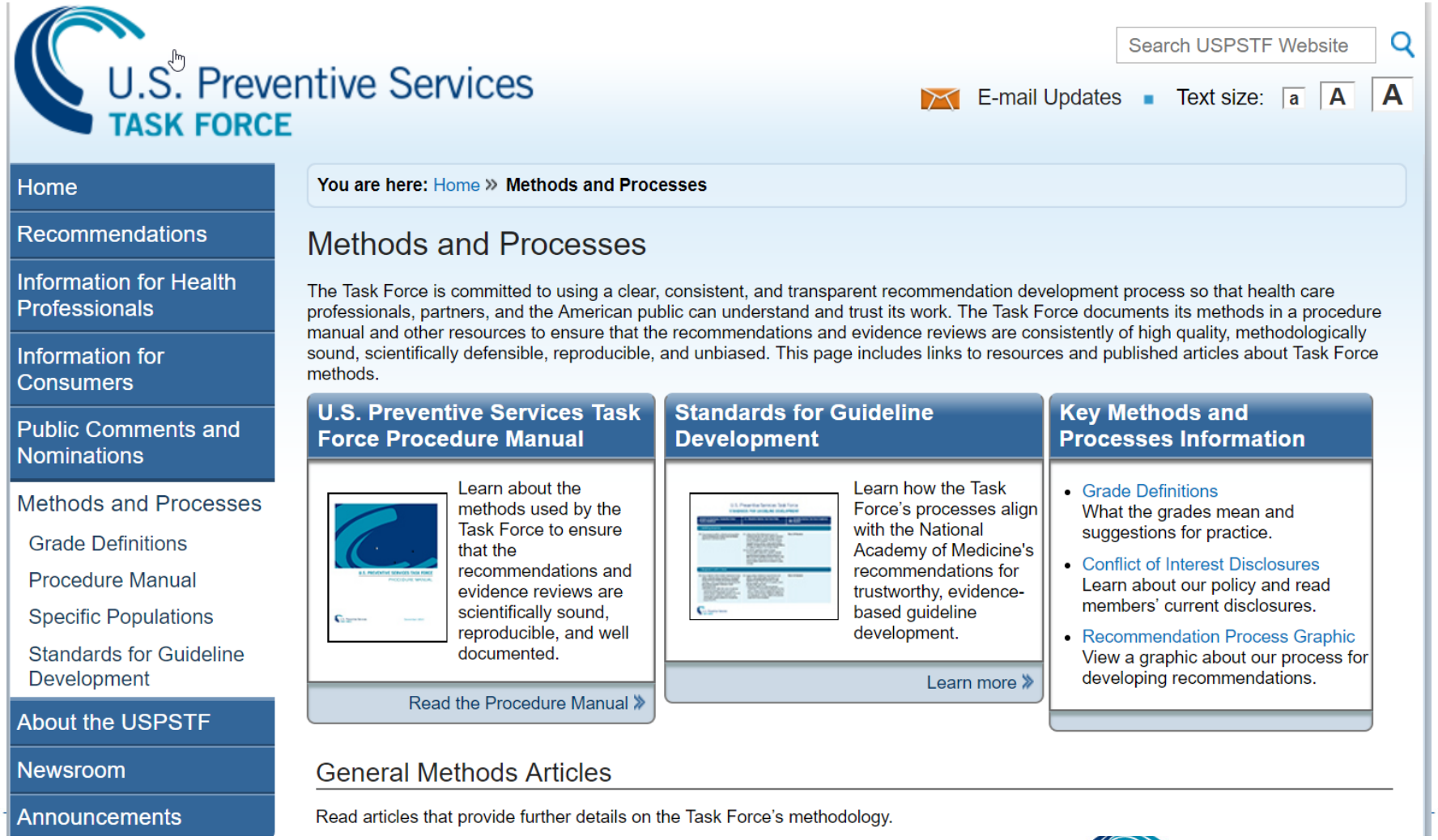


Annual Report to Congress on Evidence Gaps



- 2019 Mental health, substance use, and violence prevention
- 2018 Cancer prevention and cardiovascular health
- 2017 Prostate Cancer Screening in African American Men
- 2016 I Statements
- 2015 Health of Women
- 2014 Health of Children and Adolescents
- 2013 Health of Older Adults

Everything is on the USPSTF Methods Page



Thank you for your interest

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