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# **The Painful Truth about Behavioral Intervention Outcomes**

## Evidence Requirements for Public Policy

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U.S. Preventive Services  
**TASK FORCE**

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## **An Introduction**

What is the Task Force and  
what does it do?

# Disclaimer

*This presentation is being made on behalf of the U.S. Preventive Services Task Force (USPSTF). Some views expressed by the presenter, however, may not reflect the process and recommendations of the USPSTF. For the current findings and recommendations of the USPSTF, please see:*

**[uspreventiveservicestaskforce.org](https://uspreventiveservicestaskforce.org)**

# 4 Simple Goals

- ① Introduce the U.S. Preventive Services Task Force (USPSTF)
- ② Demonstrate the USPSTF's methods using some counseling recommendations
- ③ Provide useful information about what sort of behavioral outcomes "count"
- ④ Discuss what trials are likely to change practice, be funded, and meet evidence-based standards

# **U.S. Preventive Services Task Force**

Independent, volunteer panel of 16 national experts in prevention and evidence-based medicine

The USPSTF scope for clinical preventive services include:

- screening tests
- counseling
- preventive medications

# U.S. Preventive Services Task Force

Recommendations address only services offered in the [primary care setting](#) or services [referred by a primary care clinician](#)

Recommendations apply to adults and children with [no signs or symptoms](#) (or unrecognized condition)

uspreventiveservicestaskforce.org  
**/tftopicnon.htm**

# Public Input

Anyone can nominate a topic for the USPSTF to consider via its Web site



# USPSTF: Developing Recommendations

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

# USPSTF 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			

# Recommendation Grades

Grade	Definition
A	The USPSTF <u>recommends the service</u> . There is high certainty that the net benefit is substantial.
B	The USPSTF <u>recommends the service</u> . 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 <u>recommends selectively offering or providing this service</u> 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 <u>recommends against the service</u> . 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 <u>current evidence is insufficient to assess the balance of benefits and harms</u> of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

# Tobacco Smoking Cessation in Adults

Including Pregnant Women (example of subpopulation)

Recommendation Summary		
Population	Recommendation	Grade (What's This?)
Adults who are not pregnant	The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration (FDA)–approved pharmacotherapy for cessation to adults who use tobacco.	A
Pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant women who use tobacco.	A

# Tobacco Smoking Cessation in Adults

Including Pregnant Women

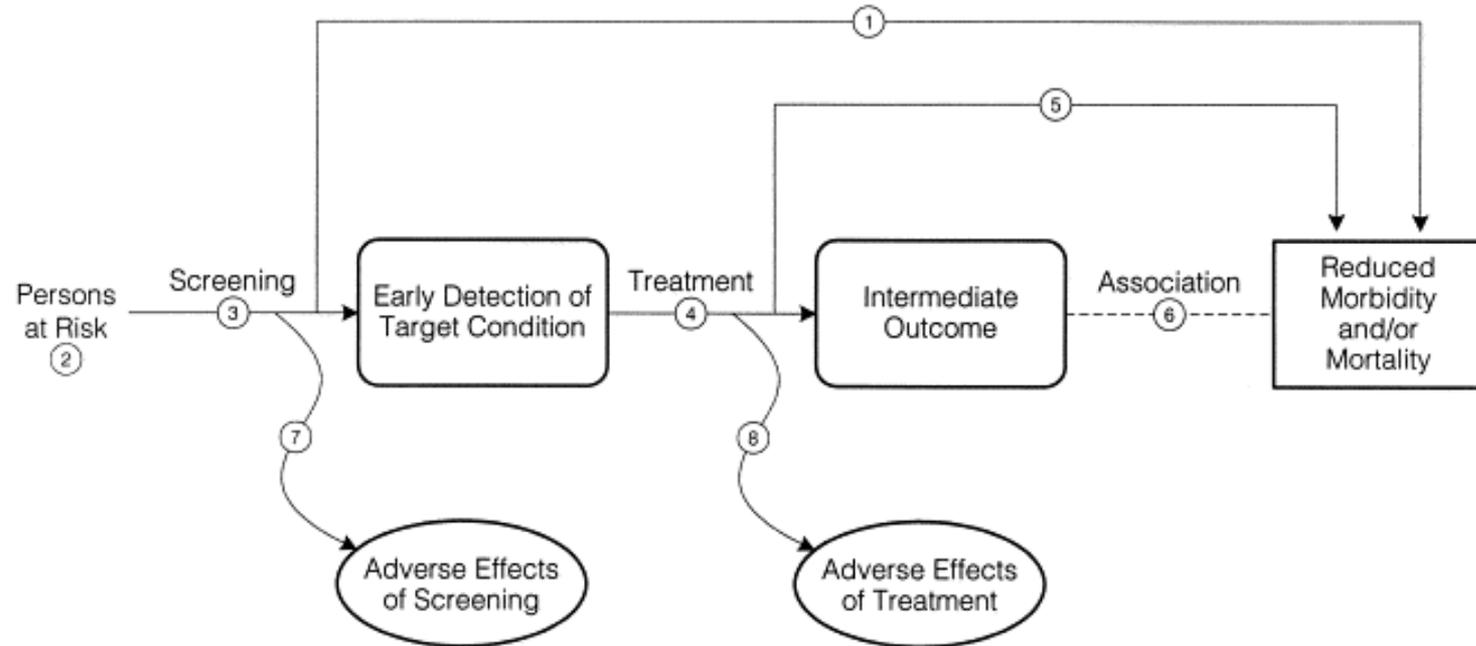
Recommendation Summary		
Pregnant women	The USPSTF concludes that the current evidence is <b>insufficient</b> to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women.	<b>I</b>
All adults, including pregnant women	The USPSTF concludes that the current evidence is insufficient to recommend electronic nicotine delivery systems (ENDS) for tobacco cessation in adults, including pregnant women. The USPSTF recommends that clinicians direct patients who smoke tobacco to other cessation interventions with established effectiveness and safety (previously stated).	<b>I</b>

# Depression in Adults Screening

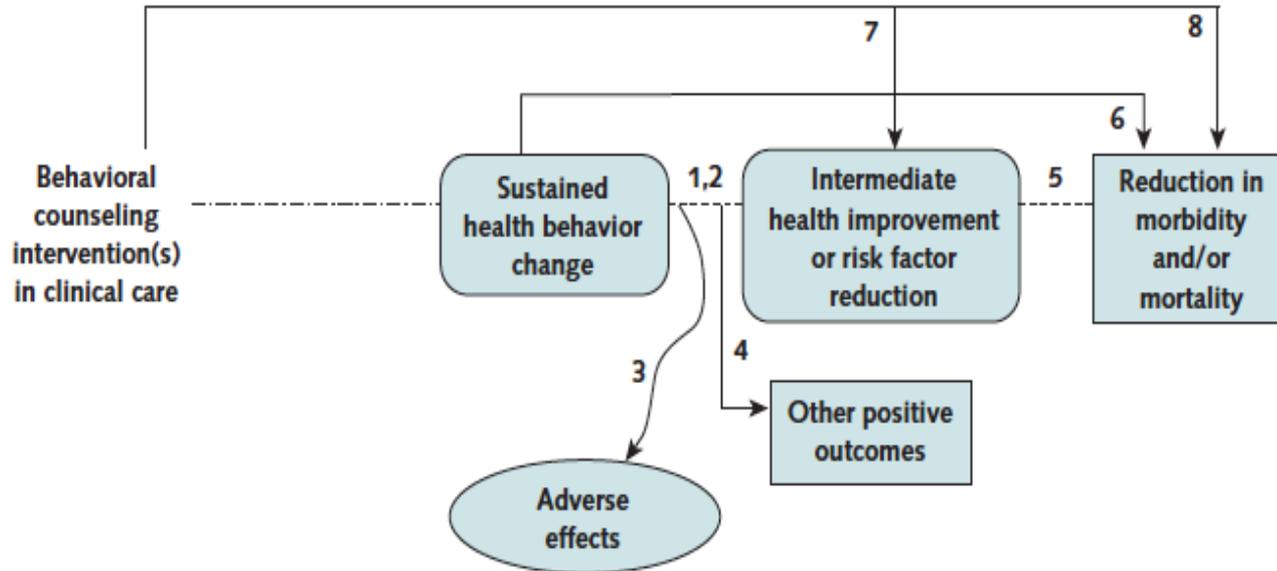
## Recommendation Summary

Population	Recommendation	Grade (What's This?)
General adult population, including pregnant and postpartum women	The USPSTF recommends screening for depression in the general adult population, including pregnant and postpartum women. Screening should be implemented with <u>adequate systems in place</u> to ensure accurate diagnosis, effective treatment, and appropriate follow-up.	<b>B</b>

# Analytic Framework on Screening for a Disease: What Outcomes Count?



# Framework on Behavioral Counseling for a Disease: What Outcomes Count?



# Definitions

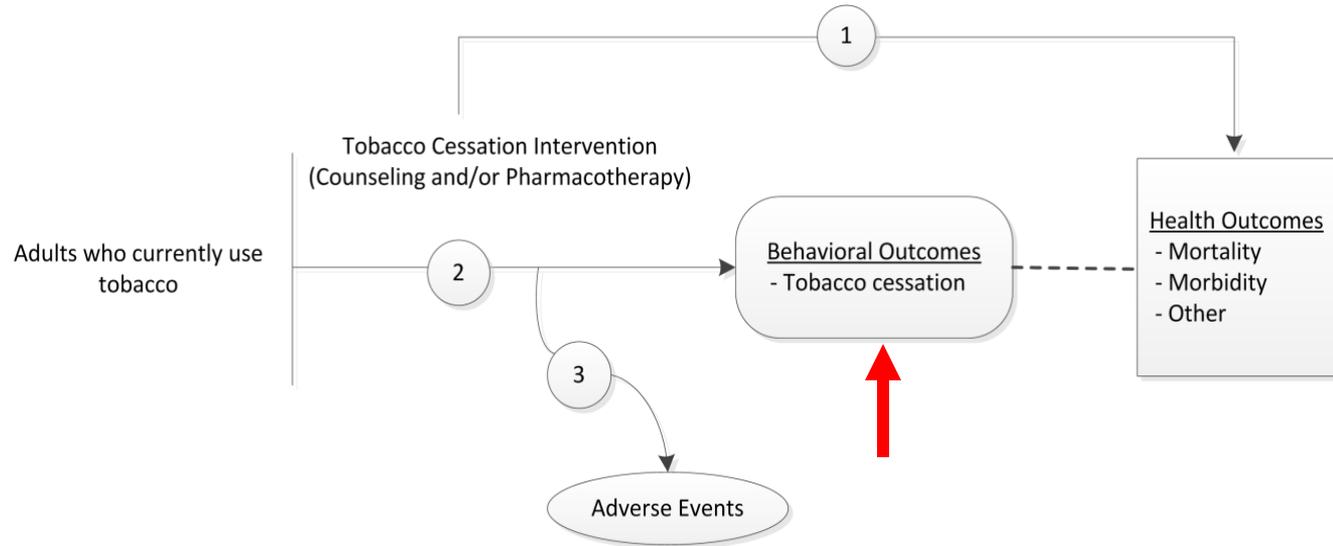
## **Health Outcomes**

are symptoms, functional levels, and conditions that patients can feel or experience and are defined by measures of physical or psychological well-being.

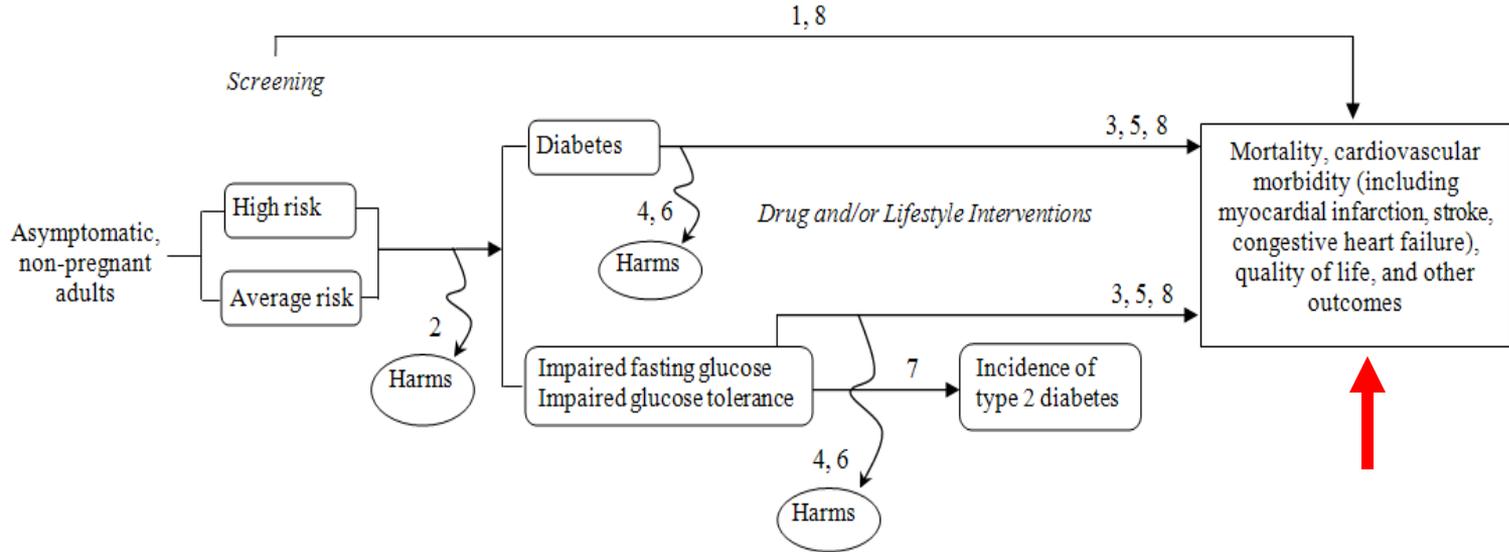
## **Intermediate Outcomes**

are outcomes that may be influenced by a preventive service but are not health outcomes in and of themselves. They are pathologic, physiological, psychological, social, or behavioral measures and other study endpoints related to a preventive intervention.

# Example of Use of Intermediate Outcome



# Example of Use of Health Outcome



# Linkage between Intermediate and Health Outcomes

- TF will exercise great caution when making a recommendation that depends in large part on the evidence linking IOs and Hos.
- Inherent limitations of the evidence, it is very unlikely that the evidence for this key question will be deemed convincing.
- Likely need to depend on observational evidence and the high potential for confounding.
- Cross-sectional associations between IOs and HOs not deemed adequate evidence.

# Counseling Interventions

17 topics – 34 recommendations

2-A's

11-B's

4-C's

2-D

8-I's

Name	Type	Year	Age Group
Skin Cancer Prevention: Behavioral Counseling	Counseling	2018	Adolescent, Adult, Pediatric, Senior
Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults Without Known Risk Factors: Behavioral Counseling	Counseling	2017	Adult, Senior
Obesity in Children and Adolescents: Screening	Counseling, Screening	2017	Adolescent, Pediatric
Breastfeeding: Primary Care Interventions	Counseling	2016	Adult
Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions	Counseling, Preventive medication	2015	Adult, Senior
Drug Use, Illicit: Primary Care Interventions for Children and Adolescents	Counseling	2014	Adolescent, Pediatric
Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: Behavioral Counseling	Counseling	2014	Adult
Sexually Transmitted Infections: Behavioral Counseling	Counseling	2014	Adolescent, Adult
Vitamin Supplementation to Prevent Cancer and CVD: Preventive Medication	Preventive medication	2014	Adult
Alcohol Misuse: Screening and Behavioral Counseling Interventions in Primary Care	Counseling, Screening	2013	Adolescent, Adult, Senior
BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing	Counseling, Screening	2013	Adult, Senior
Child Maltreatment: Primary Care Interventions	Counseling, Screening	2013	Adolescent, Pediatric
Tobacco Use in Children and Adolescents: Primary Care Interventions	Counseling	2013	Adolescent, Pediatric
Falls Prevention in Older Adults: Counseling and Preventive Medication	Counseling, Preventive medication	2012	Senior
Obesity in Adults: Screening and Management	Counseling, Screening	2012	Adult, Senior
Motor Vehicle Occupant Restraints: Counseling (Referred)	Counseling	2007	Adolescent, Adult, Pediatric, Senior
Dental and Periodontal Disease: Counseling (Inactive)	Counseling	1996	Adolescent, Adult, Pediatric, Senior
Gynecological Cancers: Counseling (Inactive)	Screening	1996	Adult
Youth Violence: Counseling (Referred)	Counseling	1996	Adolescent

# TF Initiatives to Enhance Behavior Counseling

## Evaluating Feasible and Referable Behavioral Counseling Interventions



Alex H. Krist, MD, MPH,<sup>1</sup> Linda J. Baumann, PhD, RN,<sup>2</sup> Jodi Summers Holtrop, PhD, MCHES,<sup>3</sup>  
Melanie R. Wasserman, PhD,<sup>4</sup> Kurt C. Stange, MD, PhD,<sup>5</sup> Meghan Woo, ScD, ScM<sup>4</sup>

## Standards of Evidence for Behavioral Counseling Recommendations



Robert J. McNellis, MPH, PA,<sup>1</sup> Marcia G. Ory, PhD, MPH,<sup>2</sup> Jennifer S. Lin, MD, MCR,<sup>3</sup>  
Elizabeth A. O'Connor, PhD<sup>3</sup>

## Understanding Research Gaps and Priorities for Improving Behavioral Counseling Interventions



Lessons Learned From the U.S. Preventive Services Task Force

Ann E. Kurth, PhD, CNM, MPH,<sup>1</sup> Therese L. Miller, DrPH,<sup>2</sup> Meghan Woo, ScD, ScM,<sup>3</sup>  
Karina W. Davidson, PhD<sup>4</sup>

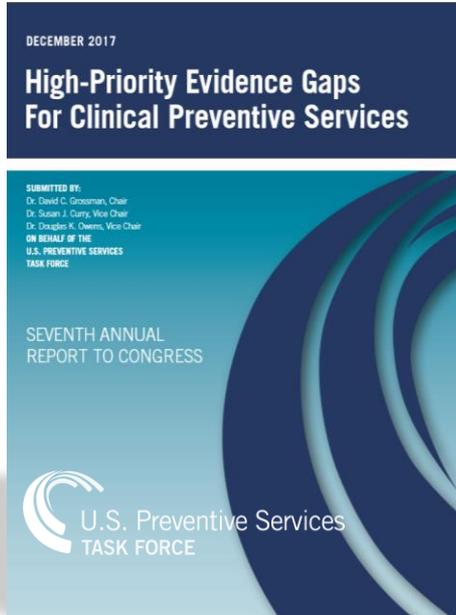
## Enhancing the Evidence for Behavioral Counseling



A Perspective From the Society of Behavioral Medicine

Carmela Alcántara, PhD,<sup>1</sup> Lisa M. Klesges, PhD,<sup>2</sup> Ken Resnicow, PhD,<sup>3</sup> Amy Stone, BA,<sup>4</sup>  
Karina W. Davidson, PhD<sup>1,5</sup>

# Seventh Annual Report to Congress



## **Clinical Preventive Services Where More Research is Needed:**

- Screening for Celiac Disease
- Screening for Obstructive Sleep Apnea in Adults
- Screening for Gynecologic Conditions with Pelvic Examination
- Vision Screening in Children Younger than Age 3 Years
- Statin Use for the Primary Prevention of Cardiovascular Disease in Adults Age 76 Years and Older

## **Evidence Gaps Relating to Specific Populations:**

- Screening for Breast Cancer in African American Women
- Screening for Prostate Cancer in African American Men
- Screening for Illicit Drug Use in Children and Adolescents
- Screening for Hearing Loss in Older Adults

# Feasible & Referable Interventions

- Design for feasibility and adoption
- Frameworks
  - Template for Intervention Description and Replication (TIDieR)
  - Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM)
  - Pragmatic-Explanatory Continuum Indicator Summary (PRECIS)

# Major Challenges

- Primary care feasible interventions
- Unpacking intervention protocols
- Aggregating outcome measures
- Linking behavior change to health outcomes
- Filling research gaps

# Filling Research Gaps

## Identified gaps

- Subpopulation studies
- Long-term health and social effects of BCIs
- Component evaluations
- Effectiveness of low and moderate intensity BCIs
- Evaluation of cost and cost effectiveness
- Examination of impact of treatment setting on effectiveness
- Consistent and validated process & outcome measures

**Thank you for  
your interest.**



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