

# Why Do We Sometimes Get It Wrong?

- What can we learn from formal systems of assessing the evidence and making recommendations?
- Comments based primarily on process of USPSTF

# Two Types of Errors

- “Unfortunate adoption”: widespread adoption of interventions later found to have net harm.
- “Unfortunate delay”: delayed adoption of interventions later found to have net benefit.

# 3 Steps to Getting It Right

- Step 1: Assess the evidence (benefits and harms) without bias
- Step 2: Make a general policy recommendation
- Step 3: Decide about action (or inaction)

# USPSTF Overview

## Step 1: Assess Evidence

- Carefully define the key question(s) and the criteria for admissible evidence
- Define outcomes: usually skeptical of intermediate outcomes (even RCTs)
- Admissible evidence: prefers but does not require RCTs; reviews other evidence when needed

# Which Evidence?

## Other Useful Designs

- Non-randomized studies with concurrent, well-matched controls
- Longer-term cohort studies of natural history with/without treatment
- Population-based prevalence (cross-sectional) studies
- Diagnostic accuracy studies
- Studies of psychological and physical harms

# USPSTF Overview

## Step 1: Assess Evidence

- Systematically review the evidence for the key questions:
  - ◆ Critical appraisal of internal validity
  - ◆ Synthesize results for each question
  - ◆ Consider extrapolation within the source population
  - ◆ Consider external validity of results

# USPSTF Overview

## Step 1: Assess Evidence

- In its consideration of the evidence, the USPSTF uses no rigid formula.
- Instead it relies on judgment based on explicit criteria.
- It seeks to be transparent about its rationale for its judgments.

# USPSTF Overview

## Step 1: Assess Evidence

- Synthesizing evidence: unexplained inconsistency is taken seriously.
- Biologic plausibility is a contributory factor; it does not automatically determine the conclusion.
- The issue is not simply whether benefits exist; it is whether we can estimate the magnitude of any benefits.

# USPSTF Overview

## Step 1: Assess Evidence

- Equal emphasis is placed on searching for evidence of harms as for benefits.
- Harms are usually present but often under-researched.
- No evidence of harm is not interpreted as evidence of no harm.

# USPSTF Overview

## Step 1: Assess Evidence

- Searching for harms often requires appraising different types of research design from benefits.
- Still requires studies of reasonable quality and consistency.

# Assessing Evidence: Judgment is Required

- Should acknowledge that judgment is required at several steps in assessing evidence.
  - ◆ Defining admissible evidence
  - ◆ Critical appraisal of internal validity
  - ◆ Synthesis of internally valid evidence
  - ◆ Willingness to extrapolate
  - ◆ Critical appraisal of external validity

# Judgment, Opinion, or Necessary Flexibility?

- Explicitly label statements of judgment
- Base judgments on a priori criteria
- Give rationale for judgment

# USPSTF Overview

## Step 2: Recommend a Policy

- Determine whether the evidence is sufficient to estimate the magnitude of benefits and harms.
- If so, weigh the magnitude and value of benefits against the magnitude and value of harms on a population level; base recommendation on net benefits.

# USPSTF Recommendation Grid

Quality of evidence	Net benefit			
	Substantial	Moderate	Small	Zero/negative
Good	A	B	C	D
Fair	B	B	C	D
Poor = I				

# Beyond the USPSTF

## Step 3: Make a Decision

- After the recommendation, decision makers must decide about implementation.
  - ◆ Local factors are involved:
    - ◆ Costs/resources
    - ◆ Availability of intervention (trained personnel; technology; quality)
    - ◆ Competing priorities of health care system or patients

# A Problem

- We don't have complete evidence about everything.
- Sometimes it makes sense to implement an intervention before we have adequate information to judge its consequences.
- In these cases, decision makers may become confused and assume that interventions that they are actively implementing are backed by better evidence than is the case.

# Two Wise Men

- Mark Twain: “It ain’t what people don’t know that hurts them. It’s what they know that ain’t so.”
- Stephen Hawking: “The greatest enemy of knowledge is not ignorance; it is the illusion of knowledge.”

# Overall Summary

- The USPSTF process is not rigid or formulaic. It allows for judgment and extrapolation.
- It admittedly errs on the skeptical side.
- It is not hesitant to admit uncertainty; that we don't know the answer.

# My Judgment (Possibly Biased)

- Such a process will probably:
  - ◆ Occasionally, but not often, lead to unfortunate adoption
  - ◆ Occasionally, but not often, lead to unfortunate delay.

# Overall Summary

- The art in the science is getting the right balance between unfortunate adoption and unfortunate delay.
- The optimal place for that balance is a value judgment.