Rightsizing Cancer Screening

The Future of Cancer Screening Guidelines: Is there a better way to move forward?

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American Cancer Society®

Cancer Screening Guidelines—A History

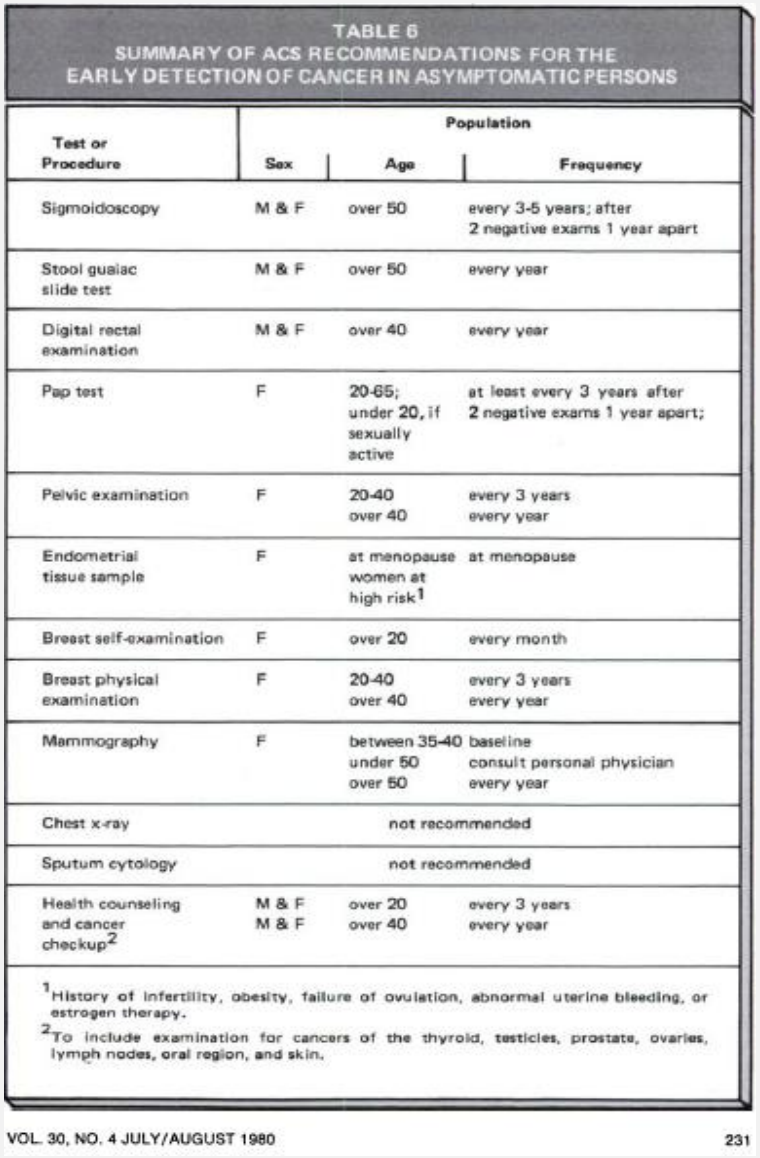

TABLE 6
SUMMARY OF ACS RECOMMENDATIONS FOR THE EARLY DETECTION OF CANCER IN ASYMPTOMATIC PERSONS

Test or Procedure	Population		
	Sex	Age	Frequency
Sigmoidoscopy	M & F	over 50	every 3-5 years; after 2 negative exams 1 year apart
Stool guaiac slide test	M & F	over 50	every year
Digital rectal examination	M & F	over 40	every year
Pap test	F	20-65; under 20, if sexually active	at least every 3 years after 2 negative exams 1 year apart;
Pelvic examination	F	20-40 over 40	every 3 years every year
Endometrial tissue sample	F	at menopause women at high risk[1]	at menopause
Breast self-examination	F	over 20	every month
Breast physical examination	F	20-40 over 40	every 3 years every year
Mammography	F	between 35-40 under 50 over 50	baseline consult personal physician every year
Chest x-ray	not recommended		
Sputum cytology	not recommended		
Health counseling and cancer checkup[2]	M & F M & F	over 20 over 40	every 3 years every year

[1] History of infertility, obesity, failure of ovulation, abnormal uterine bleeding, or estrogen therapy.

[2] To include examination for cancers of the thyroid, testicles, prostate, ovaries, lymph nodes, oral region, and skin.

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- ACS issued the 1st formal, evidence-based cancer screening guidelines in 1980
- The first cancer screening recommendations from the USPSTF were issued in 1989

Why do we have guidelines from multiple organizations?

- Multiple groups issue guidelines for the same condition and intervention, at different times, at different intervals, with different recommendations.
- ***Why is that?***
  - Different perspectives on risk, evidence, the effectiveness of the intervention, and the acceptable threshold for the balance of benefits and harms
  - Different target audience (in particular, professional specialty groups)
  - Not surprisingly… ***All think their guideline is the best***

We now have lung cancer screening guidelines…., and they're not all the same

Organization	Age to start	Age to stop	Shared/informed decisions?
ACS	55 NLST*	74	Yes
USPSTF	55 NLST	80, or once 15 years since year quit is reached	No
NCCN	55 NLST	No stopping age	Yes
NCCN High Risk*	50	No stopping age	Yes
AAFP	Insufficient evidence to recommend for or against lung cancer screening		

*NLST Criteria: Current or former smoker (quit within 15 years) ages 55-74 with 30 pack year or greater smoking history

*NCCN High Risk: Current or former smoker ≥ 50 years with ≥ 20 pack year history and one additional risk factor (asbestos, radon, family history, etc.)

Two Recent Game-Changers in Cancer Screening Guidelines

H. R. 3590

One Hundred Eleventh Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the fifth day of January, two thousand and ten

An Act

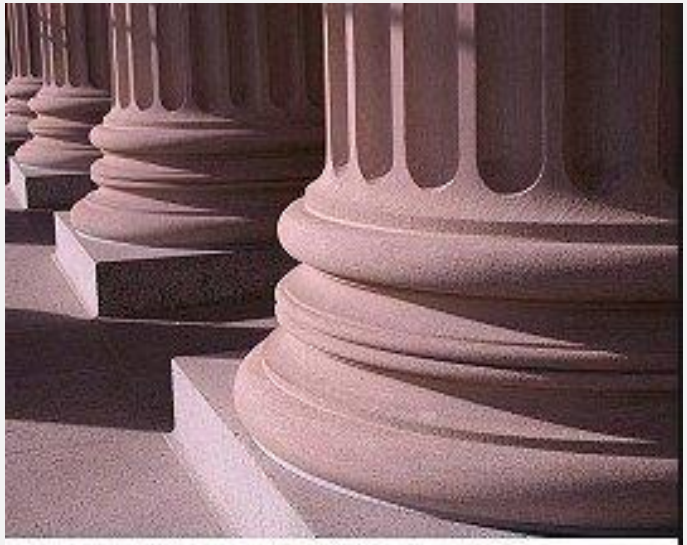
Entitled The Patient Protection and Affordable Care Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Patient Protection and Affordable Care Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:



CLINICAL PRACTICE GUIDELINES WE CAN TRUST

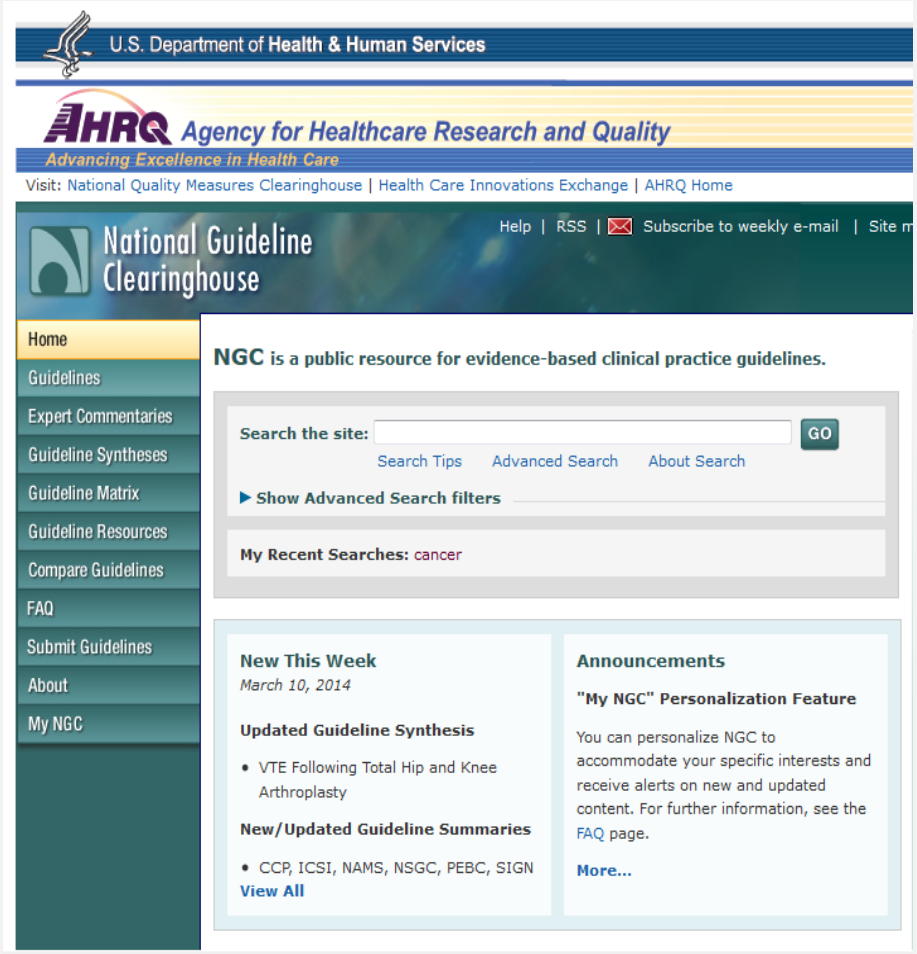
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

IOM Guideline Development Principles

The emphasis is on "trust"

1. Transparency
2. Conflicts of Interest
3. Group Composition
4. Systematic Review of Evidence
5. Grading Strength of Recommendations
6. Articulation of Recommendations
7. External Review
8. Regular updates of the recommendations

AHRQ National Guidelines Clearinghouse



http://www.guideline.gov

- There are thousands of guidelines on the NGC
- There are nearly 1,000 cancer related guidelines, of which several hundred apply to cancer screening
- How well do they measure up to the new IOM standards?

How well do existing guidelines measure up to the IOM standards?

ORIGINAL INVESTIGATION

HEALTH CARE REFORM

Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards

Two More Decades of Little, If Any, Progress

Justin Kung, MD; Ram R. Miller, MD; Philip A. Mackowiak, MD

Background: In March 2011, the Institute of Medicine (IOM) issued a new set of standards for clinical practice guidelines intended to enhance the quality of guidelines being produced. To our knowledge, no systematic review of adherence to such standards has been undertaken since one published over a decade ago.

Methods: Two reviewers independently screened 130 guidelines selected at random from the National Guideline Clearinghouse (NGC) website for compliance with 18 of 25 IOM standards.

Results: The overall median number (percentage) of IOM standards satisfied (out of 18) was 8 (44.4%), with an interquartile range of 6.3 (36.1%) to 9.3 (52.8%). Fewer than half of the guidelines surveyed met more than 50% of the IOM standards. Barely a third of the guidelines produced by subspecialty societies satisfied more than 50% of the IOM standards surveyed. Information on conflicts of interest (COIs) was given in fewer than half of the guidelines surveyed. Of those guidelines including such information, COIs were present in over two-thirds of committee chairpersons (71.4%) and 90.3% of co-chairpersons. Except for US government agency–produced guidelines, criteria used to select committee members and the selection process were rarely described. Committees developing guidelines rarely included an information scientist or a patient or patient representative. Non-English literature, unpublished data, and/or abstracts were rarely considered in developing guidelines; differences of opinion among committee members generally were not aired in guidelines; and benefits of recommendations were enumerated more often than potential harms. Guidelines published from 2000 through 2011 varied little with regard to average number of IOM standards satisfied.

Conclusion: Analysis of a random sample of clinical practice guidelines archived on the NGC website as of June 2011 demonstrated poor compliance with IOM standards, with little if any improvement over the past 2 decades.

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OVER THE PAST 2 DECADES, clinical practice guidelines have played an increasingly prominent role in dictating the practice of medicine in the United States and other developed countries. The number of organizations creating such guidelines has proliferated exponentially over time, as have the number of their guidelines. Some 2700 clinical practice guidelines are archived in the Agency for Healthcare Research and Quality's National Guideline Clearinghouse (NGC). Over 6800 reside in the Guidelines International Network.[1]

It has been hoped that, if properly developed and widely applied, clinical practice guidelines would enhance the practice of medicine by helping physicians and patients synthesize the dizzying array of clinical information, which, like piling Ossa on Pelion, expands year after year.[1,2] Unfortunately, while some studies suggest that clinical practice guidelines help to reduce inappropriate practice variation, accelerate the translation of research into clinical practice, and improve the quality and safety of health care, many have come to question the validity and reliability of such guidelines.[3,4] Their concerns have focused on the quality of the evidence on which clinical practice

See Invited Commentary at end of article

guidelines are based,[5] the tendency of guidelines to promote more care rather than more effective care,[6,7] their narrow focus and use as marketing and opinion-based pieces rather than road maps to improved medical care,[3] and the difficulties involved in customizing population-based recommendations to individual patients.[10] Also of concern has been the lack of transparency in the process by which clinical practice guidelines are

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April 8, 2013

A Perspective on the Guidelines International Network and the Institute of Medicine's Proposed Standards for Guideline Development

By Amir Qaseem, MD, PhD, MHA

- **"The IOM and G-I-N standards have been both applauded and criticized. The concern voiced most often is related to the complexity and practicality….."**
- "…funding and resource limitations are a major obstacle.."
- "…infeasible to implement fully, and consider several of the standards especially difficult to adopt. For example, a "full spectrum review by external stakeholders.."
- "..systematic reviews can be costly to produce and may not be feasible for many organizations."
- "..difficulty finding clinicians who are experts on a topic and also free from any financial or academic conflicts of interest."
- ***"…it has not been proven that using these standards will lead to the development of better guidelines which are more acceptable, implementable, and result in better clinical outcomes*** [emphasis added]."

http://www.guideline.gov/expert/expert-commentary.aspx?id=43913

How to Decide Whether a Clinical Practice Guideline Is Trustworthy

David F. Ransohoff, MD
Michael Pignone, MD, MPH
Harold C. Sox, MD

favorable balance of harms and benefits and should therefore become recommended practice.[3] Because benefits and harms are often measured in different units, quantitative estimation of net benefit is necessarily subjective and therefore potentially

- While the IOM committee provided a comprehensive set of standards, it imposed an impractical definition of trustworthiness. According to its report, “to be trustworthy, a clinical practice guideline should comply with proposed standards 1- 8.” This definition of trustworthiness sets a very high, inflexible standard: “a guideline is trustworthy only if it meets all 8 standards.”

Has the additional rigor improved cancer screening guidelines? *Yes and No*

- Strategies to improve trustworthiness are a favorable new development, but generally involve tradeoffs…..
  - Guidance on avoiding **conflicts of interest** and bias, including the *appearance of bias,* are a step in the right direction
  - **Composition of guidelines groups** is a work in progress…experts can be biased, but generalists often don't understand the data, and **non-specialization is no assurance of lack of bias, i.e., intellectual bias**
  - Standards for **systematic evidence reviews** and grading evidence/recommendations can insure that recommendations are based on sound science…..on the other hand, ***sometimes the bar is set unreasonably high.***

The NEW ENGLAND JOURNAL of MEDICINE

N ENGL J MED 367;11 NEJM.ORG SEPTEMBER 13, 2012

There Is More to Life Than Death

Pamela Hartzband, M.D., and Jerome Groopman, M.D.

Physicians and patients alike crave certainty. We all want to know that we're making the best decisions about our health. But

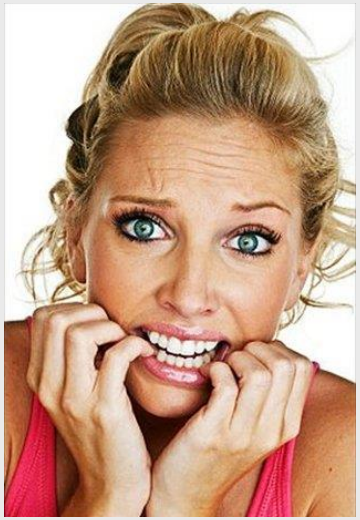
Daniel Bernoulli, an 18th-century mathematician who devised a formula to determine the "best" choice.[1] When an outcome is un-

In clinical decision analysis, the outcome that is generally measured is death. This outcome fits neatly into the Bernoulli formula

Risk, Benefit, and Harm

- "when experts judge risk, their responses correlate highly with technical estimates of annual fatalities. However, most people's conceptualization of risk is much richer than that of the experts and reflects legitimate concerns that are typically omitted from expert risk assessments."

The data suggest that there is not good agreement between our estimate of the magnitude of the harms of false positive mammography exams, and the meaning women attach to them



US women's attitudes to false positive mammography results and detection of ductal carcinoma in situ: cross sectional survey

Lisa M Schwartz, Steven Woloshin, Harold C Sox, Baruch Fischhoff, H Gilbert Welch

Abstract

Objective To determine women's attitudes to and knowledge of both false positive mammography results and the detection of ductal carcinoma in situ after screening mammography.
Design Cross sectional survey.
Setting United States.
Participants 479 women aged 18-97 years who did not report a history of breast cancer.
Main outcome measures Attitudes to and knowledge of false positive results and the detection of ductal carcinoma in situ after screening mammography.
Results Women were aware that false positive results do occur. Their median estimate of the false positive rate for 10 years of annual screening was 20% (25th percentile estimate, 10%; 75th percentile estimate, 45%). The women were highly tolerant of false positives: 63% thought that 500 or more false positives per life saved was reasonable and 37% would tolerate 10 000 or more. Women who had had a false positive result (n = 76) expressed the same high tolerance: 39% would tolerate 10 000 or more false positives. 62% of women did not want to take false positive results into account when deciding about screening. Only 8% of women thought that mammography could harm a woman without breast cancer, and 94% doubted the possibility of non-progressive breast cancers. Few had heard about ductal carcinoma in situ, a cancer that may not progress, but when informed, 60% of women wanted to take into account the possibility of it being detected when deciding about screening.
Conclusions Women are aware of false positives and seem to view them as an acceptable consequence of screening mammography. In contrast, most women are unaware that screening can detect cancers that may never progress but feel that such information would be relevant. Education should perhaps focus less on false positives and more on the less familiar outcome of detection of ductal carcinoma in situ.

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BMJ 2000;320:1635–40

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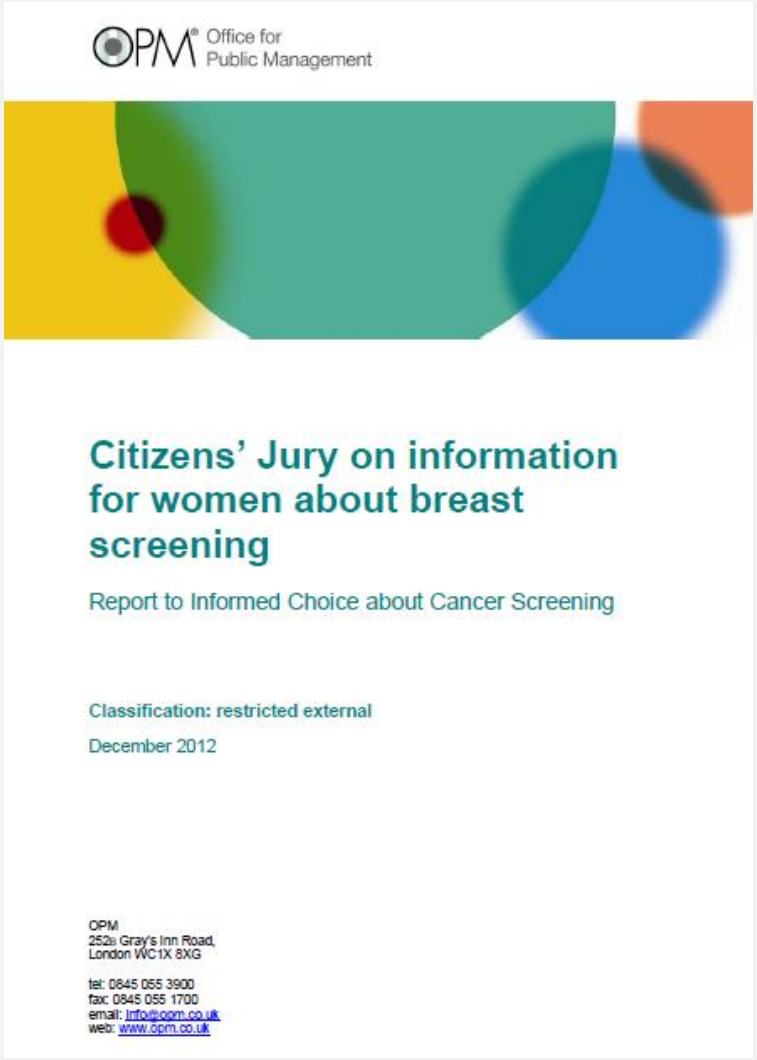
Do we really know how to assess the "balance of benefits and harms?"



- The Office for Public Management (OPM) designed and ran a Citizens' Jury to consider how to present the benefits and harms of breast screening generated by the Independent Review of Breast Screening in October 2012.

The Citizens Jury provided useful information to the NHS about how to describe breast cancer screening outcomes

The level of detail on overdiagnosis needed for an informed decision	
Jury consensus recommendations	**Areas of disagreement/lack of consensus**
• The jury strongly recommended using the term **overtreatment** to explain the impact of 'overdiagnosis' from a patient experience perspective. • Twenty one jurors preferred the term overtreatment to overdiagnosis. • The jury recommended statements in words which described the issue in 'layperson's terms' rather than using the term 'overdiagnosis' as a way to approach the topic. • The jury recommended using the terms **"risk" or "disadvantage" over "harm".** • The jury recommended figures on overdiagnosis /overtreatment to be expressed in terms of **women attending rather than women invited to screening**.	• Beyond the jury's recommendation for the term 'overtreatment' there were different preferences for the words and level of detail used to explain overtreatment. • There were a small number of jurors who questioned whether information on overdiagnosis should be included.

Going Forward….Do we accept the status quo, or is there a better way?

The IOM recommendations do not solve all problems

- **We need to identify a method to shorten the process and to more rapidly integrate new evidence**
  - Guidelines development and updates take too long—the process is lengthy and expensive
  - Ability to update guidelines quickly is limited by time, resources, and other guidelines in the pipeline
- **There is good reason to seek harmonization between guidelines groups**
  - Guidelines are developed in isolation. Lack of consensus between guidelines is a problem….

Measuring benefits vs. harms

- **Guideline developers should agree on standardized methods/metrics for measuring benefit and harms**
  - *This affects the benefits vs. harms estimate*
  - *These metrics need to be informed by the preferences of the groups undergoing screening*

- **Is there a threshold of benefit vs. harm where screening could be recommended when it is not?**
  - *If the observed balance of benefits and harms could be improved, those targets should be identified*
  - *When screening is not recommended, the acceptable threshold of benefits and harms should be stated*

How should we be thinking about harms?

- **We should recognize that:**
  - Harms range in frequency and experience from minor & inconsequential to quite serious
  - Recognize that most individuals do not experience harms in the same way
  - We need to do a better job of informing adults undergoing screening about what to expect
  - Harms occur--Stronger quality assurance programs are needed to reduce the rate of harms

Any organization can develop a guideline, but only one group's guidelines determine coverage of a clinical practice

What Elephant?

- **Coverage of preventive care is too important to be in the responsibility of a single group**
  - **There are credible challenges to the USPSTF methodology, selection and interpretation of evidence (including use of modeling), and final recommendations**
  - **The perspectives of other organizations should not be limited to reviewing the guideline development plan and final draft**
  - **Opportunities for feedback during the process are an important step forward, but there is no opportunity for in-depth discussion or appeal of final recommendations**
  - **USPSTF guidelines do not address high risk groups—this is a significant shortcoming**

Any organization can develop a guideline, but only one group's guidelines determine coverage of a clinical practice

Oh, *that* Elephant

- **What would be better?** ***This is an easier question to ask than answer!***
- **1 option--Scientific hearings on proposed USPSTF recommendations**
  - **Go beyond the existing review process to establish hearings with an opportunity for alternative interpretations of data and alternative proposals.**
  - **An independent review panel with representation of the target group would preside**
- **Alternative option—Coverage decisions would be up for renewal every 1-2 years—any group, including the USPSTF, could submit a proposal for a new guideline**
  - **Open academic process with advance notice**
  - **HHS Review Group would include broad representation of expertise (generalists and specialists) with a significant presence of consumers**
  - **Proposed new recommendations also would have a hearing**

Thank you