Mind the Gap, September 27, 2016

Making guidelines for colon cancer screening: Evidence, policy, and politics

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Making guidelines for colon cancer screening: Evidence, policy, and politics

Goals of talk

1) relationship between:
   -science (evidence)
   -policy (guidelines)
   -politics

Theme

Guidelines do not "emerge from evidence." Guidelines are a human product; quality varies.

Importance

Guidelines affect patient outcome, practice; guidelines-making is one of "highest-callings" of profession.

Subject is *big;* topics are selected.

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Organization: 2 parallel histories of

1) Evidence-Based Medicine (EBM)
2) CRC screening: science, policy, politics; challenges in 2016

Evidence-Based Medicine
(a brief history!)

Definition:

- "conscientious, explicit, and judicious use of current best evidence in making decisions about… individual patient." (related to *outcome*)
- uses "best available...clinical evidence from systematic research…"

from Sackett DL. BMJ 1996

Evidence-Based Medicine

Why was EBM developed?

- 'Preventive medicine' was, in 1950s/60s, *assumed* to be 'good'
- *Assumption of 'good'* was challenged, by clinicians and clinical epidemiologists (like Sackett), who asked:
  - 'How do we decide whether a preventive intervention is appropriate to do?'
  - 'Could prevention efforts cause net harm?'

Evidence-Based Medicine

The US Preventive Services Task Force (USPSTF) formulated questions to decide 'appropriate to screen?'

1. Is burden of disease high?
2. Does disease left untreated lead to bad outcome?
3. **Does screening/treatment *reduce* bad outcome?**
4. **What is *balance* (quantitative) re outcome: benefit vs harm**

USPSTF developed "rules of evidence".

RCT evidence was preferred.

Evidence-Based Medicine

USPSTF applied questions to ‘preventive measures,’ starting with annual physical examination

Result:

-Most parts of annual physical were no longer supported by USPSTF, Amer. Coll. Physicians (ACP), AMA.

A process (rules of evidence) **was established to evaluate how decisions (e.g., about prevention) affect outcome: benefit v harm.**

Evidence-Based Medicine

Process used by USPSTF is detailed, time-consuming, expensive; takes over a year to:

- -formulate questions
- -assemble evidence
  (e.g., systematic review, meta-analysis)
- -develop ‘recommendations’ (policy)
- -external review
- -publish systematic review, clinical recommendations
- -etc…

USPSTF product: Hierarchy of recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations according to one of five classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms).

A The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.*

B The USPSTF recommends that clinicians provide [this service] to eligible patients. *The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.*

C The USPSTF makes no recommendation for or against routine provision of [the service]. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation*

D The USPSTF recommends against routinely providing [the service] to asymptomatic patients. *The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.*

I The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. *Evidence that the [service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

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words defined explicitly

Harris R. Am J Prev Med 2001;20 (Suppl):21

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History of CRC guidelines

'In the beginning...'

Guidelines for screening: average-risk

Organization, year	FOBT alone	Sigmoid. alone	FOBT and Sigmoid.	Colonoscopy
<1996	***variable (not heeded)***			

In the beginning, there were few guidelines or guidelines-makers.

Evidence of efficacy: **FOBT RCTs**

Guaiac-based FOBT screening reduces CRC mortality:

- by 33%, using q1yr rehydrated gFOBT
  (Minnesota Study; NEJM 1993)
- by 15%-18% using q2yr non-rehydrated gFOBT
  (UK, Denmark studies; Lancet 1996)

Lessons:

- RCTs of screening are difficult to conduct!
  (i.e., 20+yrs, 250K subjects; temporary de-funding, etc)
- Is a design as reliable as RCT but more efficient?

Evidence of efficacy: **Sigmoidoscopy case-control study**

1992 Case-control study shows that sigmoidoscopy screening reduces, by ~60%, CRC deaths within reach of scope

	CRC DEATHS	
	YES	NO
Sigmoidoscopy	23 (*9%*)	210 (*23%*)
No Sigmoidoscopy	238	658
TOTAL	261	868

(Selby NEJM 1992)

Evidence of efficacy:
Sigmoidoscopy case-control study

1992: Case-control evidence was considered weak,
not acceptable for policy-making.
This study was unusually strong.

[2010: RCT evidence]
- UK (Atkin; Lancet 2010)
- US/NCI (Schoen, PLCO; NEJM 2012)

Evidence of efficacy:
Sigmoidoscopy case-control study

This 1992 case-control study was unusually **strong**:

- nested in cohort (nested case-control)
- reason for 'exposure' was known
- an 'internal control' group (L vs R colon)

USPSTF's decision to accept non-RCT evidence (1996) was a major advance in world of evidence-to-policy.

***Lesson**: We may learn to make weak designs stronger. Rules of evidence (USPSTF) may change.*

Guidelines for screening: average-risk

Organization year	FOBT alone*	Sigmoid. alone	FOBT and Sigmoid.	Colonoscopy**
<1996	varied; not heeded			
USPSTF 1996	+	+	'insufficient evidence'	'insufficient evidence'

*: every year
**: every 10 years

Evidence of efficacy: **Colonoscopy**

Concept of screening colonoscopy: dramatic evolution over ~20 years.

1992: Screening colonoscopy was a lunatic fringe idea.

2000s: Screening colonoscopy is a Medicare benefit; American Cancer Society (ACS) petitions state legislatures to provide coverage.

How did evolution occur?

What lessons about evidence, policy, politics?

Concept of screening colonoscopy has evolved dramatically over ~20 years

<1992: no controlled studies support any CRC screening
1992: sigmoidoscopy: case-control study (Selby, *NEJM*)
1993-6: FOBT: 3 RCTs (Minnesota, *NEJM*; UK, Den. *Lancet*)

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1993: National Polyp Study *NEJM*

National Polyp Study says CRC incidence is reduced 76-90% by colonoscopy

ORIGINAL ARTICLE

Volume 329:1977-1981 December 30, 1993 Number 27 Next ►

Prevention of Colorectal Cancer by Colonoscopic Polypectomy

Sidney J. Winawer, Ann G. Zauber, May Nah Ho, Michael J. O'Brien, Leonard S. Gottlieb, Stephen S. Sternberg, Jerome D. Waye, Melvin Schapiro, John H. Bond, Joel F. Panish, Frederick Ackroyd, Moshe Shike, Robert C. Kurtz, Lynn Hornsby-Lewis, Hans Gerdes, Edward T. Stewart, and The National Polyp Study Workgroup

Purpose

- Does polypectomy reduces CRC incidence?

Design

- not RCT; was observational cohort: persons receiving colonoscopy were compared to 'historical controls'

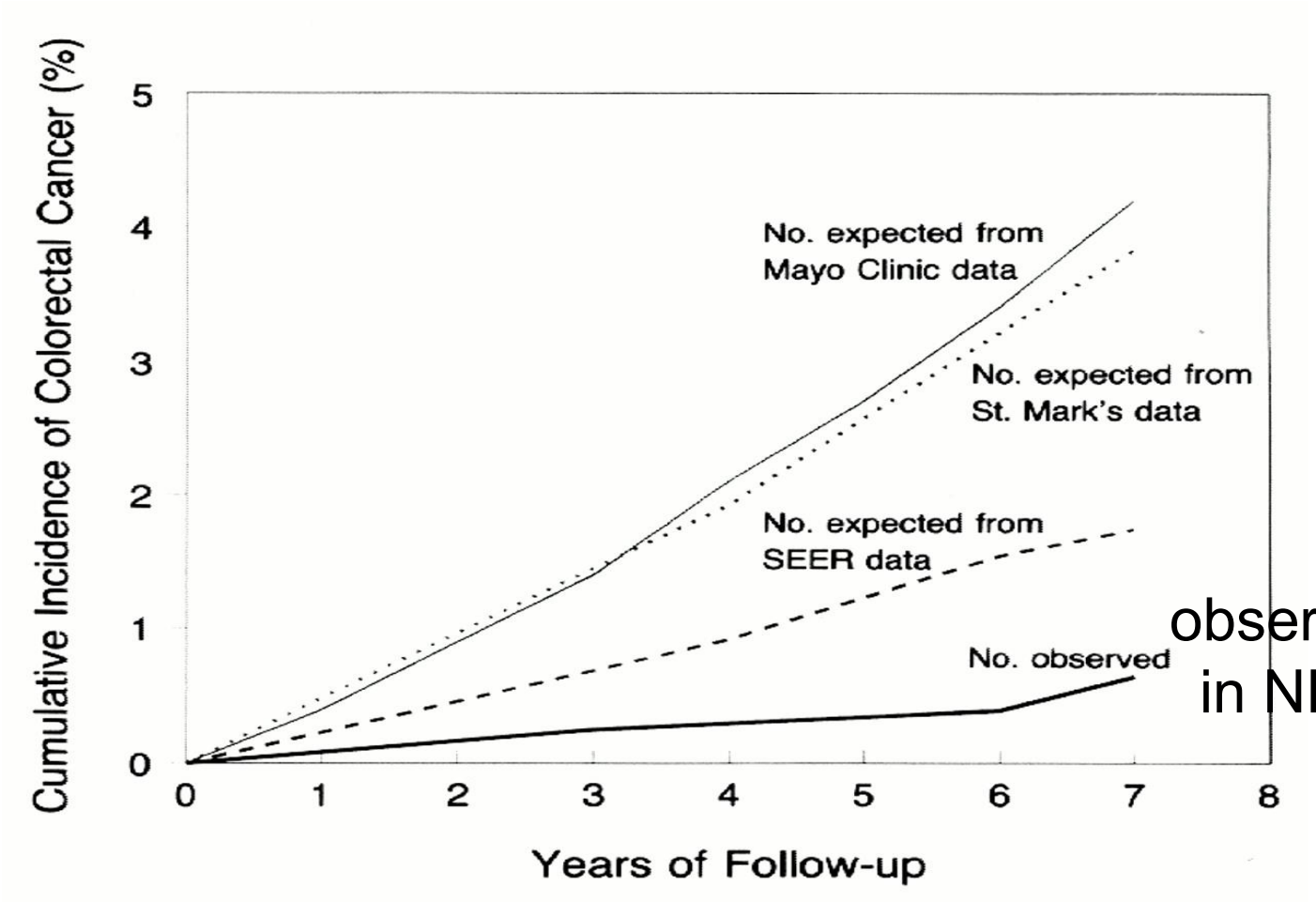
Results

- 76-90% reduction in CRC incidence

Is result (76-90) 'fair'? Answer depends on comparison .

National Polyp Study (76-90% reduction)

The 'historical control' pts differed from NPS pts 'at baseline'

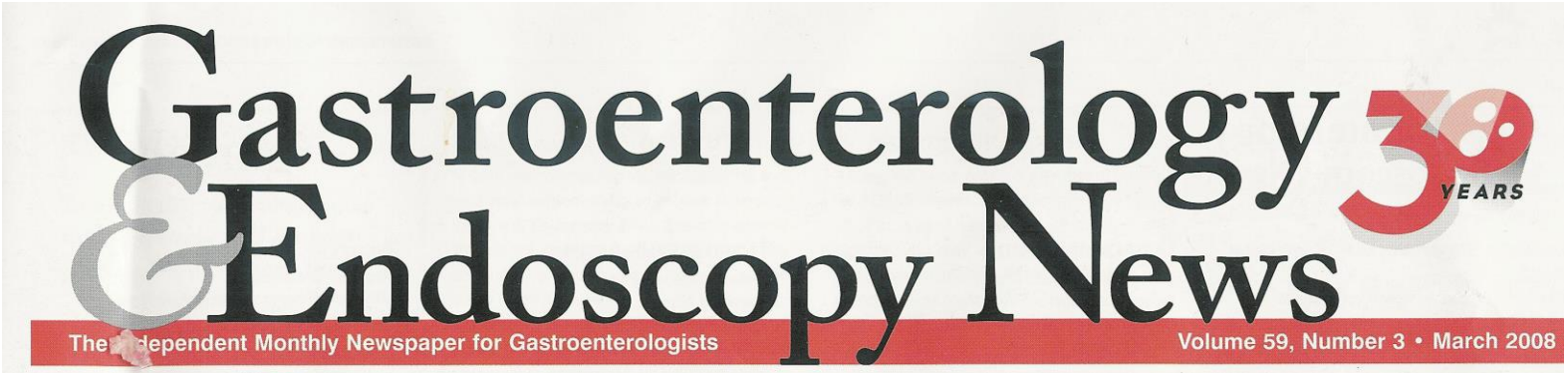


observed in NPS

New Engl J Med 1993;329:1977-81

rh

‘90% reduction’ is typical claim



“More than 150,000 people are diagnosed with colorectal cancer every year, more than 50,000 die from the disease; 90% could have been saved if they’d gone for screening colonoscopy—all of those figures are available,” Dr. Siegel said.

How much reduction of CRC incidence by colonoscopy? A fair estimate: ~50-60%?

Rationale:

a) **RCTs of sigmoidoscopy (UK, US, Norway, Italy) show ~50% reduction on Left. Shouldn't we expect ~50% on Right?**

b) Observational studies get higher #s, but are weaker

- Loberg. Long-term colorectal-cancer mortality after adenoma removal. NEJM 2014;371(9):799.
- Nishihara. Long-term colorectal-cancer incidence and mortality after lower endoscopy. NEJM 2013;369(12):1095.
- Zauber. Colonoscopic polypectomy and long-term prevention of colorectal-cancer deaths. NEJM 2012;366(8):687.
- Brenner H. Risk of colorectal cancer after detection and removal of adenomas at colonoscopy: population-based case-control study. JCO 2012;30(24):2969.

Unresolved: Does reduction come from first colonoscopy or subsequent (e.g. repeat screening, or surveillance)?

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The Consortium (of GI societies) appears; why?

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GASTROENTEROLOGY 1997;112:594–642

Colorectal Cancer Screening: Clinical Guidelines and Rationale

SIDNEY J. WINAWER, ROBERT H. FLETCHER, LAURA MILLER, FIONA GODLEE, MICHAEL H. STOLAR, CYNTHIA D. MULROW, STEVEN H. WOOLF, SETH N. GLICK, THEODORE G. GANIATS, JOHN H. BOND, LESTER ROSEN, JANE G. ZAPKA, SHARON J. OLSEN, FRANCIS M. GIARDIELLO, JANE E. SISK, ROSS VAN ANTWERP, CAROLYN BROWN–DAVIS, DEBRA A. MARCINIAK, and ROBERT J. MAYER

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In 1990s, the *field* of guidelines-making dramatically *changed*

1990s: Guidelines organizations were few and 'generalist';
e.g., USPSTF, NCI, ACS

2010s: 100s of guidelines organizations; many subspecialist;
1000s of guidelines; some conflict; varying quality

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1000s of guidelines, some conflict; varying quality

All say 'evidence-based'. US Congress will ~2008 ask Institute of Medicine "How to judge 'trustworthy'"?

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1996: USPSTF recommends CRC screening; "insufficient evidence" for/against colonoscopy

1997: GI Consortium recommends any of several tests; colonoscopy is 'an option' (*Gastroenterology 1997*)

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2000: 1) March 2000: 'Colon cancer awareness month', Katie Couric/celebrity endorsement

2) July 20, 2000: NEJM

July 20, 2000 NEJM

Two studies ask “What is found at screening colonoscopy?”

USE OF COLONOSCOPY TO SCREEN ASYMPTOMATIC ADULTS FOR COLORECTAL CANCER

DAVID A. LIEBERMAN, M.D., DAVID G. WEISS, PH.D., JOHN H. BOND, M.D., DENNIS J. AHNEN, M.D., HARINDER GAREWAL, M.D., PH.D., AND GREGORIO CHEJFEC, M.D., FOR VETERANS AFFAIRS COOPERATIVE STUDY GROUP 380*

RISK OF ADVANCED PROXIMAL NEOPLASMS IN ASYMPTOMATIC ADULTS ACCORDING TO THE DISTAL COLORECTAL FINDINGS

THOMAS F. IMPERIALE, M.D., DAVID R. WAGNER, M.S., CHING Y. LIN, B.S., GREGORY N. LARKIN, M.D., JAMES D. ROGGE, M.D., AND DAVID F. RANSOHOFF, M.D.

July 20, 2000 NEJM

Two studies ask "What is found at screening colonoscopy?"

Results:

a) In average-risk persons, the 'yield' of colonoscopy:
   ~ 1% - CRC
   ~ 5-10% - 'advanced adenomas'

b) sigmoidoscopy misses most proximal lesions

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This is not news, in the field.

It 'documents the obvious' (Feinstein).

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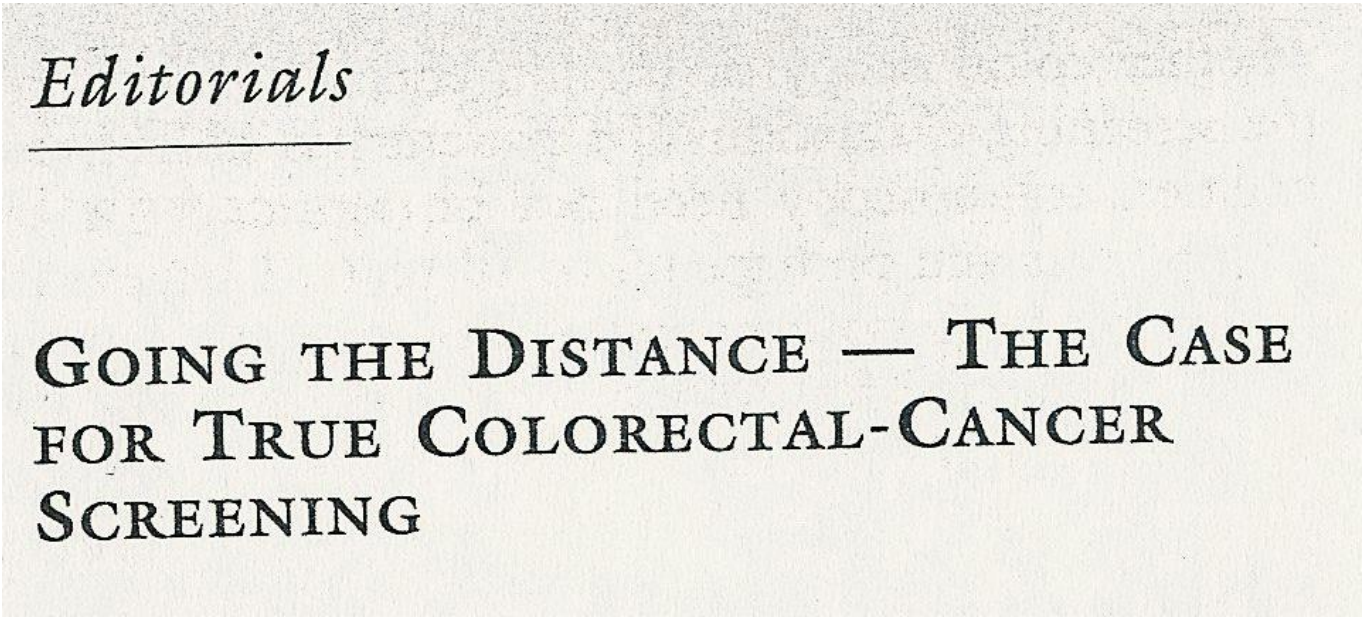
This is not news, in the field.

It 'documents the obvious' (Feinstein).

But NEJM and NY Times interpret as 'news'.

NEJM, July 20, 2000



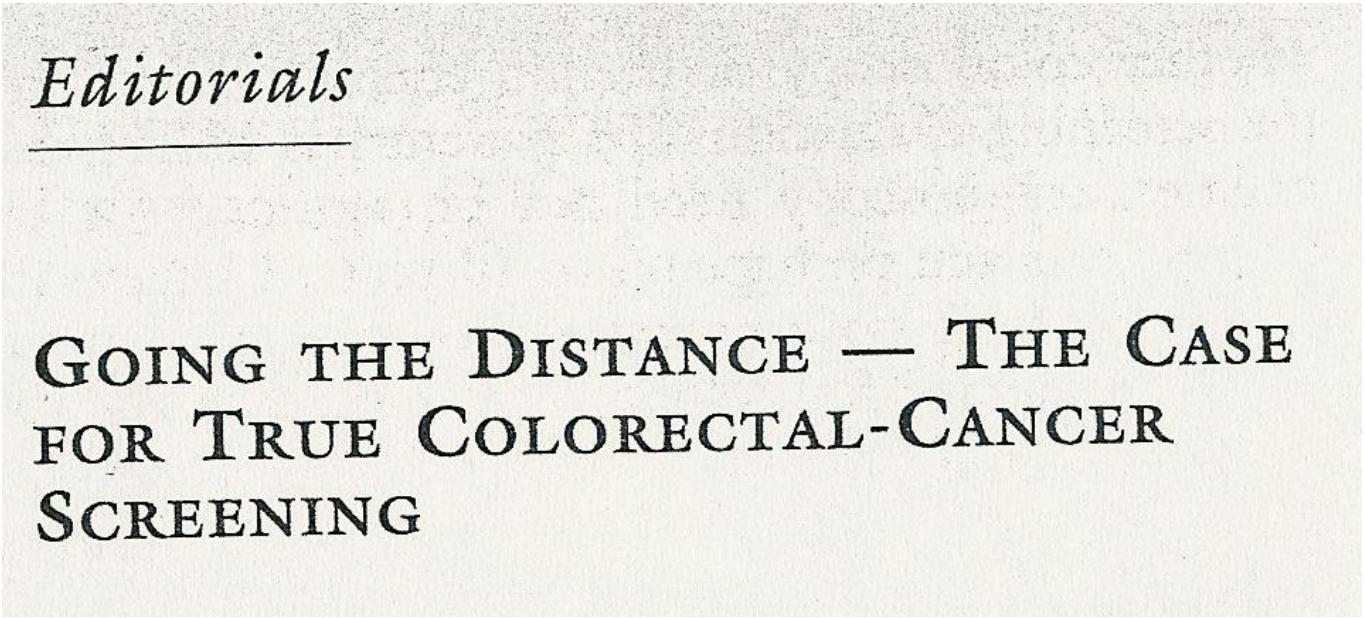
Editorials

GOING THE DISTANCE — THE CASE FOR TRUE COLORECTAL-CANCER SCREENING

NEJM 2000;343:207

NY Times, p1, reports ‘new approach’.

NEJM, July 20, 2000



Editorials

GOING THE DISTANCE — THE CASE FOR TRUE COLORECTAL-CANCER SCREENING

NEJM 2000;343:207

NY Times, p1, reports ‘new approach’.

But editorial doesn’t consider outcome (quantitative benefit of various strategies), like RCT.

So is colonoscopy the ‘preferred’ test, as NY Times says?

“The test most commonly recommended to screen healthy adults for colorectal cancer… *should be replaced* by a more extensive procedure…”

Answer: *No (tbd)*

Lesson: NEJM editorial, news reports had impact; (e.g., Policy does not just ‘emerge from evidence’)

So is colonoscopy the ‘preferred’ test?

Answer: No.

Reason:

USPSTF and Institute of Medicine did analysis of 4 cost-effectiveness analyses that assessed **outcomes** of different strategies.

USPSTF: Pignone. Ann Intern Med 2002
IOM: Pignone. Nat Acad Press 2005

So is colonoscopy the ‘preferred’ test?

- At any one ***application***, colonoscopy ***is*** best because it is very sensitive and can remove lesions.
- But in a ***program*** of screening, colonoscopy (e.g. q10y) may miss ‘new’ or rapidly-growing lesions that *could be detected* by less-sensitive test done more frequently.

I.e., This result depends on considering:

1) screening *programs (over time)* not ‘*tests*’
2) *biology*

So if CRCs that kill grow rapidly, a program of more-frequent but less-sensitive tests may be more effective.

USPSTF- Pignone. Ann Intern Med 2002;

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Organization: 2 parallel histories of

1) Evidence-Based Medicine (EBM)
2) **CRC screening: science, policy, politics; challenges in 2016**

"Consortium" evolves.
How is conflict of interest (COI) handled in Consortium (ACS-MSTF) compared to USPSTF?

USPSTF

- separate groups to report evidence, make guidelines
- generalists/methodologists make guidelines;
  subspecialists' role: limited

ACS-MSTF (Consortium of GI and radiology groups)

- same group assesses evidence, makes guidelines
- # generalists/methodologists in MSTF decreases

1997: 4 (RHF, FG, CDM, SHW)	Gastroenterology 1997;112:594
2003: 2 (RHF, SHW)	Gastroenterology 2003;124:544
2008: 0	Gastroenterology 2008;134:1570

COI – the Problem: Professional organizations wear 2 hats

1. interests of clients/patients (patients' outcomes)
2. interests of doctors (providers' economic interest)

*Consider **definition of a profession** (Louis Brandeis):*
-stewards a body of knowledge
-puts clients' interests before its own

Problem: Interests 1 and 2 are 'legitimate'; may conflict.

Example: one profession's economic interest

(AGA Institute Future Trends Committee conference, 2006)

GASTROENTEROLOGY 2006;131:1287–1312

AGA INSTITUTE

Will Screening Colonoscopy Disappear and Transform Gastroenterology Practice? Threats to Clinical Practice and Recommendations to Reduce Their Impact: Report of a Consensus Conference Conducted by the AGA Institute Future Trends Committee

The AGA Institute Future Trends Committee (FTC) developed this report based on a consensus conference is convened on April 1–2, 2006, in Washington, DC. The report was prepared for the FTC by Carol Regueiro, MD, a medical writer under contract to the

2008 CRC screening guidelines differ; why?

	Consortium ACS/MSTF	USPSTF
What they say	structural exam 'preferred' (interp:*colonoscopy)*	*any of several programs acceptable*

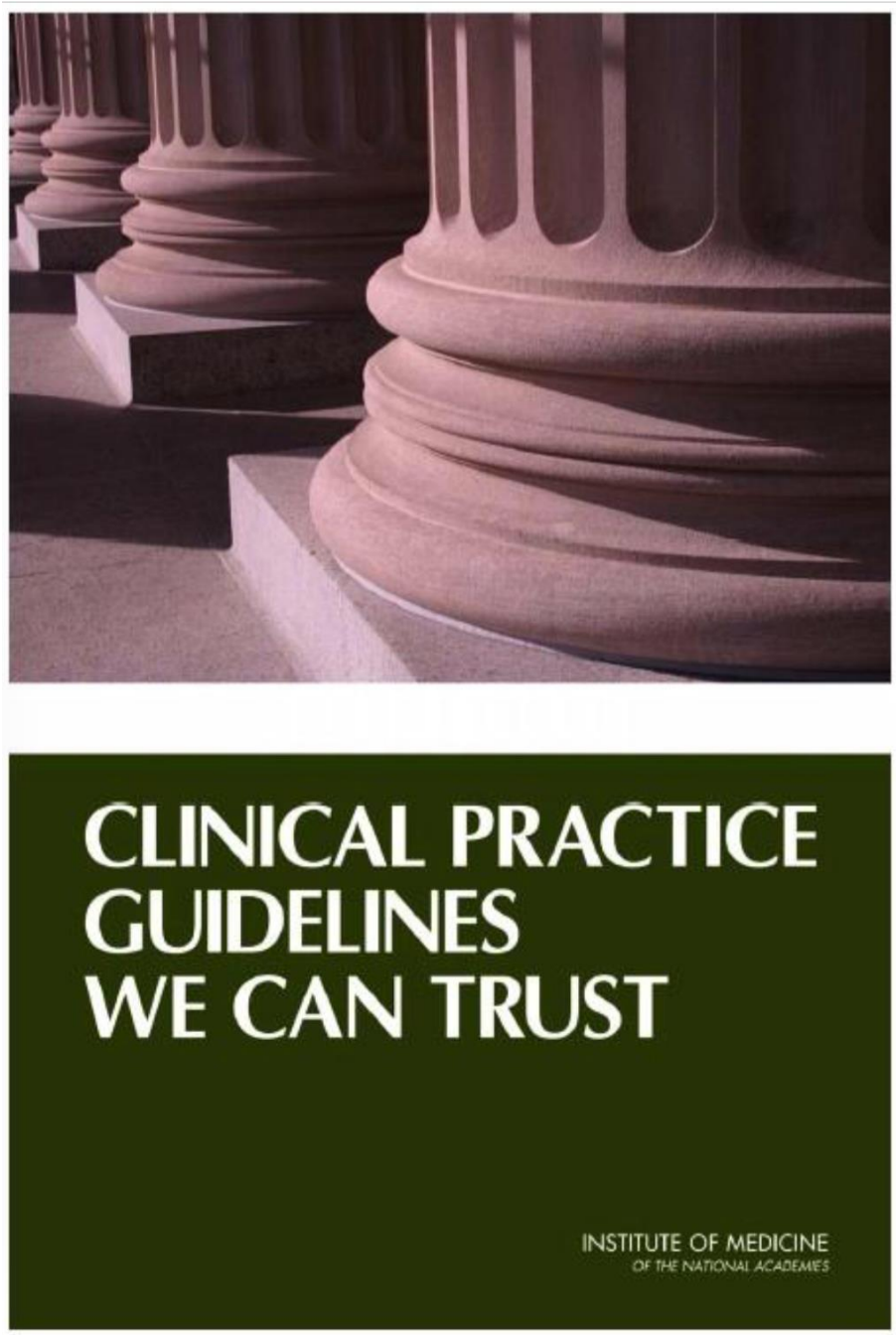
2008 CRC screening guidelines differ; why?

	Consortium ACS/MSTF	**USPSTF**
What they say	structural exam 'preferred' (interp:*colonoscopy*)	*any of several programs acceptable*
Process to develop		
Prestated rules of evidence	NO	YES
Assess outcomes (benefit/harm) quantitatively	NO	YES
COI managed	NO	YES

Congress asks Institute of Medicine "How to tell if a guideline is trustworthy"

Motivation:

So many guidelines-makers, and guidelines that may conflict. Quality varies.



Graham R.
Institute of Medicine;
The National Academies Press;
2011.

Box. A Summary of the Institute of Medicine (IOM) Standards for Trustworthiness

1. **Transparent process:** The processes by which a clinical practice guideline is developed and funded should be described transparently.
2. **Conflicts of interest:** Potential guideline development group members should declare conflicts. None, or at most a small minority, should have conflicts, including services from which a clinician derives a substantial proportion of income. The chair and co-chair should not have conflicts. Eliminate financial ties that create conflicts.
3. **Guideline development group composition:** The group should be composed of methods experts, clinicians, representatives of stakeholders, and affected populations.
4. **Systematic reviews:** Essential to the process, systematic reviews must meet the IOM's methodological standards.
5. **Evidence quality and recommendation strength:** Explain the reasoning behind each recommendation, summarize evidence for benefits and harms, characterize the quality and quantity of relevant evidence and the role of subjective judgments. Rate the level of evidence and the strength of the recommendation. Describe differences of opinion about recommendations.
6. **Articulating recommendations:** Describe the action recommended by the guideline and when it should be used; wording should facilitate measurement of adherence.
7. **External review:** Essential to the process, external review should include a full spectrum of stakeholders, reviewers not identified by name, explain all changes done in response to reviewers, and post for public comment.
8. **Updating:** Document the dates of the guideline, systematic review, and planned update; monitor the literature and update the guideline when new evidence suggests the need for change.

Source: Abstracted by the authors from the IOM committee report.[1]

But IOM "standards" are hard to apply.

Problem: IOM "standards" are broad principles; not a scale with variables, categories, criteria.

Challenge: How to judge a specific guideline: Trustworthy? How much?

Ransohoff, DF, Sox H. How to Decide Whether a Clinical Practice Guideline Is Trustworthy. JAMA.2013;209:139

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2016 USPSTF CRC Screening Guideline evolved dramatically from Draft to Final

Draft version (Oct 2015) recommended:

- 3 tests/strategies, and 2 "*alternative*" (label unclear)
- based on modeling results and "efficient frontier"

After much public comment....

Final version (June 2016) recommended:

- 7 tests/strategies that "may be discussed in 'shared decision-making'" (SDM)
- based on new considerations like compliance, quality.

Challenges:

- What reasons for change, and implications for future?
- "Where is the 'bar'?"

Ransohoff, Sox: JAMA 2016;315(23):2529

(suggest: USPSTF *update* Harris R. Am J Prev Med 2001;20

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Summary points:

- Guidelines do not "emerge from evidence." Guidelines-making is a human process; quality (and trustworthiness) may vary.
- Guidelines-making affects practice and patient outcomes, and is a "highest-calling" of our profession.
- The profession's role is to "do the science", which is hard enough - to generate evidence that can project patient outcomes (benefit vs harm). Then "where to draw the line" is arguably a separate "political" process.
- We need our best organizations (e.g. USPSTF) to be insulated from political pressures, to do the best science (foundation) and to lead the field of EBM.

Subject is *big;* topics are selected.

Questions

Send questions to prevention@mail.nih.gov

Or

Use @NIHprevents & #NIHMtG on Twitter