



The Evidence Behind Screening for Colorectal Cancer

WNC Colorectal Cancer Evidence Academy

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“ . . . If we did not respect the evidence, we would have very little leverage in our quest for the truth.”

Carl Sagan

Why Evidence-based Practice?

- ▶ Resources are, and always will be, limited.
- ▶ Resources should be used to provide forms of health care which have been shown in properly designed evaluations to be effective.
- ▶ The best available evidence, moderated by patient circumstances and preferences can be applied to
 - ▶ improve the quality of clinical judgments
 - ▶ inform individual patient decision making
 - ▶ facilitate cost-effective care

What is Evidence?

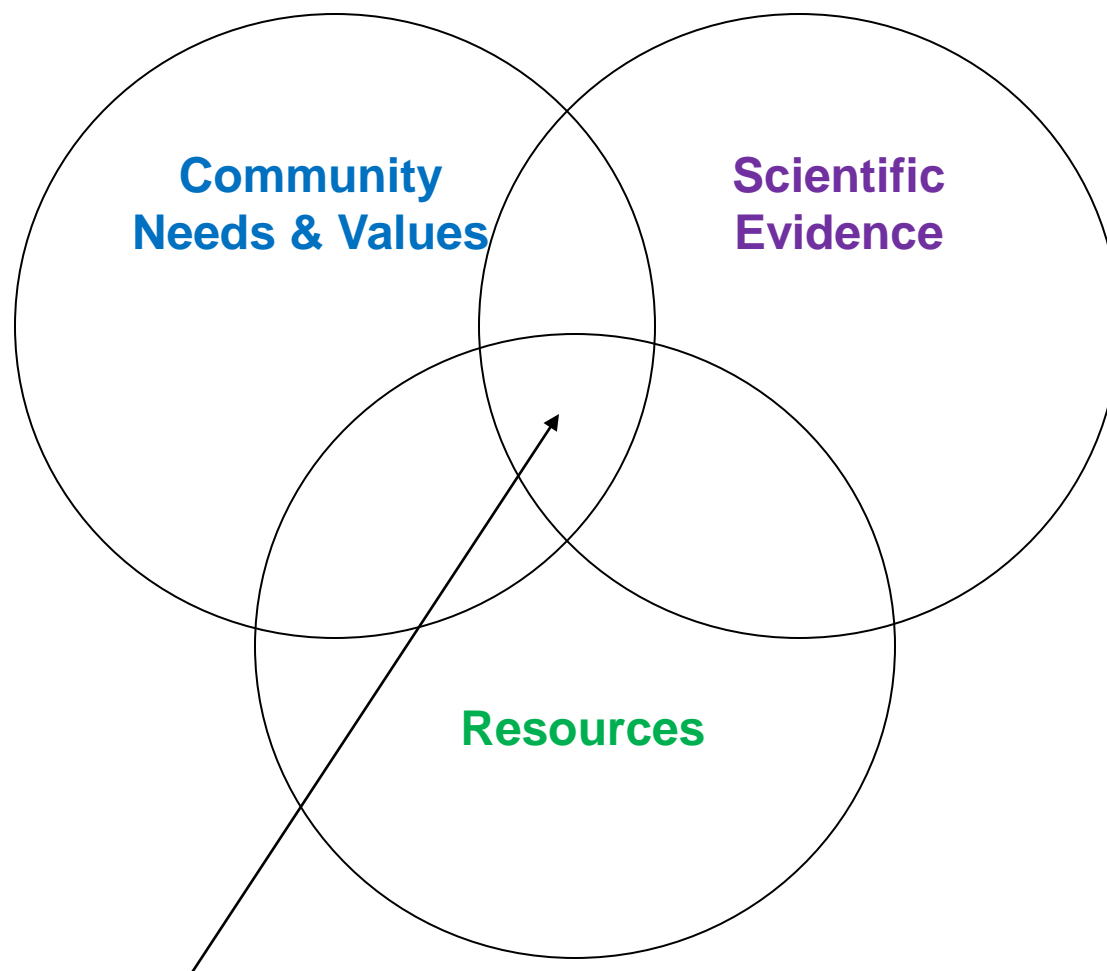
“...the available body of facts or information indicating whether a belief or proposition is true or valid.”

In public health practice, a collection

- ▶ Data or scientific evidence (guidelines)
- ▶ Input from community members
- ▶ Input from other stakeholders
- ▶ Professional experience

Framework for enhancing evidence-based public health practice

1. Develop an initial state of the issue
2. Quantify the issue
3. Search the scientific literature and organize information
4. Develop and prioritize program options
5. Develop an action plan and implement interventions.
6. Evaluate the program or policy (disseminate widely or discontinue program or policy)



(adapted from Brownson et al.)

(adapted and modified from Muir Gray)

How Do We Develop an Evidence Base?

- ▶ Knowledge synthesis
 - ▶ Single studies
 - ▶ Peer review
 - ▶ Systematic review and meta-analysis
 - ▶ Expert evaluation and assessment of clinical/public health relevance

Steps in Developing a Systematic Review

- ▶ Develop an analytic framework
- ▶ Systematic search of relevant literature
- ▶ Dual review of abstracts and full text articles
- ▶ Data abstraction for evidence tables
- ▶ Dual rating of quality of each article
- ▶ Dual “grading” of strength of evidence
- ▶ Resolve disagreements by consensus
- ▶ Vet findings with independent panel of experts

The Importance of Approaching Colorectal Cancer Screening From an Evidence-based Perspective

- 1. There are a range of screening options for colorectal cancer screening, each with its own set of potential benefits and harms.**
- 2. The range of recommended options has presented problems, making recommendations for CRC screening more complex in some ways than screening for other conditions where fewer test options are recommended. This complexity necessitates an individualized decision making approach that is difficult for both providers and patients.**
- 3. Experts disagree about whether tests that detect polyps in addition to CRC (structural tests) should be preferred over tests that detect CRC (non-structural tests).**
- 4. Inconsistencies exist across guidelines with regard to individuals “aging out” of routine and all screening for CRC.**

The Importance of Approaching Colorectal Cancer Screening From an Evidence-based Perspective

5. **Underuse of both CRC screening and patient-physician discussions of CRC screening is clear.**
6. **Problems of misuse, screening in such a way as to reduce benefits and/or increase harms, are also clear and include:**
 - a. **In-office rather than home FOBT**
 - b. **Non-return of FOBT cards**
 - c. **Lack of adequate followup of positive FOBT results**
 - d. **Colonoscopy that does not reach the cecum, has too rapid withdrawal time, that misses important lesions**
 - e. **Colonoscopy with high adverse event rates**

Evidence-based Approaches and Guidelines

- ▶ **Inform *choice of a particular test* for**
 - ▶ An individual – informs individualized decision making
 - ▶ A community – informs programmatic efforts to increase screening prevalence

- ▶ **Offer *client-oriented interventions* to**
 - ▶ Increase *community demand* for CRC screening
 - ▶ Increase *community access* for CRC screening

- ▶ **Specify *provider-oriented Interventions* to**
 - ▶ Increase delivery and referral

Choice of a Particular Test

Individual Considerations

Colorectal Cancer Screening Tests

- ▶ **Digital Rectal Exam***
- ▶ **Double Contrast Barium Enema***
- ▶ **Guaiac-based Fecal Occult Blood Test (gFOBT)**
- ▶ **Fecal Immunochemical Tests (FIT)**
- ▶ **Flexible Sigmoidoscopy (FS)**
- ▶ **Colonoscopy**
- ▶ **Fecal DNA****
- ▶ **Computed Tomographic Colonography (CTC)****

*Older, infrequently used tests

** Newer tests

Sources of Current Colorectal Cancer Screening Guidelines

- ▶ **Periodic screening recommendations from 3 national guideline groups**
 - ▶ **United States Preventive Services Task Force (USPSTF)**
 - ▶ Independent, nonfederal, volunteer body of public health and prevention experts, whose members are appointed by the Director of the Centers for Disease Control and Prevention
 - ▶ **U. S. Multi-Society Task Force on Colorectal Cancer (USMSTF)**
 - ▶ American Gastroenterological Association, American College of Gastroenterology, American Society for Gastrointestinal Endoscopy
 - ▶ **American Cancer Society (ACS)**

USPSTF Screening Guidelines

A Brief History

- ▶ **1989**: found insufficient evidence to recommend screening
- ▶ **1996**
 - ▶ Recommended **gFOBT, FS**
 - ▶ Found insufficient evidence to recommend colonoscopy due to lack of a randomized controlled trial to determine magnitude of benefit
- ▶ **2002**
 - ▶ Broadened recommendation to include screening with any of several tests: **gFOBT, FS, Colonoscopy**
- ▶ **2008**
 - ▶ Broadened recommendation to include **gFOBT, FIT, FS and Colonoscopy**
 - ▶ Found insufficient evidence to make a recommendation concerning screening with **fecal DNA or CTC**

Sources:

Screening for Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement U.S. Preventive Services Task Force; Annals of Internal Medicine 2008 149: 627-637

Holden DJ, Harris R, Porterfield DS, et al. Enhancing the Use and Quality of Colorectal Cancer Screening. RTI International–University of North Carolina Evidence-based Practice Center, Contract No. 290-2007-10056-I. Rockville, MD: Agency for Healthcare Research and Quality. February 2010.

USMSTF Screening Guidelines

A Brief History

- ▶ **1997:** Recommended five options
 - ▶ Annual FOBT
 - ▶ FS every five years
 - ▶ Annual FOBT and FS every 5 years combined
 - ▶ Double contrast barium enema every 5-10 years
 - ▶ Colonoscopy every 10 years
- ▶ **2003:** Recommendations remained the same
- ▶ **2008:** Joined by the American Cancer Society (ACS) and the American College of Radiology (ACR)
 - ▶ Recommended two categories of tests
 - ▶ Tests that detect CRC: gFOBT, FIT, fecal DNA
 - ▶ Tests that detect both CRC and colonic polyps: FS, colonoscopy, CTC and barium enema

Sources: Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology Levin B, Lieberman D, McFarland B, et al. CA Cancer J Clin, May 2008; 58: 130 - 160

Holden DJ, Harris R, Porterfield DS, et al. Enhancing the Use and Quality of Colorectal Cancer Screening. RTI International–University of North Carolina Evidence-based Practice Center, Contract No. 290-2007-10056-I. Rockville, MD: Agency for Healthcare Research and Quality. February 2010.

Primary Differences in 2008

- ▶ Age to begin and end screening in average risk adults
 - ▶ ACS/USMSTF/ACR: Begin at age 50, and end screening at a point where curative therapy would not be offered due to life-limiting co-morbidity
 - ▶ *USPSTF: Begin screening at age 50. Routine screening between ages 76-85 is not recommended. Screening after age 85 is not recommended.*
- ▶ Screening in high risk adults
 - ▶ ACS/USMSTF/ACR: Detailed recommendations based on personal risk and family history
 - ▶ *USPSTF: No specific recommendations for age to begin testing or type of testing*

Primary Differences in 2008 – Page 2

- ▶ Prioritization of tests
 - ▶ ACS/USMSTF/ACR: Tests are grouped into those that (1) primarily are effective at detecting cancer, and (2) those that are effective at detecting cancer and adenomatous polyps. Group 2 is preferred over group 1 due to the greater potential for prevention.
 - ▶ *USPSTF: specific prioritization of tests, though recommendations acknowledge that direct visualization techniques offer substantial benefit over fecal tests*

Primary Differences in 2008 – Page 3

- ▶ Fecal DNA
 - ▶ ACS/USMSTF/ACR: Acceptable option
 - ▶ *USPSTF: Insufficient evidence to recommend for or against*

- ▶ Flexible Sigmoidoscopy
 - ▶ ACS/USMSTF/ACR: Screening every 5 years, with annual gFOBt or FIT is an option
 - ▶ *USPSTF: Screening every 5 years, with gFOBt every 3 years*

- ▶ CT Colonography
 - ▶ ACS/USMSTF/ACR: Screening every 5 years
 - ▶ *USPSTF: Insufficient evidence to recommend for or against screening*

Primary Differences in 2008 – Page 4

- ▶ Double Contrast Barium Enema
 - ▶ *ACS/USMFTC/ARC: Every 5 years*
 - ▶ *USPSTF: Not considered*

- ▶ NO DIFFERENCES
 - ▶ gFOBT: Annual screening with high sensitivity guaiac based tests
 - ▶ FIT: Annual screening
 - ▶ Colonoscopy: Every 10 years

Sources:

ACS web: http://www.cancer.org/docroot/PRO/content/PRO_4_1x_ColonMD_Comparison_Guidelines.asp

Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology Levin B, Lieberman D, McFarland B, et al. CA Cancer J Clin, May 2008; 58: 130 - 160

Screening for Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement U.S. Preventive Services Task Force; Annals of Internal Medicine 2008 149: 627-637

Consensus Bottom Line

All involved organizations have one primary message for individuals

"Colorectal cancer screening saves lives; if you are 50 or older, choose a test and get screened."

Choice of a Particular Test

Population Considerations

Grading Evidence

Screening for Colorectal Cancer: Summary of Recommendations, 2008

- The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults, beginning at age 50 and continuing until age 75.
Grade: [A recommendation](#).
- The USPSTF recommends against routine screening for colorectal cancer in adults 76 to 85 years of age.
Grade: [C recommendation](#).
- The USPSTF recommends against screening for colorectal cancer in adults older than age 85 years.
Grade: [D recommendation](#).
- The USPSTF concludes that the evidence is insufficient to assess the benefits and harms of computed tomographic colonography and fecal DNA testing.
Grade: [I statement](#).

The Guide to Clinical Preventive Services, Recommendations of the U.S. Preventive Services Task Force (USPSTF)

Grade Definition	Suggestions for Practice
<p>A The USPSTF recommends the service. There is high certainty that the net benefit is substantial.</p>	<p>Offer or provide this service.</p>
<p>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.</p>	<p>Offer or provide this service.</p>
<p>C The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.</p>	<p>Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.</p>
<p>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.</p>	<p>Discourage the use of this service.</p>
<p>I Statement</p>	<p>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.</p>

The Guide to Community Preventive Services

Categories of Task Force Recommendations and Findings

Recommended	The systematic review of available studies provides strong or sufficient evidence that the intervention is effective.
Recommended Against	The systematic review of available studies provides strong or sufficient evidence that the intervention is harmful or not effective.
Insufficient Evidence	The available studies do not provide sufficient evidence to determine if the intervention is, or is not, effective. This does NOT mean that the intervention does not work. It means that additional research is needed to determine whether or not the intervention is effective.

Client-Oriented Interventions

Client-Oriented Interventions to Increase Community Demand for Colorectal Cancer Screening

* Client reminders	Recommended (strong evidence)
Client incentives, alone	Not enough research evidence to determine effectiveness
Mass media alone	Not enough research evidence to determine effectiveness
* Small media	Recommended (strong evidence)
Group education	Not enough research evidence to determine effectiveness
One-on-one education	Not enough research evidence to determine effectiveness

Effect Sizes for Recommended Interventions

Client Reminders

- There was a median increase of 11.5 percentage points in the proportion of study participants who completed colorectal cancer screening by fecal occult blood testing (FOBT).

Small Media

- Proportion of study participants completing screening by FOBT: median increase of 12.7 percentage points (8 study arms)

Client-Oriented Interventions to Increase Community Access for Colorectal Cancer Screening

* Reducing structural barriers	Recommended (strong evidence)
Reducing out of pocket expenses	Not enough research evidence to determine effectiveness

Effect Sizes for Recommended Interventions

Reducing Structural Barriers

- Costs per additional screening varied widely across studies, from \$0.64 for supplying a return FOBT kit envelope with prepaid postage versus usual in-person return to \$32.10 for mailing a return postage prepaid FOBT kit with a follow-up telephone reminder during a mass media campaign versus exposure to the mass media campaign alone which offered FOBT kit at no cost to client.

Provider-Oriented Interventions

Provider-Oriented Interventions to Increase Delivery and Referral by Providers

* Provider assessment and feedback	Recommended for FOBT only (strong evidence)
Provider incentives	Not enough research evidence to determine effectiveness
* Provider reminders and recall	Recommended for FOBT and flexible sigmoidoscopy only (strong evidence)

Effect Sizes for Recommended Interventions

Provider Assessment and Feedback

- Proportion of study participants completing FOBTs: median increase of 13 percentage points (3 studies)

Provider Reminders and Recall

- Proportion of study participants completing FOBTs and flexible sigmoidoscopy: median increase of 17.6 percentage points (6 studies or study arms)

“The best is the
enemy of the good”
-Voltaire

The problem of randomized trials
and parachutes....

The effectiveness of parachutes has not been subjected to rigorous evaluation by using randomized controlled trials.... We think that everyone might benefit if the most radical protagonists of evidence based medicine organized and participated in a double blind, randomized, placebo controlled, crossover trial of the parachute.



Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

“Public health workers...
deserve to get somewhere by
design, not just by
perseverance.”

McKinlay and Marceau



www.thecommunityguide.org



www.ahrq.gov/clinic/uspstfix.htm

