

# NATIONAL QUALITY FORUM

## Stage 1 Concept Submission and Evaluation Worksheet 1.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's concept evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the [submitting standards web page](#).

NQF #: C 2056      NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012
<b>CONCEPT SPECIFICATIONS</b>
De.1 Concept Title: Colonoscopy Quality Index
Co.1.1 Concept Steward: Quality Quest for Health of Illinois, Inc.
De.2 Brief Description of Concept: This is a composite measure of the percentage of patients undergoing screening or surveillance colonoscopy who meet all individual quality elements (Appropriate indication for colonoscopy, standardized assessments of medical risk and bowel preparation, complete examination with photo documentation, free of serious complications, withdrawal time recorded, all essential polyp information recorded if polyp(s) identified, recommendation for follow-up colonoscopy consistent with patient history and examination findings), and the completion rate of each individual quality element.
2a1.1 Numerator Statement: All patients undergoing screening or surveillance colonoscopy who meet all relevant individual quality elements (1. Appropriate indication for colonoscopy, 2. Standardized medical risk assessment, 3. Standardized assessment of bowel prep, 4. Complete examination, 5. Cecal photo taken, 6. All essential polyp information recorded, 7. Withdrawal time recorded, 8. Free of serious complication, 9. Appropriate follow-up recommendation). Elements that do not apply are excluded from numerator calculation.
2a1.4 Denominator Statement: All adults undergoing screening or surveillance colonoscopy
2a1.8 Denominator Exclusions: Patients with a personal or family history of familial adenomatous polyposis, hereditary non-polyposis colorectal cancer or inflammatory bowel disease are excluded from the denominator. Patients assessed as poor or unsatisfactory bowel preparation are excluded from the denominator.
1.1 Concept Type: Process 2a1. 25-26 Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Other, Paper Medical Records 2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Facility, Population : Regional
1.2-1.4 Is this concept paired with another measure? No
2a1.1 Numerator Statement <i>(Brief, narrative description of the concept focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome):</i> All patients undergoing screening or surveillance colonoscopy who meet all relevant individual quality elements (1. Appropriate indication for colonoscopy, 2. Standardized medical risk assessment, 3. Standardized assessment of bowel prep, 4. Complete examination, 5. Cecal photo taken, 6. All essential polyp information recorded, 7. Withdrawal time recorded, 8. Free of serious complication, 9. Appropriate follow-up recommendation). Elements that do not apply are excluded from numerator calculation.
2a1.3 Numerator Details <i>(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)</i> For new concepts, describe how you plan to identify and calculate the numerator. 1) Appropriate indication for colonoscopy: A) Appropriate indication for screening colonoscopy:

- a1) Patient has no personal or family history of colorectal cancer or pre-cancerous polyp(s), has not had a colonoscopy in the past 10 years and is > 50 years; or
- a2) Patient has one or more first-degree relatives with pre-cancerous polyp(s) or one first-degree relative with colorectal cancer after age 60, has not had a colonoscopy in the past ten years and is > 40 years; or
- a3) Patient has a first degree relative with colorectal cancer before age 60 or 2 or more first degree relatives with colorectal cancer at any age, has not had a colonoscopy in the past five years and is > 40 years

\*OR\*

B) Appropriate indication for surveillance colonoscopy:

- b1) Patient with prior diagnosis of colorectal cancer, negative clearance colonoscopy at time of resection with colonoscopy not more often than year one, year four and every five years if normal or
- b2) Patient with low anterior resection for rectal cancer without pelvic radiation or mesorectal resection with flexible sigmoidoscopy not more often than every 3 months for up to 3 years in addition to colonoscopy not more often than year one, year four and every five years if normal; or
- b3) Patient with 1-2 small tubular adenoma(s) on most recent colonoscopy, has not had colonoscopy in the past 5 years; or
- b4) Patient with three to ten adenomas <1 cm on most recent colonoscopy, has not had colonoscopy in the past 3 years; or
- b5) Patient with advanced neoplasia (>1 cm adenoma, villous histology, high-grade dysplasia) or with up to ten adenomas on most recent colonoscopy, has not had colonoscopy in the past 3 years; or
- b6) Patient with greater than ten adenomas or with > one serrated polyp on most recent colonoscopy, has not had colonoscopy in past 12 months; or
- b7) Patient with sessile polyp > 1 cm with incomplete excision on most recent colonoscopy, has not had colonoscopy in past 2 months; or
- b8) Patient with history of pre-cancerous findings with negative most recent screening colonoscopy, has not had a colonoscopy in past 5 years

2. Standardized medical risk assessment: American Society of Anesthesiology Physical Status (class 1-5) recorded

3. Standardized assessment of bowel prep: Assessment as adequate to detect polyps > 5 mm (e.g., excellent, good or fair) or inadequate (e.g., poor or unsatisfactory) recorded. Please refer to Lieberman et al 2007.

4. Complete examination: Cecal intubation or anatomically complete colonoscopy was accomplished;(element null if bowel prep is deemed poor or unsatisfactory)

5. Cecal photo taken: Picture of the cecum; N/A is acceptable if examination is not complete.

6. All essential polyp information recorded: If polyps are removed, the number, size, location, morphology (if >4mm in size), method and completeness of removal all recorded

7. Withdrawal time was recorded: Withdrawal time from cecum to extubation recorded

8. Free of serious complications: Patient did not have bowel perforation, blood transfusion, cardiopulmonary arrest, hospitalization or death prior to discharge home

9. Appropriate follow-up recommendation: Follow up recommendation is consistent with patient history and examination findings per indication for screening colonoscopy.

Patient level data is collected on each screening or surveillance colonoscopy performed by the colonoscopy center, rules are applied (e.g., exclusion for poor bowel prep) by the data collection database provided by Quality Quest, and each quarter de-identified and encrypted patient-level data is electronically transferred to the registry on the Quality Quest data portal, and calculations are made on the most recent 12 months.

Please refer to the Definitions & Abbreviations document attached as supplemental materials for additional information such as bowel prep scoring.

Lieberman D., Nadel M., Smith R.A., Atkin W., Duggirala S.B., Fletcher R., Glick S.N., Johnson C.D., Levin T.R., Pope J.B., Potter M.B., Ransohoff D., Rex D., Schoen R., Schroy P., Winawer S. (2007) Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. *Gastrointestinal Endoscopy* 65(6): 757-766.

**2a1.4 Denominator Statement** (*Brief, narrative description of the target population being measured*):

All adults undergoing screening or surveillance colonoscopy

**2a1.5 Target Population Category** (*Check all the populations for which the concept is specified and tested if any*): [Adult/Elderly Care](#), [Populations at Risk](#), [Senior Care](#)

**2a1.7 Denominator Details** (*All information required to identify and calculate the target population/denominator such as definitions,*

*timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*

**For new concepts**, describe how you plan to identify and calculate the denominator.

All adults undergoing screening or surveillance colonoscopy. Patient level data is collected on each screening or surveillance colonoscopy performed by the colonoscopy center, rules are applied (e.g., exclusion for poor bowel prep) by the data collection database provided by Quality Quest, and each quarter de-identified and encrypted patient-level data is electronically transferred to the registry on the Quality Quest data portal, and calculations are made on the most recent 12 months.

**2a1.8 Denominator Exclusions** *(Brief narrative description of exclusions from the target population):*

Patients with a personal or family history of familial adenomatous polyposis, hereditary non-polyposis colorectal cancer or inflammatory bowel disease are excluded from the denominator. Patients assessed as poor or unsatisfactory bowel preparation are excluded from the denominator.

**2a1.9 Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*

**For new concepts**, describe how you plan to identify and calculate the exclusions.

Patients with a personal or family history of familial adenomatous polyposis, hereditary non-polyposis colorectal cancer or inflammatory bowel disease are excluded from the denominator. Patients assessed as poor or unsatisfactory bowel preparation are excluded from the denominator. Patient level data is collected on each screening or surveillance colonoscopy performed by the colonoscopy center, rules are applied (e.g., exclusion for poor bowel prep) by the data collection database provided by Quality Quest, and each quarter de-identified and encrypted patient-level data is electronically transferred to the registry on the Quality Quest data portal, and calculations are made on the most recent 12 months.

**2a1.10 Stratification Details/Variables** *(All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*

**For new concepts**, if you plan to stratify the measure results, describe the plans for stratification.

None

**2a1.13 Statistical Risk Model and Variables** *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in measure testing in the stage 2 measure submission)*

**For new concepts**, **if an outcome**, describe how you plan to adjust for differences in case mix/risk across measured entities.

N/A - Procedural quality bundled measure. Although there is no data to support or refute, the quality of the colonoscopy procedure should not vary by case mix/risk as patients with a personal or family history of familial adenomatous polyposis, hereditary

**2a1.25 Data Source** *(Check all the sources for which the concept is specified and tested). If other, please describe:*

Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Other, Paper Medical Records

**2a1.26 Data Source/Data Collection Instrument** *(Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):* A colonoscopy quality measurement registry was created for the purpose of collecting and reporting on the Colonoscopy Quality Index, measures that comprise the Colonoscopy Quality Index, and adenoma detection rates by gender for screening colonoscopies. Da

**2a1.33 Level of Analysis** *(Check the levels of analysis for which the concept is specified and tested):* Clinician : Group/Practice, Clinician : Individual, Facility, Population : Regional

**2a1.34 Care Setting** *(Check all the settings for which the concept is specified and tested):* Ambulatory Care : Ambulatory Surgery Center (ASC), Hospital/Acute Care Facility

Importance to Measure and Report is the criterion that must be met in order to recommend a concept for approval. All three subcriteria must be met to pass this criterion. See [guidance on evidence](#).

1a. High Impact: H  M  L  I

(The concept directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

De.4 **Subject/Topic Areas** (Check all the areas that apply): Cancer, Cancer : Colorectal, Cancer : Screening, Gastrointestinal (GI), Gastrointestinal (GI) : Polyps, Gastrointestinal (GI) : Screening, Prevention

De.5 **Cross Cutting Areas** (Check all the areas that apply): Overuse, Prevention, Prevention : Screening, Safety, Safety : Complications

1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers; A leading cause of morbidity/mortality; Frequently performed procedure; High resource use; Patient/societal consequences of poor quality

1a.2 If "Other," please describe:

1a.3 **Summary of Evidence of High Impact** (Provide epidemiologic or resource use data):

Colorectal cancer is the second leading cause of cancer mortality in the US and affects both men and women [1]. Colonoscopy is the predominant screening modality with 61.8% of US residents aged 50-75 years reporting lower endoscopy within the past 10 years in the CDC Behavioral Risk Factor Surveillance System (BRFSS) [2]. Underuse of colonoscopy for colorectal cancer screening and surveillance is associated with increased morbidity and mortality due to undetected and untreated colorectal cancer [3-13]. In 2010, only 65.4% of persons aged 50-75 were adequately screened for colorectal cancer [2], reflecting underuse of colonoscopy and other methods of screening for colorectal cancer in 34.6% of the US population aged 50-75 years. There is also overuse of colonoscopy for colorectal cancer screening, for example, when a shorter follow-up interval is used than what is supported by evidence. Overuse of colonoscopy for colorectal cancer screening and surveillance is associated with increased morbidity (e.g., bowel perforation, bleeding) and increased costs [3-13]. By eliminating overuse of colonoscopy, resources are freed up to address underuse of colonoscopy. The fair price for a colonoscopy ranges from \$1,129 to \$1,508, with actual pricing varying by over 300% [14].

1a.4 **Citations for Evidence of High Impact cited in 1a.3:** 1. United States Cancer Statistics (USCS) 2008 Incidence and Mortality web-based report <http://www.cdc.gov/Features/CancerStatistics/> accessed on 6/25/2012

2. CDC Morbidity and Mortality Weekly Report (July 8, 2011) Vital Signs: Colorectal Cancer Screening, Incidence, and Mortality -- United States, 2002-2010. MMWR 60(26): 884-889.

3. Brink D, Barlow J, Bush K, Chaudhary N, Fareed M, Hayes R, Jafri I, Nair K, Retzer K, Rueter K. Institute for Clinical Systems Improvement. Colorectal Cancer Screening. <http://bit.ly/Colorectal0512>. Published May 2012.

4. Winawer, S., et al. (2003) American Gastroenterological Association: Colorectal Cancer Screening and Surveillance: Clinical Guidelines and Rationale. Gastroenterology. 124:544-560.

5. US Preventive Services Task Force (2008) Screening for Colorectal Cancer <http://www.uspreventiveservicestaskforce.org/uspstf08/colocancer/colors.htm> last accessed on 6/22/2012

6. Quaseem, A., et al. (2012) Screening for Colorectal Cancer: A Guidance Statement from the American College of Physicians. Ann Intern Med. 156:378-386.

7. Pignone, M., et al. (2002) Screening for Colorectal Cancer in Adults at Average Risk: A Summary of the Evidence for the U.S. Preventive Services Task Force. Archives of Internal Medicine 137(2): 132-141.

8. Rex DK, et al. (2006) Quality indicators for colonoscopy from ASGE/ACG Taskforce on Quality in Endoscopy. Am J Gastroenterol. 2006 Apr;101(4):873-85. PMID: 16635231

9. Whitlock, E.P., et al. (2008) Screening for Colorectal Cancer: An Updated Systematic Review. Agency for Healthcare Research and Quality (US) Evidence Syntheses, No. 65.1; October 2008. Report No.: 08-05-05124-EF-1. PMID: 20722162

10. Zuber, A.G., et al. (2008) Evaluating Test Strategies for Colorectal Cancer Screening—Age to Begin, Age to Stop, and Timing of Screening Intervals - A Decision Analysis of Colorectal Cancer Screening for the U.S. Preventive Services Task Force from the Cancer Intervention and Surveillance Modeling Network (CISNET). Agency for Healthcare Research and Quality (US) Evidence Syntheses, No. 65.2; March 2009. Report No.: 08-05124-EF-2. PMID: 20722163

11. Schoen, R.E., et al. for the PLCO Project Team (June 21, 2012) Colorectal-Cancer Incidence and Mortality with Screening Flexible Sigmoidoscopy. N Engl J Med 2012; 366:2345-2357.

12. Jacob BJ, et al. (May 31, 2012) Effect of colonoscopy on colorectal cancer incidence and mortality: an instrumental variable analysis. *Gastrointest Endosc.* 2012 [Epub ahead of print]
13. Zauber, A.G., et al. (February 23, 2012) Colonoscopic Polypectomy and Long-Term Prevention of Colorectal Cancer Deaths. *N Engl J Med* 2012; 366(8): 687-696.
14. Healthcare Blue Book: Your free guide to fair healthcare pricing.  
[http://www.healthcarebluebook.com/page\\_Results.aspx?SearchTerms=colonoscopy](http://www.healthcarebluebook.com/page_Results.aspx?SearchTerms=colonoscopy) accessed on 6/25/2012

1b. Opportunity for Improvement: H  M  L  I

(There is a demonstrated performance gap - variability or overall less than optimal performance)

**1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this concept:**

Underuse of colonoscopy for colorectal cancer screening and surveillance is associated with increased morbidity and mortality due to undetected and untreated colorectal cancer. Overuse of colonoscopy for colorectal cancer screening and surveillance is associated with increased morbidity (e.g., bowel perforation, bleeding) and increased costs. Existing measures look at different subsets of surveilled patients to determine if the follow-up interval recommendation was followed. Our measure looks at all patients receiving colonoscopy screening or surveillance exams and determines the appropriateness for that patient, as one part of the composite measure. Combining all components into a patient-level all-or-none composite measure answers the layperson's question: How often did patients receive the best quality colonoscopy? If the use of colonoscopy for screening or surveillance is not appropriate (e.g., patient had a colonoscopy but did not need to have a colonoscopy/overuse of colonoscopy procedure), then it is not the best quality -- but that is just one component of colonoscopy quality. Using the patient as the unit of measure also answers the provider's question: How often did I provide the best care for my patients having a screening or surveillance colonoscopy? The all-or-none composite measure of colonoscopy quality allows both patients and providers to understand the "big picture" and to drill down into the details of the components that make up the colonoscopy quality index to identify areas for improvement. Please refer to Nolan T. and Berwick D. M. (2006) All-or-None Measurement Raises the Bar on Performance. *JAMA* 295(10):1168-1170.

**1b.2 Provide data demonstrating performance gap/opportunity for improvement (Variation or overall less than optimal performance across providers). List citations in 1b.3.**

**For endorsement maintenance, provide performance data on the measure as specified (mean, std dev, distribution of scores by decile, min, max).** Describe who was included in the performance data in 1b.3. Underuse: From 2002 to 2010, the percent of people aged 50-75 years who were adequately screened for colorectal cancer increased from 52.3% to 65.4%, showing that there is underuse of colorectal cancer screening [1]. Colonoscopy is the primary method used in colorectal cancer screening [1]. Overuse: Surveys have demonstrated that a large proportion of endoscopists are conducting surveillance examinations at shorter intervals than recommended in the guidelines [2-3].

Additionally, studies of high-volume European centers found that 21% to 39% of indications were inappropriate [2]. In a US study of 9 hospitals, adequacy of preparation of colonoscopy was noted in only 45% of procedures (range 14.6% to 86.1%) and cecal landmarks were documented in 62.7% of procedures (range 11.6% to 90%)[4]. Quality Quest experience with reporting the Colonoscopy Quality Index has shown an improvement from an overall average of 54.6% in the 3rd quarter of 2009 to 87.0% in the 4th quarter of 2011 [5]. There is wide variation in performance between providers, with some providers at or near 100% [5].

Data on the Colonoscopy Quality Index collected by Quality Quest for Health is provided in the table below. This data is for the 4th quarter of 2011, and it is an analysis of data by physician (N=31 physicians, 2308 colonoscopy exams). Physicians with a volume of under 30 colonoscopies were excluded from analysis. Please note that this information is also available in the supplemental materials attached to this application.

Measure/component	High	Average	Low
Colonoscopy Quality Index	97.5%	87.0%	12.5%
Appropriate Indication	100.0%	94.2%	68.8%
Medical Risk Assessment	100.0%	99.7%	87.5%
Bowel Preparation Assessment	100.0%	98.9%	87.5%
Complete Examination	100.0%	99.5%	94.2%
Photo-documentation of Cecum	100.0%	99.6%	87.5%
Complete Polyp Information	100.0%	99.0%	92.3%
No Serious Complication	100.0%	99.9%	97.8%
Withdrawal Time Recorded	100.0%	99.6%	93.8%
Appropriate Follow-up Recommended	100.0%	93.7%	31.3%

The data above demonstrates how there is still an opportunity for improvement. Although the overall average performance of 87.0% on the colonoscopy quality index is higher than when we began measuring, we still have an opportunity to improve.

Variation between the lowest performing physician at 12.5% on the colonoscopy quality index and the highest performing physician at 97.5% on the colonoscopy quality index demonstrates the performance gap. The data on the individual components by physician indicate the areas with greatest opportunity for improvement. Amongst the components of the colonoscopy quality index, appropriate follow-up recommendations (low of 31.3%) and appropriate indication (low of 68.6%) show the greatest opportunity for improvement.

**1b.3 Citations for Data on Performance Gap provided in 1b.2.**

**For endorsement maintenance, describe who was included in the performance results reported in 1b.2** (*number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include*)

1. CDC Morbidity and Mortality Weekly Report (July 8, 2011) Vital Signs: Colorectal Cancer Screening, Incidence, and Mortality -- United States, 2002-2010. MMWR 60(26): 884-889.
2. Rex DK, et al. (2006) Quality indicators for colonoscopy from ASGE/ACG Taskforce on Quality in Endoscopy. Am J Gastroenterol. 2006 Apr;101(4):873-85. PMID: 16635231
3. Winawer S.J., et al (2006) Guidelines for Colonoscopy Surveillance after Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society. CA Cancer J Clin 56(3): 143-159.
4. Mehrotra, A., et al. (2012) Applying a natural language processing tool to electronic health records to access performance on colonoscopy quality measures. Gastrointestinal Endoscopy Journal. Article in press
5. Supplemental materials attached to this application - results from Quality Quest Colonoscopy Quality Index reporting 3Q2009-4Q2011

**1b.4 Provide data on disparities by population group. List citations in 1b.5.**

**For endorsement maintenance, provide performance data by population group on the measure as specified** (*e.g., mean, std dev*). Describe who was included in the performance data in 1b.5.

not applicable

**1b.5 Citations for Data on Disparities Cited in 1b.4:**

not applicable

**1c. Evidence** (*Concept focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)

Is the concept focus a health outcome? Yes  No  **If not a health outcome, rate the body of evidence.**

Quantity: H  M  L  I  Quality: H  M  L  I  Consistency: H  M  L  I

Quantity	Quality	Consistency	Does the concept pass subcriterion1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the concept pass subcriterion1c?  
Yes  IF rationale supports relationship

*Please see the attached Evidence Submission Worksheet for evidence specifications.*

**Was the concept approval criterion, Importance to Measure and Report, met?**

**(1a & 1b must be rated moderate or high and 1c yes) Yes  No**

**Provide rationale based on specific subcriteria:**

**3. USABILITY**

#### 4.1 Current and Planned Use

Performance results from NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement (in addition to use for performance improvement).

*(Check only the current and planned uses; for any current uses that are checked, provide a URL for the specific program)*

Current Use:

Planned Use:

### 5. COMPARISON TO RELATED AND COMPETING CONCEPTS & MEASURES

5.1 If there are related measures (*either same measure focus or target population*) or competing measures (*both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

0034 : Colorectal Cancer Screening

0572 : Follow-up after initial diagnosis and treatment of colorectal cancer: colonoscopy

0658 : Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients

0659 : Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps- Avoidance of Inappropriate Use

5a.1 If this concept has EITHER the same focus OR the same target population as [NQF-endorsed measure\(s\)](#): Are the specifications completely harmonized?

5a.2 If the specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b.1 If this concept has both the same focus and the same target population as NQF-endorsed measure(s):

Describe why this concept is superior to competing measures (*e.g., a more valid or efficient way to measure quality*); OR provide a rationale for the additive value of endorsing an additional measure. (*Provide analyses when possible*):

This is not a competing measure. Existing measures look at different subsets of surveilled patients to determine if the follow-up interval recommendation was followed. Our measure looks at all patients receiving colonoscopy screening or surveillance exams and determines the appropriateness for that patient, as one part of the composite measure.

Measure #0034 is a population measure - the percentage of members 50-75 years of age who had appropriate screening for colorectal cancer.

Measure #0572 is a population measure of people with cancer - follow-up after initial diagnosis and treatment of colorectal cancer: colonoscopy

Measure #0658 examines the subset of patients undergoing screening colonoscopy who did not have biopsy or polypectomy - endoscopy/poly surveillance: appropriate follow-up interval for normal colonoscopy in average risk patients

Measure #0659 examines the subset of patients undergoing surveillance colonoscopy - endoscopy/poly surveillance: colonoscopy interval for patients with a history of adenoamatous polyps - avoidance of inappropriate use

There are some similarities between the aggregation of measures #0658 and #0659 and the component measure "appropriate indication for colonoscopy" in our measure concept. However, the aggregation of measures #0658 and #0659 is not equivalent to the "appropriate indication for colonoscopy" measure, as our measure makes finer distinctions on follow-up interval recommendations for surveillance when a polyp is found based on the characteristics of adenoma(s)/neoplastia(s) detected previously.

### CONTACT INFORMATION

Co.1 Concept Steward (Intellectual Property Owner): [Quality Quest for Health of Illinois, Inc.](#), 416 Main Street, Suite 717 | Peoria | Illinois | 61602

Co.2 Point of Contact: [Gail | Amundson, M.D.](#) | [gamundson@qualityquest.org](mailto:gamundson@qualityquest.org) | 309-282-8823-

Co.3 Concept Developer if different from Concept Steward: [Quality Quest for Health of Illinois, Inc.](#) | 416 Main Street, Suite 717 | Peoria | Illinois, 61602

Co.4 Point of Contact: [Bonnie | Paris, MSIE, PhD candidate](#) | [bparis@qualityquest.org](mailto:bparis@qualityquest.org) | 309-282-8830-

Co.5 Submitter: [Bonnie | Paris, MSIE, PhD candidate | bparis@qualityquest.org | 309-282-8830- | Quality Quest for Health of Illinois, Inc.](#)

Co.6 Additional organizations that sponsored/participated in concept development:  
[Please refer to colonoscopy team member list in additional information.](#)

Co.7 Public Contact: [Gail | Amundson, M.D. | gamundson@qualityquest.org | 309-282-8823- | Quality Quest for Health of Illinois, Inc.](#)

#### ADDITIONAL INFORMATION

##### Concept Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the concept was first released:

Ad.4 Month and Year of most recent revision:

Ad.5 What is your frequency for review/update of this measure?

Ad.6 When is the next scheduled review/update for this measure?

Ad.7 Copyright statement: [copyright Quality Quest for Health of Illinois, Inc., 2008. All rights reserved.](#)

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (MM/DD/YY): [Jul 16, 2012](#)



**NATIONAL QUALITY FORUM—Evidence (1c) Pilot Submission Form**

**NOTE: TABLE OF CONTENTS & SUMMARY TABLE ADDED TO FACILITATE REVIEW.**

**AS REQUESTED, A SEPARATE FORM HAS BEEN COMPLETED FOR EACH COMPONENT. THE ORIGINAL COMPOSITE FORM IS ALSO INCLUDED TO FACILITATE REVIEW AND TO SHOW THE COMPONENTS IN CONTEXT.**

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Measure/subcomponent	Process?	Outcome?	Evidence
<b>Colonoscopy Quality Index</b>	<b>Yes</b>	<b>Yes</b>	<b>Peer reviewed; logic</b>
<b>1. Appropriate Indication for Colonoscopy</b>		<b>Yes</b>	<b>Peer reviewed</b>
<b>2. Standardized Medical Risk Assessment</b>	<b>Yes</b>		<b>Logic</b>
<b>3. Standardized Assessment of Bowel Prep</b>	<b>Yes</b>		<b>Logic</b>
<b>4. Complete Examination</b>	<b>Yes</b>		<b>Logic</b>
<b>5. Cecal Photo Taken</b>	<b>Yes</b>		<b>Logic</b>
<b>6. All Essential Polyp Information Recorded</b>	<b>Yes</b>		<b>Logic</b>
<b>7. Withdrawal Time was Recorded</b>	<b>Yes</b>		<b>Logic</b>
<b>8. Free of Serious Complications</b>		<b>Yes</b>	<b>Peer reviewed</b>
<b>9. Appropriate Follow-up Recommendation</b>	<b>Yes</b>		<b>Logic</b>

**Measure Title: Colonoscopy Quality Index \*\*\*COMPOSITE\*\*\***

**Date of Submission: [7/16/2012](#)**

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

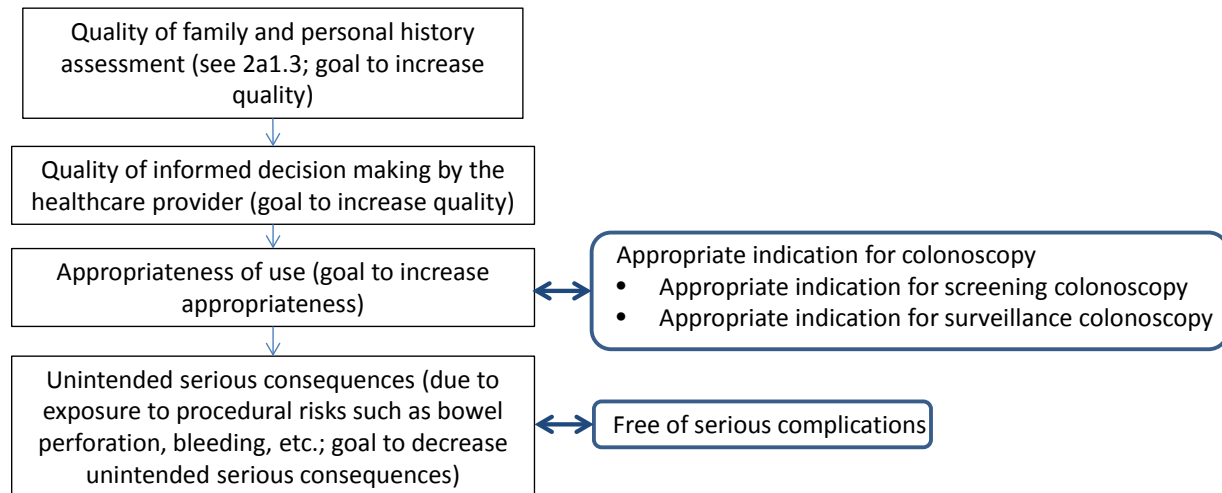
Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** If not a health outcome, skip to 1c.3

If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.

**1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.**



Quality of colonoscopy procedure (process) → Complications from procedure (outcome)

Characteristics of the process include: quality of family and personal history assessment prior to the colonoscopy procedure, quality of informed decision making by the healthcare provider with regard to the colonoscopy procedure, and appropriateness of use of the colonoscopy procedure

Characteristics of the outcome include: free of serious complications; there are no unintended serious consequences from the colonoscopy procedure due to exposure to procedural risks such as bowel perforation, bleeding, etc.

**1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.**

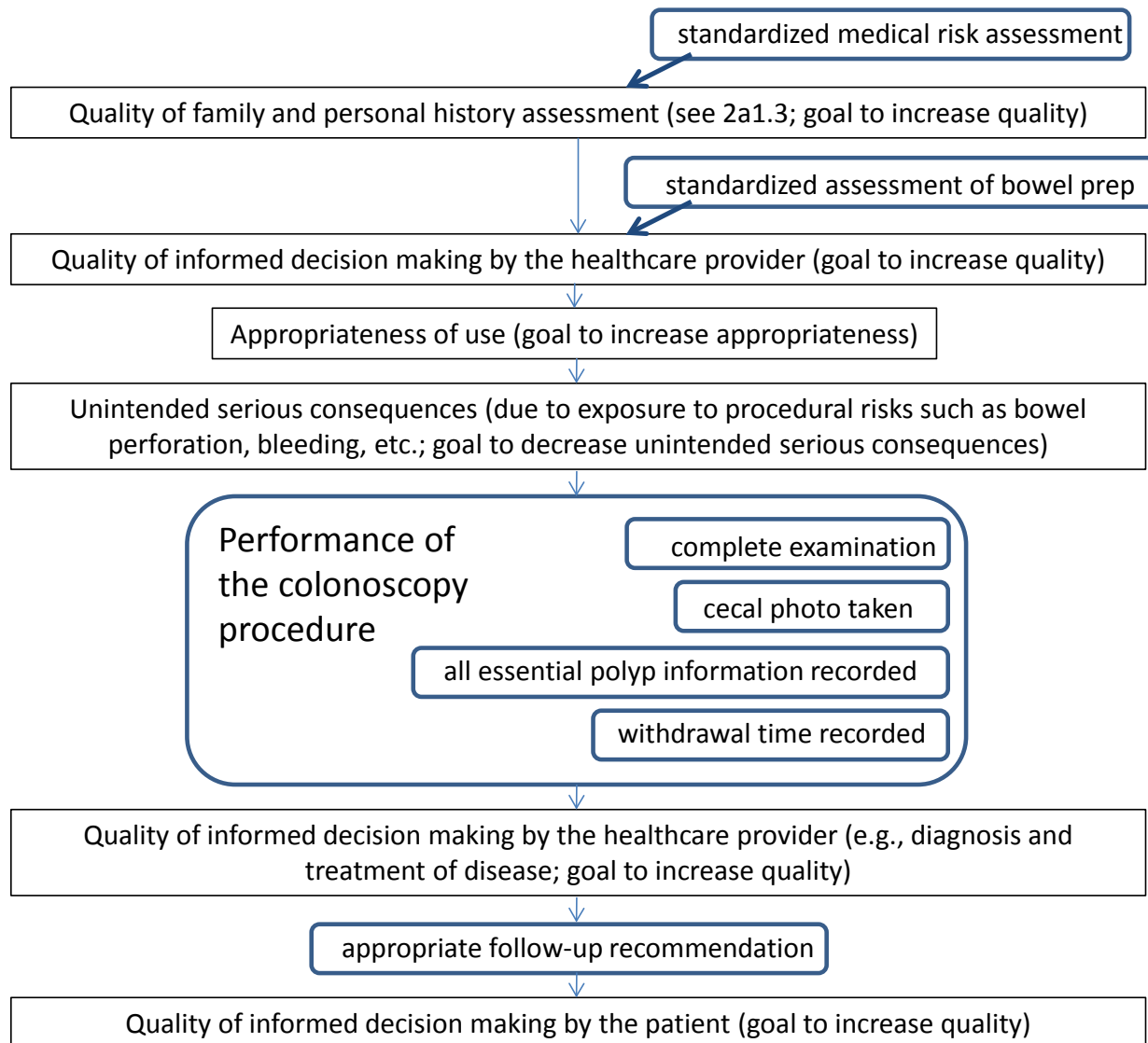
Quality of family and personal history assessment and healthcare provider knowledge of current evidence and recommendations for use of colonoscopy for screening and surveillance affect the appropriateness with which colonoscopy exams are used. Overuse of colonoscopy exams are associated with avoidable patient harm including bowel perforation and bleeding, as well as increased costs.

**Note: For health outcome measures, no further information is required**

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (Do not summarize the evidence here.)**



Appropriate use of colonoscopy examination for screening and surveillance, along with improved quality of the performance of the colonoscopy procedure (e.g., complete exam with cecal photo taken), and appropriate follow-up recommendations will ultimately lead to improved detection and therefore improved treatment of colorectal cancer. In this way, these process measures are expected to have an effect on patient outcomes (reduced morbidity and mortality due to colorectal cancer that is identified and treated; reduced morbidity from overuse of colorectal examination).

MEASURE FOCUS (standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation)

---->

PROCESS CHARACTERISTIC (quality of family and personal history assessment, quality of informed decision making by the healthcare provider, appropriateness of use, unintended serious consequences, performance of the colonoscopy procedure, quality of informed decision making by the healthcare provider, quality of informed decision making by the patient)

----->

DESIRED HEALTH OUTCOME (any cancerous and precancerous polyps of the colon which are present are identified, documented, and acted upon)

**EVIDENCE = LOGICAL ARGUMENT**

The process-based subcomponent measures of the Colonoscopy Quality Index are related to expert consensus [1] and do not require evidence from systematic reviews to support their validity [2].

We recognize that logic is the basis on which science, including modern medicine, is built. In addition to completing the systematic review portion of the evidence form for the process-based subcomponent measures of the Colonoscopy Quality Index, we would like to highlight a straightforward logical argument for each of the process-based subcomponent measures of the Colonoscopy Quality Index.

Proposition: A high quality screening or surveillance colonoscopy is one that is performed A) on a patient that needs the test, B) in a thorough manner, and C) without harming the patient.

Measure/subcomponent	Proposition A	Proposition B	Proposition C
Colonoscopy Quality Index	Yes	Yes	Yes
1. Appropriate Indication for Colonoscopy	Yes		
2. Standardized Medical Risk Assessment		Yes	
3. Standardized Assessment of Bowel Prep		Yes	
4. Complete Examination		Yes	
5. Cecal Photo Taken		Yes	
6. All Essential Polyp Information Recorded		Yes	
7. Withdrawal Time was Recorded		Yes	
8. Free of Serious Complications			Yes
9. Appropriate Follow-up Recommendation		Yes	

**Table: Relationship between Colonoscopy Quality Index and subcomponents and the propositions:**

Proposition A) A high quality screening or surveillance colonoscopy is one that is performed on a patient that needs the test

Proposition B) A high quality screening or surveillance colonoscopy is one that is performed in a thorough manner

Proposition C) A high quality screening or surveillance colonoscopy is one that is performed without harming the patient.

1. Lieberman D., Nadel M., Smith R.A., Atkin W., Duggirala S.B., Fletcher R., Glick S.N., Johnson C.D., Levin T.R., Pope J.B., Potter M.B., Ransohff D., Rex D., Schoen R., Schroy P., Winawer S. (2007) Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. *Gastrointestinal Endoscopy* 65(6): 757-766.

2. Smith G.C.S. and Pell J.P. (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *BMJ*. 327(7429): 1459–1461.

**1c.4.** Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No   
*If no, skip to #1c.6*

*If yes, answer 1c.4.1-1c.5.*

**1c.4.1. Guideline citation (including date):**

Brink D, Barlow J, Bush K, Chaudhary N, Fareed M, Hayes R, Jafri I, Nair K, Retzer K, Rueter K. Institute for Clinical Systems Improvement. Colorectal Cancer Screening. <http://bit.ly/Colorectal0512>. Published May 2012.

Additional corroborating guidelines include:

- American Gastroenterological Association: Winawer, S., et al. (2003) Colorectal Cancer Screening and Surveillance: Clinical Guidelines and Rationale. Gastroenterology. 124:544-560.
- US Preventive Services Task Force (2008) Screening for Colorectal Cancer <http://www.uspreventiveservicestaskforce.org/uspstf08/colocancer/colors.htm> last accessed on 6/22/2012
- Quaseem, A., et al. (2012) Screening for Colorectal Cancer: A Guidance Statement from the American College of Physicians. Ann Intern Med. 156:378-386.

**1c.4.2. URL (if available**

**online):** [http://www.icsi.org/colorectal\\_cancer\\_screening/colorectal\\_cancer\\_screening\\_5.html](http://www.icsi.org/colorectal_cancer_screening/colorectal_cancer_screening_5.html)

**1c.4.3. Identify guideline number and/or page number:** Pg 1 – Screening algorithm; refer to entire guideline cited above

**1c.4.4. Quote verbatim, the specific guideline recommendation:**

**Does the Patient Meet Criteria for Increased Risk?**

Risk Category	Recommendation
One first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years	Colonoscopy every five years beginning at age 40 or 10 years before the age of the youngest case in the immediate family
Two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps	Colonoscopy every five years beginning at age 40 or 10 years before the age of the youngest case in the immediate family
First-degree relative with either colorectal cancer or adenomatous polyps at greater than or equal to 60 years, or two second-degree relatives with colorectal cancer	The work group recognizes this imposes an increased risk; however, due to lack of evidence supporting the screening recommendations, the work group does not support a recommendation in this category
Inflammatory bowel disease, chronic ulcerative colitis and Crohn's disease	Colonoscopy every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis
Genetic diagnosis of familial adenomatous polyposis (FAP) or suspected FAP without genetic testing evidence	Annual flexible sigmoidoscopy beginning at age 10 to 12 years, along with genetic counseling
Genetic or clinical diagnosis of hereditary nonpolyposis colorectal cancer	Colonoscopy every one to two years beginning at age 20 to 25 years or 10 years before the age of the youngest case in the immediate family

\* First-order relatives include only parents, siblings and children.

(Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003)

From page 8 of ICSI guideline



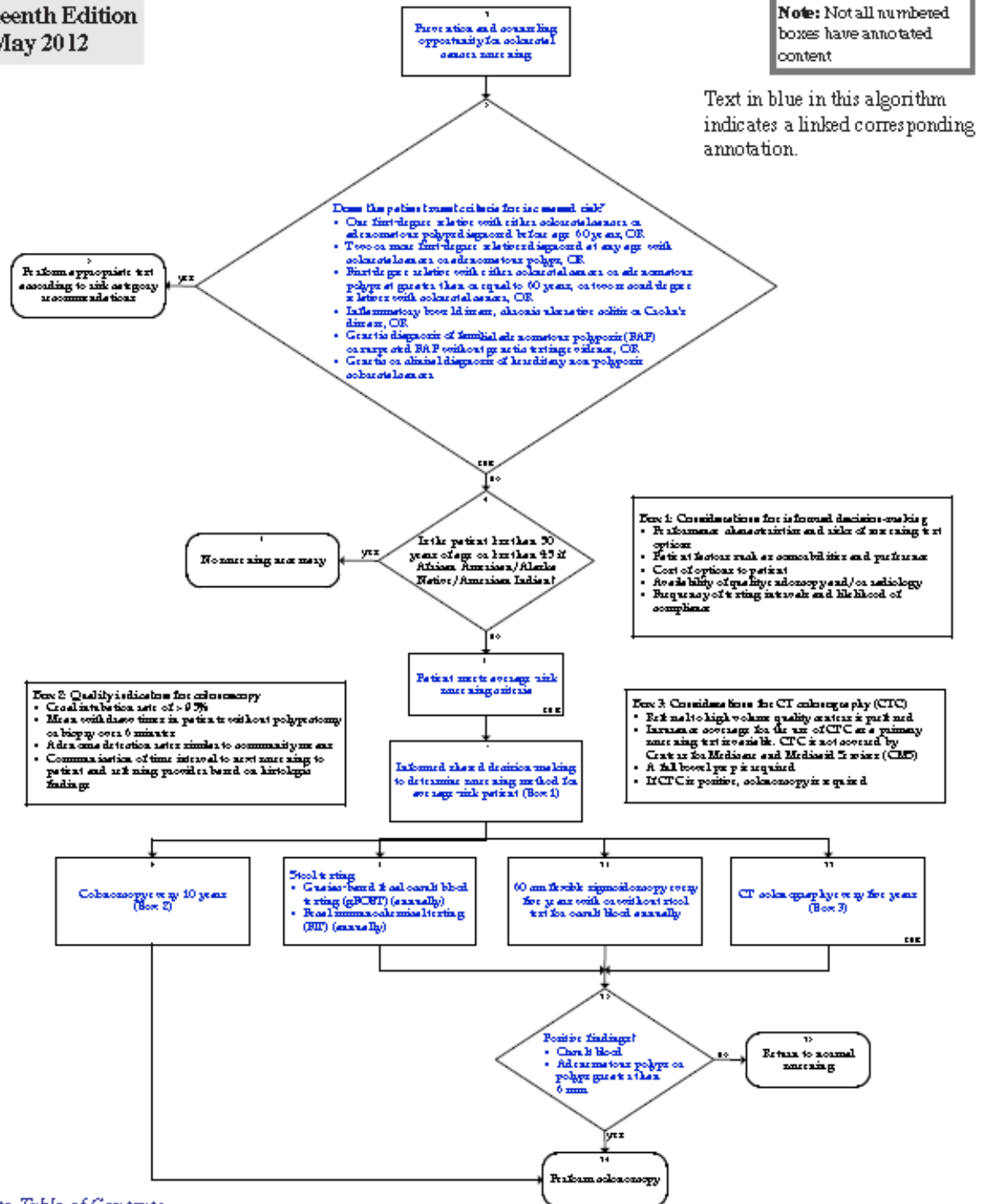
# Health Care Guideline: Colorectal Cancer Screening

INSTITUTE FOR CLINICAL  
SYSTEMS IMPROVEMENT

Fourteenth Edition  
May 2012

## Screening Algorithm

EER = Evidence-based recommendation included  
**Note:** Not all numbered boxes have annotated content



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**1c.4.5. Grade assigned to the recommendation with definition of the grade:**

**Literature Search**

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 2010 through November 2011.

The Cochrane and Pub Med databases were searched. The search was limited to screening tests only and did not include diagnostic testing. The search terms included fecal immunochemical test, colonoscopy, fecal occult blood test, flexible sigmoidoscopy and CT colonography.

**GRADE Methodology**

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international guideline developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

In the GRADE process, evidence is gathered related to a specific question. Systematic reviews are utilized first. Further literature is incorporated with randomized control trials or observational studies. The evidence addresses the same population, intervention, comparisons and outcomes. The overall body of evidence for each topic is then given a quality rating.

Once the quality of the evidence has been determined, recommendations are formulated to reflect their strength. The strength of a recommendation is either strong or weak. Only outcomes that are critical are considered the primary factors influencing a recommendation and are used to determine the overall strength of this recommendation. Each recommendation answers a focused health care question.

From page 3 of ICSI guideline



**Recommendations Table**

The following table is a list of evidence-based recommendations for the Colorectal Cancer Screening guideline.

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

Topic	Quality of Evidence	Recommendation(s)	Strength of Recommendation	Annotation Number	Relevant References
Average risk screening	High	Colorectal cancer screening is recommended for all patients 50 years of age and older – age 45 and older for African Americans or American Indians/Alaska Natives – using one of the following methods, based on joint decision-making by patient and clinician: <ul style="list-style-type: none"> <li>• Guaiac-based fecal occult blood testing (gFOBT) annually, OR</li> <li>• Fecal immunochemical testing (FIT) annually, OR</li> <li>• 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR</li> <li>• Colonoscopy every 10 years</li> </ul>	Strong	6	( <i>Perdue, 2008; U.S. Preventive Services Task Force, 2008; Agrawal, 2005; Winawer, 2003; Fuch, 1994</i> )
CT colonography	Low	CT colonography may be an option for colorectal cancer screening in the following clinical situations: after incomplete screening or diagnostic colonoscopy, for anticoagulated patients who cannot safely discontinue anticoagulation therapy.	Weak	11	( <i>Smith-Bindman 2009; Johnson, 2008; Levin, 2008; Soetikno, 2008; Cotton, 2004; Pickhardt, 2003</i> )
Increased risk screening	High	Colonoscopy should be offered at age 40 or 10 years before the age of the youngest case in the immediate family for the following individuals: <ul style="list-style-type: none"> <li>• Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years</li> <li>• Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps.</li> </ul> <p>Colonoscopy should be offered every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis.</p> <p>Colonoscopy should be offered every one to two years beginning at age 20 to 25 years, or 10 years before the age of the youngest case in the immediate family of genetic or clinical diagnosis of hereditary non-polyposis colorectal cancer.</p>	Strong	2	( <i>Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003</i> )

From page 5 of ICSI guideline

**1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation?** Yes  No  ***If no, skip to #1c.6***

*If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)*

**1c.5.1. Grade assigned to the body of evidence with definition of the grade:**

*Colorectal Cancer Screening  
Fourteenth Edition/May 2012*

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## **Evidence Grading**

### **Literature Search**

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 2010 through November 2011.

The Cochrane and Pub Med databases were searched. The search was limited to screening tests only and did not include diagnostic testing. The search terms included fecal immunochemical test, colonoscopy, fecal occult blood test, flexible sigmoidoscopy and CT colonography.

From page 3 of ICSI guideline

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
<b>High Quality Evidence</b>	Further research is very unlikely to change our confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
<b>Moderate Quality Evidence</b>	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
<b>Low Quality Evidence</b>	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

### Supporting Literature

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature are used to direct the reader to other topics of interest. This literature is not given an evidence grade and is instead used as a reference for its associated topic. These citations are noted by (*author, year*) and are found in the references section of this document.

From page 4 of ICSI guideline

**Recommendations Table**

The following table is a list of evidence-based recommendations for the Colorectal Cancer Screening guideline.

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

Topic	Quality of Evidence	Recommendation(s)	Strength of Recommendation	Annotation Number	Relevant References
Average risk screening	High	Colorectal cancer screening is recommended for all patients 50 years of age and older – age 45 and older for African Americans or American Indians/Alaska Natives – using one of the following methods, based on joint decision-making by patient and clinician: <ul style="list-style-type: none"> <li>• Guaiac-based fecal occult blood testing (gFOBT) annually, OR</li> <li>• Fecal immunochemical testing (FIT) annually, OR</li> <li>• 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR</li> <li>• Colonoscopy every 10 years</li> </ul>	Strong	6	( <i>Perdue, 2008; U.S. Preventive Services Task Force, 2008; Agrawal, 2005; Winawer, 2003; Fuch, 1994</i> )
CT colonography	Low	CT colonography may be an option for colorectal cancer screening in the following clinical situations: after incomplete screening or diagnostic colonoscopy, for anticoagulated patients who cannot safely discontinue anticoagulation therapy.	Weak	11	( <i>Smith-Bindman 2009; Johnson, 2008; Levin, 2008; Soetikno, 2008; Cotton, 2004; Pickhardt, 2003</i> )
Increased risk screening	High	Colonoscopy should be offered at age 40 or 10 years before the age of the youngest case in the immediate family for the following individuals: <ul style="list-style-type: none"> <li>• Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years</li> <li>• Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps.</li> </ul> Colonoscopy should be offered every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis.  Colonoscopy should be offered every one to two years beginning at age 20 to 25 years, or 10 years before the age of the youngest case in the immediate family of genetic or clinical diagnosis of hereditary non-polyposis colorectal cancer.	Strong	2	( <i>Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003</i> )

From page 5 of ISCI guideline

**1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)**

Yes  No  **If no, skip to #1c.7**

*If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)*

**1c.6.1. Citation (including date):**

Pignone, M., et al. (2002) Screening for Colorectal Cancer in Adults at Average Risk: A Summary of the Evidence for the U.S. Preventive Services Task Force. Archives of Internal Medicine 137(2): 132-141.

Rex DK, et al. (2006) Quality indicators for colonoscopy from ASGE/ACG Taskforce on Quality in Endoscopy. Am J Gastroenterol. 2006 Apr;101(4):873-85. PMID: 16635231

Whitlock, E.P., et al. (2008) Screening for Colorectal Cancer: An Updated Systematic Review. Agency for Healthcare Research and Quality (US) Evidence Syntheses, No. 65.1; October 2008. Report No.: 08-05-05124-EF-1. PMID: 20722162

Winawer, S., et al. (2003) American Gastroenterological Association: Colorectal Cancer Screening and Surveillance: Clinical Guidelines and Rationale. Gastroenterology. 124:544-560.

Zauber, A.G., et al. (2008) Evaluating Test Strategies for Colorectal Cancer Screening—Age to Begin, Age to Stop, and Timing of Screening Intervals - A Decision Analysis of Colorectal Cancer Screening for the U.S. Preventive Services Task Force from the Cancer Intervention and Surveillance Modeling Network (CISNET). Agency for Healthcare Research and Quality (US) Evidence Syntheses, No. 65.2; March 2009. Report No.: 08-05124-EF-2. PMID: 20722163

**1c.6.2. URL (if available online):**

**1c.6.3. Grade assigned to the body of evidence with definition of the grade:**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

**If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8**

**1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No**

*If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)*

**1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?**

**1c.7.2. Grade assigned to the body of evidence with definition of the grade:**

**1c.7.3. Describe the process used for the systematic review:**

**If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.**

## FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

*(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)*

**1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: 2002-2012:** Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

## QUANTITY AND QUALITY OF BODY OF EVIDENCE

**1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

**1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

## ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

**1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

**1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

## UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

**1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  **If no, stop****

If yes,

**1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.**

**Schoen, R.E., et al. for the PLCO Project Team (June 21, 2012) Colorectal-Cancer Incidence and Mortality with Screening Flexible Sigmoidoscopy. N Engl J Med 2012; 366:2345-2357.**

<http://www.nejm.org/doi/full/10.1056/NEJMoa1114635>

Evaluated the effect of screening with flexible sigmoidoscopy on colorectal-cancer incidence and mortality. From 1993 through 2001, the PLCO Project Team randomly assigned 154,900 men and women 55 to 74 years of age either to screening with flexible sigmoidoscopy, with a repeat screening at 3 or 5 years, or to usual care. Cases of colorectal cancer and deaths from the disease were ascertained.

Results: Of the 77,445 participants randomly assigned to screening (intervention group), 83.5% underwent baseline flexible sigmoidoscopy and 54.0% were screened at 3 or 5 years. The incidence of colorectal cancer after a median follow-up of 11.9 years was 11.9 cases per 10,000 person-years in the intervention group (1012 cases), as compared with 15.2 cases per 10,000 person-years in the usual-care group (1287 cases), which represents a 21% reduction (relative risk, 0.79; 95% confidence interval [CI], 0.72 to 0.85;  $P<0.001$ ). Significant reductions were observed in the incidence of both distal colorectal cancer (479 cases in the intervention group vs. 669 cases in the usual-care group; relative risk, 0.71; 95% CI, 0.64 to 0.80;  $P<0.001$ ) and proximal colorectal cancer (512 cases vs. 595 cases; relative risk, 0.86; 95% CI, 0.76 to 0.97;  $P=0.01$ ). There were 2.9 deaths from colorectal cancer per 10,000 person-years in the intervention group (252 deaths), as compared with 3.9 per 10,000 person-years in the usual-care group (341 deaths), which represents a 26% reduction (relative risk, 0.74; 95% CI, 0.63 to 0.87;  $P<0.001$ ). Mortality from distal colorectal cancer was reduced by 50% (87 deaths in the intervention group vs. 175 in the usual-care group; relative risk, 0.50; 95% CI, 0.38 to 0.64;  $P<0.001$ ); mortality from proximal colorectal cancer was unaffected (143 and 147 deaths, respectively; relative risk, 0.97; 95% CI, 0.77 to 1.22;  $P=0.81$ ).

Conclusions: Screening with flexible sigmoidoscopy was associated with a significant decrease in colorectal-cancer incidence (in both the distal and proximal colon) and mortality (distal colon only). (Funded by the National Cancer Institute; PLCO ClinicalTrials.gov number, NCT00002540.)

Impact on conclusions of systematic review: Additional knowledge supports current recommendations

**Jacob BJ, et al. (May 31, 2012) Effect of colonoscopy on colorectal cancer incidence and mortality: an instrumental variable analysis. *Gastrointest Endosc.* 2012 [Epub ahead of print]**

[http://www.giejournal.org/article/S0016-5107\(12\)00532-9/abstract](http://www.giejournal.org/article/S0016-5107(12)00532-9/abstract)

Using population-based health services information to estimate the effectiveness of colonoscopy on colorectal cancer (CRC) outcomes is prone to selection bias. Performed a population-based retrospective cohort study using Ontario provincial health data to determine the effect of colonoscopy on CRC incidence and mortality. This study involved average-risk persons aged 50 to 74 years from 1996 to 2000 who were alive and free of CRC on January 1, 2001.

Results: The study cohort contained 1,089,998 persons, 7.9% of whom had undergone a colonoscopy between 1996 and 2000. Using primary care physician rate of discretionary colonoscopy as an instrumental variable, the receipt of colonoscopy was associated with a 0.60% (95% confidence interval [CI], 0.31%-0.78%) absolute reduction in the 7-year colorectal cancer incidence and a 0.17% (95% CI, 0.14%-0.21%) absolute reduction in the 5-year risk of death caused by CRC. This corresponds to a 48% relative decrease in CRC incidence (risk ratio [RR] 0.52; 95% CI, 0.34-0.76) and 81% decrease in mortality caused by CRC (RR 0.19, 95% CI, 0.07-0.47). In subgroup analyses, the reduction in the risk of death due to CRC was larger in women than men. The reduction in CRC incidence was larger for complete colonoscopies and for left-sided cancers.

Conclusions: Increased use of colonoscopy procedures is associated with a reduction in the incidence and mortality of CRC in the population studied

Impact on conclusions of systematic review: Additional knowledge supports current recommendations



**Zauber, A.G., et al. (February 23, 2012) Colonoscopic Polypectomy and Long-Term Prevention of Colorectal Cancer Deaths. *N Engl J Med* 2012; 366(8): 687-696.**

<http://www.nejm.org/doi/full/10.1056/NEJMoa1100370>

In the National Polyp Study (NPS), colorectal cancer was prevented by colonoscopic removal of adenomatous polyps. They evaluated the long-term effect of colonoscopic polypectomy in a study on mortality from colorectal cancer. Analysis included all patients prospectively referred for initial colonoscopy (between 1980 and 1990) at NPS clinical centers who had polyps (adenomas and nonadenomas). The National Death Index was used to identify deaths and to determine the cause of death; follow-up time was as long as 23 years. Mortality from colorectal cancer among patients with adenomas removed was compared with the expected incidence-based mortality from colorectal cancer in the general population, as estimated from the Surveillance Epidemiology and End Results (SEER) Program, and with the observed mortality from colorectal cancer among patients with nonadenomatous polyps (internal control group).

Results: Among 2602 patients who had adenomas removed during participation in the study, after a median of 15.8 years, 1246 patients had died from any cause and 12 had died from colorectal cancer. Given an estimated 25.4 expected deaths from colorectal cancer in the general population, the standardized incidence-based mortality ratio was 0.47 (95% confidence interval [CI], 0.26 to 0.80) with colonoscopic polypectomy, suggesting a 53% reduction in mortality. Mortality from colorectal cancer was similar among patients with adenomas and those with nonadenomatous polyps during the first 10 years after polypectomy (relative risk, 1.2; 95% CI, 0.1 to 10.6).

Conclusions: These findings support the hypothesis that colonoscopic removal of adenomatous polyps prevents death from colorectal cancer. (Funded by the National Cancer Institute and others.).

Impact on conclusions of systematic review: Additional knowledge supports current recommendations

**Measure Title: 1. Appropriate Indication for Colonoscopy**

**Date of Submission:** [7/16/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

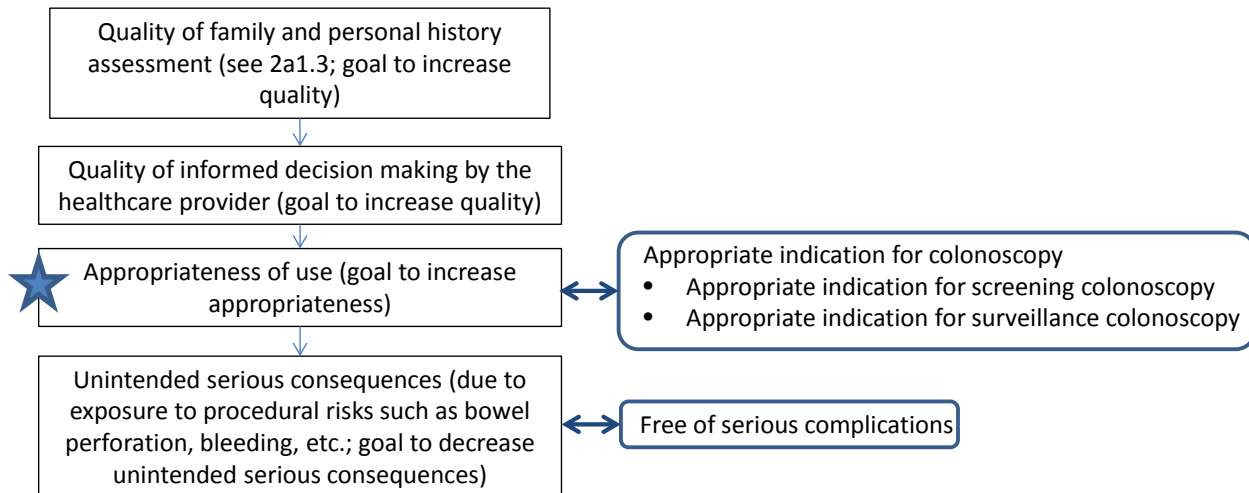
Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** If not a health outcome, skip to 1c.3

If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.

**1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.**



Quality of colonoscopy procedure (process) → Complications from procedure (outcome)

Characteristics of the process include: quality of family and personal history assessment prior to the colonoscopy procedure, quality of informed decision making by the healthcare provider with regard to the colonoscopy procedure, and appropriateness of use of the colonoscopy procedure

Characteristics of the outcome include: free of serious complications; there are no unintended serious consequences from the colonoscopy procedure due to exposure to procedural risks such as bowel perforation, bleeding, etc.

**1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.**

Quality of family and personal history assessment and healthcare provider knowledge of current evidence and recommendations for use of colonoscopy for screening and surveillance affect the appropriateness with which colonoscopy exams are used. Overuse of colonoscopy exams are associated with avoidable patient harm including bowel perforation and bleeding, as well as increased costs.

**Note: For health outcome measures, no further information is required**

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (Do not summarize the evidence here.)**

**1c.4.** Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No   
**If no, skip to #1c.6**

*If yes, answer 1c.4.1-1c.5.*

**1c.4.1. Guideline citation (including date):**

Brink D, Barlow J, Bush K, Chaudhary N, Fareed M, Hayes R, Jafri I, Nair K, Retzer K, Rueter K. Institute for Clinical Systems Improvement. Colorectal Cancer Screening. <http://bit.ly/Colorectal0512>. Published May 2012.

Additional corroborating guidelines include:

- American Gastroenterological Association: Winawer, S., et al. (2003) Colorectal Cancer Screening and Surveillance: Clinical Guidelines and Rationale. *Gastroenterology*. 124:544-560.
- US Preventive Services Task Force (2008) Screening for Colorectal Cancer <http://www.uspreventiveservicestaskforce.org/uspstf08/colocancer/colors.htm> last accessed on 6/22/2012
- Quaseem, A., et al. (2012) Screening for Colorectal Cancer: A Guidance Statement from the American College of Physicians. *Ann Intern Med*. 156:378-386.

**1c.4.2. URL (if available online):** [http://www.icsi.org/colorectal\\_cancer\\_screening/colorectal\\_cancer\\_screening\\_5.html](http://www.icsi.org/colorectal_cancer_screening/colorectal_cancer_screening_5.html)

**1c.4.3. Identify guideline number and/or page number:** Pg 1 – Screening algorithm; refer to entire guideline cited above

**1c.4.4. Quote verbatim, the specific guideline recommendation:**

**Does the Patient Meet Criteria for Increased Risk?**

<b>Risk Category</b>	<b>Recommendation</b>
One first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years	Colonoscopy every five years beginning at age 40 or 10 years before the age of the youngest case in the immediate family
Two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps	Colonoscopy every five years beginning at age 40 or 10 years before the age of the youngest case in the immediate family
First-degree relative with either colorectal cancer or adenomatous polyps at greater than or equal to 60 years, or two second-degree relatives with colorectal cancer	The work group recognizes this imposes an increased risk; however, due to lack of evidence supporting the screening recommendations, the work group does not support a recommendation in this category
Inflammatory bowel disease, chronic ulcerative colitis and Crohn's disease	Colonoscopy every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis
Genetic diagnosis of familial adenomatous polyposis (FAP) or suspected FAP without genetic testing evidence	Annual flexible sigmoidoscopy beginning at age 10 to 12 years, along with genetic counseling
Genetic or clinical diagnosis of hereditary nonpolyposis colorectal cancer	Colonoscopy every one to two years beginning at age 20 to 25 years or 10 years before the age of the youngest case in the immediate family

\* First-order relatives include only parents, siblings and children.

*(Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003)*

From page 8 of ICSI guideline



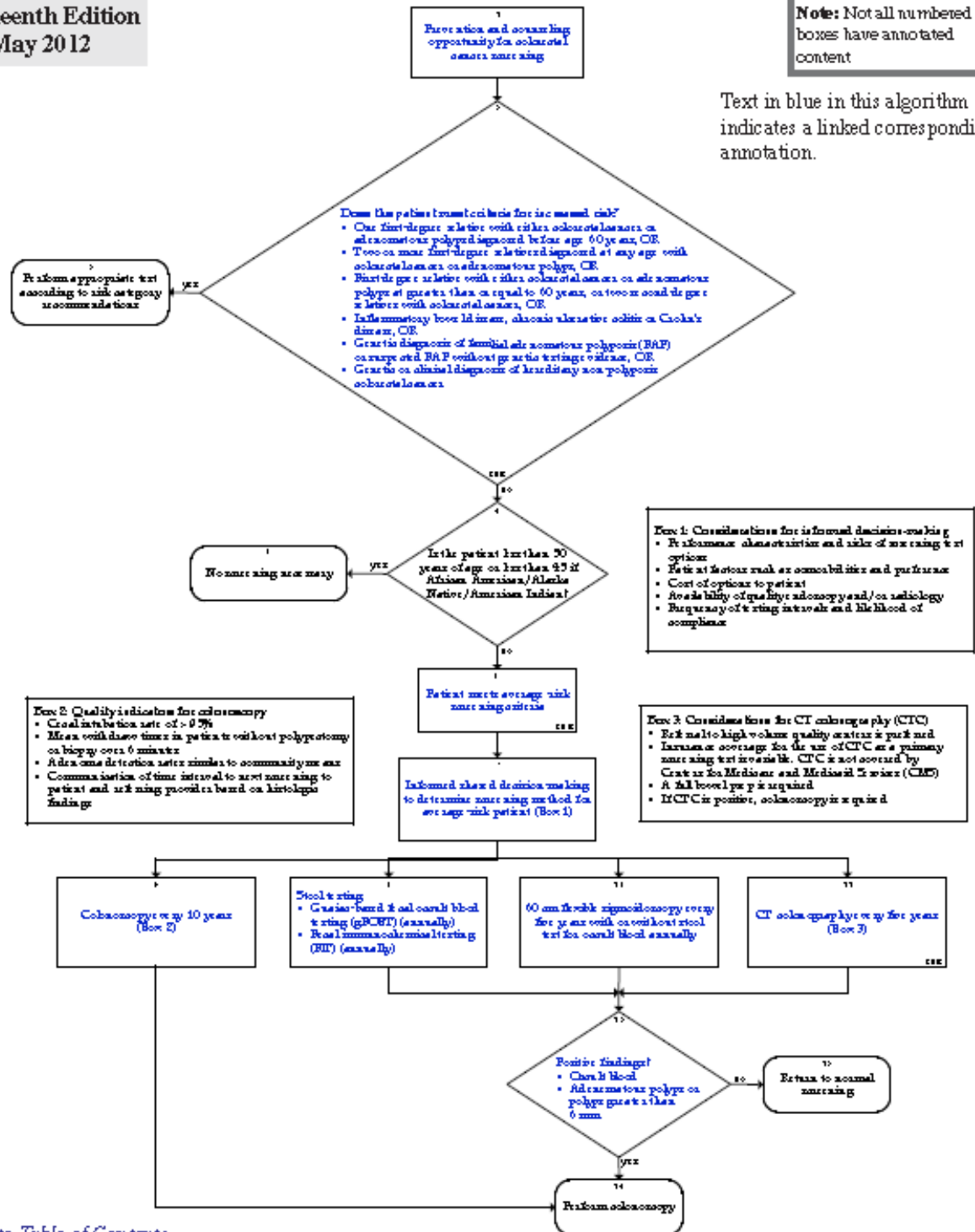
# Health Care Guideline: Colorectal Cancer Screening

INSTITUTE FOR CLINICAL  
SYSTEMS IMPROVEMENT

Fourteenth Edition  
May 2012

## Screening Algorithm

EER = Evidence-based recommendation included  
**Note:** Not all numbered boxes have annotated content



[Return to Table of Contents](#)

**1c.4.5. Grade assigned to the recommendation with definition of the grade:**

**Literature Search**

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 2010 through November 2011.

The Cochrane and Pub Med databases were searched. The search was limited to screening tests only and did not include diagnostic testing. The search terms included fecal immunochemical test, colonoscopy, fecal occult blood test, flexible sigmoidoscopy and CT colonography.

**GRADE Methodology**

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international guideline developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

In the GRADE process, evidence is gathered related to a specific question. Systematic reviews are utilized first. Further literature is incorporated with randomized control trials or observational studies. The evidence addresses the same population, intervention, comparisons and outcomes. The overall body of evidence for each topic is then given a quality rating.

Once the quality of the evidence has been determined, recommendations are formulated to reflect their strength. The strength of a recommendation is either strong or weak. Only outcomes that are critical are considered the primary factors influencing a recommendation and are used to determine the overall strength of this recommendation. Each recommendation answers a focused health care question.

From page 3 of ICSI guideline

**Recommendations Table**

The following table is a list of evidence-based recommendations for the Colorectal Cancer Screening guideline.

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

Topic	Quality of Evidence	Recommendation(s)	Strength of Recommendation	Annotation Number	Relevant References
Average risk screening	High	Colorectal cancer screening is recommended for all patients 50 years of age and older – age 45 and older for African Americans or American Indians/Alaska Natives – using one of the following methods, based on joint decision-making by patient and clinician: <ul style="list-style-type: none"> <li>• Guaiac-based fecal occult blood testing (gFOBT) annually, OR</li> <li>• Fecal immunochemical testing (FIT) annually, OR</li> <li>• 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR</li> <li>• Colonoscopy every 10 years</li> </ul>	Strong	6	( <i>Perdue, 2008; U.S. Preventive Services Task Force, 2008; Agrawal, 2005; Winawer, 2003; Fuch, 1994</i> )
CT colonography	Low	CT colonography may be an option for colorectal cancer screening in the following clinical situations: after incomplete screening or diagnostic colonoscopy, for anticoagulated patients who cannot safely discontinue anticoagulation therapy.	Weak	11	( <i>Smith-Bindman 2009; Johnson, 2008; Levin, 2008; Soetikno, 2008; Cotton, 2004; Pickhardt, 2003</i> )
Increased risk screening	High	Colonoscopy should be offered at age 40 or 10 years before the age of the youngest case in the immediate family for the following individuals: <ul style="list-style-type: none"> <li>• Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years</li> <li>• Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps.</li> </ul> <p>Colonoscopy should be offered every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis.</p> <p>Colonoscopy should be offered every one to two years beginning at age 20 to 25 years, or 10 years before the age of the youngest case in the immediate family of genetic or clinical diagnosis of hereditary non-polyposis colorectal cancer.</p>	Strong	2	( <i>Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003</i> )

From page 5 of ICSI guideline

**1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation?** Yes  No  ***If no, skip to #1c.6***

*If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)*

**1c.5.1. Grade assigned to the body of evidence with definition of the grade:**

*Colorectal Cancer Screening  
Fourteenth Edition/May 2012*

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## **Evidence Grading**

### **Literature Search**

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 2010 through November 2011.

The Cochrane and Pub Med databases were searched. The search was limited to screening tests only and did not include diagnostic testing. The search terms included fecal immunochemical test, colonoscopy, fecal occult blood test, flexible sigmoidoscopy and CT colonography.

From page 3 of ICSI guideline



Category	Quality Definitions	Strong Recommendation	Weak Recommendation
<b>High Quality Evidence</b>	Further research is very unlikely to change our confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
<b>Moderate Quality Evidence</b>	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
<b>Low Quality Evidence</b>	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

**Supporting Literature**

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature are used to direct the reader to other topics of interest. This literature is not given an evidence grade and is instead used as a reference for its associated topic. These citations are noted by (*author, year*) and are found in the references section of this document.

From page 4 of ICSI guideline

**Recommendations Table**

The following table is a list of evidence-based recommendations for the Colorectal Cancer Screening guideline.

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

Topic	Quality of Evidence	Recommendation(s)	Strength of Recommendation	Annotation Number	Relevant References
Average risk screening	High	Colorectal cancer screening is recommended for all patients 50 years of age and older – age 45 and older for African Americans or American Indians/Alaska Natives – using one of the following methods, based on joint decision-making by patient and clinician: <ul style="list-style-type: none"> <li>• Guaiac-based fecal occult blood testing (gFOBT) annually, OR</li> <li>• Fecal immunochemical testing (FIT) annually, OR</li> <li>• 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR</li> <li>• Colonoscopy every 10 years</li> </ul>	Strong	6	( <i>Perdue, 2008; U.S. Preventive Services Task Force, 2008; Agrawal, 2005; Winawer, 2003; Fuch, 1994</i> )
CT colonography	Low	CT colonography may be an option for colorectal cancer screening in the following clinical situations: after incomplete screening or diagnostic colonoscopy, for anticoagulated patients who cannot safely discontinue anticoagulation therapy.	Weak	11	( <i>Smith-Bindman 2009; Johnson, 2008; Levin, 2008; Soetikno, 2008; Cotton, 2004; Pickhardt, 2003</i> )
Increased risk screening	High	Colonoscopy should be offered at age 40 or 10 years before the age of the youngest case in the immediate family for the following individuals: <ul style="list-style-type: none"> <li>• Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years</li> <li>• Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps.</li> </ul> <p>Colonoscopy should be offered every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis.</p> <p>Colonoscopy should be offered every one to two years beginning at age 20 to 25 years, or 10 years before the age of the youngest case in the immediate family of genetic or clinical diagnosis of hereditary non-polyposis colorectal cancer.</p>	Strong	2	( <i>Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003</i> )

From page 5 of ISCI guideline

**1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)**

Yes  No  **If no, skip to #1c.7**

*If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)*

**1c.6.1. Citation (including date):**

Pignone, M., et al. (2002) Screening for Colorectal Cancer in Adults at Average Risk: A Summary of the Evidence for the U.S. Preventive Services Task Force. Archives of Internal Medicine 137(2): 132-141.

Rex DK, et al. (2006) Quality indicators for colonoscopy from ASGE/ACG Taskforce on Quality in Endoscopy. Am J Gastroenterol. 2006 Apr;101(4):873-85. PMID: 16635231

Whitlock, E.P., et al. (2008) Screening for Colorectal Cancer: An Updated Systematic Review. Agency for Healthcare Research and Quality (US) Evidence Syntheses, No. 65.1; October 2008. Report No.: 08-05-05124-EF-1. PMID: 20722162

Winawer, S., et al. (2003) American Gastroenterological Association: Colorectal Cancer Screening and Surveillance: Clinical Guidelines and Rationale. Gastroenterology. 124:544-560.

Zauber, A.G., et al. (2008) Evaluating Test Strategies for Colorectal Cancer Screening—Age to Begin, Age to Stop, and Timing of Screening Intervals - A Decision Analysis of Colorectal Cancer Screening for the U.S. Preventive Services Task Force from the Cancer Intervention and Surveillance Modeling Network (CISNET). Agency for Healthcare Research and Quality (US) Evidence Syntheses, No. 65.2; March 2009. Report No.: 08-05124-EF-2. PMID: 20722163

**1c.6.2. URL (if available online):**

**1c.6.3. Grade assigned to the body of evidence with definition of the grade:**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

**If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8**

**1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No**

*If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)*

**1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?**

**1c.7.2. Grade assigned to the body of evidence with definition of the grade:**

**1c.7.3. Describe the process used for the systematic review:**

**If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.**

## FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

*(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)*

**1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: 2002-2012:** Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

## QUANTITY AND QUALITY OF BODY OF EVIDENCE

**1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

**1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

## ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

**1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

**1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

## UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

**1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  **If no, stop****

If yes,

**1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.**

**Schoen, R.E., et al. for the PLCO Project Team (June 21, 2012) Colorectal-Cancer Incidence and Mortality with Screening Flexible Sigmoidoscopy. N Engl J Med 2012; 366:2345-2357.**

<http://www.nejm.org/doi/full/10.1056/NEJMoa1114635>

Evaluated the effect of screening with flexible sigmoidoscopy on colorectal-cancer incidence and mortality. From 1993 through 2001, the PLCO Project Team randomly assigned 154,900 men and women 55 to 74 years of age either to screening with flexible sigmoidoscopy, with a repeat screening at 3 or 5 years, or to usual care. Cases of colorectal cancer and deaths from the disease were ascertained.

Results: Of the 77,445 participants randomly assigned to screening (intervention group), 83.5% underwent baseline flexible sigmoidoscopy and 54.0% were screened at 3 or 5 years. The incidence of colorectal cancer after a median follow-up of 11.9 years was 11.9 cases per 10,000 person-years in the intervention group (1012 cases), as compared with 15.2 cases per 10,000 person-years in the usual-care group (1287 cases), which represents a 21% reduction (relative risk, 0.79; 95% confidence interval [CI], 0.72 to 0.85;  $P<0.001$ ). Significant reductions were observed in the incidence of both distal colorectal cancer (479 cases in the intervention group vs. 669 cases in the usual-care group; relative risk, 0.71; 95% CI, 0.64 to 0.80;  $P<0.001$ ) and proximal colorectal cancer (512 cases vs. 595 cases; relative risk, 0.86; 95% CI, 0.76 to 0.97;  $P=0.01$ ). There were 2.9 deaths from colorectal cancer per 10,000 person-years in the intervention group (252 deaths), as compared with 3.9 per 10,000 person-years in the usual-care group (341 deaths), which represents a 26% reduction (relative risk, 0.74; 95% CI, 0.63 to 0.87;  $P<0.001$ ). Mortality from distal colorectal cancer was reduced by 50% (87 deaths in the intervention group vs. 175 in the usual-care group; relative risk, 0.50; 95% CI, 0.38 to 0.64;  $P<0.001$ ); mortality from proximal colorectal cancer was unaffected (143 and 147 deaths, respectively; relative risk, 0.97; 95% CI, 0.77 to 1.22;  $P=0.81$ ).

Conclusions: Screening with flexible sigmoidoscopy was associated with a significant decrease in colorectal-cancer incidence (in both the distal and proximal colon) and mortality (distal colon only). (Funded by the National Cancer Institute; PLCO ClinicalTrials.gov number, NCT00002540.)

Impact on conclusions of systematic review: Additional knowledge supports current recommendations

**Jacob BJ, et al. (May 31, 2012) Effect of colonoscopy on colorectal cancer incidence and mortality: an instrumental variable analysis. *Gastrointest Endosc.* 2012 [Epub ahead of print]**

[http://www.giejournal.org/article/S0016-5107\(12\)00532-9/abstract](http://www.giejournal.org/article/S0016-5107(12)00532-9/abstract)

Using population-based health services information to estimate the effectiveness of colonoscopy on colorectal cancer (CRC) outcomes is prone to selection bias. Performed a population-based retrospective cohort study using Ontario provincial health data to determine the effect of colonoscopy on CRC incidence and mortality. This study involved average-risk persons aged 50 to 74 years from 1996 to 2000 who were alive and free of CRC on January 1, 2001.

Results: The study cohort contained 1,089,998 persons, 7.9% of whom had undergone a colonoscopy between 1996 and 2000. Using primary care physician rate of discretionary colonoscopy as an instrumental variable, the receipt of colonoscopy was associated with a 0.60% (95% confidence interval [CI], 0.31%-0.78%) absolute reduction in the 7-year colorectal cancer incidence and a 0.17% (95% CI, 0.14%-0.21%) absolute reduction in the 5-year risk of death caused by CRC. This corresponds to a 48% relative decrease in CRC incidence (risk ratio [RR] 0.52; 95% CI, 0.34-0.76) and 81% decrease in mortality caused by CRC (RR 0.19, 95% CI, 0.07-0.47). In subgroup analyses, the reduction in the risk of death due to CRC was larger in women than men. The reduction in CRC incidence was larger for complete colonoscopies and for left-sided cancers.

Conclusions: Increased use of colonoscopy procedures is associated with a reduction in the incidence and mortality of CRC in the population studied

Impact on conclusions of systematic review: Additional knowledge supports current recommendations

**Zauber, A.G., et al. (February 23, 2012) Colonoscopic Polypectomy and Long-Term Prevention of Colorectal Cancer Deaths. *N Engl J Med* 2012; 366(8): 687-696.**

<http://www.nejm.org/doi/full/10.1056/NEJMoa1100370>

In the National Polyp Study (NPS), colorectal cancer was prevented by colonoscopic removal of adenomatous polyps. They evaluated the long-term effect of colonoscopic polypectomy in a study on mortality from colorectal cancer. Analysis included all patients prospectively referred for initial colonoscopy (between 1980 and 1990) at NPS clinical centers who had polyps (adenomas and nonadenomas). The National Death Index was used to identify deaths and to determine the cause of death; follow-up time was as long as 23 years. Mortality from colorectal cancer among patients with adenomas removed was compared with the expected incidence-based mortality from colorectal cancer in the general population, as estimated from the Surveillance Epidemiology and End Results (SEER) Program, and with the observed mortality from colorectal cancer among patients with nonadenomatous polyps (internal control group).

Results: Among 2602 patients who had adenomas removed during participation in the study, after a median of 15.8 years, 1246 patients had died from any cause and 12 had died from colorectal cancer. Given an estimated 25.4 expected deaths from colorectal cancer in the general population, the standardized incidence-based mortality ratio was 0.47 (95% confidence interval [CI], 0.26 to 0.80) with colonoscopic polypectomy, suggesting a 53% reduction in mortality. Mortality from colorectal cancer was similar among patients with adenomas and those with nonadenomatous polyps during the first 10 years after polypectomy (relative risk, 1.2; 95% CI, 0.1 to 10.6).

Conclusions: These findings support the hypothesis that colonoscopic removal of adenomatous polyps prevents death from colorectal cancer. (Funded by the National Cancer Institute and others.).

Impact on conclusions of systematic review: Additional knowledge supports current recommendations

## Measure Title: 2. Standardized Medical Risk Assessment

Date of Submission: [7/16/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

### STRUCTURE-PROCESS-OUTCOME RELATIONSHIP

#### 1c.1. This is a measure of:

Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** *If not a health outcome, skip to 1c.3*

*If the measure focus identified in 1c.1 is a [health outcome](#), answer 1c.2 and 1c.2.1.*

**1c.2.** Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

**1c.2.1.** State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

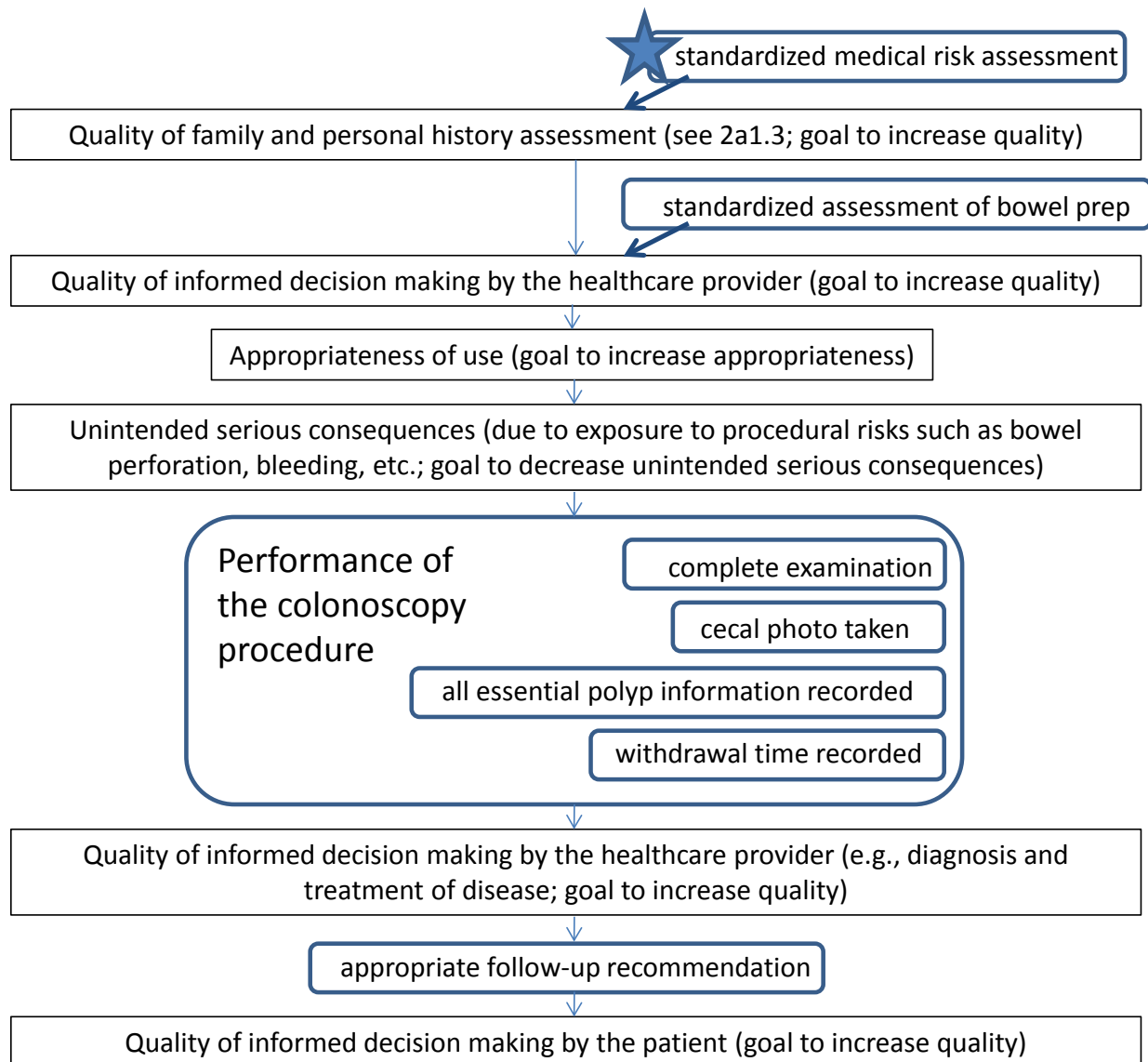
*Note: For health outcome measures, no further information is required*

### STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE

*If the measure focus identified in 1c.1 is a [structure, process, or intermediate outcome](#) answer all the following questions (except as indicated by skip pattern).*

**1c.3.** Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (*Do not summarize the evidence here.*)





Appropriate use of colonoscopy examination for screening and surveillance, along with improved quality of the performance of the colonoscopy procedure (e.g., complete exam with cecal photo taken), and appropriate follow-up recommendations will ultimately lead to improved detection and therefore improved treatment of colorectal cancer. In this way, these process measures are expected to have an effect on patient outcomes (reduced morbidity and mortality due to colorectal cancer that is identified and treated; reduced morbidity from overuse of colorectal examination).

MEASURE FOCUS (standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation)

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PROCESS CHARACTERISTIC (quality of family and personal history assessment, quality of informed decision making by the healthcare provider, appropriateness of use, unintended serious consequences, performance of the colonoscopy procedure, quality of informed decision making by the healthcare provider, quality of informed decision making by the patient)

----->

DESIRED HEALTH OUTCOME (any cancerous and precancerous polyps of the colon which are present are identified, documented, and acted upon)

**EVIDENCE = LOGICAL ARGUMENT**

The process-based subcomponent measures of the Colonoscopy Quality Index are related to expert consensus [1] and do not require evidence from systematic reviews to support their validity [2].

We recognize that logic is the basis on which science, including modern medicine, is built. In addition to completing the systematic review portion of the evidence form for the process-based subcomponent measures of the Colonoscopy Quality Index, we would like to highlight a straightforward logical argument for each of the process-based subcomponent measures of the Colonoscopy Quality Index.

Proposition: A high quality screening or surveillance colonoscopy is one that is performed A) on a patient that needs the test, B) in a thorough manner, and C) without harming the patient.

Measure/subcomponent	Proposition A	Proposition B	Proposition C
Colonoscopy Quality Index	Yes	Yes	Yes
1. Appropriate Indication for Colonoscopy	Yes		
<b>2. Standardized Medical Risk Assessment</b>		<b>Yes</b>	
3. Standardized Assessment of Bowel Prep		Yes	
4. Complete Examination		Yes	
5. Cecal Photo Taken		Yes	
6. All Essential Polyp Information Recorded		Yes	
7. Withdrawal Time was Recorded		Yes	
8. Free of Serious Complications			Yes
9. Appropriate Follow-up Recommendation		Yes	

Table: Relationship between Colonoscopy Quality Index and subcomponents and the propositions:  
 Proposition A) A high quality screening or surveillance colonoscopy is one that is performed on a patient that needs the test  
 Proposition B) A high quality screening or surveillance colonoscopy is one that is performed in a thorough manner  
 Proposition C) A high quality screening or surveillance colonoscopy is one that is performed without harming the patient.

1. Lieberman D., Nadel M., Smith R.A., Atkin W., Duggirala S.B., Fletcher R., Glick S.N., Johnson C.D., Levin T.R., Pope J.B., Potter M.B., Ransohff D., Rex D., Schoen R., Schroy P., Winawer S. (2007) Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. *Gastrointestinal Endoscopy* 65(6): 757-766.

2. Smith G.C.S. and Pell J.P. (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *BMJ*. 327(7429): 1459–1461.

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No  If no, skip to #1c.6

If yes, answer 1c.4.1-1c.5.

1c.4.1. Guideline citation (including date):

1c.4.2. URL (if available online):

1c.4.3. Identify guideline number and/or page number:

1c.4.4. Quote verbatim, the specific guideline recommendation:

1c.4.5. Grade assigned to the recommendation with definition of the grade:

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes  No  If no, skip to #1c.6

If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF) Yes  No  If no, skip to #1c.7

If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. Citation (including date):

1c.6.2. URL (if available online):

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No

If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

#### FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010).

#### QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

#### ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

#### UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  If no, stop

If yes, 1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

**Measure Title: 3. Standardized Assessment of Bowel Prep**

**Date of Submission:** [7/16/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** *If not a health outcome, skip to 1c.3*

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

**1c.2.** Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

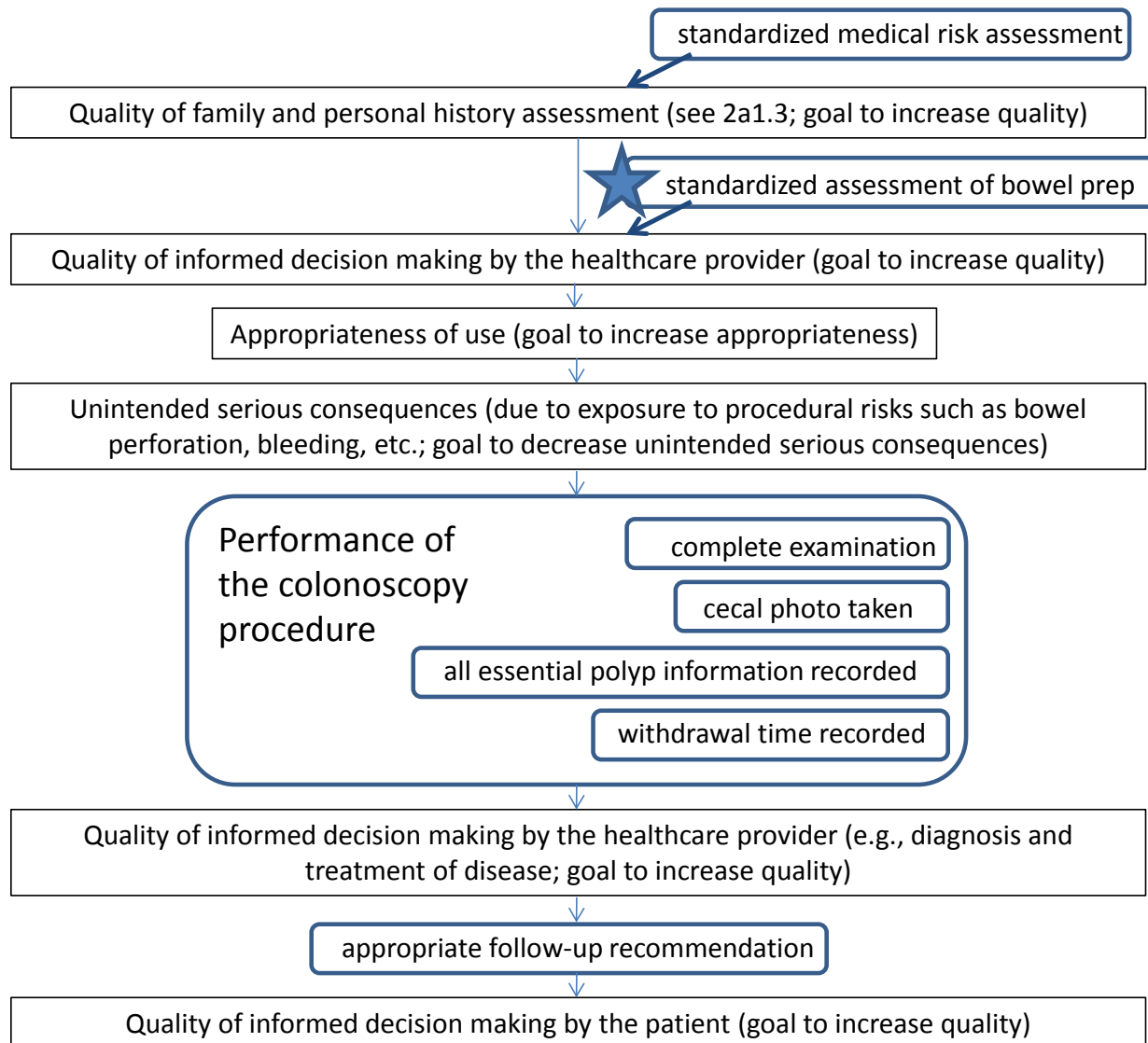
**1c.2.1.** State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

*Note: For health outcome measures, no further information is required*

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**1c.3.** Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (*Do not summarize the evidence here.*)



Appropriate use of colonoscopy examination for screening and surveillance, along with improved quality of the performance of the colonoscopy procedure (e.g., complete exam with cecal photo taken), and appropriate follow-up recommendations will ultimately lead to improved detection and therefore improved treatment of colorectal cancer. In this way, these process measures are expected to have an effect on patient outcomes (reduced morbidity and mortality due to colorectal cancer that is identified and treated; reduced morbidity from overuse of colorectal examination).

MEASURE FOCUS (standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation)

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PROCESS CHARACTERISTIC (quality of family and personal history assessment, quality of informed decision making by the healthcare provider, appropriateness of use, unintended serious consequences, performance of the colonoscopy procedure, quality of informed decision making by the healthcare provider, quality of informed decision making by the patient)

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DESIRED HEALTH OUTCOME (any cancerous and precancerous polyps of the colon which are present are identified, documented, and acted upon)

**EVIDENCE = LOGICAL ARGUMENT**

The process-based subcomponent measures of the Colonoscopy Quality Index are related to expert consensus [1] and do not require evidence from systematic reviews to support their validity [2].

We recognize that logic is the basis on which science, including modern medicine, is built. In addition to completing the systematic review portion of the evidence form for the process-based subcomponent measures of the Colonoscopy Quality Index, we would like to highlight a straightforward logical argument for each of the process-based subcomponent measures of the Colonoscopy Quality Index.

Proposition: A high quality screening or surveillance colonoscopy is one that is performed A) on a patient that needs the test, B) in a thorough manner, and C) without harming the patient.

Measure/subcomponent	Proposition A	Proposition B	Proposition C
Colonoscopy Quality Index	Yes	Yes	Yes
1. Appropriate Indication for Colonoscopy	Yes		
2. Standardized Medical Risk Assessment		Yes	
<b>3. Standardized Assessment of Bowel Prep</b>		<b>Yes</b>	
4. Complete Examination		Yes	
5. Cecal Photo Taken		Yes	
6. All Essential Polyp Information Recorded		Yes	
7. Withdrawal Time was Recorded		Yes	
8. Free of Serious Complications			Yes
9. Appropriate Follow-up Recommendation		Yes	

Table: Relationship between Colonoscopy Quality Index and subcomponents and the propositions:  
 Proposition A) A high quality screening or surveillance colonoscopy is one that is performed on a patient that needs the test  
 Proposition B) A high quality screening or surveillance colonoscopy is one that is performed in a thorough manner  
 Proposition C) A high quality screening or surveillance colonoscopy is one that is performed without harming the patient.

1. Lieberman D., Nadel M., Smith R.A., Atkin W., Duggirala S.B., Fletcher R., Glick S.N., Johnson C.D., Levin T.R., Pope J.B., Potter M.B., Ransohff D., Rex D., Schoen R., Schroy P., Winawer S. (2007) Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. *Gastrointestinal Endoscopy* 65(6): 757-766.

2. Smith G.C.S. and Pell J.P. (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *BMJ*. 327(7429): 1459–1461.

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No  If no, skip to #1c.6  
 If yes, answer 1c.4.1-1c.5.  
 1c.4.1. Guideline citation (including date):

1c.4.2. URL (if available online):

1c.4.3. Identify guideline number and/or page number:

1c.4.4. Quote verbatim, the specific guideline recommendation:

1c.4.5. Grade assigned to the recommendation with definition of the grade:

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes  No  If no, skip to #1c.6

If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF) Yes  No  If no, skip to #1c.7

If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. Citation (including date):

1c.6.2. URL (if available online):

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No

If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

#### FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010).

#### QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

#### ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

#### UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  If no, stop

If yes, 1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

**Measure Title: 4. Complete Examination**

**Date of Submission:** [7/16/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** *If not a health outcome, skip to 1c.3*

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

**1c.2.** Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

**1c.2.1.** State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

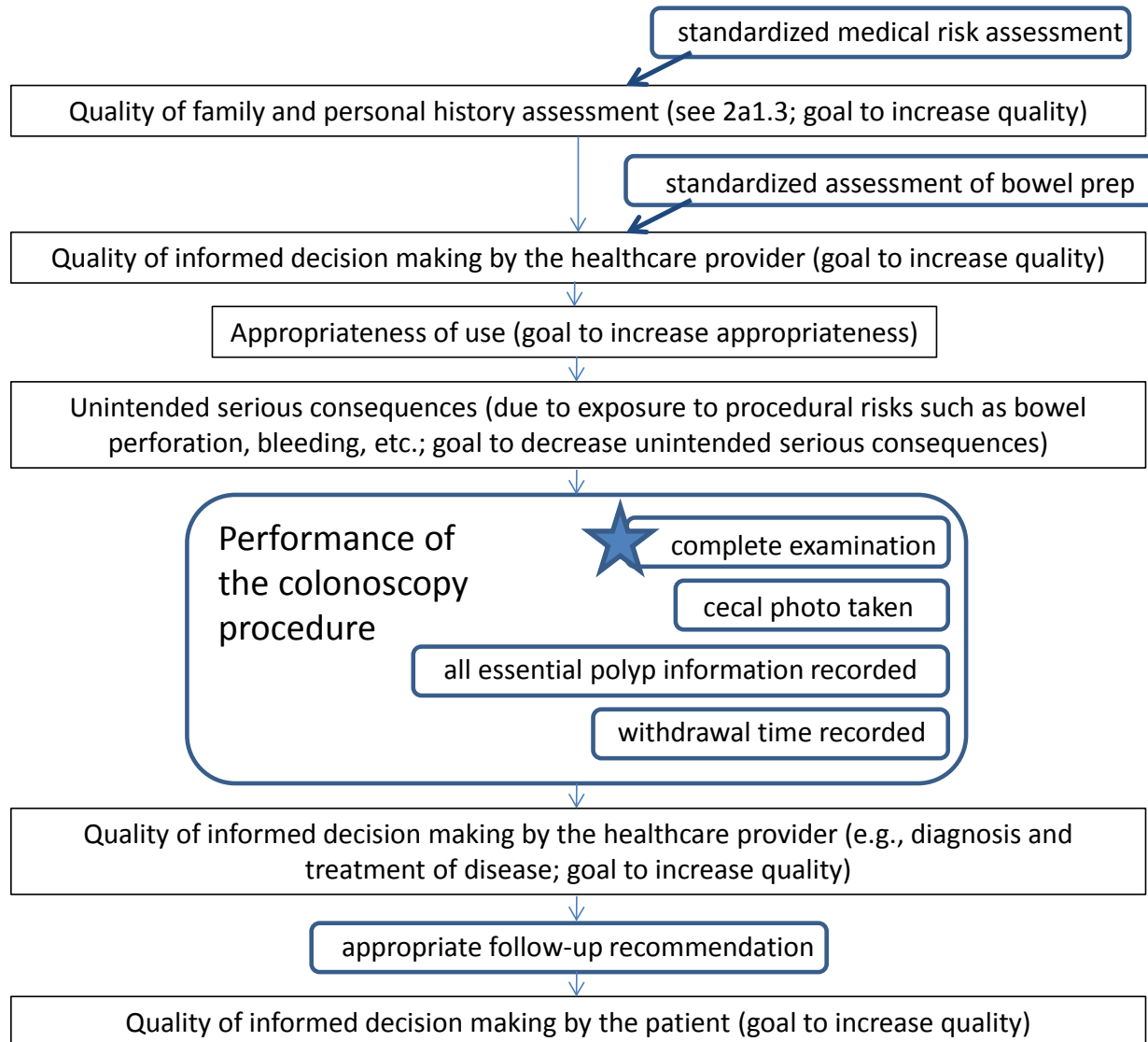
*Note: For health outcome measures, no further information is required*

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**1c.3.** Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (*Do not summarize the evidence here.*)





Appropriate use of colonoscopy examination for screening and surveillance, along with improved quality of the performance of the colonoscopy procedure (e.g., complete exam with cecal photo taken), and appropriate follow-up recommendations will ultimately lead to improved detection and therefore improved treatment of colorectal cancer. In this way, these process measures are expected to have an effect on patient outcomes (reduced morbidity and mortality due to colorectal cancer that is identified and treated; reduced morbidity from overuse of colorectal examination).

MEASURE FOCUS (standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation)

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PROCESS CHARACTERISTIC (quality of family and personal history assessment, quality of informed decision making by the healthcare provider, appropriateness of use, unintended serious consequences, performance of the colonoscopy procedure, quality of informed decision making by the healthcare provider, quality of informed decision making by the patient)

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DESIRED HEALTH OUTCOME (any cancerous and precancerous polyps of the colon which are present are identified, documented, and acted upon)

**EVIDENCE = LOGICAL ARGUMENT**

The process-based subcomponent measures of the Colonoscopy Quality Index are related to expert consensus [1] and do not require evidence from systematic reviews to support their validity [2].

We recognize that logic is the basis on which science, including modern medicine, is built. In addition to completing the systematic review portion of the evidence form for the process-based subcomponent measures of the Colonoscopy Quality Index, we would like to highlight a straightforward logical argument for each of the process-based subcomponent measures of the Colonoscopy Quality Index.

Proposition: A high quality screening or surveillance colonoscopy is one that is performed A) on a patient that needs the test, B) in a thorough manner, and C) without harming the patient.

Measure/subcomponent	Proposition A	Proposition B	Proposition C
Colonoscopy Quality Index	Yes	Yes	Yes
1. Appropriate Indication for Colonoscopy	Yes		
2. Standardized Medical Risk Assessment		Yes	
3. Standardized Assessment of Bowel Prep		Yes	
<b>4. Complete Examination</b>		<b>Yes</b>	
5. Cecal Photo Taken		Yes	
6. All Essential Polyp Information Recorded		Yes	
7. Withdrawal Time was Recorded		Yes	
8. Free of Serious Complications			Yes
9. Appropriate Follow-up Recommendation		Yes	

Table: Relationship between Colonoscopy Quality Index and subcomponents and the propositions:  
 Proposition A) A high quality screening or surveillance colonoscopy is one that is performed on a patient that needs the test  
 Proposition B) A high quality screening or surveillance colonoscopy is one that is performed in a thorough manner  
 Proposition C) A high quality screening or surveillance colonoscopy is one that is performed without harming the patient.

1. Lieberman D., Nadel M., Smith R.A., Atkin W., Duggirala S.B., Fletcher R., Glick S.N., Johnson C.D., Levin T.R., Pope J.B., Potter M.B., Ransohff D., Rex D., Schoen R., Schroy P., Winawer S. (2007) Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. *Gastrointestinal Endoscopy* 65(6): 757-766.

2. Smith G.C.S. and Pell J.P. (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *BMJ*. 327(7429): 1459–1461.

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No  If no, skip to #1c.6

If yes, answer 1c.4.1-1c.5.

1c.4.1. Guideline citation (including date):

1c.4.2. URL (if available online):

1c.4.3. Identify guideline number and/or page number:

1c.4.4. Quote verbatim, the specific guideline recommendation:

1c.4.5. Grade assigned to the recommendation with definition of the grade:

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes   
No  If no, skip to #1c.6

If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF) Yes  No  If no, skip to #1c.7

If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. Citation (including date):

1c.6.2. URL (if available online):

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No

If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

#### FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010).

#### QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

#### ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

#### UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  If no, stop  
If yes,

1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

**Measure Title: 5. Cecal Photo Taken**

**Date of Submission:** [7/16/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** *If not a health outcome, skip to 1c.3*

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

**1c.2.** Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

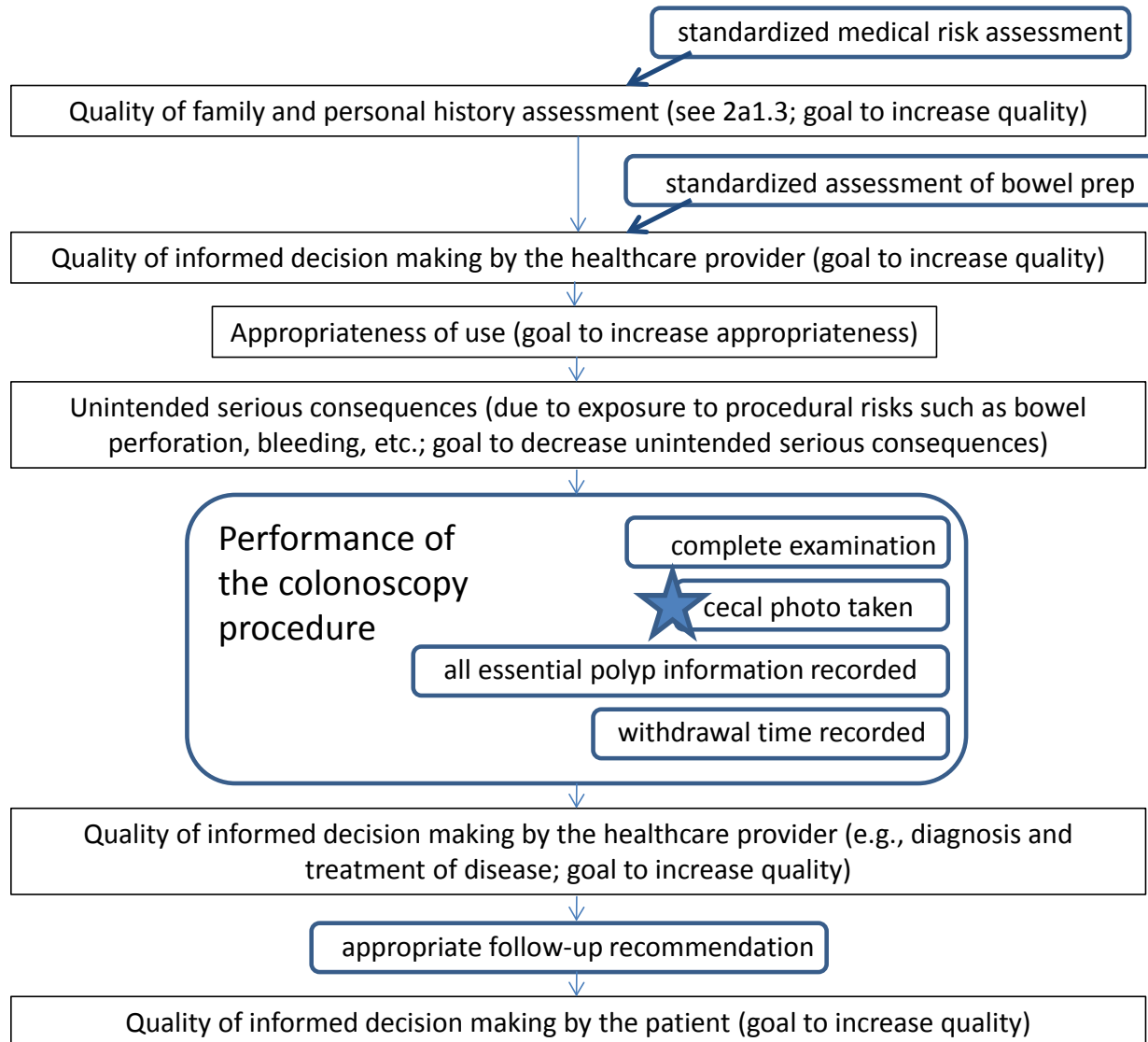
**1c.2.1.** State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

*Note: For health outcome measures, no further information is required*

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**1c.3.** Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (*Do not summarize the evidence here.*)



Appropriate use of colonoscopy examination for screening and surveillance, along with improved quality of the performance of the colonoscopy procedure (e.g., complete exam with cecal photo taken), and appropriate follow-up recommendations will ultimately lead to improved detection and therefore improved treatment of colorectal cancer. In this way, these process measures are expected to have an effect on patient outcomes (reduced morbidity and mortality due to colorectal cancer that is identified and treated; reduced morbidity from overuse of colorectal examination).

MEASURE FOCUS (standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation)

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PROCESS CHARACTERISTIC (quality of family and personal history assessment, quality of informed decision making by the healthcare provider, appropriateness of use, unintended serious consequences, performance of the colonoscopy procedure, quality of informed decision making by the healthcare provider, quality of informed decision making by the patient)

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DESIRED HEALTH OUTCOME (any cancerous and precancerous polyps of the colon which are present are identified, documented, and acted upon)

**EVIDENCE = LOGICAL ARGUMENT**

The process-based subcomponent measures of the Colonoscopy Quality Index are related to expert consensus [1] and do not require evidence from systematic reviews to support their validity [2].

We recognize that logic is the basis on which science, including modern medicine, is built. In addition to completing the systematic review portion of the evidence form for the process-based subcomponent measures of the Colonoscopy Quality Index, we would like to highlight a straightforward logical argument for each of the process-based subcomponent measures of the Colonoscopy Quality Index.

Proposition: A high quality screening or surveillance colonoscopy is one that is performed A) on a patient that needs the test, B) in a thorough manner, and C) without harming the patient.

Measure/subcomponent	Proposition A	Proposition B	Proposition C
Colonoscopy Quality Index	Yes	Yes	Yes
1. Appropriate Indication for Colonoscopy	Yes		
2. Standardized Medical Risk Assessment		Yes	
3. Standardized Assessment of Bowel Prep		Yes	
4. Complete Examination		Yes	
<b>5. Cecal Photo Taken</b>		<b>Yes</b>	
6. All Essential Polyp Information Recorded		Yes	
7. Withdrawal Time was Recorded		Yes	
8. Free of Serious Complications			Yes
9. Appropriate Follow-up Recommendation		Yes	

Table: Relationship between Colonoscopy Quality Index and subcomponents and the propositions:  
 Proposition A) A high quality screening or surveillance colonoscopy is one that is performed on a patient that needs the test  
 Proposition B) A high quality screening or surveillance colonoscopy is one that is performed in a thorough manner  
 Proposition C) A high quality screening or surveillance colonoscopy is one that is performed without harming the patient.

1. Lieberman D., Nadel M., Smith R.A., Atkin W., Duggirala S.B., Fletcher R., Glick S.N., Johnson C.D., Levin T.R., Pope J.B., Potter M.B., Ransohff D., Rex D., Schoen R., Schroy P., Winawer S. (2007) Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. *Gastrointestinal Endoscopy* 65(6): 757-766.

2. Smith G.C.S. and Pell J.P. (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *BMJ*. 327(7429): 1459–1461.

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No  If no, skip to #1c.6  
 If yes, answer 1c.4.1-1c.5.  
 1c.4.1. Guideline citation (including date):

1c.4.2. URL (if available online):

1c.4.3. Identify guideline number and/or page number:

1c.4.4. Quote verbatim, the specific guideline recommendation:

1c.4.5. Grade assigned to the recommendation with definition of the grade:

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes   
No  If no, skip to #1c.6

If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF) Yes  No  If no, skip to #1c.7

If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. Citation (including date):

1c.6.2. URL (if available online):

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No

If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

#### FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010).

#### QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

#### ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

#### UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  If no, stop  
If yes,

1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

**Measure Title: 6. All Essential Polyp Information Recorded**

**Date of Submission:** [7/16/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** *If not a health outcome, skip to 1c.3*

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

**1c.2.** Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

**1c.2.1.** State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

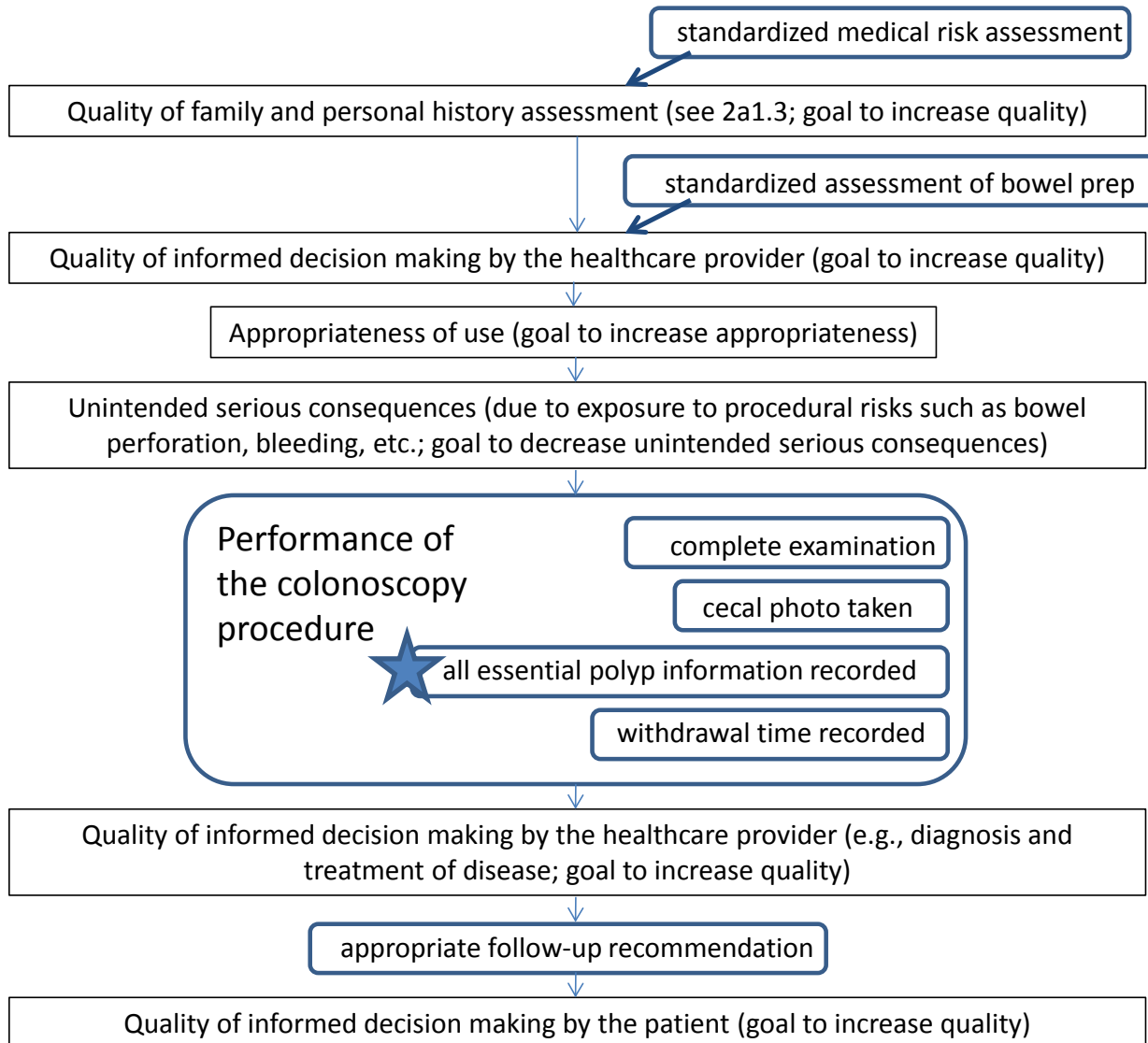
*Note: For health outcome measures, no further information is required*

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**1c.3.** Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (*Do not summarize the evidence here.*)





Appropriate use of colonoscopy examination for screening and surveillance, along with improved quality of the performance of the colonoscopy procedure (e.g., complete exam with cecal photo taken), and appropriate follow-up recommendations will ultimately lead to improved detection and therefore improved treatment of colorectal cancer. In this way, these process measures are expected to have an effect on patient outcomes (reduced morbidity and mortality due to colorectal cancer that is identified and treated; reduced morbidity from overuse of colorectal examination).

MEASURE FOCUS (standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation)

---->

PROCESS CHARACTERISTIC (quality of family and personal history assessment, quality of informed decision making by the healthcare provider, appropriateness of use, unintended serious consequences, performance of the colonoscopy procedure, quality of informed decision making by the healthcare provider, quality of informed decision making by the patient)

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DESIRED HEALTH OUTCOME (any cancerous and precancerous polyps of the colon which are present are identified, documented, and acted upon)

**EVIDENCE = LOGICAL ARGUMENT**

The process-based subcomponent measures of the Colonoscopy Quality Index are related to expert consensus [1] and do not require evidence from systematic reviews to support their validity [2].

We recognize that logic is the basis on which science, including modern medicine, is built. In addition to completing the systematic review portion of the evidence form for the process-based subcomponent measures of the Colonoscopy Quality Index, we would like to highlight a straightforward logical argument for each of the process-based subcomponent measures of the Colonoscopy Quality Index.

Proposition: A high quality screening or surveillance colonoscopy is one that is performed A) on a patient that needs the test, B) in a thorough manner, and C) without harming the patient.

Measure/subcomponent	Proposition A	Proposition B	Proposition C
Colonoscopy Quality Index	Yes	Yes	Yes
1. Appropriate Indication for Colonoscopy	Yes		
2. Standardized Medical Risk Assessment		Yes	
3. Standardized Assessment of Bowel Prep		Yes	
4. Complete Examination		Yes	
5. Cecal Photo Taken		Yes	
<b>6. All Essential Polyp Information Recorded</b>		<b>Yes</b>	
7. Withdrawal Time was Recorded		Yes	
8. Free of Serious Complications			Yes
9. Appropriate Follow-up Recommendation		Yes	

Table: Relationship between Colonoscopy Quality Index and subcomponents and the propositions:  
 Proposition A) A high quality screening or surveillance colonoscopy is one that is performed on a patient that needs the test  
 Proposition B) A high quality screening or surveillance colonoscopy is one that is performed in a thorough manner  
 Proposition C) A high quality screening or surveillance colonoscopy is one that is performed without harming the patient.

1. Lieberman D., Nadel M., Smith R.A., Atkin W., Duggirala S.B., Fletcher R., Glick S.N., Johnson C.D., Levin T.R., Pope J.B., Potter M.B., Ransohff D., Rex D., Schoen R., Schroy P., Winawer S. (2007) Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. *Gastrointestinal Endoscopy* 65(6): 757-766.

2. Smith G.C.S. and Pell J.P. (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *BMJ*. 327(7429): 1459–1461.

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No  If no, skip to #1c.6  
 If yes, answer 1c.4.1-1c.5.  
 1c.4.1. Guideline citation (including date):

1c.4.2. URL (if available online):

1c.4.3. Identify guideline number and/or page number:

1c.4.4. Quote verbatim, the specific guideline recommendation:

1c.4.5. Grade assigned to the recommendation with definition of the grade:

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes  No  If no, skip to #1c.6

If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF) Yes  No  If no, skip to #1c.7

If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. Citation (including date):

1c.6.2. URL (if available online):

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No

If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

#### FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010).

#### QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

#### ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

#### UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  If no, stop

If yes, 1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

**Measure Title: 7. Withdrawal Time was Recorded**

**Date of Submission:** [7/16/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** *If not a health outcome, skip to 1c.3*

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

**1c.2.** Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

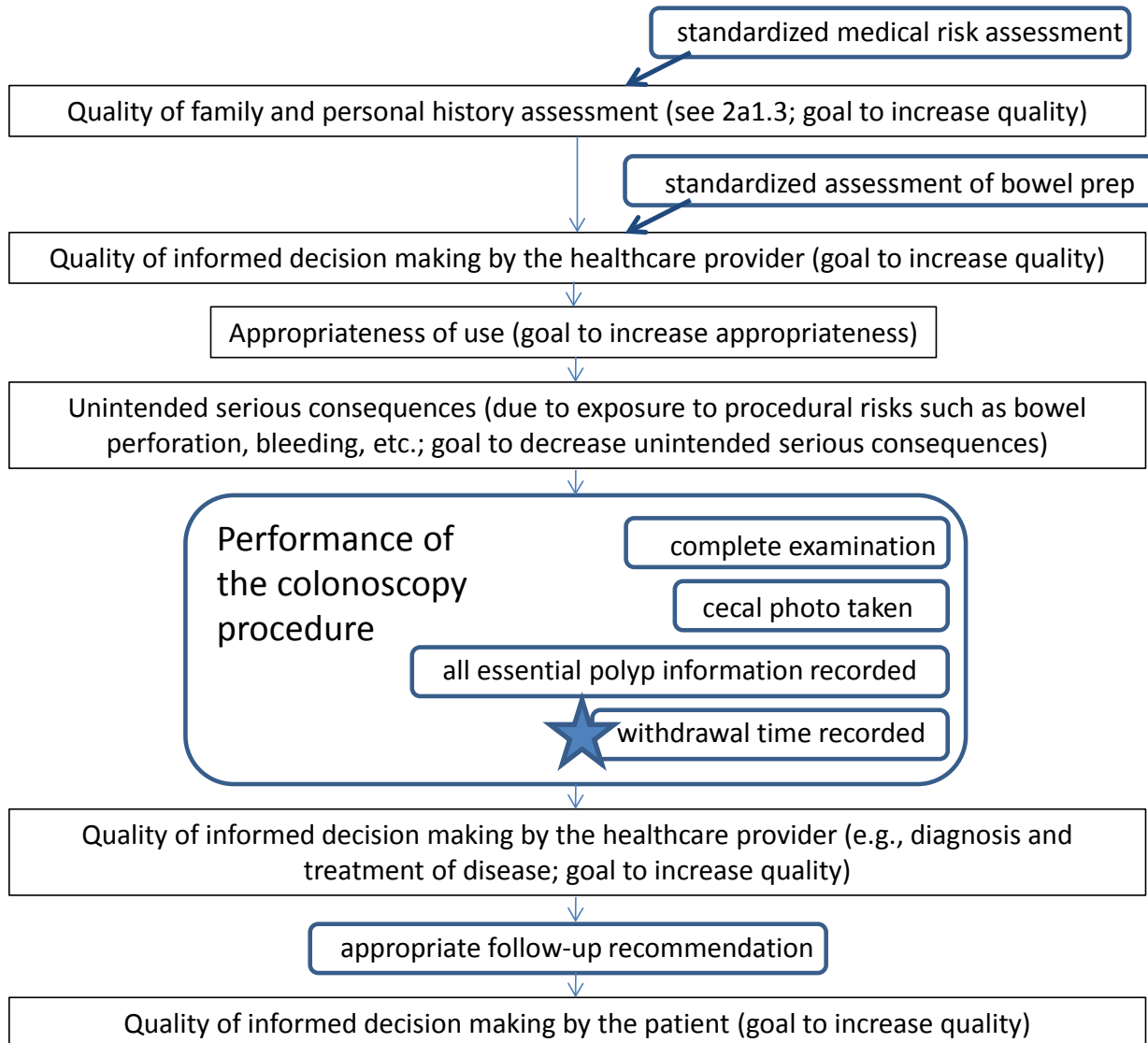
**1c.2.1.** State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

*Note: For health outcome measures, no further information is required*

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**1c.3.** Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (*Do not summarize the evidence here.*)



Appropriate use of colonoscopy examination for screening and surveillance, along with improved quality of the performance of the colonoscopy procedure (e.g., complete exam with cecal photo taken), and appropriate follow-up recommendations will ultimately lead to improved detection and therefore improved treatment of colorectal cancer. In this way, these process measures are expected to have an effect on patient outcomes (reduced morbidity and mortality due to colorectal cancer that is identified and treated; reduced morbidity from overuse of colorectal examination).

MEASURE FOCUS (standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation)

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PROCESS CHARACTERISTIC (quality of family and personal history assessment, quality of informed decision making by the healthcare provider, appropriateness of use, unintended serious consequences, performance of the colonoscopy procedure, quality of informed decision making by the healthcare provider, quality of informed decision making by the patient)

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DESIRED HEALTH OUTCOME (any cancerous and precancerous polyps of the colon which are present are identified, documented, and acted upon)

**EVIDENCE = LOGICAL ARGUMENT**

The process-based subcomponent measures of the Colonoscopy Quality Index are related to expert consensus [1] and do not require evidence from systematic reviews to support their validity [2].

We recognize that logic is the basis on which science, including modern medicine, is built. In addition to completing the systematic review portion of the evidence form for the process-based subcomponent measures of the Colonoscopy Quality Index, we would like to highlight a straightforward logical argument for each of the process-based subcomponent measures of the Colonoscopy Quality Index.

Proposition: A high quality screening or surveillance colonoscopy is one that is performed A) on a patient that needs the test, B) in a thorough manner, and C) without harming the patient.

Measure/subcomponent	Proposition A	Proposition B	Proposition C
Colonoscopy Quality Index	Yes	Yes	Yes
1. Appropriate Indication for Colonoscopy	Yes		
2. Standardized Medical Risk Assessment		Yes	
3. Standardized Assessment of Bowel Prep		Yes	
4. Complete Examination		Yes	
5. Cecal Photo Taken		Yes	
6. All Essential Polyp Information Recorded		Yes	
<b>7. Withdrawal Time was Recorded</b>		<b>Yes</b>	
8. Free of Serious Complications			Yes
9. Appropriate Follow-up Recommendation		Yes	

Table: Relationship between Colonoscopy Quality Index and subcomponents and the propositions:  
 Proposition A) A high quality screening or surveillance colonoscopy is one that is performed on a patient that needs the test  
 Proposition B) A high quality screening or surveillance colonoscopy is one that is performed in a thorough manner  
 Proposition C) A high quality screening or surveillance colonoscopy is one that is performed without harming the patient.

1. Lieberman D., Nadel M., Smith R.A., Atkin W., Duggirala S.B., Fletcher R., Glick S.N., Johnson C.D., Levin T.R., Pope J.B., Potter M.B., Ransohff D., Rex D., Schoen R., Schroy P., Winawer S. (2007) Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. *Gastrointestinal Endoscopy* 65(6): 757-766.

2. Smith G.C.S. and Pell J.P. (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *BMJ*. 327(7429): 1459–1461.

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No  If no, skip to #1c.6

If yes, answer 1c.4.1-1c.5.

1c.4.1. Guideline citation (including date):

1c.4.2. URL (if available online):

1c.4.3. Identify guideline number and/or page number:

1c.4.4. Quote verbatim, the specific guideline recommendation:

1c.4.5. Grade assigned to the recommendation with definition of the grade:

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes   
No  If no, skip to #1c.6

If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF) Yes  No  If no, skip to #1c.7

If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. Citation (including date):

1c.6.2. URL (if available online):

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No

If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

#### FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010).

#### QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

#### ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

#### UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  If no, stop  
If yes,

1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

**Measure Title: 8. Free of Serious Complications**

**Date of Submission:** [7/16/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

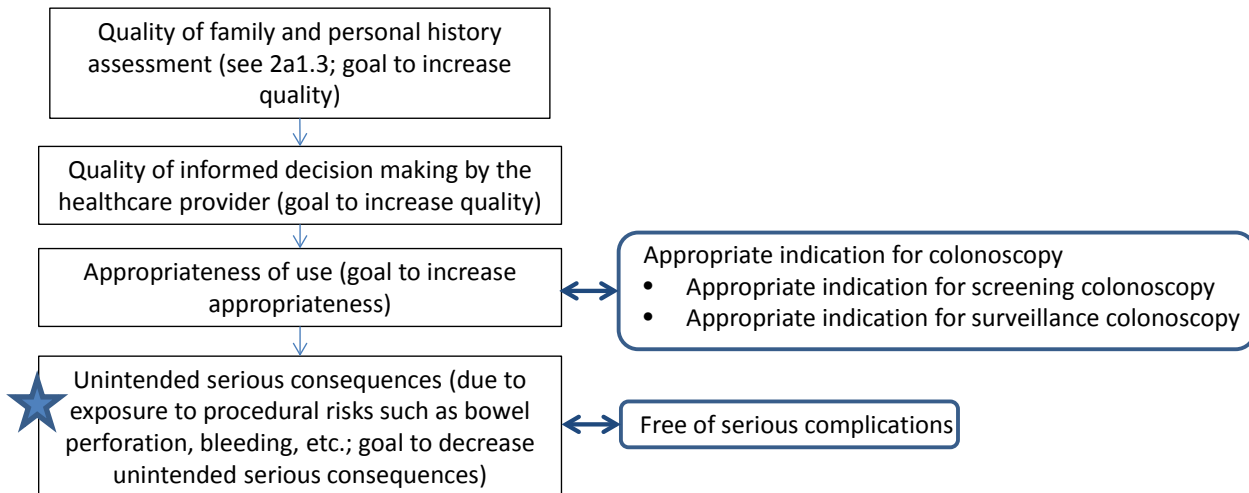
Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** *If not a health outcome, skip to 1c.3*

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

**1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.**



Quality of colonoscopy procedure (process) → Complications from procedure (outcome)

Characteristics of the process include: quality of family and personal history assessment prior to the colonoscopy procedure, quality of informed decision making by the healthcare provider with regard to the colonoscopy procedure, and appropriateness of use of the colonoscopy procedure



Characteristics of the outcome include: free of serious complications; there are no unintended serious consequences from the colonoscopy procedure due to exposure to procedural risks such as bowel perforation, bleeding, etc.

**1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.**

Quality of family and personal history assessment and healthcare provider knowledge of current evidence and recommendations for use of colonoscopy for screening and surveillance affect the appropriateness with which colonoscopy exams are used. Overuse of colonoscopy exams are associated with avoidable patient harm including bowel perforation and bleeding, as well as increased costs.

**Note: For health outcome measures, no further information is required**

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (Do not summarize the evidence here.)**

**1c.4.** Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No   
**If no, skip to #1c.6**

*If yes, answer 1c.4.1-1c.5.*

**1c.4.1. Guideline citation (including date):**

Brink D, Barlow J, Bush K, Chaudhary N, Fareed M, Hayes R, Jafri I, Nair K, Retzer K, Rueter K. Institute for Clinical Systems Improvement. Colorectal Cancer Screening. <http://bit.ly/Colorectal0512>. Published May 2012.

Additional corroborating guidelines include:

- American Gastroenterological Association: Winawer, S., et al. (2003) Colorectal Cancer Screening and Surveillance: Clinical Guidelines and Rationale. *Gastroenterology*. 124:544-560.
- US Preventive Services Task Force (2008) Screening for Colorectal Cancer <http://www.uspreventiveservicestaskforce.org/uspstf08/colocancer/colors.htm> last accessed on 6/22/2012
- Quaseem, A., et al. (2012) Screening for Colorectal Cancer: A Guidance Statement from the American College of Physicians. *Ann Intern Med*. 156:378-386.

**1c.4.2. URL (if available online):** [http://www.icsi.org/colorectal\\_cancer\\_screening/colorectal\\_cancer\\_screening\\_5.html](http://www.icsi.org/colorectal_cancer_screening/colorectal_cancer_screening_5.html)

**1c.4.3. Identify guideline number and/or page number:** Pg 1 – Screening algorithm; refer to entire guideline cited above

**1c.4.4. Quote verbatim, the specific guideline recommendation:**

**Does the Patient Meet Criteria for Increased Risk?**

<b>Risk Category</b>	<b>Recommendation</b>
One first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years	Colonoscopy every five years beginning at age 40 or 10 years before the age of the youngest case in the immediate family
Two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps	Colonoscopy every five years beginning at age 40 or 10 years before the age of the youngest case in the immediate family
First-degree relative with either colorectal cancer or adenomatous polyps at greater than or equal to 60 years, or two second-degree relatives with colorectal cancer	The work group recognizes this imposes an increased risk; however, due to lack of evidence supporting the screening recommendations, the work group does not support a recommendation in this category
Inflammatory bowel disease, chronic ulcerative colitis and Crohn's disease	Colonoscopy every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis
Genetic diagnosis of familial adenomatous polyposis (FAP) or suspected FAP without genetic testing evidence	Annual flexible sigmoidoscopy beginning at age 10 to 12 years, along with genetic counseling
Genetic or clinical diagnosis of hereditary nonpolyposis colorectal cancer	Colonoscopy every one to two years beginning at age 20 to 25 years or 10 years before the age of the youngest case in the immediate family

\* First-order relatives include only parents, siblings and children.

*(Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003)*

From page 8 of ICSI guideline



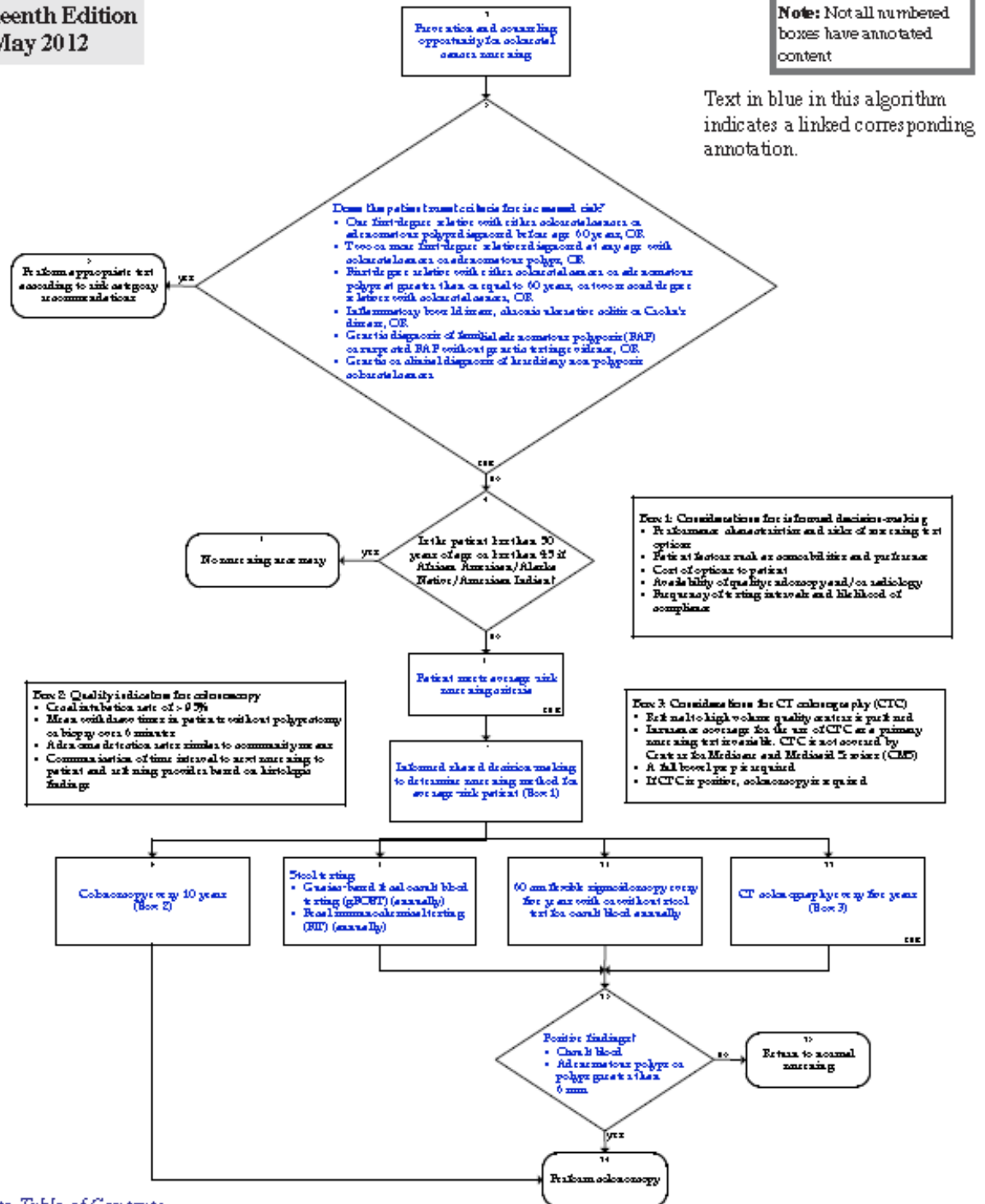
# Health Care Guideline: Colorectal Cancer Screening

INSTITUTE FOR CLINICAL  
SYSTEMS IMPROVEMENT

Fourteenth Edition  
May 2012

## Screening Algorithm

EER = Evidence-based recommendation included  
**Note:** Not all numbered boxes have annotated content



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**1c.4.5. Grade assigned to the recommendation with definition of the grade:**

**Literature Search**

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 2010 through November 2011.

The Cochrane and Pub Med databases were searched. The search was limited to screening tests only and did not include diagnostic testing. The search terms included fecal immunochemical test, colonoscopy, fecal occult blood test, flexible sigmoidoscopy and CT colonography.

**GRADE Methodology**

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international guideline developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

In the GRADE process, evidence is gathered related to a specific question. Systematic reviews are utilized first. Further literature is incorporated with randomized control trials or observational studies. The evidence addresses the same population, intervention, comparisons and outcomes. The overall body of evidence for each topic is then given a quality rating.

Once the quality of the evidence has been determined, recommendations are formulated to reflect their strength. The strength of a recommendation is either strong or weak. Only outcomes that are critical are considered the primary factors influencing a recommendation and are used to determine the overall strength of this recommendation. Each recommendation answers a focused health care question.

From page 3 of ICSI guideline

**Recommendations Table**

The following table is a list of evidence-based recommendations for the Colorectal Cancer Screening guideline.

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

Topic	Quality of Evidence	Recommendation(s)	Strength of Recommendation	Annotation Number	Relevant References
Average risk screening	High	Colorectal cancer screening is recommended for all patients 50 years of age and older – age 45 and older for African Americans or American Indians/Alaska Natives – using one of the following methods, based on joint decision-making by patient and clinician: <ul style="list-style-type: none"> <li>• Guaiac-based fecal occult blood testing (gFOBT) annually, OR</li> <li>• Fecal immunochemical testing (FIT) annually, OR</li> <li>• 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR</li> <li>• Colonoscopy every 10 years</li> </ul>	Strong	6	( <i>Perdue, 2008; U.S. Preventive Services Task Force, 2008; Agrawal, 2005; Winawer, 2003; Fuch, 1994</i> )
CT colonography	Low	CT colonography may be an option for colorectal cancer screening in the following clinical situations: after incomplete screening or diagnostic colonoscopy, for anticoagulated patients who cannot safely discontinue anticoagulation therapy.	Weak	11	( <i>Smith-Bindman 2009; Johnson, 2008; Levin, 2008; Soetikno, 2008; Cotton, 2004; Pickhardt, 2003</i> )
Increased risk screening	High	Colonoscopy should be offered at age 40 or 10 years before the age of the youngest case in the immediate family for the following individuals: <ul style="list-style-type: none"> <li>• Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years</li> <li>• Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps.</li> </ul> <p>Colonoscopy should be offered every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis.</p> <p>Colonoscopy should be offered every one to two years beginning at age 20 to 25 years, or 10 years before the age of the youngest case in the immediate family of genetic or clinical diagnosis of hereditary non-polyposis colorectal cancer.</p>	Strong	2	( <i>Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003</i> )

From page 5 of ICSI guideline

**1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation?** Yes  No  ***If no, skip to #1c.6***

*If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)*

**1c.5.1. Grade assigned to the body of evidence with definition of the grade:**

*Colorectal Cancer Screening  
Fourteenth Edition/May 2012*

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## **Evidence Grading**

### **Literature Search**

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 2010 through November 2011.

The Cochrane and Pub Med databases were searched. The search was limited to screening tests only and did not include diagnostic testing. The search terms included fecal immunochemical test, colonoscopy, fecal occult blood test, flexible sigmoidoscopy and CT colonography.

From page 3 of ICSI guideline

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
<b>High Quality Evidence</b>	Further research is very unlikely to change our confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
<b>Moderate Quality Evidence</b>	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
<b>Low Quality Evidence</b>	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

### Supporting Literature

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature are used to direct the reader to other topics of interest. This literature is not given an evidence grade and is instead used as a reference for its associated topic. These citations are noted by (*author, year*) and are found in the references section of this document.

From page 4 of ICSI guideline

**Recommendations Table**

The following table is a list of evidence-based recommendations for the Colorectal Cancer Screening guideline.

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

Topic	Quality of Evidence	Recommendation(s)	Strength of Recommendation	Annotation Number	Relevant References
Average risk screening	High	Colorectal cancer screening is recommended for all patients 50 years of age and older – age 45 and older for African Americans or American Indians/Alaska Natives – using one of the following methods, based on joint decision-making by patient and clinician: <ul style="list-style-type: none"> <li>• Guaiac-based fecal occult blood testing (gFOBT) annually, OR</li> <li>• Fecal immunochemical testing (FIT) annually, OR</li> <li>• 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR</li> <li>• Colonoscopy every 10 years</li> </ul>	Strong	6	( <i>Perdue, 2008; U.S. Preventive Services Task Force, 2008; Agrawal, 2005; Winawer, 2003; Fuch, 1994</i> )
CT colonography	Low	CT colonography may be an option for colorectal cancer screening in the following clinical situations: after incomplete screening or diagnostic colonoscopy, for anticoagulated patients who cannot safely discontinue anticoagulation therapy.	Weak	11	( <i>Smith-Bindman 2009; Johnson, 2008; Levin, 2008; Soetikno, 2008; Cotton, 2004; Pickhardt, 2003</i> )
Increased risk screening	High	Colonoscopy should be offered at age 40 or 10 years before the age of the youngest case in the immediate family for the following individuals: <ul style="list-style-type: none"> <li>• Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years</li> <li>• Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps.</li> </ul> <p>Colonoscopy should be offered every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis.</p> <p>Colonoscopy should be offered every one to two years beginning at age 20 to 25 years, or 10 years before the age of the youngest case in the immediate family of genetic or clinical diagnosis of hereditary non-polyposis colorectal cancer.</p>	Strong	2	( <i>Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003</i> )

From page 5 of ISCI guideline



**1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)**

Yes  No  **If no, skip to #1c.7**

*If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)*

**1c.6.1. Citation (including date):**

Pignone, M., et al. (2002) Screening for Colorectal Cancer in Adults at Average Risk: A Summary of the Evidence for the U.S. Preventive Services Task Force. Archives of Internal Medicine 137(2): 132-141.

Rex DK, et al. (2006) Quality indicators for colonoscopy from ASGE/ACG Taskforce on Quality in Endoscopy. Am J Gastroenterol. 2006 Apr;101(4):873-85. PMID: 16635231

Whitlock, E.P., et al. (2008) Screening for Colorectal Cancer: An Updated Systematic Review. Agency for Healthcare Research and Quality (US) Evidence Syntheses, No. 65.1; October 2008. Report No.: 08-05-05124-EF-1. PMID: 20722162

Winawer, S., et al. (2003) American Gastroenterological Association: Colorectal Cancer Screening and Surveillance: Clinical Guidelines and Rationale. Gastroenterology. 124:544-560.

Zauber, A.G., et al. (2008) Evaluating Test Strategies for Colorectal Cancer Screening—Age to Begin, Age to Stop, and Timing of Screening Intervals - A Decision Analysis of Colorectal Cancer Screening for the U.S. Preventive Services Task Force from the Cancer Intervention and Surveillance Modeling Network (CISNET). Agency for Healthcare Research and Quality (US) Evidence Syntheses, No. 65.2; March 2009. Report No.: 08-05124-EF-2. PMID: 20722163

**1c.6.2. URL (if available online):**

**1c.6.3. Grade assigned to the body of evidence with definition of the grade:**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

**If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8**

**1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No**

*If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)*

**1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?**

**1c.7.2. Grade assigned to the body of evidence with definition of the grade:**

**1c.7.3. Describe the process used for the systematic review:**

**If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.**

## FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

*(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)*

**1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: 2002-2012:** Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

## QUANTITY AND QUALITY OF BODY OF EVIDENCE

**1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

**1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

## ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

**1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

**1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?**

Please refer to section 1c.6.3. Findings of the additional reviews are consistent with knowledge at the time; the guideline we are using and preponderance of evidence was updated in May 2012 and is more recent than the above systematic reviews.

## UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

**1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  *If no, stop***

If yes,

**1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.**

**Schoen, R.E., et al. for the PLCO Project Team (June 21, 2012) Colorectal-Cancer Incidence and Mortality with Screening Flexible Sigmoidoscopy. N Engl J Med 2012; 366:2345-2357.**

<http://www.nejm.org/doi/full/10.1056/NEJMoa1114635>

Evaluated the effect of screening with flexible sigmoidoscopy on colorectal-cancer incidence and mortality. From 1993 through 2001, the PLCO Project Team randomly assigned 154,900 men and women 55 to 74 years of age either to screening with flexible sigmoidoscopy, with a repeat screening at 3 or 5 years, or to usual care. Cases of colorectal cancer and deaths from the disease were ascertained.

Results: Of the 77,445 participants randomly assigned to screening (intervention group), 83.5% underwent baseline flexible sigmoidoscopy and 54.0% were screened at 3 or 5 years. The incidence of colorectal cancer after a median follow-up of 11.9 years was 11.9 cases per 10,000 person-years in the intervention group (1012 cases), as compared with 15.2 cases per 10,000 person-years in the usual-care group (1287 cases), which represents a 21% reduction (relative risk, 0.79; 95% confidence interval [CI], 0.72 to 0.85;  $P<0.001$ ). Significant reductions were observed in the incidence of both distal colorectal cancer (479 cases in the intervention group vs. 669 cases in the usual-care group; relative risk, 0.71; 95% CI, 0.64 to 0.80;  $P<0.001$ ) and proximal colorectal cancer (512 cases vs. 595 cases; relative risk, 0.86; 95% CI, 0.76 to 0.97;  $P=0.01$ ). There were 2.9 deaths from colorectal cancer per 10,000 person-years in the intervention group (252 deaths), as compared with 3.9 per 10,000 person-years in the usual-care group (341 deaths), which represents a 26% reduction (relative risk, 0.74; 95% CI, 0.63 to 0.87;  $P<0.001$ ). Mortality from distal colorectal cancer was reduced by 50% (87 deaths in the intervention group vs. 175 in the usual-care group; relative risk, 0.50; 95% CI, 0.38 to 0.64;  $P<0.001$ ); mortality from proximal colorectal cancer was unaffected (143 and 147 deaths, respectively; relative risk, 0.97; 95% CI, 0.77 to 1.22;  $P=0.81$ ).

Conclusions: Screening with flexible sigmoidoscopy was associated with a significant decrease in colorectal-cancer incidence (in both the distal and proximal colon) and mortality (distal colon only). (Funded by the National Cancer Institute; PLCO ClinicalTrials.gov number, NCT00002540.)

Impact on conclusions of systematic review: Additional knowledge supports current recommendations

**Jacob BJ, et al. (May 31, 2012) Effect of colonoscopy on colorectal cancer incidence and mortality: an instrumental variable analysis. *Gastrointest Endosc.* 2012 [Epub ahead of print]**

[http://www.giejournal.org/article/S0016-5107\(12\)00532-9/abstract](http://www.giejournal.org/article/S0016-5107(12)00532-9/abstract)

Using population-based health services information to estimate the effectiveness of colonoscopy on colorectal cancer (CRC) outcomes is prone to selection bias. Performed a population-based retrospective cohort study using Ontario provincial health data to determine the effect of colonoscopy on CRC incidence and mortality. This study involved average-risk persons aged 50 to 74 years from 1996 to 2000 who were alive and free of CRC on January 1, 2001.

Results: The study cohort contained 1,089,998 persons, 7.9% of whom had undergone a colonoscopy between 1996 and 2000. Using primary care physician rate of discretionary colonoscopy as an instrumental variable, the receipt of colonoscopy was associated with a 0.60% (95% confidence interval [CI], 0.31%-0.78%) absolute reduction in the 7-year colorectal cancer incidence and a 0.17% (95% CI, 0.14%-0.21%) absolute reduction in the 5-year risk of death caused by CRC. This corresponds to a 48% relative decrease in CRC incidence (risk ratio [RR] 0.52; 95% CI, 0.34-0.76) and 81% decrease in mortality caused by CRC (RR 0.19, 95% CI, 0.07-0.47). In subgroup analyses, the reduction in the risk of death due to CRC was larger in women than men. The reduction in CRC incidence was larger for complete colonoscopies and for left-sided cancers.

Conclusions: Increased use of colonoscopy procedures is associated with a reduction in the incidence and mortality of CRC in the population studied

Impact on conclusions of systematic review: Additional knowledge supports current recommendations

**Zauber, A.G., et al. (February 23, 2012) Colonoscopic Polypectomy and Long-Term Prevention of Colorectal Cancer Deaths. *N Engl J Med* 2012; 366(8): 687-696.**

<http://www.nejm.org/doi/full/10.1056/NEJMoa1100370>

In the National Polyp Study (NPS), colorectal cancer was prevented by colonoscopic removal of adenomatous polyps. They evaluated the long-term effect of colonoscopic polypectomy in a study on mortality from colorectal cancer. Analysis included all patients prospectively referred for initial colonoscopy (between 1980 and 1990) at NPS clinical centers who had polyps (adenomas and nonadenomas). The National Death Index was used to identify deaths and to determine the cause of death; follow-up time was as long as 23 years. Mortality from colorectal cancer among patients with adenomas removed was compared with the expected incidence-based mortality from colorectal cancer in the general population, as estimated from the Surveillance Epidemiology and End Results (SEER) Program, and with the observed mortality from colorectal cancer among patients with nonadenomatous polyps (internal control group).

Results: Among 2602 patients who had adenomas removed during participation in the study, after a median of 15.8 years, 1246 patients had died from any cause and 12 had died from colorectal cancer. Given an estimated 25.4 expected deaths from colorectal cancer in the general population, the standardized incidence-based mortality ratio was 0.47 (95% confidence interval [CI], 0.26 to 0.80) with colonoscopic polypectomy, suggesting a 53% reduction in mortality. Mortality from colorectal cancer was similar among patients with adenomas and those with nonadenomatous polyps during the first 10 years after polypectomy (relative risk, 1.2; 95% CI, 0.1 to 10.6).

Conclusions: These findings support the hypothesis that colonoscopic removal of adenomatous polyps prevents death from colorectal cancer. (Funded by the National Cancer Institute and others.).

Impact on conclusions of systematic review: Additional knowledge supports current recommendations

**Measure Title: 9. Appropriate follow-up Recommendation**

**Date of Submission:** [7/16/2012](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

Outcome

- Health outcome: [4T](#)
- Intermediate clinical outcome: [Appropriate use of screening and surveillance colonoscopy without unintended serious consequences](#)
- Process: [Colonoscopy procedure: standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation](#)
- Structure: [4T](#)
- Other: [4T](#)

**HEALTH OUTCOME MEASURE** *If not a health outcome, skip to 1c.3*

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

**1c.2.** Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

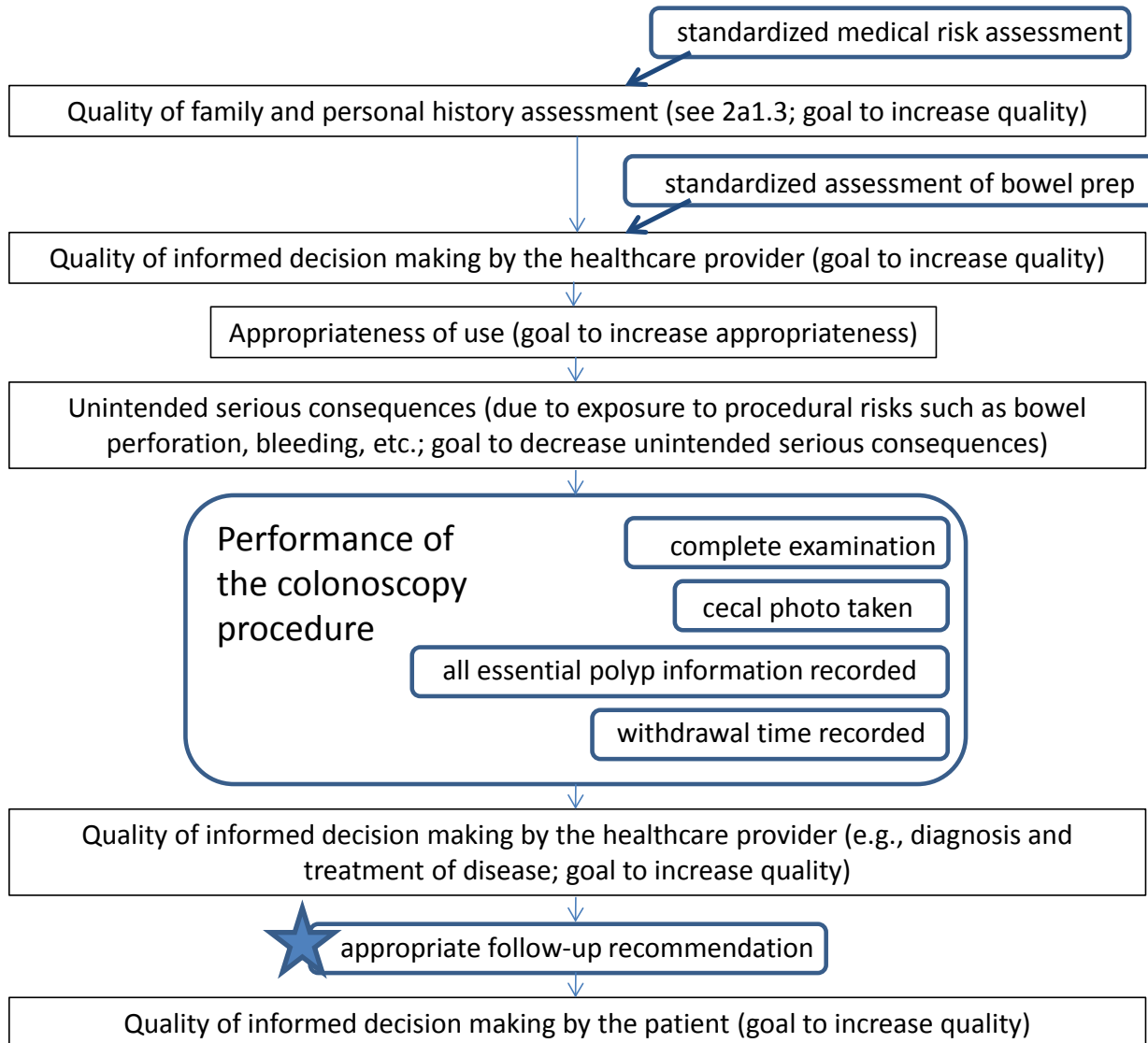
**1c.2.1.** State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

*Note: For health outcome measures, no further information is required*

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**1c.3.** Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (*Do not summarize the evidence here.*)



Appropriate use of colonoscopy examination for screening and surveillance, along with improved quality of the performance of the colonoscopy procedure (e.g., complete exam with cecal photo taken), and appropriate follow-up recommendations will ultimately lead to improved detection and therefore improved treatment of colorectal cancer. In this way, these process measures are expected to have an effect on patient outcomes (reduced morbidity and mortality due to colorectal cancer that is identified and treated; reduced morbidity from overuse of colorectal examination).

MEASURE FOCUS (standardized medical risk assessment, standardized assessment of bowel prep, complete examination, cecal photo taken, all essential polyp information recorded, withdrawal time recorded, appropriate follow-up recommendation)

---->

PROCESS CHARACTERISTIC (quality of family and personal history assessment, quality of informed decision making by the healthcare provider, appropriateness of use, unintended serious consequences, performance of the colonoscopy procedure, quality of informed decision making by the healthcare provider, quality of informed decision making by the patient)

----->

DESIRED HEALTH OUTCOME (any cancerous and precancerous polyps of the colon which are present are identified, documented, and acted upon)

**EVIDENCE = LOGICAL ARGUMENT**

The process-based subcomponent measures of the Colonoscopy Quality Index are related to expert consensus [1] and do not require evidence from systematic reviews to support their validity [2].

We recognize that logic is the basis on which science, including modern medicine, is built. In addition to completing the systematic review portion of the evidence form for the process-based subcomponent measures of the Colonoscopy Quality Index, we would like to highlight a straightforward logical argument for each of the process-based subcomponent measures of the Colonoscopy Quality Index.

Proposition: A high quality screening or surveillance colonoscopy is one that is performed A) on a patient that needs the test, B) in a thorough manner, and C) without harming the patient.

Measure/subcomponent	Proposition A	Proposition B	Proposition C
Colonoscopy Quality Index	Yes	Yes	Yes
1. Appropriate Indication for Colonoscopy	Yes		
2. Standardized Medical Risk Assessment		Yes	
3. Standardized Assessment of Bowel Prep		Yes	
4. Complete Examination		Yes	
5. Cecal Photo Taken		Yes	
6. All Essential Polyp Information Recorded		Yes	
7. Withdrawal Time was Recorded		Yes	
8. Free of Serious Complications			Yes
<b>9. Appropriate Follow-up Recommendation</b>		<b>Yes</b>	

Table: Relationship between Colonoscopy Quality Index and subcomponents and the propositions:  
 Proposition A) A high quality screening or surveillance colonoscopy is one that is performed on a patient that needs the test  
 Proposition B) A high quality screening or surveillance colonoscopy is one that is performed in a thorough manner  
 Proposition C) A high quality screening or surveillance colonoscopy is one that is performed without harming the patient.

1. Lieberman D., Nadel M., Smith R.A., Atkin W., Duggirala S.B., Fletcher R., Glick S.N., Johnson C.D., Levin T.R., Pope J.B., Potter M.B., Ransohff D., Rex D., Schoen R., Schroy P., Winawer S. (2007) Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. *Gastrointestinal Endoscopy* 65(6): 757-766.

2. Smith G.C.S. and Pell J.P. (2003) Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *BMJ*. 327(7429): 1459–1461.

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No  If no, skip to #1c.6  
 If yes, answer 1c.4.1-1c.5.  
 1c.4.1. Guideline citation (including date):



1c.4.2. URL (if available online):

1c.4.3. Identify guideline number and/or page number:

1c.4.4. Quote verbatim, the specific guideline recommendation:

1c.4.5. Grade assigned to the recommendation with definition of the grade:

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes   
No  If no, skip to #1c.6

If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

1c.5.1. Grade assigned to the body of evidence with definition of the grade:

1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF) Yes  No  If no, skip to #1c.7

If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. Citation (including date):

1c.6.2. URL (if available online):

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No

If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

#### FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010).

#### QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

#### ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

#### UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  If no, stop  
If yes,

1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.



# Quality Quest *for* Health

## **Definitions and Abbreviations Screening/Surveillance Colonoscopy**

Last updated 2.24.2011

**Acute Colonoscopic Complications:** bleeding requiring blood transfusion, bowel perforation, cardiopulmonary arrest, hospital admission or death occurring from the time of registration to discharge from the endoscopy site

**Advanced Neoplasia:** adenoma  $\geq 1$  cm; villous histology; high-grade dysplasia; or CRC

**ASA Class:** American Society of Anesthesiology Classification System (risk stratification)

**Complete Polyp Information recorded:** see page #6

**Complete colonoscopy:** Passage of colonoscope tip to a point proximal to the ileocecal valve so that the entire cecal caput, including the medial wall of the cecum between the ileocecal valve and the appendiceal orifice, is visible<sup>1</sup> (cecal intubation) or through the entire anatomical colon.

**CPA:** Cardiopulmonary arrest

**CRC:** Colorectal cancer

**CRC Screening:** Screening for colorectal neoplasia in asymptomatic, at-risk patients with no history of colorectal adenoma(s), polyp(s) or cancer.

**CRC Surveillance:** Follow up of patients with previous adenoma(s), polyp(s), colorectal cancer, or inflammatory bowel disease.

**Diagnostic Colonoscopy:** Colonoscopy performed in symptomatic patients or in those with other positive colorectal cancer screening tests.

**FAP:** Familial Adenomatosis Polyposis

**FHx:** Family History

**FDR:** First Degree Relative (Parent, sibling, child)

**HNPCC:** Hereditary Nonpolyposis Colorectal Cancer

**HPS:** Hyperplastic Polyposis Syndrome

**ID:** Site-specific de-identified Patient Descriptor

**IBD:** Inflammatory Bowel Disease (Ulcerative colitis or Crohn's disease)

**MM:** millimeter

**NA:** Not applicable

**NPI #:** National Provider's Identification number

**PHx:** Past (personal) History

**SD:** Severe or high-grade dysplasia

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<sup>1</sup> Gastrointestinal Endoscopy vol 63, supp 4-06

**SDR:** Second Degree Relative (Grandparent, aunt, uncle)

**UK:** Unknown

**V:** Villous or tubulovillous adenoma

**Previous colonoscopy:**

*Note: if blank, appropriateness of current screening or surveillance colonoscopy cannot be determined.*

- 0 = no
- 1 = Yes, year and results including polyp pathology are known (verified by patient or colonoscopy report)
- 2 = Yes, but year unknown
- 3 = Yes, but polyp pathology unknown
- 4 = Yes, but year and polyp pathology unknown
- 5 = Yes, but last colonoscopy unsatisfactory

**Date of last colonoscopy:** YYYY; if not applicable, or year could not be determined leave blank

**# of Adenomas on last colonoscopy:**

- 0 = none
- 1 = 1 or 2 adenomas
- 2 = 3 to 10 adenomas
- 3 = 11 adenomas and greater

**Appropriate Screening Indications**

<b>CRC Risk</b>	<b>Age to Initiate Screening</b>	<b>Personal and Family History</b>
Average risk	Age 50	No personal history or family history of CRC or adenomas and no colonoscopy in previous 10 years
Increased risk due to family history	Age 40 or 10 years before youngest affected relative	Two or more SDR with CRC and no colonoscopy in previous 10 years  One or more FDR with adenoma(s) before age 60 and no colonoscopy in previous 5 years  One FDR with CRC before age 60 or two or more FDR with

CRC at any age and no colonoscopy in previous 5 years

One FDR with CRC or adenoma age 60 or older and no previous colonoscopy in previous 10 years

History of FAP, HNPCC, IBD, HPS per special counseling recommendations

### Appropriate Surveillance Indications

Personal History	Pathology	Frequency (if bowel prep adequate and complete exam)
Prior colon cancer		Clearance colonoscopy around time of surgery, 1 year, 4 years, then every 5 years
Prior rectal cancer <sup>2</sup>		Clearance colonoscopy around time of surgery, 1 year, 4 years, then every 5 years
Previous non-cancerous polyp(s)	Hyperplastic polyp(s) excluding HPS	10 years
	≤ 2 small (<1 cm) tubular adenomas	5 to 10 years
	3 – 10 adenomas	3 Years
	Advanced Neoplasia	3 years
	More than 10 adenomas or serrated adenoma	1 year
	Sessile adenoma with incomplete excision	2-6 months
	Negative complete surveillance colonoscopy	5 years

<sup>2</sup> Patients with prior rectal cancer with low anterior resection who have not undergone pelvic radiation and have not had mesorectal resection may need flexible sigmoidoscopy every 3- 6 months for 2-3 years in addition to recommended colonoscopy surveillance.

## American Society of Anesthesiology (ASA) Classification System

### Class

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- 1 Patient has no organic, physiologic, biochemical or psychiatric disturbance (healthy, no comorbidity).
- 2 Mild to moderate systemic disturbance caused either by the condition to be treated surgically or by other pathophysiologic processes (mild to moderate condition, well-controlled with medical management: examples include stable diabetes, coronary artery disease, chronic pulmonary disease).
- 3 Severe, systemic disturbance or disease from whatever cause, even though it may not be possible to define the degree of disability with finality (disease or illness that severely limits normal activity and may require hospitalization or nursing home care: examples include severe stroke, poorly controlled congestive heart failure or renal failure).
- 4 Severe systemic disorder that is already life-threatening, not always correctable by the operation (examples include coma, acute myocardial infarction, respiratory failure requiring ventilator support, renal failure requiring urgent dialysis, bacterial sepsis with hemodynamic instability).
- 5 The moribund patient who has little chance of survival.

### Adequacy of Bowel Preparation Assessment<sup>3</sup>

		Adequate Y/N
<b>Excellent</b>	No or minimal solid stool and only small amounts of clear fluid requiring suction.	Y
<b>Good</b>	No or minimal solid stool with large amounts of clear fluid requiring suctioning.	Y
<b>Fair</b>	Collection of semisolid debris that are cleared with difficulty.	Y
<b>Poor</b>	Collection of semisolid debris that cannot be effectively cleared.	N
<b>Unsatisfactory</b>		N

**Complete Exam:** See 'Complete colonoscopy' definition.

**Cecal Photo:** Picture of the cecum.

### Complete Polyp(s) Documentation

Polyp(s) identified Y/N

All 6 polyp characteristics documented

- Number
- Size (Record in millimeters the colonoscopist's estimated size; however, if only described with words "small or diminutive" record as 4mm, "moderate" record as 9mm, and "large" record as 11mm)
- Anatomic location
- Gross Morphology for polyps  $\geq 5$  mm (pedunculated, sessile, flat or depressed)
- Method of removal
- Completely removed Y/N

**Withdrawal Time:** Total time in minutes recorded from the beginning of cecal scope withdrawal till extubation.

**Free of acute complication:** See 'Acute Colonoscopic Complications' definition.

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<sup>3</sup> Gastrointestinal Endoscopy vol 63, No. 4:200 S20

## Follow-Up Colonoscopy Recommendation:

*Note: if a range is submitted, e.g. 5-10 years, use the lower number*

- 0 = Not recorded
- 1 = F/U in 2 to 6 months
- 2 = F/U in 1 year
- 3 = F/U in 3 years
- 4 = F/U in 5 years
- 5 = F/U in 10 years
- 6 = F/U pending pathology results
- 7 = No F/U necessary or indicated
- 8 = Other timeframe than listed above
- 9 = Referral to another surgeon or colonoscopist for polyp removal
- 10 = Due to patient's concern and/or above average CRC risk and the incomplete colonoscopy, a follow-up colon imaging procedure (e.g. CT Colonography, Colon X-ray or a repeat Colonoscopy) should be performed as soon as possible.





# Quality Quest *for* Health



## Using Data to Change Practice

Digestive Disease Week

May 19, 2012

# Quality Quest *for Health*

## Quality Quest

### *A Regional Health Improvement Collaborative*

- Neutral forum with deep expertise
- Take on the hardest problems
- Independent and unbiased
- Create change that is otherwise not possible
- Goal: better outcomes and higher value
- Result: lower costs and healthier communities

No one and no Body is in charge, incentives are not aligned, little to no transparency or accountability.



## Quality Quest *for* Health

“Although providing the best possible care is our most important goal, we are poorly equipped to measure our ability to achieve that goal.”

David J. Bjorkman, MD, MSPH, ASGE President  
John W. Popp, Jr. MD, FACG, ACG

“Surveillance is largely unregulated and depends on the decision of the doctor.” Dr. Kosinski



## CRC Screening after Polypectomy: A National Survey Study of Primary Care Physicians

Assume: complete exam, excellent prep, no family hx

A 55 year old male undergoes screening colonoscopy.

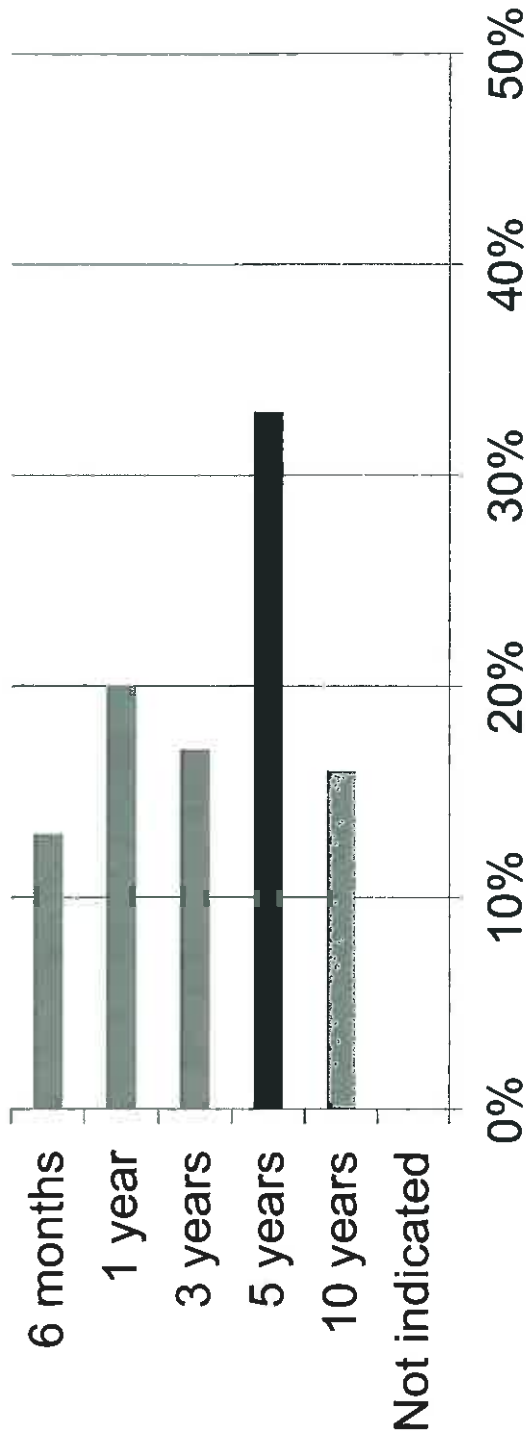
Assume that he remains in good health and asymptomatic after the colonoscopy. Based on the pathology please indicate the interval at which you would schedule him for repeat colonoscopy.

Annals of Internal Medicine 2006, 145: 654-659



# Quality Quest for Health

Scenario #1 – Single 6 mm polyp is found in the sigmoid and removed by snare cauterly. On path the polyp is found to be a tubular adenoma.

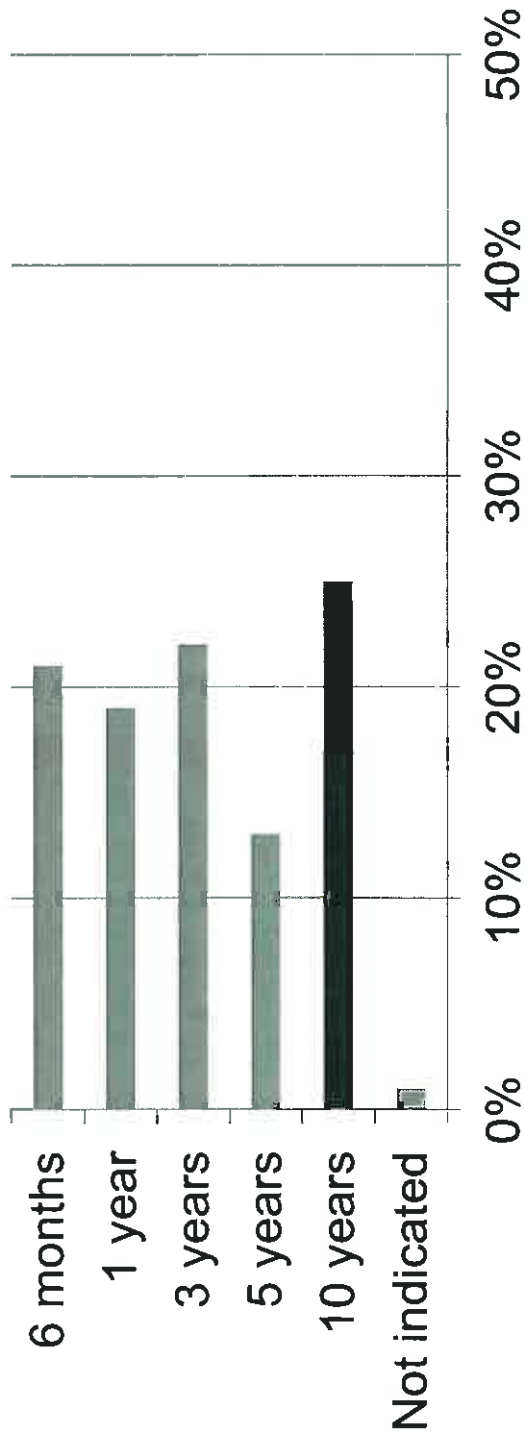


Annals of Internal Medicine 2006, 145: 654-659



# Quality Quest for Health

Scenario #2 – Single 6 mm polyp is found in the sigmoid and removed by snare cauterly. On path the polyp is found to be a hyperplastic polyp.

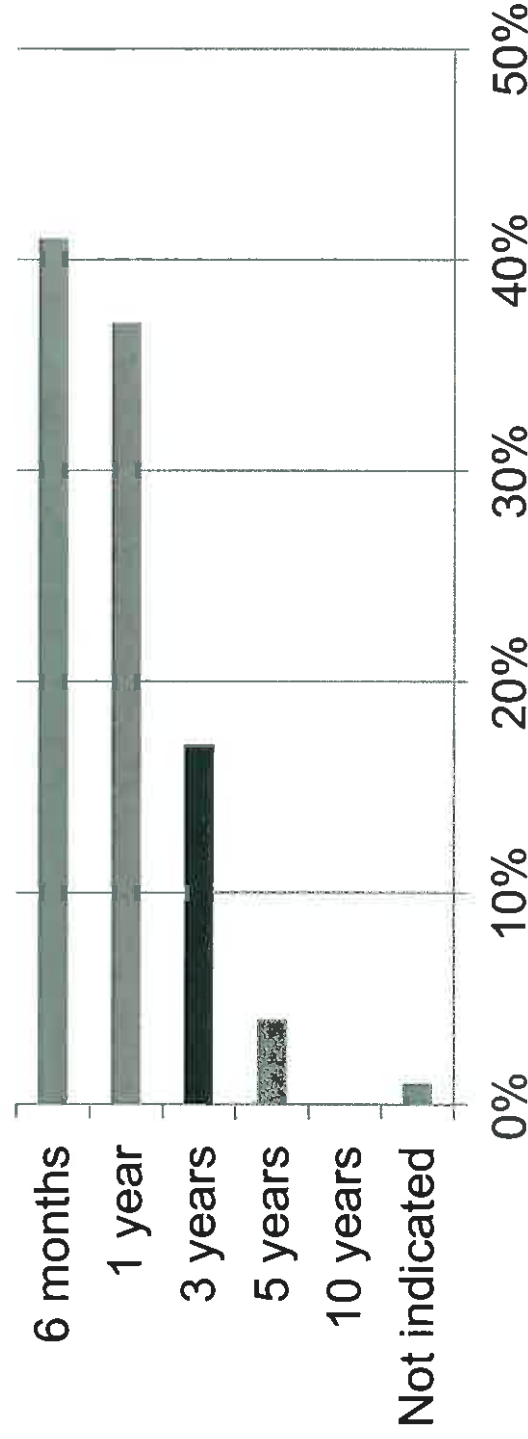


Annals of Internal Medicine 2006, 145: 654-659



## Quality Quest for Health

Scenario #3 – Single 12 mm pedunculated polyp is found in the sigmoid and removed by snare cauterly. On path the polyp is found to be a tubular adenoma with focus of high grade dysplasia away from the cauterly margin.

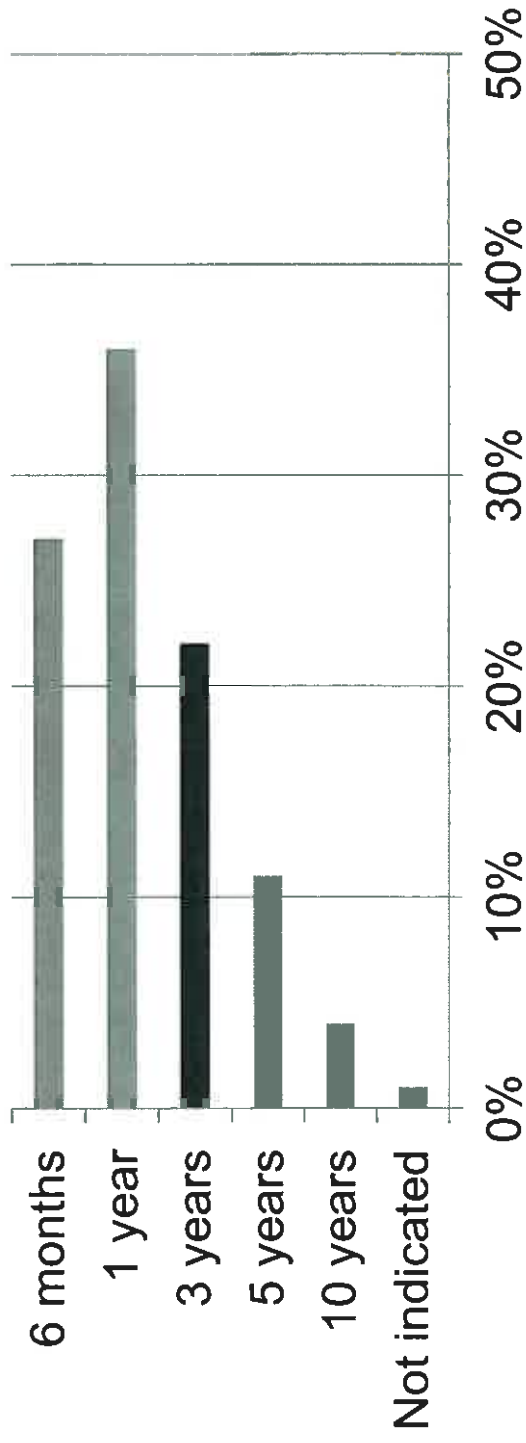


Annals of Internal Medicine 2006, 145: 654-659



# Quality Quest for Health

Scenario #4 – Single 12 mm polyp is found in the sigmoid and removed by snare cauterly. On path the polyp is found to be a tubulovillous adenoma.

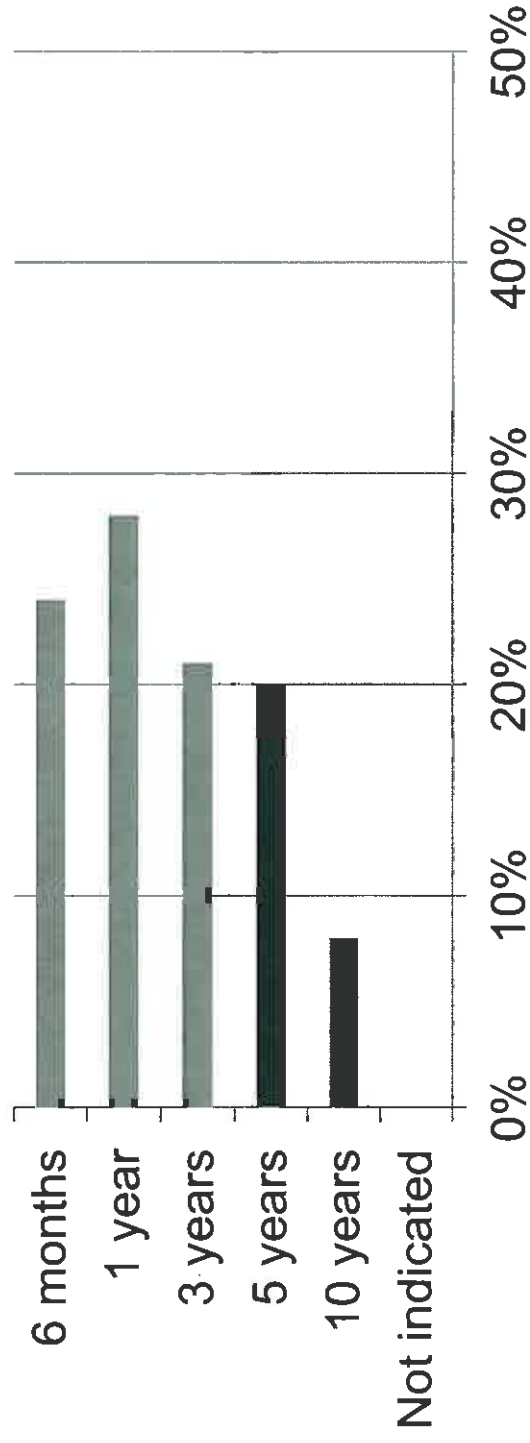


Annals of Internal Medicine 2006, 145: 654-659



# Quality Quest for Health

Scenario #5 – Two 6 mm polyps are found in the sigmoid and removed by snare cautery. On path the polyps are found to be tubular adenomas.



Annals of Internal Medicine 2006, 145: 654-659

## The 2007 Colonoscopy Team

Dr. Terry Baldwin – Team Lead .....	GI
Dr. Rick Luetkemeyer .....	Caterpillar Inc
Dr. Michael Cashman .....	GI
Dr. Michael Shekleton .....	GI
Dr. Michael Hayes .....	Pathology
Dr. Tom Rossi .....	General Surgery
Rita Menold .....	Quality Manager
Jane Brophy .....	Consumer
Rusty Hewitt .....	6 Sigma Blackbelt



## Colonoscopy Quality Index:

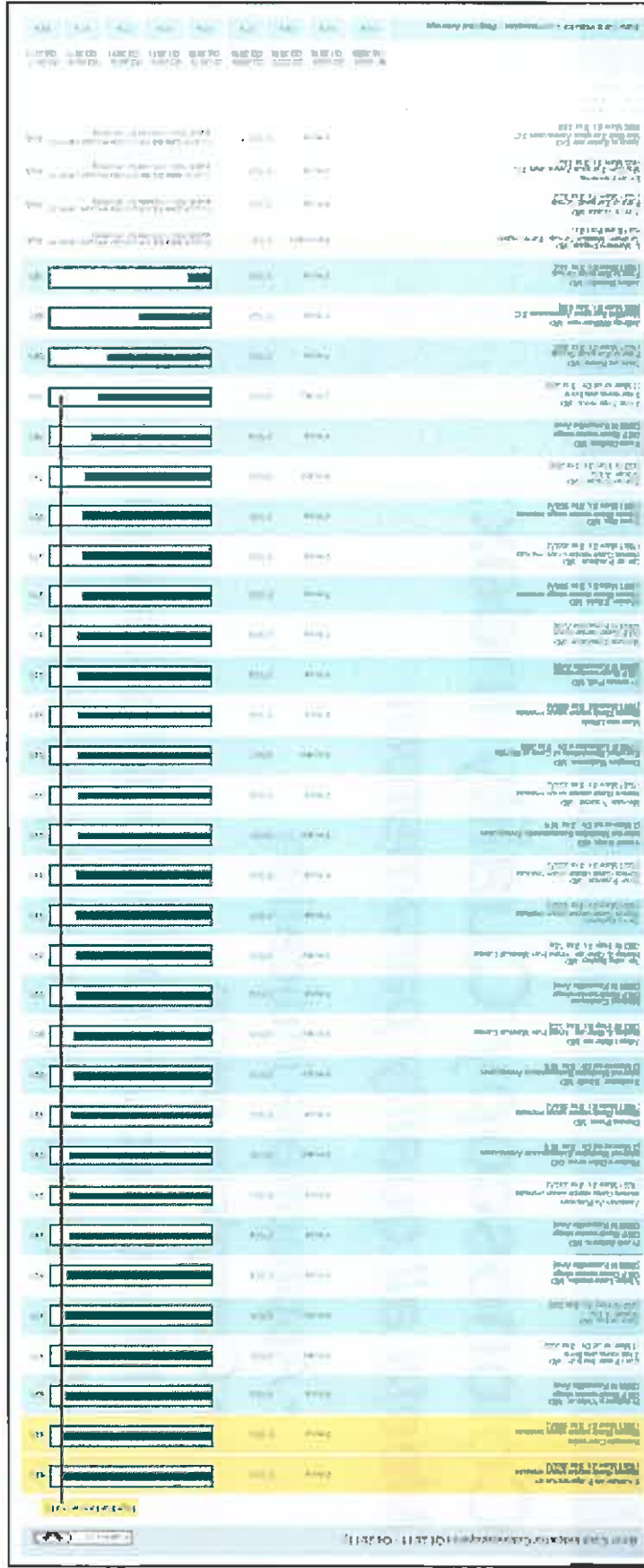
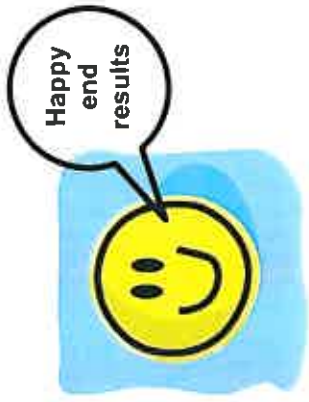
*Meets all quality parameters*

- Appropriate indication
- Complete exam
- Photo-documentation of the cecum
- No serious acute complications
- Bowel preparation assessment  
excellent/good/fair/poor/unsatisfactory
- Cardiac risk assessment
- Polyp information complete or no polyp  
#/size/location/morph/removal/method
- Withdrawal time recorded
- Appropriate follow-up recommendation



# Quality Quest for Health

## Colonoscopy Quality Index 2011 Results



# Quality Quest for Health

[Patients & Families](#)
[Providers](#)
[Employers](#)
[Insurers](#)
[Resources](#)
[Quest Projects](#)
[Quality Reports](#)

Quality Reports > Learn About Colonoscopy Quality

## Learn About Colonoscopy Quality

Doctors in the area have collaborated to determine what is the **Highest Standard of Care for Colonoscopy**.

This report compares doctors in Peoria County, Illinois who perform colonoscopies. The **Best Care Index** is based on meeting nine individual quality measures. Note Future reports will encompass additional counties

### Report generated for:

Counties: **All Counties**

Measures: **Best Care Index**

Measure Descrip: **Best Care Index**

Medical Risk Assessment

Bowel Preparation Assessment

Complete Examination

Photo-documentation of Cecum

Complete Polyp Information

No Serious Complications

Withdrawal Time Recorded

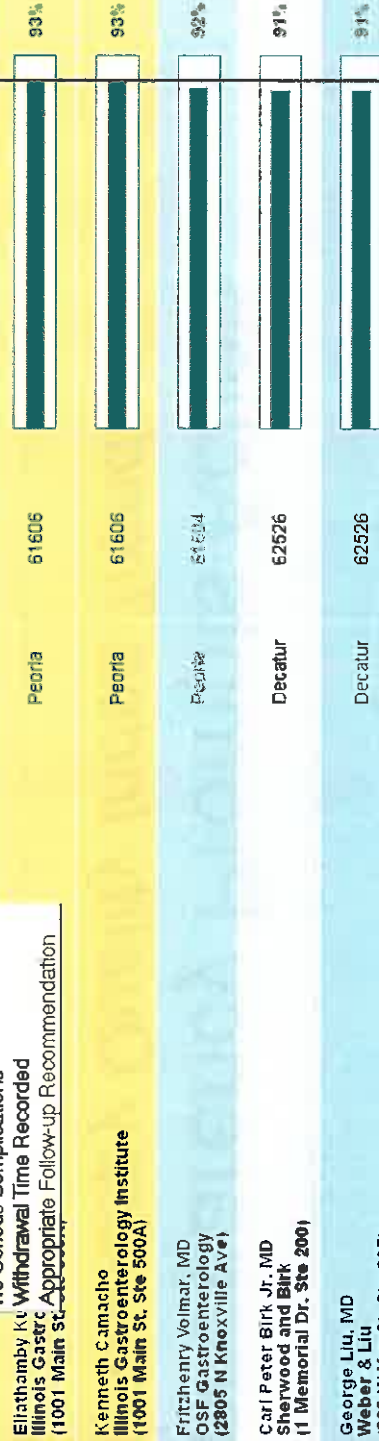
Appropriate Follow-up Recommendation

Endoscopist (> 30 for graphical display), and endoscopy site

**- Q4 2011:**

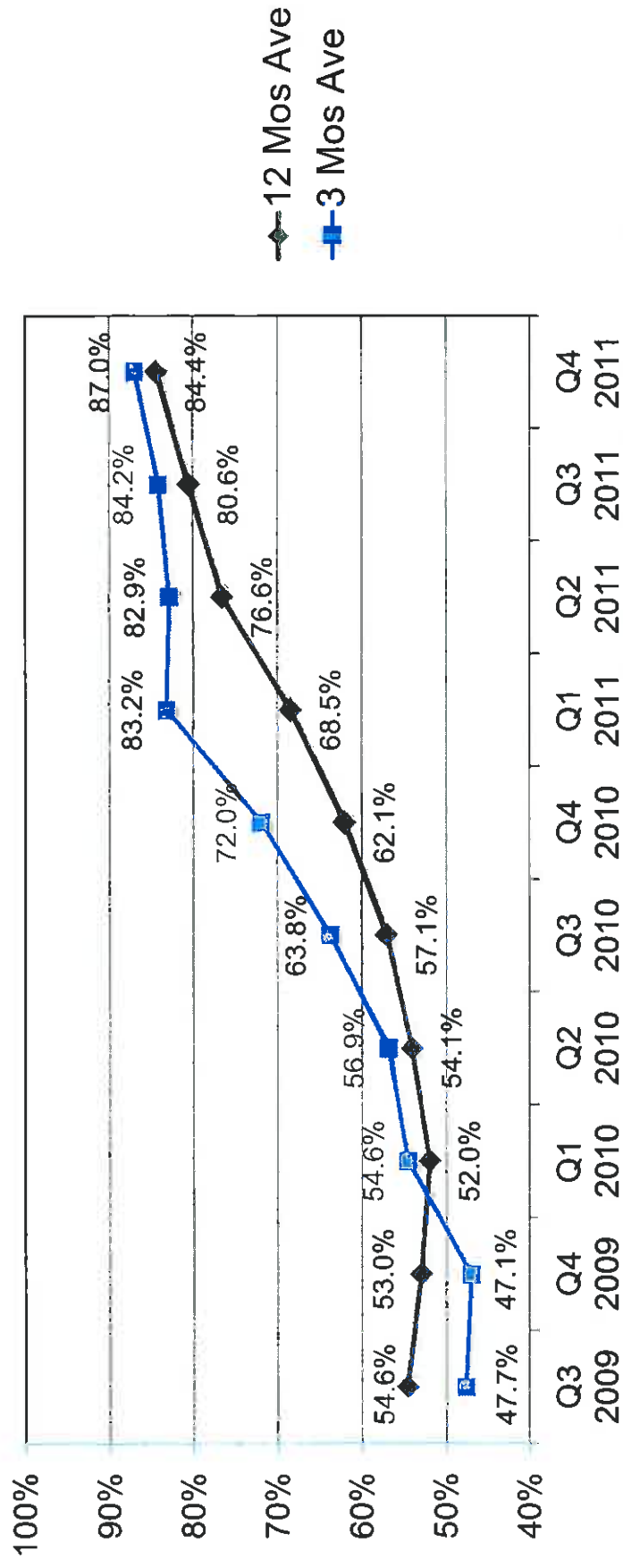
High to Low

High Performer = 93%



# Quality Quest for Health

## Transparency Prompts Action Colonoscopy Quality Index Trend



Transparency provides recognition for those doing well and motivation for those who are not.

## Q4 2011 Performance Variation

n = 2308		High	Average	Low
Colonoscopy Quality Index		97.5%	87.0%	12.5%
Appropriate Indication		100%	94.2%	68.8%
Medical Risk Assessment		100%	99.7%	87.5%
Bowel Preparation Assessment		100%	98.9%	87.5%
Complete Examination		100%	99.5%	94.2%
Photo-documentation of Cecum		100%	99.6%	87.5%
Complete Polyp Information		100%	99.0%	92.3%
No Serious Complication		100%	99.9%	97.8%
Withdrawal Time Recorded		100%	99.6%	93.8%
Appropriate Follow-up Recommended		100%	93.7%	31.3%





# Quality Quest for Health

## Top, Middle & Lowest Performance

MD	Qual Index	App Ind	ASA Score	Bowel Prep	Full Exam	Cecal Photo	Polyp Info	No Comp	Time Rec	App F/U
#1	93%	96%	99%	100%	100%	100%	100%	100%	100%	98%
#2	93%	96%	100%	99%	100%	100%	100%	100%	100%	99%
#15	85%	94%	100%	97%	100%	100%	99%	100%	100%	95%
#30	46%	89%	99%	85%	97%	93%	78%	100%	99%	68%
#31	14%	70%	95%	86%	97%	95%	95%	100%	86%	32%

## Determining Appropriateness

Screening		
CRC Risk	Age to Start Screening	Personal and Family History
Average risk	Age 50	No personal history or family history of CRC or adenomas and no colonoscopy in previous 10 years
Increased risk due to family history	Age 40 or 10 years before youngest affected relative	Two or more SDR with CRC and no colonoscopy in previous 10 years
		One or more FDR with adenoma(s) before age 60 and no previous colonoscopy in previous 5 years
		One FDR with CRC before age 60 or two or more FDR with CRC at any age and no previous colonoscopy in previous 5 years
		One FDR with CRC or adenoma age 60 or older and no previous colonoscopy in previous 10 years
		History of FAP, HNPCC, IBD, HPS per special counseling recommendations

## Surveillance

Personal History	Pathology	Frequency (if bowel prep adequate and complete exam)
Prior colon cancer		Clearance colonoscopy around time of surgery, 1 year, 4 years, then every 5 years
Prior rectal cancer		Clearance colonoscopy around time of surgery, 1 year, 4 years, then every 5 years
Prior rectal cancer with low anterior resection without pelvic Radiation and without mesorectal resection		Clearance colonoscopy around time of surgery, 1 year, 4 years, then every 5 years AND flexible sigmoidoscopy every 3-6 months for 2-3 years
Previous non-cancerous polyp(s)	Hyperplastic polyp(s) excluding HPS	10 years
	≤ 2 small (<1 cm) tubular adenomas	5 to 10 years
	3 – 10 adenomas	3 years
	Advanced Neoplasia	3 years
	More than 10 adenomas or serrated adenoma	1 year
	Sessile adenoma with incomplete excision	2-6 months
	Negative complete surveillance colonoscopy	5 years

## Outcomes

*Initial Screening, Average Risk, Age 50*

<b>Adenoma Detection</b>	
Men	44.4%
Women	30.1%

<b>Advanced Neoplasia</b>	
Average	11.0%*

\*Initial audit results confirm rate



# Quality Quest for Health

## Patient-level Data for QI Focus

Compare Results: Colonoscopy Centers Clinicians Patients

20.0% (Total # of Colonoscopies = 10)

Patient ID	Procedure Date	Colonoscopy Center	Approp. Indic.	ASA Risk	Bowel Prep Exam	Cecal Photo	Polyp Info & N/A	No Acute Complication	Withdrawal Time	Approp. F/U
[Redacted]	[Redacted]	[Redacted]	1	1	1	0	1	1	1	0
[Redacted]	[Redacted]	[Redacted]	0	1	1	1	1	1	0	0
[Redacted]	[Redacted]	[Redacted]	0	1	1	1	1	1	0	1
[Redacted]	[Redacted]	[Redacted]	1	1	1	1	1	1	1	0
[Redacted]	[Redacted]	[Redacted]	1	1	1	1	1	1	1	0
[Redacted]	[Redacted]	[Redacted]	1	1	1	1	1	1	1	0
[Redacted]	[Redacted]	[Redacted]	1	1	1	1	1	1	1	0
[Redacted]	[Redacted]	[Redacted]	1	1	1	1	1	1	1	0

Encrypted

**NOTE:** These patients were classified as not being a 100% compliant based on at least one quality element above not being met.

Values above are defined as: Y=1 and N=0

Follow-up was not appropriate for 7 patients. Addressing this single issue improves this composite performance from 20% to 70%.

<b>Patient Demographics</b>	Patient ID
	Sex
	Age (ages 90 and above will be given the value of "90")
<b>Personal Hx</b>	Personal Hx CRC: Y/N
	PHx Villous Adenoma: Y/N
	PHx Severe Dysplasia: Y/N
	PHx Serrated Adenoma: Y/N
	PHx Incomplete Polyp Removal: Y/N
	PHx Adenoma(s) # last exam: none/1-2/3-9/ten or more
	Size (mm) of largest Previous Adenoma
<b>IBD</b>	IBD: Y/N
<b>Family Hx</b>	FHx CRC: FDR/SDR/None
	Age Youngest FDR with CRC
	# FDR CRC: 0/1/2/3/etc.
	# SDR CRC: 0/1/2/3/etc.
	FDR Adenoma: Y/N
	Age Youngest FDR with Adenoma
<b>Syndromes</b>	PHx or FHx FAPS, HNPCC, HPS: Y/N
<b>Previous Tests</b>	Colonoscopy: None/ Y (Year & Polyp Info Known/ Y (Polyp info Unknown)/ Y (Year or Polyp Info Unknown)/ Y (Last Colonoscopy Unsatisfactory)
	Year of Previous Colonoscopy

<b>Procedure Logistics</b>	Procedure Date yyyy-mm-dd
	Endoscopy Facility ID
	Endoscopist First Name
	Endoscopist Last Name
	Endoscopist NPI #
<b>Colonoscopy Logistics</b>	Procedure Date yyyy/mm/dd
	Screening/Surveillance/Exclude Diagnostic
	Withdrawal Time (in minutes)
<b>Procedure</b>	ASA Class: Not Recorded/1/2/3/4/5
<b>Bowel Preparation</b>	Bowel Prep Type: Not recorded/Fleets' Phospha Soda/CoLyte/GoLyte/HalfLytey/Trilytey/Nulutely/Visicol Tabs/MoviPrep or Miralax/Mag Citrate/Mag Citrate with Dulcolax/Osmoprep/Trizol Gallon/New Type (place note for future uploads)
	Assessment of Prep: Not Recorded, Excellent (No or minimal solid stool and only small amounts of clear fluid requiring suction), Good (No or minimal solid stool with large amounts of clear fluid requiring suction), Fair (Collection of semisolid debris that are cleared with difficulty), Poor (Collection of semisolid debris that cannot be effectively cleared), Unsatisfactory

<b>Completeness</b>	Complete Exam: Y/N
<b>Polyps</b>	Cecal Photo: Y/N/Not Applicable
	Any Polyp Removed: Y/N
	Number of Polyps Removed
<b>Findings</b>	Largest Polyp Removed (mm) Colonoscopist's Estimate
	All Polyp Info Recorded: Y (includes number, size, location, morphology, method of removal, completeness of removal)/N
	Any Adenomatous Polyp(s)
	# Confirmed Adenoma(s)
	Additional Findings or Characteristics Noted by the Pathologist: Villous or Tubulovillous Adenoma/Severe or High Grade Dysplasia/Colorectal Cancer/Not Applicable
<b>Procedural Safety</b>	Any Serrated Adenoma: Y/N
	Free of Acute Complications (Blood Transfusion/ Perforation/ Cardiopulmonary Arrest/Hospital Transfer; Death): Y/N
	Recommend F/U Colonoscopy: Not recorded/2-6 months/1 year/3 years/5 years/10 years/Pending Pathology/No F/U indicated/Other/Referral to another surgeon or colonoscopist for polyp removal/F/U to visualize complete colon (i.e. CT Colonography, Colon x-ray or Barium Enema, or repeat colonoscopy) within the next 6 months
<b>Follow Up Recommendation</b>	



# Quality Quest for Health

## Common Priorities

*CRC Screening & Surveillance Colonoscopy*

## Report Results Publicly

*Quality Quest on-line reports*

## Agree on Best Care

*Six Sigma team defines quality elements*

## Redesign Care Processes

*Data system, better histories, change in practice, ongoing QI focus*

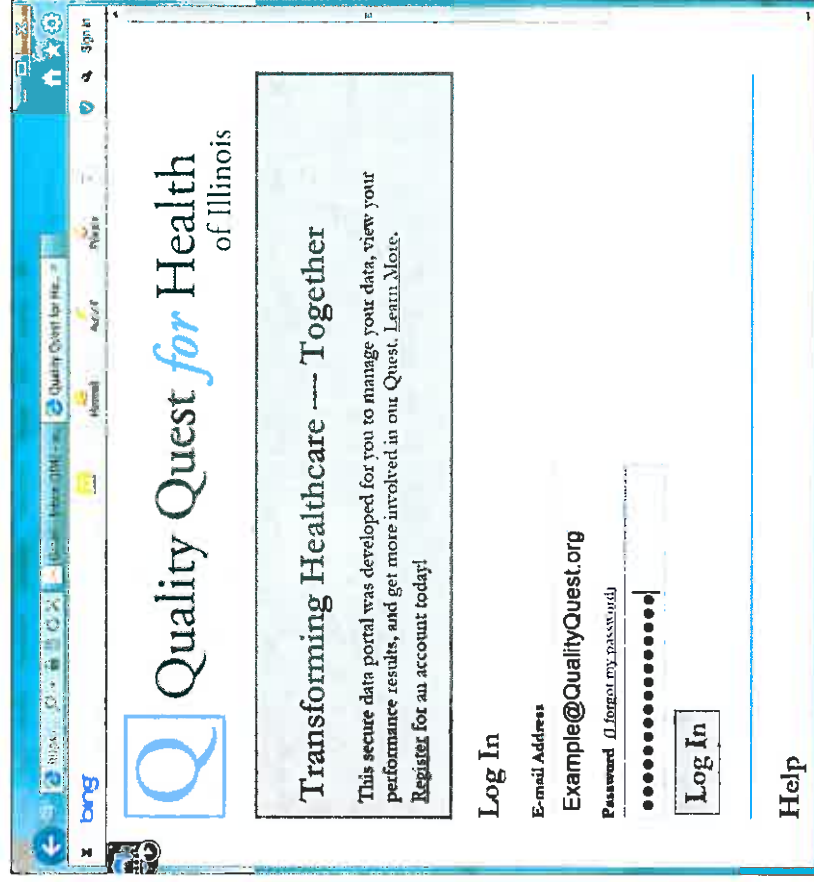
## Measure What Matters

*Colonoscopy Quality Index – ‘All-or-None’*

## Create Positive Incentives

*Caterpillar P4P & contracts require participation in data program*

# Quality Quest *for* Health



Visit our website

[www.qualityquest.org](http://www.qualityquest.org)

to register to participate

or contact me

[GAmundson@QualityQuest.org](mailto:GAmundson@QualityQuest.org)

for further information



# It Plays in Peoria!



Peoria and Decatur, Illinois are poised to  
redefine quality benchmarks for screening  
and surveillance colonoscopy.

