

GI/GU Endorsement Maintenance Pilot Project: Completed Stage Two Checklist for Colonoscopy Quality Index (#2056)

Below is the response for EACH Committee recommendation describing our rationale for implementing (or not) the recommendation and any additional considerations.

Component	Committee Recommendations for Stage 2	Developer Response
Item 1: Appropriate Indication for Colonoscopy	None	N/A

Component	Committee Recommendations for Stage 2	Developer Response
Item 2: Standardized Medical Risk Assessment	<p>This component should not be included in the composite. This assessment is standard medical practice and does not represent whether or not an endoscopist has performed a high-quality colonoscopy for colorectal cancer screening or colon polyp surveillance. <i>The committee recommends that this component be removed from the composite.</i></p>	<p>Colonoscopy is an invasive procedure. Anesthetic agents are frequently administered. Assessing the ASA status of the patient is an important safety step crucial to performing a high quality colonoscopy.</p> <p>The ASA physical status classification system is a 5 category system for assessing the fitness of patients before surgery. It was adopted by the American Society of Anesthesiologists in 1963.</p> <p>The categories are:</p> <p>1 - Patient has no organic, physiologic, biochemical or psychiatric disturbance (healthy, no comorbidity).</p> <p>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).</p> <p>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).</p> <p>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).</p> <p>5 - The moribund patient who has little chance of survival.</p> <p>Failure to follow standard medical practice signifies poor quality. We will continue to include this component in the composite.</p>

Component	Committee Recommendations for Stage 2	Developer Response
Item 3: Standardized Assessment of Bowel Prep	<p>The Committee agreed that bowel prep is an important indicator for whether a quality colonoscopy can be performed but as specified this component should not be included in the composite. Simply documenting the bowel prep is not an indicator of quality. Passing this component should be contingent on the quality of the bowel prep (e.g., whether the procedure needed to be rescheduled due to poor bowel prep).</p> <p><i>The committee recommends that this component be removed from the composite.</i></p>	<p>Bowel preparation assessment is an important quality step in a colonoscopy procedure. These are the categories of preparation: Excellent - No or minimal solid stool and only small amount of fluid requiring suction. Good - No or minimal solid stool with large amounts of clear fluid requiring suctioning. Fair - Collection of semisolid debris that are cleared with difficulty. Poor - Collection of semisolid debris that cannot be effectively cleared. Unsatisfactory</p> <p>As stated in our previous communication, 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%), Mehrotra, A., et al (2012)</p> <p>** Please Note ** If this component is excluded from the composite at a later date, the information regarding bowel prep assessment will still be needed to apply exclusion criteria.</p> <p>Failure to follow standard medical practice signifies poor quality. We will continue to include this component in the composite.</p>
Item 4: Complete Examination	None	N/A
Item 5: Cecal Photo Taken	None	N/A

Component	Committee Recommendations for Stage 2	Developer Response
Item 6: All Essential Polyp Information Recorded	The information recorded about the polyp should include whether or not adenoma was detected.	Essential polyp information recorded at the time of the procedure includes the number, size, location, morphology (if >4mm in size), method of removal, and completeness of removal. We do collect data related to adenoma detection, but confirmation of adenomas is pending the pathologist report at the time of the colonoscopy exam. Therefore we do not include whether or not an adenoma was detected in this component.
Item 7: Withdrawal Time was Recorded	Getting credit for simply documenting the withdrawal time is not an indication of a quality colonoscopy as the colonoscopist could get credit for a withdrawal time that is outside of the timeframe shown to produce the highest adenoma detection rates. Further, without any linkage to a colonoscopist's adenoma detection rate within this measure, the relevance of this component is greatly diminished. <i>The committee recommends that this component be removed from the composite.</i>	Withdrawal time is an indication of the thoroughness of the exam. Withdrawal time of 6 minutes, or greater, has been proven to correlate with adenoma detection rates. Recording of withdrawal time provides an important piece of information useful in practice evaluation. The colonoscopy quality index is at the individual patient level; adenoma detection rate is not appropriate at the individual patient level. Per Lieberman (2007), "The following times should be recorded: (1) the endoscope is inserted into the rectum, (2) withdrawal from cecum was started, and (3) the endoscope is withdrawn completely." Failure to record withdrawal time diminishes colonoscopy quality.

Component	Committee Recommendations for Stage 2	Developer Response
Item 8: Free of Serious Complications	Capturing intra-procedural complications is important, however, the timeframe where complications are most likely to occur (1-14 days post procedure) are not captured by this measure. To identify procedure related complications in the most the complete way, this timeframe should be adjusted. If, the timeframe is not adjusted, the title of this component should be renamed to "Free of Serious <i>Intra-Procedural</i> Complications".	We agree that including the timeframe in the component title adds clarity and have updated the title of this component.
Item 9: Appropriate Follow-up Recommendation	Clarify the timeframe specified for when the follow up recommendation can be given to the patient.	We have not specified a timeframe for providing the patient with the follow-up recommendation, nor do we collect information on the number of days from completion of the colonoscopy exam to when the recommendation for follow-up is made to the patient. Data on time from exam completion to patient advisement is important to understand, but we expect some variation in time related to the result of the exam. For example, we would expect same-day advisement of the patient when there are no polyps detected for a patient seen for an initial screening colonoscopy. However, we would expect a longer interval for advisement of the patient when there are polyps detected and removed during an initial screening colonoscopy (advisement pending pathology results).

Component	Committee Recommendations for Stage 2	Developer Response
General	The concept submission form and the evidence attachment must be updated to reflect the evidence submitted for the reconsideration process and the adjustments made to the measure in response to Committee recommendations.	<p>We have updated the concept submission form as indicated above, as well as to correct typographical errors in the original submission (the \geq symbol had been erroneously changed to $>$ in several instances; this has been corrected).</p> <p>We have also provided a summary of the evidence base for the Colonoscopy Quality Index under the data field Ad.9. Additional Information/Comments</p>



Measure Submission and Evaluation Worksheet 6.0

This form contains the information submitted by measure developers/stewards, organized according to NQF’s measure 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 #: 2056 NQF Project: GI and GU Project
(for Endorsement Maintenance Review) Original Endorsement Date: Most Recent Endorsement Date: Evaluation Form Created: March 22, 2013
BRIEF MEASURE INFORMATION
De.1 Measure Title: Colonoscopy Quality Index
Co.1.1 Measure Steward: QualityQuest for Health of Illinois, Inc.
De.2 Brief Description of Measure: 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 intra-procedural 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 intra-procedural 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 Measure Type: Process 2a1. 25-26 Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Other, Paper Medical Records, Electronic Clinical Data : Registry, 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. Data is collected and entered into a Microsoft Access Database provided by QualityQuest at each colonoscopy center. The process by which data is abstracted from the medical record (e.g., procedure reports, patient chart, pathology reports) may differ at each endoscopy center depending on the clinical data system(s) used at each endoscopy center. For example, some participating centers have electronic medical record systems and some have paper medical record systems. Data is abstracted by an endoscopy center staff member and entered into the Microsoft Access Database provided by QualityQuest. Details of this process are provided in the "data aggregation and reporting process" section of the appendix. After secure electronic data transfer from the Microsoft Access Database provided by Quality Quest to the colonoscopy quality measurement registry on the Quality Quest for Health of Illinois data portal, the data is aggregated and results reported. 2a1.33 Level of Analysis: Clinician : Individual, Population : Regional 1.2-1.4 Is this measure paired with another measure?

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed):

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

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

Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H M L I

(The measure 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, Gastrointestinal (GI), Gastrointestinal (GI) : Polyps, Prevention, Cancer : Screening, Gastrointestinal (GI) : Screening

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

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.

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

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. 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

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 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 measure:

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 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers):

[For Maintenance] – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

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 Intra-procedural 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: [For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]

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 Summary of Data on Disparities by Population Group (for example by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability, etc. If you do not have data on your specific measure, perform a literature search/review and report data for the measure or similar appropriate concept.): [For Maintenance – Descriptive statistics for performance results for this measure by population group]

not applicable

1b.5 Citations for Data on Disparities Cited in 1b.4: [For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]

not applicable

1c. Evidence (Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.) Is the measure 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 measure pass subcriterion 1c?
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 measure pass subcriterion 1c? Yes <input type="checkbox"/> IF rationale supports relationship	
SEE ATTACHED EVIDENCE SUBMISSION FORM			
Was the threshold criterion, <i>Importance to Measure and Report</i> , met? (1a & 1b must be rated moderate or high and 1c yes) Yes <input type="checkbox"/> No <input type="checkbox"/>			
Provide rationale based on specific subcriteria:			
<p>For a new measure if the Committee votes NO, then STOP.</p> <p>For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.</p>			

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **(evaluation criteria)**

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained?
<http://www.qualityquest.org/quality-reports/>

2a1.1 Numerator Statement (Brief, narrative description of the measure 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):
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 intra-procedural complication, 9. Appropriate follow-up recommendation). Elements that do not apply are excluded from numerator calculation.

2a1.3 Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses):

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 no 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 intra-procedural 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 measure is specified and tested if any):

Senior Care

2a1.7 Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

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, codes with descriptors, and/or specific data collection items/responses):

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, codes with descriptors, definitions, and/or specific data collection items/responses):

None

2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification **2a1.12 If "Other," please describe:**

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 2b4.):

N/A

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score:

Rate/proportion

If other:

2a1.19 Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score):

better quality = higher score

2a1.20 Calculation Algorithm/Measure Logic (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

This measure is calculated by submitting a file of individual colonoscopy exam values (e.g., Age, gender, procedure date, physician NPI number) as described in the Excel file codebook that has been uploaded to our submission. A provided Microsoft Access database is used to compile the data at each practice site and securely transmit the data to a HIPAA compliant portal. This process is described in detail in the appendix section "Data aggregation and reporting process" which begins on page (7). Programming within the data portal applies denominator exclusion criteria and numerator logic. All qualified colonoscopy exams performed at participating sites are included. This is an all-or-none measure calculated with the following logic:

High Quality Colonoscopy = Were all components met? = (Condition 1 met: appropriate indication for colonoscopy) AND (Condition 2 met: standardized medical risk assessment) AND (Condition 3 met: standardized assessment of bowel prep) AND (Condition 4 met: complete examination) AND (Condition 5 met: cecal photo taken) AND (Condition 6 met: all essential polyp information recorded) AND (Condition 7 met: withdrawal time was recorded) AND (Condition 8 met: free of serious intra-procedural complications) AND (Condition 9 met: appropriate follow-up recommendation)

If all 9 of the conditions are met, the case is calculated as a numerator case for the colonoscopy index (e.g., succeeds). If 1 or

more components "fail," the entire case fails.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

Included in attached appendix

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

Not applicable

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

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

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.):

N/A

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:

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. Data is collected and entered into a Microsoft Access Database provided by Quality Quest at each colonoscopy center. The process by which data is abstracted from the medical record (e.g., procedure reports, patient chart, pathology reports) may differ at each endoscopy center depending on the clinical data system(s) used at each endoscopy center. For example, some participating centers have electronic medical record systems and some have paper medical record systems. Data is abstracted by an endoscopy center staff member and entered into the Microsoft Access Database provided by Quality Quest. Details of this process are provided in the "data aggregation and reporting process" section of the appendix. After secure electronic data transfer from the Microsoft Access Database provided by Quality Quest to the colonoscopy quality measurement registry on the Quality Quest for Health of Illinois data portal, the data is aggregated and results reported. Included in attached appendix

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:

Available in attached Excel or csv file

Colonoscopy_-_File_structure_2011-09-19_-_Data_elements_by_Rows_and_column.xlsx

2a1.33 Level of Analysis (Check the levels of analysis for which the measure is specified and tested):

Clinician : Individual, Population : Regional

2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested):

Ambulatory Care : Ambulatory Surgery Center (ASC), Hospital/Acute Care Facility

If other:

2a. RELIABILITY. Precise Specifications and Reliability Testing: H M L I

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L I

2c. Disparities in Care: H M L I NA (If applicable, the measure specifications allow identification of disparities.)

SEE ATTACHED MEASURE TESTING FORM

Steering Committee: Overall, was the criterion, Scientific Acceptability of Measure Properties, met?

(Reliability and Validity must be rated moderate or high) Yes No

Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which potential audiences (e.g., consumers, purchasers, providers, policymakers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations. **(evaluation criteria)**

3.1 Current and Planned Use (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 performance improvement.):

Current and Planned Use (check all the current and planned uses; for any current uses that are checked, provide a URL for the specific program)

Planned	Current	For current use, Provide URL
	Public Reporting; Payment Program; Quality Improvement with Benchmarking (external benchmarking to multiple organizations); Quality Improvement (Internal to the specific organization)	http://www.qualityquest.org/quality-reports/colonoscopies/index.php ; http://www.qualityquest.org/quality-reports/colonoscopies/index.php ; https://data.qualityquest.org/login/index.php ; https://data.qualityquest.org/login/index.php

3a. Accountability and Transparency: H M L I

(Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.)

3a.1. For each CURRENT use, checked above, provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

This measure is publicly reported by Quality Quest for Health of Illinois for the purpose of making quality of colonoscopy procedures transparent to the public, including healthcare providers. Participating providers have used the publicly reported information for quality improvement with benchmarking as well as for internal quality improvement. We are aware of at least one contract that includes colonoscopy quality index as a payment program consideration.

3a.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?)

3a.3 If not currently publicly reported OR used in at least one accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)

3b. Improvement: H M L I

(Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.)

3b.1. Provide data that demonstrate improvement in performance and/or health. (Not required for initial endorsement unless available.)

Include:

- Source of Data
- Geographic area and number and percentage of accountable entities and patients included
- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)

Although not required for initial endorsement, performance on the colonoscopy index has improved over time for participating sites.

There has been an improvement in performance over time:

There were 9 physicians with at least 30 colonoscopies performed in Q1-2010 for which data was analyzed. The minimum colonoscopy quality index was 0.4545, maximum was 0.9130. The overall mean was 0.6144 with a standard deviation of 0.1282.

There were 19 physicians with at least 30 colonoscopies performed in Q4-2011 for which data was analyzed. The minimum colonoscopy quality index was 0.6452, maximum was 1. The overall mean was 0.9057 with a standard deviation of 0.07915 by physician for the period.

This demonstrates a positive shift in performance over time.

3b.2. If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations:

3c. Unintended Consequences: H M L I

(The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations)

3c.1. Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.

There have been no unintended negative consequences to individuals or populations during testing or use of this measure.

Overall, to what extent was the criterion, Usability, met? H M L I

Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (**evaluation criteria**)

4a. Data Generated as a Byproduct of Care Processes: H M L I

4a.1-2 How are the data elements needed to compute measure scores generated? (Check all that apply).

Data used in the measure are:

generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition;
Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H M L I

4b.1 Are the data elements needed for the measure as specified available electronically (Elements that are needed to compute measure scores are in defined, computer-readable fields):

Some data elements are in defined fields in electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR

provide a rationale for using other than electronic sources:

Some practices using the colonoscopy quality index use electronic health records, and some practices using the colonoscopy quality index use paper charts. The specified data elements all become available electronically in defined fields when entered into the Access database created for the purpose of aggregation and calculation of this measure. For those practices that have an EHR, many (but not all) of the data elements are available in a defined field. Some of the data elements must be abstracted by a person. We are investigating the use of natural language processing (NLP), an analytic procedure using neural networks, to abstract these elements electronically as well.

4d. Data Collection Strategy/Implementation: H M L I

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., fees for use of proprietary measures):

This measure was created by a project team in 2007/2008, and an adjustment was made in the measure in early 2009. The current measure definition has been in use since April 2009. Operational use of the measure is voluntary, and the burden of data abstraction is borne by the participating practice.

Endoscopy centers new to the process have occasionally selected an incorrect date range when exporting the data from the Access database tool. Because the data for a period is overlaid, this is an identifiable and correctable error.

Other occasional data discrepancies are identified, by the data portal, during the data portal import process. For example, a polyp is noted to be removed, but the capturing of the number of polyps or the size is not recorded. This is the primary type of data error we receive, which impacts less than 2% of the submitted data. Historically, 70% of these data errors are not correctable due to the information not being available in the patient record.

We reassessed the data submission process in the summer of 2012. We had an interesting finding that there are more steps to report the measure for practices using an EHR compared to practices using a paper chart. Our findings will be presented at the 2013 Healthcare Systems Process Improvement Conference.

4d.2 Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm):

None. We do not charge for use of any aspect of the measure nor for use of the Access database used for calculation of the measure.

Overall, to what extent was the criterion, Feasibility, met? H M L I

Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes No

Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

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. Harmonization

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

Yes

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

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF -endorsed measure(s): Describe why this measure 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/polysurveillance: appropriate follow-up interval for normal colonoscopy in average risk patients

Measure #0659 examines the subset of patients undergoing surveillance colonoscopy - endoscopy/polysurveillance: colonoscopy interval for patients with a history of adenomatous 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)/neoplasia(s) detected previously.

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): [QualityQuest for Health of Illinois, Inc.](#)

Co.2 Point of Contact: [Bonnie | Paris | bparis@qualityquest.org | 309-282-8820-](#)

Co.3 Measure Developer if different from Measure Steward: [QualityQuest for Health of Illinois, Inc.](#)

Co.4 Point of Contact: [Bonnie | Paris | bparis@qualityquest.org | 309-282-8820-](#)

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

[Dr. Gail Amundson and the 2007 Colonoscopy project team](#) developed this measure. The 2007 Colonoscopy project team includes:

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

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2008

Ad.4 Month and Year of most recent revision: 12/2011

Ad.5 What is your frequency for review/update of this measure? every 2 years

Ad.6 When is the next scheduled review/update for this measure? 12/2013

Ad.7 Copyright statement: copyright QualityQuest for Health of Illinois, Inc., 2008. All rights reserved.

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments: Regarding specification 1: measure web page URL. Direct your web browser to the indicated URL [HTTP://www.qualityquest.org/quality-reports/](http://www.qualityquest.org/quality-reports/) and then scroll to the section "Learn About Colonoscopy Quality" and click on "Report Methodology"

We would like to provide the following summary of the evidence base for the Colonoscopy Quality Index:

Appropriate Indication for Colonoscopy

- Rex et al, Quality Indicators for Colonoscopy; GIE Journal Vol 63, Issue 4 Suppl (2006)
- o "The ASGE in 2000 published a list of accepted indications for endoscopic procedures. This list was determined by a review of published literature and expert consensus. Studies have shown that when esophagogastroduodenoscopy and colonoscopy are done for appropriate reasons significantly more clinically relevant diagnoses are made." (Balaguer 2005; Vader 2000; deBosset 2002)
- o "In the average-risk population, colonoscopic screening is recommended in all current guidelines at 10-year intervals." (Winawer 2003; USPSTF 2002; Smith 2002)
- o "Use of recommended postpolypectomy and post cancer resection surveillance intervals (Tables 2 and 3) the recommended intervals assume cecal intubation, adequate bowel preparation, and careful examination."
- "Recent evidence from 4 surveys indicated that postpolypectomy surveillance colonoscopy in the United States is frequently performed at intervals that are shorter than those recommended in guidelines." (Mysliwiec 2004; Siani 2005; Burke 2005; Boolchand 2005) "These surveys underscore the importance of measuring intervals between examinations in continuous quality improvement programs. Some endoscopists in these studies performed colonoscopy in patients with only small hyperplastic polyps or a single tubular adenoma at 1 year, an interval abandoned in guidelines after publication of the National Polyp Study randomized trial in 1993." (Winawer 1993)
- USPSTF October, 2008 (addresses screening colonoscopy in average risk individuals)
- o The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary. ?Grade: A recommendation.
- o The USPSTF recommends against routine screening for colorectal cancer in adults 76 to 85 years of age. There may be considerations that support colorectal cancer screening in an individual patient. ?Grade: C recommendation.
- o The USPSTF recommends against screening for colorectal cancer in adults older than age 85 years. ?Grade: D recommendation.
- The following organizations have made statements of the need to determine the appropriateness of the screening or surveillance colonoscopy: ACG, ACS, ASGE, Duke/AHRQ-EPC 2006, National Cancer Round Table
- For higher risk patients being screened or those being followed-up (surveillance) due to previous pathology see: Screening and Surveillance for the Early detection of CRC and adenomatous Polyps, 2008: A Joint Guideline from the ACS, the USMSTF on CRC, and the ACR: CA Cancer J Clin 2008;58; 130

Standardized Medical Risk Assessment

- Lieberman et al, Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Force of the National Colorectal Cancer Roundtable; GIE Journal: Vol 65, No 6, 2007
- o "Anesthesiologists and surgeons have used the physical status of the American Society of Anesthesiology (ASA) (Table 2) for over 50 years to predict perioperative morbidity and mortality." (Prause 1997; Menke 1993; Wolters 1996) "Although few studies have been performed to validate the tool in endoscopy, the classification has been widely accepted as a surrogate of comorbidity across numerous specialties in medicine." (Rex 2002) "The classification category has an impact on the setting and the precautions, which should be considered before colonoscopy. Patients with ASA class 3 or higher should be considered at high risk for cardiopulmonary events. Endoscopists should consider performing procedures in ASA class 3 patients in a hospital setting or in a setting with full capacity for resuscitation and support."

Standardized Assessment of Bowel Preparation

- Rex et al, Quality Indicators for Colonoscopy; GIE Journal Vol 63, Issue 4 Suppl (2006)
- o "In every colonoscopy, the colonoscopist should document the quality of preparation. In clinical trials of bowel preparation terms used to commonly characterize bowel preparation include 'excellent', 'good', 'fair', and 'poor'. In clinical trials on the effectiveness of various laxative regimens for bowel preparation, excellent is typically defined as no or minimal solid stool and only small amounts of clear fluid requiring suctioning. 'Good' is typically no or minimal solid stool with large amounts of clear fluid requiring suctioning. 'Fair' refers to collections of semisolid debris that are cleared with difficulty. 'Poor' refers to solid or semisolid debris that cannot be effectively cleared."
- o "Poor bowel preparation is a major impediment to the effectiveness of colonoscopy. Poor preparation prolongs cecal intubation time and withdrawal time and reduces detection of both small and large polyps." (Harewood 2003; Froelich 2005) "In every colonoscopic practice, some colonoscopies must be repeated at intervals shorter than those recommended in Table 3 because of inadequate preparation. The task force recommends that the procedure be considered adequate if it allows detection of polyps 5 mm or larger." (Rex 2002) "The economic burden of repeating examinations because of inadequate bowel preparation is substantial." (Rex 2002) "No thresholds are recommended by the committee for the percentage of examinations that are repeated for poor preparation because the percentage of patients requiring repeat examination may depend mostly on patient population characteristics." (Rex 2002) "However, measurement of individual practitioner's percentage of examinations requiring repeat because of preparation is recommended."
- David S Weinberg, MD, MSc; Annals of IM 2011; 154: 68
- o "The quality of the laxative preparation, particularly in the proximal colon, is critical to the ability to detect polyps and other lesions"
- The National Cancer Round Table (2007) and Duke's EPC 2006 emphasized the importance of this metric

Complete Examination

- Rex et al, Quality Indicators for Colonoscopy; GIE Journal Vol 63, Issue 4 Suppl (2006)
- o "In the United State, colonoscopy is generally undertaken with the intent to intubate the cecum. Cecal intubation is defined as passage of the colonoscopy tip to a point proximal to the ileoceca valve so that the entire cecal caput, including the medial wall of the cecum between the ileocecal valve and appendiceal orifice, is visible. The need for cecal intubation is based on the persistent finding that a substantial fraction of colorectal neoplasms are located in the proximal colon, including the cecum." (Rabeneck 2003)
- o "Effective endoscopists should be able to intubate the cecum in $\geq 90\%$ of all cases (Marshall 1993) and in $> 95\%$ of cases when the indication is screening in a healthy adult." (Johnson 1990; Foutch 1991; Lieberman 1991; Rogge 1994; Rex 1993; Kadakia 1996; Lieberman 2000; Imperiale 2000; Imperiale 2004; Schoenfeld 2005) "Cases in which procedures are aborted because of poor preparation or severe colitis need not be counted in determining cecal intubation rates." This is the basis for excluding patients with 'poor' or 'inadequate' prep from the Quality Quest Colonoscopy Quality Index
- NEJM 2010;362:1795
- o "Cecal intubation rate ($>95\%$)- Quality indicators for colonoscopy and the risk of interval cancer;"

Cecal Photo taken

- Rex et al, Quality Indicators for Colonoscopy; GIE Journal Vol 63, Issue 4 Suppl (2006)
- o "Photography of the cecum is also recommended. Still photography of the cecum may not be convincing in all cases because of variations in cecal anatomy." (Rex 2000) "... however, still photography is convincing in a substantial majority of cases,"
- o Rate of photodocumentation of cecal landmarks allows an external objective metric of subjective reporting of complete examination"
- o Also allows for external blinded judging of adequacy of proximal laxative colon preparation

All Essential Polyp Information Recorded

- Rex et al, Quality Indicators for Colonoscopy; GIE Journal Vol 63, Issue 4 Suppl (2006)
- o "A complete and accurate report, describing the procedures and findings, must be completed immediately after the procedures. The report should include photo documentation of abnormalities and identification of any biopsy specimens obtained."
- Lieberman et al, Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Force of the National Colorectal Cancer Roundtable; GIE Journal: Vol 65, No 6, 2007
- o "The Quality Assurance Task Force focused on standardized descriptors for colonic polyps, because clear communication of findings is a key determinant of risk status and subsequent follow-up. Each polyp has required descriptors that describe morphology, size (in millimeters), method of removal, and completeness of removal and retrieval. Vague terms such as 'large' or 'small' should be avoided."

Withdrawal Time was Recorded

- Rex et al, Quality Indicators for Colonoscopy; GIE Journal Vol 63, Issue 4 Suppl (2006)
- o "Withdrawal times: studies have demonstrated increased detection of significant neoplastic lesions in colonoscopic examinations where the withdrawal time is 6 minutes or more. Mean withdrawal time should be > 6 minutes in colonoscopies with normal results performed in patients with intact colons." "To measure withdrawal time, the time at which the cecum is reached and the time at which the scope is withdrawn from the anus must be noted. Some electronic report-generating systems allow the time to be noted electronically when cecal photographs are taken. On the basis of the mean withdrawal times of an examiner with very low miss rate (Rex 2000) and previously cited evidence that the detection rate of large adenomas was greater for examiners who took longer than 6 minutes for withdrawal during screening colonoscopy, (Barclay 2005) it is recommended that the withdrawal phase of colonoscopy in patients without previous surgical resection should last at least 6 minutes on average."
- Barclay RL, Colonoscopic Withdrawal Times and Adenoma Detection during Screening Colonoscopy, NEJM 2006: 355:2533

Free of Serious Intra-Procedural Complications

- Rex et al, Quality Indicators for Colonoscopy; GIE Journal Vol 63, Issue 4 Suppl (2006)
- o "Perforation is the most serious complication in the short term during or after colonoscopy. About 5% of colonoscopic perforations are fatal." (Fruhmorgan 1979; Nivatvongs 1986; Silvis 1976) "The rates of colonoscopic perforation vary widely in the medical literature. One study from an established endoscopic center reported an overall perforation rate of 1 in 500 in the 1990s." (Anderson 2000) "A population-based study of Medicare patients reported an overall risk of perforation of 1 in 500 but a risk of less than 1 in 1,000 screening patients." (Gatto 2003)
- o "Bleeding is the most common complication of polypectomy." (Fruhmorgan 1979; Nivatvongs 1986; Silvis 1976; Zubarik 1999; Sorbi 2000)
- As defined, this element addresses acute complications. Current processes are adequate to capture acute serious complications but inadequate to globally capture later complications. In future, EMR will facilitate acquiring data related to later complications.

Appropriate Follow-Up Recommendation

- Rex et al, Quality Indicators for Colonoscopy; GIE Journal Vol 63, Issue 4 Suppl (2006)
- Same evidence-base as appropriate indication with added information from examination findings.
- Screening and Surveillance for the Early detection of CRC and adenomatous Polyps, 2008: A joint Guideline from the ACS, the USMSTF on CRC, and the ACR: CA Cancer J Clin 2008;58: 130

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

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:

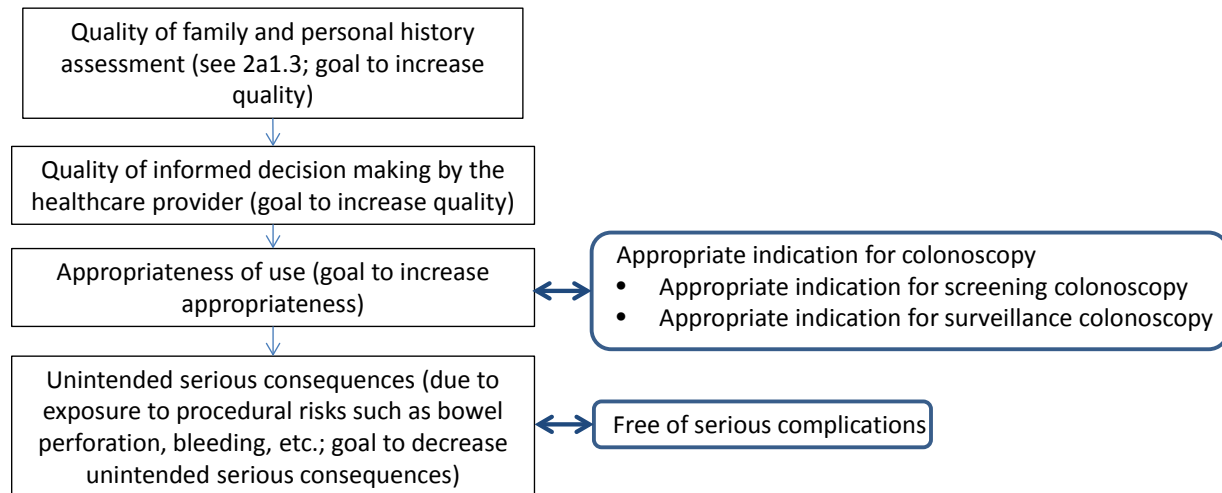
Outcome

- Health outcome: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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.

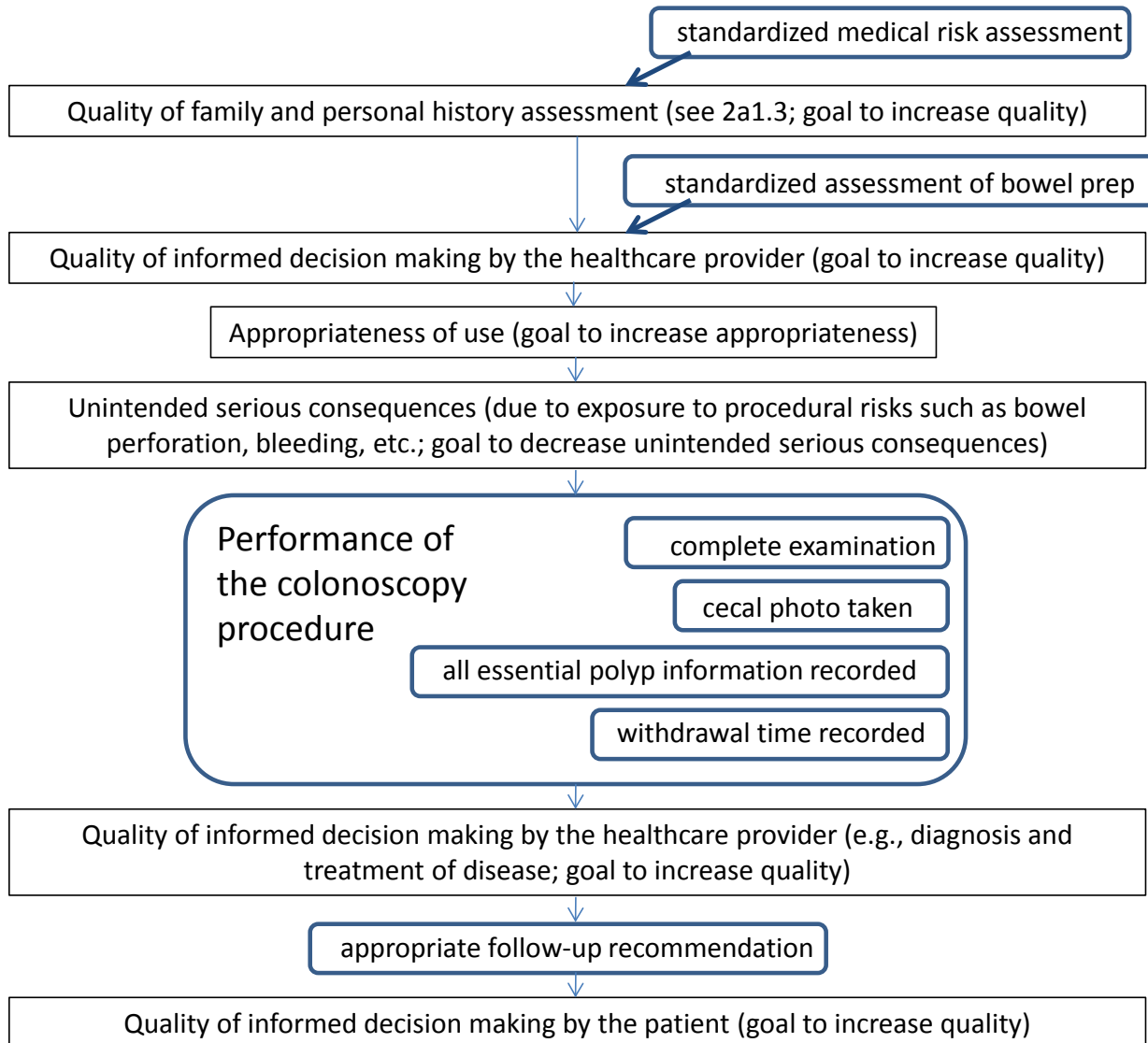
Quality of family and personal history assessment and healthcare provider knowledge of current evidence and recommendations for use of colonoscopy for screening and surveillance affect the appropriateness with which colonoscopy exams are used. Overuse of colonoscopy exams are associated with avoidable 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

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

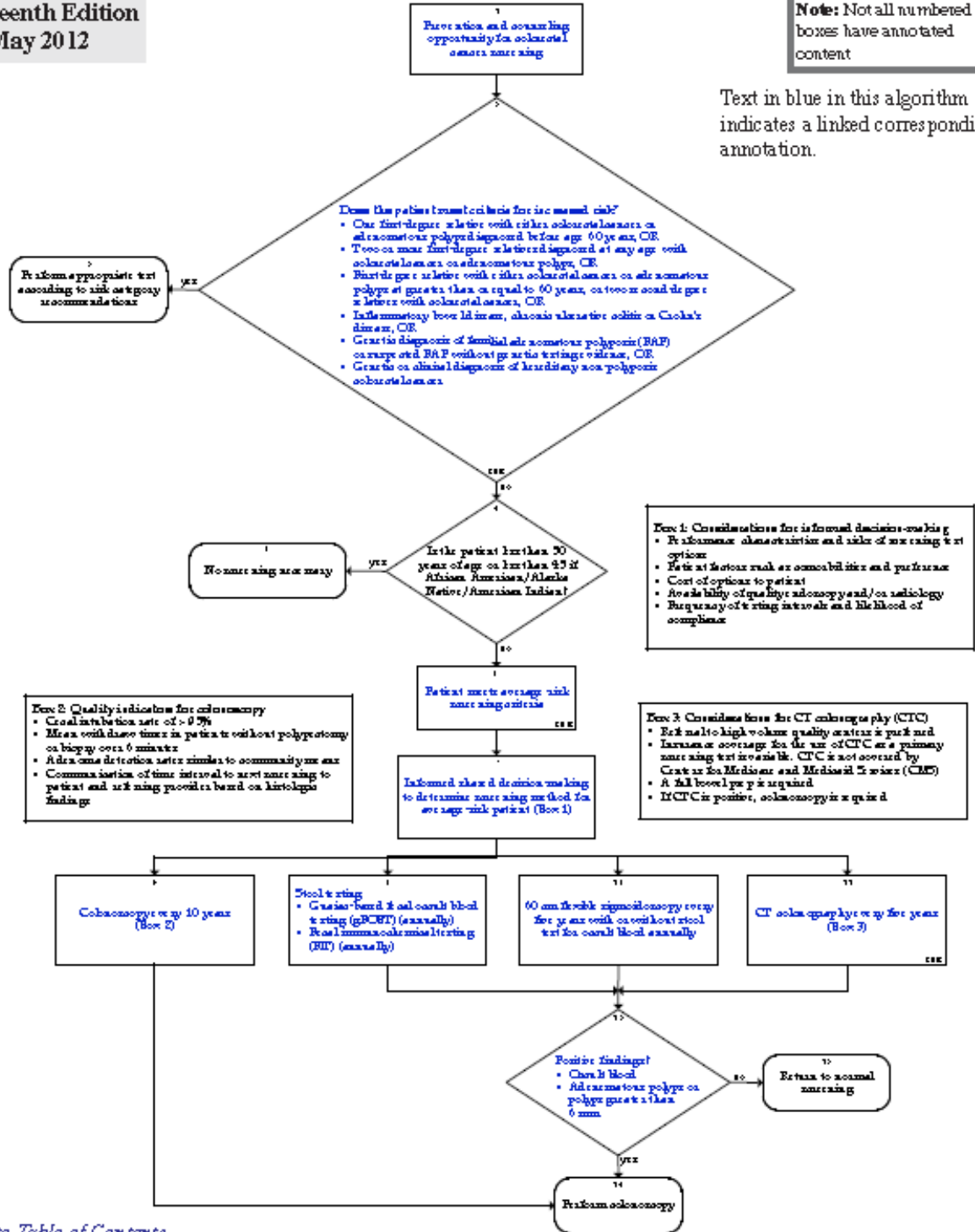
INSTITUTE FOR CLINICAL
SYSTEMS IMPROVEMENT

Fourteenth Edition
May 2012

Screening Algorithm

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

Text in blue in this algorithm indicates a linked corresponding annotation.



[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"> • Guaiac-based fecal occult blood testing (gFOBT) annually, OR • Fecal immunochemical testing (FIT) annually, OR • 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR • Colonoscopy every 10 years 	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"> • Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years • Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps. <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*

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
High Quality Evidence	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.
Moderate Quality Evidence	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.
Low Quality Evidence	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"> • Guaiac-based fecal occult blood testing (gFOBT) annually, OR • Fecal immunochemical testing (FIT) annually, OR • 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR • Colonoscopy every 10 years 	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"> • Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years • Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps. <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: 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:

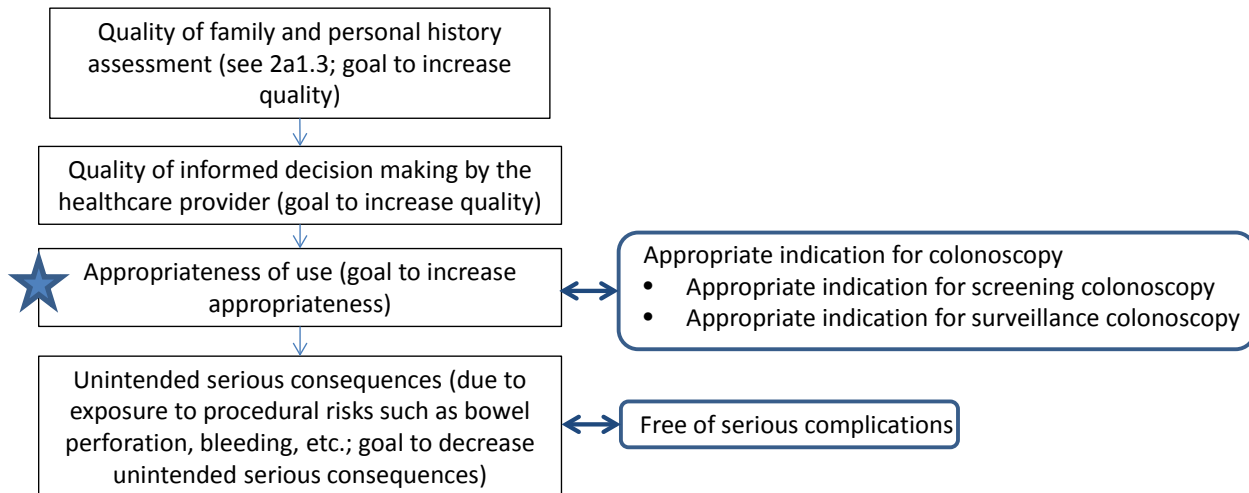
Outcome

- Health outcome: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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

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

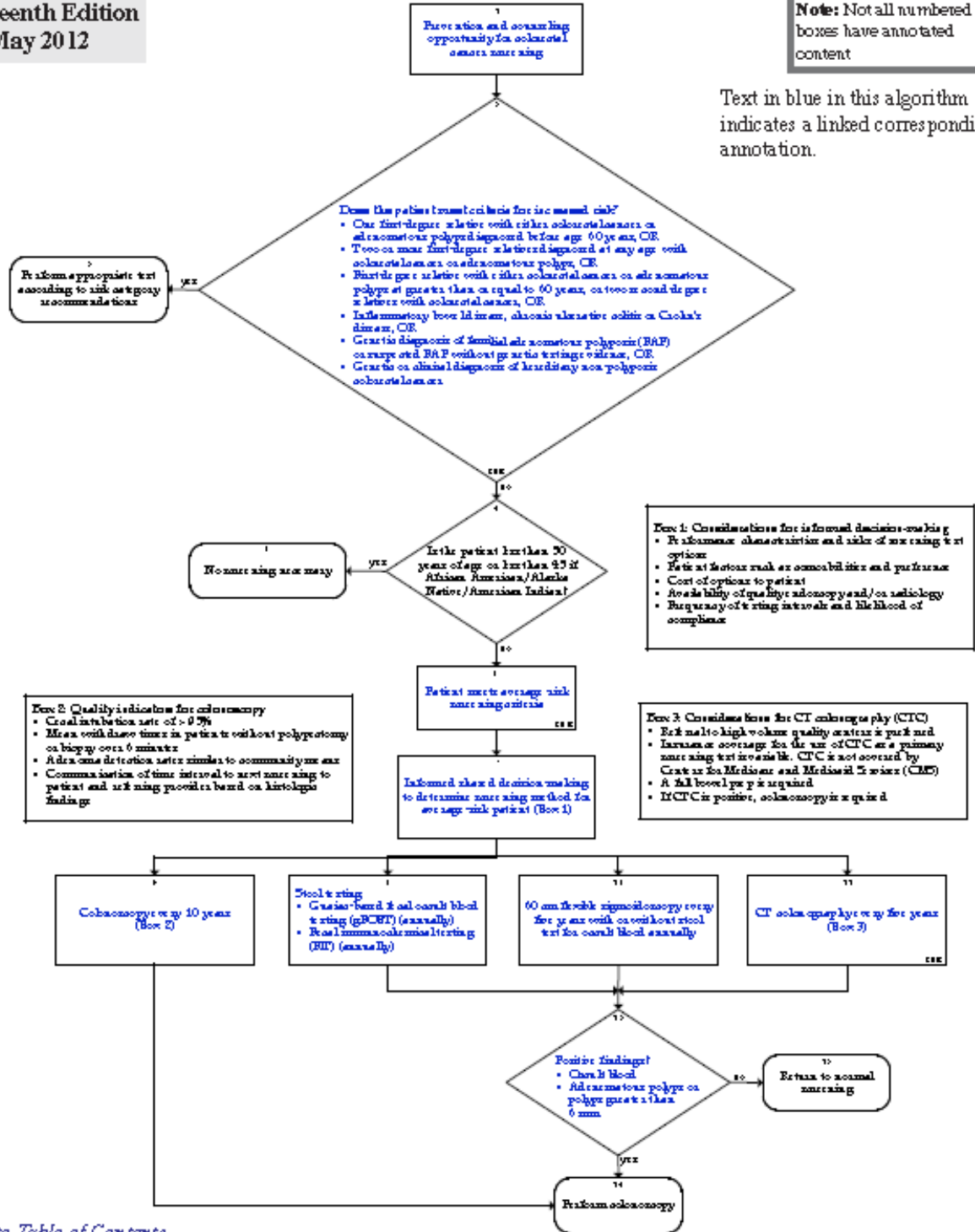
INSTITUTE FOR CLINICAL
SYSTEMS IMPROVEMENT

Fourteenth Edition
May 2012

Screening Algorithm

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

Text in blue in this algorithm indicates a linked corresponding annotation.



[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"> • Guaiac-based fecal occult blood testing (gFOBT) annually, OR • Fecal immunochemical testing (FIT) annually, OR • 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR • Colonoscopy every 10 years 	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"> • Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years • Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps. <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*

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
High Quality Evidence	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.
Moderate Quality Evidence	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.
Low Quality Evidence	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"> • Guaiac-based fecal occult blood testing (gFOBT) annually, OR • Fecal immunochemical testing (FIT) annually, OR • 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR • Colonoscopy every 10 years 	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"> • Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years • Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps. <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: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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.

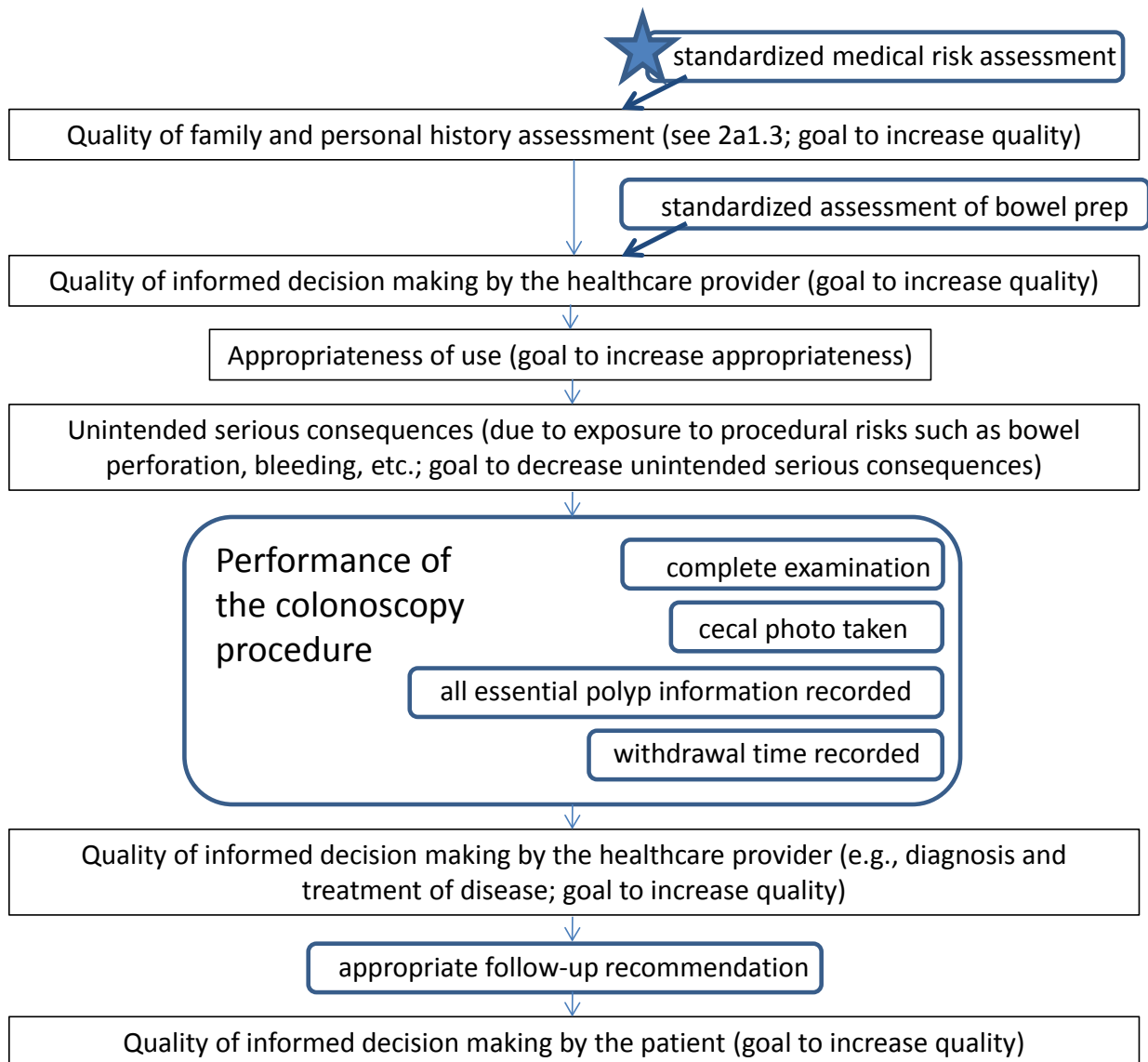
1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

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
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: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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.

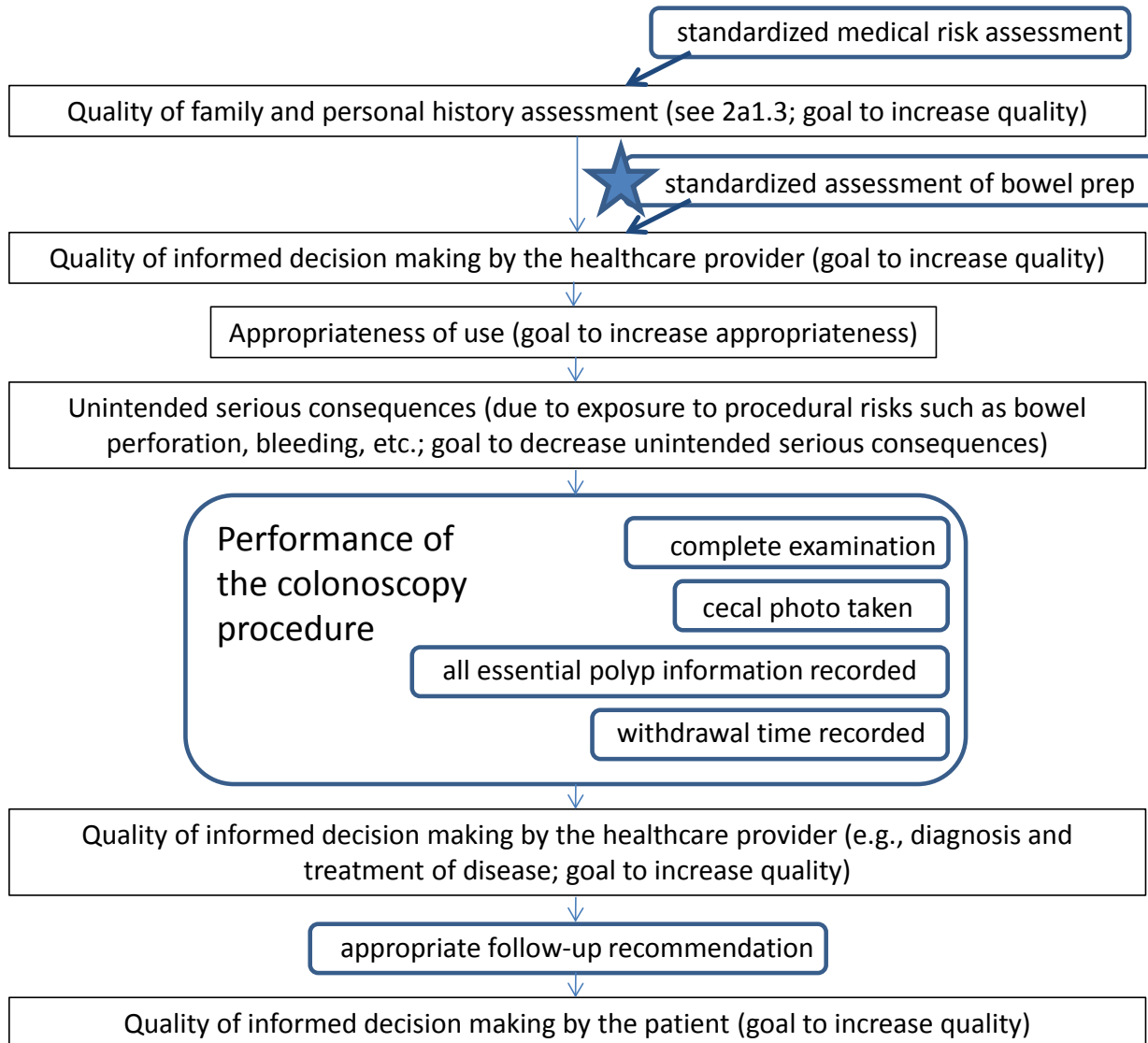
1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

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
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: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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.

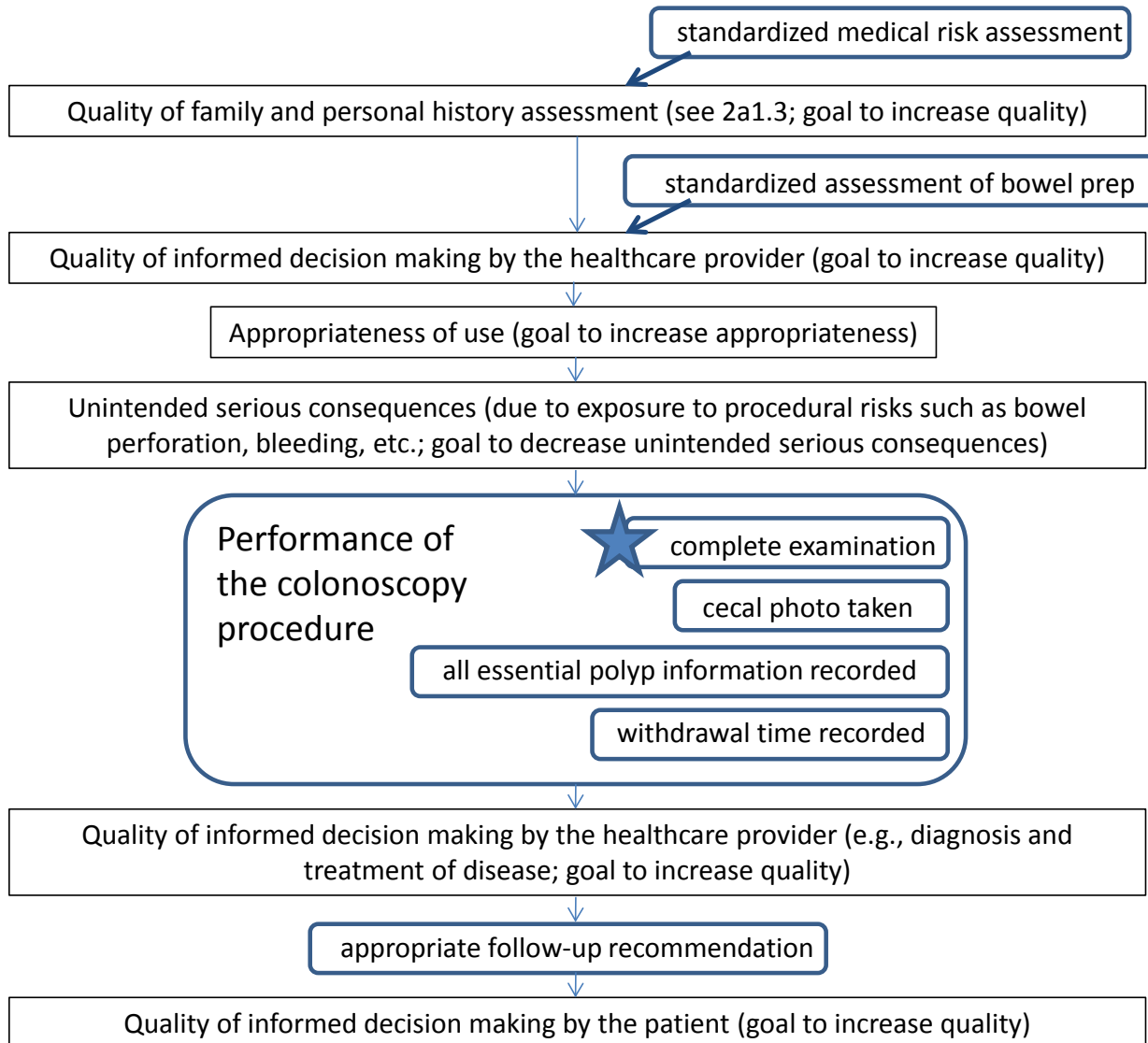
1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

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	
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: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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.

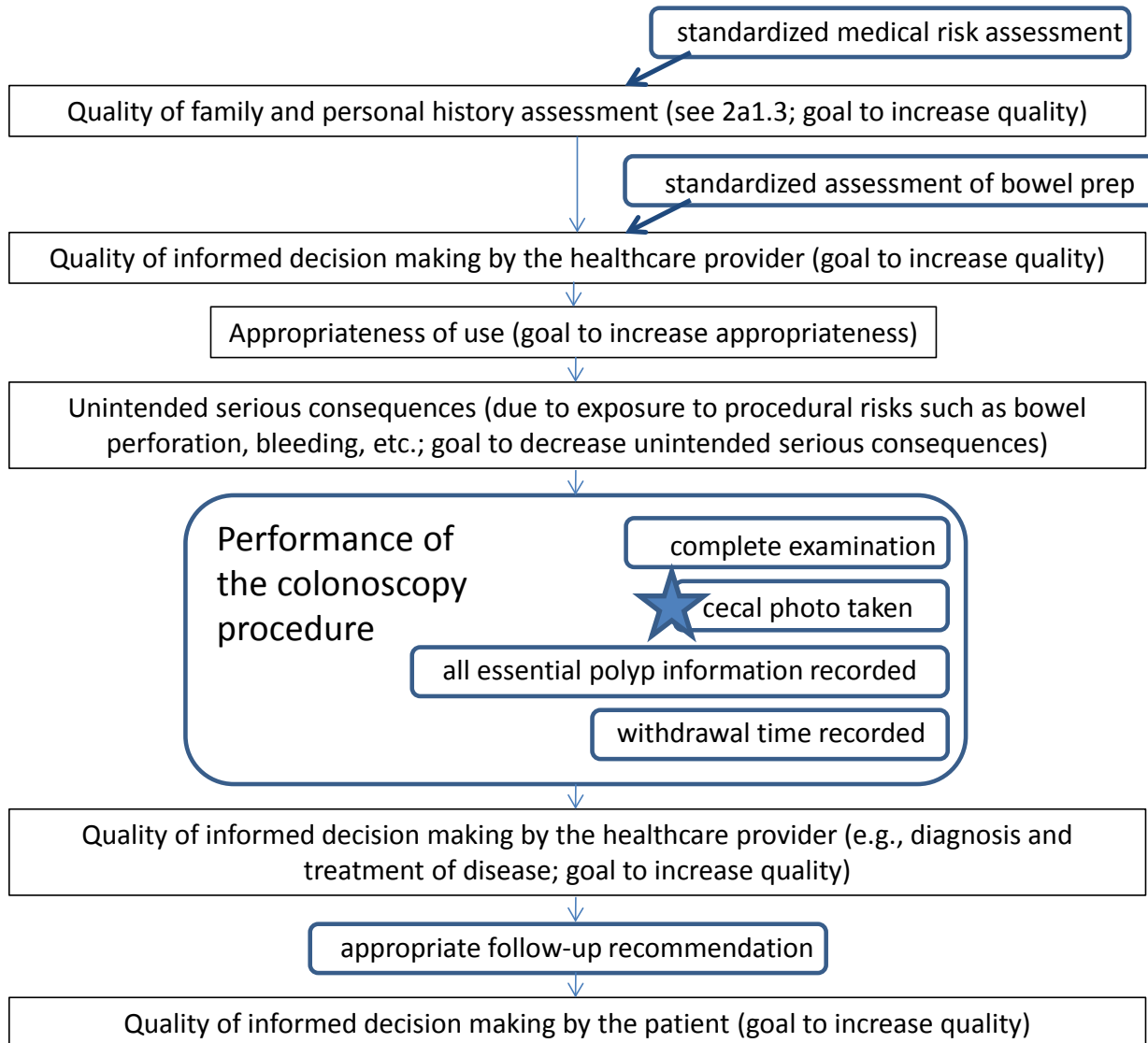
1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

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	
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: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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.

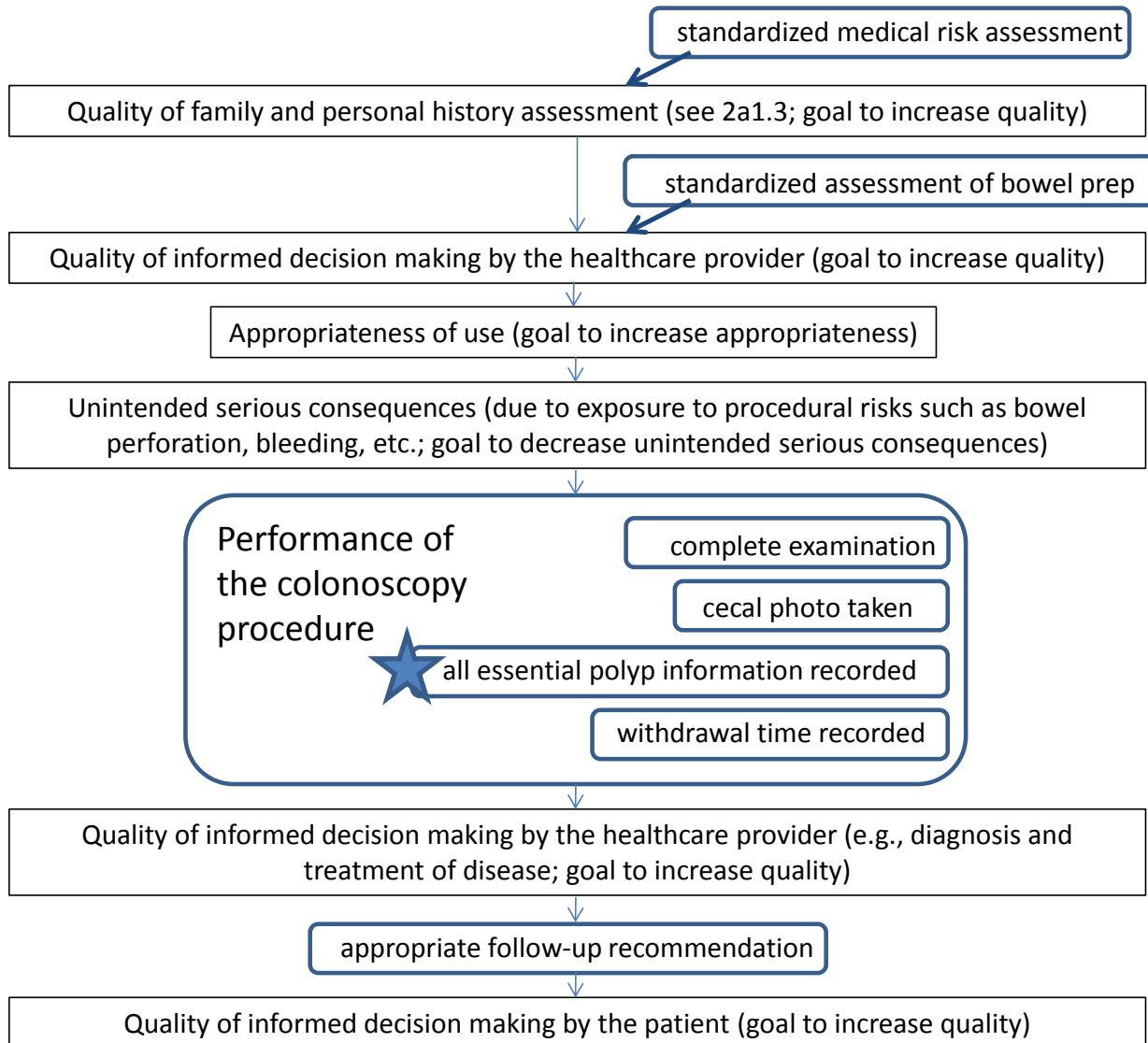
1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

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
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: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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.

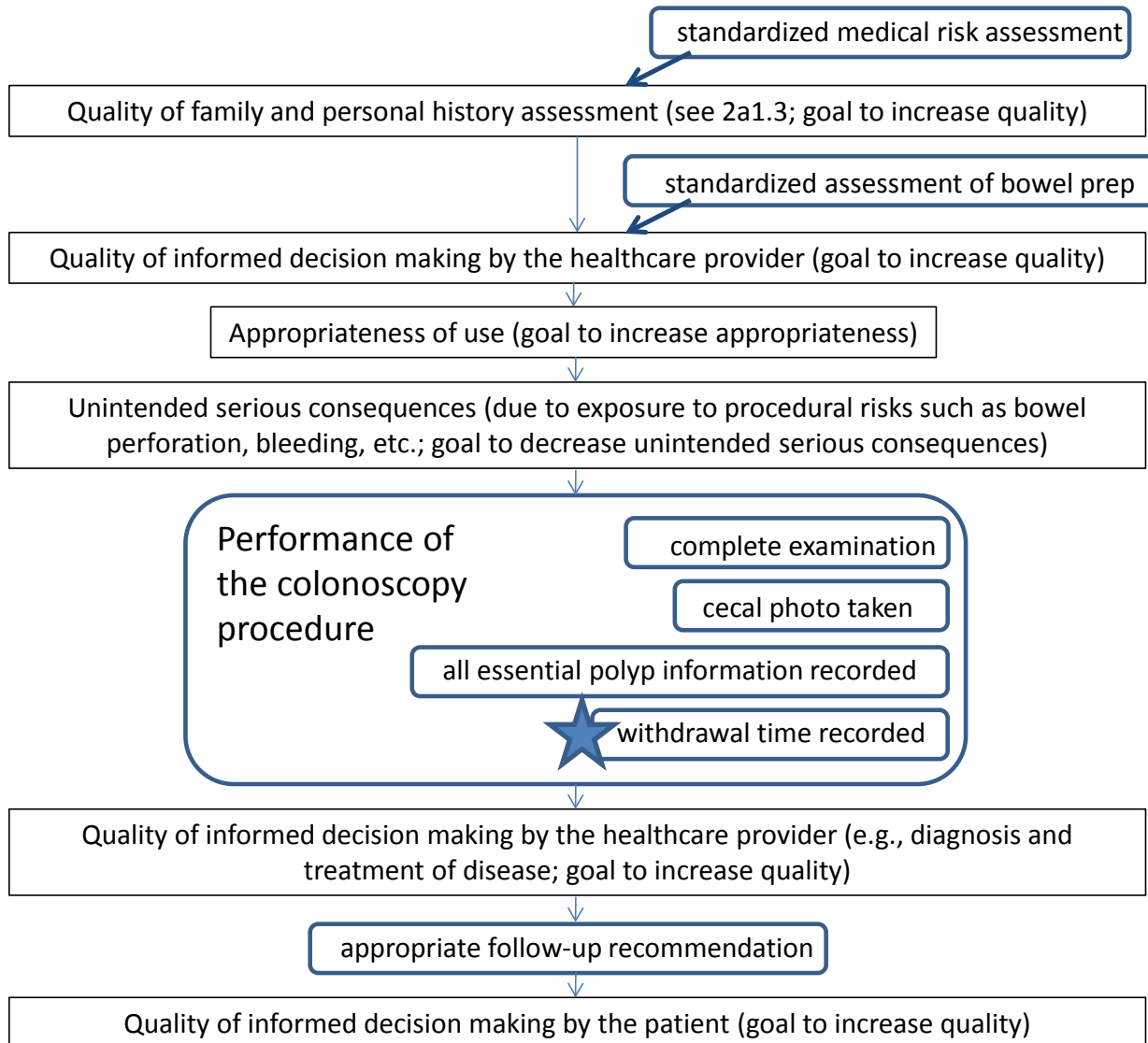
1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

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
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:

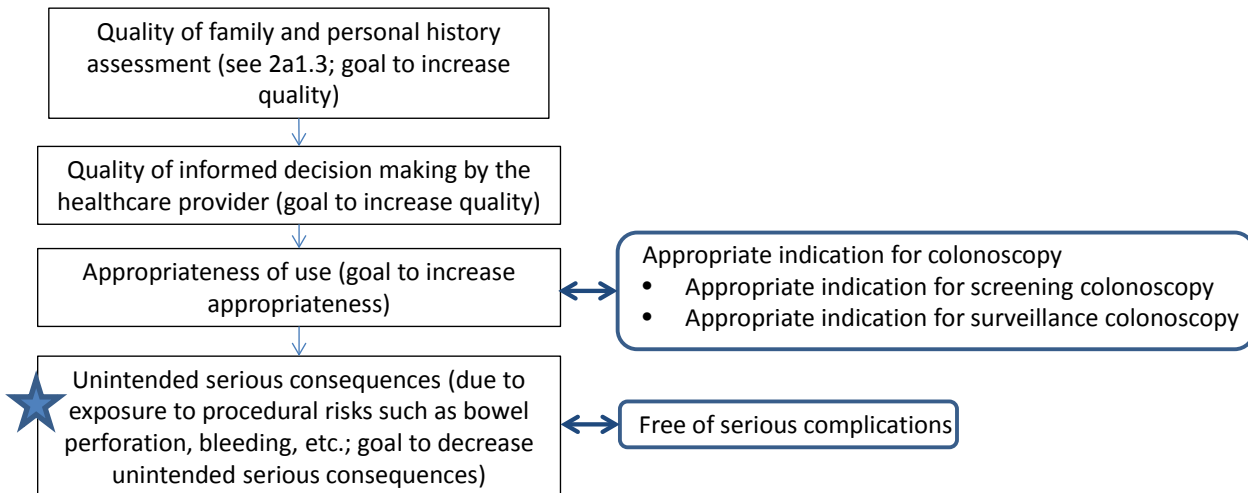
Outcome

- Health outcome: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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

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



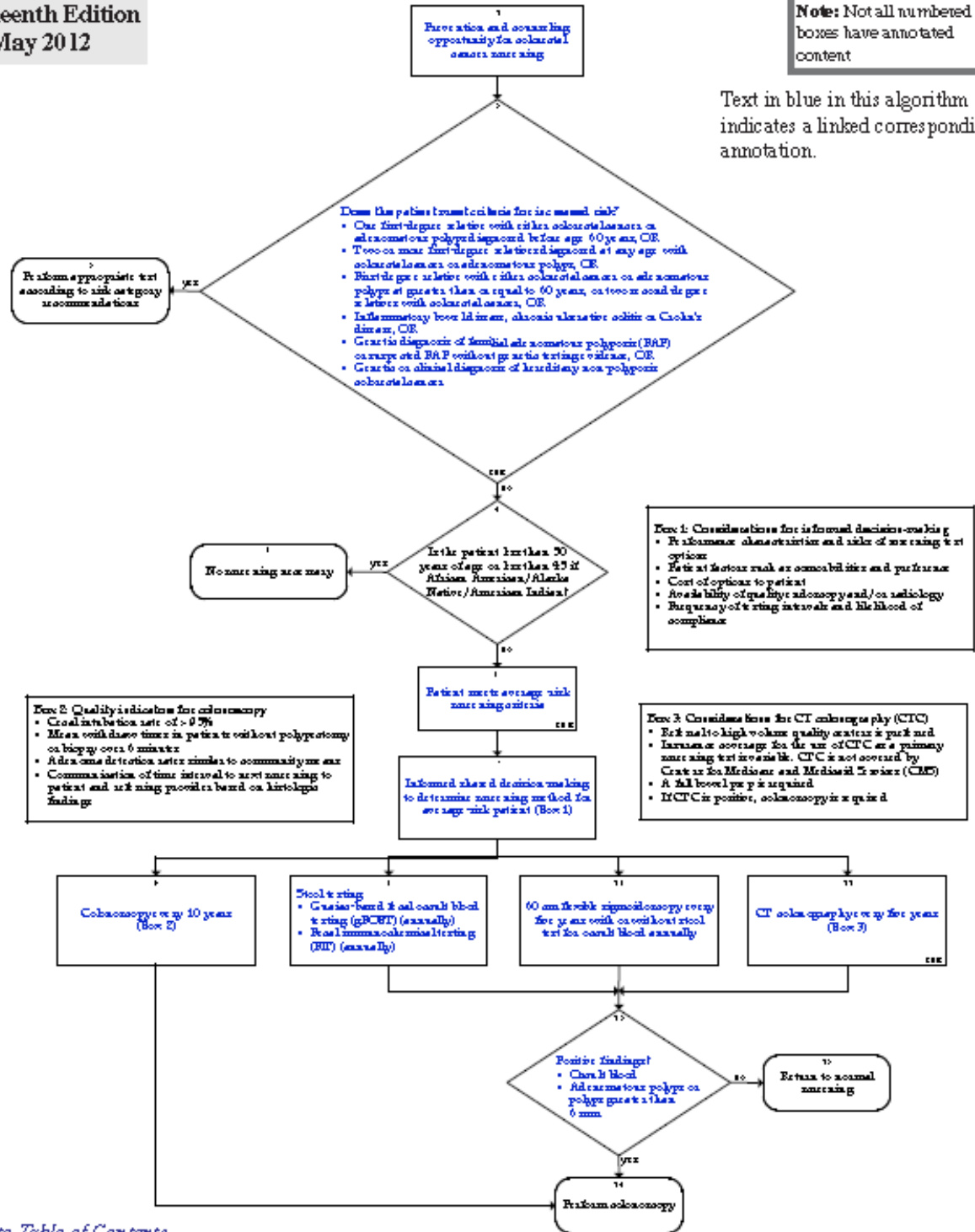
Health Care Guideline:
Colorectal Cancer Screening

INSTITUTE FOR CLINICAL
SYSTEMS IMPROVEMENT

Fourteenth Edition
May 2012

Screening Algorithm

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



[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"> • Guaiac-based fecal occult blood testing (gFOBT) annually, OR • Fecal immunochemical testing (FIT) annually, OR • 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR • Colonoscopy every 10 years 	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"> • Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years • Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps. 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 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*

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
High Quality Evidence	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.
Moderate Quality Evidence	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.
Low Quality Evidence	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"> • Guaiac-based fecal occult blood testing (gFOBT) annually, OR • Fecal immunochemical testing (FIT) annually, OR • 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR • Colonoscopy every 10 years 	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"> • Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years • Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps. <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: [Click here to name the health outcome](#)
- 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: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

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.

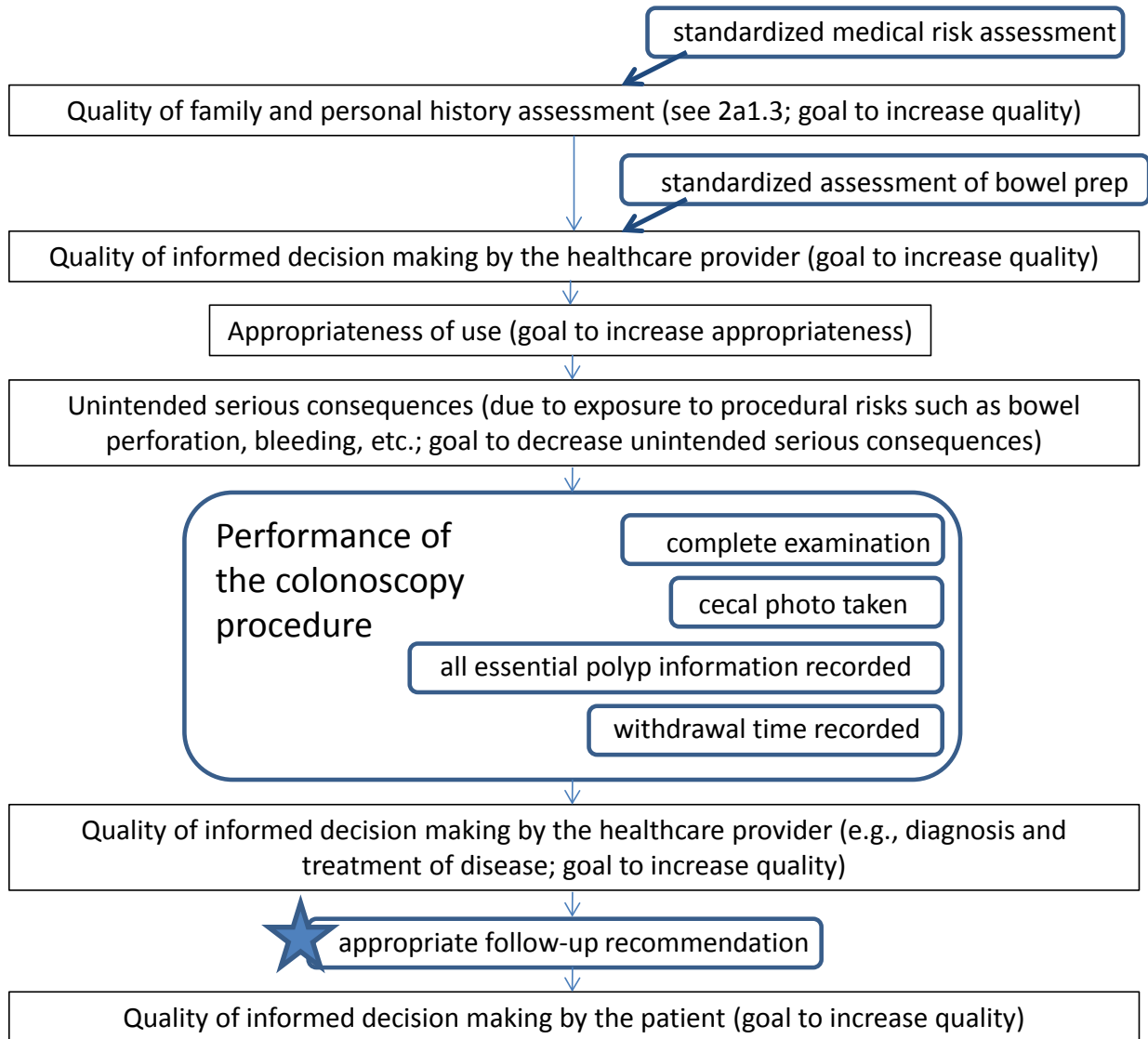
1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

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
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 Testing to Demonstrate Scientific Acceptability of Measure Properties

Measure Title: Colonoscopy Quality Index

Date of Submission: [1/11/2013](#)

Type of Measure:

<input checked="" type="checkbox"/> Composite	<input type="checkbox"/> Outcome
<input type="checkbox"/> Cost/resource	<input type="checkbox"/> Process
<input type="checkbox"/> Efficiency	<input type="checkbox"/> Structure

This Word document template must be used to submit information for measure testing.

- **For all measures, sections 1, 2a2, 2b2, 2b3, 2b5 must be completed**
- **For outcome or resource use measures, section 2b4 also must be completed**
- If specified for **multiple data sources** (e.g., claims and medical records), section **2b6** also must be completed
- Respond to all questions with answers immediately following the question (*unless meet the skip criteria or those that are indicated as optional*).
- Maximum of 10 pages (*including questions/instructions; do not change margins or font size; contact project staff if need more pages*)
- All information on testing to demonstrate meeting the [criteria for scientific acceptability of measure properties \(2a,2b\)](#) must be in this form. An appendix for *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing, (e.g., reliability vs. validity) be sure to indicate the specific differences in question 7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the types of data specified and intended for measure implementation*)

Measure Specified to Use Data From:	Measure Tested with Data From:
<input checked="" type="checkbox"/> abstracted from paper record	<input checked="" type="checkbox"/> abstracted from paper record
<input type="checkbox"/> administrative claims	<input type="checkbox"/> administrative claims
<input type="checkbox"/> clinical database/registry	<input type="checkbox"/> clinical database/registry
<input checked="" type="checkbox"/> abstracted from electronic health record	<input checked="" type="checkbox"/> abstracted from electronic health record
<input type="checkbox"/> eMeasure implemented in electronic health record	<input type="checkbox"/> eMeasure implemented in electronic health record
<input type="checkbox"/> other: Click here to describe	<input type="checkbox"/> other: Click here to describe

1.2. If used an existing dataset, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

Does not apply

1.3. What are the dates of the data used in testing? 1/1/2010-12/31/2011 (full 2 years)

1.4. What levels of analysis were tested? (testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan)

individual clinician group/practice hospital/facility/agency health plan
 other: [Click here to describe](#)

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample)

The Colonoscopy Quality Six Sigma Project Team convened on May 7, 2007 and completed final recommendations on July 10, 2008. Initial measurement testing was conducted in 2008 at one endoscopy center as a project deliverable. Initial testing included all 8 physicians performing colonoscopy at the center; at the time, data on 302 colonoscopy procedures was analyzed. The endoscopy center at which the testing was done had two gastroenterologists, a data analyst, a pathologist and the endoscopy center manager on the project team. (A presentation from the final team review is included in our appendix of supplemental materials.)

The Colonoscopy Quality Index is in production, with continuous quarterly data collection, since initial testing. Seven endoscopy centers currently participate. Data is available for 20,000+ screening and surveillance colonoscopies. **This analysis for scientific acceptability includes 18,989 colonoscopy exams provided by 39 physicians at 7 endoscopy centers in calendar years 2011 and 2012.**

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample)

All colonoscopy exams performed in calendar years 2011 and 2012 at the 7 participating endoscopy centers were included. The table below provides a breakdown volume by patient gender and physician.

Physician	Male	Female	Gender not entered	Total
MD-1	110	89	0	199
MD-2	606	574	0	1180
MD-3	1	0	0	1
MD-4	31	21	0	52
MD-5	33	34	0	67
MD-6	255	208	0	463
MD-7	664	556	0	1220
MD-8	331	249	0	580
MD-9	43	11	0	54
MD-10	664	628	0	1292
MD-11	550	591	0	1141

Physician	Male	Female	Gender not entered	Total
MD-12	593	562	0	1155
MD-13	578	477	0	1055
MD-14	68	85	0	153
MD-15	389	1302	0	1691
MD-16	725	629	0	1354
MD-17	72	74	0	146
MD-18	308	293	1	602
MD-19	114	104	0	218
MD-20	493	458	0	951
MD-21	506	554	0	1060
MD-22	63	88	0	151
MD-23	102	107	0	209
MD-24	119	79	0	198
MD-25	158	132	0	290
MD-26	9	9	0	18
MD-27	548	543	0	1091
MD-28	105	102	0	207
MD-29	78	82	0	160
MD-30	145	166	0	311
MD-31	46	59	0	105
MD-32	78	79	0	157
MD-33	259	249	0	508
MD-34	286	234	0	520
MD-35	220	181	0	401
MD-36	1	2	0	3
MD-37	11	5	0	16
MD-38	1	4	0	5
MD-39	1	4	0	5
TOTAL	9364	9624	1	18989

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

This is full population reporting of clinical data derived directly from clinical systems. Participating endoscopy centers submit data on all screening and surveillance colonoscopies. No sampling is used.

2a2. RELIABILITY TESTING

Note: *If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – report validity of data elements in 2b2*

2a2.1. What level of reliability testing was conducted? (may be one or both levels)

Critical data elements used in the measure (e.g., inter-abstractor reliability)

Performance measure score (e.g., *signal-to-noise*) (**Note:** *this is preferred level for testing composite*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

Reliability analysis of this measure follows the beta-binomial method described in “The Reliability of Provider Profiling: A Tutorial” by John L. Adams of RAND Health. The beta-binomial method was developed for provider level measures reported as rates, and it allows one to calculate a “reliability score” interpreted as the percent of variance due to the difference in measure score among providers. A high reliability score implies that performance on a measure is unlikely to be due to measurement error or insufficient sample size, but rather due to true differences in performance between the provider and other providers. This type of analysis is sometimes referred to as signal-to-noise analysis, where the signal is the “true difference” and the noise is measurement error and random error.

2a2.3. For each level checked above, what were the statistical results from reliability testing? (*e.g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis and association with case volume*)

There were 2 physicians for which an insufficient sample was available to calculate reliability. An analysis of the reliability for the 37 remaining physicians is presented in the summary table below.

	Reliability
MIN	0.3825
MAX	1.0000
AVG	0.7115
StdDev	0.1667

The individual reliability by physician with detailed information is provided in the table below.

Physician	Number of quarters	Number of colonoscopies "failed"	Number of colonoscopies "succeeded"	Total number of colonoscopies	Overall colonoscopy quality index score	Variance within MD	Variance between MD	Reliability
MD-1	8	110	89	199	0.3944	0.0654	0.0569	0.4654
MD-2	10	336	844	1180	0.7060	0.0364	0.0569	0.6102
MD-3	1	1	0	1	0.0000	#DIV/0!	0.0569	insufficient sample size
MD-4	8	24	28	52	0.6073	0.0326	0.0569	0.6356
MD-5	8	60	7	67	0.0991	0.0087	0.0569	0.8681
MD-6	8	82	381	463	0.8220	0.0084	0.0569	0.8717
MD-7	10	229	991	1220	0.8201	0.0190	0.0569	0.7497
MD-8	10	156	424	580	0.7226	0.0130	0.0569	0.8146
MD-9	8	33	21	54	0.4774	0.0721	0.0569	0.4413
MD-10	10	374	918	1292	0.7126	0.0176	0.0569	0.7643
MD-11	10	287	854	1141	0.7504	0.0248	0.0569	0.6968

NQF #2056 Colonoscopy Quality Index

Physician	Number of quarters	Number of colonoscopies "failed"	Number of colonoscopies "succeeded"	Total number of colonoscopies	Overall colonoscopy quality index score	Variance within MD	Variance between MD	Reliability
MD-12	10	303	852	1155	0.7492	0.0271	0.0569	0.6774
MD-13	10	114	941	1055	0.8994	0.0037	0.0569	0.9388
MD-14	9	46	107	153	0.6911	0.0625	0.0569	0.4767
MD-15	10	477	1214	1691	0.7164	0.0337	0.0569	0.6279
MD-16	10	351	1003	1354	0.7375	0.0327	0.0569	0.6351
MD-17	8	68	78	146	0.5343	0.0070	0.0569	0.8904
MD-18	9	107	495	602	0.8204	0.0052	0.0569	0.9165
MD-19	9	54	164	218	0.7151	0.0309	0.0569	0.6481
MD-20	9	159	792	951	0.8346	0.0100	0.0569	0.8504
MD-21	9	239	821	1060	0.7773	0.0284	0.0569	0.6673
MD-22	9	41	110	151	0.7349	0.0355	0.0569	0.6158
MD-23	9	38	171	209	0.8151	0.0037	0.0569	0.9391
MD-24	9	88	110	198	0.5750	0.0401	0.0569	0.5869
MD-25	9	78	212	290	0.7390	0.0131	0.0569	0.8130
MD-26	1	5	13	18	0.7222	#DIV/0!	0.0569	insufficient sample size
MD-27	8	226	865	1091	0.7910	0.0109	0.0569	0.8397
MD-28	8	75	132	207	0.6496	0.0502	0.0569	0.5316
MD-29	8	28	132	160	0.7370	0.0919	0.0569	0.3825
MD-30	8	57	254	311	0.8363	0.0204	0.0569	0.7358
MD-31	8	30	75	105	0.6797	0.0230	0.0569	0.7126
MD-32	8	16	141	157	0.9153	0.0027	0.0569	0.9552
MD-33	8	96	412	508	0.7808	0.0298	0.0569	0.6566
MD-34	7	74	446	520	0.8598	0.0024	0.0569	0.9598
MD-35	7	84	317	401	0.7620	0.0159	0.0569	0.7816
MD-36	3	3	0	3	0.0000	0.0000	0.0569	1.0000
MD-37	2	11	5	16	0.2937	0.0455	0.0569	0.5559
MD-38	2	4	1	5	0.1667	0.0556	0.0569	0.5061
MD-39	2	1	4	5	0.8333	0.0556	0.0569	0.5061

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.e., what do the results mean and what are the norms for the test conducted?)

The reliability score by physician observed from an analysis of 2 calendar years of data was 0.7115 with a standard deviation of 0.1667. This indicates that the “signal” of true differences between providers is stronger than the “noise” of measurement error, meaning that the colonoscopy quality index reliably distinguishes performance differences between physicians.

2b2. VALIDITY TESTING

2b2.1. What level of validity testing was conducted? (may be one or both levels)

Critical data elements

Performance measure score (*Note: this is preferred level for testing composite*)

Empirical validity testing

Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (*i.e., is an accurate reflection of performance quality or resource use and can distinguish performance*)

2b2.2. For each level checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used*)

All data elements are clinically derived from patient records. The composite score uses all-or-none scoring methodology based on these elements.

2b2.3. What were the statistical results from validity testing? (*e.g., correlation; t-test, ANOVA*)

Does not apply - Full population results are reported

2b2.4. What is your interpretation of the results in terms of demonstrating validity? (*i.e., what do the results mean and what are the norms for the test conducted?*)

The colonoscopy quality index is a highly accurate reflection of individual physician compliance with procedural quality elements included in the index.

2b3. EXCLUSIONS ANALYSIS

NA **no exclusions** — *skip to #2b5* — **NOTE: We do not exclude outliers. However, we do identify and investigate outliers to determine if the data is valid and take action, as appropriate.**

2b3.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)-NA

2b3.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)-NA

2b3.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)-NA

2b5. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b5.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used*)

The signal-to-noise ratio analysis described previously indicates that this measure identifies meaningful differences in performance.

2b5.2. What were the statistical results from testing the ability to identify differences in performance measure scores across measured entities? *(at a minimum, the distribution of performance measure scores for the measured entities by decile/quartile, mean, std dev; preferably also number and percentage statistically different from mean or some benchmark, different from expected, etc.)*

Please refer to the previous section on signal-to-noise ratio analysis. On the public website, results are reported by individual physician displayed by default in rank order. Physicians with an insufficient sample size for the period are not displayed. The reporting includes all patients at participating endoscopy centers. Standard deviation is not needed in this situation.

2b5.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and clinically/practically meaningful differences in performance across measured entities? *(i.e., what do the results mean and what are the norms for the test conducted?)*

As is apparent by viewing the individual component results by individual physician compared to the all-or-none composite by individual physician on the Quality Quest website, the all-or-none composite more effectively distinguishes differences in performance than do individual measures reported separately. <http://www.qualityquest.org/quality-reports/colonoscopies/index.php> Please refer to this website for the most recent data; both colonoscopy quality index (default display), individual components, and adenoma detection rate by gender are available.

If not an intermediate or health outcome or resource use measure, this section can be deleted

2b4. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

2b4.1. What method of controlling for differences in case mix is used?

- Statistical risk model with** Click here to enter number of factors **risk factors**
- Stratification by** Click here to enter number of categories **risk categories**
- No risk adjustment or stratification**
- Other,** Click here to enter description

2b4.2. If an outcome or resource use measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

The elements in the measure reflect important procedural processes and lack of intra-procedure avoidable complications. Risk adjustment is not appropriate. Please refer to our discussion of exclusion criteria.

2b4.3. Describe the conceptual/clinical and statistical methods and criteria used to select factors used in the statistical risk model or for stratification by risk *(e.g., potential factors identified in literature and/or expert panel; regression analysis; statistical significance of $p < 0.10$; correlation of x or higher)*

Does not apply

2b4.4. What were the statistical results of the analyses used to select risk factors?

Does not apply

2b4.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Does not apply

*Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.
if stratified, skip to 2b4.9*

2b4.6. Statistical Risk Model Discrimination Statistics: Does not apply

2b4.7. Statistical Risk Model Calibration Statistics: Does not apply

2b4.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves: Does not apply

2b4.9. Results of Risk Stratification Analysis: Does not apply

2b4.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (*i.e., what do the results mean and what are the norms for the test conducted*) - Does not apply

***2b4.11. Optional Additional Testing** (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods*) - Does not apply

Composite Performance Measure Testing

1d/e. Quality construct and purpose of the composite performance measure

1. Describe (or diagram) the quality construct—the relationship of the component measures to the overall composite and to each other.

All quality components included in the measure are material to performing a high quality colonoscopy. Including all steps in the composite strengthens the measure ability to improve consistency/reliability of this clinical process.

2. What is the purpose of the composite performance measure (i.e., how it will be used and how the composite provides a distinctive or additive value and better achieves the purpose than do the components individually)?

The composite score provides information on the overall quality for individual patients that cannot be discerned when individual components are reported separately. This composite measure assesses the reliability of colonoscopy quality processes.

3. Briefly state how the component measures are aggregated and weighted (detail should be in measure specifications) and how they are consistent with the quality construct and purpose. (Analyses should be reported below)

Scoring is all-or-none. This is consistent with the concept of process reliability as a means of achieving higher quality patient results.

2i/j. Component measure analysis to support the conceptual construct

1. Describe the conceptual/clinical and statistical methods and criteria used to select the component measures? (e.g., correlation, contribution to variation in overall composite score; frequency of contributing to failure of all-or-none composite)

The components selected are material to performing high quality colonoscopy. The components with the largest performance gap and greatest variability are: appropriateness of procedure; complete polyp information and appropriate follow-up recommendation.

2. What were the statistical results for the component measure analysis?

Does not apply. The table below provides the overall proportion of “successes” for each component and is provided for informational purposes only.

Measure/subcomponent	Score
Appropriate indication for colonoscopy	89.54%
Standardized medical risk assessment	98.86%
Standardized assessment of bowel prep	98.19%
Complete examination	99.10%
Cecal Photo taken	99.00%
All essential polyp information recorded	97.58%
Withdrawal time recorded	99.56%
Free of serious intra-procedural complications	99.97%
Appropriate follow-up recommendation	88.80%
OVERALL - Colonoscopy Quality Index	75.96%

3. What is your interpretation of the results in terms of demonstrating the components fit the quality construct?

Does not apply

2k. The aggregation and weighting rules are consistent with the quality construct

1. What analysis was conducted to demonstrate that the aggregation and/or weighting rules are consistent with the quality construct (e.g., sensitivity analysis of impact of various aggregation and/or weighting rules)?

Does not apply

2. What were the statistical results for the analysis?

Does not apply

3. What is your interpretation of the results in terms of demonstrating the aggregation and/or weighting rules support the quality construct?

Does not apply

2I. Analysis of missing component data

1. What is the frequency and pattern (e.g., random, systematic) of missing data for each component?

Only components that apply are included in the composite score. For example, if no polyp is identified, no polyp information is required. Components that are required, but not recorded, result in a 'negative' composite result (or score).

2. Briefly state how missing data are handled (e.g., case deletion, replace with average, imputation)

Does not apply

3. What analysis was conducted to support the specified handling of missing data in the aggregation rules? (e.g., sensitivity analyses of impact of various approaches)

Does not apply

4. What were the statistical results for the analysis?

Does not apply

5. What is your interpretation of the results in terms of supporting the aggregation rules and handling of missing data?

The all-or-none scoring works effectively. Results can be easily aggregated up to practice, center and region as results are maintained by individual procedure/patient.

2056 Colonoscopy Quality Index Appendix

<u>Page #</u>	<u>Section</u>
1	Stage 2 Checklist
7	Data aggregation and reporting process
35	Quality Quest Measure Specifications Document *Excel file codebook has been uploaded to submission
39	Presentation slides from project team that implemented this measure in 2008 - provides history
73	<u>Files provided to a colonoscopy center to begin reporting:</u>
73.....	File structure (format of the csv file) with acceptable values and rules
76.....	Process measure specification
80.....	Data field requirements
86.....	Definitions and abbreviations
93.....	Technical measure specifications - physician version
103.....	Import validation rules
xx.....	Access Database - not provided in appendix *database file available upon request

PCL XL error
Error:
Operator:
Position:
IllegalOperatorSequence
0xc1
5300



Quality Quest *for* Health
of Illinois



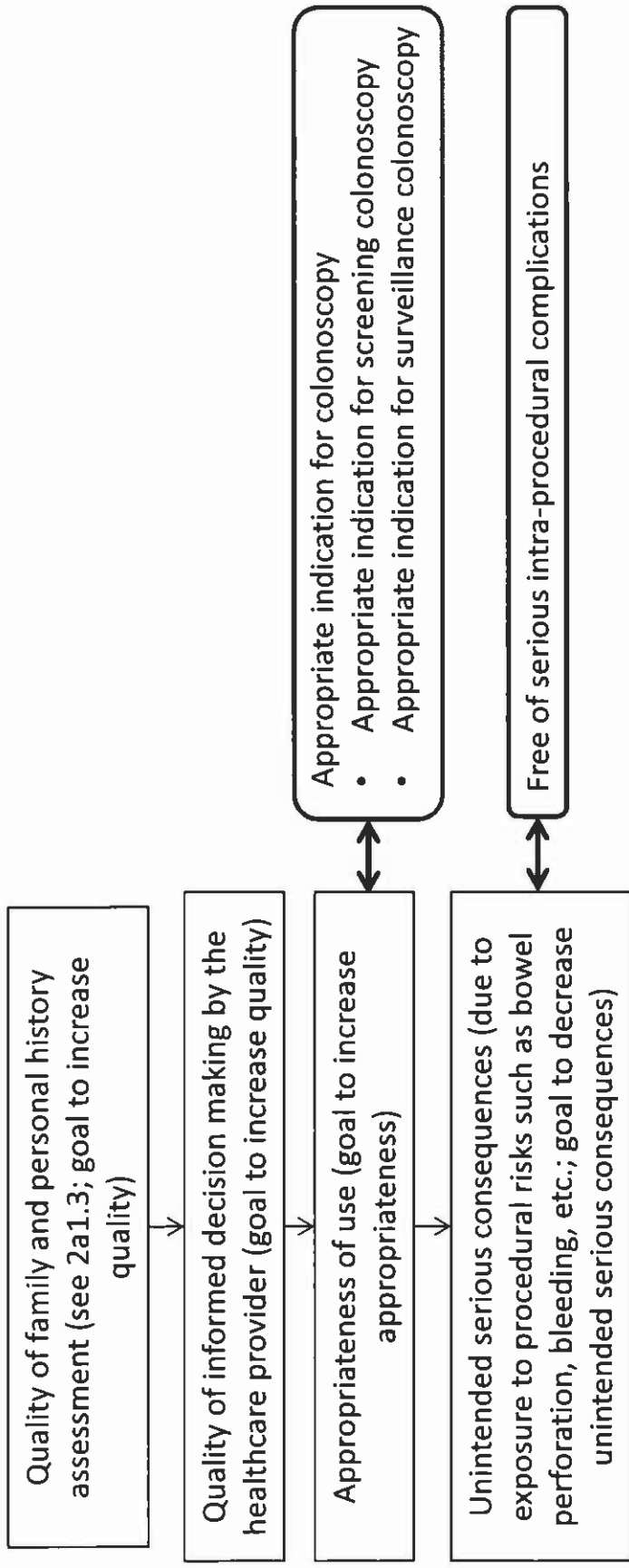
Colonoscopy Quality Index Access Database and Portal Use

www.qualityquest.org

Steps to reporting Colonoscopy Quality Index (for each participating site)

- Abstract data for all screening and surveillance colonoscopies
- Enter data into Access Database provided by Quality Quest
- Electronically transfer data to Quality Quest
- Review results in the Quality Quest data portal
 - Sites provided opportunity to review prior to public reporting of results
 - Physicians are able to view their patient-level data
 - Physicians are able to view physician-level data for all participants

Chronological order of Colonoscopy Quality Index components (relationship between the care process and the data)

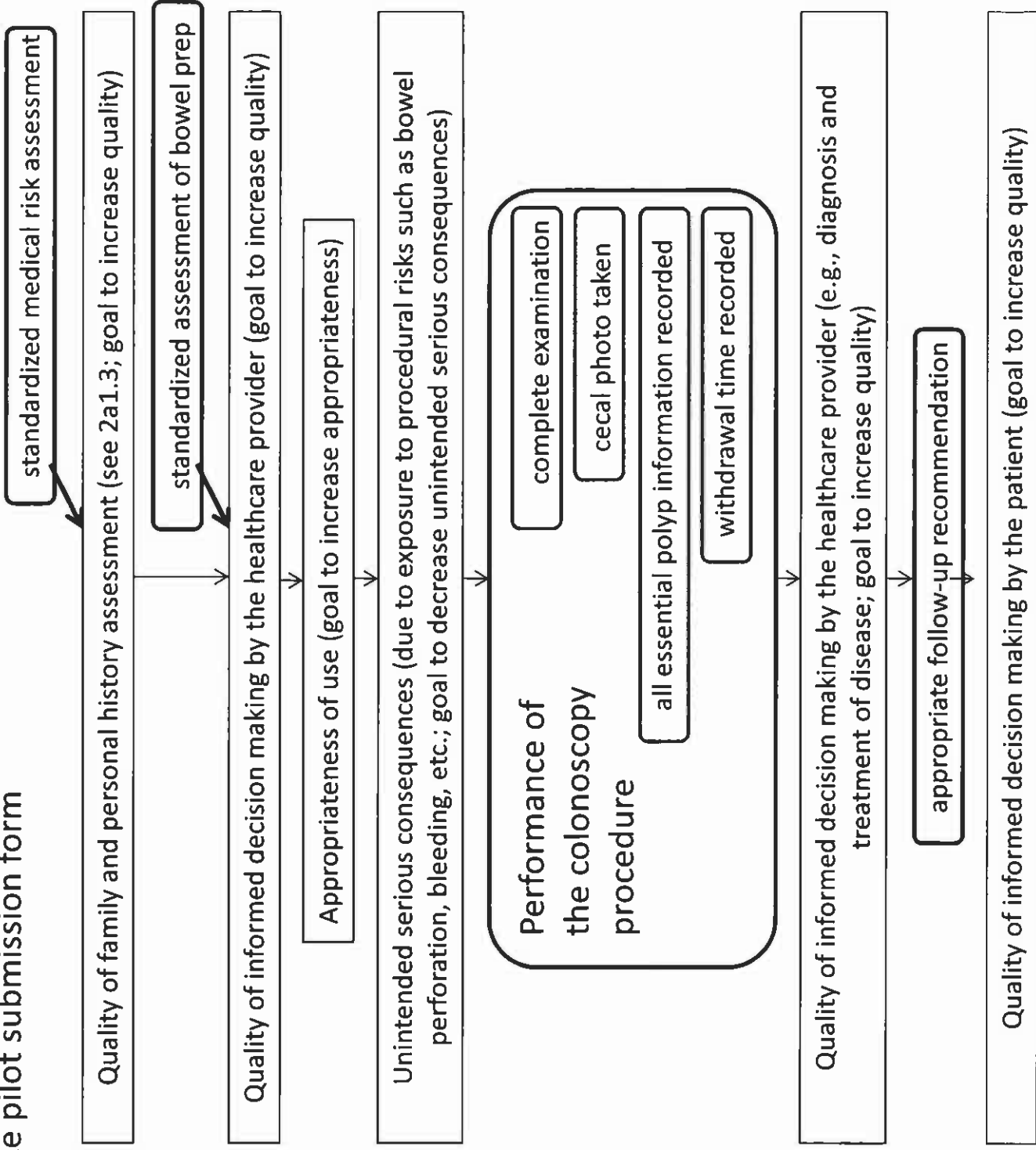


Evidence pilot submission form

1c.2

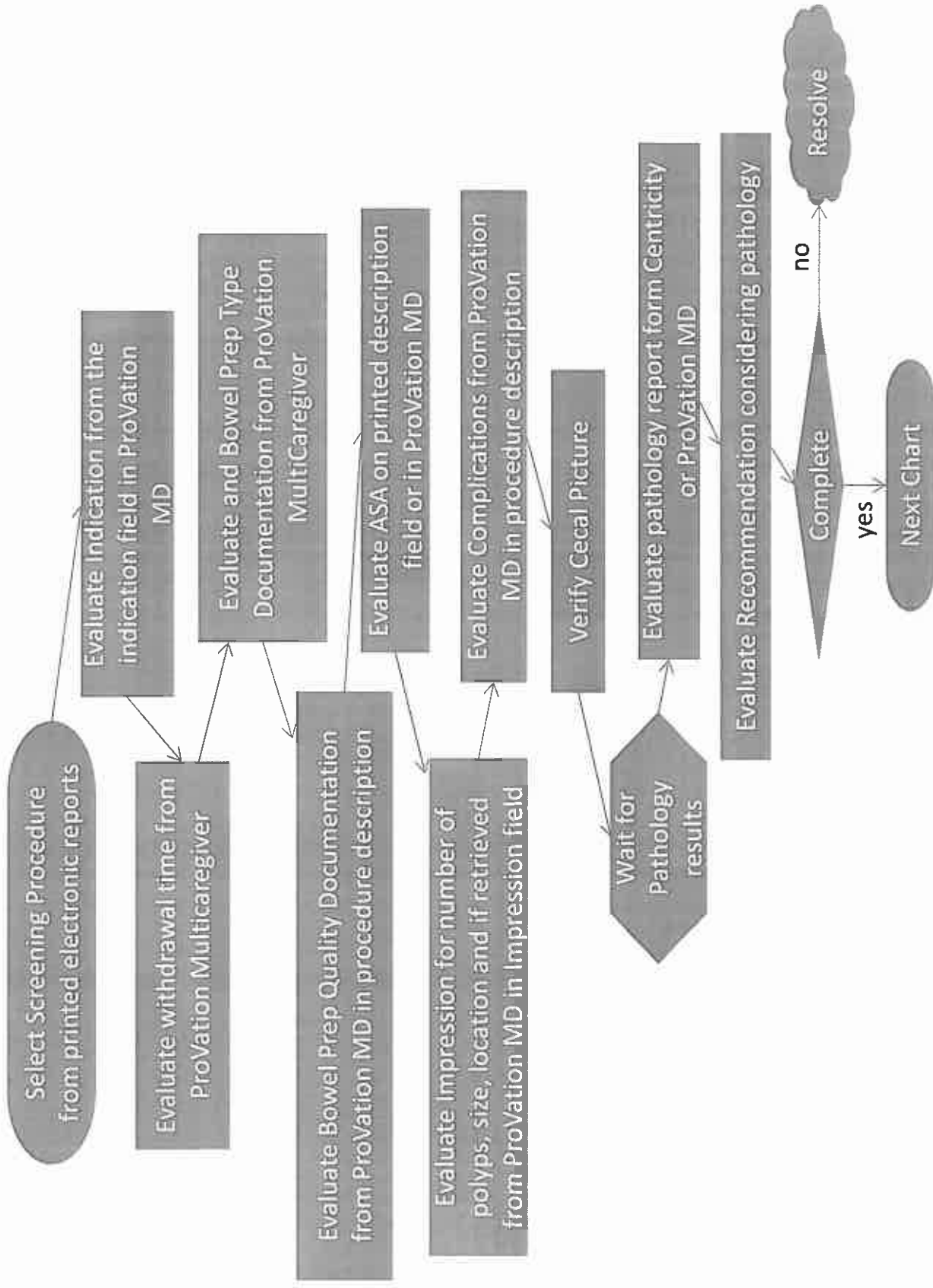
Evidence pilot submission form

1c.2



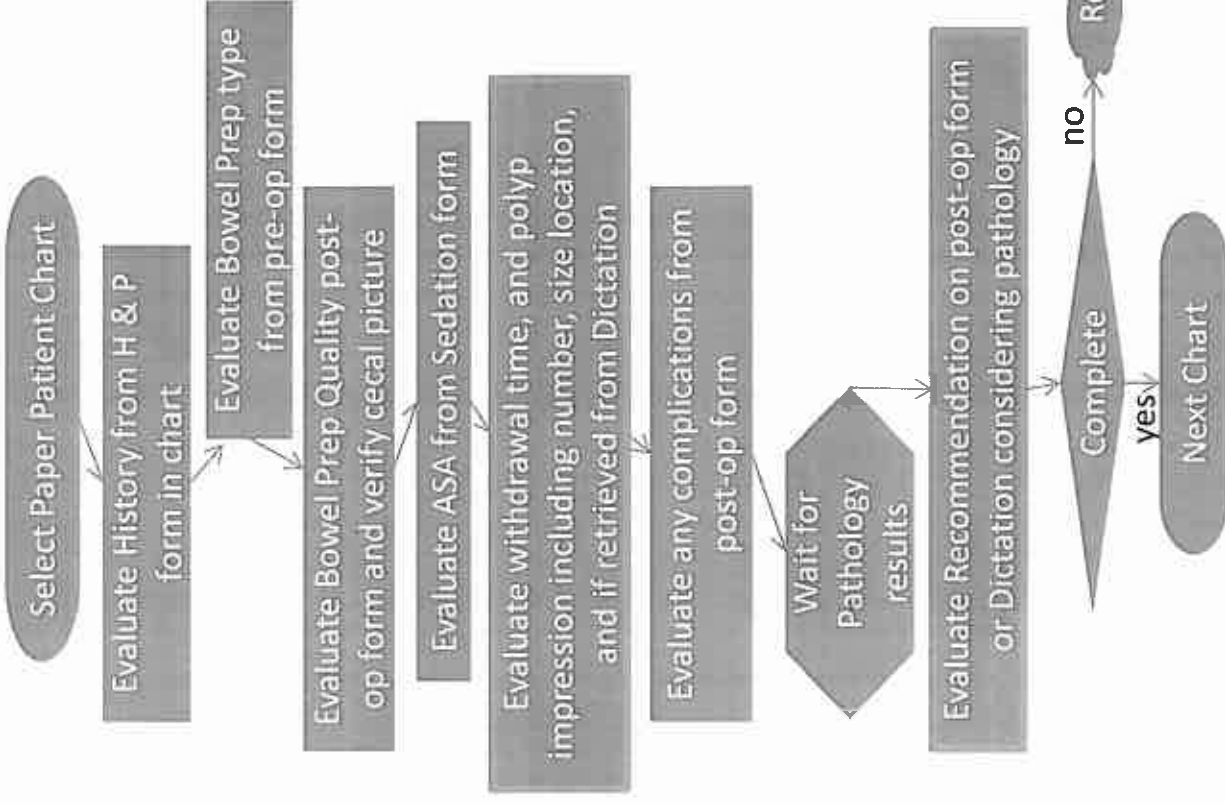
Abstracting Data for QQ Reporting- Electronic

Central Illinois Endoscopy Center

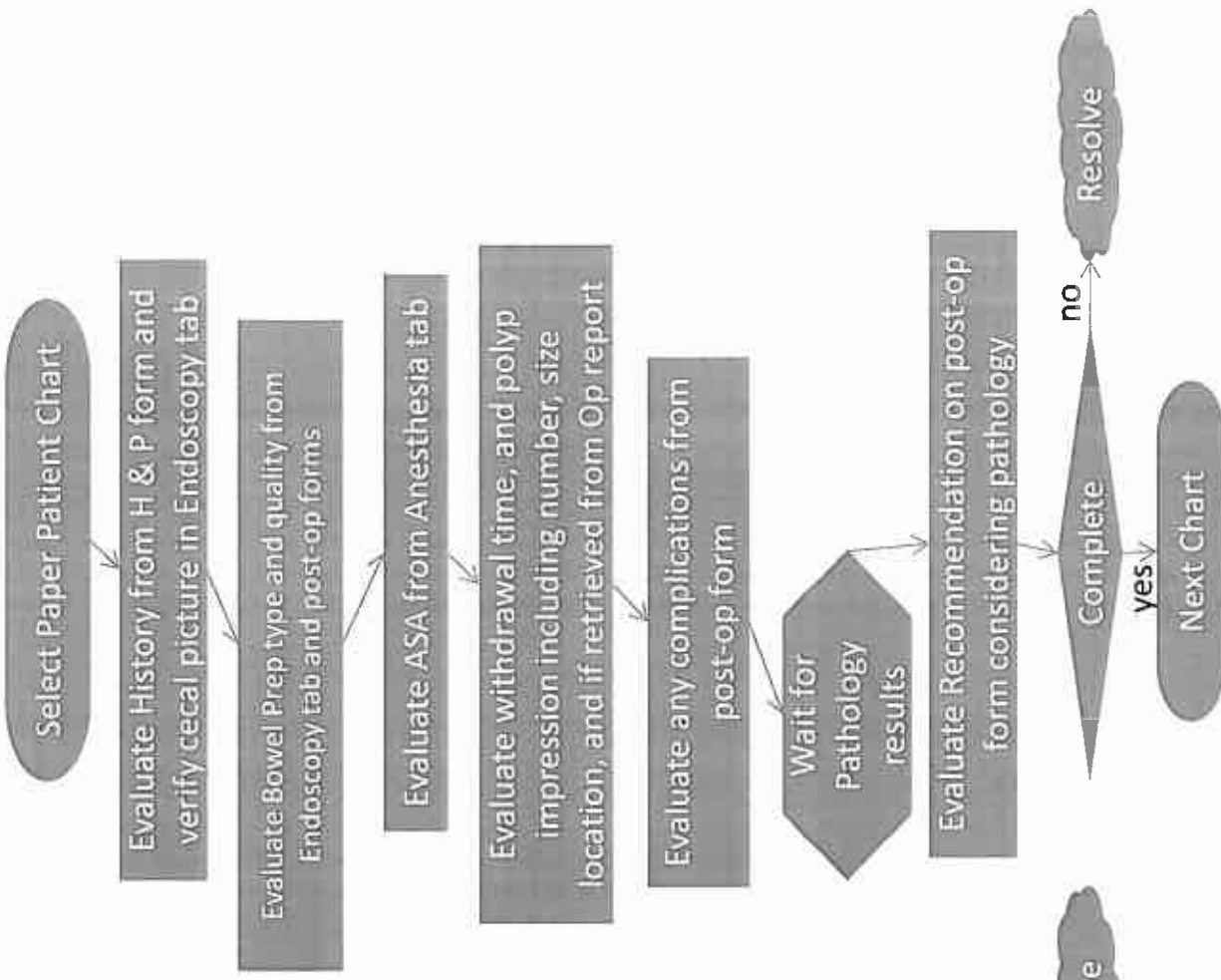


Abstracting Data for QQ Reporting- Paper

Decatur Digestive Disease Center



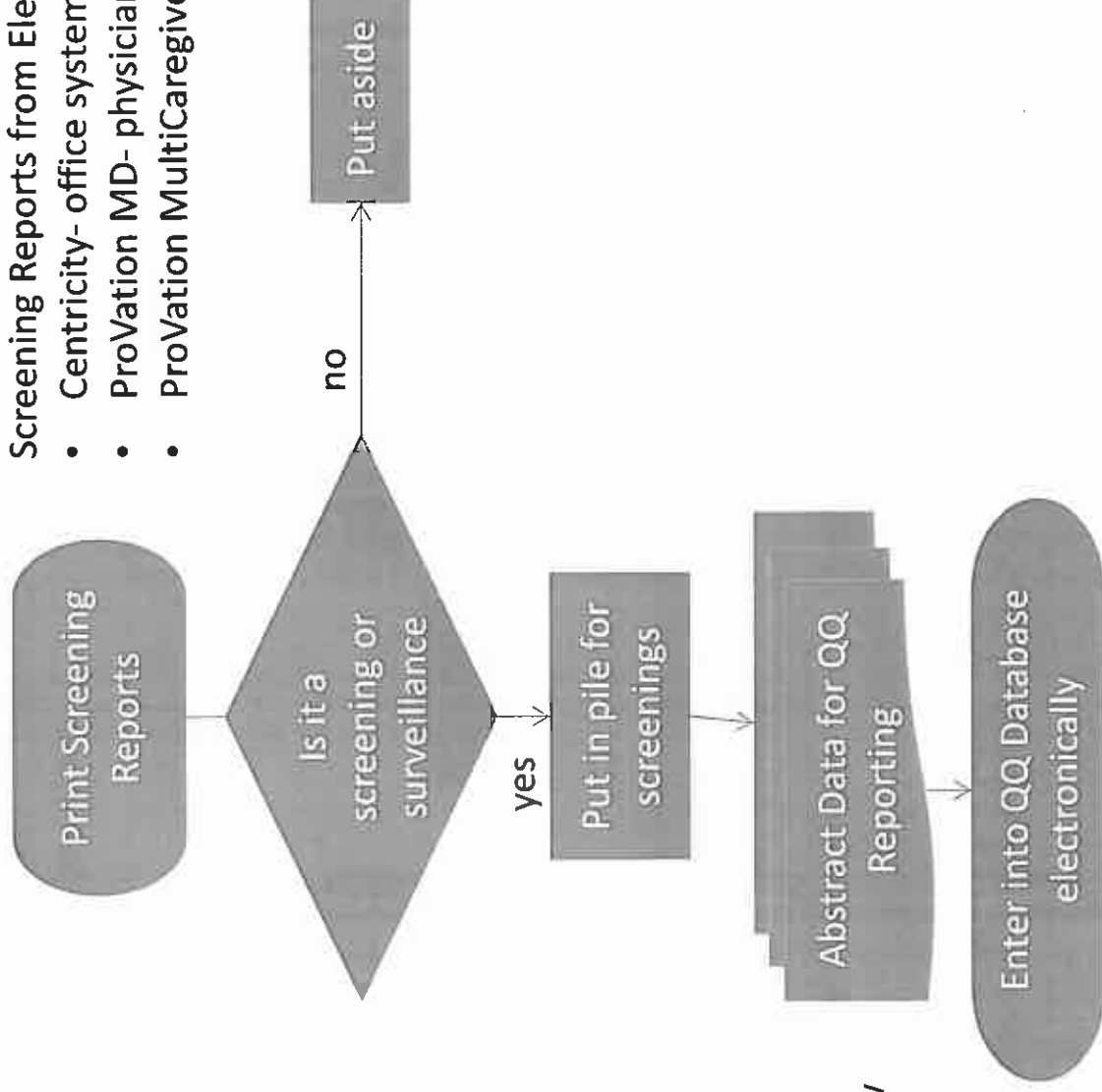
Decatur Memorial Hospital



Data Entry into Database- Electronic

Central Illinois Endoscopy Center

- Screening Reports from Electronic systems:
- Centricity- office system
 - ProVation MD- physician system
 - ProVation MultiCaregiver- RN system

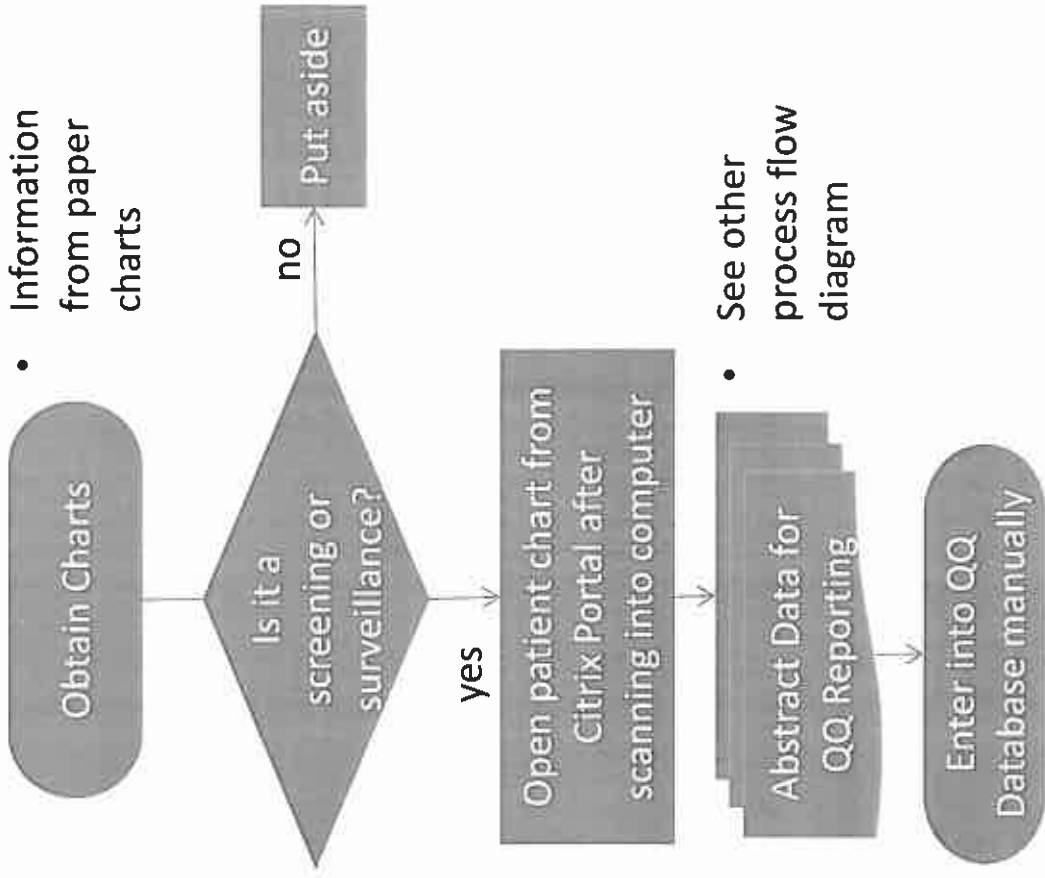
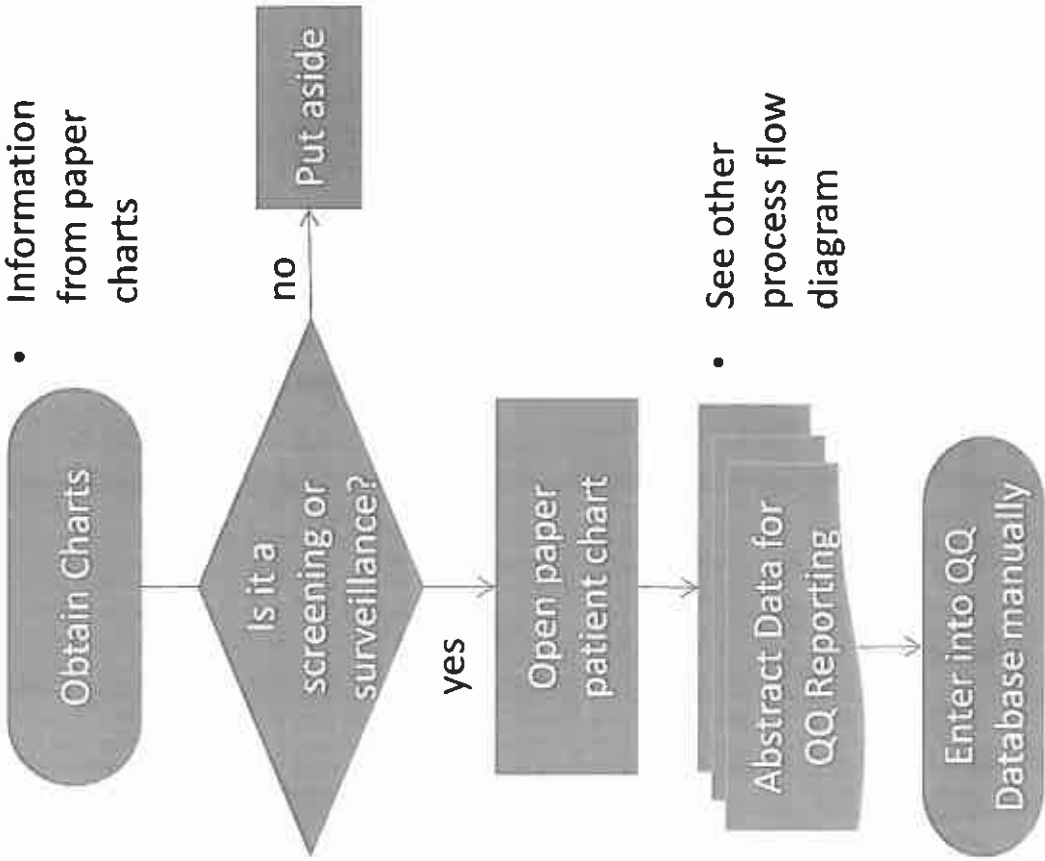


- See other process flow diagram

Data Entry Into Database- Paper

Decatur Digestive Disease Center

Endoscopy Center at Decatur Memorial Hospital



Access Database

- Standardizes data format for aggregation
- Patient identifiers stored at practice site only (e.g., MRN information not transferred to Quality Quest)

Quality Quest's Colonoscopy Database
MRN:

Date Collection Form

View Data

Export to Excel

Add MDs

Add Bowel Types

Quality Quest ID: (New)

QQ Colonoscopy Data Collection Tool

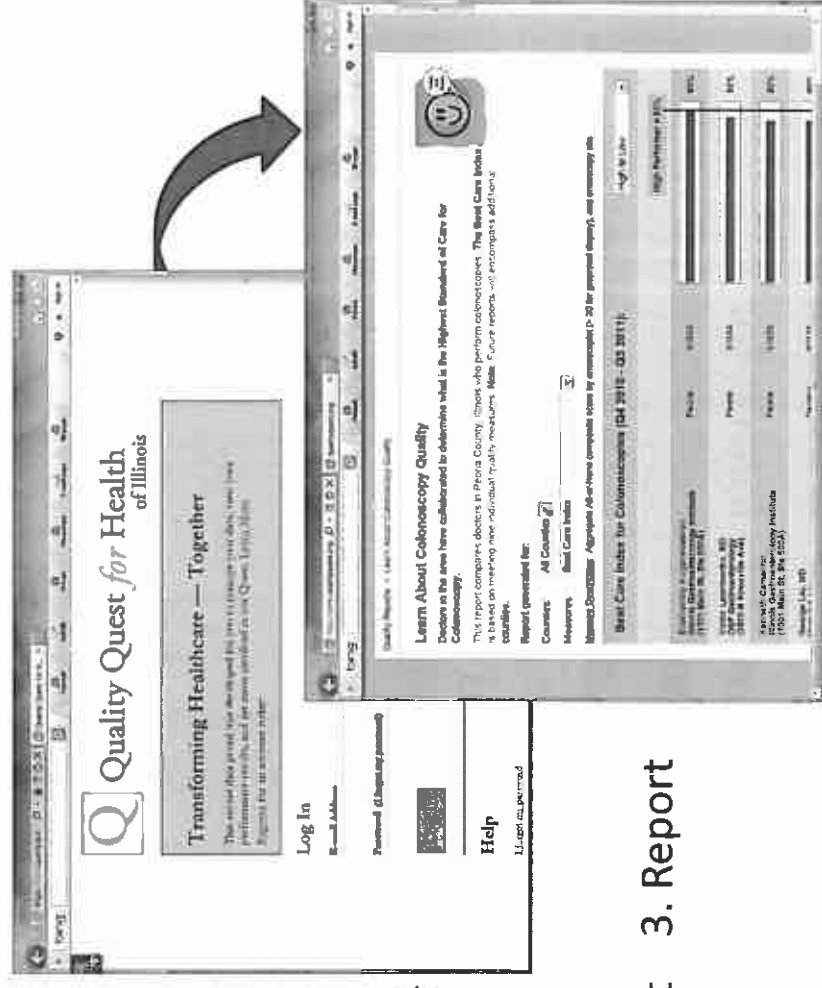
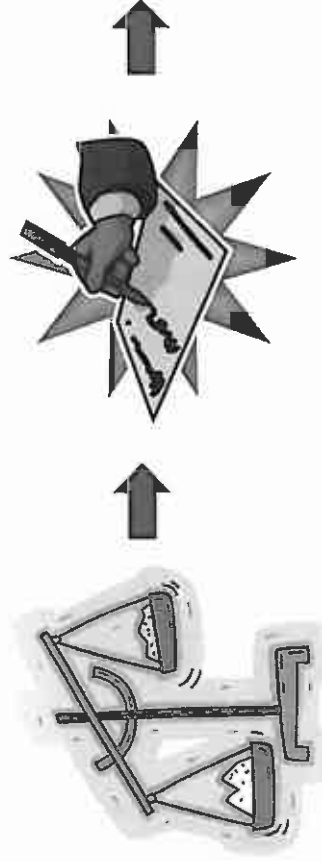
<p>Age: <input type="text"/></p> <p>Gender: <input type="text"/></p> <p>Procedure Date: <input type="text"/></p> <p>Physician NPI number: <input type="text"/></p> <p>Physician last name: (VIEW ONLY) <input type="text"/></p> <p>Physician first name: (VIEW ONLY) <input type="text"/></p> <p>PHx CRC: <input type="text"/></p> <p>PHx Adenoma: <input type="text"/></p> <p>Size (mm) of Largest previous adenoma: <input type="text"/></p> <p>PHx Villous Adenoma: <input type="text"/></p> <p>PHx Severe Dysplasia: <input type="text"/></p> <p>PHx Incomplete Polyp Removal: <input type="text"/></p> <p>PHx Serrated Adenoma: <input type="text"/></p> <p>#FDR(s) with CRC: <input type="text"/></p> <p>#SDR(s) with CRC: <input type="text"/></p> <p>PHx CRC: (VIEW ONLY) <input type="text"/></p> <p>Age of Youngest FDR with CRC: <input type="text"/></p> <p>PHx or FHx of FAP, HNPCC, HPS: <input type="text"/></p> <p>PHx IBD: <input type="text"/></p> <p>FDR Adenoma: <input type="text"/></p> <p>Age of Youngest FDR with Adenoma: <input type="text"/></p> <p>Notes: <input style="height: 40px;" type="text"/></p>	<p>Previous Colonoscopy: <input type="text"/></p> <p>Year of last colonoscopy (yyyy). (Leave blank if newer to previous question equals 0, 2 or 4)</p> <p>Bowel Prep Type: <input type="text"/></p> <p>ASA class: <input type="text"/></p> <p>Assess of bowel prep: <input type="text"/></p> <p>Exam complete mal: <input type="text"/></p> <p>Photo taken: <input type="text"/></p> <p>Any Polyps Removed this colonoscopy: <input type="text"/></p> <p>All polyp info recorded: <input type="text"/></p> <p>Withdrawal time (minutes): <input type="text"/></p> <p>Pt Free of Acute Complications: <input type="text"/></p> <p>Follow up recommendation: <input type="text"/></p> <p># polyps removed: <input type="text"/></p> <p>Size largest polyp removed (mm): small/diminutive = 4mm, medium = 9mm, large = 11mm</p> <p>Are any polyps Adenomatous: <input type="text"/></p> <p>Total number of confirmed adenomas this exam: <input type="text"/></p> <p>Other polyp histopathology: <input type="text"/></p> <p>Any serrated adenoma(s) this exam: <input type="text"/></p>
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15



The Secure Data Portal is a Tool to:

- Measure What Matters
- Report Results Publicly
- Together



1. Agree on Measure
2. Data Use Agreement
3. Report



Why use the portal?

- Ability to benchmark performance
- Build confidence in data and comfort with transparency
- Data available for review prior to comparative reports
- Public reporting necessary to affect lasting change

Public Reporting

http://www.qualityquest.org/ Quality Quest for H. x

bing Home Mail Address Private Messenger E-mail page IM page Live Messenger Sign in

Share this page with a contact using Windows Live Messenger contact blog login

Home **Quality Quest for Health of Illinois**

What is the Challenge? What Can I do? What is Quest Doing? Quest Projects Quality Reports

Quest is For Everyone

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- Doctors & Hospitals LEARN MORE
- Employers LEARN MORE
- Insurance Companies & Health Plans LEARN MORE

Performance Results

Together we can improve healthcare.

Join the Quest. Learn More.

We're on a quest to improve healthcare in our state. And you can help.

Quality Quest for Health of Illinois is a not-for-profit, independent source for unbiased information on local healthcare. We identify best practice care standards—care that is proven by science to be effective, beneficial and valuable. And we measure performance—to see how local healthcare providers are stacking up against these standards of care. Our goal is to improve the quality of care in our state, reduce waste, and get the best value for the money spent on healthcare.

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BE AWARE FOR SAFE CARE

Patient Safety Awareness Week
March 4-10, 2012

Sponsored by the
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Learn About Colonoscopy Quality

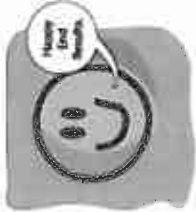
Doctors in the Peoria area have collaborated to define the highest care standard for colonoscopy.

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Report Methodology

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Overview

The *Colonoscopy Best Care Index* includes 7,537 screening and surveillance colonoscopies clinicians performed at Central Illinois Endoscopy Center, Decatur Digestive Disease Center, Decatur Memorial Hospital, Methodist Medical Center of Illinois, OSF Saint Francis Medical Center, Pekin Hospital and Proctor Hospital in Fulton, Macon and Peoria counties in Illinois between October 01, 2010 and September 30, 2011. Clinicians performing 30 or more colonoscopies at these endoscopy centers during this period are included in the report.

Particular caution is urged in interpreting these baseline results. Not all gaps in performance reflect variance from established standards. Various factors are responsible for gaps in performance. The expected rate for examining the entire colon is not 100 percent. Studies find that in one of 20 men and one of 10 women a complete exam is not possible. Gaps in care may come from the processes in one center being different than another. Physician practices may also vary.

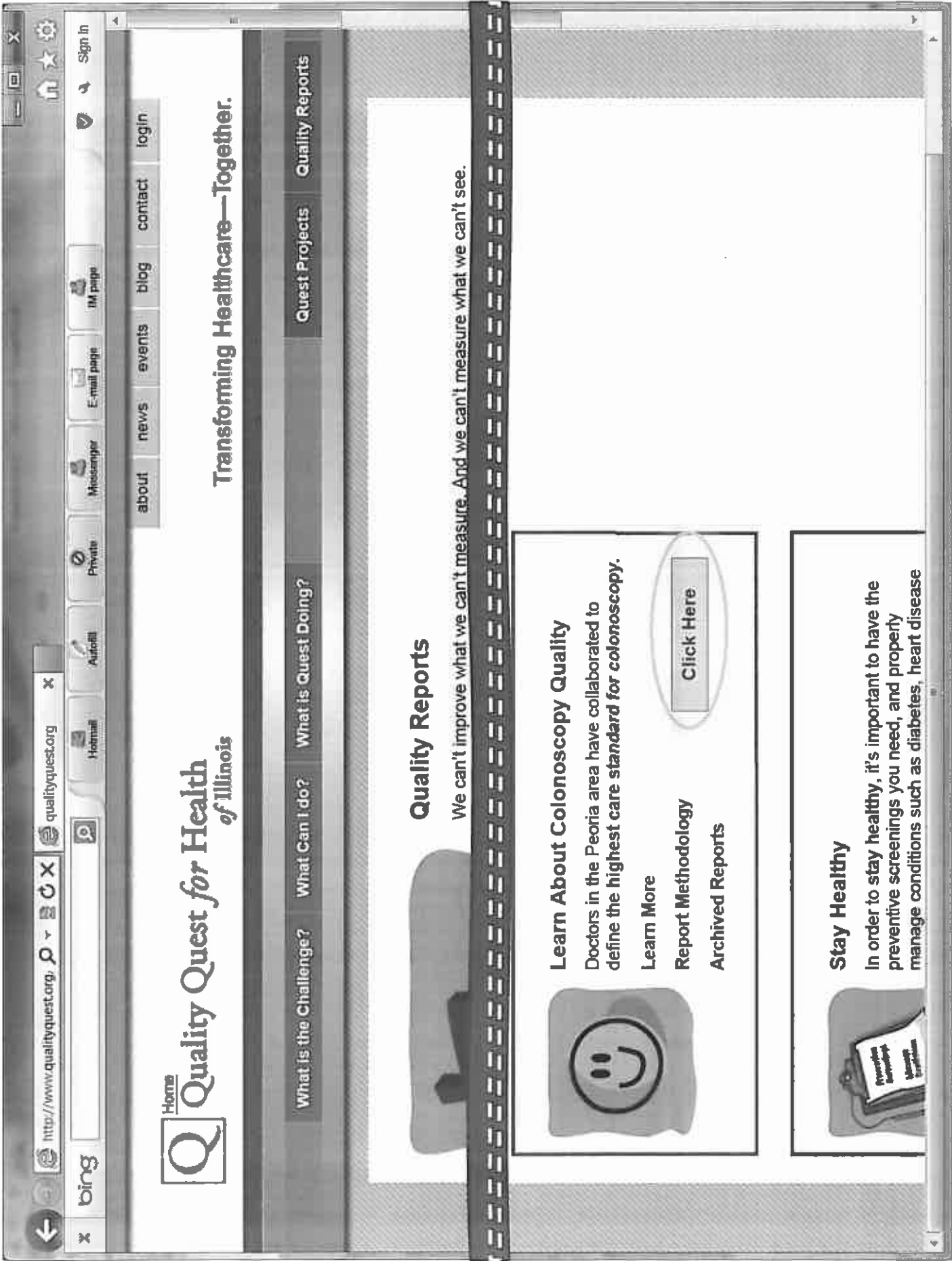
Measure Criteria

The Best Care Index was developed by Quality Quest and a team of clinicians. It measures when a patient receives **ALL** of the following.

- Patient is over 50 or has a family or personal history increasing their risk of colorectal cancer
- Patient's heart and lung risk factors have been reviewed and documented before the procedure
- Patient's bowel is well cleansed on the day of the test
- The entire colon is examined
- A Cecal photo was taken
- All appropriate information is gathered about each polyp that is found
- The patient experiences no serious complications from having the colonoscopy
- The examination time is recorded
- The patient is given the appropriate follow-up examination recommendation

Regional Rate for Q4 2010 – Q3 2011

Total Colonoscopies	7,537
Best Care Index for Colonoscopies	81%



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Quality Reports

We can't improve what we can't measure. And we can't measure what we can't see.



Learn About Colonoscopy Quality
Doctors in the Peoria area have collaborated to define the highest care *standard for colonoscopy.*
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Stay Healthy
In order to stay healthy, it's important to have the preventive screenings you need, and properly manage conditions such as diabetes, heart disease

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:

Countries:

Measures:

Measure Description: Aggregate All-or-None composite score by endoscopist (> 30 for graphical display), and endoscopy site

Best Care Index for Colonoscopies (Q4 2010 - Q3 2011):

Endoscopist	Endoscopy Site	Score	High Performer = 95%
Ellothamby Kuganeswaran Illinois Gastroenterology Institute (1001 Main St, Ste 500A)	Peoria	61606	95%
Victor Lawrinenko, MD OSF Gastroenterology (2805 N Knoxville Ave)	Peoria	61604	92%
Kenneth Camacho Illinois Gastroenterology Institute (1001 Main St, Ste 500A)	Peoria	61606	90%
George Liu, MD	Decatur	62526	89%



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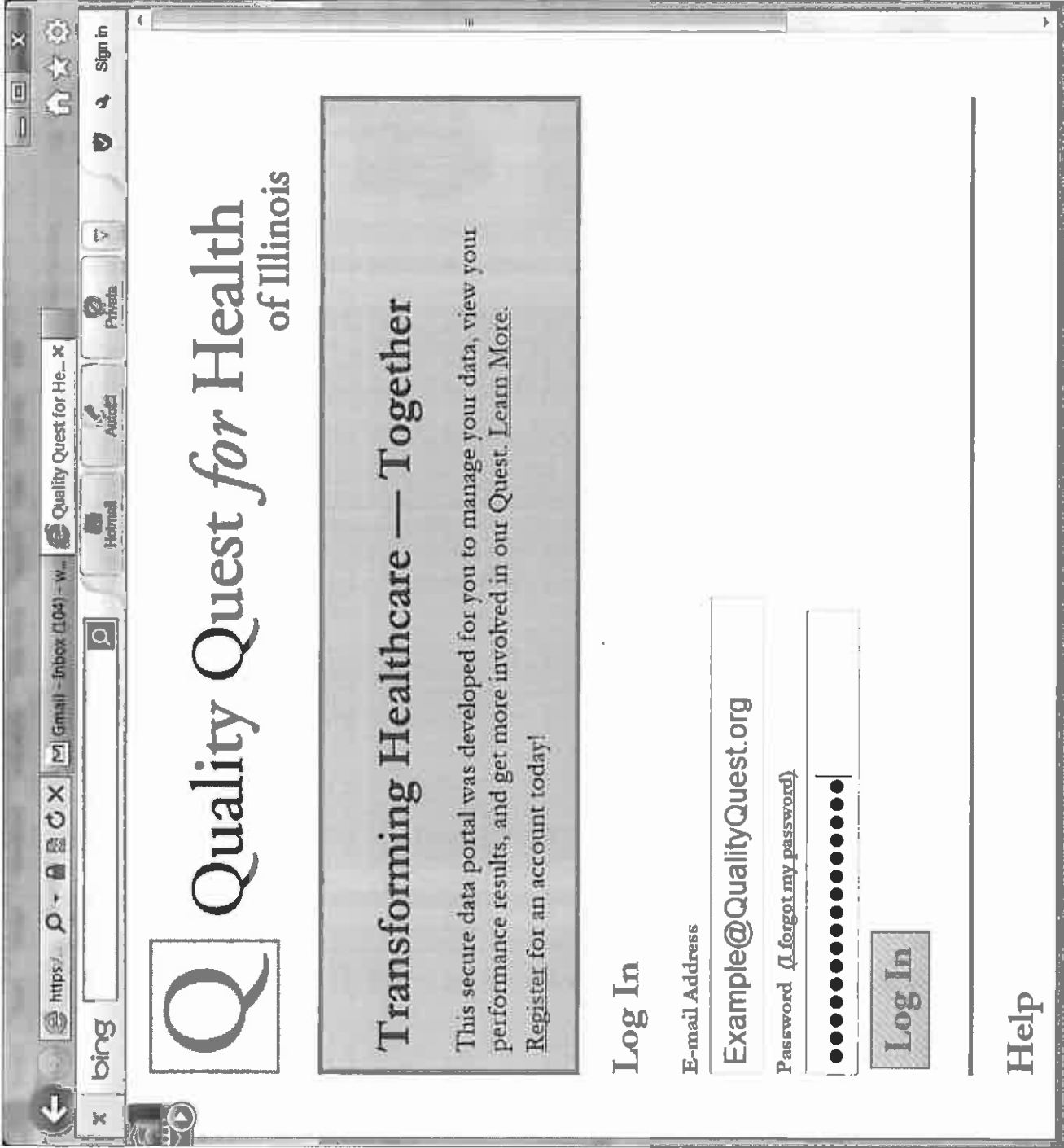
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Recent Results

Source	Measure Group	Data Entry Status	Data Entry Ends	Most Recent Period	Publishing Status	Publishing Deadline
Quality Quest	<u>Direct Submission Registry Measures</u>	Open	12/30/2010, 12:00 AM	Q4 2009 - Q3 2010	Not Published	12/31/2011, 12:00 AM
Quality Quest	<u>Flu Shot</u>	Open	03/10/2012, 12:00 AM	February 2012	Not Published	03/15/2012, 12:00 AM
Quality Quest	<u>Generic Prescribing</u>	Closed	01/31/2012, 12:00 AM	Q4 2011	Preview	03/15/2012, 12:00 AM
Quality Quest	<u>High Quality Colonoscopy</u>	Open	02/15/2012, 12:00 AM	Q4 2011	Not Published	03/15/2012, 12:00 AM
HEDIS	<u>HEDIS</u>	Open	01/31/2012, 12:00 AM	Y2011	Not Published	03/31/2012, 12:00 AM

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Results > Flu Shot

Period	Data Entry Status	Data Entry Deadline	View	Publishing Status	Publishing Deadline
February 2012	Open	03/10/2012, 12:00 AM	<u>Overall Results</u>	Not Published	03/15/2012, 12:00 AM
January 2012	Closed	02/10/2012, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	02/15/2012, 12:00 AM
December 2011	Closed	01/10/2012, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	01/15/2012, 12:00 AM
November 2011	Closed	12/10/2011, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	12/16/2011, 12:00 AM
October 2011	Closed	11/10/2011, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	11/30/2011, 12:00 AM

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Results > Flu Shot > January 2012

Compare Results: Counties Sites

Rate	Counties	Total Population	Total Compliance
89.4%	Overall Rate for All Counties	30,070	26,872
90.0%	Champaign	5,119	4,609
78.6%	Christian	196	154
96.7%	Knox	608	588
83.9%	La Salle	679	570
88.9%	Livingston	389	346
97.5%	Macon	3,245	3,163

Download Results Now

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Results > Flu Shot > January 2012

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Compare Results: Counties Sites

Rate	Location	County	Practice	Total Population	Total Compliance	Trend Graph
89.4%	Overall Rate for All Sites					
90.0%	Carle Foundation Hospital Physicians 611 W Park St, Urbana, 61801	All	Carle Clinic	5,119	4,609	Show Hide
97.4%	Decatur Memorial Hospital 2300 N Edward St, Decatur, 62526	Macon	DMH - Decatur Memorial Hospital	2,237	2,179	Show Hide

Genesis Medical

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Recent Results

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Quality Quest	<u>Direct Submission Registry Measures</u>	Open	12/30/2010, 12:00 AM	Q4 2009 - Q3 2010	Not Published	12/31/2011, 12:00 AM
Quality Quest	<u>Flu Shot</u>	Open	03/10/2012, 12:00 AM	February 2012	Not Published	03/15/2012, 12:00 AM
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Quality Quest	<u>High Quality Colonoscopy</u>	Open	02/15/2012, 12:00 AM	Q4 2011	Not Published	03/15/2012, 12:00 AM
HEDIS	<u>HEDIS</u>	Open	01/31/2012, 12:00 AM	Y2011	Not Published	03/31/2012, 12:00 AM

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Results > High Quality Colonoscopy

Period	Data Entry Status	Data Entry Deadline	View	Publishing Status	Publishing Deadline
Q4 2011	Open	02/15/2012, 12:00 AM	<u>Overall Results</u>	Not Published	03/15/2012, 12:00 AM
Q3 2011	Closed	11/15/2011, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	12/31/2011, 12:00 AM
Q2 2011	Closed	08/15/2011, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	09/30/2011, 12:00 AM
Q1 2011	Closed	05/15/2011, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	06/30/2011, 12:00 AM
Q4 2010	Closed	02/15/2011, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	04/15/2011, 12:00 AM
Q3 2010	Closed	11/15/2010, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	12/31/2010, 12:00 AM
Q2 2010	Closed	09/11/2010, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	11/30/2010, 12:00 AM
Q1 2010	Closed	08/31/2010, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	10/8/2010, 12:00 AM
Q4 2009	Closed	03/20/2010, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	07/5/2010, 12:00 AM
Q3 2009	Closed	11/1/2009, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	07/5/2010, 12:00 AM
Q2 2009	Closed	08/1/2009, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	07/5/2010, 12:00 AM
Q1 2009	Closed	05/1/2009, 12:00 AM	<u>Overall Results</u>	<u>Published</u>	07/5/2010, 12:00 AM

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Results > High Quality Colonoscopy > Q3 2011

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Period Type View: [Current Quarter](#) | [Rolling 12 Months \(Q4 2010 - Q3 2011\)](#)

Compare Results: [Colonoscopy Centers](#) | [Clinicians](#) | [Patients](#)

Rate	Colonoscopy Centers	Colonoscopy Total #	Best Care	Approp. ASA	Bowel Complete	Cecal Polyp	No Acute	Withdrawal	Approp. F/U			
			Index	Indic.	Risk Prep	Exam	Photo	Info	Complication Time			
84.2%	Overall Colonoscopy	1769	1489	1628	1764	1745	1756	1760	1732	1768	1764	1667
92.9%	Central Illinois Endoscopy Center 1001 Main St, Ste 500, Peoria, 61606	757	703	716	757	756	756	757	757	757	757	745
	Decatur											

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Results > High Quality Colonoscopy > Q3 2011

Period Type View: Current Quarter Rolling 12 Months (Q4 2010 - Q3 2011)

Compare Results: Colonoscopy Centers Sites Clinicians Patients

Page: 1 >>

Rate	Clinicians	Total #	Best Care	Approp. Indic.	ASA	Bowel Prep	Exam	Cecal Photo	Polyp Info	No Acute Complication	Withdrawal Approp. F/U	
84.2%	Overall Colonoscopy	1769	1489	1628	1764	1745	1756	1760	1732	1768	1764	1667
100%	Frank Adams, MD OSF Gastroenterology 2805 N Knoxville Ave, Peoria, 61604	12	12	12	12	12	12	12	12	12	12	12
90.6%	Abdullah Al-Rashdan Illinois Gastroenterology Institute 1001 Main St, Ste 500A, Peoria, 61606	64	58	63	64	64	63	63	63	64	64	60
76.9%	Timothy Bailey, MD Bailey & Gilman - West Hay Medical Center 302	13	10	11	13	13	13	13	13	13	13	12

Patient-level data available to physicians to facilitate performance improvement

Compare Results: Colonoscopy Centers Sites Clinicians Patients

20.0% (Total # of Colonoscopies = 10)

Patient ID	Procedure Date	Colonoscopy Center	Approp. Indic.	ASA Risk	Bowel Prep	Complete Exam	Cecal Photo	Polyp Info & N/A	No Acute Complication	Withdrawal Time	Approp. F/U
[REDACTED]	[REDACTED]	[REDACTED]	1	1	1	0	1	0	1	1	0
[REDACTED]	[REDACTED]	[REDACTED]	0	1	1	1	1	1	1	0	0
[REDACTED]	[REDACTED]	[REDACTED]	0	1	1	1	1	1	1	0	1
[REDACTED]	[REDACTED]	[REDACTED]	1	1	1	1	1	1	1	1	0
[REDACTED]	[REDACTED]	[REDACTED]	1	1	1	1	1	1	1	1	0
[REDACTED]	[REDACTED]	[REDACTED]	1	1	1	1	1	1	1	1	0
[REDACTED]	[REDACTED]	[REDACTED]	1	1	1	1	1	1	1	1	0
[REDACTED]	[REDACTED]	[REDACTED]	1	1	1	1	1	1	1	1	0

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: Yes = 1 and No = 0

- Appropriate Follow-Up was not done for 7 patients.
- Addressing this single issue would have improved this physician's composite performance from 20% to 70%.

This page is
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blank to
facilitate
ease-of-use
when printed
in duplex form.



Quality Quest *for* Health

**Colonoscopy Composite Measure
Specifications**

Colonoscopy Quality Index

Last updated 1-10-2013

Description	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 <u>intra-procedural</u> 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
Methodology	Self-reported
Reporting Level	High quality colonoscopy and individual elements by individual endoscopist (> 30 for public reporting, aggregated at a rolling 12-months)
Ages included	Ages \geq 18 at time of colonoscopy
Population	All screening and surveillance endoscopies performed at participating colonoscopy locations
Frequency	Quarterly
Numerator	All patients undergoing screening or surveillance colonoscopy who meet all relevant individual quality elements (2-10 below). <i>Elements that do not apply are excluded from numerator calculation.</i>
Denominator	All adults undergoing screening or surveillance colonoscopy
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.
Rates	Aggregate rates by endoscopist,(> 30 for public reporting)

Measures

4.—Colonoscopy Quality Index: The percentage of patients who met all individual quality elements (see below).

1. Appropriate indication for colonoscopy:

Appropriate indication for screening colonoscopy:

- 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*
- 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*
- 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

Appropriate indication for surveillance colonoscopy:

- 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*
- 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*
- Patient with 1-2 small tubular adenoma(s) on most recent colonoscopy, has not had colonoscopy in the past 5 years; *or*
- Patient with three to ten adenomas < 1 cm on most recent colonoscopy, has not had colonoscopy in the past 3 years; *or*
- 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*
- Patient with greater than ten adenomas or with $>$ one serrated polyp on most recent colonoscopy, has not had colonoscopy in past 12 months; *or*
- Patient with sessile polyp > 1 cm with incomplete excision on most recent colonoscopy, has not had colonoscopy in past 2 months; *or*
- 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 (excellent, good or fair) or inadequate (poor or unsatisfactory) recorded
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 was 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 intra-procedural 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 measure two above.

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Colonoscopy Composite Measure Final Gate Review – July 10, 2008

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Agenda

• Safety	Dr. Rick Luetkemeyer
• Reflections	Dr. Rick Luetkemeyer
• Project Introduction	Rusty Hewit
• Composite Measure	Dr. Rick Luetkemeyer
• OSF Reporting	Ara Peterson
• Other Facilities	Rusty Hewit
• MGPP	Rusty Hewit
• Replication	Rusty Hewit
• Standard Bowel Prep	Dr. Rick Luetkemeyer
• Prophylactic Antibiotics	Dr. Rick Luetkemeyer
• Pathology	Dr. Rick Luetkemeyer
• Lessons Learned	Rusty Hewit


Reflections

Data without analysis is like food without taste-

A very bland experience

Ara Peterson, RN, BSN
OSF Clinical Manager Surgery

Opportunity Statement



No
Changes

Colorectal cancer screening and surveillance colonoscopy quality of care varies. Interval recommendations are not consistently aligned with evidence-based care standards, technical quality is variable and information provided to accurately interpret biopsies is not consistently complete. Referring physicians and patients do not have access to information to allow them to make informed choices regarding colonoscopy services.



Business Case

The development and reporting of composite measures will ensure patients get consistent, high quality colonoscopies in alignment with best practice standards and referring physicians and patients have reliable information on colonoscopy care to guide clinical decision making.



Goal Statement

1. Define and adopt evidence-based colonoscopy quality-of-care standards for central Illinois.
2. Recommend adoption and implementation of key metrics for assessing and monitoring the quality and safety of colonoscopies performed in central Illinois.
3. Review options and recommend solutions for providers to self-report data on key metrics.
4. Share data from the composite measure with consumers and referring physicians.

Project Team Members

- Dr. Terry Baldwin – Team Lead Gastroenterology, LTD
- Dr. Rick Luetkemeyer
Caterpillar Corp. Medical
- Dr. Michael Cashman
OSF, SFMC Gastroenterology
- Dr. Michael Shekleton
OSF, SFMC Gastroenterology
- Dr. Michael Hayes
OSF Health Care
- Dr. Tom Rossi
Peoria Surgical Group, LTD
- Rita Menold
OSF–Clinical Manager
- Ara Peterson
OSF-Manager Process Improvement
- Jane Brophy
Caterpillar Corp. Medical
- Julie Gray
Quality Quest for Health

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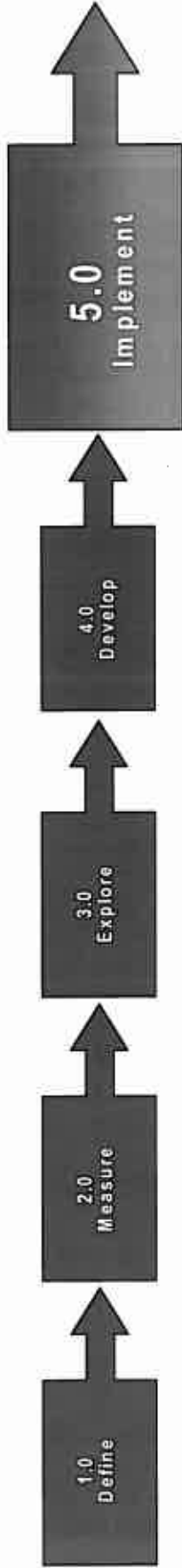
Dr. Steve Goldman

Caterpillar Medical Director

Sue Wozniak

OSF Chief Operating Officer

5.0 IMPLEMENT



Objective	Main Activities	Potential Tools and Techniques	Key Deliverables
<ul style="list-style-type: none"> Understand the purpose and the outputs of Implement Develop and execute the pilot and analyze the results Develop full-scale implementation plans and transition to process owners Evaluate the design process and make improvements 	<ul style="list-style-type: none"> Execute the Pilot and Validation Plans Analyze Results Revise/Confirm Design Scale Up Decision Develop Detail Implementation Plans Develop Communications Plans Transition Design Develop Process Owner Transition Plan Develop Communications Plans Complete Project Documentation Document Lessons Learned Recognition Project Review and Closure 		<ul style="list-style-type: none"> Validation Testing Complete Gap Analysis/Redesign Scale-Up Decision Full-Scale Implementation Plan Process Owner Transition Plan Build & Control Documentation Design Transitioned Team Lessons Learned Recognition Score Card

Metrics

The effectiveness and safety of colonoscopy depend on the quality of examination and a growing body of evidence suggests that the quality of colonoscopy in clinical practice varies.

MSTF – CRC

Gastrointestinal Endoscopy - 2007

www.qualityquestforhealth.com

Metrics

One obstacle to measuring quality within and across practices is the absence of a standardized reporting system for colonoscopy.

Colonoscopy Composite Measure

1. Appropriate Indication: Screening/Surveillance
2. Recorded American Society of Anesthesiology status (ASA)
3. Complete colonoscopy (cecal intubation w/ photo)
4. Assessment of the quality of the bowel prep
5. Reported required polyp information
6. Void of serious complications (unplanned events)
7. Withdrawal time recorded
8. Anticipated follow-up recommendation will be consistent with screening/surveillance guidelines (algorithm #1 or #2)

Colonoscopy Composite Score Data Collection Process

Ara Peterson RN, BSN

Manager Process
Improvement

Department of Surgery

OSF Saint Francis Medical
Center

Electronic Database

- Identify an electronic database suitable for storing data and producing reports regarding colonoscopy composite score variables. For example: EXCEL.

VARIABLES

PATIENT NAME	PHOTO TAKEN
PATIENT MRN	ASA SCORE
PHYSICIAN	WITHDRAWL TIME
PHYSICIAN IDENTIFIER	ICD-9 DIAGNOSIS CODE
BOWEL PREP USED	IDC-9 PROCEDURE CODE
BOWEL PREP ASSESSMENT	CPT CODE
EXTENT REACHED	DATE OF PROCEDURE

POLYP VARIABLES

NUMBER	REMOVED
SIZE	REMOVAL METHOD
LOCATION	FOLLOW UP
MORPHOLOGY	
HISTOLOGY	

PATIENT LIST

- Obtain a list of patients having completed a screening or surveillance colonoscopy.
- The list of patients should be by the month.

PATIENT LIST

- Use ICD-9 diagnosis codes V codes: to identify screening and surveillance patients.

- SCREEN CODES:** V76.51

- SURVEILLANCE CODES:**

V 12.72, 67.09, 67.59

MEDICAL RECORD REVIEW

- Review the medical record for each composite score variable.
- Documents to review include: abstract coding information, discharge location (GI lab), dictated post-operative note, H&P, pathology report and procedure record.
- Use operational definitions provided for each composite score variable.

Composite Score Measuring

- If the physician documented all composite score variables then he/she receives a score of COMPLETE for the measure.
- If one variable is not documented, then physician documentation does not meet the measure.
- If one polyp variable is not documented then physician documentation does not meet the measure.

DATA ENTRY

	MEETS	MEETS	MEETS	MEETS	MEETS	MEETS		
Appropriate Indication	YES (1)	NO (0)	Void of complications	YES (1)	NO (0)	Follow-up	YES (1)	NO (0)
Complete exam (cecum)	YES (1)	NO (0)	Bowel prep	YES (1)	NO (0)	w/draw time	YES (1)	NO (0)
Photo taken	YES (1)	NO (0)	Polyp info (all)	YES (1)	NO (0)	ASA score	YES (1)	NO (0)

All YES (1) = meets the Complete Composite Measure

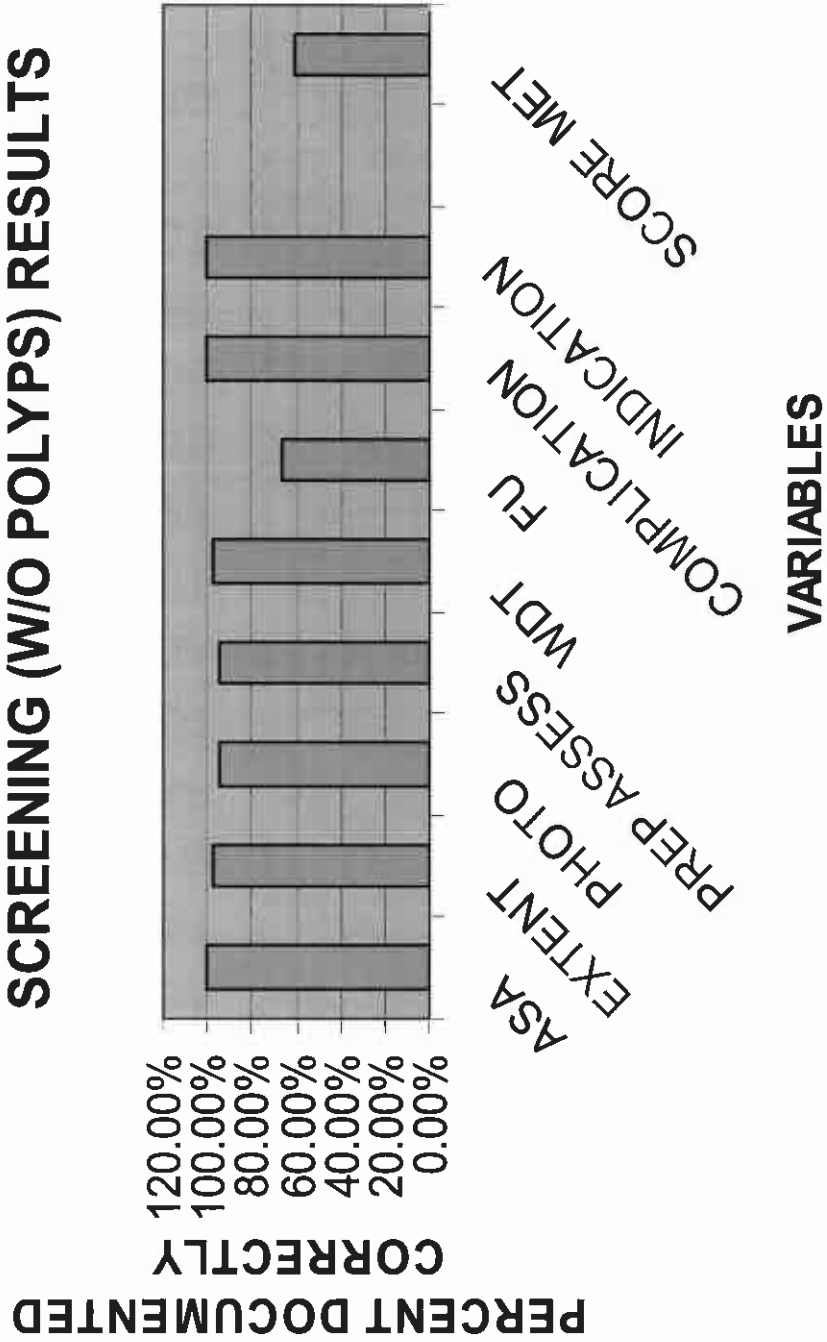
Any NO (0) = does not meet the Complete Composite Measure

SITE SPECIFIC REPORTING

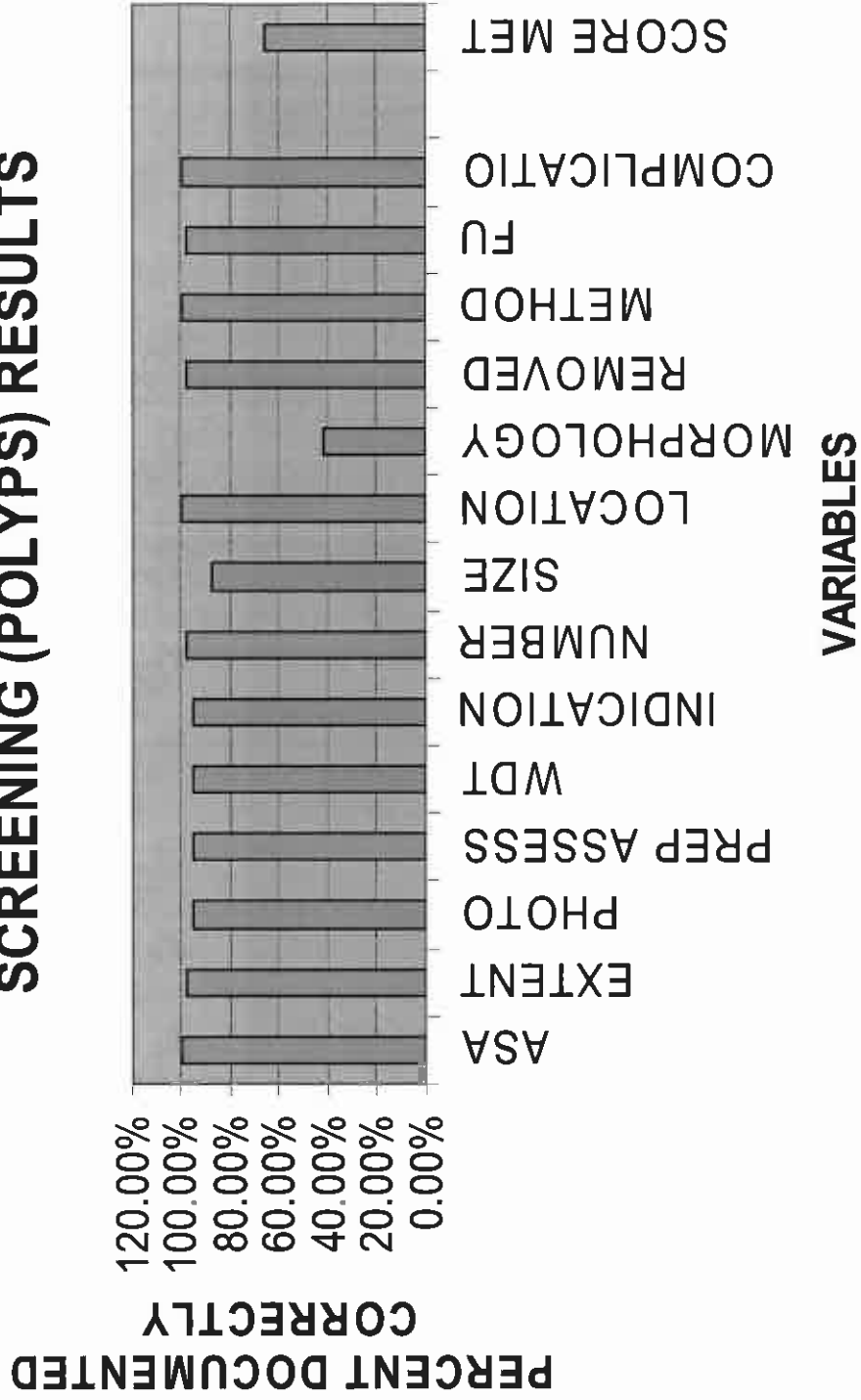
- **DEVELOP A METHOD TO ANALYZE AND REPORT SITE AND PHYSICIAN COMPOSITE SCORE RESULTS**

REPORT EXAMPLES

SCREENING (W/O POLYPS) RESULTS

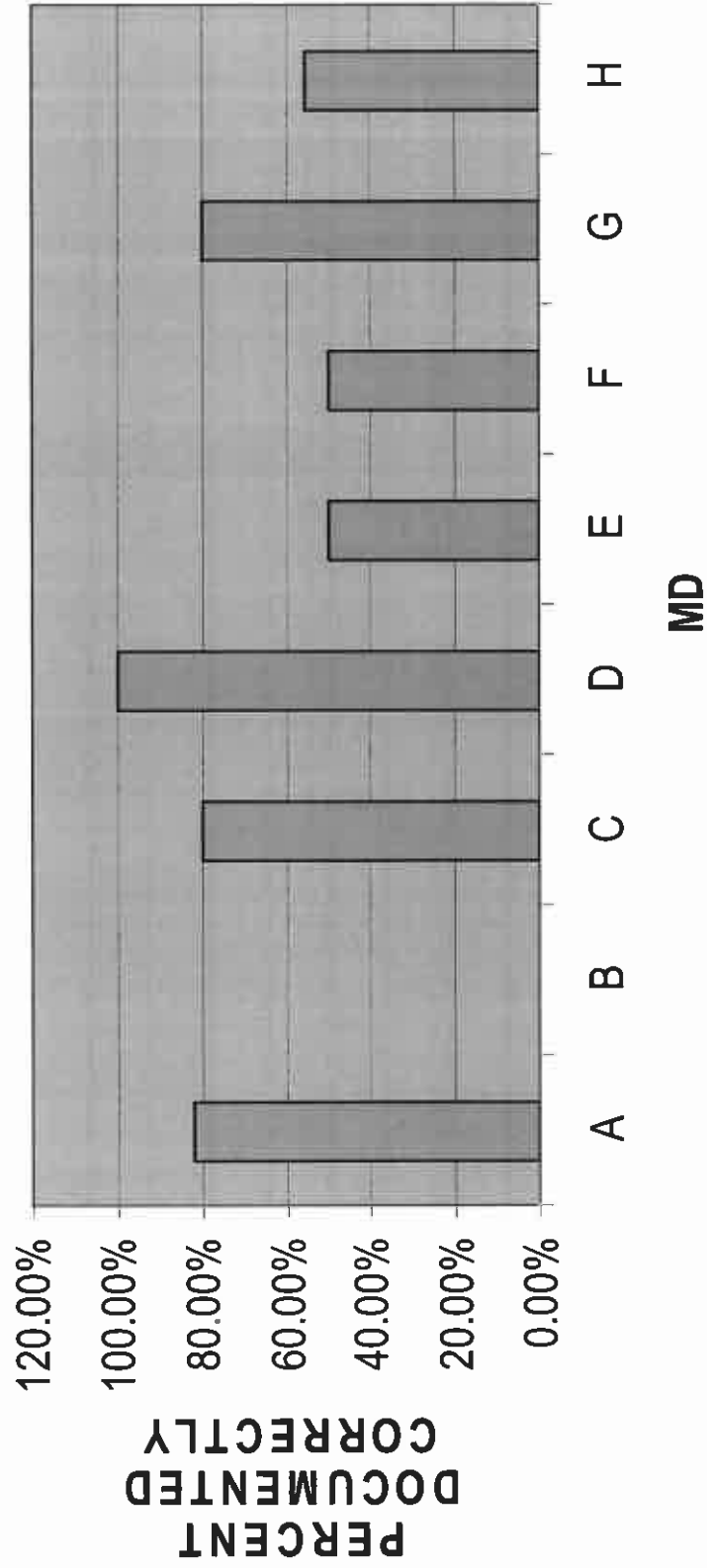


SCREENING (POLYPS) RESULTS



Quality Quest for Health

MD SCORE RESULTS



EXAMPLE INDIVIDUAL MD

ASA		100%
EXTENT		100%
PHOTO		90%
PREP ASSESS		90%
WDT		90%
INDICATION		90%
NUMBER		100%
SIZE		100%
LOCATION		100%
MORPHOLOGY		27%
REMOVED		100%
METHOD		100%
FU		100%
VOID COMPLICATIONS		100%
SCORE MET		73%

Methodist

- Methodist has agreed to undertake the scoring and data collection requirements of the composite measure
- Methodist is currently running a pilot
- Once pilot is completed Methodist can start to collect live data

Decatur

- Decatur has agreed to undertake the scoring and data collection Requirements of the composite measure
- Decatur is currently determining how they can best collect all 8 elements of the composite

Quality Quest for Health

MGPP

	Generation 1	Generation 2*	Generation 3**
Timing	11 months –effective 8/1/07	Approximately 3 months	Approximately 3 months
Vision	To create a colonoscopy composite measure to help drive more consistent high quality colonoscopies in Central Illinois. To standardize processes that will allow for greater consistency in the use of bowel prep and Antibiotic prophylaxis	Replication of the composite measure and self reporting structure to: Methodist hospital Pekin Hospital Proctor Hospital Decatur Memorial Hospital Any independent offices conducting colonoscopies	Development and standardization of anti coagulation process. Develop patient education and web site material for colonoscopy
Generation (Features & Functions)	Create a process for the completion of the composite measure on site and a structure for self collecting and reporting of the data collected from the composite measure.	Addition of the collection of the adenoma detection rate and include this in the self reported data.	Role out the standardized process to all doctors and their offices.
Platforms/ Technologies	OSF will develop a self reporting/collection process through their PICIS system along with an excel spreadsheet for reporting to Quality Quest.	Each individual hospital or office will need to develop their own ability to collect and self report data. The OSF structure should be used as the basis for this development.	

Bowel Prep

The colonoscopy composite measure team took the initiative to address bowel prep. The team agreed on a standardized bowel prep to help drive quality through a consistent application of the most effective preps.

*Consensus Document on Bowel
Preparation for Colonoscopy*
ASGE, ASCRS, SAGES
Gastrointestinal Endoscopy Vol. 63
No. 7: 2006; 894-909

Q

Guidelines for Antibiotic Prophylaxis for Colonoscopy References

- ASGE Guidelines for Antibiotic Prophylaxis for GI Endoscopy
Gastrointestinal Endoscopy Vol. 58, No. 4, 2003; 475-482
- Prevention of Infection Endocarditis from the AHA Circulation
2007; 116: 1736-1754
- Major Changes in Endocarditis Prophylaxis for Dental, GI and GU
Procedures Medical Letter Vol. 49, Dec. 3, 2007; 99-100

Antibiotic Prophylaxis for Colonoscopy

- Endocarditis antibiotic prophylaxis is no longer recommended for colonoscopy
- Antibiotic prophylaxis for vascular grafts less than a year old is optional and made on a case by case basis
- Antibiotic prophylaxis for prosthetic joints and orthopedic prosthesis within six months of placement is optional and made on a case by case basis

Pathology

U.S. Consensus Guidelines for Colonoscopic Surveillance after Polypectomy

Colonoscopic Findings

Recommended Interval Between Colonoscopies

Small, rectal, hyperplastic polyps

10 years or other average-risk screening option

1 or 2 low-risk adenomas

5 –10 years

3 – 10 Low-risk adenomas or any
High-risk adenomas

3 years

> 10 adenomas

< 3 years

Inadequately removed adenomas

2 – 6 months

NEJM 2006; 355:2553

Lessons Learned

- We must allow facilities to determine the best way they have for collection of the 8 measures as it will differ for each facility
- When a facility is actively involved they improve the product/process. OSF exceeded all expectations
- We must be patient as we are asking for a commitment of time and resources
- Running a pilot of the composite is vital for the facility to understand if their collection method will work

Quality Quest for Health



Transforming Healthcare – Together.

Thank you for your thoughtful review & for reading through to the end!

Quality Quest for Health of IL

Colonoscopy Data File Format

Field No	Field Name	Format	Values	RULE
1	Patient ID			
2	Patient's Age	999	90 and above will be given the value of "90"	As of 12/31 exam year
3	Procedure Date	yyyy-mm-dd		
4	Patient's Sex	X	M, F	
5	Endoscopist First Name	XXXXXXXXXXXXXX		
6	Endoscopist Last Name	XXXXXXXXXXXXXX		
7	Endoscopist NPI #	9999999999		
8	PHx CRC	X	Y/N	
9	PHx Adenoma(s) # <u>last exam</u>	99	0 = no adenoma; 1 = one or two adenomas; 2 = three to ten adenomas; 3 = eleven or more adenomas	
10	Size (mm) of largest Previous Adenoma anytime in the Past	99	Prefer exact numbers such as: 1, 2, 3, 4, etc. However if given verbiage, convert: - 'small' or 'diminutive' to '4' - 'medium' to '9' - 'large' to '11' If given a range, select the lowest number in the range.	If colonoscopist documents history of previous adenoma but does not know size, enter 'UK' (size unknown). If left blank, a zero will be used.
11	PHx Villous Adenoma	X	Y/N Note: Ok to leave blank; Will be treated as a 'N'	
12	PHx Severe Dysplasia	X	Y/N Note: Ok to leave blank; Will be treated as a 'N'	
13	PHx Incomplete Polyp Removal	X	Y/N Note: Ok to leave blank; Will be treated as a 'N'	
14	PHx Serrated Adenoma	X	Y/N Note: Ok to leave blank; Will be treated as a 'N'	
15	FHx CRC	XXXX	FDR,SDR,None	Can include FDR and SDR if field 16 and 17 are greater than zero.
16	#FDR CRC	99	0,1,2,3, ...	
17	#SDR CRC	99	0,1,2,3, ...	
18	Age of Youngest FDR with CRC	999		
19	PHx or FHx FAP, HNPCC, HPS	X	Y/N Note: Ok to leave blank; Will be treated as a 'N'	
20	PHx IBD	X	Y/N Note: Ok to leave blank; Will be treated as a 'N'	

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Quality Quest for Health of IL

Colonoscopy Data File Format

Field No	Field Name	Format	Values	RULE
21	FDR ADENOMA	X	Y/N Note: Ok to leave blank; Will be treated as a 'N'	
22	Age of youngest FDR with Adenoma(s)	999		
23	Previous Colonoscopy	9	0 = No 1 = Yes, Year/Polyp info known 2 = Yes, Year unknown 3 = Yes, Polyp Info unknown 4 = Yes, Year/Polyp info Unknown 5 = Yes, Last colonoscopy unsatisfactory (poor bowel prep or incomplete)	if left blank return to sender for additional information
24	Previous Colonoscopy Year	9999	9999	If Field # 23 = 0 or 2 or 4 then leave blank
25	Bowel Prep Type	99	0 = Not recorded, 1 = Fleets' Phospa Soda or Fleets Enema , 2 = CoLyte, 3 = GoLyte, 4 = HalfLyte, 5= TriLyte, 6 = NuLyte, 7 = Visicol Tabs, 8 = MoviPrep or Miralax , 9 = Mag Citrate, 10 = Mag Citrate with dulcolax, 11 = Osmoprep, 12 = Trizol gallon, 13 = Castor Oil, 14 = SuPrep, 15 = pro prep, 99 = 'New Type' and place in notes section of upload what the 99 name represents for future uploads	
26	ASA Class	9	0 = Not recorded, 1 = Healthy, no comorbidity, 2 = Medical condition controlled, 3 = Disease severely limits normal activity, 4 = Life threatening disorder, 5 = Moribund	
27	Bowel Prep Assess	9	0 = Not recorded, 1 = Excellent, 2 = Good, 3 = Fair, 4 = Poor, 5 = Unsatisfactory	
28	Complete Exam	9	1 = Yes, 0 = No	
29	Cecal Photo	9	1 = Yes or NA, 0 = No	
30	Any Polyp(s) Removed	9	1 = Yes, 0 = No	
31	All Polyp Info recorded	9	1 = Yes, 0 = No	"Yes" includes: • Number • Size • Location • Morphology • Method of removal • Completeness of removal
32	Withdrawal time	99	In minutes	

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Quality Quest for Health of IL

Colonoscopy Data File Format

Field No	Field Name	Format	Values	RULE
33	Free of Acute Complications	9	1 = Yes, 0 = No	Complic. Includes: Blood transfusion Perforation CPA Hospital transfer Death
34	Rec. F/U Colonoscopy or Other	9	0 = Not recorded, 1 = 2 - 6 mos, 2 = 1 yr, 3 = 3 yr, 4 = 5 yr, 5 = 10 yr, 6 = Pending, 7 = No F/U indicated, 8 = Other, 9 = Referral to another surgeon or colonoscopist for polyp removal, 10 = Follow-up to visualize complete colon (i.e. CT Colonography, Colon x-ray or Barium Enema, or repeat colonoscopy) within the next 6 months, 11 = 5 yr > and < 10 yr	If given a range, choose the lower number of the range.
35	# Polyp(s) removed	99	0, 1, 2,	
36	Largest polyp (mm) removed this exam; size estimated by colonoscopist	99		
37	Any adenomatous polyp(s) this exam	9	1 = Yes, 0 = No	
38	Total # of confirmed adenomas this exam	99	0, 1, 2	
39	Additional findings/ characteristics noted by the pathologist (formaly a.k.a. Histopathology)	XXX	V,SD,CRC, NA Note: 'NA' means adenoma is not villous, severely dysplastic nor cancer	V = Villous or Tubulovillous Adenoma, SD = Severe or High-grade dysplasia, CRC = Colorectal Cancer, NA = Not applicable
40	Any serrated adenomas this exam	9	1 = Yes, 0 = No	

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Quality Quest *for* Health

**Colonoscopy Composite Measure
Specifications**

Colonoscopy Quality Index

Last updated 1-10-2013

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Description 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 intra-procedural 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

Methodology Self-reported

Reporting Level High quality colonoscopy and individual elements by individual endoscopist (> 30 for public reporting, aggregated at a rolling 12-months)

Ages included Ages \geq 18 at time of colonoscopy

Population All screening and surveillance endoscopies performed at participating colonoscopy locations

Frequency Quarterly

Numerator All patients undergoing screening or surveillance colonoscopy who meet all relevant individual quality elements (2-10 below).

Elements that do not apply are excluded from numerator calculation.

Denominator All adults undergoing screening or surveillance colonoscopy

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.

Rates Aggregate rates by endoscopist,(> 30 for public reporting)

Measures

4. Colonoscopy Quality Index: The percentage of patients who met all individual quality elements (see below).

1. Appropriate indication for colonoscopy:

Appropriate indication for screening colonoscopy:

- 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**
- 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**
- 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

Appropriate indication for surveillance colonoscopy:

- 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**
- 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**
- Patient with 1-2 small tubular adenoma(s) on most recent colonoscopy, has not had colonoscopy in the past 5 years; or
- Patient with three to ten adenomas <1 cm on most recent colonoscopy, has not had colonoscopy in the past 3 years; or
- 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
- Patient with greater than ten adenomas or with > 1 serrated polyp on most recent colonoscopy, has not had colonoscopy in past 12 months; or
- Patient with sessile polyp > 1 cm with incomplete excision on most recent colonoscopy, has not had colonoscopy in past 2 months: or
- 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 (excellent, good or fair) or inadequate (poor or unsatisfactory) recorded
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 was 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 intra-procedural 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 measure two above.



Quality Quest *for* Health

**Data Field Requirements
Screening/Surveillance
Colonoscopy**

Last updated 3.1.2013

Data Submission Rules

Introduction:

This document will serve as a data collection guideline for organizations sending Quality Quest data. Send data only on screening and surveillance colonoscopies

Following are data column names, definitions and format for reporting to Quest.

Columns for data transfer to Quest:

Each organization will use same column/field names as defined below:

1. **Patient ID:** de-identified patient number assigned by endoscopic site
2. **Patient's Age:** age in years as of 12-31 of the exam year
3. **Procedure Date:** (mm/dd/yyyy)
4. **Patient's Sex:** (M/F)
5. **Endoscopist's First Name:**
6. **Endoscopist's Last Name:**
7. **Endoscopist's NPI Number:** National Provider's Identification Number
8. **PHx CRC:** Yes /No
9. **PHx Adenoma:** Number of adenomas removed during last colonoscopy utilizing the following ranges (0 = none; 1 = 1 or 2 adenomas; 2 = 3 thru 10 adenomas; 3 = 11 adenomas and greater)
10. **Size (mm) of largest previous adenoma any time in the past (as estimated by the colonoscopist)**
11. **PHx Villous Adenoma on last colonoscopy:** Yes / No
12. **PHx Severe Dysplasia on last colonoscopy:** Yes / No
13. **PHx Incomplete Polyp Removal on last colonoscopy:** Yes / No
14. **PHx Serrated Adenoma:** Yes / No
15. **FHx CRC:** FDR, SDR, None (family history of CRC)¹
16. **# FDR(s) with CRC:**
17. **# SDR(s) with CRC:**
18. **Age of Youngest FDR with CRC:** age of youngest FDR at time diagnosed with CRC
19. **PHx or FHx of FAP, HNPCC, HPS:** Yes / No
20. **PHx IBD:** Yes (ulcerative colitis or Crohn's disease) / No

¹ If FHx (family history) has both FDR and SDR, enter this into the submitted data as "FDR, SDR", capturing them both.

21. FDR Adenoma: Yes / No

22. Age of Youngest FDR with Adenoma: age of youngest FDR at time diagnosed with adenoma

23. Previous Colonoscopy: *if blank unable to determine appropriateness of exam*

- 0 = No
- 1 = Yes, year and pathology verified by patient or colonoscopy report
- 2 = Yes, year of last exam unknown
- 3 = Yes, polyp pathology unknown
- 4 = Yes, year and polyp pathology unknown
- 5 = Yes, last colonoscopy unsatisfactory (inadequate bowel prep or completeness)

24. Year of last colonoscopy: YYYY; **leave blank** if not applicable or year of last colonoscopy is unknown
(Field # 23 = 0, 2 or 4)

25. Bowel Prep Type:

- 0 = not recorded
- 1 = Fleets' Phospa Soda
- 2 = CoLyte
- 3 = GoLytely
- 4 = HalfLytely
- 5 = TriLytely
- 6 = NuLytely
- 7 = Visicol Tabs
- 8 = Moviprep or Miralax
- 9 = Mag Citrate
- 10 = Mag Citrate with dulcolax
- 11 = Osmoprep
- 12 = Trizol gallon
- 13 = Castor Oil
- 14 = SuPrep
- 15 = pro prep
- 99 = new one not on list. Please notify quality quest of new one so we can update our list

26. ASA Class:

- 0 = Not recorded
- 1 = Healthy, no comorbidities
- 2 = Mild-to- moderate medical condition(s)- controlled
- 3 = Disease severely limits activities

- 4 = Severe life-threatening disorder(s)
- 5 = Moribund

27. Bowel Prep Assessment: Adequate preparation = 1, 2, or 3; Inadequate preparation = 4 or 5

- 0 = Not recorded
- 1 = Excellent
- 2 = Good
- 3 = Fair
- 4 = Poor
- 5 = Unsatisfactory

28. Complete Exam: 1 = Yes; 0 = No

29. Cecal Photo taken: 1 = Yes or Not applicable (lack of cecum); 0 = no

30. Any Polyps Removed this Colonoscopy: 1 = Yes; 0 = No

31. All Polyp Information Recorded: 1 = Yes (info includes: number, location, morphology if size \geq 5 mm, method of removal, completeness of removal and size in mm); OK to allow small/diminutive, medium or large to classify polyp size; small/diminutive = 4mm; medium = 9mm; and large = 11 mm for entry onto Field #36; or enter:

1 = Yes, if all info recorded or if no polyp was removed

0 = No, if polyp removed but missing any info listed above

32. Withdrawal Time Recorded: time (minutes) from beginning of cecal withdrawal till extubation

33. No Acute Complications: 1= Yes (free of major complications); 0 = No (major complication occurred).
See Definition and Abbreviation document for information on what is considered a major complication.

34. Follow-Up Colonoscopy Recommendation:

- 0 = not recorded
- 1 = two to six months
- 2 = one year
- 3 = three years
- 4 = five years
- 5 = 10 years
- 6 = pending pathology report
- 7 = Follow-up colonoscopy not necessary
- 8 = other timeframe than listed above
- 9 = Referral to another surgeon or colonoscopist for polyp removal
- 10 = Follow-up to visualize complete colon (i.e. CT Colonography, Colon x-ray or Barium Enema, or repeat colonoscopy) within the next 6 months
- 11 = 5 years < and < 10 years

35. Number of Polyps removed: 0 to 99

36. Colonoscopist's estimated size (mm) of largest polyp removed during this exam: size in mm or leave blank if no polyp removed. Field requires only numeric values. Convert words (i.e. small/diminutive = 4mm; medium = 9mm; large = 11mm).

37. Any adenomatous polyp(s) this exam: 1 = Yes (determined by pathology report); 0 = no adenomas

38. Total number of confirmed adenomas this exam:

39. Other specific polyp histopathology:

- V = villous or tubulovillous adenoma
- SD = severely or high-grade dysplastic polyp
- CRC = colorectal cancer

40. Any serrated adenoma(s) this exam: 1 = Yes; 0 = No

Quality Quest, based on data from Fields 1 – 40, will assign the following fields:

41. Screening or Surveillance: 1 = Screening; 2 Surveillance

42. Appropriate Indication for colonoscopy: 1 = Yes; 0 = No

43. ASA (medical risk) Recorded: 1 = Yes; 0 = No

44. Bowel Prep Assessed: 1 = Yes; 0 = No

45. Complete Exam: 1 = Yes; 0 = No

46. Cecal Photo taken: 1 = Yes or NA; 0 = No

47. All Required Polyp Information recorded: 1 = Yes; 0 = No

48. Withdrawal Time recorded: 1 = Yes (or if any removed polyp =1 or if complete exam = 0); 0 = No

49. Free of Acute Complications: 1 = Yes; 0 = No

50. Appropriate Follow-up Colonoscopy recommendation: 1 = Yes; 0 = No

51. All-or None Colonoscopy Quality Index: 1 = Yes (42 thru 50 all equal 1); 0 = No

52. Rate of appropriate indications

53. Rate of ASA recorded

54. Rate of bowel preps assessed

55. Rate of complete exams

56. Rate of cecal photo taken

57. Rate of all polyp information recorded

58. Rate of withdrawal times recorded

59. Rate of colonoscopies void of complications

60. Rate of appropriate follow-up recorded



Quality Quest *for* Health

**Definitions and Abbreviations
Screening/Surveillance
Colonoscopy**

Last updated 3.1.2013

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 ≥ 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 visible¹ (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

¹ Gastrointestinal Endoscopy vol 63, supp 4-06

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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

CRC Risk	Age to Initiate 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 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 ²		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

² 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

- 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 Assessment³

		Adequate Y/N
Excellent	No or minimal solid stool and only small amounts of clear fluid requiring suction.	Y
Good	No or minimal solid stool with large amounts of clear fluid requiring suctioning.	Y
Fair	Collection of semisolid debris that are cleared with difficulty.	Y
Poor	Collection of semisolid debris that cannot be effectively cleared.	N
Unsatisfactory		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 ≥ 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.

³ 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.

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Quality Quest *for* Health

**Technical Measure Calculation
Physician Version
Screening/Surveillance
Colonoscopy**

Last updated 3.1.2013

Individual quality elements for determining colonoscopy quality index:

Exclusions from population:

- Field # 19 = Yes **OR**
- Field # 20 = Yes **OR**
- Endoscopy sites are **not** to transmit data on diagnostic colonoscopies (i.e. all non-screening or surveillance colonoscopies)

Field # 41: To determine **Screening** (1) or **Surveillance** (2)

Assign 1 for Screening, if:

- Field # 8 = (No or blank) **and** Field # 9 = (0 or blank) **and** Field # 10 = (0 or blank) **and** Field # 11 = (No or blank) **and** Field # 12 = (No or blank) **and** Field # 13 = (No or blank) **and** Field # 14 = (No or blank)

Assign 2 for Surveillance, if scenario above is not met.

Field # 42: Appropriate Indication for:

Screening colonoscopy (Appropriateness is dependent upon patient's age, personal or Family History.):

Assign 1, if at least one the following scenarios exist:

1. Field # 2 ≥ 50 **and** (Field # 23 = 0, 2, 4, or 5) **OR**
 - a. Patient is 50 years or older AND
 - i. has not previously had a colonoscopy OR
 - ii. last colonoscopy year unknown OR
 - iii. last colonoscopy year and polyp information unknown OR
 - iv. last colonoscopy was unsatisfactory
2. Field # 2 ≥ 50 **and** (Field # 23 = 1 or 3) **and** (Field # 3 minus Field # 24 ≥ 10) **OR**
 - a. Patient is 50 years or older AND
 - b. last colonoscopy was 10 or more years ago
3. Field # 2 ≥ 40 **and** Field # 17 ≥ 2 **and** (Field # 23 = 0, 2, 4, or 5) **OR**
 - a. Patient is 40 years or older AND
 - b. has two or more SDRs diagnosed with CRC AND
 - i. has not previously had a colonoscopy OR
 - ii. last colonoscopy year unknown OR
 - iii. last colonoscopy year and polyp information unknown OR
 - iv. last colonoscopy was unsatisfactory
4. Field # 2 ≥ 40 **and** Field # 17 ≥ 2 **and** (Field # 23 = 1 or 3) **and** (Field # 3 minus Field # 24 ≥ 10) **OR**
 - a. Patient is 40 years or older AND
 - b. has two or more SDRs diagnosed with CRC AND
 - c. last colonoscopy was 10 or more years ago

5. Field # 2 ≥ 40 **and** Field # 16 ≥ 2 **and** (Field # 23 = 0, 2, 4, or 5) **OR**
 - a. Patient is 40 years or older AND
 - b. has two or more FDRs diagnosed with CRC AND
 - i. has not previously had a colonoscopy OR
 - ii. last colonoscopy year unknown OR
 - iii. last colonoscopy year and polyp information unknown OR
 - iv. last colonoscopy was unsatisfactory
6. Field # 2 ≥ 40 **and** Field # 16 ≥ 2 **and** (Field # 23 = 1 or 3) **and** (Field # 3 minus Field # 24 ≥ 5) **OR**
 - a. Patient is 40 years or older AND
 - b. has two or more FDRs diagnosed with CRC AND
 - c. last colonoscopy was 5 or more years ago
7. Field # 2 ≥ 40 **and** Field # 15 = FDR **and** (Field # 18 > 0 **and** Field # 18 < 60) **and** (Field # 23 = 0, 2, 4, or 5) **OR**
 - a. Patient is 40 years or older AND
 - b. has at least one FDR under the age of 60 diagnosed with CRC AND
 - i. has not previously had a colonoscopy OR
 - ii. last colonoscopy year unknown OR
 - iii. last colonoscopy year and polyp information unknown OR
 - iv. last colonoscopy was unsatisfactory
8. Field # 2 ≥ 40 **and** Field # 15 = FDR **and** (Field # 18 > 0 **and** Field # 18 < 60) **and** (Field # 23 = 1 or 3) **and** (Field # 3 minus Field # 24 ≥ 5) **OR**
 - a. Patient is 40 years or older AND
 - b. has at least one FDR under the age of 60 diagnosed with CRC AND
 - c. last colonoscopy was 5 or more years ago
9. Field # 2 ≥ 40 **and** Field # 21 = Yes **and** (Field # 22 > 0 **and** Field # 22 < 60) **and** (Field # 23 = 0, 2, 4, or 5) **OR**
 - a. Patient is 40 years or older AND
 - b. has at least one FDR under the age of 60 diagnosed with an adenomatous polyp AND
 - i. has not previously had a colonoscopy OR
 - ii. last colonoscopy year unknown OR
 - iii. last colonoscopy year and polyp information unknown OR
 - iv. last colonoscopy was unsatisfactory
10. Field # 2 ≥ 40 **and** Field # 21 = Yes **and** (Field # 22 > 0 **and** Field # 22 < 60) **and** (Field # 23 = 1 or 3) **and** (Field # 3 minus Field # 24 ≥ 5) **OR**
 - a. Patient is 40 years or older AND
 - b. has at least one FDR under the age of 60 diagnosed with an adenomatous polyp AND
 - c. last colonoscopy was 5 or more years ago
11. Field # 2 ≥ 40 **and** Field # 16 = 1 **and** Field # 18 ≥ 60 **and** (Field # 23 = 0, 2, 4, or 5) **OR**
 - a. Patient is 40 years or older AND
 - b. has at least one FDR diagnosed with CRC at age 60 or older AND
 - i. has not previously had a colonoscopy OR
 - ii. last colonoscopy year unknown OR
 - iii. last colonoscopy year and polyp information unknown OR
 - iv. last colonoscopy was unsatisfactory
12. Field # 2 ≥ 40 **and** Field # 16 = 1 **and** Field # 18 ≥ 60 **or** **and** (Field # 23 = 1 or 3) **and** (Field # 3 minus Field # 24 ≥ 10) **OR**
 - a. Patient is 40 years or older AND
 - b. has at least one FDR diagnosed with CRC at age 60 or older AND

- c. last colonoscopy was 10 or more years ago
13. Field # 2 ≥ 40 **and** Field # 21 = Yes **and** Field # 22 ≥ 60 **and** (Field # 23 = 0, 2, 4, or 5) **OR**
- a. Patient is 40 years or older AND
 - b. has a FDR diagnosed with an adenomatous polyp at age 60 or older AND
 - i. has not previously had a colonoscopy OR
 - ii. last colonoscopy year unknown OR
 - iii. last colonoscopy year and polyp information unknown OR
 - iv. last colonoscopy was unsatisfactory
14. Field # 2 ≥ 40 **and** Field # 21 = Yes **and** Field # 22 ≥ 60 **and** (Field # 23 = 1 or 3) **and** (Field # 3 minus Field # 24 ≥ 10) **OR**
- a. Patient is 40 years or older AND
 - b. has a FDR diagnosed with an adenomatous polyp at age 60 or older AND
 - c. last colonoscopy was 10 or more years ago
15. Field # 2 < 40 **and** Field # 16 ≥ 1 **and** ((Field # 18 > 0) **and** (Field # 18 minus 10 \leq Field # 2)) **and** (Field # 23 = 0, 2, 4, or 5) **OR**
- a. Patient is less than 40 years old AND
 - b. has a FDR diagnosed with CRC at an age 10 years or less than the patient's current age AND
 - i. has not previously had a colonoscopy OR
 - ii. last colonoscopy year unknown OR
 - iii. last colonoscopy year and polyp information unknown OR
 - iv. last colonoscopy was unsatisfactory
16. Field # 2 < 40 **and** Field # 16 ≥ 1 **and** ((Field # 18 > 0) **and** (Field # 18 minus 10 \leq Field # 2)) **and** (Field # 23 = 1 or 3) **and** (Field # 3 minus Field # 24 ≥ 5) **OR**
- a. Patient is less than 40 years old AND
 - b. has at least one FDR under the age of 60 diagnosed with CRC at an age 10 years or less than the patient's current age AND
 - c. last colonoscopy was 5 or more years ago
17. Field # 2 < 40 **and** Field # 21 = Yes **and** ((Field # 22 > 0) **and** Field # 22 minus 10 \leq Field # 2) **and** (Field # 23 = 0, 2, 4, or 5) **OR**
- a. Patient is less than 40 years old AND
 - b. has a FDR diagnosed with an adenomatous polyp at an age 10 years or less than the patient's current age AND
 - i. has not previously had a colonoscopy OR
 - ii. last colonoscopy year unknown OR
 - iii. last colonoscopy year and polyp information unknown OR
 - iv. last colonoscopy was unsatisfactory
18. Field # 2 < 40 **and** Field # 21 = Yes **and** ((Field # 22 > 0) **and** Field # 22 minus 10 \leq Field # 2) **and** (Field # 23 = 1 or 3) **and** (Field # 3 minus Field # 24 ≥ 5)
- a. Patient is less than 40 years old AND
 - b. has a FDR diagnosed with an adenomatous polyp at an age 10 years or less than the patient's current age AND
 - c. last colonoscopy was 5 or more years ago

Assign 0 to Field # 42 if **none** of the above statements (1 thru 18) are true **or** if Field # 23 is blank.

- OR -

Surveillance colonoscopy (Appropriateness depends on patient's Personal History of CRC, one or more precancerous polyps, number of previous adenomas, completeness of previous polyp removal and date of last colonoscopy.):

Assign 1, if at least one the following scenarios exist:

1. **Field # 8 = Yes; OR**
 - a. Patient has history of CRC
2. **Field # 9 = 1 and Field # 10 < 10 and Field # 23 = 1 and (Field # 3 minus Field # 24 ≥ 5); OR**
 - a. Patient has a history of one or two small (<10 mm) adenomatous polyp(s) AND
 - b. last colonoscopy was 5 or more years ago
3. **Field # 9 = 1 and Field # 10 < 10 and (Field # 23 = 2, 4, or 5); OR**
 - a. Patient has a history of one or two small (<10 mm) adenomatous polyp(s) AND
 - i. could not determine year of last colonoscopy OR
 - ii. polyp information was unsatisfactory OR
 - iii. last colonoscopy was unsatisfactory
4. **Field # 9 = 2 and Field # 23 = 1 and (Field # 3 minus Field # 24 ≥ 3) OR**
 - a. Patient has a history of 3 to ten adenomatous polyps AND
 - b. last colonoscopy was 3 or more years ago
5. **Field # 9 = 2 and (Field # 23 = 2, 4, or 5); OR**
 - a. Patient has a history of 3 to ten adenomatous polyps AND
 - i. could not determine year of last colonoscopy OR
 - ii. polyp information was unsatisfactory OR
 - iii. last colonoscopy was unsatisfactory
6. **Field # 9 ≥ 1 and (Field # 10 ≥ 10 or Field # 11 = Yes or Field # 12 = Yes) and Field # 23 = 1 and (Field # 3 minus Field # 24 ≥ 3) OR**
 - a. Patient has a history of advanced neoplasia (adenoma ≥ 10 mm or villous or severely dysplastic (high grade)) AND
 - b. last colonoscopy was 3 or more years ago
7. **Field # 9 ≥ 1 and (Field # 10 ≥ 10 or Field # 11 = Yes or Field # 12 = Yes) and (Field # 23 = 2, 4, or 5); OR**
 - a. Patient has a history of advanced neoplasia (adenoma ≥ 10 mm or villous or severely dysplastic (high grade)) AND
 - i. could not determine year of last colonoscopy OR
 - ii. polyp information was unsatisfactory OR
 - iii. last colonoscopy was unsatisfactory
8. **(Field # 9 = 3 or Field # 14 = Yes) and Field # 23 = 1 and (Field # 3 minus Field # 24 ≥ 1); OR**
 - a. Patient has a history of 11 or more adenomas or a serrated adenoma AND
 - b. last colonoscopy was 1 or more years ago
9. **(Field # 9 = 3 or Field # 14 = Yes) and (Field # 23 = 2, 4, or 5); OR**
 - a. Patient has a history of 11 or more adenomas or a serrated adenoma AND
 - i. could not determine year of last colonoscopy OR
 - ii. polyp information was unsatisfactory OR
 - iii. last colonoscopy was unsatisfactory
10. **(Field # 9 ≥ 1 or Field # 11 = Yes or Field # 12 = Yes) and Field # 13 = Yes; OR**
 - a. Patient has a history of adenoma or villous adenoma or severely dysplastic polyp AND

- b. had incomplete removal
- 11. Field # 23 = 3; **OR**
 - a. Could not determine last polyp information
- 12. Field # 9 = 0 **and** (Field # 10 > 0 or Field # 10 = "UK") **and** Field # 23 = 1 **and** (Field # 3 minus Field # 24 ≥ 5); **OR**
 - a. Patient did not have an adenoma on last colonoscopy AND
 - b. patient had a prior history of an adenoma AND
 - c. last colonoscopy was 5 or more years ago
- 13. Field # 9 = 0 **and** (Field # 10 > 0 or Field # 10 = "UK") **and** (Field # 23 = 2, 4, or 5)
 - a. Patient did not have an adenoma on last colonoscopy AND
 - b. patient had a prior history of an adenoma AND
 - i. could not determine year of last colonoscopy OR
 - ii. polyp information was unsatisfactory OR
 - iii. last colonoscopy was unsatisfactory

Assign 0 to Field # 42 if **none** of the above statements (1 thru 13) are true **or** if Field # 23 is blank.

Field # 43: Medical Risk – ASA recorded

Assign 1 (Yes, if Field # 26 ≥ 1 and < 6)

Assign 0 (No, if Field # 26 = 0 or ≥ 6 or blank)

Field # 44: Bowel Prep Assessed

Assign 1 (Yes, if Field # 27 ≥ 1 and < 6)

Assign 0 (No, if Field # 27 = 0 or ≥ 6 or blank)

Field # 45: Complete Exam

Assign 1 (Yes, if Field # 28 = 1)

Assign 0 (No, if Field # 28 = 0 or > 1 or blank)

Field # 46: Cecal Photo taken

Assign 1 (Yes, if Field # 29 = 1 or Field # 29 = 'NA')

Assign 0 (No, if Field # 29 = 0 or > 1 or blank)

Field # 47: All polyp information recorded

Assign 1 (Yes, if Field # 31 = 1 or Field # 30 = 0)

Assign 0 (No, if Field # 31 = 0 or > 1)

Field # 48: Withdrawal Time Recorded

Assign 1 (Yes, if (Field # 32 > 0 min and Field # 32 < 99 min) or Field # 30 = 1 or Field # 28 = 0)

Assign 0 (No, if Field # 32 = 0 or 99)

Field # 49: Free of Acute Complications

Assign 1 (Yes, if Field # 33 = 1)

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Assign 0 (No, if Field # 33 = 0 or > 1 or blank)

Field # 50: Appropriate F/U Colonoscopy

Assign 1 (Yes) if:

1. Field # 34 = 5; **OR**
 - a. 10 years
2. Field # 34 = 4 **and** Field # 41 = 1 **and** Field # 15 = FDR **and** Field # 16 = 1 **and** Field # 18 > 0 **and** Field # 18 < 60; **OR**
 - a. 5 years AND
 - b. Screening Exam AND
 - c. has at least one FDR under the age of 60 diagnosed with CRC
3. Field # 34 = 4 **and** Field # 41 = 1 **and** Field # 15 = FDR **and** Field # 16 ≥ 2 **and** Field # 18 > 0; **OR**
 - a. 5 years AND
 - b. Screening Exam AND
 - c. has at least two FDR diagnosed with CRC
4. Field # 34 = 4 **and** Field # 41 = 1 **and** Field # 21 = Yes **and** Field # 22 > 0 **and** Field # 22 < 60; **OR**
 - a. 5 years AND
 - b. Screening Exam AND
 - c. has at least one FDR with an adenomatous polyp under the age of 60
5. (Field # 34 = 4 or Field # 34 = 11) **and** (Field # 38 = 1 or 2) **and** Field # 36 < 10; **OR**
 - a. 5 thru 9 years AND
 - b. Total number of confirmed Adenomas either 1 or 2 AND
 - c. The largest Polyp removed is less than 10mm
6. Field # 34 = 3 **and** Field # 37 = 1 **and** Field # 36 ≥ 10; **OR**
 - a. 3 years AND
 - b. Polyp is an Adenomas AND
 - c. The largest Polyp removed is 10mm or greater
7. Field # 34 = 3 **and** Field # 38 ≥ 3 or < 11; **OR**
 - a. 3 years AND
 - b. Total number of confirmed Adenomas is between 3 and 10
8. Field # 34 = 3 **and** (Field # 39 = V or SD); **OR**
 - a. 3 years AND
 - b. Polyp has characteristics of either a Villous/Tubulovillous or Severe/High-grade dysplasia
9. Field # 39 = CRC; **OR**
 - a. Polyp has characteristics of Colorectal Cancer
10. Field # 34 = 2 **and** Field # 38 ≥ 11; **OR**
 - a. 1 year AND
 - b. Total number of confirmed Adenomas is 11 or greater
11. Field # 34 = 2 **and** Field # 40 = 1 **OR**
 - a. 1 year AND
 - b. Serrated Adenoma
12. Field # 34 = 1 **and** Field # 27 ≥ 4; **OR**
 - a. 2 – 6 months AND
 - b. Bowel Prep Assessed is rated poor to unsatisfactory
13. Field # 34 = 1 **and** Field # 28 = 0; **OR**
 - a. 2 – 6 months AND
 - b. Was NOT a Complete Exam
14. Field # 34 = 1 **and** Field # 13 = Yes; **OR**

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- a. 2 – 6 months AND
- b. Prior History Polyp removal was incomplete
- 15. Field # 34 = 4 **and** Field # 41 = 2 **and** Field # 30 = 0; **OR**
 - a. 5 years AND
 - b. Surveillance Exam AND
 - c. No polyps were removed
- 16. Field # 34 = 6 **and** Field # 30 = 1; **OR**
 - a. Recommended follow-up is pending AND
 - b. At least one polyp was removed
- 17. Field # 34 = 1 **and** Field # 23 = 5; **OR**
 - a. 2 – 6 months AND
 - b. Last colonoscopy was unsatisfactory
- 18. Field # 34 = 7; **OR**
 - a. No follow-up indicated
- 19. Field # 34 = 4 **and** Field # 9 = 0 **and** (Field # 10 > 0 or Field #10 = 'UK') ; **OR**
 - a. 5 years AND
 - b. Total number of confirmed Adenomas, this exam, is zero AND
 - c. At least one adenomas documented in the past prior to this exam
- 20. Field # 8 = Yes; **OR**
 - a. Prior history Colon Rectal Cancer
- 21. Field # 34 = 9; **OR**
 - a. Referral to another surgeon or colonoscopist for polyp removal
- 22. Field #28 = 0 and Field #34 = 10
 - a. Colonoscopy Exam was NOT complete AND
 - b. Further visualization (e.g.CT Colonography, Colon x-ray etc.) is recommended

Assign 0 to Field # 50 if none of the above statements (1- 19) are true.

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Measurement 1: All-or-None Quality Colonoscopy (Composite Score)

- **Exclude** from this metric if Field # 27 ≥ 4 ;

Assign 1 to Field # 51 if:

Field # 42 = 1 **and** Field # 43 = 1 **and** Field # 44 = 1 **and** Field # 45 = 1 **and** Field # 46 = 1 **and** Field # 47 = 1 **and** Field # 48 = 1 **and** Field # 49 = 1 **and** Field # 50 = 1

Assign 0 to Field # 51 if any of the above fields = 0

Measurement 2: Quality rate for each specific quality element (Fields # 42 thru # 50)

- **Exclude** from this metric if Field # 27 ≥ 4 ;
- Field # 52 Appropriateness criteria met: Numerator = sum of the ones (yeses) in Field # 42; Denominator = sum of the ones (yeses) plus the number of zeroes (no) in Field # 42
- Field # 53 Rate of ASA recorded: Numerator = sum of the ones (yeses) in Field # 43; Denominator = sum of the ones (yeses) plus the sum of the zeroes (no) in Field # 43
- Field # 54 Rate of bowel prep assessed: Numerator = sum of the ones (yeses) in Field # 44; Denominator = sum of the ones (yeses) plus the sum of the zeroes (no) in Field # 44
- Field # 55 Rate of complete exams: Numerator = sum of the ones (yeses) in Field # 45; Denominator = sum of the ones (yeses) plus the sum of the zeroes (no) in Field # 45
- Field # 56 Rate of cecal photos: Numerator = sum of the ones (yeses) in Field # 46; Denominator = sum of the ones (yeses) plus the sum of the zeroes (no) in Field # 46
- Field # 57 Rate of all polyp information recorded: Numerator = sum of the ones (yeses) in Field # 47; Denominator = sum of the ones (yeses) plus the sum of the zeroes (no) in Field # 47
- Field # 58 Rate of withdrawal times recorded: Numerator = sum of the ones (yeses) in eligible Field # 48 cases; Denominator = sum of the ones (yeses) plus the sum of the zeroes (no) in eligible Field # 48 cases
- Field # 59 Rate of void of acute complications: Numerator = sum of the ones (yeses) in Field # 49; Denominator = sum of the ones (yeses) plus the sum of the zeroes (no) in Field # 49
- Field # 60 Rate of appropriate colonoscopy follow-up: Numerator = sum of the ones (yeses) in Field # 50; Denominator = sum of the ones (yeses) plus the sum of the zeroes (no) in Field # 50

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Future Quality Improvement Colonoscopy Measurements

(distributed only to colonoscopists with peer blinded comparisons)

*Measurement 3: Adenoma detection rate on initial screening colonoscopy in average risk adults (aged 50 to 74) by sex: (% having at least one adenoma). **Threshold population for publicly displaying clinician results is 50.***

- **Exclude** from this metric if Field # 27 ≥ 4 ;

Male Rate:

Numerator = Total number of colonoscopies with Field # 41 = 1 (screening) **and** Field # 23 = 0 **and** Field # 2 $\geq 50 < 75$ **and** Field # 4 = M **and** Field # 19 = No **and** Field # 20 = No **and** Field # 37 = 1

Denominator = Total number colonoscopies with Field # 41 = 1 (screening) **and** Field # 23 = 0 **and** Field # 2 $\geq 50 < 75$ **and** Field # 4 = M **and** Field # 19 = No **and** Field # 20 = No

Female Rate:

Numerator = Total number colonoscopies with Field # 41 = 1 (screening) **and** Field # 23 = 0 **and** Field # 2 $\geq 50 < 75$ **and** Field # 4 = F **and** Field # 19 = No **and** Field # 20 = No **and** Field # 37 = 1

Denominator = Total number colonoscopies with Field # 41 = 1 (screening) **and** Field # 23 = 0 **and** Field # 2 $\geq 50 < 75$ **and** Field # 4 = F **and** Field # 19 = No **and** Field # 20 = No

*Measurement 4: Average number of adenomas detected on initial screening colonoscopies in average risk adults aged 50 thru 74. **Threshold population for publicly displaying clinician results is 100.***

- **Exclude** from this metric if Field # 27 ≥ 4 ;
- Eligible Population: Field # 41 = 1 (screening) **and** Field # 23 = 0 **and** Field # 2 $\geq 50 < 75$ **and** Field # 19 = No **and** Field # 20 = No **and** Field # 37 = 1;

Numerator = sum of total adenomas recorded in Field # 38 in this population

Denominator = eligible population #

Rate = N/D

*Measurement 5; Advanced neoplasia detection rate on initial screening colonoscopy in average risk adults, aged 50 to 74. **Threshold population for publicly displaying clinician results is 100.***

- **Exclude** from this metric if Field # 27 ≥ 4 ;
- Eligible Population: Field # 41 = 1 (screening) **and** Field # 23 = 0 **and** Field # 2 $\geq 50 < 75$ **and** Field # 19 = No **and** Field # 20 = No;

Numerator = sum of total # of individuals with (Field # 37 = 1 **and** Field # 36 ≥ 10 mm) or (Field # 39 = V or SD or CRC)

Denominator = Total # of individuals meeting above eligible population criteria

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Import Validation rules for the colonoscopy import

1. validate_measure_y_and_n(phx_crc)
2. validate_int(phx_adenoma_no_last_exam)
3. validate_int(size_of_largest_previous_adenoma or value of "UK")
4. validate_measure_y_and_n(phx_villous_adenoma)
5. validate_measure_y_and_n(phx_severe_dysplasia)
6. validate_measure_y_and_n(phx_incomplete_polyp_removal)
7. validate_measure_y_and_n(phx_serrated_adenoma)
8. validate(fhx_crc is "FDR", or "SDR" or "NONE")
9. validate_int(no_fdr_crc)
10. validate_int(no_sdr_crc)
11. validate_int(age_youngest_fdr_crc)
12. validate (no_fdr_crc > 0 and age_youngest_fdr_crc > 0)
13. validate_measure_y_and_n(phx_or_fhx_fap_hnpcc_hps)
14. validate_measure_y_and_n(phx_ibd)
15. validate_measure_y_and_n(fdr_adenoma)
16. validate_int(age_youngest_fdr_adenoma)
17. validate(previous_colonoscopy is 0, 1, 2, 3, 4 or 5)
18. validate_measure_year(previous_colonoscopy_year)
19. validate(BowelPrepType is in our database list)
20. validate (asa_class_no is 0, 1, 2, 3, 4, or 5)
21. validate (bowel_prep_assessed is 0, 1, 2, 3, 4, or 5)
22. validate_measure_0_and_1(complete_exam)
23. validate_measure_0_and_1(cecal_photo)
24. validate_measure_0_and_1(any_polyps_removed)
25. validate_measure_0_and_1(all_polyps_info_recorded)
26. validate_int(withdrawal_time)
27. validate(no_acute_complications is documented)
28. validate_measure_0_and_1(no_acute_complications)
29. validate(rec_fu_colonoscopy is 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or 11)
30. validate (no_of_polyps_removed == 0 and any_polyps_removed == 0)
31. validate (no_of_polyps_removed > 0 and any_polyps_removed == 1)
32. validate_int(no_of_polyps_removed)
33. validate (no_of_polyps_removed == 0 and largest_polyp_removed == 0)
34. validate (largest_polyp_removed > 0 and no_of_polyps_removed > 0)
35. validate (no_of_polyps_removed > 0 and any_adenomatous_polyps > 0)
36. validate_int(largest_polyp_removed)
37. validate_measure_0_and_1(any_adenomatous_polyps)
38. validate_int(total_no_of_confirmed_adenomas)
39. validate (histopathology is "V", "SD", "CRC" or "NA")
40. validate_measure_0_and_1(any_serrated_adenoma)

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