NATIONAL QUALITY FORUM

Stage 1 Concept Submission and Evaluation Worksheet 1.0

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

NQF #: 0658 NQF Project: GI and GU Project

Date Submitted: Jul 09, 2012

CONCEPT SPECIFICATIONS

De.1 Concept Title: Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients

Co.1.1 Concept Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

De.2 Brief Description of Concept: Percentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.

2a1.1 Numerator Statement: Patients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report

2a1.4 Denominator Statement: All patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy

2a1.8 Denominator Exclusions: Documentation of medical reason(s) for not recommending at least a 10 year follow-up interval (eg, above average risk patient, inadequate prep)

1.1 Concept Type: Process
2a1. 25-26 Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Registry
2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

1.2-1.4 Is this concept paired with another measure? No

2a1.1 Numerator Statement *(Brief, narrative description of the concept focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Patients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report

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, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, describe how you plan to identify and calculate the numerator.
Patients will be counted in the numerator if there is reference in the final colonoscopy report that the appropriate follow-up interval for the next colonoscopy is at least 10 years from the date of the current colonoscopy (ie, the colonoscopy performed during the measurement period).
For claims specifications, a CPT Category II code will be reported for this measure. For EHR specifications, we will use SNOMED-CT to identify the information in the final colonoscopy report.
In Stage 2 of this pilot, we will submit EHR specifications and claims specifications; the combination of the two types of specifications can be used for registry reporting. The data stream for registries can be claims, EHR or manual data entry.

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy

2a1.5 Target Population Category *(Check all the populations for which the concept is specified and tested if any)*: Adult/Elderly Care

2a1.7 Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, describe how you plan to identify and calculate the denominator.
The denominator of this measure includes patients at least 50 years of age who receive a screening colonoscopy during the measurement period. The denominator details will include the patient age criterion and applicable CPT, G-Codes and SNOMED-CT procedure codes for a screening colonoscopy. The procedures that will be identified include only those without biopsy or polypectomy, meaning the patient did not have any polyps removed or biopsied during the colonoscopy procedure.
In Stage 2 of this pilot, we will submit EHR specifications and claims specifications.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Documentation of medical reason(s) for not recommending at least a 10 year follow-up interval (eg, above average risk patient, inadequate prep)

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, describe how you plan to identify and calculate the exclusions.
The PCPI methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure 0658, exceptions may include medical reason(s) (eg, above average risk patient, inadequate prep) for not recommending at least a 10 year follow-up interval. Where examples of exceptions are included in the measure language, these examples are coded and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception.
Additional information by data source includes:
For claims specifications, a CPT Category II modifier will be reported by the physician to indicate the patient has an allowable exception for the measure.
For EHR specifications, we will develop value sets for the examples provided in the measure.

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*
For new concepts, if you plan to stratify the measure results, describe the plans for stratification.
We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in measure testing in the stage 2 measure submission)*
For new concepts, <u>if an outcome,</u> describe how you plan to adjust for differences in case mix/risk across measured entities.
Not applicable.

2a1.25 Data Source *(Check all the sources for which the concept is specified and tested*). If other, please describe:
Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, 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.*): Not applicable.

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

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

IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

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

1a. High Impact: H☐ M☐ L☐ I ☐
(*The concept directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas *(Check all the areas that apply)*: Gastrointestinal (GI), Gastrointestinal (GI) : Polyps, Gastrointestinal (GI) : Screening, Prevention
De.5 Cross Cutting Areas (*Check all the areas that apply)*: Overuse, Prevention

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers; Frequently performed procedure; High resource use

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

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
Colorectal cancer is the 2nd leading cause of cancer death in the United States. Inappropriate interval recommendations can result in overuse of resources and can lead to significant patient harm. Performing colonoscopy too often not only increases patients' exposure to procedural harm, but also drains resources that could be more effectively used to adequately screen those in need (Lieberman et al, 2009).

1a.4 Citations for Evidence of High Impact cited in 1a.3: Zauber, et al. Evaluating test strategies for colorectal cancer screening; a decision analysis for the US preventive services task force. Ann Int Med Vol 149, 2008.
Lieberman, DA, Faigel, DO, Logan, J, Mattek, N, Holub, J, Eisen, G, Morris, C, Smith, R, Nadel, M. Assessment of the Quality of Colonoscopy Reports: Results from a multi-center consortium. Gastrointest Endosc Vol 69, 2009.

1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this concept:
Guideline recommendations support screening colonoscopy at 10 year intervals, for average risk patients. Non-adherence to guideline recommendations increases patients to unnecessary risk via procedural harms and complications. Colonoscopy screening at more frequent intervals also contributes to increased costs to patients and insurers.

1b.2 Provide data demonstrating performance gap/opportunity for improvement *(Variation or overall less than optimal performance across providers).* List citations in 1b.3.
For endorsement maintenance, provide performance data on the measure as specified *(mean, std dev, distribution of scores by decile, min, max).* Describe who was included in the performance data in 1b.3.A recent community based multi-organ cancer

screening study in 3627 patients noted that 49 % of low risk patients with adequate negative colonoscopic examinations underwent follow-up surveillance procedures within 7 years (median 3.1 yrs) of their first study, and 35% of low risk patients with two negative exams underwent a third study at a median of 3.3 years after the prior study, despite guidelines for repeat examination at 10 years (Schoen, 2010). Variations in the recommended time interval between colonoscopies also exist for patients with normal colonoscopy findings. In a 2006 study of 1282 colonoscopy reports, recommendations were consistent with current guidelines in only 36.7% of cases. (Krist et al, 2007).

1b.3 Citations for Data on Performance Gap provided in 1b.2.
For endorsement maintenance, describe who was included in the performance results reported in lb.2 *(number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include)*
Schoen R, Pinsky PF, Weissfeld JL, et al. Utilization of Surveillance Colonoscopy in Community Practice. Gastroenterology Vol 138, 2010.
Krist, AH, jones, RM, Woolf, SH et al. Timing of Repeat Colonoscopy: Disparity Between Guidelines and Endoscopists' Recommendation. American Journal of Preventive Medicine. 2007.

1b.4 Provide data on disparities by population group. List citations in 1b.5.
For endorsement maintenance, provide performance data by population group on the measure as specified *(e.g., mean, std dev)*. Describe who was included in the performance data in 1b.5.
After a search of the medical literature, we are not aware of any publications/evidence outlining disparities in this area.

1b.5 Citations for Data on Disparities Cited in 1b.4:
n/a

1c. Evidence (*Concept focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the concept focus a health outcome? Yes☐ No☐ If not a health outcome, rate the body of evidence.

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

Quantity	Quality	Consistency	Does the concept pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the concept pass subcriterion1c? Yes☐ IF rationale supports relationship

Please see the attached Evidence Submission Worksheet for evidence specifications.

Was the concept approval criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐
Provide rationale based on specific subcriteria:

3. USABILITY

4.1 Current and Planned Use
Performance results from NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement (in addition to use for performance improvement).
(Check only the current and planned uses; for any current uses that are checked, provide a URL for the specific program)

Current Use: Professional Certification or Recognition Program; Quality Improvement with Benchmarking (external benchmarking to multiple organizations); Quality Improvement (Internal to the specific organization)
Planned Use: Public Reporting, Quality Improvement (Internal to the specific organization)

5. COMPARISON TO RELATED AND COMPETING CONCEPTS & MEASURES

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:
0572 : Follow-up after initial diagnosis and treatment of colorectal cancer: colonoscopy
0659 : Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps- Avoidance of Inappropriate Use
ACP-018-10 : Endoscopy/Polyp Surveillance: Comprehensive Colonoscopy Documentation
0034 : Colorectal Cancer Screening
0392 : Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade

5a.1 If this concept has EITHER the same focus OR the same target population as NQF-endorsed measure(s): Are the specifications completely harmonized?
No

5a.2 If the specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:
The list of measures above, includes several different populations and capture different elements in the numerator. None of them are aiming to capture the same information as measure 0658. Measures 0572, ACP-018-10, and 0392 actually aim to capture specific elements within the colonoscopy report or pathology report (after colon/rectum resection). Measure 0034 has an entirely different patient population, as it captures patients ages 51-75 only. Measure 0659 focuses on a different patient population, as the patients in 0659 have had a history of a prior colonic polyp in previous colonoscopy findings. The patient population in measure 0659 has a different follow up interval recommendation, according to evidence based guidelines.

5b.1 If this concept has both the same focus and the same target population as NQF-endorsed measure(s):
Describe why this concept is superior to competing measures *(e.g., a more valid or efficient way to measure quality);* OR provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:
There are no competing measures.

CONTACT INFORMATION

Co.1 Concept Steward (Intellectual Property Owner): American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI), 515 N State St. | Chicago | Illinois | 60654

Co.2 Point of Contact: Mark S. | Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement | mark.antman@ama-assn.org | 312-464-5056-

Co.3 Concept Developer if different from Concept Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) | 515 N State St. | Chicago | Illinois, 60654

Co.4 Point of Contact: Mark S. | Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement | mark.antman@ama-assn.org | 312-464-5056-

Co.5 Submitter: Katherine | Ast, MSW, LCSW | katherine.ast@ama-assn.org | 312-464-4920- | American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

Co.6 Additional organizations that sponsored/participated in concept development:
American Society for Gastrointestinal Endoscopy (ASGE)/American Gastroenterological Association (AGA)/National Committee for Quality Assurance

Co.7 Public Contact: Mark S. | Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement | mark.antman@ama-assn.org | 312-464-5056- | American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

ADDITIONAL INFORMATION

Concept Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the concept was first released: 2008

Ad.4 Month and Year of most recent revision: 08/2008

Ad.5 What is your frequency for review/update of this measure? Every 3-4 years or as new evidence becomes available that materially affects the measures

Ad.6 When is the next scheduled review/update for this measure? 08/2011

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (*MM/DD/YY*): Jul 09, 2012

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

Measure Title: Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients
Date of Submission: 7/16/12

- 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: Click here to name the intermediate outcome

X Process: Recommendation and documentation of follow-up interval for normal colonoscopy

☐ 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.)*

Recommendation and documentation of 10 year follow up interval >>>physician adherence to guideline recommendations>>>reduction in patient risk/complications and decrease in cost

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? YesX No☐

If no, skip to #1c.6

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

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

American Cancer Society/US Multisociety Task Force on Colorectal Cancer/American College of Radiology (ACS/USMSTF/ACR). Screening and surveillance for the early detection of colorectal cancer

and adenomatous polyps, 2008: a joint guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. CA Cancer J Clin 2008 May-Jun;58(3):130-60.

Douglas K. Rex , MD, FACG, David A. Johnson , MD,FACG, et al, American College of Gastroenterology Guidelines for Colorectal Cancer Screening 2008. Am J Gastroenterology advance online publication, 24 February 2009; doi: 10.1038/ajg.2009.104.

1c.4.2. **URL** (*if available online*):
http://www.gastrojournal.org/article/S0016-5085(08)00232-1/fulltext

http://www.medicine.nevada.edu/residency/lasvegas/internalmed/documents/coloncaGuideline.pdf

1c.4.3. **Identify guideline number and/or page number**:
ACS/USMSTF/ACR: p. 1582; Rex, et al: pp. 2-3

1c.4.4. **Quote verbatim, the specific guideline recommendation**:
At present, CSPY (colonoscopy) every 10 years is an acceptable option for CRC screening in average-risk adults beginning at age 50 years. (ACS/USMSTF/ACR 2008)

The preferred CRC prevention test is colonoscopy every 10 years, beginning at age 50. (Grade 1B) (Rex, et al, 2009)

1c.4.5. **Grade assigned to the recommendation with definition of the grade**:
ACS/USMSTF/ACR 2008: Not graded.

Rex, et al, 2009: Grade 1B, which is defined as 1B/Strong recommendation, moderate quality evidence; Benefits clearly outweigh risk and burdens, or vice versa; RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies; Strong recommendation, can apply to most patients in most circumstances without reservation

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes X 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**:

ACS/USMSTF/ACR 2008:The guideline developer indiated that an evidence review was performed, but the body of evidence was not graded.

Rex, et al, 2009: The guideline developers did not assign a specific grade to the body of evidence, but explained their systematic evidence review as follows: “The evidence that colonoscopy prevents incident CRCs and reduces the consequent mortality from CRC is indirect but substantial. No prospective randomized controlled trial, comparing colonoscopy with no screening, has been carried out. However in a randomized controlled trial, involving only 800 patients, in which flexible sigmoidoscopy with colonoscopy carried out for any polyp detected was compared with no screening, the screening strategy

resulted in an 80 % reduction in the incidence of CRC. In addition, at the University of Minnesota, a randomized controlled trial was carried out comparing annual vs. biennial fecal occult blood testing with rehydration with no screening. Screening resulted in a 20% incidence reduction in CRC, which appeared to have resulted from detection of large adenomas by fecal occult blood testing and subsequent colonoscopy and polypectomy. Cohort studies involving patients, who have undergone colonoscopy and polypectomy with apparent clearance of colonic neoplasia, have shown a 76 – 90% reduction in the incidence of CRC in comparison with reference populations. Case – control studies of colonoscopy showed a 50% reduction in mortality from CRC in a US Veterans Administration population, and there was an 80% reduction in the CRC incidence in the German population . Population-based studies in the United States have associated increases in the use of colonoscopy with earlier and more favorable stages in CRC presentation , and with reductions in the incidence of CRC. Additional evidence for a benefit from colonoscopy screening is extrapolated from case – control studies of sigmoidoscopy, which have shown mortality and incidence reductions of distal CRC of 60 and 80%, respectively, in screening populations."

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☐ NoX *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 identifed 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:

ACS/USMSTF/ACR 2008: January 2002 and March 2007

Rex, et al, 2009: The date range of the studies reviewed is not provided.

QUANTITY AND QUALITY OF BODY OF EVIDENCE

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

ACS/USMSTF/ACR 2008: While the number and type of study designs are not described by the guideline developers, the article did say, "Most of the information supporting the use of the other colorectal screening tests [including CSPY] is based on observational and inferential evidence. In this review, priority was placed on studies of asymptomatic average-risk or higher-risk populations that were followed by testing with colonoscopy in all or nearly all study participants as a validation measure."

Rex, et al, 2009: The number and type of study designs are not provided.

1c.10. What is the overall quality of evidence <u>across studies</u> 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*)

The overall quality of evidence across studies was not addressed in the guidelines or in the 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) <u>across studies</u> 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*)

ACS/USMSTF/ACR 2008: Again, while the magnitude and direction across studies was not described, the guideline developers did summarize other studies as follows: "The evaluation of incidence rates of CRC in adenoma cohorts after baseline CSPY and polypectomy is another form of evidence commonly cited to support CSPY for CRC screening. In the National Polyp Study, the incidence of CRC after clearing CSPY was reduced by 76% to 90% compared with 3 nonconcurrent reference populations. In an Italian adenoma cohort study with removal of at least one adenoma ≥5 mm, there was an 80% reduction in CRC incidence compared with expected incidence in a reference population. However, not all studies have shown the same level of protection. Combined data from 3 US chemoprevention trials showed incidence rates of CRC after clearing CSPY approximately 4 times that seen in the National Polyp Study, with no reduction in CRC incidence compared with data from the Surveillance Epidemiology and End Results (SEER) database in the United States, and 2 US dietary intervention trials also showed higher rates of incident CRC after clearing CSPY than were observed in the National Polyp Study. These differences may reflect exclusion of patients with sessile adenomas >3 cm in the National Polyp Study, more effective baseline clearing (13% of patients in the National Polyp Study had 2 or more baseline CSPY to complete clearing), or unmeasured differences in the average quality of CSPY between the studies. Overall, the data support the conclusion that CSPY with clearing of neoplasms by polypectomy has a significant impact on CRC incidence and thus, by extension, mortality. The magnitude of the protective impact is uncertain; it is not absolute, nor are apparent failures well understood. In a study of 35,000 symptomatic patients in Manitoba who had undergone a negative CSPY and who then were followed for 10 years, the investigators observed significant reductions in CRC incidence over time, but

the incidence reductions were less than 50% for each of the first 5 years and no more than 72% by 10 years. These findings suggest detection failures during the initial, apparently normal, CSPY."

Rex, et al, 2009: The magnitude and direction across studies was not described, but the guideline developers summarized the benefits of a number of studies as follows: "The evidence that colonoscopy prevents incident CRCs and reduces the consequent mortality from CRC is indirect but substantial. No prospective randomized controlled trial, comparing colonoscopy with no screening, has been carried out. However in a randomized controlled trial, involving only 800 patients, in which flexible sigmoidoscopy with colonoscopy carried out for any polyp detected was compared with no screening, the screening strategy resulted in an 80 % reduction in the incidence of CRC. In addition, at the University of Minnesota, a randomized controlled trial was carried out comparing annual vs. biennial fecal occult blood testing with rehydration with no screening. Screening resulted in a 20% incidence reduction in CRC, which appeared to have resulted from detection of large adenomas by fecal occult blood testing and subsequent colonoscopy and polypectomy. Cohort studies involving patients, who have undergone colonoscopy and polypectomy with apparent clearance of colonic neoplasia, have shown a 76 – 90% reduction in the incidence of CRC in comparison with reference populations. Case – control studies of colonoscopy showed a 50% reduction in mortality from CRC in a US Veterans Administration population, and there was an 80% reduction in the CRC incidence in the German population . Population-based studies in the United States have associated increases in the use of colonoscopy with earlier and more favorable stages in CRC presentation , and with reductions in the incidence of CRC. Additional evidence for a benefit from colonoscopy screening is extrapolated from case – control studies of sigmoidoscopy, which have shown mortality and incidence reductions of distal CRC of 60 and 80%, respectively, in screening populations."

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?
ACS/USMSTF/ACR 2008: The guideline developers have identified the following harms that have been studied, which they deem minimal in comparison to the benefits: "Controlled studies have shown the CSPY miss rate for large adenomas (≥10 mm) to be 6% to 12%. The reported CSPY miss rate for cancer is about 5%. CSPY can result in significant harm, most often associated with polypectomy, and the most common serious complication is postpolypectomy bleeding. The risk of postpolypectomy bleeding is increased with large polyp size and proximal colon location; however, small polyp bleeds are more numerous than large polyp bleeds because small polyps are so numerous. Another significant risk associated with CSPY is perforation. Perforation increases with increasing age and the presence of diverticular disease and was recently estimated to occur in 1 in 500 of a Medicare population and approximately 1 in 1000 screened patients overall.123 Because of the age effect, perforation rates measured in the Medicare population may overestimate the overall risk of perforation in CSPY; however, a large study in the Northern California Kaiser Permanente population also identified a perforation rate of 1 in 1000. In addition, cardiopulmonary complications such as cardiac arrhythmias, hypotension, and oxygen desaturation may occur, although these events rarely result in hospitalization. Cardiopulmonary complications represent about one half of all adverse events that occur during CSPY and usually are related to sedation. Thus, while screening CSPY has established benefits with regard to the detection of adenomas and cancer, complications related to CSPY are a significant public health challenge." However, despite these risks of harm, "A principal benefit of CSPY is that it allows for a full structural examination of the colon and rectum in a single session and for the detection of colorectal polyps and cancers accompanied by biopsy or polypectomy. All other forms of screening, if positive, require CSPY as a second procedure. Patient surveys indicate that patients willing to undergo invasive testing tend to choose CSPY as their preferred test. In addition to being a complete examination of the colon, individuals may also regard sedation during the procedure as an advantage. Patients in the same

practice who had undergone unsedated FSIG screening were more than twice as likely to say that they would not return for additional screening compared with those who had undergone CSPY with sedation."

Rex, et al, 2009: The guideline developers have identified the following harms that have been studied, which they deem outweighed by the benefits: "Screening colonoscopy can be associated with significant harm, particularly colonic perforation. Many perforations are related to polypectomy and because small polyps are so numerous, small polyp polypectomy perforations contribute substantially to the overall perforation risk. Perforations associated with removal of small polyps are unfortunate, because the overwhelming majority of these polyps will not harm patients. Effective removal of these polyps by cold snare polypectomy or biopsy techniques is possible, at least for very small polyps, and is not associated with either bleeding or perforation. In general, there are insufficient data available from randomized controlled trials to guide or mandate particular polypectomy techniques. Pending such trials, the ACG recommends that colonoscopists consider carefully the polypectomy techniques they utilize for small polyps with an aim to reduce the burden of perforation. On the other hand, the ACG acknowledges that use of effective polypectomy techniques is critical for adequate resection of larger polyps. Two studies have suggested that about one-quarter of incident cancers occurring after colonoscopy result from ineffective polypectomy. Overall, the perforation risk and the requirement for thorough bowel preparation are the major downsides of colonoscopy. [On the other hand,] Major advantages of colonoscopy as a screening test include that it is widely available, examines the entire colon, allows single-session diagnosis and treatment, is comfortable when carried out with sedation, and is the only test recommended at 10-year intervals. The incremental benefit of colonoscopy over sigmoidoscopy is the detection of patients with proximal colon neoplasia (particularly advanced adenomas), as well as large hyperplastic polyps that are not associated with distal neoplasia. Overall, sigmoidoscopy detects 60 – 70 % of the significant neoplasia detected by complete colonoscopy. The preference of most American patients is for highly effective strategies, as well as for strategies that provide high levels of comfort and thereby increase the chance that patients will return for additional testing. These are important rationales for the use of colonoscopy rather than sigmoidoscopy."

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☐ NoX *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**.

Sample PCPI Calculation Algorithm

Calculation for Performance

For performance purposes, a measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

Numerator (A) Includes:
Number of patients meeting numerator criteria
Denominator (PD) Includes:
Number of patients meeting criteria for denominator inclusion

Denominator Exclusions (C) Include:
Number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure)

Performance Calculation

$$\frac{\text{A (\# of patients meeting numerator criteria)}}{\text{PD (\# patients in denominator)} - \text{C (\# patients with valid denominator exclusions)}}$$

If a measure does not allow for exclusion(s), it is calculated by creating a fraction with the following components: Numerator and Denominator.

Numerator (A) Includes:
Number of patients meeting numerator criteria
Denominator (PD) Includes:
Number of patients meeting criteria for denominator inclusion

$$\frac{\text{A (\# of patients meeting measure criteria)}}{\text{PD (\# of patients in denominator)}}$$

It is also possible to calculate the percentage of patients excluded overall, or excluded by medical, patient, or system reason where applicable:

Overall Exclusion Calculation

$$\frac{\text{C (\# of patients with any valid exclusion)}}{\text{PD (\# patients in denominator)}}$$

OR

Exclusion Calculation by Type

$$\frac{C_1 \text{ (\# patients with medical reason)}}{\text{PD (\# patients in denominator)}} \qquad \frac{C_2 \text{ (\# patients with patient reason)}}{\text{PD (\# patients in denominator)}} \qquad \frac{C_3 \text{ (\# patients with system reason)}}{\text{PD (\# patients in denominator)}}$$

Basic Measure Calculation:

$$\frac{(N)}{(D) - (E)} = \%$$

The PCPI strongly recommends that exception rates also be computed and reported alongside performance rates as follows:

Exception Calculation:

$$\frac{(E)}{(D)} = \%$$

Exception Types:
E= E1 (Medical Exceptions) + E2 (Patient Exceptions) + E3 (System Exceptions)
For patients who have more than one valid exception, only one exception should be be counted when calculating the exception rate

Initial Patient Population (IPP)	Denominator (D)	Numerator (N)	Denominator Exceptions (E)
Definition: The initial patient population identifies the general group of patients that the performance measureis designed to address; usually focused on a specific clinical condition (e.g., coronary artery disease, asthma). For example, a patient aged 18 years and older with a diagnosis of CADwho has at least 2 Visits during the measurement period.	**Definition:** The denominator defines the specific group of patients for inclusion in a specific performance measure based on specific criteria (e.g., patient's age, diagnosis, prior MI). In some cases, the denominator may be I dentical to the initial patient population.	**Definition:** The numerator defines the group of patients in the denominator for whom a process or outcome of care occurs (e.g., flu vaccine received).	**Definition:** Denominator exceptions are the valid reasons why patients who are included in the denominator population did not receive a process or outcome of care (described in the numerator). Patients may have Denominator Exceptions for medical reasons (e.g., patient has an egg allergy so they did not receive flu vaccine); patient reasons (e.g., patient declined flu vaccine); or system reasons (e.g., patient did not receive flu Vaccine due to vaccine shortage). These cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported. This group of patients constitutes the Denominator Exception reporting population – patients for whom the numerator was not achieved and a there is a valid Denominator Exception.
Find the patients who meet the Initial Patient Population criteria (IPP)	Find the patients who qualify for the denominator (D): o From the patients within the Patient Population criteria (IPP) select those people who meet Denominator selection criteria. (In some cases the IPP and D are identical).	Find the patients who qualify for the Numerator (N): o From the patients within the Denominator (D) criteria, select those people who meet Numerator selection criteria. o Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator	From the patients who did not meet the Numerator criteria, determine if the patient meets any criteria for the Denominator Exception (E1 + E2+E3). If they meet any criteria, they should be removed from the Denominator for performance calculation. As a point of reference, these cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported.