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 #: 0659 NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012
CONCEPT SPECIFICATIONS
De.1 Concept Title: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use
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 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report
2a1.1 Numerator Statement: Patients who had an interval of 3 or more years since their last colonoscopy
2a1.4 Denominator Statement: All patients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior colonic polyp in a previous colonoscopy
2a1.8 Denominator Exclusions: Documentations of medical reason(s) for an interval of less than 3 years since the last colonoscopy (eg, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas) OR Documentation of a system reason(s) for an interval of less than 3 years since the last colonoscopy (eg, unable to locate previous colonoscopy report, previous colonoscopy report was incomplete)
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 an interval of 3 or more years since their last colonoscopy 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 the current colonoscopy (in the denominator was performed at least 3 years after the date of the prior colonoscopy. In Stage 2, we will submit EHR specifications and claims specifications; the combination of the 2 specifications can be used in registry reporting. The data stream for registries can be claims, EHR or manual data entry. For EHR, patients will be counted based on looking back to determine if at least 3 years passed between the current and prior

colonoscopies. The date of the prior colonoscopy will be searched in the EHR, and then compared to the date of the current colonoscopy (ie, colonoscopy performed during the measurement period). If the prior colonoscopy was performed at least 3 years prior to the current colonoscopy, then the patient will meet the measure.
For claims data, a CPT Category II code will be reported to indicate that the interval between the current colonoscopy and the prior colonoscopy was at least 3 years.

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All patients aged 18 years and older receiving a surveillance colonoscopy with a history of a prior colonic polyp in a previous colonoscopy

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 includes patients at least 18 years of age who have a history of colonic polyps who also received a colonoscopy during the measurement period. The denominator details will include the patient age criterion, applicable ICD-9-CM, ICD-10-CM, SNOMED-CT diagnosis codes for history of colonic polyps, and applicable CPT, G codes and SNOMED-CT codes for receiving a surveillance colonoscopy.
In Stage 2, we will submit EHR specifications and claims specifications; the combination of the 2 specifications can be used in registry reporting. The data stream for registries can be claims, EHR or manual data entry.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Documentations of medical reason(s) for an interval of less than 3 years since the last colonoscopy (eg, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas)
OR
Documentation of a system reason(s) for an interval of less than 3 years since the last colonoscopy (eg, unable to locate previous colonoscopy report, previous colonoscopy report was incomplete)

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 exception methodology uses three categories of reasons for which a patient may be removed 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 this measure, exceptions may include medical reason(s) (eg, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas) or system reason(s) for an interval of less than 3 years since the last colonoscopy (eg, unable to locate previous colonoscopy report, previous colonoscopy report was incomplete). Where examples of exceptions are included in the measure language, value sets for these examples are developed 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. Additional details by data source are as follows:
For EHR:
Patients will be excluded from the denominator if there is documentation of a medical or system reason for performing a colonoscopy within 3 years (less than 3 years) since the last colonoscopy

- Examples of medical reasons include: the last colonoscopy was incomplete or had inadequate prep, there was piecemeal removal of adenomas, or the last colonoscopy found greater than 10 adenomas
- Examples of system reasons include: unable to locate previous colonoscopy report, previous colonoscopy report was incomplete)

Value sets for the examples included in the medical or system reasons will be developed to identify patients with allowable exceptions.
For Claims:
Patients will also be excluded from the denominator if there is documentation of a medical or system reason for recommending a subsequent colonoscopy within 3 years from the current colonoscopy. A CPT Category II code will be reported for patients who have an allowable exception to 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. Stratification by insurance coverage (Commerical, Medicare and Med

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in measure testing in the stage 2 measure submission)*
For new concepts, if an outcome, describe how you plan to adjust for differences in case mix/risk across measured entities.
N/A

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.*): N/A

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, Hospital/Acute Care Facility

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, 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. Colonoscopy is the recommended method of surveillance after the removal of adenomatous polyps because it has been shown to significantly reduce subsequent Colorectal Cancer incidence. The time interval for the development of malignant changes in adenomatous polyps is estimated at 5 to 25 years (ICSI, 2006). 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: Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 50 p.
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:
Several published literature studies indicate that repeat colonoscopy is often overutilized and is not tied to clinical data on initial colonoscopy. The use of this measure is intended to increase physicians´ adherence to the evidence based guideline and subsequently may reduce unnecessary tests, costs, and patient risk.

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 pooled analysis of surveillance colonoscopy in 9167 patients from 8 studies confirmed the relative discrimination between high and low risk groups on the basis of patient features and endoscopic findings (Martinez, 2009). The index findings of advanced histology or greater size or number of polyps correlated with risk for subsequent advanced neoplasia. Hence, the timing of follow-up colonoscopy should be tailored to the number, size, and pathologic findings of the adenomatous polyps removed (Levin 2008).
In a large multi-state community-based study of colorectal cancer surveillance, one third of those with only 1-2 low risk adenomas were noted to undergo relatively premature repeat colonoscopy within 4 years (median 3.1 yrs), despite recommendations for repeat examination in 5 years, and more recently, 5 to 10 years (Schoen, 2010). Similarly, 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 (Rex et al, 2006). Some endoscopists in these studies performed colonoscopy in patients with only small hyperplastic polyps or a single tubular adenoma at 1 year. These surveys underscore the importance of measuring intervals between examinations in continuous quality improvement programs.
In a 2006 study of 1282 colonoscopy reports, recommendations were consistent with current guidelines in only 36.7% of cases. (Krist et al, 2007).
This measure was used in the 2009-2012 CMS Physician Quality Reporting Initiative/System. There is a gap in care as shown by this data; 98.01% is the aggregate performance rate in the total patient population and 97.26% is the mean performance rate of TIN/NPI's.
10th percentile: 93.40%
25th percentile: 100.00%
50th percentile: 100.00%
75th percentile: 100.00%
90th percentile: 100.00%
Exception Rate: 13.50%

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 Ib.2 *(number of measured*

entities; number of patients; dates of data; if a sample, characteristics of the entities include)

Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 50 p.
Martinez ME, Baron JA, Lieberman DA, et al. A Pooled Analysis of Advanced Colorectal Neoplasia Diagnoses after Colonoscopic Polypectomy. Gastroenterology Vol 136, 2009.
Levin B, Lieberman DA, McFarland B et al. 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 Vol, No 58; 2008.
Schoen R, Pinsky PF, Weissfeld JL, et al. Utilization of Surveillance Colonoscopy in Community Practice. Gastroenterology Vol 138, 2010.
Rex DK. Overuse of postpolypectomy surveillance colonoscopy. - - Rev Gastroenterol Disord Vol 6, No 3; 2006.
Krist, AH, jones, RM, Woolf, SH et al. Timing of Repeat Colonoscopy: Disparity Between Guidelines and Endoscopists' Recommendation. American Journal of Preventive Medicine. 2007.
Confidential CMS PQRI 2010 Performance Information by Measure. Jan 2010-Feb2011 TAP file.

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:
Planned Use: Professional Certification or Recognition Program, 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:
0034 : Colorectal Cancer Screening
0658 : Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients
ACP-018-10 : Endoscopy/Polyp Surveillance: Comprehensive Colonoscopy Documentation
0392 : Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade
0572 : Follow-up after initial diagnosis and treatment of colorectal cancer: colonoscopy

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 than measure 0658, as the patients in 0659 have had a history of a prior colonic polyp in previous colonoscopy findings. The patient population in measure 0658 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 16, 2012

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

Measure Title: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps- Avoidance of Inappropriate Use
Date of Submission: 7/16/12

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages incudes 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

☐ Process: Click here to name the process

☐ Structure: Click here to name the structure

X Other: Overuse Measure, looking at time interval between colonoscopies

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.)*

Follow up interval of minimum 3 years>>>physician adherence to guideline recommendations>>>reduction in overuse

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*):

Winawer, Sidney J, Ann G. Zauber, Robert H. Fletcher, et al. Guidelines for Colonoscopy Surveillance After Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society. GASTROENTEROLOGY 2006;130:1872–1885.

1c.4.2. **URL** (*if available online*):
http://download.journals.elsevierhealth.com/pdfs/journals/0016-5085/PIIS0016508506005610.pdf

1c.4.3. **Identify guideline number and/or page number**:
Guidelines 2 & 3; page 1873

1c.4.4. **Quote verbatim, the specific guideline recommendation**:
Patients with only 1 or 2 small (<1 cm) tubular adenomas with only low-grade dysplasia should have their next follow-up colonoscopy in 5–10 years; the precise timing within this interval should be based on other clinical factors (such as prior colonoscopy findings, family history, and the preferences of the patient and judgment of the physician). Patients with 3 to 10 adenomas, or any adenoma ≥1 cm, or any adenoma with villous features, or high-grade dysplasia should have their next follow-up colonoscopy in 3 years providing that piecemeal removal has not been performed and the adenoma(s) are removed completely; if the follow-up colonoscopy is normal or shows only 1 or 2 small tubular adenomas with low-grade dysplasia, then the interval for the subsequent examination should be 5 years. (Winawer, et al, 2006)

1c.4.5. **Grade assigned to the recommendation with definition of the grade**:
Recommendation is not graded.

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**:

The guideline developer indiated that an evidence review was performed, but the body of evidence was not graded.

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 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: 1990 to 2005

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*)

The guideline developers stated: 13 relevant studies [were included] according to the following criteria: (1) colonoscopy studies specifically addressing the relationship between baseline examination findings and the detection of advanced adenoma or of any adenoma during follow-up colonoscopy; or (2) sigmoidoscopy studies, with large cohorts and follow-up periods longer than 10 years, specifically addressing the association between baseline examination findings and the detection of advanced adenomas during follow-up evaluation. After the initial review of published data, we added 1 relevant abstract and a newly published article to the review… Our final review was based on 15 studies that met the inclusion criteria…There is strong evidence that the adenoma cohort can be stratified according to the risk for development of subsequent advanced adenomas. Recommendations for surveillance intervals in persons with multiple adenomas and those with advanced adenomas are based primarily on the National Polyp Study, an RCT, and observational cohort studies. Recommendations in the low-risk group of 1 to 2 small tubular adenomas are based on the low incidence of advanced adenomas in observational cohort studies and the National Polyp Study over 3- to 6-year intervals and the observation by Atkin et al that persons with small tubular adenomas are not at increased risk for developing colorectal cancer. (Winawer, et al, 2006)

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*)

"These guidelines are based on all of the available evidence, clinical experience, knowledge of the adenomacarcinoma sequence, and expert opinion." (Winawer, et al, 2006) A link to more information titled: Appendix: Review of the literature: Evidence Tables for Predictors of Risk Factors for Subsequent

Neoplasia in Post-polypectomy Surveillance in Adenoma Patients was included at the end of the guideline—http://download.journals.elsevierhealth.com/mmcs/journals/0016-5085/PIIS0016508506005610.mmc1.doc

The systematic review was explained as follows: Review of the evidence was confounded by variations in definitions, design of the studies, timing and multiplicity of surveillance intervals, and quality of the baseline colonoscopy. Because of these variations, the review of the literature cited was descriptive rather than a single summary value of risk (ie, meta-analysis) for all studies. The literature cited is grouped by type of study design: (1) RCTs in which the surveillance interval is set and maintained as much as possible although eligibility requirements may vary; (2) observational cohort studies that are primarily registry studies with more passive recruitment for surveillance. The RCTs provide stronger evidence for the timing of follow-up examinations because those who received surveillance colonoscopy were not a special subset of all enrolled.

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*)

While the magnitude and direction across studies was not described, the guideline developers did summarize some studies as follows: "Trials designed specifically to evaluate surveillance, in which colonoscopy is performed by experienced endoscopists, such as the National Polyp Study, have shown that a low incidence of cancer can be achieved in postpolypectomy patients. The National Polyp Study required meticulous clearing at the initial baseline with repeat colonoscopy if this was not achieved with high confidence. On the other hand, studies designed for other purposes, such as the pooled chemoprevention studies reported by Robertson et al, and community studies clearly show that higher miss rates commonly occur. Incomplete removal of large sessile polyps, particularly by piecemeal polypectomy, could contribute to a higher subsequent incidence of a colon cancer as in the chemoprevention trials. Atkin et al also showed that inadequate removal of sessile rectosigmoid adenomas at baseline was associated with a marked increase in risk for rectal cancer in a rigid sigmoidoscopy study. The National Polyp Study exclusion of patients with sessile adenomas larger than 3.0 cm and provision for individualized follow-up evaluation for these patients could be another factor that contributed to the low incidence of cancer during the follow-up period in this study. Loeve et al assessed colorectal cancer incidence after adenoma detection in Holland based on 78,473 patients and found that colorectal cancer incidence was not greatly reduced until 5–6 years after the initial diagnosis, and attributed the lack of earlier effect to inadequate removal of adenomas when initially diagnosed. It is therefore important to consider early and late-appearing cancers separately in postpolypectomy trials to separate true incidence reduction from missed cancers. This point is shown in the chemoprevention trials in which a large proportion of cancers were found early; this was probably caused in part by the inadequate removal of large adenomatous polyps. For example, 9 of 19 cancers in the study of Robertson et al were found within 26 months of the initial colonoscopy." (Winawer, et al, 2006)

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

While the guideline did not addresses the harms, the developers had this to say about benefits: "There is a consensus among many of the studies that the group at lower risk for subsequent advanced adenomas has only 1 or 2 adenomas, all less than 1 cm in size with no high-grade dysplasia or villous features. The risk for colon cancer in such low-risk patients, over an average of 14 years, has been shown in a rigid sigmoidoscopy polypectomy study to be similar to the average-risk population. In colonoscopy studies patients have been followed-up for only 5–6 years after colonoscopic polypectomy

to assess their subsequent risk for neoplasia. Sigmoidoscopic polypectomy without colonoscopic assessment is insufficient to establish colonoscopic surveillance intervals. In the Atkin et al study, colon risk was assessed in an anatomic area where polypectomy was not performed (ie, above the rectosigmoid). Postpolypectomy surveillance guidelines ideally should be based on colonoscopic follow-up evaluation of patients who have had colonoscopic polypectomy. Based on the available evidence, we can project that apparently low-risk patients can wait 5 and possibly 10 years for repeat colonoscopy. However, further evaluation of this low-risk group is required to confirm the safety of these intervals."

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**.