

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 #: 0622	NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012	
CONCEPT SPECIFICATIONS	
De.1 Concept Title: GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms	
Co.1.1 Concept Steward: ActiveHealth Management	
De.2 Brief Description of Concept: The percentage of adult patients with gastroesophageal reflux disease (GERD) with alarm symptoms who have had an upper gastrointestinal study.	
2a1.1 Numerator Statement: Patients who have had an upper gastrointestinal study	
2a1.4 Denominator Statement: Patients, 18 years and older, diagnosed with GERD with alarm symptoms (e.g., dysphagia, iron deficiency anemia, weight loss)	
2a1.8 Denominator Exclusions: Specific Exclusions: 1. Patients with a documented gastrointestinal malignancy 2. Patients with other causes of the alarm symptoms including esophageal varices, known Barrett's esophagus, or gastric restrictive procedures General Exclusions: Metastatic malignancy, chemotherapy/radiation therapy, hospice and Skilled Nursing Facility, feedback from physician indicating GI study contraindicated or not applicable.	
1.1 Concept Type: Process 2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Pharmacy, Healthcare Provider Survey, Patient Reported Data/Survey 2a1.33 Level of Analysis: Population : National, Population : Regional	
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 have had an upper gastrointestinal study	
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. One of the following is correct a. Evidence of at least 1 esophageal procedure, upper GI study (Upper GI radiologic exam with high density barium, with or without delayed films, esophageal or gastric motility study, gastric emptying study, gastric analysis test, upper GI endoscopy, or upper GI series), or gastrectomy from claims or HIE in the past 12 months b. Evidence of at least 1 gastric or esophageal cancer diagnosis from claims or HIE in the past 12 months; note-cancer diagnosis implies diagnostic testing was done, and therefore completes numerator c. Presence of provider or patient feedback indicating that a GI Evaluation already implemented in the past 12 months.	

d. Presence of patient self-reported data confirming at least 1 EGD or Upper GI Study in past 12 months

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

Patients, 18 years and older, diagnosed with GERD with alarm symptoms (e.g., dysphagia, iron deficiency anemia, weight loss)

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

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.

DENOMINATOR

All of the following are correct:

1. Age = 18 Years
2. One of the following is correct:
 - a. Presence of patient self-reported data, via PHR or telephonic nurse assessment in our disease management program, confirming they have GERD and GERD warning symptoms in the past 12 months
 - b. All of the following are correct:
 - i. Presence of at least 2 diagnosis codes from claims or 1 diagnosis code from HIE for GERD in the past 12 months
 - ii. One of the following:
 - A. At least 2 diagnosis codes from claims or 1 diagnosis code from HIE for weight loss in the past 12 months
 - B. At least 2 diagnosis codes from claims or 1 diagnosis code from HIE for dysphagia in the past 12 months
 - C. Patient data via feedback survey or PHR indicating that they have GERD with warning symptoms in the past 12 months
 - iii. One of the Following are correct:
 - A. Presence of at least 1 fill for a 60 total days supply of a PUD/GERD medication in the past 12 months from claims
 - B. Presence of at least 1 fill for a PUD/GERD medication in the past 3 months from HIE

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

Specific Exclusions:

1. Patients with a documented gastrointestinal malignancy
2. Patients with other causes of the alarm symptoms including esophageal varices, known Barrett's esophagus, or gastric restrictive procedures

General Exclusions:

Metastatic malignancy, chemotherapy/radiation therapy, hospice and Skilled Nursing Facility, feedback from physician indicating GI study contraindicated or not applicable.

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.

SPECIFIC DENOMINATOR EXCLUSIONS

1. Presence of at least 2 diagnosis codes from claims or 1 diagnosis code from HIE for Barrett's esophagus in the past 24 months
2. Presence of at least 2 diagnosis codes from claims or 1 diagnosis code from HIE for esophageal varices in the past 24 months
3. Presence of at least 2 diagnosis codes from claims or 1 diagnosis code from HIE for a gastrointestinal cancer in the past 24 months
4. Presence of at least diagnosis code from claims or HIE for weight loss surgery or a gastric restrictive procedure anytime in the past

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.

This measure is not stratified.

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.
No risk adjustment or risk stratification

2a1.25 Data Source (Check all the sources for which the concept is specified and tested). If other, please describe:
Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Pharmacy, Healthcare Provider Survey, Patient Reported Data/Survey

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.): We allow data from several different sources including claims, health information exchanges, provider and patient surveys, our patient health portal, and through feedback given to our nurses via telephonic engagement. All data is processed through Active

2a1.33 Level of Analysis (Check the levels of analysis for which the concept is specified and tested): Population : National, Population : Regional

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

IMPACT, OPPORTUNITY, 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) : Gastro-Esophageal Reflux Disease (GERD)/Peptic Ulcer

De.5 Cross Cutting Areas (Check all the areas that apply):

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers; 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):

Gastroesophageal reflux disease (GERD) is a condition when stomach contents are refluxed into the esophagus and result in troublesome symptoms (e.g., heartburn or acid regurgitation) or complications (e.g., esophagitis, stricture). GERD is a common disorder of the upper gastrointestinal tract and has an incidence of 10-38% in the western adult population. In 2004, 27 percent of elderly Medicare patients used GERD medications, spending a total of \$5.6 billion [1]. Hospitalizations for esophageal disorders increased from 516,895 to 646,785 from 1998 to 2005. Alarming symptoms have been considered a marker suggesting complications of GERD or malignancy [4,5]. In 2005, 9.1 percent of hospitalizations with a primary GERD diagnosis had alarm symptoms, which are serious enough to warrant further exploration for esophageal disorders. In the same year, 4.2 percent of hospitalizations with a GERD diagnosis had an esophageal disorder. From 1998 to 2005, dysphagia, esophageal adenocarcinoma, and esophagitis were the fastest growing esophageal disorders with a GERD diagnosis, increasing by 264 percent, 195 percent, and 94 percent, respectively. The number of primary GERD hospitalizations with alarm symptoms increased by 39 percent since 1998 [1]. In a 2002 questionnaire study, the odds ratio of patients with dyspepsia and alarm symptoms for both gastrointestinal cancer and mortality over a 3-year period were significantly raised [6]. With the increase in incidence of esophageal adenocarcinoma and esophagitis, along with some evidence suggesting delays in cancer diagnosis due to

failure to investigate patients with alarm features [7,8], the need for endoscopic evaluation upon such alarm symptoms in patients with GERD becomes more vital.

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. Zhao, Encinosa. AHRQ Statistical Brief: Gastroesophageal reflux disease (GERD) hospitalizations in 1998 and 2005

2. Nwokediuko. Gastroesophageal reflux disease: a population based study. Gastroenterology Research 2009;2(3):152-156

3. Pohl, Welch. The role of overdiagnosis and reclassification in the marked increase of esophageal adenocarcinoma incidence. J Natl Cancer Inst 2005 97(2):142-6

4. British Society of Gastroenterology. Dyspepsia management guidelines. London: British Society of Gastroenterology, 2002.

5. Talley NJ, Silverstein MD, Agreus L, et al. AGA technical review: evaluation of dyspepsia. American Gastroenterological Association. Gastroenterology 1998;114:582-95

6. Meineche-Schmidt V, Jorgensen T. "Alarm symptoms" in patients with dyspepsia: a three-year prospective study from general practice. Scand J Gastroenterol 2002;37:999-1007

7. Martin IG, Young S, Sue-Ling H, et al. Delays in diagnosis of oesophagogastric cancer: a consecutive case series. BMJ 1997;314:467-70

8. Christie J, Shepherd NA, Codling BW, et al. Gastric cancer below the age of 55: implications for screening patients with uncomplicated dyspepsia. Gut 1997;41:513-17

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:

This measure is aimed at optimizing the care and identifying complications of GERD in the presence of alarm symptoms. The principal reason to evaluate via endoscopy in patients with GERD and alarm symptoms is to detect structural abnormalities that may need additional diagnostic evaluation, evaluate the success of medical therapy, and for potential biopsy opportunities as part of a diagnostic differential for such symptomatology. This measure was developed with the goal to help reduce the progression of complicated esophageal diseases and investigate patients with a higher-risk of upper gastrointestinal malignancy.

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. There are currently no large population studies summarizing the performance gap of upper endoscopy on GERD patients with alarm symptoms (i.e., either dysphagia or unintentional weight loss). From a test of this measure done on a sample population of 2.46 million, we found 392 patients with GERD AND either dysphagia or unintentional weight loss. Of these patients, 260 had an upper endoscopy performed during the measurement year. This translates to a performance gap of 33.7% [1].

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

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

2.46 million lives were included in the sample population, representing a cross-sectional nationwide sample from our client population, 49% male, 51% female, with an average age of 37 years. Test was performed in 2012. 392 patients had both GERD and at least one alarm symptom. 260 of these patients had an Upper GI study done.

1. ActiveHealth Management, Inc., testing done from June 3rd, 2009 to June 3rd, 2010, includes both commercial and Medicare population.

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.

Most large population studies are done in Asian countries due to the higher rate of upper gastrointestinal malignancy; however there is insufficient data demonstrating the disparities between different population groups within the United States.

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

No citations.

<p>1c. Evidence (<i>Concept focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.</i>) Is the concept focus a health outcome? Yes <input type="checkbox"/> No <input type="checkbox"/> If not a health outcome, rate the body of evidence.</p> <p>Quantity: H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/> Quality: H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/> Consistency: H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/></p>			
Quantity	Quality	Consistency	Does the concept pass subcriterion1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>
Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service		Does the concept pass subcriterion1c? Yes <input type="checkbox"/> IF rationale supports relationship	
<p><i>Please see the attached <u>Evidence Submission Worksheet</u> for evidence specifications.</i></p>			
<p>Was the concept approval 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>			

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: [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:

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

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

5b.1 If this concept has both the same focus and the same target population as NQF-endorsed measure(s): Describe why this concept is superior to competing measures (*e.g., a more valid or efficient way to measure quality*); OR provide a rationale for the additive value of endorsing an additional measure. (*Provide analyses when possible*):

CONTACT INFORMATION

Co.1 Concept Steward (Intellectual Property Owner): [ActiveHealth Management, 1333 Broadway | New York | New York | 10018](#)

Co.2 Point of Contact: Bani Vir, MD bvir@activehealth.net 212-651-8200-
Co.3 Concept Developer if different from Concept Steward: ActiveHealth Management 1333 Broadway New York New York, 10018
Co.4 Point of Contact: Bani Vir, MD bvir@activehealth.net 212-651-8200-
Co.5 Submitter: Bani Vir, MD bvir@activehealth.net 212-651-8200- ActiveHealth Management
Co.6 Additional organizations that sponsored/participated in concept development:
Co.7 Public Contact: Vir, MD bvir@activehealth.net 212-651-8200- ActiveHealth Management

ADDITIONAL INFORMATION
<p>Concept Developer/Steward Updates and Ongoing Maintenance Ad.3 Year the concept was first released: Ad.4 Month and Year of most recent revision: Ad.5 What is your frequency for review/update of this measure? Ad.6 When is the next scheduled review/update for this measure?</p>
<p>Ad.7 Copyright statement: This information, including any attachments hereto, is the sole, exclusive, proprietary and confidential property of ActiveHealth Management, Inc., and is for the exclusive use of The National Quality Forum. Any use, copying, disclosure, dissemination or distribution by anyone other than the National Quality Forum is strictly prohibited.</p>
Ad.8 Disclaimers:
Ad.9 Additional Information/Comments:
Date of Submission (<i>MM/DD/YY</i>): Jul 16, 2012

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

Measure Title: GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms

Date of Submission: [6/25/2012](#)

- 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: [3T](#)

Intermediate clinical outcome: [3T](#)

Process: Upper GI study for GERD w/alarm symptoms

Structure: [3T](#)

Other: [3T](#)

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.)

High risk patients with GERD who present with dysphagia or unintentional weight loss → investigate by endoscopy → early identification of complicated esophageal diseases (e.g., strictures, malignancies) → early treatment → improved function & survival

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):

*American Society for Gastrointestinal Endoscopy – Role of Endoscopy in the Management of GERD
Gastrointestinal Endoscopy 2007;66(2):219-224*

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

<http://www.asge.org/WorkArea/showcontent.aspx?id=4182>

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

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

Endoscopy is recommended for patients who have symptoms suggesting complicated GERD or alarm symptoms (2A).

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

2A, intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values

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:

2A, intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values

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):

*American Gastroenterological Association Institute Technical Review on the Management of Gastroesophageal Reflux Disease
Gastroenterology 2008;135:1392-1413*

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

<http://gastro.ucsd.edu/fellowship/materials/Documents/GERD/AGA%20guidelines%20on%20management%5B1%5D.pdf>

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

USPSTF grade B, quality fair. The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

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: 1966-2005

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)

15 prospective evaluation of alarm features with excellent agreement between reviewers.

3 further studies gave data on individual alarm features.

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)

Fair/intermediate quality

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)

Upon review of the two specific alarm features, namely weight loss and dysphagia, the positive likelihood ratios of developing an upper GI malignancy range from 1.9 to 21.2 for weight loss and 1.8 to 10.4 for dysphagia across the various studies reviewed in this analysis

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

None were reviewed with the current study.

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.