

# NATIONAL QUALITY FORUM

## Stage 1 Concept Submission and Evaluation Worksheet 1.0

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

NQF #: C 2054      NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012
<b>CONCEPT SPECIFICATIONS</b>
De.1 Concept Title: <a href="#">Assessment of treatment within one year of SUI surgery</a>
Co.1.1 Concept Steward: <a href="#">American Urological Association</a>
De.2 Brief Description of Concept: <a href="#">Percentage of female patients who had SUI surgery, who had an assessment of response to surgical treatment performed within 1 year post-surgery</a>
2a1.1 Numerator Statement: <a href="#">Female patients without concomitant prolapse who had SUI surgery and who received the following as part of their postoperative assessment within one year:</a> <ul style="list-style-type: none"> <li>• <a href="#">Characterization of incontinence: focused history (questions asked of patient: duration of incontinence; number of episodes; use of protective products, i.e. "bother")</a></li> <li>• <a href="#">focused physical exam</a></li> <li>• <a href="#">post void residual analysis</a></li> <li>• <a href="#">urinary analysis, and urinary culture, if indicated</a></li> </ul>
2a1.4 Denominator Statement: <a href="#">Female patients who had SUI surgery without concomitant surgery for prolapse seen at follow up within one year post-treatment</a> <a href="#">Patients with concomitant surgery for prolapse were excluded from the denominator because these measures are based on the AUA SUI guidelines which focused on an index patient without concomitant prolapse surgery. Prolapse surgery patients complicate the interpretation of the quality measures for SUI surgery such as characterization of prolapse symptoms, documentation of the involved compartments, and the severity of prolapse of each of the compartments as part of the physical exam. These elements are not necessary for stress incontinence patients.</a>
2a1.8 Denominator Exclusions: <a href="#">Documentation of medical reason(s) for not performing all or one of these elements (concomitant prolapse).</a> <a href="#">Documentation of patient reason(s) for not performing all or one of these elements (inability to make and keep an appointment with the treating physician due to relocation, incapacity, inability to travel).</a>  <a href="#">Documentation of system reason(s) for not performing all or one of these elements (visits are not reimbursable by the patient's insurer)</a>
1.1 Concept Type: <a href="#">Process</a> 2a1. 25-26 Data Source: <a href="#">Administrative claims, Paper Medical Records</a> 2a1.33 Level of Analysis: <a href="#">Clinician : Individual</a>
1.2-1.4 Is this concept paired with another measure? <a href="#">No</a>
2a1.1 Numerator Statement ( <i>Brief, narrative description of the concept focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome</i> ): <a href="#">Female patients without concomitant prolapse who had SUI surgery and who received the following as part of their postoperative assessment within one year:</a> <ul style="list-style-type: none"> <li>• <a href="#">Characterization of incontinence: focused history (questions asked of patient: duration of incontinence; number of episodes; use of protective products, i.e. "bother")</a></li> </ul>

- focused physical exam
- post void residual analysis
- urinary analysis, and urinary culture, if indicated

**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.

The numerator will be calculated using CPT codes. The timeframe is a follow up assessment at any point within 12 months of surgery. A focused physical exam includes an abdominal exam and a pelvic exam. Objective demonstration stress incontinence includes either incontinence demonstrated on pelvic exam when the patient coughs or performs a Valsava maneuver or stress incontinence is demonstrated through urodynamic testing.

Urinalysis is performed in all patients. If there is evidence of pyuria, bacteriuria or other findings suggestive of a possible urinary tract infection, then a urine culture should be obtained.

Claims data will be linked to identify follow up visits post surgery through the use of a physician's unique identifier, NPI. If a patient is seen postoperatively by the same NPI, then this meets the criteria.

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

Female patients who had SUI surgery without concomitant surgery for prolapse seen at follow up within one year post-treatment. Patients with concomitant surgery for prolapse were excluded from the denominator because these measures are based on the AUA SUI guidelines which focused on an index patient without concomitant prolapse surgery. Prolapse surgery patients complicate the interpretation of the quality measures for SUI surgery such as characterization of prolapse symptoms, documentation of the involved compartments, and the severity of prolapse of each of the compartments as part of the physical exam. These elements are not necessary for stress incontinence patients.

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

**2a1.7 Denominator Details** *(All information required to identify and calculate the target population/denominator such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*

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

The denominator will be calculated using CPT codes and patient characteristics, such as gender and age (adult patients). Concomitant prolapse surgery includes repair of cystocele, enterocele, rectocele or vaginal vault prolapse or hysterectomy performed due to uterine prolapse.

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

Documentation of medical reason(s) for not performing all or one of these elements (concomitant prolapse).

Documentation of patient reason(s) for not performing all or one of these elements (inability to make and keep an appointment with the treating physician due to relocation, incapacity, inability to travel).

Documentation of system reason(s) for not performing all or one of these elements (visits are not reimbursable by the patient's insurer)

**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.

Exclusions will be calculated using CPT II codes and patient characteristics, such as gender and age. Concomitant prolapse surgery includes repair of cystocele, enterocele, rectocele or vaginal vault prolapse or hysterectomy performed due to uterine prolapse. While prolapse patients should be seen by their surgeon postoperatively, these patients fall outside the scope of this measure set, based on the evidence from the AUA SUI guidelines.

Patients may travel long distances for surgery and may not be able to afford to travel again for a postoperative visit. In these instances, the assessment may be conducted via phone or performed by a local physician. The discharge summary will often specify the postop date or documentation of a phone call. It is important for the surgeon to take responsibility for arranging follow up, but there are instances where the follow up may occur locally.

**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.

**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.

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

**2a1.26 Data Source/Data Collection Instrument** (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):

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

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

### 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): GU/GYN : Incontinence

**De.5 Cross Cutting Areas** (Check all the areas that apply): Health and Functional Status

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

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

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

Stress urinary incontinence (SUI) is clinically defined as uncontrolled leakage of urine during events that result in increased abdominal pressure such as sneezing, coughing, physical exercise, lifting, bending and even changing positions [1]. Estimations of prevalence for SUI in women vary due to disparities in epidemiological methodologies, however recent studies suggest incidence rates ranging from 4% to 35% in the female population [2-4]. Millions of women are affected, thus there is a substantial financial burden not only for the healthcare system to manage and treat SUI, but also for the individual who pays routine care costs (e.g. pads, laundry, dry cleaning). The estimated annual direct cost of SUI treatment in the United States exceeded \$13 billion dollars (measured in 1995 USD) [5-7]. Furthermore, 29% of women with SUI describe their symptoms as moderately to extremely bothersome, reflecting the overall emotional and social burden that comes with the condition [8].

A 2005 study of complications associated with surgery for SUI determined overall incidence rates of 13.0%, including bleeding (2.8%), surgical injury (1.4%), and infection (4.4%) [9]. Similarly, hospital costs increased with morbidity: from \$7,918 to \$15,181 for those with 0 up to 2 complications, respectively. The percentage of patients requiring post-discharge home care increased with

morbidity as well from 4.4% for 0 complications to 14.3% for those with two complications.

- 1a.4 Citations for Evidence of High Impact cited in 1a.3:**
1. Dmochowski RR, Blaivas JM, Gormley EA, Juma S, Karram MM, Lightner DJ, Luber KM, Rovner ES, Staskin DR, Winters JC, et al: Update of AUA guideline on the surgical management of female stress urinary incontinence. *The Journal of urology* 2010, 183:1906-1914.
  2. Luber KM: The definition, prevalence, and risk factors for stress urinary incontinence. *Reviews in urology* 2004, 6 Suppl 3:S3-9.
  3. Hampel C, Artibani W, Espuna Pons M, Haab F, Jackson S, Romero J, Gavart S, Papanicolaou S: Understanding the burden of stress urinary incontinence in Europe: a qualitative review of the literature. *European urology* 2004, 46:15-27.
  4. Hampel C, Wienhold D, Benken N, Eggersmann C, Thuroff JW: Definition of overactive bladder and epidemiology of urinary incontinence. *Urology* 1997, 50:4-14; discussion 15-17.
  5. Cortes E, Kelleher C: Costs of female urinary incontinence. *Women's health med* 2005, 2:3-5.
  6. Wilson L, Brown JS, Shin GP, Luc KO, Subak LL: Annual direct cost of urinary incontinence. *Obstetrics and gynecology* 2001, 98:398-406.
  7. Chong EC, Khan AA, Anger JT: The financial burden of stress urinary incontinence among women in the United States. *Current urology reports* 2011, 12:358-362.
  8. Fultz NH, Burgio K, Diokno AC, Kinchen KS, Obenchain R, Bump RC: Burden of stress urinary incontinence for community-dwelling women. *American journal of obstetrics and gynecology* 2003, 189:1275-1282.
  9. Taub DA, Hollenbeck BK, Wei JT, Dunn RL, McGuire EJ, Latini JM: Complications following surgical intervention for stress urinary incontinence: a national perspective. *Neurourology and urodynamics* 2005, 24:659-665.

**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:**

The proposed measure is expected to encourage practitioners to perform an assessment of response to surgery for SUI within one year of treatment. This follow up within 12 months will provide better evaluation of the effectiveness of the procedure by allowing the patient to experience a transition back to a routine lifestyle and more appropriately rate the improvement of their symptoms. Follow up intervals after surgery can vary considerably among providers and at different institutions. Complications are a major concern as well as improvement of symptoms, and this measure emphasizes an appropriate time interval for post-surgery follow up.

**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. Here we summarize studies that report high variability in the timing and procedures for follow up after surgery for SUI, which indicates a potential performance gap/opportunity for improvement that would be addressed by the proposed measure.

Haliloglu and Rizk report in a 2010 editorial that there has been a lack of consensus in the urogynecological community regarding postoperative evaluation of the efficacy of surgical procedures for SUI [10]. Citing a recent study of 91 surgical series of SUI [11], the authors note that only 63% of the studies used both subjective and objective measures to define "cure" as an outcome. This large disparity in outcome definition explains differing cure/dry rates among similar studies analyzed by the authors.

In a retrospective review, Ballert et al. found that among a series of patients who underwent synthetic sling placement, success rates for patients lost to follow up were similar to those who appeared for routine follow up [12]. The overall failure rate of patients with at least 3-month follow up was 19% (23 of 124), indicating that a substantial number of failures can occur in the population of patients lost to follow up. Among patients with treatment failure who did not appear for follow up, the most common reason recorded was patient dissatisfaction. This suggests that a gap in performance for patient-centered care may exist with follow up. If providers could perform more rigorous follow up, they may be able to restore satisfaction of some patients with treatment failure.

In a postal questionnaire survey of surgeons in the United Kingdom known to perform continence surgery [14], there was substantial variability in opinion on the most appropriate time for follow up after intervention. Among the respondents, 26% of surgeons followed patients for 6 – 8 weeks after the surgery; 43% followed up routinely between 2 and 6 months, and only 31% followed up women for more than 6 months. Three percent of respondents failed to follow up patients routinely. Protocols for follow up also varied considerably: for example, urodynamic studies were routinely utilized by 26% of subspecialists, 9% of urologists, 8% of special interest urogynaecologists, but only 3% of general gynaecologists.

In a study by Cindolo and colleagues, the authors reported follow up examinations periodically at 7, 30 and 90 days from intervention (mean follow up 4 months, 1-8) for patients who underwent tension-free transobturator surgery for SUI [13].

In one study of tension-free vaginal tape (TVT) procedures, mean follow-up was 11.4 months with a range of 5 to 17 months [15]. In a similar study of TVT outcomes [16], patients were seen postoperatively at 6 weeks, 3, 6, 12 months and yearly after intervention. However, the authors noted that patients with poor follow up adherence probably have lower cure rates after TVT. In another study of patient outcomes after midurethral sling surgery, mean reported follow up of the study population was 14 months with a dramatic range of 2 to 34 months [17].

**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*)

10. Haliloglu B, Rizk DE: Subjective versus objective measurement of surgical outcomes of treatment of female stress urinary incontinence: it is not just black and white. International urogynecology journal 2010, 21:761-762.
11. Castillo PA, Espallat-Rijo LM, Davila GW: Outcome measures and definition of cure in female stress urinary incontinence surgery: a survey of recent publications. International urogynecology journal 2010, 21:343-348.
12. Ballert KN, Rose AE, Biggs GY, Rosenblum N, Nitti VW: Outcomes of patients lost to followup after mid urethral synthetic slings--successes or failures? The Journal of urology 2010, 183:1455-1458.
13. Cindolo L, Salzano L, Rota G, Bellini S, D'Aferio A: Tension-free transobturator approach for female stress urinary incontinence. Minerva urologica e nefrologica = The Italian journal of urology and nephrology 2004, 56:89-98.
14. Duckett JR, Jain S, Tamilselvi A, Moran PA, Richmond D: National audit of incontinence surgery in the United Kingdom. Journal of obstetrics and gynaecology : the journal of the Institute of Obstetrics and Gynaecology 2004, 24:785-793.
15. Groutz A, Gordon D, Wolman I, Jaffa AJ, David MP, Lessing JB: Tension-free vaginal tape for stress urinary incontinence: Is there a learning curve? Neurourology and urodynamics 2002, 21:470-472.
16. Wein AJ: Tension-free vaginal tape: do patients who fail to follow-up have the same results as those who do? The Journal of urology 2005, 174:1009-1010.
17. Houwert RM, Venema PL, Aquarius AE, Bruinse HW, Kil PJM, Vervest HAM: Predictive value of urodynamics on outcome after midurethral sling surgery for female stress urinary incontinence. American journal of obstetrics and gynecology 2009, 200:649.e641-612.

**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.

Data on population disparities specific to follow up after surgery for SUI are not currently available.

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

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

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

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

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

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

Does the concept pass subcriterion1c?  
Yes  IF rationale supports relationship

Please see the attached Evidence Submission Worksheet for evidence specifications.

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

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

Provide rationale based on specific subcriteria:

### 3. USABILITY

#### 4.1 Current and Planned Use

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

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

Current Use:

Planned Use:

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

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

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):

As a rule, AUA/ACOG seek to harmonize proposed measures with those currently in use for the same topics. For example, the first of the proposed measures "Complete Workup for Assessment of Stress Urinary Incontinence" describes procedures consistent with common standard practices. In developing the proposed set of measures, extant performance measures were considered and kept in mind but were of limited usefulness because they were designed to apply to urinary incontinence in general and to women over 65 years of age. In contrast, we required measures that focused on the surgical intervention for SUI in particular and included women under 65 year of age who constitute the majority of those affected by SUI.

### CONTACT INFORMATION

Co.1 Concept Steward (Intellectual Property Owner): American Urological Association, 1000 Corporate Boulevard | Linthicum | Maryland | 20910

Co.2 Point of Contact: Jennifer | Bertsch | [jbertsch@auanet.org](mailto:jbertsch@auanet.org) | 410-689-4043-

Co.3 Concept Developer if different from Concept Steward: American Urological Association | 1000 Corporate Boulevard | Linthicum | Maryland, 20910

Co.4 Point of Contact: Jennifer | Bertsch | [jbertsch@auanet.org](mailto:jbertsch@auanet.org) | 410-689-4043-

Co.5 Submitter: Jennifer | Bertsch | [jbertsch@auanet.org](mailto:jbertsch@auanet.org) | 410-689-4043- | American Urological Association

Co.6 Additional organizations that sponsored/participated in concept development:  
American Congress of Obstetricians and Gynecologists (ACOG)

Co.7 Public Contact: Jennifer | Bertsch | [jbertsch@auanet.org](mailto:jbertsch@auanet.org) | 410-689-4043- | American Urological Association

### ADDITIONAL INFORMATION

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

Ad.3 Year the concept was first released:

Ad.4 Month and Year of most recent revision:

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

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

Ad.7 Copyright statement: © 2012 American Urological Association. All Rights Reserved

Ad.8 Disclaimers: Physician Performance Measures (Measures) and related data specifications have been developed by the American Urological Association (AUA) and the American Congress of Obstetricians and Gynecologists (ACOG). These performance Measures are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications. Neither AUA, ACOG, the American Medical Association (AMA), the AMA-convened Physician Consortium for Performance Improvement® (PCPI™) nor its members shall be responsible for any use of the Measures. AUA and ACOG encourage use of these Measures by other health care professionals, where appropriate.

Ad.9 Additional Information/Comments:

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

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

**Measure Title:** [Follow up within one year of treatment](#)

**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: [2T](#)

Intermediate clinical outcome: [2T](#)

**Process:** [Follow up assessment within one year of SUI surgery](#)

Structure: [2T](#)

Other: [2T](#)

### 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 within one year of treatment >>

ensures that patients have had time to experience the effects on their daily lives that a reduction or elimination of SUI symptoms could provide >>

allows for a thorough examination of the patient post-surgery to evaluate the effectiveness of the procedure resulting in >>

additional case-specific information on procedural efficacy

If there is no postoperative assessment by the surgeon, then the surgeon cannot assess symptoms and quality of life. In addition, new problems can arise as a result of surgery and the physician must assess these issues. Certain complications, such as mesh erosion or extrusion, may not be identifiable without being seen and evaluated in the physician's office.



**1c.4.** Is there a guideline recommendation supporting the measure focus identified in 1c.1.? **Yes**

No  **If no, skip to #1c.6**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS**  
*(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)*

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

#### **QUANTITY AND QUALITY OF BODY OF EVIDENCE**

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

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

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

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

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

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

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

If yes,

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