

## 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 2050      NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012
<b>CONCEPT SPECIFICATIONS</b>
De.1 Concept Title: Patient counseling on treatment options, including behavioral and surgical treatments prior to SUI surgery
Co.1.1 Concept Steward: American Urological Association
De.2 Brief Description of Concept: Percentage of female patients who had SUI surgery for whom there was documentation that treatment options were discussed with the patient, including behavioral and surgical treatments, and expectations for treatment (discuss cure/dry rates)
2a1.1 Numerator Statement: Female patients who had SUI surgery for whom there was documentation that treatment options were discussed with the patient, including behavioral and surgical, and expectations for treatment (discuss cure/dry rates)
2a1.4 Denominator Statement: Female patients who had SUI surgery (without concomitant surgery for prolapse)
2a1.8 Denominator Exclusions: Documentation of medical reason(s) for not counseling patient (e.g. patients who had concomitant prolapse or who are severely cognitively impaired). Documentation of patient reason(s) for not counseling patient (patients who might be uncomfortable with the responsibility of making choices regarding their care).
1.1 Concept Type: Process 2a1. 25-26 Data Source: Administrative claims, Paper Medical Records 2a1.33 Level of Analysis: Clinician : Individual
1.2-1.4 Is this concept paired with another measure? No
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> Female patients who had SUI surgery for whom there was documentation that treatment options were discussed with the patient, including behavioral and surgical, and expectations for treatment (discuss cure/dry rates)
2a1.3 Numerator Details <i>(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)</i> <b>For new concepts</b> , describe how you plan to identify and calculate the numerator. The numerator will be calculated using CPT codes. The timeframe is within 12 months. Surgery includes, but is not limited to, pubovaginal and midurethral sling procedures, injection therapies, retropubic and laparoscopic suspensions, with at least one of these procedures being discussed. Behavioral treatment includes biofeedback, fluid restriction, pelvic floor muscle exercises, and timed voiding. Discussion on cure/dry rates should indicate that some patients are cured while others are improved. AUA SUI guidelines report cure/dry rates as follows: All suspensions at 12-23 months range from 69-82%. Slings at 12-23 months range from 74-90%. Collagen injectables at 12-23 months were approximately 48%.

However, individual results can vary considerably; the surgeon should discuss his/her specific rates with the patient.

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

Female patients who had SUI surgery (without concomitant surgery for prolapse)

**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. The timeframe is within 12 months. Concomitant surgery for prolapse includes repair of cystocele, enterocele, rectocele or vaginal vault prolapse or hysterectomy performed due to ureterine prolapse.

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

Documentation of medical reason(s) for not counseling patient (e.g. patients who had concomitant prolapse or who are severely cognitively impaired).

Documentation of patient reason(s) for not counseling patient (patients who might be uncomfortable with the responsibility of making choices regarding their care).

**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 codes and patient characteristics, such as gender.

**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): Patient and Family Engagement

1a.1 Demonstrated High Impact Aspect of Healthcare: A leading cause of morbidity/mortality; 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].

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.

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 provide improved counseling for the range of possible treatment options for SUI. Through this more detailed guidance, the patient will develop more accurate expectations of treatment results, reflect on the potential consequences of each treatment choice, and feel more involved in her own medical decisions.

Counseling patients on their treatment options, including behavioral and surgical choices is critical for providing patient-centered care that effectively qualifies the patient's expectations on improvement of symptoms and possible side effects after treatment. In addition, the FDA's 2011 warning on the use of vaginal mesh encourages healthcare providers to discuss the benefits and risks of surgical mesh with their patients, emphasizing that patients should be informed about possible complications and their effect on quality of life.

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. The following data from peer-reviewed literature demonstrate a performance gap/opportunity for improvement in establishing more consistent and detailed counseling of patients on the range of treatment options for SUI.

A Dutch study by Albers-Heitner and colleagues recognized that many UI patients get pads from their general practitioner (GP) without sufficient diagnostics or treatment. The authors used a postal survey to assess what further treatment UI patients receive from their GP in addition to pads and to measure patient satisfaction with their care. Out of 208 questionnaires, 29.3% of pad users had no direct communication with their GP for a pad prescription. Of 147 UI patients who visited their GP, only 50.3% successfully obtained pads. One out of four patients were not satisfied with the information on UI received from their GP, especially younger female patients [9].

One study found significant disagreement in the appropriate usage of the drug duloxetine to treat SUI. The recently released NICE guideline on management of female urinary incontinence advised that duloxetine should not routinely be utilized as a first-line treatment for women with stress predominant UI, or as a second-line treatment for stress UI, unless surgical treatment is contraindicated or declined. A total of 25-39% of practitioners who responded disagreed with these statements. The authors agreed stating "in an era of patient choice, this limits the choice of using the only available option of drug therapy for women with SUI. This has the effect of limiting treatment options for both the clinician and patient" [10].

The importance of setting realistic expectations for the patient in the improvement of symptoms was a point of focus for several studies. In a study of patients who underwent Burch colpopexy or autologous fascial sling for treatment of SUI, 82% were completely or mostly satisfied with their surgery related to urine leakage. In multivariate analysis, patient satisfaction was associated with greater reduction in SUI symptoms and greater reductions in symptom distress (OR = 1.16). The authors concluded that women with SUI who also have urge incontinence symptoms may benefit from additional counseling to set realistic expectations [11]. A second study of SUI patients undergoing fascial sling and Burch colposuspension procedures found that most women (98%) had an expectation that urine leakage would be completely or almost completely eliminated [12].

Another study evaluated changes in female sexual function after a transobturator vaginal tape operation and its correlation with patients' expectations. Sexual dysfunction is often reported after vaginal surgery. Overall 52 out of 62 treated women resumed their sexual activity early within 8 weeks after surgery [13]. There was a difference between the patient's sensation of vaginal length abnormalities during coitus (n=2) and patient expectation (n=18). The authors recommend counseling the patient for this procedure to correct false ideas and expectations about future sexual activity. A similar study of the tension-free vaginal tape procedure (TVT) found that from the patients' perspective, the overall success rate was 79%, whereas the authors' audit showed an overall success rate of 86%. Thus a patient's perception regarding the success of TVT often differed from that of the clinician, though not significantly (P = 0.22, McNemar test). Again the authors stated the importance of realistic cure rates when counseling patients for surgery [14].

In a prospective study of 100 women with SUI given options to select treatment, 22% patients chose major surgery, 39% minor surgery, 27% an office procedure and 12% medication. This was affected by age, symptom severity and quality of life influence. After clinical and urodynamic evaluation, 34% shifted to a different treatment modality; this correlated significantly with young age, severe symptoms, limited urethral mobility and low Valsalva leak point pressure. This study concluded that patients' initial choice for treatment of SUI is affected by age, symptom severity and quality of life; but more importantly, their final decision was more influenced by the clinical and urodynamic evaluation [15].

In a postal and email survey of American urologists (associated with the American Urological Association), Kim et al. assessed practice patterns in treating female incontinence [16]. For type I, II, and III stress urinary incontinence, 44%, 68%, and 94% of surveyed urologists, respectively, recommended a sling procedure as treatment. For type I SUI, older urologists were more likely than younger urologists to perform needle bladder neck suspension (P=0.001). Therefore, even among American urologists, there is significant disparity in recommended treatments for patients with SUI, which is likely influenced by the level and type of training for each practitioner.

**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*)

9. Albers-Heitner P, Berghmans B, Nieman F, Lagro-Janssen T, Winkens R: How do patients with urinary incontinence perceive care given by their general practitioner? A cross-sectional study. *International journal of clinical practice* 2008, 62:508-515.

10. Basu M, Duckett JR, Moran P, Freeman R: Clinicians' views on the NICE guideline on the management of female urinary incontinence. *Journal of obstetrics and gynaecology : the journal of the Institute of Obstetrics and Gynaecology* 2009, 29:529-532.

11. Burgio KL, Brubaker L, Richter HE, Wai CY, Litman HJ, France DB, Menefee SA, Siris LT, Kraus SR, Johnson HW, Tennstedt SL: Patient satisfaction with stress incontinence surgery. *Neurourology and urodynamics* 2010, 29:1403-1409.
12. Mallett VT, Brubaker L, Stoddard AM, Borello-France D, Tennstedt S, Hall L, Hammontree L, Urinary Incontinence Treatment N: The expectations of patients who undergo surgery for stress incontinence. *American journal of obstetrics and gynecology* 2008, 198:308.e301-306.
13. El-Enen MA, Ragb M, El Gamasy AE-N, El-Ashry O, El-Sharaby M, Elbadawy A, Fayed N: Sexual function among women with stress incontinence after using transobturator vaginal tape, and its correlation with patient's expectations. *BJU international* 2009, 104:1118-1123.
14. Manikandan R, Kujawa M, Pearson E, O'Reilly PH, Brown SC: Results of the tension-free vaginal tape procedure for stress incontinence: patient's perspective. *International journal of urology : official journal of the Japanese Urological Association* 2004, 11:206-212.
15. Elmissiry M, Mahdy A, Ghoniem G: Treatment of female stress urinary incontinence: what women find acceptable and the impact of clinical and urodynamic evaluation on their final choice. *Scandinavian journal of urology and nephrology* 2011, 45:326-331.
16. Kim HL, Gerber GS, Patel RV, Hollowell CM, Bales GT: Practice patterns in the treatment of female urinary incontinence: a postal and internet survey. *Urology* 2001, 57:45-48.

**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 counseling for SUI treatment options are not currently available. However, the following data from peer-reviewed literature demonstrate potential (but inconclusive) disparities in patient counseling with respect to rare/ethnicity.

Anger et al. analyzed Medicare claims data to identify racial differences in the diagnosis, treatment and outcomes of women with SUI. A total of 27,120 slings surgeries were performed on the Medicare population during the study period. Among women with a diagnosis of SUI, white and Hispanic women were significantly more likely to undergo a sling than were black or Asian women (p<0.01). The authors note that further research is needed to determine whether such differences are due to racial/cultural differences in SUI incidence or disparities in care for minorities [17].

A second study examined the prevalence, demographics and complications of SUI surgery stratified across races in the United States. Using data from the 2003 National Census and National Hospital Discharge Survey, the researchers revealed that by race, rates (per 10,000 women, 95% CI) of SUI surgery were: ten (7-12) in white women, three (0-9) in black women, and six (0-13) in women of other races. Though these results are not statistically significant, the authors state that this presents the possibility of racial disparities in the counseling/receipt of surgical choices for SUI [18].

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

17. Anger JT, Rodriguez LV, Wang Q, Chen E, Pashos CL, Litwin MS: Racial disparities in the surgical management of stress incontinence among female Medicare beneficiaries. *The Journal of urology* 2007, 177:1846-1850.
18. Shah AD, Kohli N, Rajan SS, Hoyte L: Surgery for stress urinary incontinence in the United States: does race play a role? *International urogynecology journal and pelvic floor dysfunction* 2008, 19:1085-1092.

**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 subcriterion 1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the concept pass subcriterion 1c? Yes <input type="checkbox"/> IF rationale supports relationship
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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:

0030 : Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment – A patient reported measure

0100 : Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

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:

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. Other existing endorsed measures focus on screening of patients in a primary care population. However, this measure set is limited to patients undergoing surgery.

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): [American Urological Association, 1000 Corporate Boulevard | Linthicum | Maryland | 21090](#)

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

Co.3 Concept Developer if different from Concept Steward: <a href="#">American Urological Association   1000 Corporate Boulevard   Linthicum   Maryland, 21090</a>
Co.4 Point of Contact: <a href="#">Jennifer   Bertsch   jbertsch@auanet.org   410-689-4043-</a>
Co.5 Submitter: <a href="#">Jennifer   Bertsch   jbertsch@auanet.org   410-689-4043-   American Urological Association</a>
Co.6 Additional organizations that sponsored/participated in concept development: <a href="#">American Congress of Obstetricians and Gynecologists (ACOG)</a>
Co.7 Public Contact: <a href="#">Jennifer   Bertsch   jbertsch@auanet.org   410-689-4043-   American Urological Association</a>

#### ADDITIONAL INFORMATION

<b>Concept Developer/Steward Updates and Ongoing Maintenance</b> 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: <a href="#">Physician Performance Measures (Measures)</a> and related data specifications have been developed by the <a href="#">American Urological Association (AUA)</a> and the <a href="#">American Congress of Obstetricians and Gynecologists (ACOG)</a> . 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 <a href="#">American Medical Association (AMA)</a> , the <a href="#">AMA-convened Physician Consortium for Performance Improvement® (PCPI™)</a> 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): <a href="#">Jul 16, 2012</a>

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

**Measure Title:** Patient counseling on treatment options, including behavioral and surgical treatments

**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:** [Counseling SUI patients on treatment options, including behavioral and surgical treatments](#)

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.)**

[Counseling the patient on her options for care of SUI >>](#)

[helps to ensure that the patient is not given more or less care than is required; enables the patient to participate in decision making about her treatment >>](#)

[avoidance of unnecessary SUI surgery; confirmation that SUI surgery was indicated; patient-centered care](#)

[As with any counseling measure, there is concern that the patient is receiving appropriate counseling, appropriate treatment or receiving the treatment they want. This measure ensures that the discussion of all management options are document which is likely to encourage a detailed discussion between doctor and patient. NQF has endorsed multiple counseling measures, such as counseling on tobacco cessation, physical activity in older adults, and the use of antioxidant supplements for patients with age-related macular degeneration.](#)



**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):**

Lucas MG, Bosch J, Cruz FR, Madden TB, Nambiar A, Neisius A, Pickard RS, de Ridder DJ, Tubaro A, Turner WH. *Guidelines on Urinary Incontinence*. European Association of Urology (EAU), 2012 Feb.

*Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update*. American Urological Association (AUA), 2009.

*Urinary incontinence: the management of urinary incontinence in women*. National Collaborating Centre for Women's and Children's Health Commissioned by the National Institute for Health and Clinical Excellence, London: RCOG Press, 2006 Oct.

*Urinary incontinence in women*. American College of Obstetricians and Gynecologists (ACOG). Washington (DC), ACOG practice bulletin; no. 63, 2005 Jun.

*Management of urinary incontinence in primary care – a national clinical guideline*. Scottish Intercollegiate Guidelines Network, 2004 Dec.

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

European Association of Urology (2012):

[http://www.uroweb.org/gls/pdf/18\\_Urinary\\_Incontinence\\_LR\\_June%203rd.pdf](http://www.uroweb.org/gls/pdf/18_Urinary_Incontinence_LR_June%203rd.pdf)

American Urological Association (2009):

<http://www.auanet.org/content/clinical-practice-guidelines/clinical-guidelines.cfm?sub=stress2009>

National Institute for Health and Clinical Excellence (2006):

<http://www.nice.org.uk/CG40>

American College of Obstetricians and Gynecologists (2005):

<http://guidelines.gov/content.aspx?id=10931>

Scottish Intercollegiate Guidelines Network (2004):

<http://www.sign.ac.uk/pdf/sign79.pdf>

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

European Association of Urology (2012): Guideline section 5 – pp. 64, 76-77, Guideline section 3.3 – p. 46

American Urological Association (2009): Standard – p. 30; Option – p. 31

National Institute for Health and Clinical Excellence (2006): Recommendation for surgical management – p. 86

American College of Obstetricians and Gynecologists (2005): Major recommendations section (Level B)

Scottish Intercollegiate Guidelines Network (2004): Guideline section 2.2 – p. 4

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

The following evidence statements are quoted verbatim from the referenced *clinical guidelines*:

European Association of Urology (2012):

“Some generic principles apply to good surgical practice. Any operation for UI should be preceded by a discussion with the patient and/or caregivers, about the purpose of the operation, the likely benefits and possible risks. It is also important to explain when there are alternative approaches, even if these procedures are not available locally.” (p. 64) – This is not an official recommendation, but a comment from the guideline.

**Recommendations for surgery for uncomplicated stress urinary incontinence in women (p. 76-77)**

- Offer the mid-urethral sling to women with uncomplicated stress urinary incontinence as the preferred surgical intervention whenever available. (Grade A)
- Offer colposuspension (open or laparoscopic) or autologous fascial sling to women with stress urinary incontinence if mid-urethral sling cannot be considered. (Grade A)
- Warn women who are being offered a retropubic insertion synthetic sling about the relatively higher risk of peri-operative complications compared to transobturator insertion. (Grade A)
- Warn women who are being offered transobturator insertion of mid-urethral sling about the higher risk of pain and dyspareunia in the longer term. (Grade A)
- Warn women undergoing autologous fascial sling that there is a high risk of voiding difficulty and the need to perform clean intermittent self-catheterisation; ensure they are willing and able to do so. (Grade A)

**Recommendations for behavioural and physical therapies (p.46)**

- Offer supervised PFMT, lasting at least 3 months, as a first-line therapy to women with stress or mixed urinary incontinence. (Grade A)
- Consider using biofeedback as an adjunct in women with stress urinary incontinence. (Grade A)

American Urological Association (2009):

**Standard:** The patient should be counseled regarding the surgical and nonsurgical options including both benefits and risks. Choice of the procedure should be made as a collaborative effort between the surgeon and patient and should consider both patient preferences and the surgeon’s experience and judgment.

**Option:** The five major types of procedures (injectables, laparoscopic suspensions, midurethral slings, pubovaginal slings and retropubic suspensions), although not equivalent, may be considered for the index patient.

National Institute for Health and Clinical Excellence (2006): Any woman wishing to consider surgical treatment for UI should be informed about the benefits and risks of surgical and non-surgical options. Counselling should include consideration of the woman's childbearing wishes.

American College of Obstetricians and Gynecologists (2005): Long-term data suggest that Burch colposuspension and sling procedures have similar objective cure rates; therefore, selection of treatment should be based on patient characteristics and the surgeon's experience.

Scottish Intercollegiate Guidelines Network (2004): Patients with urinary incontinence should be offered information and advice on the treatment options available to them in both primary and secondary care.

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

European Association of Urology (2012): (Grades for each EAU recommendation are specified in **1c.4.4** above.) Definitions: Grade **A** – Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial.

American Urological Association (2009): Graded treatment guidelines for the index patient:

**Standard:** A guideline statement is a standard if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred; **Option:** A guideline statement is an option if (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or (2) preferences are unknown or equivocal.

National Institute for Health and Clinical Excellence (2006): Grade **D (GPP)** - A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group.

American College of Obstetricians and Gynecologists (2005): Grade **Level B** - Recommendations are based on limited or inconsistent scientific evidence.

Scottish Intercollegiate Guidelines Network (2004): (Guideline section 2.2) Grade **D** – Evidence level 3 or 4; or extrapolated evidence from studies rated as 2<sup>+</sup>. (See **1c.5.1** for evidence level definitions.)

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

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

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

European Association of Urology (2012): Body of evidence grades described by this guideline are not directly associated with the proposed measure, but rather support each specific recommendation's benefits and risks, which are then translated into recommendations for counseling the patient. Nevertheless, the body of evidence grades associated with these recommendations are levels **1a**, **1b**, and **2**: **1a** is defined as evidence obtained from meta-analysis of randomised trials; **1b** is defined to be evidence obtained from at least one randomised trial; **2** is defined as evidence obtained from at least one other type of well-designed quasi-experimental study.

American Urological Association (2009): **Standard** – No grade provided for body of evidence associated with this specific recommendation, but states that the guideline was based on “Panel Consensus”; **Option** – No grade provided for body of evidence associated with this specific recommendation, but states that the guideline was based on “Panel Consensus.”

National Institute for Health and Clinical Excellence (2006): No grade provided for body of evidence associated with this specific recommendation, but states that recommendation is “based on the experience of the Guideline Development Group.”

American College of Obstetricians and Gynecologists (2005): No grade provided for body of evidence associated with this specific recommendation, but states that the recommendation is “based on limited or inconsistent scientific evidence.”

Scottish Intercollegiate Guidelines Network (2004): Body of evidence grade: 3 – non-analytic studies, e.g. case reports, case series; 4 – expert opinion.

**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:**

European Association of Urology (2012): 2008-2012

Scottish Intercollegiate Guidelines Network (2004): 1995-2003

**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)**

European Association of Urology (2012): The body of evidence for these recommendations is not directly associated with the proposed measure, but rather the specific procedures themselves.

Scottish Intercollegiate Guidelines Network (2004): 2 cross-sectional survey studies; 2 randomized controlled trials; 1 case series; 1 study of unknown design

**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)**

European Association of Urology (2012): The body of evidence for these recommendations is not directly associated with the proposed measure, but rather the specific procedures themselves.

Scottish Intercollegiate Guidelines Network (2004): The quality of evidence for this guideline was classified as grade 3/4 suggesting the associated studies were limited to non-analytic comparisons and expert opinion, but otherwise no quality assessment was described.

**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)**

European Association of Urology (2012): No quantified estimated benefits were provided.

Scottish Intercollegiate Guidelines Network (2004): No quantified estimated benefits were provided.

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

European Association of Urology (2012): No description of any harm was associated with this proposed measure.

Scottish Intercollegiate Guidelines Network (2004): No description of any harm was associated with this guideline or proposed measure.

**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.**