

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 2049 NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012
CONCEPT SPECIFICATIONS
De.1 Concept Title: Complete Workup for Assessment of Stress Urinary Incontinence Prior to Surgery
Co.1.1 Concept Steward: American Urological Association
De.2 Brief Description of Concept: Percentage of female patients who had SUI surgery and who received a complete workup assessing stress urinary incontinence and for whom SUI is objectively demonstrated within 12 months prior to surgery
2a1.1 Numerator Statement: Female patients who received the following as part of their complete workup within 12 months prior to surgery: Characterization of incontinence: focused history (questions asked of patient: duration of incontinence; number of episodes; use of protective products; i.e. "bother") focused physical exam; objective demonstration of stress incontinence; post void residual analysis; urinary analysis and urine culture, if indicated
2a1.4 Denominator Statement: All female patients who had SUI surgery without concomitant surgery for prolapse. 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. Prolapse patients should be excluded prior to SUI surgery to avoid potential complications.
2a1.8 Denominator Exclusions: Documentation of medical reason(s) for not performing a complete workup for assessment of stress urinary incontinence (such as prolapse; cognitive impairment limiting characterization of SUI--information might be obtained via caregiver).
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 (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): Female patients who received the following as part of their complete workup within 12 months prior to surgery: Characterization of incontinence: focused history (questions asked of patient: duration of incontinence; number of episodes; use of protective products; i.e. "bother") focused physical exam; objective demonstration of stress incontinence; post void residual analysis;

urinary analysis and urine 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 12 months. 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.

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

All female patients who had SUI surgery without concomitant surgery for prolapse.

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. Prolapse patients should be excluded prior to SUI surgery to avoid potential complications.

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 a complete workup for assessment of stress urinary incontinence (such as prolapse; cognitive impairment limiting characterization of SUI--information might be obtained via caregiver).

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 age (adult population) and gender. Concomitant prolapse surgery includes repair of cystocele, enterocele, rectocele or vaginal vault prolapse or hysterectomy performed due to uterine prolapse.

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 : Gynecology](#)

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

1a.1 **Demonstrated High Impact Aspect of Healthcare:** [Affects large numbers; 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 clinical workup assessment for SUI is critical for defining appropriate treatment options and providing patient-centered care. The proposed measure is expected to encourage a more thorough evaluation of patients with suspected SUI. This improvement in quality for the initial assessment of the patient will more accurately determine if the patient does in fact have SUI and if so, the corresponding degree of severity. Ultimately, this enhanced information will better guide treatment decisions, preventing over- or under-treatment of the condition.

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 complete workup protocols for assessment of SUI by practitioners.

A recent evaluation of 100 participating gynecologists aimed to determine to what extent current clinical practice correlated with recommendations released by the International Continence Society [9]. Responding to a scenario with a female patient exhibiting genuine SUI symptoms, ninety-five participants (95%) requested a midstream urine sample for culture and sensitivity, 74% of the participants considered urodynamics an appropriate initial investigation, and 76% recommended physiotherapy as a first line treatment for the SUI patient. Overall, this study demonstrated a concerning degree of variability in the evaluation and management of patients who present with symptoms of stress urinary incontinence.

One study evaluating adherence to the Guideline on Urinary Incontinence of the Dutch College of General Practitioners found that with respect to initial assessment, a bladder diary was only utilized by 35% of participating Dutch general practitioners [10]. The authors concluded that overall compliance with diagnostic recommendations was "good," but that guidelines are only followed partially by general practitioners.

In 2009, a survey study investigating the opinions of members of the British Society of Urogynaecology regarding recommendations contained in the 2006 NICE guideline: The management of female urinary incontinence found that only 51% of responders strongly agreed that three-day bladder diaries should be used in the initial assessment of patients [11]. Additionally, 80% of respondents disagreed or "strongly disagreed" that cystometry was not necessary in clinically pure SUI patients prior to treatment. Finally, the authors concluded that over half of the respondents would not modify their practice protocols to fully comply with the NICE recommendations. This suggests that even with modern practice guidelines, there can be significant disagreement over protocols for workup of the patient.

One postal survey study performed in the United Kingdom showed that about 10% of responding specialists performed continence surgery without proper evaluation; and that although preoperative cystometry in women undergoing surgery for SUI is considered a marker of good practice, 14% of general gynaecologists do not always perform urodynamic investigations [12].

A study evaluating the utilization of urodynamic investigations by gynecologists in the UK, USA, Australia, New Zealand, and Canada revealed that when evaluating patients with stress incontinence, cystometry was utilized by 72% of subspecialists and 44% of generalists, and uroflowmetry was utilized by 73% of subspecialists and 46% of generalists. The authors concluded that this high variability between gynecologist subgroups could be explained by disparities in the understanding of preoperative evaluation methods [13].

Recently a standardized tool was developed to improve diagnosis of male and female patients with particular incontinence conditions [14]. The questionnaire addressed issues associated with stress, urge, frequency, or urinary obstructive symptoms relevant to a complete clinical workup of the patient. This tool, called the Urinary Symptoms Profile, was only developed in 2008, reflecting the continuing advancement of workup strategies for patients with suspected urinary incontinence.

In a systematic literature review by Rovner and colleagues [15], the authors sought to assess whether the recommendations proposed by the American Urological Association (AUA) Female Stress Urinary Incontinence Clinical Guidelines were adhered to in published literature. With respect to preoperative evaluation, 100% of collected studies performed a history and physical examination on each patient. However, other workup procedures such as a bladder diary, pad test, urodynamic study, and assessment of urgency exhibited a wide range of utilization rates. For example, bladder diary usage was documented less than

25% of retrieved studies. The authors noted that the absence of documentation for these procedures does not necessarily mean they were not performed.

Office-based primary care physicians also display wide variation in the initial workup and diagnosis of potential SUI. A questionnaire study of 211,648 patients consulting office-based primary care physicians determined that patients with symptoms of stress incontinence (according to the questionnaire) were undiagnosed by their physician in 38.1% of cases [16]. The authors believe that educational programs for patients and physicians are needed to improve the quality of diagnosis and treatment for urinary incontinence. This variability was supported by an additional study of 1,500 family physicians in Canada. Only 35.0% of respondents felt very comfortable dealing with incontinence. Physical examination, urodynamic studies, urinalysis, and testing blood sugar levels were all considered important investigations by more than 90% of the respondents [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)

9. Agnew G, Byrne P: The evaluation and treatment of female urinary incontinence--a comparison of clinical practice in the Republic of Ireland with the recommendations of the International Continence Society. *Irish medical journal* 2004, 97:238-240.
10. Albers-Heitner P, Berghmans B, Nieman F, Lagro-Janssen T, Winkens R: Adherence to professional guidelines for patients with urinary incontinence by general practitioners: a cross-sectional study. *Journal of evaluation in clinical practice* 2008, 14:807-811.
11. 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.
12. 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.
13. Duggan PM, Wilson PD, Norton P, Brown AD, Drutz HP, Herbison P: Utilization of preoperative urodynamic investigations by gynecologists who frequently operate for female urinary incontinence. *International urogynecology journal and pelvic floor dysfunction* 2003, 14:282-287; discussion 286-287.
14. Haab F, Richard F, Amarenco G, Coloby P, Arnould B, Benmedjahed K, Guillemain I, Grise P: Comprehensive evaluation of bladder and urethral dysfunction symptoms: development and psychometric validation of the Urinary Symptom Profile (USP) questionnaire. *Urology* 2008, 71:646-656.
15. Rovner ES, Wright CJ, Messer H: Adherence to the 1997 American Urological Association guidelines for the surgical treatment of stress urinary incontinence. *Urology* 2008, 71:239-242.
16. Goepel M, Hoffmann JA, Piro M, Rubben H, Michel MC: Prevalence and physician awareness of symptoms of urinary bladder dysfunction. *European urology* 2002, 41:234-239.
17. Swanson JG, Skelly J, Hutchison B, Kaczorowski J: Urinary incontinence in Canada. National survey of family physicians' knowledge, attitudes, and practices. *Canadian family physician Medecin de famille canadien* 2002, 48:86-92.

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 disparities regarding the level of detail associated with workup for SUI are not available. However, the following data from peer-reviewed literature demonstrate that there is substantial disparity in healthcare seeking behavior for different subgroups of women suffering from urinary incontinence. This supports the notion that a complete workup of patients will promote patient-centered care and better education the female population about this condition.

One 2011 cross-sectional study recently aimed to examine the prevalence of (and barriers to) healthcare seeking amongst a population-based sample of black and white community-dwelling women (ages 35-64) with self-reported UI [18]. Of 571 interviewed women (278 black and 293 white) self-identified as having urinary incontinence, 51% responded that they had sought care from a healthcare provider. There was no statistically significant difference between the two races (53% black, 50.6% white, $P=?.64$) in those seeking care. In the subset of women who talked to a healthcare provider about their incontinence, racial disparities were found in usage of Kegels (20.7% black, 32.7% white, $p=0.02$), fluid restriction (21.7% black, 10.7% white, $p=0.007$), and avoidance of problematic activities (5.4% black, 0.5% white, $p=0.002$). The authors state that while no significant differences were noted between races regarding reasons for not seeking care for UI, the vast majority of the women surveyed admitted that they did not discuss UI with a doctor because they felt that it could not be effectively treated. This study indicates that there are disparities in treatment for UI with respect to race, and that targeted education bears the potential to assist women suffering from UI.

A recent large-scale survey aimed to determine predictors of health care utilization in women over 40 years of age with urinary

incontinence (UI) from the Bladder Health Survey (BHS) [19]. The overall prevalence of any UI based on responses to the BHS was 1,618/4,064 (40%). Of the 1,618 women with UI, there were only 398 (25%) women with clinical diagnosis of UI. After adjusting for confounders, variables significantly associated with clinical UI diagnosis included: older age (OR=?1.96), higher parity (>?1 birth) (OR=?1.76), higher urgency UI (OR=?1.08), adaptive behavior (OR=?1.2), and UI bother scores (OR=?1.01), as well as more frequent outpatient visits (OR=?1.03), $P<?0.05$. The authors concluded that while UI is highly prevalent condition in women, only a minority seek care, and that factors associated with health care seeking behavior include older age, parity (1+), number of doctor visits, urgency UI subtype, and UI bother.

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

18. Berger MB, Patel DA, Miller JM, Delancey JO, Fenner DE: Racial differences in self-reported healthcare seeking and treatment for urinary incontinence in community-dwelling women from the EPI Study. *Neurourology and urodynamics* 2011, 30:1442-1447.

19. Minassian VA, Yan X, Lichtenfeld MJ, Sun H, Stewart WF: Predictors of care seeking in women with urinary incontinence. *Neurourology and urodynamics* 2012, 31:470-474.

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 <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
 0098 : Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older – an administrative measure
 0099 : Urinary Incontinence: Characterization of 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?

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.

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

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

Co.5 Submitter: [Jennifer | Bertsch | 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 | 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: [Complete workup for assessment of stress urinary incontinence](#)

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: [Complete workup for assessment of stress urinary incontinence prior to 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.)

A complete workup within 12 months prior to surgery for stress urinary incontinence (SUI) results in improved determination of whether the patient suffers from SUI & improved diagnosis of the severity of SUI leading to avoidance of unnecessary SUI surgery; helps the provider/patient select the most appropriate treatment resulting in maximized patient functioning and decrease in SUI symptoms. The indication to perform SUI surgery includes multiple factors such as responsiveness to previous therapy, and patient expectations and desires, so this is a “preference-sensitive” surgery. Therefore, it is difficult to identify “appropriate” or “inappropriate” use of the surgery. The requirements for objective identification of incontinence do address this at least in part because of the avoidance of unnecessary surgery for patients who do not have stress incontinence.

SUI is a very subjective condition and the concept of “bother” is important. Some women are very bothered by minimal incontinence and others are not bothered by severe amounts of leakage. This is elective surgery driven by patient desire for symptom improvement or resolution; this predicates

surgery. Also, if different types and intensities of interventions (i.e. sling vs. bulking) are offered, this is clearly a patient choice balanced against expectations and risks/benefits.

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):

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

Fritel X, Fauconnier A, Bader G, Cosson M, Debodinance P, et al. *Diagnosis and management of adult female stress urinary incontinence: Guidelines for clinical practice by the French College of Gynaecologists and Obstetricians.* French College of Gynaecologists and Obstetricians, 2009 Dec.

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.

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

American Urological Association (2009):

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

French College of Gynaecologists and Obstetricians (2009):

<http://www.ejog.org/article/S0301-2115%2810%2900107-7>

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>

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

American Urological Association (2009): Diagnostic guidelines for the index patient: standard – p. 16; diagnostic guidelines for the index patient: recommendation – p. 16.

French College of Gynaecologists and Obstetricians (2009): Guideline section 1.1 – p. 5; guideline section 1.2 – p. 6.

National Institute for Health and Clinical Excellence (2006): 2.1 Key recommendation – p. 11.

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

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

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

American Urological Association (2009):

Standard: The evaluation of the index patient should include the following components: focused history, focused physical examination, objective demonstration of SUI, assessment of postvoid residual urine volume, and urinalysis and culture if indicated.

Recommendation: Elements of the history should include the following: characterization of incontinence (stress, urgency, etc.), frequency, bother and severity of incontinence episodes, impact of symptoms on lifestyle, and patient's expectations of treatment.

French College of Gynaecologists and Obstetricians (2009):

(Guideline section 1.1) In a patient consulting for urinary incontinence, it is recommended that the circumstances, frequency and severity of leaks of urine be specified ... The cough test is recommended for documenting stress urinary incontinence prior to surgery ... It is recommended to assess urethral mobility prior to urinary incontinence surgery.

(Guideline section 1.2) In case of pure stress urinary incontinence, urodynamic investigations are not essential prior to surgery provided the clinical assessment is fully comprehensive (standardised questionnaire, cough test, bladder diary, establishment of postvoid residual volume) with concordant results.

National Institute for Health and Clinical Excellence (2006): At the initial clinical assessment, the woman's UI should be categorised as stress UI, mixed UI, or urge UI/OAB. Initial treatment should be started on this basis.

American College of Obstetricians and Gynecologists (2005): Patients with urinary incontinence should undergo a basic evaluation that includes a history, physical examination, measurement of postvoid residual volume and urinalysis.

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

American Urological Association (2009): Graded diagnostic 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.

Recommendation: A guideline statement is a recommendation if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) an appreciable, but not unanimous majority agrees on which intervention is preferred.

French College of Gynaecologists and Obstetricians (2009):

(Guideline section 1.1) Grade **B** - represents a scientific presumption; also Grade **C** – based on a low level

of evidence, generally founded on LE3 (case-control studies) or LE4 (non-randomised comparative studies with large biases, retrospective studies, transversal studies, series of cases).

(Guideline section 1.2) Grade **C** – based on a low level of evidence, generally founded on LE3 (case-control studies) or LE4 (non-randomised comparative studies with large biases, retrospective studies, transversal studies, series of cases).

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 C** - Recommendations are based primarily on consensus and expert opinion.

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:

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.”

Recommendation – No grade provided for body of evidence associated with this specific recommendation, but states that the guideline was based on “Panel Consensus.”

French College of Gynaecologists and Obstetricians (2009):

(Guideline section 1.1) Body of evidence grades: LE2 – Not very powerful randomised trials, well-run non randomised comparative studies, cohort studies; LE4 – non-randomised comparative studies with large biases, retrospective studies, transversal studies, series of cases).

(Guideline section 1.2) No grade provided for body of evidence associated with this specific recommendation, but rated as PC (professional consensus), i.e. “agreement between all the members of the working group.”

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 primarily on consensus and 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:

French College of Gynaecologists and Obstetricians (2009): (Guideline section 1.1) – 2009-2009.

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)

French College of Gynaecologists and Obstetricians (2009): (Guideline section 1.1) – not described.

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)

French College of Gynaecologists and Obstetricians (2009): (Guideline section 1.1) – not 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)

French College of Gynaecologists and Obstetricians (2009): (Guideline section 1.1) – No quantified estimated benefits were provided.

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

French College of Gynaecologists and Obstetricians (2009): (Guideline section 1.1) – No description of any harm was associated with this guideline.

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.