

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 2052 NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012
CONCEPT SPECIFICATIONS
De.1 Concept Title: Reduction of Complications through the use of Cystoscopy during Surgery for Stress Urinary Incontinence
Co.1.1 Concept Steward: American Urological Association
De.2 Brief Description of Concept: Percentage of SUI surgeries for which cystoscopy was used during the surgical procedure to reduce complications
2a1.1 Numerator Statement: Female patients who had SUI surgery for which cystoscopy was used during the surgical procedure to reduce complications
2a1.4 Denominator Statement: Female patients who had SUI surgeries (without concomitant surgery for prolapse)
2a1.8 Denominator Exclusions: Documentation of medical reason(s) for not using cystoscopy during SUI surgery (patients for whom the use of a cystoscope may not be appropriate, such as the presence of a new cystostomy repair). The panel noted that endoscopy after a new repair should be cautiously used. Concomitant prolapse surgery is an exclusion.
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 which cystoscopy was used during the surgical procedure to reduce complications
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> For new concepts, describe how you plan to identify and calculate the numerator. The numerator will be calculated using CPT codes.
2a1.4 Denominator Statement <i>(Brief, narrative description of the target population being measured):</i> Female patients who had SUI surgeries (without concomitant surgery for prolapse)
2a1.5 Target Population Category <i>(Check all the populations for which the concept is specified and tested if any):</i> Adult/Elderly Care, Maternal Health, Senior Care
2a1.7 Denominator Details <i>(All information required to identify and calculate the target population/denominator such as definitions,</i>

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 using cystoscopy during SUI surgery (patients for whom the use of a cystoscope may not be appropriate, such as the presence of a new cystostomy repair). The panel noted that endoscopy after a new repair should be cautiously used. Concomitant prolapse surgery is an exclusion.

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 and age.

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):* Safety : Complications

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.

Oliphant and colleagues found a substantial increase in SUI surgeries using the National Hospital Discharge Survey (NHDS) from 1979 to 2004 [10]. The number of women who underwent SUI surgery per year increased from 48,345 in 1979 to 103,467 in 2004, corresponding to a 2004 incidence rate of 85 per 100,000 women. This was very consistent with the Wu et al. study, which reported 106,862 women underwent SUI procedures in 2004 with a crude incidence rate of 97.9 per 100,000 women [11]. With regard to complications associated with SUI surgery, the authors found an overall complication rate of 20.2% reflecting various scenarios including: urinary tract infection/cystitis/pyelonephritis, accidental puncture, fever, catheter-related infection, and anemia.

Cystoscopy was recorded as a concomitant procedure in only 14% of the women. Most often, intraoperative cystoscopy during surgery for SUI is imperative for detecting bladder injury and repairing accidental puncture, which were documented in 1.42% of all SUI surgeries during the study period.

In a 2007 study, Duckett et al. performed a retrospective review of 100 women who underwent SUI tension-free vaginal tape (TVT) surgery with routine cystoscopy [12]. Overall, they found that 19% women had abnormalities identified by cystoscopy including carcinoma (1), fibroid (1), erythematous patches (6), petechial haemorrhages (6), and bladder perforation (5). The authors concluded that cystoscopy is a low risk procedure and should be performed in all women undergoing surgery for incontinence.

In a postal/email questionnaire study to 720 surgeons, Abdel-fattah and Ramsey assessed the views and practice regarding the transobturator tape procedures, noting that of the respondents, only 31.4% utilized routine cystoscopy as part of SUI procedures [13]. In another survey of 231 gynaecologic surgeons, Farrell et al. reported that only 48% of respondents used intraoperative cystoscopy routinely (primarily for during TVT procedures) [14]. This study also pointed to an earlier MEDLINE literature review [15] that found the use of intraoperative cystoscopy led to the detection of 90% of unsuspected ureteric injuries and 85% of bladder injuries during gynaecologic surgery.

In a study of the TVT procedure learning curve for surgeons [16], 23 residents performed 278 total procedures, which were then assessed by cystoscopy. Overall, the less experienced residents missed 35 of 95 injuries (37%) on initial cystoscopic inspection. This indicates that surgeon experience is critical for TVT procedures, as well as cystoscopic training during residency to detect injuries. In a smaller analysis of the TVT learning curve, Groutz et al. found that in a series of 30 procedures, 17% of women experienced bladder perforations, all of which were detected by intraoperative cystoscopy [17].

From a large case series of 524 patients undergoing TVT, Neuman reported that 68 (13%) had TVT bladder penetrations, all of which were diagnosed and corrected during surgery [18]. The author advocates for "meticulous" cystoscopy as part of any TVT procedure to detect and repair injury.

Intraoperative cystoscopy increases the overall safety of the patient during surgery for SUI, and so this proposed measure aims to expand this practice.

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.
10. Oliphant SS, Wang L, Bunker CH, Lowder JL: Trends in stress urinary incontinence inpatient procedures in the United States, 1979-2004. *American journal of obstetrics and gynecology* 2009, 200:521 e521-526.
11. Wu JM, Gandhi MP, Shah AD, Shah JY, Fulton RG, Weidner AC: Trends in inpatient urinary incontinence surgery in the USA, 1998-2007. *International urogynecology journal* 2011, 22:1437-1443.
12. Duckett J, Aggarwal I, Basu M, Vella M, Patil A: The value of cystoscopy and bladder biopsy taken at the time of tension-free vaginal tape insertion. *Journal of obstetrics and gynaecology : the journal of the Institute of Obstetrics and Gynaecology* 2007, 27:297-299.
13. Abdel-Fattah M, Ramsay I: Transobturator tension free vaginal tapes: are they the way forward in the surgical treatment of urodynamic stress incontinence? *International journal of surgery* 2007, 5:3-10.
14. Farrell SA, Baskett TF, Baydock S: The use of intraoperative cystoscopy by general gynaecologists in Canada. *Journal of obstetrics and gynaecology Canada : JOGC = Journal d'obstetrique et gynecologie du Canada : JOGC* 2009, 31:48-53.
15. Gilmour DT, Dwyer PL, Carey MP: Lower urinary tract injury during gynecologic surgery and its detection by intraoperative cystoscopy. *Obstetrics and gynecology* 1999, 94:883-889.
16. McLennan MT, Melick CF: Bladder perforation during tension-free vaginal tape procedures: analysis of learning curve and risk factors. *Obstetrics and gynecology* 2005, 106:1000-1004.
17. 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.
18. Neuman M: Trans vaginal tape readjustment after unsuccessful tension-free vaginal tape operation. *Neurourology and urodynamics* 2004, 23:282-283.

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 utilize cystoscopy during surgery for SUI. This safety precaution will enable surgeons to immediately repair areas damaged during SUI surgery, thereby reducing the post-surgical complication rate, and minimizing patient recovery time.

The benefits of cystoscopy outweigh the harms to the patient; the addition of cystoscopy introduces no additional risk to the patient but the avoidance of bladder injury is significant. One of the known complications of surgery is mesh erosion or extrusion, and the only way to ensure proper mesh placement is through the use of cystoscopy.

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 utilization of cystoscopy to augment surgical treatment for SUI.

Although it is largely acknowledged that intraoperative cystoscopy improves safety for the patient, multiple studies have stated that cystoscopy is not necessary, and that it is economical to avoid performing the technique [10-12].

Wang et al. studied the frequency of lower urinary tract injury for women with SUI undergoing the tension-free vaginal tape procedure with or without concomitant procedures [13]. All study subjects underwent intraoperative cystoscopy; the bladder perforation rate related to the TVT device was 0.8% (5/600). The authors concluded that due to a high rate of reported bladder injury in literature, intraoperative urethroscopy is imperative in the TVT procedure.

Gill et al. reported that routine usage of cystoscopy was effective for patients undergoing the Burch procedure for SUI. One obstructed left ureter was detected by cystoscopy and relieved by the release of left paravaginal repair sutures. No unsuspected injuries that were detected by cystoscopy were attributable to the Burch procedure. The authors discuss other literature reporting the usage of cystoscopy, and note that without the technique, reported injuries during surgery were significantly lower: only 12% of injuries to the lower urinary tract were detected at the time of surgery [14].

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. Fischer A, Fink T, Zachmann S, Eickenbusch U: Comparison of retropubic and outside-in transoburator sling systems for the cure of female genuine stress urinary incontinence. *European urology* 2005, 48:799-804.
11. Abdel-Fattah M, Ramsay I, Pringle S: Lower urinary tract injuries after transoburator tape insertion by different routes: a large retrospective study. *BJOG : an international journal of obstetrics and gynaecology* 2006, 113:1377-1381.
12. Cindolo L, Salzano L, Rota G, Bellini S, D'Aferio A: Tension-free transoburator approach for female stress urinary incontinence. *Minerva urologica e nefrologica = The Italian journal of urology and nephrology* 2004, 56:89-98.
13. Wang AC: The techniques of trocar insertion and intraoperative urethroscopy in tension-free vaginal taping: an experience of 600 cases. *Acta obstetrica et gynecologica Scandinavica* 2004, 83:293-298.
14. Gill EJ, Elser DM, Bonidie MJ, Roberts KM, Hurt WG: The routine use of cystoscopy with the Burch procedure. *American journal of obstetrics and gynecology* 2001, 185:345-348.

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 intraoperative cystoscopy with 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 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 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:

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

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?

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 | 20910](#)

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, 20910](#)

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: Reduction of complications through the use of cystoscopy during surgery for 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: Reduction of complications through the use of cystoscopy during surgery for stress urinary incontinence

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.)

The use of cystoscopy during surgery for SUI >>

allows surgeons to detect and correct problems (e.g. torn tissue) and promotes overall patient safety >>

avoids the need for subsequent surgery and provides care as soon as it is needed leading to >>

greater improvement in quality of life and a reduction in subsequent health care utilization required to address complications

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.

Pelvic organ prolapse. American College of Obstetricians and Gynecologists (ACOG). Washington (DC), ACOG practice bulletin; no. 85, 2007 Sep.

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

American Urological Association (2009):

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

American College of Obstetricians and Gynecologists (2007):

<http://guidelines.gov/content.aspx?id=12624>

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

European Association of Urology (2012): Guideline section 5.1 – p. 77

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

American College of Obstetricians and Gynecologists (2007): 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*:

European Association of Urology (2012): Do a cystoscopy as part of retropubic insertion of a mid-urethral sling, or if difficulty is encountered during transobturator sling insertion, or if there is a significant cystocele.

American Urological Association (2009): **Standard:** Intraoperative cystourethroscopy should be performed in all patients undergoing sling surgery.

American College of Obstetricians and Gynecologists (2007): Cystoscopy should be performed intraoperatively to assess for bladder or ureteral damage after all prolapse or incontinence procedures during which the bladder or ureters may be at risk of injury.

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

European Association of Urology (2012): Grade **C** – Made despite the absence of directly applicable clinical studies of good quality.

American Urological Association (2009): **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.

American College of Obstetricians and Gynecologists (2007): 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:

European Association of Urology (2012): No grade provided for body of evidence associated with this specific recommendation. Recommendation based on expert opinion rather than available literature.

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.”

American College of Obstetricians and Gynecologists (2007): 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:

The three guidelines cited: European Association of Urology (2012), American Urological Association (2009), and American College of Obstetricians and Gynecologists (2007) do not report a body of evidence for this specific recommendation, but rather indicate consensus and expert opinion.

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.