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 2051 NQF Project: GI and GU Project

Date Submitted: Jul 16, 2012

CONCEPT SPECIFICATIONS

De.1 Concept Title: Patients Counseled About Risks Associated with the Use of Mesh in Sling Surgery Prior to Surgery

Co.1.1 Concept Steward: American Urological Association

De.2 Brief Description of Concept: Percentage of female patients who undergo mesh sling surgery for whom there was documentation that they were counseled about the risks associated with the use of mesh in sling surgery (erosion/extrusion, pain, permanence) prior to surgery

2a1.1 Numerator Statement: Female patients who undergo mesh sling surgery for whom there was documentation that they had been counseled about the risk of mesh erosion/extrusion, pain, and permanence prior to performing a mesh sling surgery

2a1.4 Denominator Statement: All female patients who undergo Mesh sling surgery (without concomitant surgery for prolapse)

2a1.8 Denominator Exclusions: Documentation of medical reason(s) for not performing a complete workup for assessment of stress urinary incontinence (such as use of a nonsynthetic material for the sling; conomitant 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 undergo mesh sling surgery for whom there was documentation that they had been counseled about the risk of mesh erosion/extrusion, pain, and permanence prior to performing a mesh sling surgery

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.

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All female patients who undergo Mesh sling 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 (adult population). The timeframe is 12 months.
Concomitant prolapse surgery includes repair of cystocele, enterocele, rectocele or vaginal vault prolapse or hysterectomy perofrmed 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 use of a nonsynthetic material for the sling; conomitant 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 CTP 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, OPPORTUITY, 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, Safety : Complications

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers; A leading cause of morbidity/mortality; Frequently performed procedure; 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)*:
Several studies have concluded the large majority of SUI surgeries in the United States are now mesh sling-based:
Using the Nationwide Inpatient Sample (NIS) dataset from 1998 to 2007, Wu et al. performed a comprehensive analysis of women at least 20 years of age who underwent SUI surgery based on the International Classification of Diseases, 9th Revision (ICD-9) procedure and diagnosis codes [1]. From 1998 to 2007, a total of 759,821 women in the US underwent inpatient surgery for SUI. The total number of procedures per year increased from 37,953 in 1998 to 94,910 in 2007, with incidence rates of 37.2 and 84.3 per 100,000 women, respectively. The authors further provide evidence that much of the increase in SUI surgeries over this period can be attributed to the midurethral sling procedure, which has been widely adopted by practitioners in the US. The procedure code reflecting the midurethral mesh sling represented over 75% of all SUI procedures in 2007. Although there was no exclusive ICD code for midurethral mesh sling, the authors' findings suggest that the majority of current SUI procedures utilize mesh. There was no distinction between synthetic and non-synthetic mesh materials.
Oliphant and colleagues [2] found a similar increase in SUI surgeries using the National Hospital Discharge Survey (NHDS) from 1979 to 2004. 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 consistent with the Wu et al. study, which reported that 106,862 women underwent SUI procedures in 2004 with a crude incidence rate of 97.9 per 100,000 women [1]. This study also reported the issue of no exclusive code for midurethral mesh slings in the NHDS, but demonstrated that the general code including this procedure increased dramatically to become the dominant reported code by 2004 with an incidence rate of 64 per 100,000 women. Again there was no distinction between synthetic and synthetic mesh materials.
Complications associated with mesh sling surgery include the development of fistulae, urethral erosion, infections, rejection, dyspareunia and other pain syndromes requiring additional surgery or complete removal of the foreign sling material. Different midurethral sling procedures and mesh types have been found to have varying complication rates:
In a review by Baessler and Maher [3], the authors note that the current gold standard for SUI surgery is the suburethral sling providing midurethral support, and that the mesh materials applied can have very different properties. Documented rates of vaginal mesh erosions and defective healing after the tension-free vaginal tape (TVT) and other SUI sling procedures are usually below 3%. In another literature review, Blaivas and Sandhu found that the likelihood of urethral erosion was 15 times higher in patients with synthetic compared with non-synthetic slings [4], suggesting that mesh materials should be considered very carefully by surgeons.

In a retrospective review of 149 women who underwent polypropylene mesh insertion for SUI, Bafghi and colleagues reported that 11 patients (7.4%) subsequently presented with retropubic infection symptoms within 17 months of surgery [5]. Ten patients required surgical exploration, drainage of the collection, and removal of the mesh.
One large prospective study of 597 women documented adverse events over a 24-month period after midurethral sling surgery (either retropubic or transobturator) [6]. A total 383 adverse events were observed among 253 patients (42%), including bladder perforation, infection, mesh exposure, and neurologic symptoms. Overall, mesh-specific complications occurred in ~4% of patients: mesh exposure (3.5%) and tissue/organ erosion (0.3%).
Chae et al. performed a retrospective review of 615 patients to compare clinical outcomes of those undergoing outside-in transobturator tape (TOT) or inside-out transobturator tape (TVT-O) procedures [7]. The authors reported mesh erosion in 14 patients (2.3%) across both treatment groups, three of which required surgical removal of the mesh material.
In a systematic review of transobturator tape complications, Latthe and colleagues searched published literature from 1966 – 2006 using several databases including MEDLINE and EMBASE [8]. Eleven RCTs were assessed, with reported erosion complication incidence rates ranging from 0% to 5.9% in patient populations. In the majority of RCTs, erosion was a rare mesh complication typically occurring in 1 or 2 patients.
In a comprehensive MEDLINE literature review published in 2007 by Gomelsky and Dmochowski, recorded incidence rates of mesh-based erosion related to midurethral slings ranged from 0.1% to 2.4% for TVT procedures, and from 5.4% to 13.4% for ObTape procedures [9]. In a one-year follow-up study of 52 ObTape mesh implants for SUI, Dobson et al. reported an erosion rate of 15% [10]. In another follow-up study of 93 transobturator tape procedures, Domingo et al. found 10% of patients experienced mesh erosion [11]. A different study of 65 patients who underwent transobturator tape surgery found a similar rate of 13.8% for vaginal mesh erosion [12].

1a.4 Citations for Evidence of High Impact cited in 1a.3:

1. 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.
2. 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.
3. Baessler K, Maher CF: Mesh augmentation during pelvic-floor reconstructive surgery: risks and benefits. Current opinion in obstetrics & gynecology 2006, 18:560-566.
4. Blaivas JG, Sandhu J: Urethral reconstruction after erosion of slings in women. Current opinion in urology 2004, 14:335-338.
5. Bafghi A, Benizri EI, Trastour C, Benizri EJ, Michiels JF, Bongain A: Multifilament polypropylene mesh for urinary incontinence: 10 cases of infections requiring removal of the sling. BJOG : an international journal of obstetrics and gynaecology 2005, 112:376-378.
6. Brubaker L, Norton PA, Albo ME, Chai TC, Dandreo KJ, Lloyd KL, Lowder JL, Sirls LT, Lemack GE, Arisco AM, et al: Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study. American journal of obstetrics and gynecology 2011, 205:498 e491-496.
7. Chae HD, Kim SR, Jeon GH, Kim DY, Kim SH, Kim JH, Kim CH, Kim YM, Kim YT, Kang BM, Nam JH: A comparative study of outside-in and inside-out transobturator tape procedures for stress urinary incontinence. Gynecologic and obstetric investigation 2010, 70:200-205.
8. Latthe PM, Foon R, Toozs-Hobson P: Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG : an international journal of obstetrics and gynaecology 2007, 114:522-531.
9. Gomelsky A, Dmochowski RR: Biocompatibility assessment of synthetic sling materials for female stress urinary incontinence. The Journal of urology 2007, 178:1171-1181.
10. Dobson A, Robert M, Swaby C, Murphy M, Birch C, Mainprize T, Ross S: Trans-obturator surgery for stress urinary incontinence: 1-year follow-up of a cohort of 52 women. International urogynecology journal and pelvic floor dysfunction 2007, 18:27-32.
11. Domingo S, Alama P, Ruiz N, Lazaro G, Morell M, Pellicer A: Transobturator tape procedure outcome: a clinical and quality of life analysis of a 1-year follow-up. International urogynecology journal and pelvic floor dysfunction 2007, 18:895-900.
12. Domingo S, Alama P, Ruiz N, Perales A, Pellicer A: Diagnosis, management and prognosis of vaginal erosion after transobturator suburethral tape procedure using a nonwoven thermally bonded polypropylene mesh. The Journal of urology 2005, 173:1627-1630.

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 possible risk of mesh erosion/extrusion, pain, and permanence prior to performing mesh sling surgery for SUI. Through this more detailed guidance, the patient will appropriately reflect on the potential consequences of this treatment choice, and feel more involved in her own medical decisions.

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 provide evidence that mesh in sling surgery has newly identified complications that should be described to the patient prior to surgery. This evidence indicates a probable performance gap/opportunity for improvement in establishing more consistent and detailed counseling of patients on the risks associated with mesh sling surgery for SUI.
In one relevant study, Deng et al. performed a retrospective review of all cases of midurethral sling complications that presented to their institution (UCLA Medical Center from 2001-2005) [10]. Researchers also performed a literature review of complications due to midurethral slings and searched the FDA manufacturer and user facility device experience (MAUDE) database for corresponding self-reported complications. At the authors' institution, a total of 26 patients with voiding dysfunction after sling surgery were found to have mesh in the urethra or bladder. Moreover, the MAUDE database contained significantly more major reported complications than incidence rates reported in published literature. Overall, the authors concluded that major complications of mesh sling surgery

are more common than published literature suggests.
A retrospective chart review sought to quantify the complicate rate of vaginal mesh sugery at the authors' institution. The authors found that 6/35 (17%) of patients had presented with defective vaginal healing manifested by extrusion of the sling material [11]. The average time to presenting complicating symptoms was 9 months (range 2-15), and all patients required surgical removal of the sling material. However, no urethral erosions were noted. The authors concluded that their mesh sling surgical procedure results in an unacceptably high rate of defective vaginal wound healing and mesh extrusion.
Another institutional retrospective review of medical records by Tijdink and colleagues identified 75 patients from the gynecology department who underwent surgical mesh excision to treat complications after prior mesh-augmented pelvic floor reconstructive surgery [12]. These 75 patients underwent 81 total operations, including 30 complete and 51 partial mesh excisions. Severe mesh complications (contraction, displacement, chronic inflammation, infection, granuloma) were found in 15 patients (20%). Additionally, some excision procedures of problematic mesh also resulted in further complications. The authors state that complete excision should be reserved for those with relatively serious complaints and severe mesh-related complications because there exists a higher risk of surgical complications and recurrence of pelvic organ prolapse.

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 Ib.2 *(number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include)*

10. Deng DY, Rutman M, Raz S, Rodriguez LV: Presentation and management of major complications of midurethral slings: Are complications under-reported? Neurourology and urodynamics 2007, 26:46-52.
11. Siegel AL, Kim M, Goldstein M, Levey S, Ilbeigi P: High incidence of vaginal mesh extrusion using the intravaginal slingplasty sling. The Journal of urology 2005, 174:1308-1311.
12. Tijdink MM, Vierhout ME, Heesakkers JP, Withagen MIJ: Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh. International urogynecology journal 2011, 22:1395-1404.

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 mesh sling surgery risks are not currently available. We also did not identify data on population disparities related to the utilization/complications of mesh sling surgery.

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

1c. Evidence (*Concept focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the concept focus a health outcome? Yes☐ No☐ If not a health outcome, rate the body of evidence.

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

Quantity	Quality	Consistency	Does the concept pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the concept pass subcriterion1c? Yes☐ IF rationale supports relationship

Please see the attached Evidence Submission Worksheet for evidence specifications.

Was the concept approval criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐

Provide rationale based on specific subcriteria:

3. USABILITY

4.1 Current and Planned Use
Performance results from NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement (in addition to use for performance improvement).
(Check only the current and planned uses; for any current uses that are checked, provide a URL for the specific program)
Current Use:
Planned Use:

5. COMPARISON TO RELATED AND COMPETING CONCEPTS & MEASURES

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

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: Patients counseled about risks associated with the use of mesh in sling surgery
Date of Submission: 6/25/2012

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages incudes 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
X **Process**: Patients counseled about risks associated with the use of mesh in sling 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.)*

Counseling the patient about risks associated with using mesh in sling surgery >>
informs the patient of recent complication rates due to synthetic mesh sling to treat prolapse surgery >>
provides improved patient-centered care and shared-decision making between the provider and patient

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.

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

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

European Association of Urology (2012): Guideline section 5.1 – pp. 76-77

American Urological Association (2009): **Notice** - p. 1 (Guideline cover page)

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):
Recommendations for surgery for uncomplicated stress urinary incontinence in women:
-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)
-Women being offered a single-incision sling device for which an evidence base exists, should be warned that short-term efficacy is inferior to standard mid-urethral slings and that long-term efficacy remains uncertain. (Grade C)

American Urological Association (2009):
Notice of FDA Warning regarding the use of vaginal mesh:
The U.S. Food and Drug Administration (FDA) has issued several safety communications about the use of mesh for pelvic organ prolapse (POP). However, this AUA guideline reviews the current literature regarding SUI alone, and covers neither POP nor mini-incision slings. The FDA warning does not apply to biologicals used in POP. Based on continuing adverse event reports that have been received by the FDA since their initial warning in 2008, the FDA has stated that serious complications associated with surgical mesh in transvaginal POP repairs are not rare. The AUA will continue to monitor the FDA's alerts and notices and will update the guideline as additional warnings or alerts regarding this device are issued. Informed consent requires that patients be advised of the risks of vaginal mesh.

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; Grade **C -** Made despite the absence of directly applicable clinical studies of good quality.

American Urological Association (2009): No grade was defined for this specific notice statement.

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): Body of evidence grades for recommendations specified in **1c.4.4** above were either level **1a** or **1b**. Level **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.

American Urological Association (2009): No grade provided for body of evidence was associated with this specific notice statement.

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*):

Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse. FDA Center for Devices and Radiological Health, 2011 Jul.

1c.6.2. **URL** (*if available online*):
FDA alert (2011):
www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf

1c.6.3. **Grade assigned to the body of evidence with definition of the grade**:
"Recommendations for healthcare providers:
- Inform the patient about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally and the likely success of these alternatives compared to transvaginal surgery with mesh.
- Notify the patient if mesh will be used in her POP surgery and provide the patient with information about the specific product used.
- Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data." (p. 11)
No grade was determined for these above FDA recommendations, but the alert was based on literature presented from all relevant RCTs, systematic reviews, and a subset of observational studies that

presented data on adverse events associated with transvaginal repair of POP using mesh from January 1996 through April 2011.

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 identifed 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

FDA alert (2011): 1996-2011

QUANTITY AND QUALITY OF BODY OF EVIDENCE

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

European Association of Urology (2012): Cumulative study design totals in the body of evidence associated with recommendations specified in **1c.4.4** were: 9 systematic reviews, 64 randomized controlled trials, 1 meta-analysis, 1 quasi-RCT, and 9 case series.

FDA alert (2011): 24 studies including RCTs, systematic reviews, and observational studies.

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 all recommendations specified in **1c.4.4** was either stated as level **1a** or **1b,** indicating high-quality studies were identified including 64 RCTs. However, a direct measure of quality was not utilized in this guideline.

With respect to the mid-urethral recommendations, an analysis of the heterogeneity of trials in this meta-analysis suggested that the evidence is generalisable to women, who have predominantly SUI, and no other clinically severe lower genitourinary tract dysfunction. The evidence is not adequate to guide choice of surgical treatment for those women with MUI, severe pelvic organ prolapse, or a history of previous surgery for SUI. (p. 67)

Unfortunately these studies only reflect the utilization of mesh sling surgery for patients, rather than counseling patients about the risks of mesh sling surgery. However, these EAU recommendations confirm that the body of evidence evaluating the substantial risks of mesh sling surgery is abundant, and therefore that our measure focus is valid.

FDA alert (2011): 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): (Results of meta-analysis and systematic literature review) Thirteen RCTs (n = 1037) compared mid-urethral sling (retropubic) and colposuspension (open and laparoscopic). The guideline meta-analysis found no difference in patient-reported cure rates at 12 months and 5 years, but bladder perforation was higher for the mid-urethral sling (15% vs. 9%, and 7% vs. 2%, respectively). A single randomised trial, comparing the mid-urethral sling (transobturator) with open colposuspension, reporting similar rates of patient-reported and clinician-reported cure and no evidence of differential harms. (p. 67)

Thirty-four RCTs (5786 women) compared insertion of the mid-urethral sling by the retropubic and transobturator routes. There was no difference in cure rates at 12 months in either patient-reported or clinically reported cure rates (77% and 85%, respectively). Voiding dysfunction was less common (4%) following transobturator insertion compared to retropubic insertion (7%), as was the risk of bladder perforation (0.3%) or urethral perforation (5%). Similarly, the risks of de-novo urgency and vaginal perforation were 6% and 1.7%, respectively. Chronic perineal pain at 12 months after surgery was reported by 21 trials and meta-analysis of these data showed strong evidence of a higher rate in women undergoing transobturator insertion (7%) compared to retropubic insertion (3%). (p. 67)

A Cochrane systematic review and meta-analysis found that the skin-to-vagina direction (outside in) for retropubic insertion of mid-urethral slings was less effective than the vagina-to-skin (inside out) direction and was associated with higher rates of voiding dysfunction, bladder perforation, and vaginal erosion. (p. 67)

Meta-analysis showed that the outcome of single-incision sling insertion was consistently worse compared with mid-urethral slings in terms of patient-reported cure of UI. Single-incision techniques had a shorter operating time, lower blood loss and lower pain levels compared to a standard mid-urethral sling. (p. 72)

The meta-analysis and literature review performed by this guideline focused on quantifying the relative risks associated with utilization of sling surgery rather than informing patients about specific risks. Therefore these results are not directly applicable to outcomes of the proposed measure, but rather evidence that supports the notion of the proposed measure.

FDA alert (2011): No benefits associated with mesh sling surgery were described in this alert.

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?
European Association of Urology (2012):
As described in **1c.11**, an EAU guideline meta-analysis reported consistent adverse effects associated with mesh sling surgery that may outweigh the benefits for the patient. Again these results focus on quantifying the risks associated with utilization of sling surgery rather than informing patients about the specific risks, but this provides the rationale for our measure.

FDA alert (2011):
The literature review identified the following safety concerns with transvaginally placed surgical mesh for POP repair:
- Patients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh (10 studies);
- Adverse events associated with transvaginally placed mesh can be life-altering for some women (3 studies). Sequelae (e.g., pain) may continue despite mesh removal;
- Mesh-associated complications are not rare. The most common mesh-related complication experienced by patients undergoing transvaginal POP repair with mesh is vaginal mesh erosion (10 studies). One study reported a meta-analysis based on data from 110 studies including 11,785 women, and found that approximately 10 percent of women undergoing transvaginal POP repair with mesh experienced mesh erosion within 12 months of surgery;
- More than half of the women who experienced erosion from non-absorbable synthetic mesh required surgical excision in the operating room. Some women required two to three additional surgeries (1 study). (p. 8).

These results from the FDA alert focus on the risks associated with utilization of mesh sling surgery rather than informing patients about the specific risks, but this provides the rationale for our 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**.