NQF #C 2063 Use of cystoscopy concurrent with prolapse repair surgery, Date Submitted: Jul 16, 2012

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 <u>submitting standards web page</u>.

NQF #: C 2063 NQF Project: GI and GU Project

Date Submitted: Jul 16, 2012

CONCEPT SPECIFICATIONS

De.1 Concept Title: Use of cystoscopy concurrent with prolapse repair surgery

Co.1.1 Concept Steward: American Urogynecologic Society

De.2 Brief Description of Concept: Percentage of patients that undergo concurrent cystoscopy at the time of surgery for correction of anterior and/or apical vaginal prolapse to check for lower urinary tract injury.

2a1.1 Numerator Statement: Numerator is the number of female patients where a concurrent intraoperative cystoscopy was performed at the time of surgery for correction of anterior and/or apical vaginal prolapse to check for lower urinary tract injury...

2a1.4 Denominator Statement: Denominator is the number of female patients undergoing any prolapse repair surgery for correction of anterior and/or apical vaginal prolapse.

2a1.8 Denominator Exclusions: There are no exclusions from the target population.

1.1 Concept Type: Process

2a1. 25-26 Data Source: Administrative claims, Paper Medical Records 2a1.33 Level of Analysis: Clinician : Group/Practice, 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): Numerator is the number of female patients where a concurrent intraoperative cystoscopy was performed at the time of surgery for correction of anterior and/or apical vaginal prolapse to check for lower urinary tract injury..

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.

Numerator is measured by all women undergoing any vaginal prolapse repair where a concurrent intraoperative cystoscopy was perform. The cystoscopy will be identified by CPT code(s). Any vaginal prolapse repair will be located int he patient's record using CPT codes for anterior and/or apical vaginal prolapse surgeries.

2a1.4 **Denominator Statement** *(Brief, narrative description of the target population being measured)*: Denominator is the number of female patients undergoing any prolapse repair surgery for correction of anterior and/or apical vaginal prolapse.

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

Denominator is identified as the number of female patients undergoing any prolapse repair surgery for correction of anterior and/or apical vaginal prolapse and these female patients will be identified by using CPT codes for these procedures.

2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population): There are no exclusions from the target population.

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. There are no exclusions from the target population.

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. We do not plan to stratify the results.

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, <u>if an outcome</u>, describe how you plan to adjust for differences in case mix/risk across measured entities. We are not planning to risk adjust this measure.

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.*): Practice Patterns Associated with Surgical Care of Pelvic Organ Prolapse: A Targeted Chart Review

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

2a1.34 Care Setting (Check all the settings for which the concept is specified and tested): Hospital/Acute Care Facility

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 <u>guidance on evidence</u>.

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, GU/GYN : Gynecology 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; 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):

Unrecognized lower urinary tract injury at the time of prolapse repair is a cause of significant morbidity in frequently performed surgical procedures to treat vaginal prolapse(1,2,3,4,8,9). Latent recognition of lower urinary tract injury leads to high resource use and thousands of dollars in additional expense in treating the injury after the fact(5). The consequences of poor quality, i.e., unrecognized injury, are highly morbid and costly to reconcile, but rarely result in mortality(5). Unrecognized lower urinary tract injury can lead to short term morbidity (weeks to months) with hospital readmission, subsequent staged reconstructive surgeries, prolonged hospitalization, and prolonged recovery requiring indwelling ureter stents and urethral catheterization . Long term (years) consequences may include sequelae from nerve injury and scarring, including chronic urinary tract injury depends on the degree and location of the injury, and may vary from prolonged short term recovery to long term loss of normal urinary tract organ function(6,7,10).

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1. Rates of urinary tract injury from gynecologic surgery and the role of intraoperative cystoscopy. Gilmour, DT, Das, S, Flowerdew, G. Obstet Gynecol 2006; 107:1366.

2. Urinary tract injury during hysterectomy based on universal cystoscopy. Ibeanu, OA, Chesson, RR, Echols, KT, et al. Obstet Gynecol 2009; 113:6.

3. The incidence of urinary tract injury during hysterectomy: a prospective analysis based on universal cystoscopy. Vakili, B, Chesson, RR, Kyle, BL, et al. Am J Obstet Gynecol 2005; 192:1599.

4. Incidence of lower urinary tract injury at the time of total laparoscopic hysterectomy. Jelovsek, JE, Chiung, C, Chen, G, et al. JSLS 2007; 11:422.

5. Cost-effectiveness of universal cystoscopy to identify ureteral injury at hysterectomy. Visco, AG, Taber, KH, Weidner, AC, et al. Obstet Gynecol 2001; 97:685.

6. Disability and litigation from urinary tract injuries at benign gynecologic surgery in Canada. Gilmour, DT, Baskett, TF. Obstet Gynecol 2005; 105:109.

7. Evaluation and treatment of iatrogenic ureteral injuries during obstetric and gynecologic operations for nonmalignant conditions. Meirow, D, Moriel, EZ, Zilberman, M, Farkas, A. J Am Coll Surg 1994; 178:144.

8. The incidence of ureteral obstruction and the value of intraoperative cystoscopy during vaginal surgery for pelvic organ prolapse. Gustilo-Ashby AM, Jelovsek JE, Barber MD, Yoo EH, Paraiso MF, Walters MD. Am J Obstet Gynecol. 2006 May;194(5):1478-85.

9. The value of intra-operative cystoscopy at the time of laparoscopic hysterectomy. Ribeiro S, Reich H, Rosenberg J, Guglielminetti E, Vidali A. Hum Reprod. 1999 Jul;14(7):1727-9.

10. P. Sakellariou, A.G. Protopapas, Z. Voulgaris, N. Kyritsis, A. Rodolakis, G. Vlachos et al. Management of ureteric injuries during gynecological operations: 10 years experience Eur J Obstet Gynecol Reprod Biol, 101 (2002), pp. 179–184

1b. Opportunity for Improvement: H M L

(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:

Universal intraoperative cystoscopy with vaginal prolapse repair is not consistent across providers performing these procedures. This quality measure will quantify the percentage of women undergoing vaginal prolapse repair who have an intraoperative cystoscopy done to detect intraoperative injury, with the goal of making universal cystoscopy standard for all vaginal prolapse procedures and preventing missed lower urinary tract injury. The measure will quantify the performance gap in pelvic surgeons' use of universal intraoperative cystoscopy and highlight those surgeons' care where a higher level of quality is easily obtained. Patient care will be improved by avoiding unrecognized injury to the lower urinary tract during hysterectomy and vaginal prolapse surgery, thus preventing a highly morbid complication and reoperation for unrecognized injury.

Cost-effectiveness of universal cystoscopy at the time of hysterectomy and vaginal prolapse repair has been demonstrated costsavings above a threshold incidence of ureteral injury of 1.5%. Ureteral injury at the time of hysterectomy and prolapse repair occurs with incidence up to 5.1%. Universal cystoscopy is cost-effective in preventing unrecognized lower urinary tract injuries. Universal cystoscopy at the time of hysterectomy and vaginal prolapse repair will prevent unnecessary morbidity in unrecognized injury, will prevent hospital readmission, will prevent re-operation, and will save health care dollars.

1b.2 Provide data demonstrating performance gap/opportunity for improvement (Variation or overall less than optimal performance across providers). List citations in 1b.3.

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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 majority of hysterectomy and vaginal prolapse procedures done in the US are performed by gynecologists. Although gynecologists receive mandatory training in cystoscopy during residency, as few as 12% use routine cystoscopic exam during hysterectomy procedures done in practice (1,2). The specialties of urogynecology and female urology also perform hysterectomy and prolapse procedures and standardly use universal intraoperative cystoscopy as a check point to evaluate for occult lower urinary tract injury. Amongst gynecologists, urogynecologists, and female urologists, there is approximately an 88% performance gap in offering a simple cost-saving step to avoid lower urinary tract injury during vaginal surgery (1). 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) 1. Current cystoscopy practice of recent graduates of obstetrics and gynecology residency: a survey study. Nosti PA, Isaacson MA, Iglesia CB. J Reprod Med. 2011 Sep-Oct;56(9-10):373-5. 2. Credentialing residents for intraoperative cystoscopy. Hibbert ML, Salminen ER, Dainty LA, Davis GD, Perez RP. Obstet Gynecol. 2000 Dec:96(6):1014-7 3. Credentialing criteria for ACGME accredited residency programs include cystoscopy as a core skill in urology, obstetrics and gynecology, and fellowship training in urogynecology. 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. There are no disparities by population group regarding universal cystoscopy done at the time of hysterectomy and vaginal prolapse repair. 1b.5 Citations for Data on Disparities Cited in 1b.4: None 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 Yes M-H L M-H Μ 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 Does the concept pass subcriterion1c? one healthcare structure, process, intervention, or service **Yes** IF rationale supports relationship Please see the attached Evidence Submission Worksheet for evidence specifications. Was the concept approval criterion, Importance to Measure and Report, met? (1a & 1b must be rated moderate or high and 1c yes) Yes No Provide rationale based on specific subcriteria:

3. USABILITY

4.1 Current and Planned Use

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

5. COMPARISON TO RELATED AND COMPETING CONCEPTS & MEASURES

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

5a.1 If this concept has EITHER the same focus OR the same target population as <u>NQF-endorsed measure(s)</u>: Are the specifications completely harmonized?

5a.2 If the specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b.1 If this concept has both the same focus and the same target population as NQF-endorsed measure(s): Describe why this concept is superior to competing measures (*e.g.*, *a more valid or efficient way to measure quality*); OR provide a rationale for the additive value of endorsing an additional measure. (*Provide analyses when possible*):

CONTACT INFORMATION

Co.1 Concept Steward (Intellectual Property Owner): American Urogynecologic Society, 2025 M. Street, Suite 800 | Washington | District Of Columbia | 20036

Co.2 Point of Contact: Colleen | Koski | Colleen@augs.org | 202-367-1240-

Co.3 Concept Developer if different from Concept Steward: American Urogynecologic Society | 2025 M. Street, Suite 800 | Washington | District Of Columbia, 20036

Co.4 Point of Contact: Colleen | Koski | Colleen@augs.org | 202-367-1240-

Co.5 Submitter: Colleen | Koski | Colleen@augs.org | 202-367-1240- | American Urogynecologic Society

Co.6 Additional organizations that sponsored/participated in concept development:

Co.7 Public Contact: Colleen | Koski | Colleen@augs.org | 202-367-1240- | American Urogynecologic Society

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:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

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

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

Measure Title: Use of cystoscopy concurrent with prolapse repair surgery **Date of Submission**:7/16/2012

- 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 <u>evidence criterion (1c)</u> 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: Click here to name the health outcome
- Intermediate clinical outcome: Click here to name the intermediate outcome
- ⊠ Process: Use of cystoscopy concurrent with prolapse repair surgery
- Structure:Click here to name the structure
- Other:Click here to name what is being measured

HEALTH OUTCOME MEASURE *If not a health outcome, skip to 1c.3*

If the measure focus identified in 1c.1 is a <u>health outcome</u>, 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 onehealthcare 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 <u>structure, process, or intermediate outcome</u>answerall the <i>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.*)

Vaginal prolapse repair surgery to suspend the vaginal apex (the top of the vagina) or the anterior part of the vaginal wall (cystocele), involve tissues very close to the bladder and the ureters (tubes connecting the kidneys to the bladder). \rightarrow Injury to these structures (injury rate of up to 5.1%) is often not identified at the time of surgery \rightarrow Cystoscopy at the time of surgery can identify ureteral and bladder injury that can then be repaired at the time of surgery \rightarrow Repair at the time of index surgery decreases patient morbidity, and prevents the need for repeat surgery.

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes \boxtimes No \square If no, skip to #1c.6

<u>If yes</u>, answer 1c.4.1-1c.5. 1c.4.1.**Guideline citation**(*including date*): ACOG Practice Bulletin No. 85: Pelvic organ prolapse. ObstetGynecol 2007; 110:717.

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

http://www.acog.org/~/media/Practice%20Bulletins/Committee%20on%20Practice%20Bulletins%20-%20Gynecology/pb085.pdf?dmc=1&ts=20120620T1521149723

1c.4.3.Identify guideline number and/or page number: ACOG Practice Bulletin #85, page 5 **1c.4.4.Quote verbatim, the specific guideline recommendation**:

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 <u>with definition</u> of the grade:

No grade is assigned to this recommendation.

1c.5.Did the guideline developer systematically review and grade the <u>body of evidence</u> for the specific guideline recommendation?Yes Nox*lf no, skip to #1c.6*

<u>If yes</u>, 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 <u>with definition</u> of the grade:

1c.6. Is there another published systematic review of the <u>body of evidence</u> supporting the measure

focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF) Yes \boxtimes No \square If no, skip to #1c.7

<u>If yes</u>, 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*):

Rates of Urinary Tract Injury From Gynecologic Surgery and the Role of

Intraoperative Cystoscopy *Obstetrics and Gynecology*, VOL. 107, NO. 6, JUNE 2006

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

http://journals.lww.com/greenjournal/Abstract/2006/06000/Rates_of_Urinary_Tract_Injury_From_Gyn ecologic.24.aspx

1c.6.3.Grade assigned to the body of evidence <u>with definition</u> of the grade:

No grade was assigned to the body of evidence.

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

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

<u>If yes</u>, 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 criterioncan not be met.

FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items <u>1c.8-1c.13 must be answered</u> 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: 1966 to 2004

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)

Fourty-seven studies.

- 42 Retrospective Case Series
- 2 Prospective Case Series
- 2 Case-Control Studies
- 1 Retrospective Cohort Study

1c.10.What is the overall quality of evidence <u>across studies</u> 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)

The topic of lower urinary tract injury is of universal interest in gynecologic surgery, and this systematic review represents decades of experience with genitourinary surgery involving hysterectomy. It includes more than 130,000 benign hysterectomies and directly addresses the proposed measure. Gilmour et al's application of inclusion and exclusion criteria was appropriate and met the standards of a systematic review. Many authors through the decades have published smaller series which either over or underestimate the risks of lower urinary tract injury. In our opinion, Gilmour appropriately included for non-routine cystoscopy only those series of >500 cases. This strategy helped to minimize error from outlier estimates.

This review did not identify any randomized controlled trials comparing the practices of selected versus universal cystoscopy. However, the evidence demonstrates a remarkable and profound improvement in the detection of lower urinary tract injuries. The benefits of intraoperative detection (and management as necessary) so clearly outweigh potential harms (UTI) and the minimal increase in resource use that it would be unethical to randomize patients at this time.

In this systematic review, the percentage of injuries identified during benign hysterectomies and other urogynecologic surgery that included non-routine intraoperative cystoscopy (7% for ureteric injury and 43% for bladder injury) is compared to the percentage of injuries identified during similar procedures that included routine cystoscopy (89% for ureteric injury and 95% for bladder injury). The large number of subjects included in the evaluation contributes to the certainty of the findings. This is particularly important given the relatively infrequent occurrence of bladder and ureteral injury. In addition, the target population of our measure is directly addressed, as the authors included a category for all types of hysterectomy, and for patients undergoing additional urogynecologic procedures.

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)

Routine intraoperative cystoscopy identified 89% of ureteric and 95% of bladder injuries. Without routine cystoscopy 7% of ureteric and 43% of bladder injuries were identified. These findings suggest that routine cystoscopy identifies up to five fold more injuries than non-routine cystoscopy. The magnitude and direction of effect on outcomes is universally in support of routine cystoscopy.

The ureteric injury rates for hysterectomy with other urogynecologic surgery <u>without</u> routine cystoscopy were 2.2/1000 surgeries (95%CI 0.8-4.3). The bladder injury rate for hysterectomy with other urogynecologic surgery <u>without</u> routine cystoscopy was) and 11.2/1000 surgeries (95% CI 5.0-19.8) respectively. The ureteric and bladder injury rates <u>with</u> routine cystoscopy were 6.4 (95%CI 2.3-12.6) and 13.1/1000 (95%CI 4.3-12.6).

1c.12.What harms were studied and how do they affect the net benefit—benefits over harms? No harms of routine intraoperative cystoscopy to the patient were studied.

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 x \square No \square *If no, stop*

<u>If yes</u>,

1c.13.1.For <u>eachnew study provide</u>: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

1. Urinary tract injury during hysterectomy based on universal cystoscopy. Ibeanu, OA ObstetGynecol 2009; 113:6.

Prospective observational study of 839 patients.Rate of urinary tract injury 4.3% Intraoperative detection rate by routine cystoscopy 97.4%.Supports the value of routine intraoperative cystoscopy.

2. The incidence of urinary tract injury during hysterectomy: a prospective analysis based on universal cystoscopy. Vakili, B Am J ObstetGynecol 2005; 192:1599.

Prospective observational study of 839 patients undergoing hysterectomy for benign diagnosis. Ureteral injury was associated with hysterectomy for prolapse repair (7.3% vs 1.2%; P = .025). Incidence of urinatry tract injury was 4.8%. Only 12.5% of ureteral injuries and 35.3% of bladder injuries were detected before cystoscopy. Supports the value of routine intraoperative cystoscopy.

3. Incidence of lower urinary tract injury at the time of total laparoscopic hysterectomy. Jelovsek, JE. JSLS 2007; 11:422.

Retrospective study of 126 consecutive patients undergoing laparoscopic hysterectomy with routine intraoperative cystoscopy. 4% rate of lower urinary tract injury. 50% of cystotomies were not identified before cystoscopy. Supports the value of routine intraoperative cystoscopy

 The incidence of ureteral obstruction and the value of intraoperative cystoscopy during vaginal surgery for pelvic organ prolapse. Gustilo-Ashby AM Am J Obstet Gynecol. 2006 May;194(5):1478-85.

Retrospective study of 700 consecutive patients undergoing vaginal surgery for anterior or apical pelvic organ prolapse and routine intraoperative cystoscopy. The incidence of intraoperative ureteral obstruction was 5.1%. The false-positive and negative cystoscopy rates were 0.4% and 0.3%. Intraoperative cystoscopy was accurate in 99.3% of cases, with a sensitivity and specificity of 94.4% and 99.5%. This supports the value of routine intraoperative cystoscopy.