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 2038 NQF Project: GI and GU Project

Date Submitted: Jul 16, 2012

CONCEPT SPECIFICATIONS

De.1 Concept Title: Performing vaginal apical suspension (uterosacral, iliococygeus, sacrospinous or sacral colpopexy) at the time of hysterectomy to address uterovaginal prolapse

Co.1.1 Concept Steward: American Urogynecologic Society

De.2 Brief Description of Concept: Percentage of female patients undergoing hysterectomy for the indication of uterovaginal prolapse in which a concomitant vaginal apical suspension (i.e.uterosacral, iliococygeus, sacrospinous or sacral colpopexy)is performed.

2a1.1 Numerator Statement: The number of female patients who have a concomitant vaginal apical suspension (i.e.uterosacral, iliococygeus, sacrospinous or sacral colpopexy) at the time of hysterectomy for uterovaginal prolapse.

2a1.4 Denominator Statement: Hysterectomy, performed for the indication of uterovaginal prolapse

2a1.8 Denominator Exclusions: • Patients with a gynecologic or other pelvic malignancy noted at the time of hysterectomy
- Patients undergoing a concurrent obliterative procedure (vaginectomy)
- Patients undergoing excision of prolapsed cervix only (prior sub-total hysterectomy)

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)*:
The number of female patients who have a concomitant vaginal apical suspension (i.e.uterosacral, iliococygeus, sacrospinous or sacral colpopexy) at the time of hysterectomy for uterovaginal prolapse.

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.
CPT codes for uterosacral, iliococygeus, sacrospinous or sacral colpopexy

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
Hysterectomy, performed for the indication of uterovaginal 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.
Hysterectomy, performed for the indication of uterovaginal prolapse as identified the ICD-9 diagnosis codes for utero/vaginal prolapse and the CPT codes for hysteretomy.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
- Patients with a gynecologic or other pelvic malignancy noted at the time of hysterectomy
- Patients undergoing a concurrent obliterative procedure (vaginectomy)
- Patients undergoing excision of prolapsed cervix only (prior sub-total hysterectomy)

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.
ICD-9 diagnosis codes for gynecologic cancers.
CPT codes for vaginectomy.

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.
No, we do not plan to stratify the measure 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, if an outcome, describe how you plan to adjust for differences in case mix/risk across measured entities.
No, we do not plan to risk adjust the 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 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, GU/GYN : Gynecology

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

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers; A leading cause of morbidity/mortality; Frequently performed procedure; High resource use

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
Uterovaginal prolapse is a common and debilitating condition in which the pelvic viscera herniate through the genital hiatus. Observed in 14.2% of 27,342 participants in the Women's Health Initiative, uterine prolapse is strongly associated with anterior vaginal support which in turn affects lower urinary tract function (1). The more than 78,000 hysterectomies performed annually in the United States for uterovaginal prolapse (2) are a reflection of the symptom burden related to prolapse and its associated genitourinary conditions. A most troubling challenge of prolapse surgery is recurrence and need for reoperation for 14% having a primary procedure and 26% having a repeat procedure (3). These recurrence data and the projection that the prevalence of prolapse will increase 46% between 2010 and 2050 (4) underscore the need to focus on appropriate surgical procedures being performed for uterovaginal prolapse.

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1) Hendrix SL, et al Pelvic Organ Prolapse in the WHI: gravity and gavidity. Am J Obstet Gynecol 2002;186:1160-66
2) Wu J et al, Hysterectomy Rates in the United States 2003. OBG 2007;110:1091
3) Denham MA et al. Reoperation rates 10 years after surgically managed pelvic organ prolapse and urinary incontinence. AJOG 2008:198:555
4) Wu J et al, Forecasting the Prevalence of Pelvic Floor Disorders in US Women, 2010 to 2050. OBG 2009;114:1278.

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:
Women with uterovaginal prolapse who undergo hysterectomy have a greater lifetime risk of having additional surgery for pelvic floor disorders. Implementation of this measure will improve quality by decreasing the number of women seeking retreatment for vaginal vault prolapse and other pelvic floor disorders. Recent studies report more than 200,000 surgical procedures are performed for prolapse annually at a cost of more than 1 billion dollars. Implementation of this quality measure will decrease the cost of providing care to our middle aged and Medicare populations, those most commonly affected by prolapse.

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.Hysterectomy for prolapse (1-3) and the omission of appropriate prolapse repairs (1, 2) are risk factors for reoperation of prolapse. The incidence of reoperation within 10 years of surgery is 7.4 % when vaginal hysterectomy is done alone for prolapse and just 2% when concomitant pelvic floor repairs are undertaken at the time of hysterectomy (1). Despite a guideline recommendation from the American Congress of Obstetrics and Gynecology that a colpopexy be performed at the time of hysterectomy for prolapse (4), an analysis of discharge data from 343 California hospitals between 2002 and 2006 revealed that only 35% of women have a concurrent colpopexy at the time of hysterectomy. Better rates of compliance with the recommended guideline were found among teaching institutions while those hospitals receiving primarily Medicaid reimbursement had the lowest rates of compliance with the guideline (5). The long recognized importance of apical vaginal support (6) has also recently been quantified in mechanistic studies. Support of the vaginal apex eliminates anterior vaginal wall laxity in 63% of women with Stage 3 or 4 apical prolapse (7). Mechanistic analyses reveal that >70% of anterior wall prolapse is accounted for by loss of uterine or apical vaginal prolapse (8, 9).

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) Blandon RE, et al Incidence of Pelvic Floor Repair after Hysterectomy: A population-based cohort study. Am J Obstet Gynecol. 2007;197(6):664.e 1-7
2) Altman D et al. Pelvic Organ Prolapse Surgery Following Hysterectomy on Benign Indications. Am J Obstet Gynecol.

2008;198 (5): 572.e1-572.e6.
3) Forsgren et al. Vaginal hysterectomy and risk of pelvic organ prolapse. Int Urogyncol J 2012; 23:43-48.
4) American Congress of Obstetrics and Gynecology. Pelvic Organ Prolapse. Practice Bulletin #85: page 5, September 2007.
5) Rhoads et al Variation in the quality of surgical care for uterovaginal prolapse Med Care 2011;49:46-5
6) DeLancey JO. Anatomic Aspects of Vaginal Eversion After Hysterectomy. Am J Obstet Gyncol 1992 Jun 166(6pt 1): 1717-24.
7) Lowder JL, et al. The Role of Apical Vaginal Support in the Appearance of Anterior and Posterior Vaginal Prolapse. Obstet Gynecol 2008 Jan;111(1):152-7
8) Summers A, et al. The relationship between anterior and apical compartment support. Am J Obstst Gynecol 2006 May;194(5):1438-43 Epub 2006 Mar 30
9) Hsu Y et al. Anterior vaginal wall length and the degree of anterior compartment prolapse seen on dynamic MRI. Int Urogynecol J 2008 19:137-42.

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 is no data on disparities.

1b.5 Citations for Data on Disparities Cited in 1b.4:
There is no data on disparities.

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:

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:

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--- | 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: Performing vaginal apical suspension (uterosacral, iliococygeus, sacrospinous or sacral colpopexy) at the time of hysterectomy to address uterovaginal prolapse

Date of Submission: July 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 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:Click here to name the health outcome

☐Intermediate clinical outcome:Click here to name the intermediate outcome

XProcess: Performing vaginal apical suspension (uterosacral, iliococygeus, sacrospinous or sacral colpopexy) at the time of hysterectomy to address uterovaginal prolapse

☐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 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 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 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.)*

Uterine prolapse is a defect in vaginal support at the top (apex) of the vagina (called a Level 1 defect) → Hysterectomy is a procedure to remove the uterus, not a procedure providing support to the vaginal apex → Performing vaginal apical suspension procedure (uterosacral, iliococygeus, sacrospinous or sacral colpopexy) at the time of hysterectomy performed for the indication of apical vaginal prolapse is necessary to provide this support → providing apical support decreases the recurrence rate of apical vaginal prolapse and the need for repeat surgery

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

If yes, *answer 1c.4.1-1c.5.*

1c.4.1.**Guideline citation**(*including date*):

Pelvic Organ Prolapse. ACOG Practice Bulletin #85, September 2007

Committee 15 Pelvic Organ Prolapse Brubaker et al. 4th international Consultation on Incontinence, 2009 and re-affirmed in 2011.

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=20120615T1436095832

1c.4.3.**Identify guideline number and/or page number**:
Page 5, ACOG Practice Bulletin #85, September 2007

1c.4.4.**Quote verbatim, the specific guideline recommendation**:
ACOG: *When hysterectomy is performed for uterine prolapse attention must be directed toward restoration of apical support once the uterus is removed.*

1c.4.5.**Grade assigned to the recommendation with definition of the grade**:
ACOG: Guideline Documents state recommendation is based on a systematic review of the evidence, but no grade assigned.

1c.5.Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes No☐x *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**:
The guideline document states that the recommendation is based on a systemic review of evidence, but the specific grade and summary of the body of evidence was not provided. ***

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)*
Yesx 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*):
Genital Prolapse in Women. Clinical Evidence March 14 2012; 03:817

1c.6.2.**URL** (*if available online*):
http://clinicalevidence.bmj.com/x/pdf/clinical-evidence/en-gb/systematic-review/0817.pdf

1c.6.3.**Grade assigned to the body of evidence with definition of the grade**:

Quality of evidence in this systemic review was based on the GRADE system. This system is described in The Journal of Clinical Epidemiology, Volume 64, Issue 4 , Pages 383-394, April 2011
http://www.jclinepi.com/article/S0895-4356%2810%2900330-6/fulltext .

Studies are not evaluated as a single unit, but rather each outcome is evaluated across a body of evidence. High quality evidence is defined as evidence for which "further evidence is very unlikely to change our confidence in the estimate of effect". Moderate quality evidence is defined as " evidence in which further research is likely to have an important impact on our confidence in the estimate of effect or may change the estimate".

Some of the evidence was graded as high quality, including evidence of lower recurrence rates with Sacrocolpopexy vs. Sacrospinous colpopexy, and lower reoperation rates for vaginal hysterectomy when compared to sacrohysteropexy. Some evidence was of moderate quality, including evidence of lower recurrence rates with vaginal hysterectomy and repair vs. sacrohysteropexy, lower reoperation rates with sacrocolpopexy vs. Sacrospinous colpopexy.

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: 1950-2011

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*)

3 Randomized controlled trials

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*)

The overall quality of evidence across studies was considered to be moderate to high quality. However, although the body of evidence addresses the target population (women undergoing hysterectomy for uterovaginal prolapse), it indirectly addresses the measure focus. The focus of the systematic review is to evaluate the efficacy of the various types of colpopexy. The focus of the

measure is to identify the percentage of patients undergoing a colpopexy of any kind (sacral , sacrospinous or iliococcygeus or uterosacral) when they have a hysterectomy for uterovaginal prolapse. There are no randomized controlled trials evaluating outcomes for hysterectomy with or without colpopexy for uterovaginal prolapse, likely because the reccomended practice in repairing uterovaginal prolapse includes a colpopexy procedure following a hysterectomy. The ethical limitations of constructing a randomized trial to directly address this question are prohibitive.

Despite the ethical concerns limiting our ability to perform a randomized trial, there is evidence that patients undergoing hysterectomy for uterovaginal prolapse are not receiving colpopexy. Rhoads et al (see 1c. 13) found that only 35% of women undergoing hysterectomy for uterovaginal prolapse underwent a concomitant colpopexy. Olsen et al (Obstet Gynecol. 1997 Apr;89(4):501-6found that 11% of women undergo surgery for uterovaginal prolapse, and 29% will undergo a repeat procedure. There is also evidence that the vaginal apex contributes to support of the anterior wall and may prevent recurrence of prolapse in other compartments, such as the anterior compartment.

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*)

For symptom relief from vaginal hysterectomy with repair, the proportion of women with symptoms one year after the procedure was 12% for women in the hysterectomy group, vs. 39% in the sacrohysteropexy group experienced symptom relief. RR 3.20 with 95% confidence interval 1.29 to 7.92. This outcome favors vaginal hysterectomy.

For Re-operation at one year following the procedure, 2% of women in the vaginal hysterectomy with repair group, and 22% of patients in the sacrohysteropexy group underwent reoperation for prolapse repair. RR 9.00 95% confidence interval 1.19 to 67.85, p=0.033, favoring the vaginal hysterectomy group. For reoperation at 8 years following the procedure, 14% in the vaginal hysterectomy with repair group and 26% in the sacrohysteropexy group underwent reoperation for prolapse repair. RR 1.83, 95% confidence interval 0.75 to 4.50, p=0.19, not a significant difference.

For symptom relief with sacrocolpopexy vs. sacrospinous colpopexy, 11% of sacrocolpopexy subjects and 21% of sacrospinous colpopexy patients experienced prolapse symptoms, not a significant difference. For recurrence or persistence of symptoms, 4% with sacralcolpopexy and 15% with sacrospinous colpopexy experienced a recurrence, RR0.13(95%CI 0.07 to 0.77). For reoperation rate,

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

Specific adverse effects were not delineated, however, for adverse effects not specified, 12% of the vaginal hysterectomy and repair group vs. 15% of the sacrohysteropexy group experienced adverse effects. RR 1.20, 95% CI 0.40 to 3.62, not statistically significant.

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? YesX No☐ *If no, stop*

If yes,

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

- **Forsgren et al. Vaginal hysterectomy and risk of pelvic organ prolapse. Int Urogyncol J 2012; 23:43-48**. Prospective case: control study (1:3), comparing all women undergoing hysterectomy (cases) for begin reasons (118,601) matched to 579,200 without hysterectomy (controls). Those with prior surgery for pelvic organ prolapse (POP) or incontinence (SUI) were excluded. 6.8% had hysterectomy for POP. The greatest risk of recurrent POP or SUI was seen after vaginal hysterectomy for POP with hazard ratios of 4.9 (95% CI 3.4-6.9) for POP and 6.3 (95%CI 4.4-9.1) for SUI. In addition, compared to control, the risk of POP after vaginal hysterectomy for any reason was 5 times higher. The authors conclude that hysterectomy in general was associated with an increased risk for subsequent POP or SUI. This study adds (level II) support to the ACOG practice bulletin recommendation that coincident surgery to address the vaginal apex performed with hysterectomy for the indication of uterine prolapse.

- **Rhoads et al *Variation in the quality of surgical care for uterovaginal prolapse* Med Care 2011; 49:46-51.** Retrospective analysis of linked California hospital and financial data using ICD-9-CM codes for prolapse with concomitant coding for surgical procedures. They compared "compliant" hospitals as those that addressed the vaginal apex at the time of hysterectomy done for prolapse,(i.e. compliant with ACOG recommendations) to those that did not. Of 28,539 cases only 35% were compliant with the recommendation. Patients in hospitals serving mostly a Medicaid population were less likely to comply with the guideline compared to private hospitals and teaching hospitals. Based on anatomic and MRI studies performed since 1992, the uterus (uterosacral ligaments) is responsible for vaginal apical support. Uterine prolapse by definition is an apical support defect which is not corrected by hysterectomy alone. This study reaffirms the ACOG guideline that the apical support defect needs to be corrected when hysterectomy is performed for the indication of POP and demonstrates that there is disparity in practice when Medicare populations are compared to the privately insured.

- **Blandon RE, et. Al. Incidence of pelvic floor repair after hysterectomy: A population-based cohort study. Am J Obstet Gynecol. 2007; 197:664.e1-7**. Using the Rochester Epidemiology Project database, the authors tracked the incidence of pelvic floor repairs (PFRs) in women who had a hysterectomy for benign indications. They found the cumulative incidence of PFR after hysterectomy was 5.1% by 30 years. The risk of subsequent PFR was at least 2-fold higher if the hysterectomy was indicated for prolapse. In addition, among women who had prolapse, the incidence of a subsequent PFR was lower after vaginal hysterectomy and PFR, compared with vaginal hysterectomy alone, suggesting that concurrent PFR may protect against recurrent prolapse in patients with prolapse undergoing vaginal hysterectomy. Additionally, subsequent PFR was more frequently required in women who had prolapse, whether they underwent a hysterectomy alone [hazard ratio (HR) 4.3; (95% CI 2.5 to 7.3) or a hysterectomy with PFR [HR 1.9; 95% CI 1.3 to 2.7]. data suggest that POP as an indication for hysterectomy is a more important risk factor for a subsequent PFR. The study is limited in that it does not directly compare women who had vaginal vault

prolapse alone but rather lumps all POP and subsequent PFRs into one category. Overall it supports ACOG's position that apical support be addressed at the time of hysterectomy for POP.

- **Hsu Y et al. Anterior vaginal wall length and the degree of anterior compartment prolapse seen on dynamic MRI. Int Urogynecol J 2008 19:137-42.** The authors evaluated MRIs of 145 women with and without POP. They then did linear regression modeling too determine the contribution of vaginal apical descent and vaginal length to cystocele size. They found that 77% of anterior wall descent can be explained by apical descent and midsagittal anterior wall length. This study reinforces the idea that vaginal apical support is important in subsequent pelvic support. Therefore, vaginal apical support defects must be addressed at surgeries designed to correct POP. Failure to do so may contribute to future prolapse.

- **Dällenbach P et al. Risk factors for pelvic organ prolapse repair after hysterectomy. Obstet Gynecol 2007;110:625-32.** A retrospective case-control study. Cases (n=114) were women who required POP surgery after hysterectomy Controls (n=236) were those who did not have recurrent POP during the same period. They performed univariable and multivariable analysis to identify the variables associated with prolapse repair after hysterectomy. The incidence of pelvic organ prolapse that required surgical correction after hysterectomy was 1.3 per 1,000 women-years. The risk of prolapse repair was 4.7 times higher in women whose initial hysterectomy was indicated by prolapse and 8.0 times higher if preoperative prolapse grade 2 or more was present (adjusted odds ratio [OR] 12.6, 95% confidence interval [CI] 4.6-34.7).