PROJECT PROTOCOL
Quality in Anti-Incontinence Surgery
(QuAIlS)

The AUGS Quality Improvement and Outcomes Research Network
Concept Approval: June 27th, 2015

ABBREVIATIONS

ABIM	American Board of Internal Medicine
ANOVA	Analysis of Variance
AUGS	American Urogynecologic Society
CPT®	Current Procedural Terminology ®
CST	Cough Stress Test
FDA	Food and Drug Administration
FPMRS	Female Pelvic Medicine and Reconstructive Surgery
H&P	History & Physical
ICD-9-CM	International Classification of Disease, Ninth Revision, Clinical Modification
ICD-10-CM	International Classification of Disease, Tenth Revision, Clinical Modification
LOS	Length of Stay
NPI	National Provider Identification
NQF	National Quality Forum
QI-ORN	Quality Improvement and Outcomes Research Network
QuAIIs	Quality in Anti-Incontinence Surgery Study
QuIPS	Quality in Prolapse Surgery Study
PHI	Protected Health Information
PFME	Pelvic Floor Muscle Exercises
POP	Pelvic Organ Prolapse
POP-Q	Pelvic Organ Prolapse- Quantification exam
PVR	Post-void residual
REDCap™	Research Electronic Data Capture™
SSI	Surgical Site Infection
UI	Urinary Incontinence
UPI	Unique Personal Identifiers
UTI	Urinary tract infection
VALUE	VALUE study

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A. STUDY OBJECTIVE AND PURPOSE

The main objective of the QuAIlS study is to collect data on (variation in) practice patterns and outcomes among surgeons performing surgeries for the treatment of female urinary incontinence (UI) at 10 different institutions participating in the American Urogynecologic Society Quality Improvement and Outcomes Research Network (AUGS QI-ORN). This data will be used to develop evidence-based data for quality metrics for these procedures.

Specifically, we will examine performance differences among low, intermediate, and high-volume surgeons. We will also examine the difference in performance of these quality metrics between surgeons with and without board certification in Female Pelvic Medicine and Reconstructive Surgery (FPRMS). Board-eligible surgeons will also be considered. Finally, we examine outcomes based on surgeon training (e.g. gynecology, urology, and/or fellowship training).

The QuAIlS study aims to expand upon the work of the previously conducted VALUE trial, and will include all surgeries performed for the correction of female UI. The main objective of the VALUE trial was to delineate variation in practice patterns among surgeons performing hysterectomies for pelvic organ prolapse (POP) in order to develop data for meaningful quality metrics for these procedures. These data met the testing requirement of the National Quality Forum and have been published in the peer-reviewed literature.

The NQF endorsed quality measures that resulted from the VALUE trial include:

1) NQF Measure #2038—Performance of apical vault suspension at the time of hysterectomy for POP
2) NQF Measure #2063—Performance of cystoscopy at the time of hysterectomy for POP (POP)
3) NQF Measure #2677—Performance of preoperative cough stress test (CST) prior to hysterectomy for POP

To accomplish this objective, the 10 sites in the AUGS QI-ORN are:

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University of Michigan	Dan Morgan	
Vanderbilt	Rony Adam	
Massachusetts General	Samantha Pulliam	
Dartmouth Hitchcock	Kris Strohbehn	
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B. BACKGROUND AND SIGNIFICANCE

Female Pelvic Medicine and Reconstructive Surgery (FPMRS) within the field of gynecology is truly unique surgical specialty. Gynecology is one of a very few specialties that is responsible for the management, both non-surgical and surgical, of an entire organ system. While gynecologic

procedures are extremely common, there is substantial variability in the practice of gynecology across the United States. This variability includes the geographic gynecologic surgical rate, administration of prophylactic antibiotics consistent with ACOG guidelines, and the offering of non-surgical treatment alternatives prior to surgery.(1-4) The performance of most gynecologic procedures is an elective preference-sensitive choice with most gynecologic procedures for benign indications having both non-surgical and surgical management options. Corona et al, demonstrated that many women (38%) are not offered alternative treatments prior to hysterectomy.(4) As recently suggested by Wright et al, focusing on the appropriateness of surgical indications and offering alternative treatments prior to surgery for benign gynecologic conditions should serve an important role in the future measurements of the quality care women receive in the United States.(5)

Quality Metrics: what should be measures? How should it be measured?

Value-based care is quality health care delivered effectively and efficiently. The success of value-based health care models is contingent on reducing over-use or waste. While many current efforts to improve quality are centered on reducing under-use (e.g. performing the appropriate screening tests as recommended, increasing appropriate vaccination rates), the best way to control health care spending to reduce over-use (e.g. unnecessary testing) and focus on the elimination of low-value care.(6) One promising strategy to reduce low-value care is the Choosing Wisely® campaign sponsored by the American Board of Internal Medicine. (7) The second main focus to reduce low-value care is the investment in accountable-care organizations (ACO) that contract to provide care for given populations, assuming risk in order to gain in shared savings resulting from the provision of high quality care.(8-10)

The first step in reducing low-value care and determining the quality of care delivered in both FPMRS and gynecology is creating meaningful ways to measure the care women receive. Using claims data (e.g. data based solely on billing) to determine quality care is limited and often inaccurate.(11) Often claims data misclassifies events, fails to measure severity of complications, and does not provide enough high quality information for adequate risk-adjustment. Therefore, chart reviews are currently necessary to determine performance gaps, variations in practice that deviate from the standard of care, and outcomes from many gynecologic surgical procedures.

C. STUDY SCHEMA

a. Study Design

The QuAIlS study is a RETROSPECTIVE review of surgeries performed for the indication of urinary incontinence between September 1st, 2011 and August 30th, 2013. The objective of the study is to evaluate the quality of care women received in the surgical treatment of urinary incontinence. We will assess quality by adherence to sixteen proposed Quality Measures (section G), multiple metrics that reflect efficiency of care (operative time, length of hospital stay), and rates of peri-operative complications (might delineate here). Analyses will include:

1) Descriptive statistics on focused on variation in practice and performance gaps focused on the relationship between adherence to standard practice protocols and (national and international) society guidelines

2) Risk adjusted outcomes for surgical procedures measuring intra-operative and peri-operative morbidity
3) Comparative analysis on adherence to standards of care and outcomes based on surgical volume, and surgeon training and certification

After the volume of surgeries performed for UI at all 10 institutions is determined, a sample of approximately 2,000 charts will be selected for review. The (electronic) medical records from these surgeries will then be reviewed. The 10 participating sites in the AUGS QIORN will each review approximately 200 cases. Preoperative office evaluations, admission history and physical (H&P), operative reports, and discharge summaries will be reviewed in order to assess the practice patterns of surgeons and collect/abstract information on patient outcomes. Data abstracted will be entered into a secure REDCap^{TM} database. Patients' charts will be reviewed through September 1st, 2015 to capture any interval repeat surgeries.

After IRB approval, each site will determine the number of eligible surgical procedures conducted at their institution during the study period/timeframe. Rather than review all medical records, we will then take a sample of these procedures with oversampling of low and mid-volume surgeons in order to obtain adequate representation of different practice patterns and practice variation.

D. STUDY POPULATION

The study population of interest for this study will be all women undergoing urinary incontinence surgery.

a. Denominator Definition

A critical component of the development of reliable and valid outcome measures is the development of a reliable denominator. A denominator definition in quality metrics clearly defines the population eligible for inclusion in the evaluation of the measure.

The denominator definition for this study be women undergoing surgery for urinary incontinence based on Current Procedural Terminology® (CPT ®) codes confirmed by accompanying international classification of disease, ninth revision, clinical modification (ICD-9-CM) diagnosis codes. A crosswalk between ICD-9-CM diagnosis codes and the new ICD-10 codes will be created to allow for these measures to be valid/consistent with the institution of ICD-10 in October 2015.

Please refer to Table 2 delineating CPT®, ICD-9-CM, and ICD-10-CM codes to be used as the denominator definition for the QuAIIS study.

Table 2: CPT® and ICD-9-CM codes used to define inclusion criteria

CPT Codes		&	ICD-9-CM diagnosis codes	
51840	anterior vesicourethropexy or urethropexy (Burch or Marshall-Marchetti-Krantz), simple		599.8	Other specified disorders of the urethra and urinary tract
51841	anterior vesicourethropexy or urethropexy (Burch or Marshall-Marchetti-Krantz), complicated (eg, secondary repair)		599.81	urinary incontinence due to urethral hypermobility
51845	abdomino-vaginal vesical neck suspension, with or without endoscopic control (Stamey, Raz, modified Pereyra, eg.)		599.82	urinary incontinence due to urethral sphincter incompetence
51990	laparoscopic urethral suspension; urethral suspension for stress incontinence		599.83	Urinary incontinence due to urethral instability
51992	sling operation for stress incontinence (laparoscopic)		625.6	female stress urinary incontinence
51999	unlisted laparoscopy procedure, bladder		788.3	Urinary incontinence
57220	urethral plication, vaginal approach (Kelly plication, eg.)		788.30	urinary incontinence, urinary incontinence in female, unspecified
57288	sling operation for stress incontinence (fascia or synthetic)		788.33	mixed urinary incontinence (stress and urge)
57289	Pereyra procedure		788.34	urinary incontinence without sensory awareness
53899	Unlisted procedure, urinary system		788.35	Urinary incontinence with post-void dribbling
58152	TAH with colpourethrocystopexy (MMK)		788.37	urinary incontinence with continuous leakage
58267	TVH with colpourethrocystopexy (MMK)		788.39	other urinary incontinence
58293	TVH for uterus > 250gm; with colpourethrocystopexy (MMK)		618.03	Urethrocele
58294	TVH for uterus > 250gm; with colpourethrocystopexy (MMK), with enterocele repair			

b. Inclusion and Exclusion Criteria

All women undergoing surgery for urinary incontinence during the study period are eligible for inclusion in the present sample/study. In general, surgery for urinary incontinence is performed in women who have completed childbearing. Therefore, both men of any age and women under the age of 18 will not be included in this study. The minimum age for a woman to be included in this study is 18. There is no maximum age, however, if a women is ≥ 90 years old, her exact age will not be recorded. This will be recorded as ≥90 years instead.

Information on the reliability of the denominator definition (based on CPT® and ICD-9-CM codes) is critical to this study and the development of reliable quality metrics. Therefore, if the medical record of a surgery that is not performed for urinary incontinence is identified despite having matching CPT® and ICD-9-CM consistent with urinary incontinence, the chart will be reviewed to determine why the billing codes do not match the surgery performed. Due to the vital nature of determining denominator reliability, these surgeries will not be excluded from the present analyses.

QuAIls is looking exclusively at procedures for urinary incontinence NOT performed at the time of concomitant repair of prolapse. Exclusion criteria for this study include procedures for cancer, procedures for fistula, urethral diverticulum and prolapse. See Table 3 for specific ICD-9-CM codes for exclusion.

Table 3: Exclusion criteria

ICD-9-CM codes	
Cancer	
180	Primary malignant neoplasm of the uterine cervix
182	Primary malignant neoplasm of the corpus uteri
183	Primary malignant neoplasm of the ovary and fallopian tubes
Fistula	
619	Fistula of the female genital tract
619.0	Urinary-genital tract fistula-female
619.1	Digestive-genital fistula
599.1	Urethral fistula
593.82	Ureteral fistula
565.1	Anal fistula
569.81	Intestinal fistula
Urethral diverticulum	
599.2	Urethral diverticulum
Pelvic Organ Prolapse	
618.0	Prolapse of vaginal walls without mention of uterus
618.00	unspecified prolapse of vaginal walls
618.01	Cystocele, midline
618.02	Cystocele, lateral
618.03	Urethrocele

618.04	Rectocele
618.05	Perineocele
618.09	Other female genital prolapse
618.1	Uterine prolapse
618.2	Uterovaginal prolapse, incomplete
618.3	Uterovaginal prolapse, complete
618.4	Uterovaginal prolapse, unspecified
618.5	Vaginal vault prolapse after hysterectomy
618.6	Vaginal enterocele
618.7	Old laceration of muscles of the pelvic floor
618.8	Other specified genital prolapse
618.81	Incompetence or weakening of the pubocervical tissue
618.82	Incompetence or weakening of the rectovaginal tissue
618.83	Pelvic muscle wasting
618.84	Cervical stump prolapse
618.89	Other specified genital prolapse
618.9	Unspecified genital prolapse

E. TIME FRAME

Surgical procedures of interest will include all procedures performed at each institution for urinary incontinence (identified by CPT® and ICD-9-CM codes) from September 1st, 2011 to August 30th, 2013. Patients' medical records will be reviewed through September 1st, 2015 to determine if repeat surgical procedures have been necessary in the first two years after their initial index procedure.

September 1st, 2011 is selected for the start date of this retrospective chart review for two very important reasons. The first is that this will allow for at least 2 years of postoperative follow-up from the index surgery for all patients. The second is that these dates are consistent with the concurrently planned QuIPS trial, looking at surgical procedures for pelvic organ prolapse.

F. DATA TO BE COLLECTED

As this study focuses on quality metrics, information will be collected both on surgeons and the surgeries performed, as well as patient characteristics and outcomes.

Initially, surgeons will be identified based on national provider identifier (NPI) number from the billing data. This will be used to determine surgical volume and categorize surgeons as high, intermediate and low volume surgeons. In addition, information collected on surgeons will include publically available information on board certification status (obstetrics and gynecology, urology, and female pelvic medicine and reconstructive surgery (FPMRS)) as well as information on post-graduate surgical training.

The medical record, including preoperative office evaluation (if available), admission history and physical (H&P), operative reports and discharge summaries, of sampled cases will be reviewed.

Clinical and demographic information abstracted will include AGE, race/ethnicity, parity, height, weight, surgical history, and physical examination variables including preoperative pelvic organ prolapse quantification (POP-Q) examination, Baden-Walker assessment, preoperative post-void residual (PVR), and cough stress test. In addition, the medical records will be reviewed for evidence that conservative management with pelvic floor muscle exercises (a.k.a Kegel's), avoidance of bladder irritants, weight loss, pelvic floor physical therapy, or a pessary was offered prior to surgery, and a discussion of the risks of synthetic mesh placement documented. Surgical variables abstracted will include the surgical procedures performed (including cystoscopy, and specific mesh or graft employed), intra-operative events (including operative time, estimated blood loss and lower urinary tract injury/perforation), length of hospital stay (LOS), post-operative complications (including blood transfusions, surgical site infection (SSI), urinary tract infection (UTI), mesh erosion and voiding dysfunction requiring catheterization or sling release), 30-day readmission or reoperation rates, and 1 &2 year reoperation rates.

All information will be abstracted into the REDCap™ web-application for the secure collection of protected health information (PHI). Unique personal identifiers (UPI) that could be used to identify the patient will never be linked to PHI. UPI will not be shared outside of the primary institution. Additionally, specific surgeon information will not be transmitted outside of an institution. Rather, each surgeon at an institution will be assigned a de-identified study ID number and only be identified in the REDCap™ database by this study ID number, not by name.

G. OUTCOME MEASURES

Using proposed quality measures from the AUGS quality committee and the 5 measures from the AUGS collaboration with the Choosing Wisely® program sponsored by the American Board of Internal Medicine (ABIM), the QuAIIS database will study the following quality metrics:

Performance Measures

1) Documentation of preoperative POP-Q or Baden-Walker examination prior to surgery for UI
2) Documentation of discussion of non-surgical options—pessary or pelvic floor muscle exercises (PFME a.k.a. Kegel's), pelvic floor physical therapy, exercise and weight loss for the treatment of UI (*)
3) Performance of preoperative cough stress test (CST)
4) Performance of preoperative postvoid residual (PVR)
5) Performance of intra-operative cystoscopy at the time of surgery for UI
6) Use of biologic or synthetic graft

Risk-adjusted outcome measures

7) Rate of ureteral injury recognized at the time of surgery for UI and delayed recognition of these injuries
8) Rate of bladder injury recognized at the time of surgery for UI and delayed recognition of these injuries
9) Rate of bowel injury recognized at the time of surgery for UI and delayed recognition of these injuries
10) Peri-operative blood transfusion (both intra-operative and postoperative blood transfusion)
11) Hospital LOS

12) 30-day readmission rates following surgery for UI
13) 30-day UTI rates following surgery for UI
14) 30-day SSI rates following surgery for UI
15) 1-year reoperation rates following surgery for UI
    a. May include surgery for mesh exposure/complication, voiding dysfunction, treatment failure, or prolapse surgery
16) 2-year reoperation rates following surgery for UI
    a. May include surgery for mesh exposure/complication, voiding dysfunction, treatment failure, or prolapse surgery

(*)Denotes a AUGS Choosing Wisely® proposed measures to the ABIM

Outcomes measures (measures 8-16) will be risk-adjusted. The QuAIIS dataset will provide baseline data regarding the rates of complications in patients undergoing surgical treatment for urinary incontinence and will allow for the development of risk-adjusted models that meaningfully reflect quality. Additionally, 1 and 2-year reoperation rates may not be accurate if the patient does not return to the same physician. However, because initial identification of these patients will be through the hospital system billing data rather than the individual surgeon, we hope to capture a more accurate reflection of true reoperations rates in general. We also will censor patients if follow-up is not known.

H. STATISTICAL CONSIDERATIONS AND ANALYTIC PLAN

Analyses will include:

1) Descriptive statistics on focused on variation in practice and performance gaps focused on the relationship between adherence to standard practice protocols and (national and international) society guidelines
2) Risk adjusted outcomes for surgical procedures measuring intra-operative and peri-operative morbidity
3) Comparative analysis on adherence to standards of care and outcomes based on surgical volume, and surgeon training and certification

a. Sampling of Charts

Approximately 2,000 urinary incontinence surgeries will be reviewed with approximately 200 charts reviewed per site. Selection of surgeries for chart review at each of the 10 sites will be random with 2 constraints. First, the division of chart review across sites will be distributed as equitably as possible with each site reviewing approximately 200 charts. Second, to adequately evaluate the association between surgical volume and outcomes, adequate numbers of surgeries from high, intermediate and low volume surgeons, an oversampling of the low and medium volume surgeons will be necessary.

b. Data Collection and Management

Study data will be abstracted from individual sites and managed using the Research Electronic Data Capture™ (REDCap™) tools hosted by the University of Michigan. REDCap™ is a secure, web-based application designed to support data capture for research studies, providing an intuitive interface for validated data entry; automated

export procedures for data downloads to common statistical packages; and procedures for importing data from external sources.

c. Analytic Plan

The first important statistic that will be delineated from this data set will be reliability information about the denominator. Specifically, we will determine how many surgeries identified be CPT® and ICD-9-CM billing codes are actually women undergoing surgery for urinary incontinence.

The second important statistic will focus on numerator information for the 7 process measures proposed. Analysis of variance (ANOVA) will be used for continuous variables. For categorical variables, Chi-squared and Fisher's exact test will be used as appropriate.

The final important statistic for this dataset will focus on the risk-adjustment outcome measures. Adequate risk-adjustment for outcome measures will be necessary to avoid unintended consequences of quality metric development.

Stratified analyses by board certification, surgeon training, and provider group practices will be conducted.

I. ETHICAL CONCERNS

This study is a retrospective chart review. Informed consent is not requested as a part of this retrospective research. A HIPAA waiver will also be requested at individual sites according to guidance of individual site IRBs and written policy to be able to retrospectively review charts.

This project is requesting a waiver of informed consent, as any attempt at informed consent is not necessarily feasible and may place the subject at risk of breach of confidentiality (e.g. to put a consent form in the mail, have them provide an un-witnessed signature, mail back the consent form and then have us store the consent form with name).

All PHI data that will be collected for this project will be de-identified and will be stored in a password-protected electronic file (REDCap™) on a secure server.

A separate dataset with patient subject identifiers (e.g. Unique Personal Identifiers (UPI)) will be maintained at each institution. UPI will not be shared across institutions. The dataset containing UPI will not contain any PHI in order to protect patient confidentiality. Finally, specific surgeon information will not be transmitted outside of an institution. Rather, each surgeon at a given institution will be assigned a de-identified study ID number and only be identified in the REDCap™ database by this study ID number, not by name.

J. REFERENCES

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