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An International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Report on the Terminology for Reporting Outcomes of Surgical Procedures for Pelvic Organ Prolapse

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Introduction and Hypothesis: Standardized terminology has yet to be developed for reporting the outcomes for surgery for pelvic organ prolapse (POP). **Methods:** This report combines the input of the Terminology and Standardization Committees of the International Urogynecological Association (IUGA) and the International Continence Society (ICS) and a joint Working Group on this topic, as well as expert external referees. The aim was to present a standardized terminology for the definitions of surgery and propose a structure for reporting the outcomes of surgical procedures for POP. An extensive drafting and review process was undertaken, as well as open review on both IUGA and ICS websites. **Results:** A terminology report was developed outlining the recommended structure for reporting outcomes of surgical trials involving POP. This document does not define success and failure. The report includes patient-reported subjective and objective outcomes to enable researchers to report on their results and compare them with other studies. **Conclusions:** A consensus-based method for standardizing terminology for reporting outcome measures of POP surgery was developed to aid clinicians working in this area of research. *Neurourol. Urodynam. 31:415–421, 2012.* © 2012 Wiley Periodicals, Inc.

Key words: terminology; outcomes; surgical procedures; pelvic organ prolapse; female pelvic floor dysfunction

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INTRODUCTION

Whereas recommendations for reporting outcomes of surgery for stress urinary incontinence have been reported[1,2] few exist for surgery of pelvic organ prolapse (POP). In addition, there has been ambiguity in reporting of "prolapse surgery outcomes," particularly with regards to success/failure and further surgery/re-operation. Within the literature, there is limitation in the methodology as evidenced by the recent Food and Drug Administration (FDA) report[3,4] and other reviews.[5] For example, information is often incomplete or limited relative to the inclusion and exclusion criteria and study design. In addition, the power calculation is often poorly described. Issues such as detection bias (lack of blinding), conflict of interest and reporting of adverse events are problematic

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and make it difficult to interpret the information. In addition, many studies include both primary and repeat prolapse repairs, as well as additional procedures including other prolapse and/or stress incontinence surgery. Long-term follow-up past 2 years is infrequent. As a result, it is difficult to draw conclusions from these studies relative to other studies or populations in order to provide guidance for patient care. Standardized information is required to help answer the important questions regarding efficacy and safety of traditional and new POP procedures. The aim of this report, therefore, is to present a standardized terminology for the definitions of POP surgery and propose a structure for reporting the outcomes of surgical procedures. Consistency in reporting has the potential to help produce meta-analyses and reliable clinical guidelines.

The document does not define success and failure, but outlines the recommended structure for reporting outcomes of surgical trials involving POP. It complements published IUGA-ICS Joint Standardization Reports on (i) Terminology for Female Pelvic Floor Dysfunction[6] and (ii) Terminology and Classification of Complications related directly to the insertion of prostheses and grafts in female pelvic floor surgery[7] and (iii) concomitantly published terminology and classification of complications related to native tissue female pelvic floor surgery.[8]

BACKGROUND

The perceived ambiguity in the reporting of POP surgery outcomes might have arisen from two studies assessing success/failure and further surgery/re-operation.[9,10] The former study by Olsen et al.[9] suggested that the lifetime risk of requiring incontinence and/or prolapse surgery was 11% (for prolapse surgery alone, the figure was 6.7%) and 29.2% of patients required repeat surgery/re-operation. The definition of repeat surgery was any operation for prolapse or urinary incontinence following an index (first) procedure, often some years previously. While the 29.2% re-operation rate is still commonly quoted and often interpreted similarly to that stated by the authors (i.e., that this implies a high rate of surgical failure), the failure to adjust for both time and variation in operative site reduces the usefulness of the conclusions and might be misleading with regards to the true failure rate of POP surgery. This observation is borne out when the same cohort was reviewed 10 years later with the authors quoting a 17% re-operation rate.[11] On further analysis of the same compartment recurrence (i.e., repeat anterior repair), the re-operation rate was significantly lower at 4.6%.[12] More recently, several investigators have looked specifically at the issue of site-specific recurrence, with re-operation rates ranging from 2.8% to 9.7%.[13–15] A recent Cochrane review[16] looking at vault suspension suggested that re-operation rates after POP surgery, which includes suspension of the vaginal vault/apex, are 1.3–3.9% at 17–32 months respectively, depending upon the type of vault suspension. These data become more useful in terms of site and timescales.

The second study[10] reported a 58–70% anatomical failure rate for anterior colporrhaphy. This study has recently been subject to further analysis, as the definitions of objective success and failure were based on POP quantification (POPQ) changes of small magnitude. When more clinically relevant criteria for success are used (anatomic recurrence beyond the hymen, symptomatic recurrence and re-operation), the outcome is considerably better with only 10% of subjects developing anatomic recurrence beyond the hymen, and 5% developing symptomatic recurrence and re-operations in $<1\%$ (at 23 months follow-up).[17]

The lack of subjective/patient-reported outcomes was highlighted in a systematic review on mesh repairs commissioned by the National Institute for Clinical Excellence (NICE) in the UK.[18,19] As a consequence of this and the uncertainty following further consideration of the studies mentioned above, there is a need for clear definitions and standardization for reporting of outcomes for POP surgery.

NEW DEFINITIONS

It is understood that there is close interaction among three commonly defined compartments: apical/vaginal vault, anterior, and posterior, when discussing pelvic organ support or prolapse. However, for ease of use, the definitions are limited to "primary" or "recurrence at specific sites" defined as apical/vaginal vault, anterior and posterior. As our understanding of how these compartments interact improves, the definitions of "primary prolapse surgery/different site" and "repeat surgery/same site" will evolve.

The following standardized terminology is proposed for surgical trials and clinical audit:

A. Primary Surgery:This indicates the first procedure required for the treatment of POP in any compartment.
B. Further Surgery:Provides a global term for the number of subsequent procedures the patient undergoes, directly or indirectly, relating to the primary surgery. Further surgery per se should not be interpreted as a measure or failure as the definitions of success and failure will be defined within the context of the individual study. Further surgery is subdivided into:

I. *Primary prolapse surgery/different site*: a prolapse procedure in a new site/compartment following previous surgery (e.g., anterior repair following previous posterior repair).
II. *Repeat surgery*: a repeat operation for prolapse arising from the same site. Where combinations of procedures arise, such as new anterior repair plus further posterior repair, these should be reported separately as primary anterior repair and repeat posterior repair.
III. *Surgery for complications*: mesh exposure or extrusion, pain, or patient compromise such as hemorrhage (see Complications section).
IV. *Surgery for non-POP related conditions*: subsequent surgery for stress urinary incontinence or fecal incontinence.

STANDARDIZATION OF REPORTING OUTCOMES—OVERVIEW

One of the major difficulties in reporting the results of prolapse surgery is that, unlike most surgeries, there is a range of outcomes which are not reported in a consistent manner; this makes uniform assessment of procedures difficult.

The International Consultation on Incontinence (ICI) has already suggested that POP and urinary incontinence surgery should report subjective, objective, and quality of life outcomes.[1] This is significant in that there are a number of measures that can be used to generate useful information to benchmark practice for and against a particular procedure, as well as inform patients about potential outcomes. Therefore, it is recommended that in clinical research studies, entry criteria, design, methodology, power, and absence of bias are addressed to allow the reader to assess the reliability of findings which have the potential to influence clinical practice.

Conflict of interest should be reported due to the potential for positive reporting bias and this declaration should be at the start of the paper.

REPORTING OF METHODOLOGICAL DATA

General Criteria

The following should be defined:

A. Inclusion criteria.
B. Exclusion criteria.
C. Recruitment time span.
D. Flow diagram including[20]

(i) Number of patients evaluated.
(ii) Number suitable for inclusion.
(iii) Number agreed to participate.
(iv) Clear documentation accounting for all patients' progress throughout the study period.

Comparative Studies

A. Clear explanation of patient allocation to treatment groups.
B. Allocation concealment from surgeon and/or patient.
C. Randomized trials: explanation of randomization process.
D. Stratification of associated issues utilized such as concomitant continence surgery or hysterectomy.

Interventions

A. Clear documentation of interventions performed, experience level of surgeons and number of interventions performed prior to study commencement.
B. Criteria for performing concomitant surgery.

Evaluation Process

A. Who performed the evaluation and the training received.
B. Were reviewers and/or participants blinded.
C. Evaluation tools: were validated, patient-completed assessments standardized.
D. Evaluation timeline:

i. Very early (up to 3 months).
ii. Early (up to 1 year).
iii. Intermediate (12–36 months).
iv. Late (3–5 years).
v. Very late (>5 years).

Power Analysis

Details of the assumptions made in the Power calculation, estimate of the type 1 error and sample size should be reported.

REPORTING DEMOGRAPHICS IN POP SURGICAL RESULTS

The reporting of minimum demographics in POP surgery should include:

A. Age,
B. Parity,
C. Body mass index (BMI),
D. Menopause status,
E. Hormone replacement therapy (HRT) usage,
F. Prior hysterectomy,
G. Prior POP surgery,
H. Prior continence surgery,
I. Chronic cough,
J. Chronic constipation,
K. Smoking.

REPORTING OF RANDOMIZED CONTROLLED TRIALS (RCTs)

There are already accepted standards for reporting RCTs such as the CONSORT (Consolidated Standards of Reporting Trials)[20] which requires detailed information provided by authors to reviewers with a checklist added as an appendix. However, many studies fail to provide complete descriptions of critical information.

REPORTING OF SYSTEMATIC REVIEWS AND META-ANALYSES

Due to the lack of consistent descriptions of critical information reported from RCTs, a new instrument, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA),[21] has been introduced to evaluate systematic reviews and meta-analyses. The aim of the PRISMA statement is to give authors an evidence-based minimum set of items to improve the reporting of systematic reviews and meta-analyses in POP issues. Other standards include the Standards for the Reporting of Diagnostic (STARD) accuracy studies,[22] and STROBE (STrengthening the Reporting of OBservational studies in Epidemiology).[23] Researchers should quote which standard they adopt and reference accordingly.

REPORTING OF PATIENTS' PRE-OPERATIVE GOALS AND EXPECTATIONS

To date, few studies have provided data on patients' preoperative goals and expectations.[24–27] These might have advantages over objective measures of outcome. With this in mind, goals should be reported using SMART criteria.[28] The aim of the SMART criteria is to help clinicians review and confirm the utility of the chosen endpoint and how it will relate to other studies and reports. Criteria comprise:

Specific	Defining goal (for POP: absence of bulge)
Measureable	Validated symptom scale or objective measure such as the POPQ
Appropriate	Relevant to improving patient lifestyle
Realistic	Achievable by treatment
Timely	For example at 6 months/2 years

The following is an example of good and poor reporting of patient expectations and outcomes, using the SMART Schema:

Good example: "The absence of bother from a vaginal bulge as measured using a defined tool at 2 years." This statement has Specific, Measurable, Appropriate, Realistic, and Timely attributes.

Poor example: "Feeling perfect" when followed-up. "Perfect" is not specific (OB compared with absence of bulge), is less measurable (because it is difficult to define), has no defined timepoint and is not appropriate or relevant to the surgery as many factors define "perfect."

Definitions relating to the SMART criteria should be derived from the symptoms the researchers feel are important. When designing a study, the symptoms should be listed and then SMART should be applied. Authors should use this as a *checklist* to ensure that the methodology is sound and relevant.

REPORTING OF OUTCOMES FOLLOWING SURGICAL TREATMENT OF POP

Perioperative Data

Perioperative data includes blood loss (ml) and/or hemoglobin change, operating time, length of hospital stay, return to normal daily activities and complications.

Patient Reported Outcomes

The primary patient reported outcome should be subjective and would usually be the absence of a bulge.[29] This can be regarded as a "subjective cure"[29] and can be recorded as part of a symptom scale. Details of validated questionnaires for patient reported outcomes can be found on ICI's website.[30] To adhere with the SMART criteria, patient/subjective outcomes should be defined at a specific time interval and classified on a 7-point Likert scale (i.e., very much better, moderately better, a little better, no change, slightly worse, moderately worse, very much worse) such as the Patient Global Impression of Improvement (PGI-I) scale.[31]

Patient Satisfaction

Patient satisfaction can be measured using qualitative measures, such as a patient-defined measure or a validated instrument (PGI-I scale).[31] Qualitative assessment can include Expectations, Goal setting, Goal achievement and Satisfaction (EGGS).[32] Again these should be in accordance with the SMART acronym. The number of pre-specified goals and the number achieved post-operatively should be recorded and reported for responsiveness and reliability of goal achievement.[24]

Quality of Life

Appropriate and fully validated quality of life instruments should be used to cover prolapse, urinary, bowel and sexual function.[30]

New questionnaires can be included when they have demonstrated good psychometric properties (i.e., validity, reliability and responsiveness) in women with POP. It is important to verify that the questionnaire has been validated in the language of the trial investigator(s).

Objective Outcomes

Objective outcomes (e.g., POPQ[33]) should be tabulated with percentages achieving each level to allow studies to compare results, as definitions of success will vary among studies (see below). This report does not attempt to provide a definition for success and failure, as these are unknown. However, authors should report data on the leading edge of the prolapse for each site (e.g., patients who achieve points -1 and 0 post-operatively having had prolapse greater than -1 or 0 before surgery). These data, which may help identify the level of anatomical restoration that leads to improvement in symptoms, should be reported separately.

When possible, raw data should be provided for POPQ, quality of life measures and all primary symptoms. These should be reported in separate tables, which can be published as supplementary material in the electronic (online) version rather than the printed version.

Reoperation or Further Surgery

See Further Surgery in "New Definitions" above.

Timelines

Timelines should be described chronologically, as outlined below, using the classification above. Of note, these timescales are different to those described in the classifications of complications reports related to female pelvic floor surgery using either prosthese and meshes[7] or native tissue.[8]

I. Very early (up to 3 months).
II. Early (up to 1 year).
III. Intermediate (12–36 months).
IV. Late (3–5 years).
V. Very late (>5 years).

Economic Evaluation/Cost Analysis

Despite considerable cost, sparse cost-effectiveness data exists related to POP surgery. Investigators are encouraged to include economic analyses in their studies whenever possible. Further details are below in the section Reporting on Economic Evaluation/Cost Analysis.

COMPLICATIONS

Complications specifically related to prostheses and grafts[7] and native tissues[8] should be reported as per the IUGA-ICS classifications of complications directly related to the insertion of prostheses and grafts or the use of native tissue in female pelvic floor surgery.[5,6] These classifications both use the CTS Classification System:

(C) Category of complication.
(T) Time the complication was diagnosed in relation to primary surgery.
(S) Site of the complication.

There are seven Categories with subdivsions of (A–D). For the majority of complications, this would mean:

(A) Asymptomatic,
(B) Symptomatic,
(C) Infection,
(D) Abscess.

For complications involving bowel or bladder injury or patient compromise, variations in the pattern of the increasing index of severity exist: e.g., Category 5: rectal or bowel injury (both classifications—[7,8]) (A) Small intraoperative defect; (B) rectal injury or compromise; (C) small or large bowel injury or compromise; (D) abscess.

Studies, in particular of a specific surgical procedure, should have a procedure-specific list of complications using the CTS Classification Systems[7,8] as part of the reporting. Only in this way can the nature and chronology of possible complications be determined (in relation to time of surgery) and at which sites they might most commonly occur.

Note is also made of the generic Clavien-Dindo complication classification[34] which consists of four severity grades of complications. This has been modified to include a fifth category:[35]

Grade I	Requires no treatment
Grade II	Requires drug therapy
Grade III	Requires a procedure or intervention (a: in local; b: general anesthesia)

Grade IV	IC/ICU organ or system dysfunction (a: single organ; b: multi-organ dysfunction)
Grade V	Death

POSTOPERATIVE PAIN

Pain associated with surgical complications is addressed separately in the IUGA-ICS classifications of complications of female pelvic floor surgery (7,8). The addition of a letter (*a* to *e*), as part of a subclassification to the CTS Classification System, specifies the presence of pain as part or all of the abnormal finding or complication and the grade in terms of the presence and severity of symptoms.

(a) Asymptomatic or no pain.
(b) Provoked pain only (during vaginal examination).
(c) Pain during sexual intercourse.
(d) Pain during during physical activties.
(e) Spontaneous pain.

Additional information on pain may include "permanent or temporary" and "severity" as measured by impact on quality of life and treatment required (e.g., simple oral analgesia, compound analgesia, opiates, referral and management by pain team or further surgery).

REPORTING OF SECONDARY OUTCOMES

Secondary outcomes to be reported include an assessment of other symptoms known to be associated with prolapse:

Lower urinary tract symptoms (LUTS): Overactive bladder, stress urinary incontinence (either pre-existing or de-novo) and voiding dysfunction.

Bowel dysfunction: Obstructed defecation, feeling of incomplete emptying, constipation and digitation.

Sexual dysfunction: Dyspareunia, loss of libido, abstinence due to prolapse symptoms and change in sexual satisfaction. Authors should report numbers of all patients who are sexually active with and without pain, pre and post-intervention.

Figure 1 has been developed to illustrate the reporting of these data. All participants in trials should be accounted for pre- and post-intervention.

De novo/new onset symptoms (if not previously reported): LUTS, sexual dysfunction, pain and bowel dysfunction.

Backache: Backache is a common presenting symptom, the resolution of this may be an important outcome.

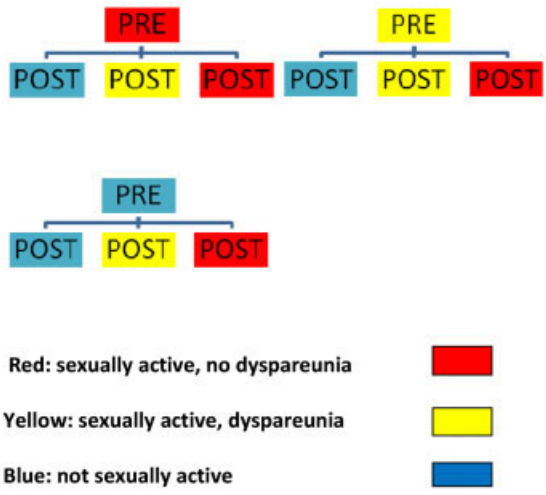

Fig. 1. Reporting of sexual function.

REPORTING ON ECONOMOIC EVALUATION AND COST ANALYSIS

Economic evaluation techniques provide systematic methods of comparing the costs and consequences of clinical and other health sector interventions. Cost-utility analysis (CUA), a form of cost-effectiveness analysis (CEA), is by far the most commonly used and requires quantifying the effects of interventions on both morbidity and mortality.

In a CUA, benefits are measured in units of health gain (or loss), most commonly using quality-adjusted life-years (QALYs) and combined with estimates of cost to create a ratio of incremental costs to incremental consequences (e.g., "incremental cost per QALY"). QALYs are usually calculated using a generic health status measure, such as Short Form (SF)36 or *EuroQOl*EQ-5D, which can be used with a standard set of health state values or by other measures of utility, such as the standard gamble or time-trade off technique. These incremental cost effectiveness ratios (ICERs) enable comparison of competing interventions on the basis of the cost at which they create improvements in health-related quality-of-life.

In economic evaluations, it is important to consider the perspective (e.g., patients, hospital, third-party payer, government and society) of the evaluation, as this will have significant influence on which costs should be included in the analysis. For example, the perspective of the analysis will influence whether it should include both direct and indirect costs. Direct medical costs typically relate to the intervention and the immediate impact of the intervention on the health system: e.g., personnel costs/time (physician, nurse, technician), diagnostic and laboratory tests, hospital costs, treatment costs (drugs, operating room time, etc.), treatment of side effects and outpatient visits. Indirect costs will be of more relevance to a patient and/or societal perspective (e.g., loss of productivity, time lost from work, loss of service to family and community and premature mortality) and are often more difficult to quantify and to put a monetary value on.

DISCUSSION

This document was born from the recognition that contemporary practice lacks sufficient reproducible evidence to help clinicians translate published literature into clinical practice and enable patients to be aware of likely outcomes.

For example, the assessment of prolapse surgery has been subject to a number of limitations. First, and perhaps most important, is the quality of the studies. The majority are case series, with very few well-constructed and sufficiently powered RCT. As a result, the quality of the available evidence is questionable.[3,4] The emphasis then lies within systematic reviews and meta-analyses, which may be less robust due to the lack of good quality data.

New surgical procedures for POP reconstructive surgery have evolved dramatically in recent years, suggesting that the perceived dissatisfaction with conventional/traditional surgery as expressed by White[36] at the turn of the twentieth century persists. This perception is based on clinical experience and reports of anatomical failure and re-operation.[9,10] As the findings of these studies[9,10] have been questioned by more recent studies,[12,13,17] this highlights the need for a standardized method of reporting surgical outcomes so that appropriate recommendations for patient care can be provided from meta-analyses and systematic reviews. This report sets out to provide a framework through which researchers and clinicians can standardize reporting and allow results to become more transferable.

TABLE I. Recommendations for Reporting in Audit of Clinical Practice and Surgical Trials

	Audit	Research trial
Type of surgery	R	R
Primary outcome including patient satisfaction	R	R
Secondary outcomes	O	R
Timelines	O	R
Cost analysis	N	O[a]
Complications	R	R
Commitment to longer term follow-up	O	R
Audit database	R	O

R, routine; O, optional; N, not required.
[a]It is recognized that this is ideal and not all researchers will be able to do this, but it is recommended.

History has taught that surgical complications (particularly in the case of implants) may be long-term and researchers should be encouraged to revisit early results (e.g., 1 year) and include long-term data of 5–10 years.

The Austrian and Finnish experiences with mid-urethral slings have demonstrated that, in addition to properly constructed prospective trials, there is a moral and ethical responsibility for users of advanced techniques, such as those employing implants, to contribute to clinical governance and audit through local, regional or national databases.

SUMMARY OF RECOMMENDATIONS FOR POP SURGICAL OUTCOMES

In all surgical trials of POP surgery, authors should clearly report their Methodology. These should follow CONSORT/STROBE and type of surgery (primary or further using the agreed definitions, see above) should be stated. Table I outlines what should be reported in both clinical audit and surgical trials. In addition, researchers should give a commitment in the original trial design and at publication of early results, to publish longer term data at a minimum of 5 years.

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