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DEVELOPMENT OF QUALITY INDICATORS FOR WOMEN WITH URINARY INCONTINENCE

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Abstract

AIMS—To develop a means to measure the quality of care provided to women treated for urinary incontinence (UI) through the development of quality-of-care indicators (QIs).

METHODS—We performed an extensive literature review to develop a set of potential quality indicators for the management of urinary incontinence. QIs were modeled after those previously described in the Assessing the Care of Vulnerable Elders (ACOVE) project. Nine experts ranked the indicators on a nine-point scale for both validity and feasibility. We analyzed preliminary rankings of each indicator using the RAND Appropriateness Method. A forum was then held in which each indicator was thoroughly discussed by the panelists as a group, after which the indicators were rated a second time individually using the same nine-point scale.

RESULTS—QIs were developed that addressed screening, diagnosis, work-up, and both non-surgical and surgical management. Areas of controversy included whether routine screening for incontinence should be performed, whether urodynamics should be performed before non-surgical management is initiated, and whether cystoscopy should be part of the pre-operative work-up of uncomplicated stress incontinence. Following the expert panel discussion, 27 of 40 potential indicators were determined to be valid for UI with a median score of at least seven on a nine-point scale.

CONCLUSIONS—We identified 27 quality indicators for the care of women with UI. Once these QIs are pilot-tested for feasibility, they will be applied on a larger scale to measure the quality of care provided to women with UI in the United States.

Keywords

Quality Indicators; Outcomes; RAND Appropriateness Method; Stress Urinary Incontinence; Urge Urinary Incontinence

Introduction

The need to decrease costs of health care while improving the quality of the care delivered in the US has made the investigation of the appropriateness of medical and surgical interventions a priority in health services research. Female urinary incontinence (UI) is a field in which insufficient evidence-based recommendations for the diagnosis and treatment of this condition have been a barrier to the delivery of quality care. This paucity of adequate data exists, despite a widespread prevalence of female urinary incontinence[1]. Quality-of-care indicators (QIs) are used to investigate the quality of care provided for various diseases.[2–6] As part of the Assessing Care of Vulnerable Elders (ACOVE) project[5], QIs specifically for vulnerable community-dwelling adults with UI were measured in 372 randomly selected patients.[6] Only 50% of eligible patients received medical treatment for UI, 20% received a pelvic examination, and 13% were prescribed behavioral intervention, despite its known efficacy.

These findings from the ACOVE project indicate a quality problem in the treatment of UI older adults. At the present time, there remains a paucity of data on quality of care for younger and older groups of women with UI who do not necessarily qualify as vulnerable elders, and who may undergo more invasive procedures. Under the hypothesis that the care of urinary incontinence varies by provider and is often suboptimal, we sought to develop an infrastructure for measuring the quality of care provided to women with UI.

Materials and Methods

Identification of Candidate QIs

Most quality indicators outline the minimum care appropriate for a patient with a certain condition, i.e., “the floor.” If a specific element of care, as measured by a quality indicator, is not performed, then such care would in the great majority of cases be considered inadequate.[7] Alternatively, clinical guidelines outline optimal care, i.e., “the ceiling.” Twelve expert interviews were conducted with providers who have expertise in the fields of urology, urogynecology, internal medicine, geriatrics, and behavioral treatment. These experts are each active members of either the Society for Urodynamics and Female Urology (SUFU), the American Urological Association (AUA), the American Urogynecologic Society (AUGS), or the International Continence Society (ICS). These experts were asked for their opinions regarding the relevance and significance of the domains of care identified during the literature search (unpublished data). We also conducted patient focus groups, which further informed the creation of the QIs.[8]

Literature Review

Clinical practice reviews and algorithms addressing stress urinary incontinence (SUI) and urge urinary incontinence (UUI) were identified by searching various websites of professional societies such as National Guideline Clearinghouse, SUFU, AUA and the Joint Commission on Accreditation of Healthcare Organization (JCAHO). Domains of care fell under the general categories of “prevention and screening,” “diagnosis,” and “treatment.” In order to generate specific evidence-based quality indicators for each of the selected areas, PubMed and Cochrane Library searches were performed and the relevant literature identified. The highest level of evidence for each area was identified.

Potential quality indicators were constructed in an “if-then-because” format, as described by the ACOVE project.[5] “If” describes the criteria that make the quality indicator applicable to a specific type of patient. “Then” introduces the intervention that should or should not be performed. “Because” provides the anticipated impact the intervention will have on the

patient. For example, “if” a woman presents with new or worsening symptoms of incontinence, “then” a thorough history should be obtained, including whether symptoms of urge, stress or both types of incontinence are present, “because” treatment strategies vary for the different types of incontinence.

RAND Appropriateness Methodology

Experts from a wide variety of specialties were selected for the expert panel. RAND Appropriate Panels apply a multidisciplinary approach, but are generally limited to nine panelists. Prior to selecting the panel we sought to include a mix of three groups of panelists (gynecologists, urologists, and internists) so that diversity would be maintained within each specialty, rather than having only one panelist representing a specialty. The panel included three urologists with expertise in UI, three urogynecologists, and three internists with expertise in quality-of-care and incontinence research. A document compiling the potential quality indicators and systematic literature reviews for each domain was provided to each of the expert panel members. Panel members were asked to use the modified RAND Appropriateness Method, to evaluate the validity and feasibility of the proposed quality indicators.[9] In this method, panel members reviewed the quality indicators and literature reviews, then provided initial rankings of the validity and feasibility of each quality indicator on a nine-point scale.

A two-day expert panel was convened at UCLA and discussions were conducted regarding each QI, moderated by two physicians, one with extensive experience in the panel process and the other a reconstructive urologist with training in health services research.[10] Experts were encouraged to evaluate the advantages and disadvantages of each indicator and to cite relevant literature in addition to their own opinions and experiences. The experts were also allowed to modify any of the QIs, or add entirely new QIs, as they felt appropriate. Panelists completed a second round of validity and feasibility rankings for each QI after each discussion.

Utilization of the Validity and Feasibility Scales

An indicator was considered valid if there was sufficient evidence or professional consensus to demonstrate that performance of care described by the indicator leads to an improvement in health experienced by patients. QIs were rated on a nine-point scale. A score of 1–3 designates that the indicator is not a valid measure of good quality, 4–6 indicates uncertain or equivocal validity and 7–9 that the indicator is clearly valid. A median score from the first and second round ratings was calculated for each quality indicator. A quality indicator was defined as valid if the median score from the second round of ratings was seven or above. Feasibility addresses the likelihood that a given indicator, if performed, will be documented in the medical record. The same 9-point scoring system was used for feasibility.

Results

Definitions

A list of definitions for terms relevant to SUI and overactive bladder (OAB)/UUI was generated during the literature review and presented to panelists prior to the panel meeting (Appendix 1).

Candidate Quality Indicators

The expert panel accepted 27 of the 40 proposed process QIs in their second round of rankings (Table 1). Domains of care fell under the general categories of “prevention and screening,” “diagnosis,” and “treatment.” The QIs are applicable to both generalists and specialists.

Highlights of Panel Discussions

Screening—The Brigham and Women's Hospital Urinary Incontinence Guidelines recommend that primary care clinicians should initiate discussion about UI because only half of incontinent women will report this problem at office visits.[11] However, it was discussed that screening for UI might not be reasonable for a primary care doctor who must address many health issues for a given patient. With no evidence that screening for UI improves treatment outcomes and a significant concern for over-treatment of non-bothersome symptoms, the panel rejected this QI (Table 1, QI 1).

Targeted exam—The ICS[12] and the European Association of Urology (EAU)[13] recommend pelvic and perineal examination and stress testing as part of the initial evaluation of women with UI. The panel determined that a pelvic exam to rule out associated pelvic pathology, in addition to an assessment of pelvic organ prolapse, is necessary (Table 1, QI 3b). The panel rejected the QI that a stress test should be performed in the evaluation of UI, but approved the QI that states that a woman should have a pre-operative stress test.

Diagnostic testing—The ICS recommends uroflow only for patients with symptoms suggestive of urinary voiding dysfunction or physical signs of pelvic organ prolapse or bladder distension.[12] The expert panel approved the QI stating that uroflow should *not* be performed on a woman who presents with new or worsening bothersome symptoms of UI unless she also has signs or symptoms of voiding dysfunction. Uroflow represents a negative indicator (Table 1, QI 5) in that the process of care, if performed, is either of no benefit or even harmful to the patient, and, at the same time, increases the cost of care. The expert panel accepted the quality indicator affirming that urodynamics studies should *not* be performed in a woman with previously untreated symptoms (including behavioral treatments) of UUI without neurologic disease or voiding dysfunction, which is another negative indicator (Table 1, QI 7).

Initial Management of UI—The ICS recommends the use of pelvic floor muscle training (PFMT) for women with UI based on Grade A evidence.[12] Although PFMT does not have high absolute cure rates, it is related to significant improvements in symptoms and perceived quality of life[14,15]. The efficacy of biofeedback as an adjunctive therapy to PFMT is also indeterminate.[16] The QI stating that women presenting with new or worsening bothersome UI should initially be offered PFMT was accepted by the panel due to the Level I evidence supporting its efficacy (Table I, QI 8).

Management of SUI—Since many providers treat incontinence with medical therapy, regardless of type of incontinence, the panel accepted the negative QI stating that anticholinergic medications should *not* be offered to women with SUI (without symptoms of UUI) in order to detect the inappropriate use of these drugs (Table 1, QI 10).

Pre-operative Urodynamics Testing—As previously mentioned, the ICS recommends that urodynamics before surgery for SUI be reserved for patients with complicated incontinence, UI refractory to treatment or recurring UI.[12] The panel concluded that pre-operative urodynamics should not be required until there is evidence demonstrating that it improves outcomes for certain populations of patients with SUI (Table 1, QI 12).

Pre-operative Post-void Residual (PVR)—The ICS cautions that patients with voiding dysfunction with a PVR>30% of total bladder capacity may have bladder outlet obstruction or detrusor underactivity.[12] The expert panel accepted the quality indicator stating that a

woman with SUI who undergoes surgery should receive a pre-operative PVR analysis (Table 1, QI 13).

Pre-operative Cystoscopy—Because sling procedures involve a cystoscopy at the time of surgery, a pre-operative cystoscopy in a woman without microhematuria (or other complicating features such as prior incontinence surgery or urinary tract infections) is not indicated. Therefore, the expert panel accepted the negative quality indicator stating that a women with SUI and no other urologic diagnosis or prior incontinence surgery should *not* undergo diagnostic cystoscopy prior to surgery (Table 1, QI 14).

Intraoperative Cystoscopy—Based on a "standard" recommendation, the AUA advocates for intraoperative cystourethroscopy in all patients undergoing sling surgery.[17] A significant risk of trocar placement into the bladder exists with minimally invasive retropubic sling placement. Although transobturator slings have a lower rate of bladder perforation, a risk of bladder perforation does still exist with this procedure.[18] Therefore, the expert panel supported the QI requiring that intraoperative cystoscopy be performed during sling placement for SUI (Table 1, QI 18).

Use of Mesh—While the use of synthetic material for sling procedures is associated with improved efficacy, the risks of mesh erosion, pain and infection exist.[19.20] In 2008, the Food and Drug Administration (FDA) issued on official warning to health care providers alerting them to the significant number of complications that were reported associated with surgical mesh used in procedures to repair pelvic organ prolapse and SUI.[21] Although the FDA warning was updated in July of 2011 and restricted the warning to vaginally placed mesh for prolapse, the expert panel approved the quality indicator stating that a woman who undergoes surgical management of SUI with mesh should be counseled pre-operatively about the risks of mesh (Table 1, QI 11).

Surgical Procedures for SUI—Needle suspension procedures, anterior colporrhaphy, and the Kelly plication have been shown to produce suboptimal outcomes compared to other incontinence procedures.[22,23,24] As a result, the expert panel accepted the quality indicator advising that women should *not* undergo Kelly plication, anterior colporrhaphy or needle suspension for the treatment of SUI (Table 1, QI 16). The ICS supports the use of injectable bulking agents for SUI patients with limited bladder neck mobility.[12,25] Furthermore, based an "optional" recommendation, the AUA endorses the use of injectable bulking agents as one of the five types of procedures for the treatment of SUI, which include laparoscopic suspensions, midurethral slings, pubovaginal slings and open retropubic suspensions.[17]

Informed Consent Regarding Risks of Surgical Procedures for SUI—Informed consent is needed to ensure that women planning to undergo surgical procedures for SUI are aware of all of the major risks and benefits associated with these procedures (Table 1, QI 17). Many institutions and surgeons use general language on consent forms, which may limit the feasibility of these indicators.

Management of UUI—It was determined that a woman with UUI/OAB prescribed anticholinergic medications should also be counseled about behavioral therapy, given that anticholinergic agents are more effective with behavioral therapy than alone (Table 1, QI 22).

Sacral Neuromodulation—The panel did not pass the quality indicator advising that a woman who has persistent bothersome UUI/OAB after pharmacologic therapy or is not a candidate for pharmacologic therapy should be offered sacral neuromodulation (Table 1, QI

24). The panel did not consider it bad care to not offer neuromodulation, and therefore it was not ranked highly enough to be passed.

Botox Injections—Since Botox risks urinary retention and is only FDA-approved for specific populations with UI, the panel did not endorse this QI. However, the panel did accept the indicator stating that a woman who does elect to undergo Botox injection should be counseled on the risk of urinary retention and associated increased in the risk of urinary tract infections (Table 1, QIs 25–7).

Discussion

QIs can be used retrospectively to measure the quality of care provided to certain patient populations, and may also be used prospectively as a guide for the minimum level of care that should be provided to patients. They may also be useful for regulatory agencies and payors.[3] The Pay for Performance (P4P) initiative is a reimbursement scheme adopted by the Center for Medicare and Medicaid Services to provide financial incentives for providers who meet quality measures for patient care. QIs can potentially be used as quality measures for P4P initiatives.[3] Given the widespread implementation of P4P, the subspecialties of Urology and Urogynecology need to be actively involved in the development of feasible performance measures for pelvic floor disorders.[26,27] UI is uniquely problematic in that outcomes can be measured in a multitude of ways, and identifying a process-outcome relationship may not be possible for many quality measures. Though the QIs we developed address the care for both generalists and specialists, they include a large number of items and therefore may not be acceptable to larger entities addressing quality improvement, such as the American Medical Association's Physician Consortium for Performance Improvement (PCPI). The PCPI, in conjunction with the American Urological Association (AUA) and the American College of Obstetricians and Gynecologists have developed performance measures for UI among adults age 65 and over. We seek not to duplicate the efforts of these groups, but to provide the ability to measure the quality of care at the local level, with the ultimate goal of improving care.

The RAND Appropriateness Method is a validated means to synthesize the literature and expert opinion in areas where there is little level I evidence. Unlike a consensus panel, the formal ranking process allows each panelist to have an equal vote in the process, preventing the possibility of bias towards the opinions of the more senior or vocal members of the panel.[3,28] Nonetheless, this work has limitations. Although the main limitation of this methodology is the level of evidence available, the Appropriateness Method had been used to develop quality indicators that have been shown to have predictive validity, meaning that patients who have received better care according to the quality indicators have subsequently had better outcomes.[29]

The next step will be to operationalize these candidate QIs through a pilot test to determine the feasibility of identifying these QIs from medical records of women with UI. After the pilot test, we seek to conduct studies to identify variation in the quality of care provided to women between different health care systems, with the ultimate goal of developing an intervention to improve incontinence care. Such interventions have proven successful in the primary care setting among vulnerable elders using the ACOVE QIs.[30]

Conclusions

In conclusion, we developed a set of process-focused quality indicators for female stress and urge incontinence. This set of quality indicators can be modified with time, as additional evidence is contributed to the current literature on urinary incontinence.

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3. Thomas Mattimore, MD-UCLA, Internal Medicine
4. Victor Nitti, MD- New York University, Urology
5. Neil Resnick, MD- Internal Medicine/Geriatrics; University of Pittsburgh
6. Larissa Rodriguez, MD- UCLA, Urology
7. Christopher Tarnay, MD- UCLA, Urogynecology
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References

1. Nygaard BM, Barber MD, Burgio KL, et al. Prevalence of symptomatic pelvic floor disorders in US women. JAMA. 2008 Sep; 300(11):1311–6. [PubMed: 18799443]
2. Spencer BA, Steinberg M, Malin J, et al. Quality-of-care indicators for early-stage prostate cancer. J Clin Oncol. 21:1928–36. [PubMed: 12743145]
3. McGory ML, Shekelle PG, Ko CY. Development of quality indicators for patients undergoing colorectal cancer surgery. J Natl Cancer Inst. 2006; 98:1623–33. [PubMed: 17105985]
4. McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. N Engl J Med. 2003; 348:2635–45. [PubMed: 12826639]
5. Wenger NS, Solomon DH, Roth CP, et al. The quality of medical care provided to vulnerable community-dwelling older patients. Ann Intern Med. 2003; 139:740–7. [PubMed: 14597458]
6. Gnanadesigan N, Saliba D, Roth CP, et al. The quality of care provided to vulnerable older community-based patients with urinary incontinence. J Am Med Dir Assoc. 2004 May-Jun;5(3): 141. [PubMed: 15115573]
7. Higashi T, Shekelle PG, Adams JL, et al. Quality of care is associated with survival in vulnerable older patients. Ann Intern Med. 2005 Aug 16; 143(4):274–81. [PubMed: 16103471]
8. Anger JT, Nissim HA, Le TX, et al. Women's experience with severe overactive bladder symptoms and treatment: insight revealed from patient focus groups. Neurourol Urodyn. 2011 Sep; 30(7): 1295–9. [PubMed: 21538495]
9. Brook RH, Chassin MR, Fink A, et al. A method for the detailed assessment of the appropriateness of medical technologies. Int J Technol Assess Health Care. 1986; 2(1):53–63. [PubMed: 10300718]
10. Min LC, Reuben DB, Adams J, et al. Does better quality of care for falls and urinary incontinence result in better participant-reported outcomes? J Am Geriatr Soc. 2011 Aug; 59(8):4135–43. Epub 2011 Aug 1. 10.1111/j.1532-5415.2011.03517.x
11. Bengtson, J.; Chapin, MD.; Kohli, N., et al. Urinary Incontinence: Guide to diagnosis and management. Boston MA: Brigham and Women's Hospital; 2004.
12. Abrams P, Andersson KE, Birder L, et al. Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and Treatment of Urinary Incontinence, Pelvic Organ Prolapse and Fecal Incontinence. Neurourol Urodyn. 2010; 29(1):213–40. [PubMed: 20025020]
13. Thuroff, J.; Abrams, P.; Andersson, KE., et al. European Association of Urology. 2006. Guidelines on Urinary Incontinence.

14. Shamliyan TA, Kane RL, Wyman J, et al. Systematic review: Randomized clinical controlled trials of nonsurgical treatments for urinary incontinence in women. Ann Intern Med. 2008; 148:459–73. [PubMed: 18268288]
15. Doumoulin C, Hay-Smith J. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database Syst Rev. 2010 Jan 20. (1):CD005654. [PubMed: 20091581]
16. Weatherall M. Biofeedback or pelvic floor muscle exercise for female genuine stress incontinence: a meta-analysis of trials identified in a systematic review. Br J Urol Int. 1999; 83:1015–1016.
17. Dmochowski RR, Blaivas JM, Gormley EA, et al. Update of AUA Guideline on the Surgical Management of Female Stress Incontinence. J Urol. 2010; 183:1906–14. [PubMed: 20303102]
18. Latthe PM, Foon R, Tooza-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG. 2007; 144:522–31. [PubMed: 17362484]
19. Latthe PM, Singh P, Foon R, et al. Two routes of transobturator tape procedures in stress urinary incontinence: a meta-analysis with direct and indirect comparison of randomized trials. BJU Int. 2010 Jul; 106(1):68–76. [PubMed: 19912182]
20. Sweat SD, Itano NB, Clemens JQ, et al. Polypropylene mesh tape for stress urinary incontinence: Complications of urethral erosion and outlet obstruction. J Urol. 2002; 168(1):144–6. [PubMed: 12050509]
21. Schultz, DG. FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence. US Food and Drug Administration; Oct 20. 2008 15 Sep. 2010. < http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm>
22. Glazener CM, Cooper K. Bladder neck needle suspension for urinary incontinence in women. Cochrane Database Syst Rev. 2004; (2):CD003636. [PubMed: 15106209]
23. Glazener CM, Cooper K. Anterior vaginal repair for urinary incontinence in women (Review). Cochrane Database Syst Rev. 2001; (1):CD001755. [PubMed: 11279728]
24. Thaweekul Y, Bunyavejchevin S, Wisawasukmongchol W, et al. Long term result of anterior colporrhaphy with Kelly plication for the treatment of stress urinary incontinence. J Med Assoc Thai. 2004; 87(4):357–60. Apt. [PubMed: 15217169]
25. Keegan PE, Atiemo K, Cody J. Periurethral injection therapy for urinary incontinence in women. Cochrane Database Syst Rev. 2007 Jul 18.(3):CD003881. [PubMed: 17636740]
26. Erekson EA, Sung VW, Myers DL. Pay for performance: what the urogynecologist should know. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Aug; 19(8):1039–41. [PubMed: 18629563]
27. Gonzalez CM, Penson D, Kosiak B, et al. Pay for performance: rationale and potential implications for urology. J Urol. 2007 Aug; 178(2):402–8. [PubMed: 17561159]
28. Jones J, Hunter D. Consensus methods for medical and health services research. BMJ. 1995 Aug 5; 311(7001):376–80. [PubMed: 7640549]
29. Zingmond DS, Ettner SL, Wilber KH, et al. Association of claims-based quality of care measures with outcomes among community-dwelling vulnerable elders. Med Care. 2011 Jun; 49(6):553–9. [PubMed: 21499140]
30. Wenger NS, Roth CP, Shekelle PG, et al. A practice-based intervention to improve primary care for falls, urinary incontinence, and dementia. J Am Geriatr Soc. 2009 Mar; 57(3):547–55. [PubMed: 19175441]

Appendix 1. Definitions of terms used with respect to urinary incontinence

Urinary Incontinence (UI): Complaint of any involuntary leakage of urine. Some classify UI based on symptoms, whereas others use pathophysiology to define subgroups. Also, there may be overlap among subgroups. Therefore, for this study we propose the following categories of UI:

- **Stress Urinary Incontinence (SUI):** The complaint of involuntary leakage on effort or exertion or on sneezing or coughing.

- In SUI, there is a spectrum of urethral characteristics ranging from a highly mobile urethra with good intrinsic function to an immobile urethra with poor intrinsic function.
- Urodynamic stress incontinence is noted during filling cystometry and is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of detrusor contraction.

- **Urge Urinary Incontinence (UUI):** The complaint of involuntary leakage accompanied by or immediately preceded by urgency.
  - UUI is often associated with detrusor overactivity which may be spontaneously provoked.
  - UUI is part of the overactive bladder symptom complex.
  - **Overactive Bladder (OAB)** is defined as urgency, usually with frequency and nocturia with or without UUI, that occurs in the absence of urinary tract infection or other obvious pathology.

Urethral Hypermobility: A cause of SUI where the urethra fails to close and becomes overly moveable. This condition results in sub-optimal urethral functioning and induces a lack of pressure transmission on the bladder neck.

Uroflow: Measurement of flow, flow rate and force of urine stream.

Post void Residual (PVR): Volume of urine left in the bladder at the completion of micturition.

Urodynamics Testing: Functional study of the lower urinary tract. Uroflowmetry and post void residual volume measurement are generally performed prior to filling and voiding cystometry.

Pelvic Floor Muscle Training: Repetitive, selective, voluntary contraction and relaxation of specific pelvic floor muscles. It is used as a non-surgical, non- pharmacological treatment for lower urinary tract rehabilitation.

Bulking Agent: Ideally a non-immunogenic and biocompatible agent, usually comprised of particles suspended in a bio-degradable carrier gel. Currently available injectables include polytetrafluoroethylene, bovine collagen, autologous fat, silicon particles, carbon beads, calcium hydroxyapatite, ethylene vinyl alcohol copolymer and porcine dermal implant. The bulking agent is injected into urethral sub-mucosa to create artificial cushions with the goal of improving urethral coaptation and restore continence.

Sling Procedure: Vaginally-approached surgical technique used for the treatment of UI whereby the surgeon creates an artificial suspension support for the urethra through the use of a narrow band or either autologous or synthetic material.

Burch Procedure: Traditional gold standard for surgical treatment of SUI. In this abdominally-approached procedure, the surgeon evaluates and fixes the patient's anterior vaginal wall and paravesical tissues to the ileopectinal line of the pelvic sidewall, creating a broad sling that supports and elevates the bladder neck.

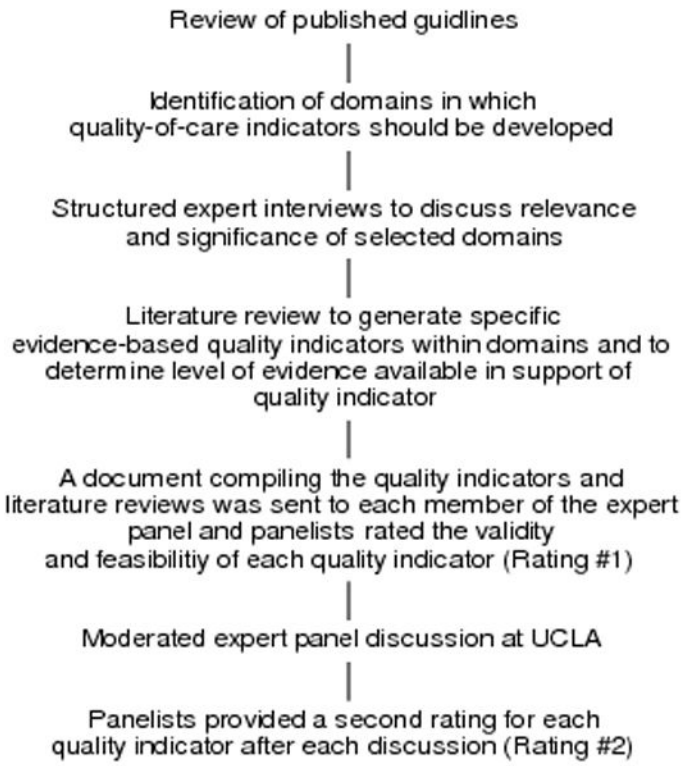

Figure 1.
Summary of the development and ranking of quality indicators for stress and urge urinary incontinence using the modified RAND Appropriateness Method

Table 1

Results of second round of panelist ratings of the validity and feasibility of each quality indicator after discussion and level of evidence supporting quality indicator determined after systematic literature review. Shaded indicators were not passed by the panel.

Indicator	Evidence Level	Validity* Rating	Feasibility* Rating
Prevention/Screening: Initial Evaluation			
1. A woman who presents to her primary care physician for a new office visit should be screened for symptoms of urinary incontinence (UI).	III	5.0, 3–8	6.0, 5–8
Diagnosis: Targeted Evaluation/Basic History			
2. A basic history should be obtained from a woman presenting with complaints of new or worsening bothersome UI, including:			
a. Determining whether stress, urge, or both symptoms are present.	III	8.0, 7–8	8.0, 6–8
b. Any previous pharmaceutical treatment.	III	7.0, 2–8	7.0, 1–8
ci. Lifestyle factors (fluid intake) if urge urinary incontinence (UUI) is present.	III	7.0, 3–8	6.0, 5–8
cii. Lifestyle factors (fluid intake) for all types of UI	III	5.0, 3–7	7.5, 7–8
d. Severity assessment.	III	7.0, 5–8	6.0, 4–7
Targeted Physical Exam			
3. A physical exam should be performed on a woman presenting with complaints of new/worsening bothersome UI symptoms, including:			
a. Assessment of her ability to initiate voluntary contraction of the pelvic floor muscles.	III	5.0, 1–7	5.0, 3–7
b. Vaginal exam to assess for contributors to UI (fibroids, pelvic organ prolapse), including assessment of pelvic floor muscle strength (ability to perform Kegel exercises).	III	7.0, 4–9	7.0, 6–8
c. Stress test for stress urinary incontinence (SUI).	II	4.0, 1–7	7.0, 1–8
Diagnostic Testing			
4. Urinalysis should be performed on a woman who presented with new/worsening bothersome SUI to screen for microhematuria or urinary tract infection	III	8.0, 6–9	8.0, 7–9
5. Uroflow should not be performed on a woman who presents with new or worsening bothersome symptoms of SUI unless she also has signs of voiding dysfunction.	III	7.0, 1–8	7.0, 3–9
6. A woman who presents with SUI should undergo a post-void residual (PVR).	III	5.0, 2–6	7.0, 5–8
7. Urodynamic testing should not be performed in a woman with previously untreated symptoms (including behavioral treatments) of UUI without neurologic disease or voiding dysfunction	II	7.0, 3–9	8.0, 7–9
Treatment/Management UI			

Indicator	Evidence Level	Validity* Rating	Feasibility* Rating
Behavioral therapy			
8. A woman who presents with new or worsening bothersome UI should initially be offered pelvic floor muscle training (PFMT).	I	7.0, 3–9	7.0, 4–8
Treatment/Management of SUI			
Behavioral therapy			
9. A woman who is overweight (BMI>25) with new or worsening symptoms should be advised to lose weight.	I	7.0, 7–9	7.0, 6–9
Pharmacological therapy			
10. Anticholinergic therapy should not be offered as a treatment to a woman who presents with new or worsening bothersome SUI without symptoms of overactive bladder (OAB).	III	8.0, 7–9	8.0, 6–9
Surgical Management			
11. If a woman undergoes surgical management of SUI and/or pelvic organ prolapse with synthetic mesh, it should be documented that she was counseled pre-operatively about the risks of mesh.	III	8.0, 7–9	7.5, 6–9
12. Pre-operative urodynamic testing should be performed:			
a. in a woman who has surgery for SUI and (a) presented for symptoms of mixed urinary incontinence, or (b) has recurrent incontinence after prior surgery for SUI.	III	5.0, 2–7	7.0, 5–9
b. Pre-operative urodynamic testing should be performed in a woman over the age of 75, but not for mixed urinary incontinence or recurrent incontinence after prior surgery.	III	5.0, 3–8	7.0, 5–9
13. A woman with SUI who undergoes surgery should undergo a pre-op PVR.	III	7.0, 6–9	8.0, 6–9
14. A woman with new or worsening SUI and has no other urologic diagnosis or prior incontinence surgery should not undergo diagnostic cystoscopy	III	8.0, 7–9	9.0, 7–9
15. A woman who elects to undergo surgery should have a pre-operative stress test for SUI as a part of the physical exam.	III	8.0, 6–9	9.0, 7–9
16. A woman should not undergo Kelly plication, anterior colporrhaphy or needle suspension for the treatment of SUI.	I	8.0, 3–9	8.0, 7–9
17. A woman who has surgery for SUI should be counseled on the risks associated with each type of procedure, including:			
a. Risk of bladder perforation with retropubic slings.	III	7.0, 2–8	4.5, 1–9
b. Risk of leg pain and neurologic symptoms with tranobturator slings.	III	6.0, 2–7	4.5, 1–9
c. Lower efficacy of the Burch colposuspension vs. bladder neck slings.	III	7.0, 1–8	4.5, 1–9
d. Higher morbidity of bladder neck slings and open Burch colposuspension due to larger abdominal incision.	III	7.0, 1–7	4.5, 1–9
e. Common risks of all incontinence procedures, including post-operative voiding dysfunction including urinary retention, urge incontinence, surgical complications and mesh complications.	III	7.0, 4–9	6.5, 1–9
f. Need for repeat bulking procedures.	III	7.0, 4–7	5.5, 1–8

Indicator	Evidence Level	Validity* Rating	Feasibility* Rating
18. When a sling is performed for SUI, an intraoperative cystoscopy should be performed.	III	8.0, 7–9	8.0, 6–9
Follow-up after Treatment for SUI			
19. A woman who is treated for SUI should be re-evaluated within 3 months of initiation of intervention for the efficacy and/or complications of any intervention.	III	7.0, 2–8	6.0, 2–9
Treatment/Management of UUI			
Behavioral therapy			
20. If a woman presents with new or worsening bothersome UUI, then a history about fluid intake should be obtained.	III	7.0, 4–9	7.0, 4–7
21. A woman presenting with new or worsening symptoms of UUI/OAB should initially be counseled about behavioral modification, including fluid restriction and bladder training.	I	7.0, 7–9	7.0, 6–9
Pharmacological therapy			
22. A woman with UUI/OAB who is prescribed anticholinergic medications should also be counseled about behavioral therapy.	I	7.0, 5–8	7.0, 6–9
23. A woman age 65 or older with UUI/OAB who elects to undergo treatment with anticholinergic medication should be counseled regarding the risks of cognitive impairment.	III	6.0, 2–8	5.5, 2–7
Surgical Management			
24. A woman with UUI/OAB who has persistent bothersome UUI/OAB symptoms after pharmacologic therapy or is not a candidate for pharmacologic therapy should be offered sacral neuromodulation (SNM).	I	3.0, 1–5	5.5, 2–7
Botox Injections			
25. A woman whose UUI/OAB symptoms are refractory to conservative therapy, and who is not a candidate or chooses not to pursue SNM, should be offered intravesical injection of Botox.	III	3.0, 1–5	4.0, 1–7
26. A woman who elects to undergo BTX injections should be counseled about the risks of urinary retention (that may require a catheter) and an associated increase in the risk of urinary tract infection.	III	7.0, 2–7	7.0, 5–7
27. A woman with UUI/OAB who is treated with BTX injections should be followed up for efficacy and retention within to weeks.	III	3.0, 1–5	3.0, 1–8
Follow-up after Treatment for UUI			
28. Any woman who is treated for UUI/OAB should be re-evaluated for the efficacy of any intervention within 3 months of initiation of the intervention.	III	5.5, 2–9	4.0, 2–7

*median score, range of second round rankings. Shaded boxes indicate quality indicator was rejected.