

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 #: 0098 NQF Project: GI and GU Project
Date Submitted: Jul 16, 2012
CONCEPT SPECIFICATIONS
De.1 Concept Title: Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older – an administrative measure
Co.1.1 Concept Steward: National Committee for Quality Assurance
De.2 Brief Description of Concept: This is a clinical performance measure which assesses whether women age 65+ were provided appropriate treatment for urinary incontinence (UI). This measure has three rates: (A) Assessment for UI: Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months. (B) Characterization of UI: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence whose urinary incontinence was characterized at least once within 12 months (C) Plan of Care for UI: Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months
2a1.1 Numerator Statement: This measure has three rate. The numerator for each of the rates is as follows: (A) Assessment for UI: Patients who were assessed for the presence or absence of urinary incontinence within 12 months (B) Characterization of UI: Patients whose urinary incontinence was characterized at least once within 12 months (C) Plan of Care for UI: Patients with a documented plan of care for urinary incontinence at least once within 12 months Urinary incontinence is defined as any involuntary leakage of urine. Characterization of urinary incontinence may include one or more the following: frequency, volume, timing, type of symptoms, and/or how bothersome to the patient Plan of care may include behavioral interventions (e.g., bladder training, pelvic floor muscle training, prompted voiding), referral to specialist, surgical treatment, reassess at follow-up visit, lifestyle interventions, addressing co-morbid factors, modification or discontinuation of medications contributing to urinary incontinence, or pharmacologic therapy.
2a1.4 Denominator Statement: There are two denominators for the rates in this measure. (A) Assessment of UI: All female patients aged 65 years and older who visited and eligible provider in the measurement year (B&C) Characterization and Plan of Care for UI: All female patients aged 65 years and older with a diagnosis of urinary incontinence who visited an eligible provider in the measurement year.
2a1.8 Denominator Exclusions: Documentation of medical reason(s) for not assessing the presence or absence of urinary incontinence within 12 months
1.1 Concept Type: Process 2a1. 25-26 Data Source: Administrative claims 2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team
1.2-1.4 Is this concept paired with another measure? No
2a1.1 Numerator Statement <i>(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):</i> This measure has three rate. The numerator for each of the rates is as follows:

- (A) Assessment for UI: Patients who were assessed for the presence or absence of urinary incontinence within 12 months
- (B) Characterization of UI: Patients whose urinary incontinence was characterized at least once within 12 months
- (C) Plan of Care for UI: Patients with a documented plan of care for urinary incontinence at least once within 12 months

Urinary incontinence is defined as any involuntary leakage of urine.

Characterization of urinary incontinence may include one or more the following: frequency, volume, timing, type of symptoms, and/or how bothersome to the patient

Plan of care may include behavioral interventions (e.g., bladder training, pelvic floor muscle training, prompted voiding), referral to specialist, surgical treatment, reassess at follow-up visit, lifestyle interventions, addressing co-morbid factors, modification or discontinuation of medications contributing to urinary incontinence, or pharmacologic therapy.

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.

The numerator for this measure is based on reporting CPT Category II codes. The codes for each rate numerator are as follows:

- (A) Assessment of UI: 1090F - Presence or absence of urinary incontinence assessed
- (B) Characterization of UI: 1091F - Urinary incontinence characterized
- (C) Plan of Care for UI: 0509F - Urinary incontinence plan of care documented

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured):*

There are two denominators for the rates in this measure.

- (A) Assessment of UI: All female patients aged 65 years and older who visited and eligible provider in the measurement year
- (B&C) Characterization and Plan of Care for UI: All female patients aged 65 years and older with a diagnosis of urinary incontinence who visited an eligible provider in the measurement year.

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.

The denominator for rate (A) Assessment of UI, is based on office visits to an eligible provider. CPT codes are used to identify female patients age 65 + with an office visit to an eligible provider.

The denominator for rates (B&C) Characterization and Plan of Care for UI, is based on office visits and a documented diagnosis using ICD-9 codes.

(A) Assessment of UI:

CPT codes:

99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, 99387, 99397, 99401, 99402, 99403, 99404

(B&C) Characterization & Plan of Care:

ICD-9 diagnosis codes

307.6, 625.6, 788.30, 788.31, 788.33, 788.34, 788.35, 788.36, 788.37, 788.38, 788.39

AND

CPT service codes

99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, 99387, 99397, 99401, 99402, 99403, 99404

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population):*

<p>Documentation of medical reason(s) for not assessing the presence or absence of urinary incontinence within 12 months</p> <p>2a1.9 Denominator Exclusion Details <i>(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)</i> For new concepts, describe how you plan to identify and calculate the exclusions. CPT Category II code: 1090F-1P - Documentation of medical reason(s) for not assessing for the presence or absence of urinary incontinence</p>
<p>2a1.10 Stratification Details/Variables <i>(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)</i> For new concepts, if you plan to stratify the measure results, describe the plans for stratification.</p> <p>2a1.13 Statistical Risk Model and Variables <i>(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)</i> For new concepts, <u>if an outcome</u>, describe how you plan to adjust for differences in case mix/risk across measured entities. N/A</p>
<p>2a1.25 Data Source <i>(Check all the sources for which the concept is specified and tested)</i>. If other, please describe: Administrative claims</p> <p>2a1.26 Data Source/Data Collection Instrument <i>(Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):</i></p> <p>2a1.33 Level of Analysis <i>(Check the levels of analysis for which the concept is specified and tested):</i> Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>2a1.34 Care Setting <i>(Check all the settings for which the concept is specified and tested):</i> Ambulatory Care : Clinician Office/Clinic</p>

IMPACT, OPPORTUNITY, 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 : Incontinence](#), [Prevention : Screening](#)
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](#); [High resource use](#); [Patient/societal consequences of poor quality](#)

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

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data):*
[Prevalence of Urinary Incontinence: An estimated 25 million Americans, and 200 million worldwide, suffer from the involuntary leakage of urine—urinary incontinence \(UI\) \(NAFC, 2008\). The severity of UI ranges from occasionally leaking urine during a cough or sneeze \(stress incontinence\) to having an urge to urinate that’s so sudden and strong \(urge incontinence\) there is no time to get to a bathroom \(Mayo Clinic, 2011\). UI affects between 30 and 60 percent of older women \(Markland, 2011\).](#)

Impact of UI on Health and Well-Being: Data analysis from the Medicare Health Outcomes Survey (HOS) indicates that compared with 14 other chronic conditions, UI was associated with the lowest mental health related quality of life scores, second only to gastrointestinal disease (Hawkins 2011). In addition, studies have shown a strong, statistically significant positive association between UI symptoms and depressive symptoms ($p < 0.001$), (Coyne 2008). UI is associated with a wide range of morbidity in the elderly, including urinary tract infections (OR 2.90; 95% CI 2.49, 3.37), constipation (OR 1.83; 95% CI 1.49, 2.24), and depression (OR 1.81; 95% CI 1.45, 2.26) (Van Gerwen 2007). UI also has a significant negative effect on the psychological well-being of family caregivers (Fultz 2005).

Financial Impact of UI: Urinary incontinence poses a heavy financial burden. Annual direct cost of treating UI was estimated at \$26.3 billion in 1995 and rose to \$32 billion in 2000 (Wagner, 1998; Levy, 2006). In 2000, the cost incurred by community and institutional residents was \$9.1 and \$3.5 billion, respectively (Hu, 2000). Medicare pays for nearly half of all UI-related medical services with the rest covered by out-of-pocket expenses or other insurance products. UI poses a significant financial burden to the family caregivers who provide support to an individual with UI. One study estimated a national annual cost of more than \$6 billion for incontinence-related informal care (Langa, 2002). While costs incurred from UI are high, the underlying causes of UI can be diagnosed and effectively managed by a practitioner (Tannenbaum, 2001; Lee, 2000). Several simple office visit tests are available to assess UI; cough test, measurement of voided volume, urinalysis, urine culture and measurement of post-void residual volume (Gibbs, 2007).

1a.4 Citations for Evidence of High Impact cited in 1a.3: Coyne KS, Sexton CC, Irwin DE, Kopp ZS, Kelleher CJ, Milsom I. The impact of overactive bladder, incontinence and other lower urinary tract symptoms on quality of life, work productivity, sexuality and emotional well-being in men and women: results from the EPIC study. *BJU Int.* 2008; 101(11):1388-95.

Fultz NH, Rahrig Jenkins K, Ostbye T, Taylor DH, Kabeto MU, Langa KM. The impact of own and spouse's urinary incontinence on depressive symptoms. *Soc Sci Med* 2005;60(11): 2537-48.

Gibbs CF., Johnson TM., and Ouslander JG. Office management of geriatric urinary incontinence. *Am J Medicine* 2007; 120:211-220.

Hawkins K, Pernarelli J, Ozminkowki RJ. The prevalence of urinary incontinence and its burden on the quality of life among older adults with Medicare supplement insurance. *Qual Life Res* 2011;20:723-32.

Hu TW, Wagner TH, Bentkover JD, Leblanc K, Zhou SZ, Hunt T. Costs of urinary incontinence and overactive bladder in the United States: a comparative study. *Urology.* 2004; 63(3):461-465.

Langa K, Fultz N, Saint S, Kabeto MU, & Herzog AR. Informal Caregiving Time and Costs for Urinary Incontinence in Older Adults in the United States. *JAGS* 2002; 50(4):733-7.

Levy R & Muller N. Urinary Incontinence: Economic Burden and New Choices in Pharmaceutical Treatment. *Advances in Therapy* 2006;23(4):556-73.

Markland AD (2), Vaughan CP, Johnson TM, Burgio KL, & Goode PS. Incontinence. *Medical Clinics of North America* 2011; 95(3):539-54.

Mayo Clinic. (2011). Urinary Incontinence. Accessed June 23, 2012 from: <http://www.mayoclinic.com/health/urinary-incontinence/DS00404>

National Association for Continence (NAFC). Statistics. 2008. Accessed June 23, 2012 from: <http://www.nafc.org/media/statistics/>

Tannenbaum C., Perrin L., DuBeau C.E., Kuchel G.A. Diagnosis and Management of Urinary Incontinence in the Older Patient. *Arch Phys Med Rehabil.* 2001; 82: 134-138.

Van Gerwen M, Schellevis F, Largo-Jansse T. Comorbidities Associated with Urinary Incontinence: A Case-Control Study from the Second Dutch National Survey of General Practice. *Journal of the American Board of Family Medicine.* 2007; 20(6): 608-610.

Wagner T.H., Hu T-W. Economic costs of urinary incontinence in 1995. *Urology.* 1998; 51:355-361.

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:

The intent of this measure is to evaluate the rate of appropriate screening, characterization and treatment of UI among older women living in the community. The first rate assesses whether a health care provider asked the patient if they experienced any problems with UI. For those women who are identified as having UI, this measure assesses whether the health care provider characterized the UI and provided a plan of care to the patient. The improvement in quality envisioned by use of this measure is increased discussion of UI between patients and health care providers and increased use of appropriate treatment to manage the symptoms of UI. Tracking and reporting the rate of discussing, characterizing and treating UI among older adults will help to identify gaps in care and increase awareness among practitioners and patients. Despite the prevalence of UI and the significant negative impact UI

can have on quality of life, there is a stigma associated with the condition. Health care providers need to proactively address UI among their patients and need to be aware of the many treatment options available.

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. Data are from the Physician Quality Reporting System (PQRS) most recent available data. Rates are averaged at the level of eligible provider. The Percent of eligible providers reporting is the proportion of eligible providers participating in PQRS who chose to report on this quality measure.

(A) Assessment of UI

YEAR | Rate | Percent of Eligible Providers Reporting

2007 | 84.4% | 0.5%

2008 | 75.0% | 0.7%

2009 | 57.3% | 1.3%

2010 | 66.5% | 1.3%

(B) Characterization of UI

YEAR | Rate | Percent of Eligible Providers Reporting

2007 | 96.4% | 1.4%

2008 | 85.7% | 1.4%

2009 | 68.9% | 2.0%

2010 | 82.5% | 2.0%

(C) Plan of Care for UI

YEAR | Rate | Percent of Eligible Providers Reporting

2007 | 94.9% | 1.5%

2008 | 85.2% | 1.4%

2009 | 76.4% | 1.8%

2010 | 82.7% | 2.0%

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 1b.2 (*number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include*)

2010 Physician Quality Reporting System and eRx Experience Report. Appendix B: 2010 Physician Quality Reporting System Detailed Tables

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.

Racial Disparities: This measure is not reported by racial/ethnic subgroup. Studies have shown no significant differences among race associated with reporting of UI with 30.6% of Hispanics reporting UI, 30.3% of African Americans reporting UI, 38.3% of whites reporting UI and 31.6% of Asians reporting (Mardon 2006). A 2011 study examined the prevalence of health care seeking, barriers of care and use of therapeutic modalities among black and white community dwelling black and white women who self-reported for UI. The researchers found that black and white women seek treatment for UI at similar, albeit low, levels. They found no association between perceived barriers and race, nor did they find any association between race and most self-care strategies. Black women were more likely to restrict fluid intake and slightly less likely to perform Kegel exercises (Berger, 2011). Another study did find racial differences between races for remission, admission and frequency of UI, indicating that although common in all races, presentation of UI may vary by race (Townsend, 2011).

1b.5 Citations for Data on Disparities Cited in 1b.4:

Berger MB, Patel DA, Miller JM, Delancey JO, & Fenner DE. Racial Differences in Self-Reported Healthcare Seeking and Treatment for Urinary Incontinence in Community-Dwelling Women From the EPI Study. *NeuroUrol Urodyn* 2011; 30(8): 1442-7.

Mardon R., Halim S., Pawlson G., and Haffer S. Management of Urinary Incontinence in Medicare Managed Care Beneficiaries. *Arch Internal Med* 2006; 166:1128-1133.

Townsend MK, Curhan GC, Resnick NM, & Grodstein F. Original Research: Rates of Remission, Improvement and Progression of

Urinary Incontinence in Asian, Black and White Women. American Journal of Nursing 2011; 111(4):26-33.

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 <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the concept pass subcriterion1c? Yes <input type="checkbox"/> 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: Professional Certification or Recognition Program, Public Reporting, Quality Improvement (Internal to the specific organization)

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:

0030 : Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment – A patient reported measure

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?

Yes

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

See 5b.1. for answer.

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):
Answer for 5a.2.
 UI is defined in both measures as involuntary or accidental leakage of urine.
 Treatment options for UI across both measures is defined as any of the following: bladder training, pelvic floor muscle training (exercises), surgical treatment (surgery), pharmacologic therapy (medication).
 There are several treatment options of UI which are included in measures 0098 which are not included in 0030 because they could not be described in a way which was easy for patients to recall and self-report:
 prompted voiding, lifestyle interventions, addressing co-morbid factors, modification or discontinuation of medications contributing to urinary incontinence.
 There are two treatment options which are specific to measure 0098 which are not included in 0030 because they refer to a transfer of care to another provider at point in time: referral to specialist and reassess at follow-up visit.
 Measure 0098 focuses exclusively on women, whereas 0030 refers to all patients. Since women are more likely to experience UI, 0098 was developed to specifically target the care provided to women. The panel of experts who developed 0098 felt the benefits of measurement would be highest for women.
Answer for 5b.1
 Measure 0098 assesses whether there is documentation in the medical record that older women were assessed for UI, and whether there is documentation in the medical record that those women identified as having UI had their UI characterized and were provided a plan of care to manage their UI. This information complements the survey-based measure (0030) which assess whether patients who experience problems with UI report discussing UI with their health care provider and receiving treatment for their UI. Both measures are necessary to allow for continued measurement of this important quality gap at different levels of accountability and using different complimentary data sources.
 Measure 0098 uses administrative claims coding to determine if UI processes of care (screening, characterization and plan of care) are documented in the medical record for patients who have an in-person visit with an eligible provider. This measure uses codes specifically designed for quality measurement and measures care at the individual provider level. This measure provides detailed information about specific processes of care being provided during a visit with an eligible provider. Unlike measure 0030 it is not susceptible to recall bias and can provide more detailed information. However, this measure has several limitations: (1) documented processes in a medical record are one-sided – they only reflect the provider’s point of view and do not include the patient’s perspective, (2) the codes used for this measure are infrequently reported by providers and (3) this measure excludes individuals who did not see an eligible provider in the previous year and therefore excludes care that may be provided outside of the clinician office such as in the community setting.
 Measure 0030 uses patient reported information to determine if patients in a health plan received UI processes of care (discuss and treatment). This measure captures the patient perception of care provision which complements the provider point-of-view documented in the medical record. Unlike measure 0098 this measure is not reliant on administrative codes being reported and can be applied to a population of patients regardless of whether they visited an eligible provider in the previous year.

CONTACT INFORMATION

- Co.1 Concept Steward (Intellectual Property Owner):** National Committee for Quality Assurance, 1100 13th Street NW, Suite 1000 | Washington | District Of Columbia | 20005
- Co.2 Point of Contact:** Bob | Rehm, Assistant Vice President, Performance Measurement | Rehm@ncqa.org | 202-955-1728-
- Co.3 Concept Developer if different from Concept Steward:** National Committee for Quality Assurance | 1100 13th Street NW | Washington | District Of Columbia, 20005
- Co.4 Point of Contact:** Dawn | Alayon, MPH, CPH | alayon@ncqa.org | 202-955-3533-
- Co.5 Submitter:** Dawn | Alayon, MPH, CPH, Senior Health Care Analyst | alayon@ncqa.org | 202-955-3533- | National Committee for Quality Assurance
- Co.6 Additional organizations that sponsored/participated in concept development:**
[AMA-PCPI](#)
- Co.7 Public Contact:** Bob | Rehm, Assistant Vice President, Performance Measurement | Rehm@ncqa.org | 202-955-1728- | National Committee for Quality Assurance

ADDITIONAL INFORMATION
<p>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?</p>
<p>Ad.7 Copyright statement: © 2012 by the National Committee for Quality Assurance 1100 13th Street, NW, Suite 1000 Washington, DC 20005</p>
<p>Ad.8 Disclaimers: N/A</p>
<p>Ad.9 Additional Information/Comments:</p>
<p>Date of Submission (MM/DD/YY): Jul 16, 2012</p>

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

Measure Title: Urinary Incontinence: Assessment, Characterization, and Plan of Care Urinary Incontinence in Women Aged 65 Years and Older - an administrative measure

Date of Submission: [2T](#)

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes 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: [2T](#)
- Intermediate clinical outcome: [2T](#)
- X Process: [Discussion of urinary incontinence with a health care provider and treatment of urinary incontinence](#)
- Structure: [2T](#)
- Other: [2T](#)

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 one healthcare 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.)

The two rates in this measure relate to the desired outcome in the following way:

Discussing urinary incontinence with a health care provider (*Rate A: Assessment for UI*)>>>

Identification of whether urinary incontinence is a problems (impact on quality of life and function) >>>>

Health care provider conducts evaluation to characterize type and cause of urinary incontinence (*Rate B: Characterization of UI*) >>>>

Health care provider and patient discuss risks and benefits of treatment options and documents plan of care in medical record (*Rate C: Plan of Care for UI*) >>>>

Patient receives treatment for urinary incontinence symptoms >>>>

Urinary incontinence symptoms reduced >>>>

Improvement in quality of life and functioning for patient (*Desired outcome*)

1c.4. Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes

No **If no, skip to #1c.6**

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

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

- (1) Scottish Intercollegiate Guidelines Network (SIGN). Management of urinary incontinence in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Dec. (guideline was reaffirmed for currency by the developer in 2011)
- (2) American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin #63: Urinary incontinence in women, *Obstetrics & Gynecology* 2005; 105(6): 1533-1545.

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

<http://www.sign.ac.uk/guidelines/fulltext/79/index.html>

1c.4.3. Identify guideline number and/or page number:

Guideline No. 79, ISBN 1 899893 14 8, December 2004

1c.4.4. Quote verbatim, the specific guideline recommendation:

This measure assesses whether health care providers (A) Assessed all older female patients for and then for those patients diagnosed with UI (B) Characterized the type and severity of UI and (C) documented a plan of care to treat the UI. This measure is based on guidelines (cited below) that patients with urinary incontinence should be offered assessment, treatment and referral as appropriate.

Methods of characterizing UI recommended by the guidelines include measure 0098 are as follows: frequency, volume, timing, type of symptoms and how bothersome to the patient.

Potential treatment for UI recommended by the guidelines included in measure 0098 are as follows: bladder training, pelvic floor muscle training, prompted voiding, referral to a specialist, surgical treatment, lifestyle interventions, or pharmacologic therapy.

Other treatments included in the measures are based on expert opinion of the steering committee: addressing co-morbid factors, modification or discontinuation of medications contributing to urinary incontinence, and assess at follow-up visit.

SIGN Guidelines for Management of Urinary Incontinence in Primary Care	Grade of Recommendation	Levels of Evidence
Assess: Assessment, treatment, and referral, as appropriate, should be offered to all patients with urinary continence problems.	B	2+, 2++
Assess: Health professionals should recognize the difficulty that some patients have in raising concerns about continence and should be proactive in questioning patients about continence during consultations	C	2+, 2+-

Characterization: Initial assessment of a female patient with urinary incontinence should include completion of a voiding diary, urinalysis and, where symptoms of voiding dysfunction or repeated UTIs are present, estimation of post void residual volume	D	2- ,2+ ,4, 2++
Characterization: Healthcare practitioners should consider using a validated quality of life and incontinence severity questionnaire to evaluate the impact of urinary symptoms and to audit the effectiveness of any management strategy	B	2+-
Pelvic floor muscle exercises should be the first choice of treatment offered to patients suffering from stress or mixed incontinence. Exercise programs should be tailored to be achievable by the individual patient.	A	1++
Bladder retraining should be offered to patients with urge urinary incontinence.	C	1++
Pharmacological Therapy: Duloxetine should be used only as part of an overall management strategy in addition to pelvic floor muscle exercises and not in isolation. A 4 week trial of duloxetine is recommended for female patients with moderate to severe stress incontinence. Patients should be reviewed again after 12 weeks of therapy to assess progress and determine whether it is appropriate to continue treatment	A	1+
Pharmacological Therapy: A trial of oxybutynin, propiverine, tolterodine, or trospium should be given to patients with significant urgency with or without urge incontinence. The dose should be titrated to combat adverse effects.	A	1+, 1++
Referral: Patients should be referred to secondary care if previous surgical or non-surgical treatments for urinary incontinence have failed or if surgical treatments are being considered	D	4
Lifestyle Interventions: As excessively small or large urine output can contribute to urinary incontinence, patients should be encouraged to adjust their fluid intake to produce a 24 hour urinary output of between 1,000 ml and 2,000 ml.	Not graded	4

ACOG: Urinary incontinence in women practice guidelines	Grade of Recommendation	Levels of Evidence
Characterization: Patients with urinary incontinence should undergo a basic evaluation that includes a history, physical examination, measurement of postvoid residual volume, and urinalysis.	C	Expert opinion/ consensus
Prompted voiding: Behavioral therapy, including bladder training and prompted voiding, improves symptoms of urge and mixed incontinence and can be recommended as a noninvasive treatment in many women.	A	Good/ consistent
Pelvic floor training appears to be an effective treatment for adult women with stress and mixed incontinence and can be recommended as a noninvasive treatment for many women.	A	Good/ consistent
Pharmacologic agents, especially oxybutynin and tolterodine, may	A	Good/

have a small beneficial effect on improving symptoms of detrusor overactivity in women.		consistent
Surgical treatment: Long-term data suggest that Burch colposuspension and sling procedures have similar objective cure rates; therefore, selection of treatment should be based on patient characteristics and the surgeon's experience	B	Limited/ inconsistent

1c.4.5. Grade assigned to the recommendation with definition of the grade:

(1) SIGN: The grades assigned by SIGN to the guideline varied by the guideline recommendation. The grades varied from A -C. See table under 1c.4.4 for the grade given to each guideline.

SIGN Grades of Recommendation

- Grade A: At least one meta-analysis, systematic review of RCTs, or RCT rated as 1++ and directly applicable to the target population. A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.
- Grade B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or* Extrapolated evidence from studies rated as 1++ or 1+
- Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results or extrapolated evidence from studies rated as 2++
- Grade D: Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+

(2) ACOG: The grades assigned by ACOG to the guidelines varied by the guideline recommendation. The grades varied from A to B. See table under 1c.4.4 for the grade given to each guideline.

ACOG Levels of Recommendation

- Grade A: Recommendations are based on good and consistent scientific evidence.
- Grade B: Recommendations are based on limited or inconsistent scientific evidence
- Grade C: Recommendations are based primarily on consensus and expert opinion.

1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes No **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 grade assigned by SIGN to the level evidence varied by the guideline recommendation. The level of evidence varied from 1++ to 3. See table under 1c.4.4 for the level of evidence grade given to each guideline.

SIGN Levels of Evidence

- 1++: High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
- 1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
- 1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
- 2++: High quality systematic reviews of case control or cohort studies

- 2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
- 2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
- 3: Non-analytic studies, e.g. case reports, case series
- 4: Expert opinion

ACOG did not grade the evidence using a separate system from the overall grading of the recommendation.

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)
Yes 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):

Agency for Healthcare Research and Quality (AHRQ). Overview: Urinary Incontinence in Adults: Clinical Practice Guideline Update. March 1996. Accessed June 25, 2012.

<http://www.ahrq.gov/clinic/uioverview.htm>

Dumoulin C, Hay-Smith J. Pelvic floor muscle training versus no treatment for urinary incontinence in women. A Cochrane systematic review. Eur J Phys Rehabil Med. 2008; 44(10): 47-63.

Price N, Dawood R, Jackson SR. Pelvic floor exercise for urinary incontinence: a systematic literature review. Maturitas 2010; 67(4): 309-15.

Talley KM, Wyman JF, Shamliyan TA. State of the science: conservative interventions for urinary incontinence in frail community-dwelling older adults. Nurs Outlook 2011; 59(4): 215-20.

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

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

Not graded.

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 identified 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: [2T](#)

- (1) SIGN Management of urinary incontinence in primary care: 1995-2003
- (2) ACOG Urinary Incontinence in Women: January 1985-February 2005

QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

- (1) SIGN: A total of 128 studies were included in this review of the literature. Studies included meta-analysis, systematic review of RCTs, randomized controlled trials, case control and cohort studies, and non-analytic studies including case reports and case series. The guideline developers did not provide a breakdown of specific number of RCTs.
- (2) ACOG: A total of 70 studies were included in this review of the literature. Studies included meta-analysis, systematic review of RCTs, randomized controlled trials, case control and cohort studies, and non-analytic studies including case reports and case series. The guideline developers did not provide a breakdown of specific number of RCTs.

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)

Overall, the quality of the evidence regarding assessment and treatment of UI is high.

The evidence for assessment of UI is weakest, relying mostly on expert opinion or case control/cohort studies with a high risk of confounding or bias. However, there was consensus from the evidence review was that despite the lack of high quality evidence linking assessment of UI to improved outcomes the benefits far outweigh the potential harms.

The evidence for characterization of UI is also weak, relying mostly on expert opinion. However, the consensus from the evidence review was that despite the lack of high quality evidence linking characterization of UI to improved outcomes, the benefits far outweigh the potential harms.

The evidence for treatment is high, however the effectiveness of treatment is highly dependent on the type and severity of the UI. Evidence is the strongest for the broad effectiveness of pelvic floor training exercises as a first line of treatment to reduce the symptoms of UI. Multiple RCTs have demonstrated improved outcomes for patients who engage in pelvic floor training exercises. Two high quality systematic reviews provide weak evidence (multiple RCTs) that retraining for an overactive bladder is more effective than no treatment in urge urinary incontinence. Bladder retraining is most effective if

symptoms are mild (SIGN, pg 10). High quality evidence for pharmacotherapy (multiple RCTs) shows moderate to limited benefit. Treatment is often unpredictable and side effects are common (ACOG, pg. 1536). High quality evidence for surgery (multiple RCTs) shows limited evidence for the effectiveness of surgery. Surgery is recommended as a line of treatment only if all other treatments have failed. The evidence for referral and lifestyle interventions is very weak, based solely on expert opinion. These treatment options have not been tested.

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)

The evidence supporting this measure can be broken down into three categories: (1) Assess patients for UI, (2) Characterize UI and (3) Appropriate treatment of UI. The magnitude of benefit from individual processes or treatments has not been calculated mainly due to heterogeneity among the populations included in RCTs and variation in the measurement of UI symptoms and severity. In general, behavioral treatments such as lifestyle changes, pelvic floor rehabilitation exercises, timed voiding, and bladder training can reduce symptoms by 50–75 percent in most individuals (AHRQ, 2006; Price, 2010; Dumoulin, 2008; Talley, 2011). Below we describe where there is benefit to sub-populations of patients.

- (1) Assess patients for UI: Benefit is positive and undefined magnitude. The evidence for this recommendation shows consistent benefit of assessment, however the magnitude of the benefit has not been summarized across studies. Assessment alone does not lead to improved outcomes for patients; assessment is the necessary first step to providing the appropriate treatment for UI. While many studies cite the under reporting of urinary incontinence by older individuals, the exact reasons for why treatment utilization remain significantly lower are not well understood. The physician could be unaware of possible treatments or the patient may not want treatment. “Many studies highlight the fact that women with continence problems find seeking help from health professionals difficult, mainly due to the belief that little or nothing can be done to help. Embarrassment or uncertainty about how to raise the issue of continence in a consultation may be a barrier to seeking help. Men with continence problems and women with the most severe problems are the most likely to ask for help. Studies show that even patients with less severe problems would like help in managing their continence. There is evidence to support the need for a change in attitudes of health professionals to become more proactive in the approach to continence and its positive management. This evidence is applicable to all staff working in the primary care setting who should recognize that there are many consultations when it would be appropriate to raise the issue of continence, provided it is done in a sensitive manner. (SIGN, pg. 7)”
- (2) Characterize of UI in patients: Benefit is positive and undefined magnitude. Although evidence does not draw a direct link between the asking patients about their UI symptoms (frequency and volume) and the impact of symptoms on the patient’s life there is widespread agreement that objective assessment of the UI symptoms is essential to developing an effective plan of care. (SIGN, pg 3)
- (3) Appropriate treatment of UI. The evidence for appropriate treatment varies by treatment. The measure lists four possible treatment options as examples but does not limit the patient to any one type of treatment.

2.1 Pelvic Floor Muscle Exercises: Benefit is positive and of high magnitude.

“Pelvic floor muscle exercises (PFME) are effective in the treatment of stress and mixed urinary incontinence, but there is insufficient evidence to assess their efficacy in the treatment of urge incontinence. Expert opinion suggests that pelvic floor muscle exercises may have a role in treatment of urge incontinence in combination with bladder training (SIGN, pg 9).”

2.2 Bladder retraining – Benefit is positive and of small magnitude.

The benefit of bladder training is small, but is more effective than no treatment in urge urinary incontinence. Bladder retraining is most effective if symptoms are mild (SIGN, pg 10).

2.3 Pharmacotherapy – Benefit is positive and of moderate to small magnitude.

Medications for urinary incontinence should be used as a second line of treatment only if more conservative treatments have failed. Evidence for pharmacotherapy shows moderate to limited benefit. Treatment is often unpredictable and side effects are common (ACOG, pg. 1536).

2.4 Surgical Treatments – Benefit is positive and of small magnitude.

Surgery for urinary incontinence should only be used if all other treatments have failed. The evidence for surgical treatments, specifically retropubic colposuspension and sling procedures, in the treatment of UI has shown small limited benefits (ACOG, pg. 1537).

2.5 Lifestyle modification – Benefits is positive and of varied (high to low) magnitude.

“A review of conservative treatment in women examined the evidence for the use of lifestyle interventions in the management of urinary incontinence. Massive (surgically induced) weight loss significantly decreases incontinence in morbidly obese women. Moderate weight loss may also result in decreased incontinence. Fluid intake has only a minor, if any, role in the pathogenesis of incontinence. Although large cross-sectional surveys of caffeine intake indicate no association with incontinence, small clinical trials do suggest that decreasing caffeine intake improves continence. No conclusive association between smoking and urinary incontinence has been found.” (SIGN pg. 10)

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

The majority of research on harms has been done with regard to surgical treatment of UI. The following table from the ACOG Urinary Incontinence in Women review of the literature shows the following rates of complications for surgical procedures:

Table 2. Complication Rates Following Surgical Treatment for Stress Urinary Incontinence

Complication	Rate	Procedure
Bladder perforation	3–9%	Tension-free tape ^{1, 2}
	2%	Colposuspension ¹
Detrusor overactivity/ urge incontinence	5–27%	Burch colposuspension ³
	0–30%	Sling ^{4, 5}
	6%	Tension-free tape ⁶
Erosion of surgical materials	≤5%	Sling ⁵
Sling revision or removal	5–35%	Sling ⁷
Voiding disorders	2–37%	Sling ⁸
	4–11%	Tension-free tape ^{1, 2, 9}

¹Ward K, Hilton P. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. United Kingdom and Ireland Tension-free Vaginal Tape Trial Group. *BMJ* 2002;325:67–70.

²Tamussino KF, Hanzal E, Kollé D, Ralph G, Riss PA. Tension-free vaginal tape operation: results of the Austrian registry. *Austrian Urogynecology Working Group. Obstet Gynecol* 2001;98:732–6.

³Dainer M, Hall CD, Choe J, Bhatia NN. The Burch procedure: a comprehensive review. *Obstet Gynecol Surv* 1999;54:49–60.

⁴Bezerra CA, Bruschini H, Cody DJ. Suburethral sling operations for urinary incontinence in women. *The Cochrane Database of Systematic Reviews* 2001, Issue 3. Art. No.: CD001754. DOI: 10.1002/14651858.CD001754.

⁵Bidmead J, Cardozo L. Sling techniques in the treatment of genuine stress incontinence. *BJOG* 2000;107:147–56.

⁶Nilsson CG, Falconer C, Rezapour M. Seven-year follow-up of the tension-free vaginal tape procedure for treatment of urinary incontinence. *Obstet Gynecol* 2004;104:1259–62.

⁷Persson J, Iosif C, Wolner-Hanssen P. Risk factors for rejection of synthetic suburethral slings for stress urinary incontinence: a case-control study. *Obstet Gynecol* 2002;99:629–34.

⁸Jarvis GJ. Surgery for genuine stress incontinence. *Br J Obstet Gynaecol* 1994; 101:371–4.

⁹Klutke C, Siegel S, Carlin B, Paszkiewicz E, Kirkemo A, Klutke J. Urinary retention after tension-free vaginal tape procedure: incidence and treatment. *Urology* 2001;58:697–701.

UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes No **If no, stop**

If yes,

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

There have been many (>100) individual studies published since the systematic reviews used to generate guidelines for the treatment of UI. In November of 2011, SIGN conducted a review of their original systematic evidence review and guideline. The conclusion of the review of additional evidence was: “The new evidence will not impact on current assessment and treatment, which, if the present guideline is used, provides an excellent model of care.”

Scottish Intercollegiate Guidelines Network. Proposed review of SIGN Guideline Consultation Summary. Accessed June 25, 2012. Available at http://www.sign.ac.uk/pdf/SIGN79_incontinence_review.pdf