

## 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 #: 0030      NQF Project: <a href="#">GI and GU Project</a>
Date Submitted: <a href="#">Jul 16, 2012</a>
<b>CONCEPT SPECIFICATIONS</b>
De.1 <b>Concept Title:</b> <a href="#">Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment – A patient reported measure</a>
Co.1.1 <b>Concept Steward:</b> <a href="#">National Committee for Quality Assurance</a>
De.2 <b>Brief Description of Concept:</b> <a href="#">This is a patient-reported measure collected through the Health Outcomes Survey with two rates that address management of urinary incontinence in older adults.</a> <a href="#">Discussing urinary incontinence: Percentage of patients 65 years of age and older who self-report having a urine leakage problem in the last six months and who discussed their urinary leakage problem with their health care provider.</a> <a href="#">Receiving urinary incontinence treatment: The percentage of patients 65 years of age and older who self-report having a urine leakage problem in the last six months and who received treatment for their current urine leakage problem.</a>
2a1.1 <b>Numerator Statement:</b> <a href="#">a) Discussing Urinary Incontinence: The number of patients who reported having a problem with urine leakage in the past 6 months and indicated they discussed their urine leakage problem with their current provider.</a> <a href="#">b) Receiving Urinary Incontinence Treatment: The number of patients who reported having a problem with urine leakage in the past 6 months and indicated they received treatment for their current urine leakage problem.</a>
2a1.4 <b>Denominator Statement:</b> <a href="#">The number of patients 65 years and older who responded to the survey indicating they had accidentally leaked urine in the past 6 months and their urine leakage was a problem.</a>
2a1.8 <b>Denominator Exclusions:</b> <a href="#">N/A</a>
1.1 <b>Concept Type:</b> <a href="#">Process</a> 2a1. 25-26 <b>Data Source:</b> <a href="#">Patient Reported Data/Survey</a> 2a1.33 <b>Level of Analysis:</b> <a href="#">Health Plan, Integrated Delivery System</a>
1.2-1.4 <b>Is this concept paired with another measure?</b> <a href="#">No</a>
2a1.1 <b>Numerator Statement</b> <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> <a href="#">a) Discussing Urinary Incontinence: The number of patients who reported having a problem with urine leakage in the past 6 months and indicated they discussed their urine leakage problem with their current provider.</a> <a href="#">b) Receiving Urinary Incontinence Treatment: The number of patients who reported having a problem with urine leakage in the past 6 months and indicated they received treatment for their current urine leakage problem.</a>
2a1.3 <b>Numerator Details</b> <i>(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)</i> <b>For new concepts,</b> describe how you plan to identify and calculate the numerator. <a href="#">a) Discussing Urinary Incontinence</a> <b>Question 3:</b> <a href="#">Have you talked to your current doctor or other health provider about your urine leakage problem?</a>

Answer="Yes"

b) Receiving Urinary Incontinence Treatment

Question 4: There are many ways to treat urinary incontinence including bladder training, exercises, medication and surgery. Have you received these or any other treatments for your current urine leakage problem?

Answer= "Yes"

Individuals with dementia and other cognitive disabilities may be unable to answer these questions. To address this limitation, the Health Outcomes Survey allows for a family member or "proxy" to fill out the survey. The survey is mailed to patients with the following instructions: "If you are unable to complete this survey, a family member or "proxy" can fill out the survey about you" At the end of the survey, the respondent is asked the following question:

Q5 = Who completed this survey form?

Answer = "Person to whom survey was addressed" or "Family member or relative of person to whom the survey was addressed" or "Friend of person to whom the survey was addressed" or "Professional caregiver of person to whom the survey was addressed"

This information is used to determine if information from proxy respondents is systematically biased or different from patient self-reported data.

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

The number of patients 65 years and older who responded to the survey indicating they had accidentally leaked urine in the past 6 months and their urine leakage was a problem.

**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.

Member choices must be as follows to be included in the denominator:

Q1= Many people experience problems with urinary incontinence, the leakage of urine. In the past 6 months, have you accidentally leaked urine?

Answer= "Yes"

Q2= How much of a problem, if any, was the urine leakage for you?

Answer= "A big problem" or "a small problem" (Note: Patients who "not a problem" are not included in the measure denominator).

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

N/A

**2a1.9 Denominator Exclusion Details** (All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)

For new concepts, describe how you plan to identify and calculate the exclusions.

N/A

**2a1.10 Stratification Details/Variables** (All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)

For new concepts, if you plan to stratify the measure results, describe the plans for stratification.

N/A

**2a1.13 Statistical Risk Model and Variables** (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in measure testing in the stage 2 measure submission)

For new concepts, if an outcome, describe how you plan to adjust for differences in case mix/risk across measured entities.

N/A

2a1.25 **Data Source** (Check all the sources for which the concept is specified and tested). If other, please describe:  
[Patient Reported Data/Survey](#)

2a1.26 **Data Source/Data Collection Instrument** (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): [Medicare Health Outcomes Survey](#)

2a1.33 **Level of Analysis** (Check the levels of analysis for which the concept is specified and tested): [Health Plan, Integrated Delivery System](#)

2a1.34 **Care Setting** (Check all the settings for which the concept is specified and tested): [Other](#)

### 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): [Behavioral Health : Alcohol, Substance Use/Abuse, GU/GYN, GU/GYN : Incontinence](#)

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 and between 10 and 35 percent of older men in the community, and up to 80 percent of nursing home residents (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 score, 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). This undesired impact of UI highlights the need for more effective management of the condition (Sims, et al., 2011). 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 asses 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., Johson 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/>

Sims J, Browning C, Lundgren-Lindquist B, &Kendig H. Urinary Incontinence in a Community Sample of Older Adults: Prevalence and Impact on Quality of Life. *Disability & Rehabilitation* 2011; 33(15/16):1389-98.

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:**

For the population of older adults who experience a problem with UI, this measure assesses whether the patient and a health care provider discussed the patient's problem with UI and whether the patient received treatment for their UI problem. 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 and treating UI among older adults will help health plans to identify gaps in care and increase awareness among practitioners and patients. For example, one health plan reporting on this measure began a targeted education campaign for both practitioners and patients to provide information about appropriate treatment options with the hopes of increasing the rate of discussing and treating UI among its older adult population. 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. Urinary incontinence (UI) is a common condition among older adults which can be treated though a variety of methods, yet it remains grossly under-treated in the United States (Wenger 2003). One study of adults age 60 and older showed that nearly 70% of those with UI were not asked about it by their providers or failed to initiate a discussion (Dugan, 2001). The reasons for under-treatment are varied. A 2008 survey conducted among women ages 60-90 years identified that 30% believed their urine loss was due to uncontrollable factors, 6% due to being female, and 18% to lifestyle factors (Melville, 2008). Previous studies have identified potential reasons for not consulting with providers to include embarrassment, viewing it as a normal part of aging, feeling they can cope on their own and having low

expectation of benefit from treatment (Kinchen, 2003). Similarly, knowledge among providers about appropriate treatment for UI is limited. A survey of family physicians in 2002 found that only 37% thought they had an organized approach to management of UI (Swanson, 2002).

Performance data from Health Outcomes Survey on Measure #0030

Rates are averaged at the health plan level

a) Discussing UI

YEAR | N PLANS | MEAN | STD DEV | 10TH | 25TH | 50TH | 75TH | 90TH

2007 | 240 | 57.8 | 5.2 | 51.4 | 57.5 | 54.6 | 60.7 | 63.9

2008 | 294 | 57.6 | 4.8 | 51.2 | 54.0 | 57.1 | 60.9 | 64.3

2009 | 377 | 57.7 | 4.9 | 51.3 | 54.2 | 57.6 | 60.5 | 64.5

2010 | 433 | 58.1 | 5.2 | 51.5 | 54.2 | 57.5 | 61.4 | 65.3

B) Receiving UI Treatment

YEAR | N PLANS | MEAN | STD DEV | 10TH | 25TH | 50TH | 75TH | 90TH

2007 | 241 | 35.5 | 5.2 | 30.0 | 35.4 | 32.4 | 38.0 | 41.3

2008 | 294 | 35.8 | 4.2 | 30.3 | 33.0 | 35.7 | 38.3 | 41.3

2009 | 377 | 36.0 | 4.3 | 30.8 | 33.1 | 35.7 | 38.8 | 41.8

2010 | 432 | 36.0 | 4.5 | 30.8 | 33.0 | 36.0 | 38.8 | 41.11

### 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)**

Dugan E., Roberts C., Cohen S., et al. Why Older Community-Dwelling Adults Do Not Discuss Urinary Incontinence with Their Primary Care Physicians. *Am Geriatr Soc* 2001; 49:462-465.

Kichen KS., Burgio K., Diokno AC., Fultz NH., Bump R., and Obenchain R. Factors associated with women's decisions to seek treatment for urinary incontinence. *J Womens Health*. 2003;12(7); 687-98.

Melville, J. Wagner L., Fan M., Katon W., and Newtown K. Women's perceptions about the etiology of urinary incontinence. *Journal of Women's Health*. 2008; 17(7):1093-1098.

Swanson JG, Skell J, Hutchinson B, Kaczorowski J. Urinary incontinence in Canada. National survey of family physicians' knowledge, attitudes and practices. *Cn Fam Physician* 2002; 48:86-92

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(9): 740-47.

The Medicare Health Outcome Survey (HOS) is a survey of older adults (65+) enrolled in Medicare Advantage health plans across the United States. Respondents are randomly selected from enrolled health plan members to ensure adequate sample size within each health plan for comparison. The 2010 survey was conducted by certified survey vendors between January 1 and December 31 of 2010 through mailed surveys with telephone follow-up. The sample used for the analysis in section 1b.4 was restricted to respondents age 65 and older, the resulting sample size was 423,125. The response rate for the survey in 2010 was 63%.

### 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.**

Gender Disparities: In the 2010 Medicare Health Outcomes Survey (HOS), women were more likely than men to report urinary incontinence in the past six months (46.1% of females in sample vs. 27.9% of men in the sample).

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:



The Medicare Health Outcome Survey (HOS) is a survey of older adults (65+) enrolled in Medicare Advantage health plans across the United States. Respondents are randomly selected from enrolled health plan members to ensure adequate sample size within each health plan for comparison. The 2010 survey was conducted by certified survey vendors between January 1 and December 31 of 2010 through mailed surveys with telephone follow-up. The sample used for the analysis in section 1b.4 was restricted to respondents age 65 and older, the resulting sample size was 423,125. The response rate for the survey in 2010 was 63%.  
 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
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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:** Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

### 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:  
 0098 : Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older – an administrative 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:

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).

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*):

Measure 0030 assesses whether the patient believes their urinary incontinence was discussed and treated. This information complements the clinical measure (0098) which assess documentation of management of urinary incontinence in the medical record. 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 limitation: (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 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 measures 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:

N/A

Co.7 Public Contact: Bob | Rehm, Assistant Vice President, Performance Measurement | Rehm@ncqa.org | 202-955-1728- | National Committee for Quality Assurance

#### ADDITIONAL INFORMATION

NQF #0030 Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment - A patient reported measure, Date Submitted: Jul 16, 2012

Concept Developer/Steward Updates and Ongoing Maintenance Ad.3 Year the concept was first released: Ad.4 Month and Year of most recent revision: Ad.5 What is your frequency for review/update of this measure? Ad.6 When is the next scheduled review/update for this measure?
Ad.7 Copyright statement: © 2012 by the National Committee for Quality Assurance 1100 13th Street, NW, Suite 1000 Washington, DC 20005
Ad.8 Disclaimers: N/A
Ad.9 Additional Information/Comments:
Date of Submission (MM/DD/YY): Jul 16, 2012



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

**Measure Title:** [Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment - a survey 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: Discuss 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 >>>>

Health care provider and patient discuss risks and benefits of treatment options >>>>

Patient receives treatment for urinary incontinence symptoms (*Rate B: Treat UI*) >>>>

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 patients and health care providers discussed urinary incontinence and whether the patient received treatment for their urinary incontinence. This measure is based on guidelines (cited below) that patients with urinary incontinence should be offered assessment, treatment and referral as appropriate. Appropriate treatments which are recommended by guidelines include pelvic floor muscle exercises (referred to in the measure as “exercises”), bladder retraining (referred to in the measure as “bladder training”), pharmacotherapy (referred to in the measure as “medication”) and retropubic colposuspension and sling procedures (referred to in the measure as “surgery”).

<b>SIGN Guidelines for Management of Urinary Incontinence in Primary Care</b>	<b>Grade of Recommendation</b>	<b>Levels of Evidence</b>
Health professional should be vigilant and adopt a proactive approach in consultations with patients who are at greatest risk of developing urinary incontinence through factors including age, the menopause, pregnancy and childbirth, high body mass index (BMI), and experience of continence problems in childhood.	B	2+, 3
Assessment, treatment, and referral, as appropriate, should be offered to all patients with urinary continence problems.	B	2+, 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++
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 trail of duloxetine is recommended for female	A	1+

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 trial of oxybutynin, propiverine, tolterodine, or trospium should be given to patients with significant urgency with our without urge incontinence. The does should be titrated to combat adverse effects.	A	1+, 1++

<b>ACOG: Urinary incontinence in women practice guidelines</b>	<b>Grade of Recommendation</b>	<b>Levels of Evidence</b>
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 have a small beneficial effect on improving symptoms of detrusor overactivity in women.	A	Good/ consistent
Long-term data suggest that Burch colposuspension and sling procedures have similar objective cure rates; therefore, selection of treatment should 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++

(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

**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

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: 21**

- (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 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 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.

#### **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 two categories: (1) Assess patients for UI and (2) 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) 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).

**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 <sup>1, 2</sup>
	2%	Colposuspension <sup>1</sup>
Detrusor overactivity/ urge incontinence	5–27%	Burch colposuspension <sup>3</sup>
	0–30%	Sling <sup>4, 5</sup>
Erosion of surgical materials	6%	Tension-free tape <sup>6</sup>
	≤5%	Sling <sup>5</sup>
Sling revision or removal	5–35%	Sling <sup>7</sup>
Voiding disorders	2–37%	Sling <sup>8</sup>
	4–11%	Tension-free tape <sup>1, 2, 9</sup>

<sup>1</sup>Ward 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.

<sup>2</sup>Tamussino KF, Hanzal E, Kolle 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.

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

<sup>4</sup>Bezerra 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.

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

<sup>6</sup>Nilsson 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.

<sup>7</sup>Persson 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.

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

<sup>9</sup>Klutke 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.**

NQF #0030 Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment – A patient reported measure, Date Submitted: Jul 16, 2012

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](http://www.sign.ac.uk/pdf/SIGN79_incontinence_review.pdf)