Memo

NATIONAL QUALITY FORUM

TO: National Committee for Quality Assurance

FR: NQF GI/GU Project Staff

RE: GI/GU Endorsement Maintenance Pilot Project: Stage two checklist

DA: September 28, 2012

GI/GU Endorsement Maintenance Pilot Project, 2012

Thank you for your participation and concept submission to the GI/GU Endorsement Maintenance Pilot Project. Please carefully review the instructions below for next steps.

Preparation for submission of approved concepts to stage two

1. Review all requirements for measure submission and criteria to be suitable for endorsement:
    *   Consider harmonization opportunities for related concepts and measures
        o   C2050 - Patient counseling on treatment options, including behavioral and surgical treatments prior to SUI surgery, AUA
    *   Ensure that evidence remains current and consistent with concept
        o   Check if there have been any major changes in the evidence base supporting the approved concept. If yes, provide the citation and copy of the study or article and discuss the impact on the measure concept.
        o   If there are any changes in the concept from that which was approved, identify those changes and discuss the relevance of the evidence to the approved concept and the updated concept.
    *   Ensure that testing requirements have been satisfied
        o   Testing requirements are available in the Measure Testing Task Force report

2. Review the Developer Guidebook for additional resources and information for preparing your stage two measure submission. The updated guidebook will be available once stage two submission forms are opened and will also be distributed by NQF Technical Assistance Staff.

3. **Notify NQF project staff by October 25, 2012** if you plan to submit full specifications and testing for approved concepts by the December 19, 2012 stage two measure submission deadline.

4. You will be required to submit at least one of your fully specified and tested measures on or prior to the **technical assistance deadline on December 3, 2012**, for a technical review for completeness and responsiveness by the NQF staff.

5. Measure submissions must be complete and responsive to ALL questions in order to be advanced to the Steering Committee for consideration and evaluation.

GU Concepts Recommended for Approval: NCQA

Provide a response for EACH Committee recommendation describing your rationale for implementing (or not) the recommendation and any additional considerations.

Upload this document to your online measure submission form for review by the Committee in stage two.

0030 Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment – A patient reported measure	
Committee Recommendations to Developer	**Developer Response**

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

Consider adjusting the numerator to also include patients who were offered treatment, but refused. Currently, the numerator specifies that the patient had to receive treatment. Because treatment is a patient choice, not receiving treatment may not actually represent poor quality.	This measure is currently undergoing re-evaluation by NCQA's Measurement Advisory Panels (MAPs). The MAPs raised similar concerns to the NQF Steering Committee about the treatment indicator. The suggestion of the NCQA MAPs was to revise the indicator to assess whether treatment options had been discussed and to add an outcome indicator to assess whether urinary incontinence was well managed. The proposed questions are: 1) Many People experience leaking of urine, also called urinary incontinence. In the past six months, have you experienced leaking of urine? (Yes, No) 2) Have you ever talked with a doctor, nurse, or other health care provider about leaking of urine? (Yes, No) 3) There are many ways to control or manage the leaking or urine, including bladder training, exercises, medication and surgery. Have you ever talked with a doctor, nurse, or other health care provider about any of these approaches? (Yes, No) 4) During the past six months, how much did leaking of urine make you change your daily activities or interfere with your sleep? *(Not at all, Somewhat, A lot)* These changes are currently under consideration with our MAPs and will be completed in June of 2013. NQF staff asked us to submit the original measure version to the Committee for stage 2 review and submit the revised measure during annual update.

0030 Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment – A patient reported measure	
Update submission form (evidence attachment) to clarify the number (quantity) of studies, particularly RCT's that support the measure focus.	The guideline developers did not provide a breakdown of specific number of RCTs for each recommendation. Given the number of studies included in the systematic reviews (>100 studies) we did not feel comfortable re-conducting the evidence review and delineating all the RCTs for each guideline. However, to respond to the request of the Committee we have identified where there are RCTs available to support each of the guidelines. This review is not comprehensive and represents only a portion of the research on this area.
Expand age group to include commercial and menopausal population.	We appreciate the committee's recommendation, however are not currently able to make this change to the measure. The measure is collected through the Health Outcomes Survey which is only administered to Medicare Advantage beneficiaries. We agree the measure could be applied in a younger age group but do not currently have a mechanism for testing this measure in this age group.

0098 Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older – an administrative measure	
Committee Recommendations to Developer	**Developer Response**
eMeasure specifications are strongly recommended.	Two of the three rates in this measure were selected for e-specification under a contract for use in Meaningful Use Stage 2. However e-specifications for these measures were not finalized because the measure was dropped from the final rule for Meaningful Use. NCQA and AMA are open to completing the e-specifications for all three rates in this measure when funding is made available to do so.
Consider the addition of an option for patient choice of no treatment.	We appreciate the Steering Committee concerns, however upon review of the treatment options in the measure have concluded that the current options allow for patient choice of no active treatment (i.e. reassess at follow-up visit, address co-morbid factors, modification or discontinuation of medications, lifestyle interventions). Even if a patient refuses treatment, providers should continue with follow-up to re-assess the patient preferences for treatment at a future date.
Expand age group to include commercial and menopausal population.	While we appreciate the Steering Committee suggestion, expanding the age range is not currently feasible. This is a change that will be considered in future re-evaluation of this measure during 2013.

NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 6.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure 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
(for Endorsement Maintenance Review) **Original Endorsement Date: Most Recent Endorsement Date: Evaluation Form Created:** March 22, 2013
BRIEF MEASURE INFORMATION
De.1 Measure 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 Measure Steward: National Committee for Quality Assurance
De.2 Brief Description of Measure: 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
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 Measure Type: Process **2a1. 25-26 Data Source:** Administrative claims, Paper Medical Records, N/A **2a1.33 Level of Analysis:** Clinician : Group/Practice, Clinician : Individual, Clinician : Team **1.2-1.4 Is this measure paired with another measure?** No **De.3 If included in a composite, please identify the composite measure** (*title and NQF number if endorsed*): N/A

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I☐
(*The measure 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, GU/GYN : 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: N/A

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 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 blatter, 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

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

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 measure:
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 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*:
[*For Maintenance* – *Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
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%

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

2010 | 82.7% | 2.0%

1b.3 Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
2010 Physician Quality Reporting System and eRx Experience Report.

1b.4 Summary of Data on Disparities by Population Group *(for example by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability, etc. If you do not have data on your specific measure, perform a literature search/review and report data for the measure or similar appropriate concept.)*: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
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: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
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 (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes ☐ No ☐   <u>If not a health outcome</u>, 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 measure pass subcriterion1c?
M-H	M-H	M-H	Yes ☐
L	M-H	M	Yes ☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise **No** ☐
M-H	L	M-H	Yes ☐ IF potential benefits to patients clearly outweigh potential harms: otherwise **No** ☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes ☐ IF rationale supports relationship

SEE ATTACHED EVIDENCE SUBMISSION FORM

Was the threshold 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:

For a new measure if the Committee votes NO, then STOP.

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 **Measure Web Page** *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained)*. Do you have a web page where current detailed specifications for this measure can be obtained?

2a1.1 Numerator Statement *(Brief, narrative description of the measure 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)*:

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

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, codes with descriptors, and/or specific data collection items/responses)*:

The following definitions are used in the numerator for all three rates:

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 *(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 measure is specified and tested if any)*:

Senior Care

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:

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,

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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)*:
Documentation of medical reason(s) for not assessing the presence or absence of urinary incontinence within 12 months

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
Documentation of medical reason(s) for not assessing for the presence or absence of urinary incontinence within 12 months.

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
N/A

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: **2a1.12** If "Other," please describe: 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 2b4.)*:
N/A

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score:
Rate/proportion

If other: N/A

2a1.19 Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*:
better quality = higher score

2a1.20 Calculation Algorithm/Measure Logic *(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
(A) Assessment for UI
1. Identify eligible population: All female patients aged 65 years and older identified through CPT services codes for an ambulatory care office visit.
2. Identify numerator: Identify patients in eligible population who have documentation of being assessed for urinary incontinence.
3. Identify exclusions: Identify patients in eligible population with documented medical reason(s) for not assessing the presences or

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

absence of urinary incontinence.
4. Calculate Rate: Step 2/(Step 1-Step 3)
(B) Characterize UI
1. Identify eligible population: All female patients aged 65 years and older identified through CPT services codes for an ambulatory care office visit.
2. Identify denominator: Identify eligible population with diagnosis of Urinary Incontinence (through ICD-9 codes)
3. Identify numerator: Identify denominator patients who have documentation of having their UI characterized.
4. Calculate Rate: Step 3/Step 2
(C) Plan of Care for UI
1. Identify eligible population: All female patients aged 65 years and older identified through CPT services codes for an ambulatory care office visit.
2. Identify denominator: Identify eligible population with diagnosis of Urinary Incontinence (through ICD-9 codes)
3. Identify numerator: Identify denominator patients who have documentation of a plan of care for UI.
4. Calculate Rate: Step 3/Step 2

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested)*. If other, please describe:
Administrative claims, Paper Medical Records

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.*):
N/A

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:
N/A

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested*):
Clinician : Group/Practice, Clinician : Individual, Clinician : Team

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*:
Ambulatory Care : Clinician Office/Clinic

If other: N/A

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐
2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>: H☐ M☐ L☐ I☐
2c. Disparities in Care: H☐ M☐ L☐ I☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

SEE ATTACHED MEASURE TESTING FORM

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

If the Committee votes No, STOP

3. USABILITY

Extent to which potential audiences (e.g., consumers, purchasers, providers, policymakers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations. (underline)evaluation criteria(underline)

3.1 Current <u>and</u> Planned Use *(NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported withi n 6 years of initial endorsement in addition to performance improvement.)*:

Current and Planned Use (check all the current and planned uses; for any current uses that are checked, provide a URL for the specific program)

Planned	Current	For current use, Provide URL
	Public Reporting; Payment Program; Professional Certification or Recognition Program; Quality Improvement with Benchmarking (external benchmarking to multiple organizations)	http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/2010-Physician-Quality-Reporting-System.html; http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/AnalysisAndPayment.html; http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Maintenance_of_Certification_Program_Incentive.html; http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/2010-Physician-Quality-Reporting-System.html

3a. Accountability and Transparency: H☐ M☐ L☐ I☐
(Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.)

3a.1. For each CURRENT use, checked above, provide:
- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

NAME OF PROGRAM: Physician Quality Reporting System
SPONSOR: Centers for Medicare and Medicaid Services (CMS)
PURPOSE: "The Physician Quality Reporting System (Physician Quality Reporting or PQRS) is a reporting program that uses a combination of incentive payments and payment adjustments to promote reporting of quality information by eligible professionals. The program provides an incentive payment to practices with eligible professionals (identified on claims by their individual National Provider Identifier [NPI] and Tax Identification Number [TIN]) who satisfactorily report data on quality measures for covered Physician Fee Schedule (PFS) services furnished to Medicare Part B Fee-for-Service (FFS) beneficiaries (including Railroad Retirement Board and Medicare Secondary Payer). Beginning in 2015, the program also applies a payment adjustment to eligible professionals who do not satisfactorily report data on quality measures for covered professional services." CMS Website available

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html
GEOGRAPHIC AREA AND NUMBER OF ACCOUNTABLE ENTITIES: This program covers all 50 states in the U.S. In 2010 19,232 practices qualified for an incentive.

3a.2. **If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons?** *(e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?)*
N/A

3a.3 **If not currently publicly reported OR used in at least one accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement.** *(Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)*
N/A

3b. Improvement: H☐ M☐ L☐ I ☐
(Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.6 If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.)

3b.1. **Provide data that demonstrate improvement in performance and/or health. (Not required for initial endorsement unless available.)**
Include:
- Source of Data
- Geographic area and number and percentage of accountable entities and patients included
- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)

SOURCE OF DATA: PQRS program.
GEOGRAPHIC AREA: Nationally representative
NUMBER AND PERCENTAGE OF ACCOUNTABLE ENTITIES: Providers who choose to participate in the PQRS program decide which measures they would like to report on based on their practice goals and patient population. Data below show the number of eligible providers for each measure, the number of reporting providers and the % of eligible providers who chose to report on this measure. These numbers are shown for the past two years of available data for each rate.
(A) Assessment of UI
Year | N Eligible Providers | N Reporting Providers | % Reporting Providers
2009 | 527,926 | 6,863 | 1.30%
2010 | 539,520 | 7,014 | 1.30%
(B) Characterization of UI
Year | N Eligible Providers | N Reporting Providers | % Reporting Providers
2009 | 125,467 | 2,509 | 2.00%
2010 | 125,304 | 2,506 | 2.00%
(C) Plan of Care for UI
Year | N Eligible Providers | N Reporting Providers | % Reporting Providers
2009 | 125,346 | 2,256 | 1.80%
2010 | 125,324 | 2,506 | 2.00%
PROGRESS (PERFORMANCE DATA OVER TIME): The data below show improved performance (higher quality care) from 2009 to 2010 for all three rates in this measure.
(A) Assessment of UI
YEAR | Rate
2009 | 57.3%
2010 | 66.5%

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

(B) Characterization of UI
YEAR | Rate
2009 | 68.9%
2010 | 82.5%
(C) Plan of Care for UI
YEAR | Rate
2009 | 76.4%
2010 | 82.7%

3b.2. If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations:
Improvement demonstrated in trends.

3c. Unintended Consequences: H☐ M☐ L☐ I☐
(The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations)

3c.1. Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.
No negative consequences to individuals or populations were identified during testing or through subsequent implementation of the measure.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (**evaluation criteria**)

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H☐ M☐ L☐ I☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*:
Some data elements are in defined fields in electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:
Two of the rates in this measure were selected for e-specification under a contract for use in Meaningful Use Stage 2 (assessment of UI and characterization of UI). However e-specifications for these measures were not finalized because the measure was dropped from the final rule for meaningful use. NCQA and AMA are open to completing the e-specifications for all three rates in this measure when funding is made available to do so.

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I☐

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues *(e.g., fees for use of proprietary measures)*:
The specific costs for implementing or using this measure have not been measured, however the successful use in a national reporting program (PQRS) support the feasibility and utility of the measure concept.

4d.2 Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*:

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

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. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):
Are the measure specifications completely harmonized?

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:
See 5b.1. for answer.

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure 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)*:

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner):** National Committee for Quality Assurance

Co.2 **Point of Contact:** Bob | Rehm, Assistant Vice President, Performance Measurement | Rehm@ncqa.org | 202-955-1728

Co.3 **Measure Developer if different from Measure 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

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
The workgroup members advised the measure developers in the development of this measure.
Caroline Blaum, MD (Work Group Co-Chair) (Geriatrics/Internal Medicine) Associate Professor of Internal Medicine, University of Michigan, Ann Arbor, MI
Carol M. Mangione, MD (Work Group Co-Chair) (Internal Medicine) Professor of Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA
Chris Alexander, III, MD, FACP (Methodology) Social Security Administration, Office of Hearings and Appeals, Earlysville, VA
Patricia P. Barry, MD, MPH (Internal Medicine) American College of Physicians, Gloucester Point, VA
Frederick W. Burgess, MD, PhD (Anesthesia) Rhode Island Hospital, Department of Anesthesia, Providence, RI
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Stephen R. Connor, PhD Vice President, Research and International Development, National Hospice and Palliative Care Organization, Alexandria, VA
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Sam J. W. Romeo, MD, MBA General Partner, Tower Health & Wellness Center, LP, Turlock, CA
David J. Satin, MD (Family Medicine/Bioethics) Assistant Professor, University of Minnesota, Minneapolis, MN

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Knight Steel, MD (Internal Medicine/Geriatrics) Chief, Geriatrics, Internist, Professor of Medicine Emeritus, Hackensack University Medical Center, Hackensack, NJ

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Laura Tosi, MD (Orthopaedic Surgery) American Academy of Orthopaedic Surgery, Director, Bone Health Program, Washington, DC

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Neil S. Wenger, MD (Internal Medicine/Geriatrics) Professor of Medicine, UCLA, Los Angeles, CA

Jill Epstein- American Geriatrics Society

Min Gayles- National Committee for Quality Assurance

Phil Renner- National Committee for Quality Assurance

Karen Kmetik- American Medical Association

Heidi Bossley- American Medical Association

Joanne Schwartzberg- American Medical Association

Patricia Sokol- American Medical Association

Ronald Bangasser- Beaver Medical Group in Redlands

Peter Jonstone-Indiana University School of Medicine

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2008

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

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

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 incudes 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 X ☐
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	D	2- ,2+ ,4,

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		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 trail 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 our without urge incontinence. The does 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 is 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 have a small beneficial effect on improving symptoms of detrusor	A	Good/ consistent

overactivity in women.		
Surgical treatment: 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 <u>with definition</u> 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.
<u>SIGN Grades of Recommendation</u>

- 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 consistence 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.
<u>ACOG Levels of Recommendation</u>

- 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 <u>body of evidence</u> for the specific guideline recommendation? Yes X ☐   No ☐   *If no, skip to #1c.6*

<u>If yes</u>, *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 <u>with definition</u> 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.

<u>SIGN Levels of Evidence</u>
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 <u>body of evidence</u> supporting the measure focus identified in 1c.1? *(other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)*
YesX☐   No☐   <mark>*If no, skip to #1c.7*</mark>

If <u>yes</u>, *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/uiovervw.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 <u>with definition</u> of the grade**:
Not graded.

<mark>*If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8*</mark>

1c.7. <u>If a systematic review of the body of evidence was not identifed and reported in 1c.5 or 1c.6</u>, did the measure developer perform a systematic review of the <u>body of evidence</u> supporting the measure focus identified in 1c.1? Yes☐   No☐

If <u>yes</u>, *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 <u>body of evidence</u>**?

1c.7.2. **Grade assigned to the body of evidence <u>with definition</u> of the grade**:

1c.7.3. **Describe the process used for the systematic review**:

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 inlcuded 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 <u>across studies</u> 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) <u>across studies</u> 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 uncertainly 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 sypmptoms (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]

[1]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.

[2]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.

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

[4]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.

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

[6]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.

[7]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.

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

[9]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 X ☐   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

Measure Testing to Demonstrate Scientific Acceptability of Measure Properties

Measure Title: Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older – an administrative measure
Date of Submission: 1/11/2013
Type of Measure:

☐ Composite	☐ Outcome
☐ Cost/resource	X☐ Process
☐ Efficiency	☐ Structure

This Word document template must be used to submit information for measure testing.
- **For all measures, sections 1, 2a2, 2b2, 2b3, 2b5 must be completed**
- **For outcome or resource use measures**, section **2b4** also must be completed
- If specified for **multiple data sources** (e.g., claims and medical records), section **2b6** also must be completed
- Respond to all questions with answers immediately following the question (*unless meet the skip criteria or those that are indicated as optional*).
- Maximum of 10 pages (*incuding questions/instructions; do not change margins or font size; contact project staff if need more pages*)
- All information on testing to demonstrate meeting the criteria for scientific acceptability of measure properties (2a,2b) must be in this form. An appendix for *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.

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1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE
Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the types of data specified and intended for measure implementation*)

Measure Specified to Use Data From:	Measure Tested with Data From:
☐ X abstracted from paper record	☐ X abstracted from paper record
☐ administrative claims	☐ administrative claims
☐ clinical database/registry	☐ clinical database/registry
☐ X abstracted from electronic health record	☐ X abstracted from electronic health record
☐ eMeasure implemented in electronic health record	☐ eMeasure implemented in electronic health record
☐ other:	☐ other:

1.2. If used an existing dataset, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

N/A

1.3. What are the dates of the data used in testing? Testing was performed from January-July of 2010.

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)
X ☐ individual clinician ☐ group/practice ☐ hospital/facility/agency ☐ health plan
☐ other: 2T

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

Reliability: Testing for reliability was done with three physician practices with electronic medical records and one physician practice with paper medical records. Sites were located in the Northeastern, Midwestern and Southern regions of this country.

Validity: An expert panel was used to assess face validity of the measure. This panel consisted of 33 members, whose specialties included internal medicine, geriatrics, anesthesia, orthopaedic surgery, physical medicine & rehabilitation, neurology, palliative medicine, urology, geriatric psychiatry, emergency medicine, nephrology, radiation oncology, ophthalmology, medical epidemiology, methodology, hospital medicine, family medicine, and bioethics.

Meaningful Difference in Performance: This measure was used in the 2010 CMS PQRS.
(A) Assess UI
Eligible professionals: 539,410
Professionals Reporting: 5,658
% Professionals Reporting: 1.1%
# Professional Satisfactorily Reporting: 1,502
% Professional Satisfactorily Reporting: 26.6%
Average Reporting Rate per Eligible Professional: 37.8%

(B) Characterize UI
Eligible professionals: 125,261
Professionals Reporting: 2,027
% Professionals Reporting: 1.6%
# Professional Satisfactorily Reporting: 909
% Professional Satisfactorily Reporting: 44.8%
Average Reporting Rate per Eligible Professional: 66.9%

(C) Plan of Care for UI
Eligible professionals: 125,261
Professionals Reporting: 1,947
% Professionals Reporting: 1.6%
# Professional Satisfactorily Reporting: 852
% Professional Satisfactorily Reporting: 43.8%
Average Reporting Rate per Eligible Professional: 65.5%

1.6. How many and which <u>patients</u> were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

<u>Reliability</u>: A random sample of 55 medical records for patients qualifying for the measures were reviewed by two trained abstractors.

<u>Validity</u>: The full list of panel members is provided under the section Additional Information, Ad.1. Workgroup/Expert Panel Involved in Measure Development

<u>Meaningful Difference in Performance</u>:
(A) Assess for UI
N= 256,215 cases

(B) Characterize UI and Plan of Care for UI
N= 55,010 cases

(C) Plan of Care for UI
N= 51,891 cases

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

Validity was demonstrated through a systematic assessment of face validity. Per NQF instructions we have described the composition of the technical expert panel which assessed face validity in the data sample questions above.

2a2. RELIABILITY TESTING
<u>Note</u>: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – report validity of data elements in 2b2

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)
☐ **X Critical data elements used in the measure** (*e.g., inter-abstractor reliability*)
☐ **Performance measure score** (e.g., *signal-to-noise*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests
(*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

Reliability was tested by assessing whether two abstractors, reviewing the same data from the same data source, would come to the same conclusion as to the patient meeting the measure, not meeting the measure, or qualifying as an exception. Agreement between abstractors was measured using the kappa statistic (a measure of agreement adjusted for agreement that can occur by chance).

2a2.3. For each level checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis and association with case volume*)

Measure	Performance	Kappa	95% C.I.	% Agreement
(A) Assessment of UI	92.74%	1.0	(1.0-1.0)	100%
(B) Characterization of UI	72.49%	0.94	(0.87-1.0)	97.8%
(C) Plan of Care for UI	78.65%	0.96	(0.90-1.00)	98.92%

Note on EHR versus Paper Record Abstraction: In 2008, Part of the project examined documentation processes and the use of standardized means to capture and store information, i.e. whether or not the data are stored in a codified field; what clinical code sets are utilized/available; and where in the record are the data found. The sites using EHRs were asked about the use of nomenclature code sets such as SNOMED CT and LOINC. In 2008, none of the practices was aware of these code sets or the intended use. The sites were aware of the various coding standards used in the front end user interface, e.g. ICD9 (used for diagnosis coding); CPT (mainly used for procedure coding); and Medi-Span (used for medication coding), but not that the EHRs were set up to store this information on the backend database in a code set such as SNOMED CT.

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

These results show near perfect agreement between abstractors for all three rates (Kappa>0.9). For reference, the Kappa statistic has the following interpretation:
0.00   Poor
0.01 – 0.20   Slight
0.21 – 0.40   Fair
0.41 – 0.60   Moderate
0.61 – 0.80   Substantial
0.81 – 0.99   Almost perfect

This suggests these measures can be reliably abstracted from medical records.
_____

2b2. VALIDITY TESTING
2b2.1. What level of validity testing was conducted? (*may be one or both levels*)
☐ **Critical data elements**

☐ **Performance measure score**
   ☐ **Empirical validity testing**
   ☐ **X** **Systematic assessment of face validity of** <u>performance measure score</u> **as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance quality or resource use and can distinguish performance*)

2b2.2. For each level checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements*

compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)

All NCQA/AMA-PCPI performance measures are assessed for content validity by a panel of expert work group members throughout the development process. Additional input on the content validity of draft measures is obtained through a 30-day public comment period and by also soliciting comments from a panel of consumer, purchaser, and patient representatives convened by the PCPI specifically for this purpose. All comments received are reviewed by the expert work group and the measures adjusted as needed. Other external review groups (eg, focus groups) may be convened if there are any remaining concerns related to the content validity of the measures. An expert panel also assessed face validity of the measure using a Delphi process. The panel was asked to rate their agreement with the following statement:

"The scores obtained from the measure as specified will accurately differentiate quality across providers."

Scale 1-5, where 1=Strongly Disagree; 3=Neither Disagree nor Agree; 5=Strongly Agree

2b2.3. What were the statistical results from validity testing? (*e.g., correlation; t-test, ANOVA*)
(A) Assess UI:

The results of the Expert Panel rating of the validity statement were as follows: N=23; Mean rating = 4.22 and 82.60% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality.

The results of the Expert Panel rating of the validity statement were as follows:
Frequency Distribution of Ratings
1- 0 (Strongly Disagree)
2- 0
3- 4 (Neither Disagree nor Agree)
4- 10
5- 9 (Strongly Agree)

(B) Characterize UI:

The results of the Expert Panel rating of the validity statement were as follows: N=23; Mean rating = 4.13 and 78.26% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality.

The results of the Expert Panel rating of the validity statement were as follows:
Frequency Distribution of Ratings
1- 0 (Strongly Disagree)
2- 0
3- 5 (Neither Disagree nor Agree)
4- 10
5- 8 (Strongly Agree)

(C) Plan of Care for UI:

The results of the Expert Panel rating of the validity statement were as follows: N=23; Mean rating = 4.22 and 82.60% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality.

The results of the Expert Panel rating of the validity statement were as follows:
Frequency Distribution of Ratings
1- 0 (Strongly Disagree)
2- 0
3- 4 (Neither Disagree nor Agree)
4- 10
5- 9 (Strongly Agree)

2b2.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)

These results indicate the technical expert panel showed good agreement that the measures as specified will accurately differentiate quality across providers. Our interpretation of these results is that this measure has sufficient face validity.

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2b3. EXCLUSIONS ANALYSIS
NA ☐ **no exclusions** — *skip to #2b5*

2b3.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

Exclusions were tested for reliability by assessing whether two abstractors, reviewing the same data from the same data source, would come to the same conclusion as to the patient qualifying as an exception. Agreement between abstractors was measured using the kappa statistic (a measure of agreement adjusted for agreement that can occur by chance).

2b3.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

Measure	Rate of exclusions	Kappa	95% C.I.	% Agreement
(A) Assessment of UI - Exception	1.27%	0.62	(0.04-1.00)	90.0%

2b3.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. Note: **If patient preference is an exclusion**, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

The data show reasonable reliability for identifying exclusions in medical record documents. However, it is important to note that the small sample size limits the inferences which can be drawn from this test.

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2b5. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE
2b5.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified
(*describe the steps—do not just name a method; what statistical analysis was used*)

To demonstrate meaningful differences in performance, NCQA/AMA/PCPI calculates an inter-quartile range (IQR) for each indicator. The IQR provides a measure of the dispersion of performance. The IQR can be interpreted as the range is the difference between the 25th and 75th percentile on a measure.

2b5.2. What were the statistical results from testing the ability to identify differences in performance measure scores across measured entities? (*at a minimum, the distribution of performance measure scores for the measured entities by decile/quartile, mean, std dev; preferably also number and percentage statistically different from mean or some benchmark, different form expected, etc*.)

(A) Assess for UI
10th percentile: 8.33%
25th percentile: 72.58%
50th percentile: 100.00%
75th percentile: 100.00%
90th percentile: 100.00%
Mean= 78.62%
IQR= 27.42

(B) Characterize UI
10th percentile: 88.37%
25th percentile: 100.00%
50th percentile: 100.00%
75th percentile: 100.00%
90th percentile: 100.00%
Mean= 97.44%
IQR= 0.00

(C) Plan of Care for UI
10th percentile: 91.67%
25th percentile: 100.00%
50th percentile: 100.00%
75th percentile: 100.00%
90th percentile: 100.00%
Mean= 97.26%
IQR= 0.00

2b5.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and clinically/practically meaningful differences in performance across measured entities? (i.*e., what do the results mean and what are the norms for the test conducted?*)
These results show minimum to no difference in performance across providers. However it is important to note the limitation of this data. These providers represent a self-selecting group and may not be representative the larger population of providers. Beginning in 2015, the PQRS program will apply a

payment adjustment to eligible professionals who do not satisfactorily report data on quality measures for covered professional services. We anticipate results will show a wider variation in performance once this changes has taken place.

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