
STAGE 2 TECHNICAL REPORT

December 2013
National Voluntary Consensus Standards:
Gastrointestinal and Genitourinary Endorsement
Maintenance: Two-Stage Pilot, 2012 – 2013

Introduction

Gastrointestinal conditions such as cancer, acid reflux, and GERD impact a large number of Americans. These disorders not only cause symptoms and pose a heavy burden of illness, but also impact the quality and length of life, as well as work productivity:

- In 2007 (the most recent year for which statistics are available), 142,672 Americans were diagnosed with colorectal cancer, including 72,755 men and 69,917 women. It is estimated that as many as 60% of colorectal cancer deaths could be prevented if all men and women aged 50 years or older were screened routinely.\(^1\)
- The estimated annual national expenditure for colorectal cancer treatment in 2012 was $14 billion; inpatient hospital care accounted for 80% of this cost.\(^2\)
- The prevalence of weekly heartburn and other symptoms of acid reflux rose nearly 50% over the last decade.\(^3\) A study in 2007 from the JeSTARx Group in Newfoundland, New Jersey, found that each worker with gastroesophageal reflux disease (GERD) costs their employer an average of $3355 each year. Total costs included direct medical costs (65% of this figure), prescription drug costs (17%) and indirect costs (19%). Employees with GERD were approximately 10% less productive at work than those without GERD. The cost to US employers is estimated to be $75 billion annually in lost productivity.\(^4\)

Similarly, genitourinary (GU) conditions, including urinary tract infections (UTI), cystitis, benign prostate hypertrophy (BPH), and urinary incontinence (UI) pose a heavy burden on quality of life and healthcare spending:

- In 2000, costs associated with evaluation and treatment of BPH cost were estimated at $1.1 billion annually.\(^5\)
- 8.27 million of the adult outpatient visits in 2000 (1.41 million men; 6.86 million women) were attributed to UTIs as the primary diagnosis with an estimated $3.5 billion expended for evaluation and treatment.\(^6\)
- In 2007, UI was estimated to affect 9-22 percent of U.S. adults with an estimated cost of $463.1 million expended annually for evaluation and treatment.\(^7\)

NQF has endorsed several consensus standards to evaluate the quality of care for topic areas related to gastrointestinal and genitourinary diseases over the last several years. As quality measurement has matured, better data systems have become available, electronic health records are closer to widespread adoption, and the demand for meaningful performance measures has prompted development of more sophisticated measures of healthcare processes and outcomes for gastrointestinal and genitourinary conditions. An evaluation of the NQF-endorsed\(^8\) gastrointestinal and genitourinary measures and consideration of new measures will ensure the currency of NQF’s portfolio of voluntary consensus standards.
Two-Stage Consensus Development Process

This GI/GU measure endorsement project is a pilot of the proposed two-stage consensus development process. The Stage 1 Final Report details the evaluation of the submitted concepts against the Importance to Measure and Report criterion. The evaluation, comments and feedback received during this project specifically related to the two-stage CDP process have been addressed separately in the two-stage evaluation report.

Stage 2

Developers whose concepts were approved in Stage 1 have up to 18 months to fully develop, specify and test the measure before submitting it for Stage 2 review against the remaining NQF criteria. Seven measures were submitted for this Stage 2 review by January 11, 2013.

Stage 2 review includes:

- **Checklist Review**: A checklist was provided to each developer following the Committee’s review and recommendations for concepts in Stage 1. Each checklist summarizes the Committee’s recommendations for improving the concept(s) and considerations for specifying and testing the measure that must be addressed prior to submission to Stage 2.
- **Evaluation of approved concepts**: Fully specified measures for which the concepts were approved in Stage 1 are evaluated against the remaining criteria of scientific acceptability, usability, and feasibility.

The tables below summarize the status of each concept/measure in the two stages of the project.

### Gastrointestinal Concepts and Measures

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>0622 GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms (ActiveHealth)</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>0635 Chronic Liver Disease - Hepatitis A Vaccination (ActiveHealth)</td>
<td>Yes</td>
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<td>0658 Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients (AMA PCPI)</td>
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<td>C 2056 Colonoscopy Quality Index (QualityQuest)</td>
<td>Yes</td>
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<td>C 2059 Inflammatory Bowel Disease (IBD) preventive care: corticosteroid sparing therapy (AGA)</td>
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<td>C 2065 Gastrointestinal Hemorrhage Mortality Rate (AHRQ)</td>
<td>Yes</td>
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<td>C 2062 Inflammatory Bowel Disease (IBD) preventive care: corticosteroid related iatrogenic injury – bone loss assessment (AGA)</td>
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**Genitourinary Concepts and Measures**

<table>
<thead>
<tr>
<th><strong>(18) Submitted Concepts – Stage 1</strong></th>
<th><strong>(5) Approved Concepts – Stage 1</strong></th>
<th><strong>(1) Submitted Measures – Stage 2</strong></th>
<th><strong>Maintenance Measures</strong></th>
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<tbody>
<tr>
<td>0030 Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment (NCQA)</td>
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<tr>
<td>0098 Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (NCQA)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>C 2038 Performing vaginal apical suspension (uterosacral, iliococcygeus, sacrospinous or sacral colpopexy) at the time of hysterectomy to address uterovaginal prolapse (AUGS)</td>
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<td>C 2052 Reduction of Complications through the use of Cystoscopy during Surgery for Stress Urinary Incontinence (SUI) (AUA)</td>
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<td>C 2063 Use of cystoscopy concurrent with prolapse repair surgery (AUGS)</td>
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<td>C 2037 Objective characterization of pelvic organ prolapse prior to surgery (AUGS)</td>
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<tr>
<td>C 2049 Complete Workup for Assessment of Stress Urinary Incontinence (SUI) Prior to Surgery (AUA)</td>
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<tr>
<td>C 2050 Patient counseling on treatment options, including behavioral and surgical treatments prior to Stress Urinary Incontinence (SUI) surgery (AUA)</td>
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<td>C 2051 Patients Counseled About Risks Associated with the Use of Mesh in Sling Surgery Prior to Surgery (AUA)</td>
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<td>C 2054 Assessment of treatment within one year of Stress Urinary Incontinence (SUI) surgery (AUA)</td>
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Purpose

The purpose of this report is to summarize the review of seven fully specified measures that passed the concept review in Stage 1 (detailed in the Stage 1 Final Report). The Stage 1 evaluation is included in the summary tables below to describe the complete evaluation against all criteria.

Measure Evaluation

In April 2013, the GI/GU Steering Committee met on several conference calls to evaluate seven measures submitted for evaluation against the three remaining criteria. The Steering Committee ultimately recommended five measures for approval. A summary of each measure’s evaluation and recommendations throughout the process is captured in the evaluation tables beginning on page 8.

GI MEASURES ENDORSEMENT MAINTENANCE, 2013 SUMMARY

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<th>Maintenance</th>
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<td>Endorsed Measures</td>
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<tr>
<td>Measures Not Recommended</td>
<td>2</td>
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<tr>
<td>Approved Concepts that did not pass Stage 2 Checklist Review</td>
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GU MEASURES ENDORSEMENT MAINTENANCE, 2013 SUMMARY

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<tr>
<th>Maintenance</th>
<th>New</th>
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<tbody>
<tr>
<td>Measures under review (passed Stage 1 review)</td>
<td>1</td>
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</tr>
<tr>
<td>Endorsed Measures</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Measures Not Recommended</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Maintenance measure approved in Stage 1, not reviewed in Stage 2</td>
<td>1</td>
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</tbody>
</table>

Overarching Issues

Evaluation of eMeasures

Two maintenance measures were submitted with new eMeasure specifications in addition to the original measure specifications. The Committee attempted to compare the specifications but found it difficult without a crosswalk between the two versions of the measure. As the two measures are supposed to measure the same thing, the Committee was looking for alignment of the definitions and value sets in both sets of specifications. The developer provided a crosswalk of the specifications for the Committee to review at the post-comment conference call. After reviewing the crosswalk, the Committee agreed the two versions of the measures were same, and voted to recommend the eSpecifications for endorsement as well as the original measure specifications.
Recommendations for Future Measure Development

During their discussions the Committee identified numerous areas where additional measure development is needed:

- Referral of nonalcoholic steatohepatitis (NASH) patients with BMI>40 for weight loss therapy including nutritional, cognitive, medical and/or surgical therapy
- Outcome measures of whether adenomas or cancers are found on colonoscopies
- Outcome measures of the performance of the colonoscopy
- Outcome measures for the 10-year follow-up on colonoscopies
- Composite measures of outcomes of colonoscopy
- Measures of overuse of colonoscopy
- Measure of effective interventions for non-muscle invasive bladder cancer
- Measures for kidney transplants and GI complications
- Measures that use clinical registries as data sources
- Measures of population engagement and systems approaches, particularly those that address issues of cultural competency and patient preferences

Measure Evaluation Summary

Endorsed GI Measures
1. 2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18) ................................................................. 8
2. 0658 Endoscopy/Polypl Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients .................................................................................................................. 15
3. 0659 Endoscopy/Polypl Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polypl- Avoidance of Inappropriate Use ........................................................................... 19

GU Measures Not Recommended for Endorsement
1. 0098 Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older .............................................................................. 25

GI Measures Not Recommended for Endorsement
1. 0622 GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms .................................................. 30
2. 0635 Chronic Liver Disease - Hepatitis A Vaccination ................................................................................... 34

Approved Concepts That Did Not Pass Stage 2 Checklist Review
1. C 2056 Colonoscopy Quality Index ............................................................................................................. 38

Endorsed Maintenance Measure, Approved in Stage 1, Not Reviewed in Stage 2
1. 0030: Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment – A patient reported measure ......................................................... 45
Endorsed GI Measures

2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18)

Measure Submission Form | Specifications

Status: New Submission

Description: Percent of discharges with an in-hospital death among cases with a principal diagnosis of gastrointestinal hemorrhage

Numerator Statement: Number of in-hospital deaths among cases meeting the inclusion and exclusion rules for the denominator

Denominator Statement: All discharges, age 18 years and older, with a principal diagnosis code for gastrointestinal hemorrhage OR a principal diagnosis of predisposing condition for esophageal varices and a secondary diagnosis of esophageal varices in condition classified elsewhere with bleeding (456.20)

Exclusions: Exclude cases:
- transferred to another short-term hospital
- with MDC 14 (pregnancy, childbirth, and puerperium)
- with missing discharge disposition, gender, age, quarter, year or principal diagnosis

Adjustment/Stratification: Statistical risk model The predicted value for each case is computed using a two-stage hierarchical model (the first stage is a logistic regression using Generalized Estimating Equations (GEE) to account for clustering of patients within hospitals; the second stage is a reliability weight). The covariates in the logistic regression include age (in 5-year age groups pooled), APR-DRG and APR-DRG Risk of Mortality subclass, MDC and transfer-in status. The reference population used in the regression is the universe of discharges for states that participate in the HCUP State Inpatient Data (SID) for the years 2008, a database consisting of 42 states and approximately 30 million adult discharges.

Level of Analysis: Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Agency for Healthcare Research and Quality

STAGE 1

STAGE 1 PRE-REVIEW MEMBER COMMENTS (August 7-21, 2012)

- America's Health Insurance Plans - This measure may be subject to a small numbers problem raising reliability issues.

STEERING COMMITTEE MEETING (August 27-28, 2012)

1. Importance to Measure and Report:

1a. High Impact: H-14; M-0; L-0; I-0

Discussion: There is general agreement this measure focus addresses a high impact area. GI hemorrhage is a common problem.

1c. Evidence

14: Yes, body of evidence meets guidance for quantity, quality, consistency
0: No, body of evidence does not meet guidance for quantity, quality, consistency
0: No, inadequate information to rate quantity, quality, consistency of body of evidence

Discussion: Outcome measures do not require evidence; however, the Committee agreed that the developer did provide a rationale that supports the relationship of the health outcome to processes or structures of care.

1b. Performance Gap: H-10; M-4; L-0; I-0

Discussion:
2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18)

- The odds ratio of bleeding ranges from 17 to 22 based on the type of hospital and from 14 to 25 based on insurance status.
- Risk adjusted using 3M APR-DRG's and it is publicly available to implement this measure. While gender is included in the risk adjustment model, race and ethnicity are not. This allows for stratification by race and ethnicity as the data submitted demonstrates significant differences in the outcomes among white, black, and Hispanic patients.
- The Committee agreed based on the above discussions, that there is a performance gap for this measure focus.

Recommendations to Developer for Stage 2:
- Numerator and denominator only include patients with primary diagnosis of GI bleed, consider how this might impact the capture of other patients with GI bleed who do not have it as a primary diagnosis.
- Consider stratifying by esophageal bleeds and lower GI bleeds.

Stage 1 Steering Committee Recommendation for Approval of Concept: Y-14; N- 0

STAGE 1 MEMBER & PUBLIC COMMENT (September 26 – October 25, 2012)
Member & Public Comments:
- One comment in support of this concept.

STAGE 1 CSAC REVIEW (November 7-8, 2012)
- Decision: Approved with the requirement that the Steering Committee recommendations must be addressed in the stage 2 submission.

STAGE 1 BOD REVIEW (November 29 – December 11, 2012)
Decision: Ratification of concept approval.

STAGE 2

STAGE 2 PRE-REVIEW MEMBER COMMENT (March 4-18, 2013)
- This measure received two supportive comments, noting that it measures an important health outcome that is both usable and feasible.

STAGE 2 STEERING COMMITTEE CHECKLIST REVIEW (March 2013)
Checklist recommendations satisfactorily addressed: Y-11; N-2; A-1
Move forward to full Stage 2 review: Y-12; N-1; A-1
- The Committee requested that the developer stratify the measure by esophageal bleeds and lower GI bleeds. They also requested the developer consider how only including patients with a primary diagnosis of GI bleed might impact the capture of other patients who have a GI bleed, but not as primary diagnosis. The developer stratified the measure into esophageal varices and all other cases. They explained their mortality measures use the principal diagnosis because using a secondary diagnosis results in a measure with a heterogeneous denominator, which makes it less meaningful to both providers and consumers, and also reduces the specificity of the measure. The Committee agreed this was a satisfactory answer.

STAGE 2 STEERING COMMITTEE REVIEW (April 3, 2013)
2. Scientific Acceptability: The measure meets the Scientific Acceptability criteria (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: H-0; M-13; L-0; I-0 2b. Validity: H-2; M-11; L-0; I-0
- This is a hospital-level measure based on administrative claims.
- In response to a question about validity of the diagnosis codes for GI bleeding, the developer advised the Committee that “we know that the accuracy of the principal diagnosis is on the order of 95 percent, at least at the level at which we are using it here, which is an aggregation of principal...
# 2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18)

Additionally a specific study comparing claims to chart or registry data showed 88% predictive value for GI hemorrhage in any diagnosis field in the claim.

- The Committee noted that this measure has been thoroughly tested. Reliability of the measure score was tested using signal-to-noise analysis, with reasonable results. The developer explained that the testing looked at how much of the total variation in performance is due to systemic variation across hospitals, and how much is random variation due to some hospitals having very small few cases. With small numbers the sampling variability must be taken into account for a more reliable measure.

- Empiric validity testing of the measure identified several hypotheses as to what the relationship should be between the score and the observations such as high volume will have better outcomes and transfer patients may have poorer outcomes. The results indicated a negative association between the hospital risk-adjusted mortality and the hospital volume and an opposite relationship between mortality and transfers out, which fit with their initial hypothesis.

- The measure is risk adjusted to account for comorbidities and severity, and transfers and excludes patients who transfer out, and stratifies patients who are transferred in (who tend to have worse outcomes than patients who complete all care at the same hospital). The c-statistic is 0.831.

- The only exclusion is the patients who are transferred out to an acute hospital because the outcome is not determined within the hospital where the patient presented.

- In an analysis to determine the ability to identify differences in performance, the information presented noted that “low volume hospitals are more likely to be identified as performing worse than the reference population rate primarily because of the volume/persistence effect. Although more hospitals are likely to be identified as performing worse than performing better, because patients are concentrated in high volume hospitals, about 5.1% of patients are in better performing hospitals, and 8.0% of patients are in worse performing hospitals.”

### 3. Feasibility: H-10; M-2; L-0; I-0
- The data source is claims data. The outcome of death is unlikely to be miscoded.

### 4. Use & Usability: H-11; M-1; L-0; I-0
- Though this measure is newly submitted to NQF, it has been in use for several years and is publicly reported.
- The submission lists four current uses of the measure for accountability that include a large number of hospitals across the nation.

### 5. Related and Competing Measures
- No related or competing measures noted.

**Stage 2 Steering Committee Recommendation for Endorsement:** Y-12; N-0

**Public & Member Comment**

**Comments received:**
- This measure received comments from six organizations or individuals. Four of these comments, those from consumers and purchasers, were supportive, noting that this is an outcome measure that focuses on a topic important to consumers, and that it appears to be both usable and feasible.
- One commenter noted the “small numbers problem” which may affect reliability, and suggested adding the secondary diagnosis to capture relevant data and increase reliability.
- The American Hospital Association does not support the measure, raising concerns with the importance and the reliability:
2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18)

- Importance
  - “NQF-endorsed measures should focus on the most meaningful, highest impact areas with an opportunity for improvement. ... we do not believe IQI 18 is up to the task of helping to guide these efforts and provide reliable information to patients and providers. We agree that GI bleeds are common and important health problems that often warrant hospitalization, but are not confident that the data suggest it is important to measure mortality. Rather, the argument for including a GI bleed mortality measure among those that are endorsed by the NQF should convince us that GI Hemorrhage Mortality is more common than it could be if the right care was provided at the right time and in the right manner, and that by illuminating performance through measurement and reporting, we have the opportunity to spur efforts to produce better care and better outcomes.”
  - “The developer notes that among community hospitals in the Healthcare Cost and Utilization Project (HCUP), the risk-adjusted GI hemorrhage mortality rate was 1.94% in 2008. They also note that this rate “has steadily declined over the past 14 years, from 5.78% in 1994....to 3.02% in 2005.” This decline shows significant progress in adopting new diagnostic and treatment modalities that have saved lives. Unfortunately, because the HCUP data have such a significant lag between the provision of the care and the production of the data, we have no idea if progress has hit a plateau or if it continues.”
  - “Further, for the Committee to know if it is important to recommend endorsement of this measure as a national standard, it needs information suggesting that the mortality rate could be lower than it is through the implementation of new strategies or more rigorous attention to implementing existing strategies. The studies and guidelines showing strategies for better diagnosis and management of bleeding that the developer has included are largely written just before or at the time that mortality began to decline precipitously, according to the submission. The developer does not offer compelling evidence that further improvement is likely to ensue from the collection and reporting of these IQI data. The measure developer fails to even address the question of how the use of a measure whose data are so out of date by the time numbers are produced is capable of informing the public or guiding improvement efforts. This critical question of how can we steer a clear path forward toward improved care and outcomes for patients by looking in the rearview mirror is the most essential question to be answered about this and all of the HCUP IQI / PSI measures, and the one that is simply unaddressed in this application.”
  - We believe hospitals should continue to take steps to minimize the risk of harm to patients with GI bleeding. An ongoing focus on interventions that more quickly identify and provide appropriate care to hospitalized patients with GI hemorrhages should result in a continued decline in mortality rates. Thus, an NQF-endorsed measure in this area does not appear to be warranted at this time.

- Measure reliability
  - While the developer presents reliability testing data in their submission, they do not provide final risk-adjusted performance scores. They also do not provide a recommendation on a minimum number of cases needed to reliably report the measure and compare results across multiple hospitals. We believe such information should inform the committee’s determination of whether a measure is suitable for NQF endorsement, especially given that NQF-endorsed measures often become publicly
Available evidence suggests that IQI 18’s reliability in a public reporting application is poor. In 2012, Mathematica conducted a study on behalf of CMS assessing the reliability of claims-based measures used in several CMS programs, including IQI 18. (Reference A) The CMS-commissioned study defines reliability of outcomes measures as “…the extent to which variation in the measure is due to variation in quality of care rather than random variation due to the sample of cases observed.”

To determine the reliability of IQI 18, the CMS-commissioned study uses a “reliability weight” in the AHRQ measure calculation software. This weight is equal to the ratio of the variance in scores between hospitals to the total variance divided by the number of observations. In this case, “total variance” is the sum of the variance in scores between different hospitals and the variance within a hospital’s score.

The study defines the “lower limit of moderate reliability” as $R=0.4$. The study shows that IQI 18 has a median reliability of $R=0.12$ using the same amount of data (12 months) as the measure submission. Even with 24 months of data, reliability improves only to $R=0.22$. With 24 months data, only 25% of hospitals would have a case size large enough to meet $R=0.4$. A measure that fails to meet even the lower limit of moderate reliability when applied in a public reporting program should not receive NQF endorsement.

Developer response:

- We appreciate your concerns regarding reliability of the measure and want to be sure it is clear how we assess the psychometrics of a measure within the AHRQ QIs.
- The reliability of a measure is actually an attribute of the measure when applied to a particular population. What is meant by “the reliability of a measure” is the average reliability across a set of hospitals for a particular population. The particular population in the CMS-commissioned study was Medicare fee-for-service patients only, which is only a portion (indeed, a minority at many hospitals) of the total denominator eligible population. It is not surprising therefore that applying IQI 18 to a smaller population of patients results in risk-adjusted rates with less reliability. The results in our submission reported an average reliability across 4,000 community hospitals and an all-payer (including uninsured) population of $R=0.47$, which exceeds the threshold proposed by the commenter. In addition, the average reliability alone does not determine the value of a measure for purposes of public reporting. Rather, we use the hospital level reliability as a “shrinkage weight” to calculate each organization’s performance score. The usefulness of this reliability-adjusted performance score for purposes of public reporting is discussed below. The shrinkage approach adopted by both AHRQ and CMS in its risk-adjusted outcome measures obviates the need for a minimum volume threshold by "shrinking" performance scores for small hospitals toward the overall mean value.
- Health care providers should, and often do, have internal mechanisms for tracking outcomes on a nearly real-time basis, especially with current availability of electronic health information systems. However, public reporting and other accountability applications require a prior time period over which experience can be accumulated and compared across providers, with adequate reliability. “Looking in the rearview mirror,” as the commenter describes it, allows stakeholders outside a provider organization to compare the performance of multiple providers, given available benchmarks, and to make appropriate decisions based on this assessment. "Looking in the rearview mirror" may not tell us where we are going in the future, but it does tell
In our original submission to NQF, we reported hospital level regression results that demonstrated that the prior year performance score was more predictive of current performance on the risk-adjusted rate than other hospital attributes (e.g. volume or transfer-out rate) with a coefficient of 0.65 (where a coefficient of 1.00 would be perfect persistence). We are currently in the process of updating the data to 2011, but the coefficient of 0.65 confirms the usefulness of using prior time-period data to inform current decision-making.

Potential opportunities for improvement related to GI hemorrhage mortality were extensively addressed in AHRQ’s Stage 1 submission. Specific opportunities noted at that time included:

- Prompt recognition of gastrointestinal hemorrhage as the cause of a patient’s symptoms, necessitating inpatient admission for further evaluation and treatment.
- Prompt assessment of the severity of the patient’s hemorrhage and the associated risk of mortality, to guide initial decisions about where to admit the patient and how much nursing care to provide.
- Appropriate stabilization of acutely ill patients with prompt but safe administration of fluids, blood products, vaspessors, and other resuscitative maneuvers.
- Appropriate diagnostic and evaluation processes to identify the source of bleeding and to characterize the risk of rebleeding.
- Appropriate monitoring by nurses, physicians, and other health professionals to identify early warning signs of clinical deterioration and to implement “rapid response” as appropriate.
- Appropriate treatment of high-risk bleeding sources with pharmacologic and procedural interventions that have been demonstrated to reduce the risk of re-bleeding and transfusion requirements.
- Appropriate timing of transfer from the intensive care setting to the regular unit setting, with appropriate handoffs to ensure that all important information is transmitted and that the care plan is continued and modified as needed.

In the Stage 1 submission, 16 references were provided to clinical practice guidelines, observational studies, and randomized controlled trials on the topic of GI hemorrhage management and mortality.

Hospitals may download the AHRQ Quality Indicator software and calculate the IQI 18 rate on the hospital’s patient population in real-time (or as soon as an abstract of discharge data are available). The capacity to calculate baseline rates and to evaluate the impact of current interventions is an important component of usability of IQI 18 for purposes of quality improvement. The data suggest that hospitals will find opportunity for improvement (see attached Table 8). Using the reliability adjusted performance scores, our estimate is that 24.7% of IQI 18 events are potentially preventable, if all patients selected hospitals that performed at the benchmark level of performance (defined as the 20th percentile in the probability score distribution).

The recent trend data suggest that performance on IQI 18 may, in fact, have reached a plateau. The 2008 reference population used to estimate measure prevalence in Version 4.4 of the AHRQ QI software had an observed rate of 2.46%. The 2010 reference population used in the recently released Version 4.5 (May, 2013) has an observed rate of 2.41%. However, disparities across hospitals persist, and hospital performance scores are persistent over time (see data above), meaning that past performance is predictive of current performance (and that past performance is in fact more predictive of current performance than other hospital attributes such as case
### 2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18)

volume or overall transfer-out rate). Thus, the data suggest that the performance scores provide useful information to consumers and other stakeholders.

- The denominator for this indicator, as for all of the risk-adjusted mortality indicators submitted by AHRQ and CMS, is defined using the principal diagnosis, which is defined in regulation as the condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care. The reason is that using a secondary diagnosis code results in a measure with a heterogeneous denominator, making the measure less useful for providers (in terms of allocating quality improvement resources) and less meaningful to consumers (in terms of knowing the likelihood of being in the population at risk). As previously noted, adding a denominator inclusion criterion for secondary diagnosis code of GI Hemorrhage would result in an increase in the denominator of 262% (from 458,307 cases to 1,660,884 cases). The denominator would be very heterogeneous, consisting of an additional 2,700 individual diagnosis codes in 538 different MS-DRG codes (with osteoarthritis as the most common). These concerns outweigh the potential benefit of increasing measure reliability in accountability applications, for which the topic of accountability (in this case, care of patients admitted with GI hemorrhage) must be clearly defined.

- The denominator of this indicator does not capture patients in whom GI hemorrhage was just a comorbid condition, and it does not capture patients who were admitted for unrelated reasons and developed stress ulceration during the hospital stay. Conversely, the numerator captures all inpatient deaths occurring among eligible admissions for GI hemorrhage, without regard to the final cause of death. This is a routine definitional practice for short-term mortality measures, due to the uncertainty in identifying causes of death among critically ill patients with multiple related conditions (e.g., GI hemorrhage may lead to hypotension and shock, which may lead to a myocardial infarction or stroke, leading to confusion about the cause of death). Usual practice in the quality measurement field is to link a death after this type of worsening trajectory back to the original cause of admission.

**Committee response:**

- The Committee discussed both the comments and the developers’ responses. They agreed that while the measure will miss some cases that have GI hemorrhage as the secondary code, restricting the measure to the primary diagnosis code allows for a greater degree of confidence in those being counted.
- Committee members acknowledge that miscoding is possible.
- Committee members discussed the small numbers issue and noted that the shrinkage methodology is intended to account for this issue.
- The Committee did not change their recommendation on the measure.

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CSAC Review (July 10, 2013): Y-13; N-1; A-0
Decision: Approved for endorsement

Board Review (August 12, 2013)
Decision: Approved for endorsement
Measure Submission Form | Specifications

**Status:** Maintenance, Original Endorsement: Jan 17, 2011, Time-limited status not yet removed

**Description:** Percentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.

**Numerator Statement:** Patients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report

**Denominator Statement:** All patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy

**Exclusions:** Documentation of medical reason(s) for not recommending at least a 10 year follow-up interval (eg, above average risk patient, inadequate prep)

**Adjustment/Stratification:** No risk adjustment or risk stratification N/A We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

**Level of Analysis:** Clinician: Group/Practice, Clinician: Individual, Clinician: Team

**Type of Measure:** Process

**Data Source:** Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Imaging/Diagnostic Study, Electronic Clinical Data: Registry

**Measure Steward:** American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

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**STAGE 1**

**STAGE 1 PRE-REVIEW MEMBER COMMENTS (August 7-21, 2012)**

- None

**STAGE 1 STEERING COMMITTEE MEETING (August 27-28, 2012)**

1. Importance to Measure and Report:
   1a. High Impact: **H-15; M-0; L-0; I-0**

   **Discussion:** There is general agreement this concept meets the high impact criterion.

1c. Evidence

   **15:** Yes, body of evidence meets guidance for quantity, quality, consistency

   **0:** No, body of evidence does not meet guidance for quantity, quality, consistency

   **0:** No, inadequate information to rate quantity, quality, consistency of body of evidence

   **Discussion:**
   - There is a significant amount of evidence to support this measure focus.
   - There was discussion on whether the 10 year interval specified in this concept is based on evidence or consensus. Most polyps > 1 cm in diameter appear to grow for 5-10 years before becoming colorectal cancer. Usefulness of an interval beyond 10 years has not been studied. Committee members noted that prospective studies have demonstrated that very few patients (< 3%) have advanced adenomas when colonoscopy is repeated 5 years after a normal screening colonoscopy. Evidence in the submission form was not graded, but it is supported in the guidelines.

1b. Performance Gap: **H-15; M-0; L-0; I-0**

   **Discussion:** Based on the data provided for this maintenance measure, the Committee agrees there is still a performance gap and an opportunity for improvement.
### Recommendations to Developer for Stage 2:

- Rather than measuring whether the appropriate interval was recommended, consider specifying the measure, for example, patients aged 60 years or older receiving a screening colonoscopy who are documented to have had their last screening colonoscopy 10 or more years prior. Implementing these changes would make the measure closer to an outcome measure that would be more impactful. The Committee recognized that to implement a prospective outcome measure is difficult based on availability of data.
- Account for patients aged 50 years and older receiving a screening colonoscopy that had a recommendation to repeat colonoscopy in 1 year or less due to poor bowel cleansing.
- Consider adjusting the upper age limit for older patients, including inflammatory bowel disease, and better define "above average risk".
- Clarify in the specifications whether the exceptions are included in the denominator or should be calculated as a separate measure.
- Due to the differences in populations and the measure focus, harmonization between this concept and 0659 will not be needed.

### Stage 1 Steering Committee Recommendation for Approval of Concept: Y-15; N-0

**STAGE 1 MEMBER & PUBLIC COMMENT (September 26 – October 25, 2012)**

**Member & Public Comments:**

- Commenters were concerned that the measure exclusions provide loopholes for providers to manipulate the measure results.
- The lack of information about previous colonoscopies may hide evidence of poor care.
- Pairing this measure with an appropriate outcome measure would make it more meaningful to all stakeholders.

**Committee response:**

- The Committee agreed that manipulation of results through gaming is a concern; however, the specific medical reason for the exclusion must be documented through the use of CPT-II codes. The Committee recommended that the specifications for the exclusions include a specific list of the types of medical reasons that are acceptable for this exclusion when the measures are submitted for the Stage 2 measure evaluation.

**STAGE 1 CSAC REVIEW (November 7-8, 2012)**

- **Decision:** Concept Approved with the requirement that the Steering Committee recommendations must be addressed in the stage 2 submission.

**STAGE 1 BOD REVIEW (November 29 – December 11, 2012)**

- **Decision:** Ratification of concept approval

### Stage 2

#### STAGE 2 PRE-REVIEW MEMBER COMMENT (March 4-18, 2013)

- Several supportive comments were received for this measure, noting that it was both useable and feasible, and would improve the safety and quality of care.
- One commenter did not support the measure without the addition of an upper age limit of 75 years, as recommended in the March 2013 Guidance Statement of the American College of Physicians (ACP).

#### STAGE 2 STEERING COMMITTEE CHECKLIST REVIEW (MARCH 2013)

Checklist recommendations satisfactorily addressed: **Y-12; N-1; A-1**

Move forward to full Stage 2 review: **Y-13; N-0; A-1**
# 0658 Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients

- The Committee’s checklist recommendations included suggesting that the measure be re-specified to be a look-back measure, but the developer thought it would be an undue burden on the referring and performing physician 10 years later. The Committee also requested some clarifications and suggested an adjustment to the upper age limit and the exceptions. The developer will review these recommendations when the measure is due for their internal review, and also clarified that the exceptions are not included in the denominator if there is a valid medical reason. They encourage exception rates to be reported as well, but do not require it.

- During the checklist review, the Committee clarified that the measure looks at whether the colonoscopist knows that the patient’s last normal colonoscopy was 10 years ago (which they agreed was important) but they had actually wanted the developer to add whether the provider recommends a repeat colonoscopy in ten years if the results are normal. The developer does not have the ability to do so at this time, but the Committee agreed the measure should move on to Stage 2.

## STAGE 2 STEERING COMMITTEE REVIEW (April 3 & 8, 2013)

2. **Scientific Acceptability: The measure meets the Scientific Acceptability criteria**

   (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

   2a. Reliability: **H-4; M-7; L-0; I-0**
   2b. Validity: **H-0; M-10; L-1; I-0**

   - The Committee agreed the results of reliability testing of the measure score were straightforward with good results.
   - Specifications for an eMeasure were submitted. The developer did not provide a crosswalk for the codes between the eMeasure and the original measure specification. Committee members pointed out several differences between the specifications, particularly which procedures are included as a “screening colonoscopy” and conditions listed as high risk. The Committee was concerned this would lead to different results from each version of the measure. The developer agreed that the measures should be consistent and will bring back a crosswalk of both specifications for review by the Committee at the post-comment call. Final recommendation of the eMeasure will wait until that review.
   - Validity was tested by a systematic assessment of face validity.
   - In response to the comment from ACP about the lack of an upper age limit, the Committee acknowledged that ACP and the US Preventive Services Task Force do not recommend screening colonoscopy beyond age 75 years (USPSTF Grade C recommendation for ages 76-85 years and D recommendation for >85 years.) However, Committee members noted that the guidelines from the three GI professional societies do not include an upper age limit. The measure is aligned with the guidelines of the professional societies. Some Committee members were concerned about potential harms to elderly patients.

3. **Feasibility: H-0; M-13; L-0; I-0**

   - This measure is reported through data collection for the American Gastroenterological Association (AGA) outcome registry. The committee agreed it is feasible and is currently in use.
0658 Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients

4. Use & Usability: H-0; M-13; L-0; I-0
   • Committee members noted that older specifications have two different calculations, one for reporting on the measure and one for performance. Committee members were concerned that the two calculations would yield very different percentages, leading to confusion. The developer explained this modification was to allow the measure to be implemented in PQRS. NQF staff clarified that the measure being evaluated for endorsement is the percentage of patients aged 50 and older receiving screening colonoscopy with or without biopsy or polypectomy with a recommended follow up of at least ten years as specified above.

5. Related and Competing Measures
   • No related or competing measures noted.

Steering Committee Recommendation for Endorsement: Y-13; N-0
   • After reviewing the crosswalk between the eSpecifications and the original measure coding, the Committee agreed the two versions were aligned. The Committee voted 11-0 to also recommend the eMeasure for endorsement.

Public & Member Comment
Comments received:
   • This measure received six comments; all were supportive. Commenters noted the measure’s usability and feasibility, and applauded the focus on reducing unnecessary care and decreasing costs.
   • Two comments suggested it be linked with 0659 and reported as a paired measure. However, the developer responded this was not possible:
     o Developer response: Although 0658 and 0659 are both intended to reduce unnecessary colonoscopies, there remain differences in populations and the measure focus between the two measures and therefore linking them together would not be feasible.

Committee response: The Committee did not wish to change their recommendation.

CSAC Review (July 10, 2013): Y-13; N-0; A-0
Decision: Approved for endorsement

Board Review (August 12, 2013)
Decision: Approved for endorsement
0659 Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use

Measure Submission Form | Specifications

**Status:** Maintenance, Original Endorsement: Jan 17, 2011 , Time-limited status not yet removed

**Description:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy

**Numerator Statement:** Patients who had an interval of 3 or more years since their last colonoscopy

**Denominator Statement:** All patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp(s) in previous colonoscopy findings

**Exclusions:** Documentation of medical reason(s) for an interval of less than 3 years since the last colonoscopy (e.g., patients with high risk for colon cancer, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas)

Documentation of system reason(s) for an interval of less than 3 years since the last colonoscopy (e.g., unable to locate previous colonoscopy report)

**Adjustment/Stratification:** No risk adjustment or risk stratification N/A We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

**Level of Analysis:** Clinician: Group/Practice, Clinician: Individual, Clinician: Team

**Type of Measure:** Process

**Data Source:** Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Imaging/Diagnostic Study, Electronic Clinical Data: Registry

**Measure Steward:** American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

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**STAGE 1**

**STAGE 1 PRE-REVIEW MEMBER COMMENTS (August 7-21, 2012)**

- None

**STAGE 1 STEERING COMMITTEE MEETING (August 27-28, 2012)**

1. Importance to Measure and Report:

1a. High Impact: H-15; M-0; L-0; I-0

**Discussion:** There is general agreement this measure focus addresses a high impact area as it is one of the most overused procedures.

1c. Evidence

14: Yes, body of evidence meets guidance for quantity, quality, consistency

0: No, body of evidence does not meet guidance for quantity, quality, consistency

1: No, inadequate information to rate quantity, quality, consistency of body of evidence

**Discussion:**
- The Committee discussed the length of screening intervals and the yield of identifying adenomas.
- The Committee reviewed evidence cited in the guidelines that was not specifically provided by the measure developer. Based on this review, the Committee determined that there is high quality of evidence demonstrating that these are appropriate intervals, and that the expected benefits are consistent.
- The interval specified in the measure does not match the recommendations in the
0659 Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use

<table>
<thead>
<tr>
<th>evidence 3+ years versus 5 years</th>
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<tr>
<td><strong>1b. Performance Gap: H-4; M-10; L-0; I-1</strong></td>
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**Discussion:**
- While the PQRS data does not suggest a performance gap, few physicians reported on this measure. However, the Committee did not believe that the submitted data is representative of the likely performance gap. The use of EHRs for this measure could demonstrate a larger performance gap. PQRS also only takes patients 65 years and older, so it is not capturing patients in the commercial population.

**Recommendations to Developer for Stage 2:**
- The developer should expand on the available evidence and on the details of the meta-analysis to better demonstrate the body of evidence available to support this measure focus.
- eMeasure specifications should be submitted in stage 2.
- The interval specified in the measure does not match the recommendations in the evidence 3+ years versus 5 years; consider how these can be aligned to ensure the measure is evidence-based.
- Due to the differences in populations and the measure focus, harmonization between this concept and 0658 will not be needed.

**Stage 1 Steering Committee Recommendation for Approval of Concept: Y-15; N-0**

**STAGE 1 MEMBER & PUBLIC COMMENT (September 26 – October 25, 2012)**

**Member & Public Comments:**
- Commenters were concerned that the measure exclusions provide loopholes for providers to manipulate the measure results.
- The lack of information about previous colonoscopies may hide evidence of poor care.
- Pairing this measure with an appropriate outcome measure would make it more meaningful to all stakeholders.

**Committee response:**
- The Committee agreed that manipulation of results through gaming is a concern; however, the specific medical reason for the exclusion must be documented through the use of CPT-II codes. The Committee recommended that the specifications for the exclusions include a specific list of the types of medical reasons that are acceptable for this exclusion when the measures are submitted for the Stage 2 measure evaluation.

**STAGE 1 CSAC REVIEW (November 7-8, 2012)**
- **Decision:** Concept Approved with the requirement that the Steering Committee recommendations must be addressed in stage 2 submission.

**BOD REVIEW (November 29 – December 11, 2012)**
- **Decision:** Ratification of concept approval.
STAGE 2 PRE-REVIEW MEMBER COMMENT (March 4-18, 2013)

- This measure received one supportive comment and several critical comments.
- Critical comments raised the issue that the exclusions provide a large loophole for providers to manipulate the results, and a lack of information about previous colonoscopies may hide evidence of poor care. The commenters suggested that the exclusions be better defined, and stated that it is unacceptable that a patient would be asked to undergo an unnecessary procedure because the provider is unable to track down their prior medical records.
- One commenter was concerned that the measure could lead to overuse, as not all patients need another screen at a three-year interval. Another commenter suggested that the measure include minimum and maximum interval ranges.

STAGE 2 STEERING COMMITTEE CHECKLIST REVIEW (March 2013)

Checklist recommendations satisfactorily addressed: Y-9; N-4; A-1

Move forward to full Stage 2 review: Y-11; N-2; A-1

- The Committee requested additional evidence to support the measure, eMeasure specifications, and requested that the Committee align the interval specified in the measure with the guideline recommendations. The developer submitted an eMeasure for review in stage 2 but did not expand on the evidence as requested. The developer explained that the interval for the measure (at least three years) was consistent with evidence-based guidelines recommending an interval of 3-5 years.
- The Committee recognized that the availability of data limits the ability of the measure to capture as many inappropriate colonoscopies as they would wish, but agreed that this measure should catch the intermediate-risk patients by excluding those with normal results who would not need follow up for 10 years, and those with cancer or other high-risk conditions that would need earlier screening.

STAGE 2 STEERING COMMITTEE REVIEW (April 8, 2013)

2. Scientific Acceptability: The measure meets the Scientific Acceptability criteria
   (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
   2a. Reliability: H-1; M-12; L-0; I-0  2b. Validity: H-0; M-11; L-2; I-0

- Similar to measure 0658, the Committee identified issues with alignment of the original specifications and the eMeasure specifications. The developer and the Committee agreed the code sets should be harmonized between both versions of the measure.
- Committee members discussed the 3-5 year target and acknowledged that the measure still allows for inappropriate repeat colonoscopy in the 3-5 year interval but will capture inappropriate use prior to 3 years.
- The Committee agreed this measure had been tested in the same manner as the previous measure, 0658.
- Some Committee members questioned whether some of the conditions in the high-risk value set, such as eosinophilic gastroenteritis, are really high-risk for malignancy.

3. Feasibility: H-0; M-12; L-0; I-0

- The Committee again noted the similarity to measure 0658, and had no additional concerns about the feasibility of the original measure.
- Concerns about feasibility of the eMeasure will be discussed when the Committee reviews the crosswalk of the specifications.
Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps

4. Use & Usability: H-0; M-12; L-0; I-0
   - The measure is currently in use in PQRS.

5. Related and Competing Measures
   - No related or competing measures were noted.

Steering Committee Recommendation for Endorsement: Y-11; N-1
   - The Committee noted the measure could be improved but they agreed the measure does help prevent some overuse, particularly for repeat colonoscopies performed in less than three years. The Committee strongly recommends that the developer bring forward a better measure in the future.
   - After reviewing the crosswalk between the eSpecifications and the original measure coding, the Committee agreed the two versions were aligned. The Committee voted 11-0 to also recommend the eMeasure for endorsement.

Public & Member Comment
Comments received:
   - This measure received six comments; only one was supportive.
   - The supportive comment noted the concerns with the measure, but that “we should not let the perfect be the enemy of the good”, as there is wide variability with the follow up recommendations, and that this is a decent interim measure.
   - The unsupportive comments noted that while the measure focus—reducing overuse—is strong, the measure has numerous problems. Commenters noted the concern that the broad exclusions allow for “gaming” and provider manipulations of results, and were very concerned about hiding poor care by not including information from prior colonoscopies. One commenter stated that “With the growth of electronic health records and the mandate for care coordination, it is not acceptable to give a green light to colonoscopy without including information about previous colonoscopies.” Another comment suggested collecting the data for the measure would be burdensome.

Developer response:
   - This measure was submitted for endorsement with electronic clinical/registry data as the intended data source. The measure is currently in use in two different GI-focused registries.
   - Contrary to the commenter’s suggestion that this measure fails to include information about previous colonoscopies, eligibility for the measure is defined by the finding of prior colonic adenomatous polyp(s) in a previous colonoscopy. The identification of pre-cancerous colon polyps on a previous colonoscopy implies a certain level of quality as the primary goal of colon cancer screening is the timely removal of such lesions to prevent colon cancer. The published literature indicates that repeat colonoscopy is often overutilized and is not tied to clinical data on initial colonoscopy. The use of this measure is intended to increase physicians’ adherence to the evidence based guideline and subsequently may reduce unnecessary tests, costs, and patient risk.
   - The use of “medical reason” was not and is not intended to be purposefully vague, but rather stems from current PCPI exception methodology. This method uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure,
Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use

there must be a clear rationale to permit an exception for a medical, patient, or system reason. A non-exhaustive list of examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) (eg, patients with high risk for colon cancer, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas) or system reason(s) for an interval of less than 3 years since the last colonoscopy (eg, unable to locate previous colonoscopy report). Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eSpecifications.

- Since this measure’s review during the 2nd stage of NQF’s process and posting for public comment, we have made a few minor modifications to the language and corresponding value set for one of the examples noted above (ie, patients with high risk for colon cancer). In consultation with expert work group members, we have further clarified the conditions that would signify a patient being at high risk for colon cancer to include 4 categories: Crohn’s disease, ulcerative colitis, rectal/lower GI bleeding, personal or family history of colon cancer. Accordingly, we have revised the description of the medical reason example to read “...[eg, patients with high risk for colon cancer (ie, Crohn’s disease, ulcerative colitis, lower gastrointestinal bleeding, personal or family history of colon cancer)...” and created new value sets that reflect those categories. This will hopefully correct the misperception that the list of exclusions included are so broad as to enable exception reporting.

- This issue of exception reporting --the potential for physicians to inappropriately exclude patients to enhance their performance statistics- has been raised by these comments. Research has indicated that levels of exception reporting occur infrequently and are generally valid. (Doran et al., 2008), (Kmetik et al., 2011) Furthermore, exception reporting has been found to have substantial benefits: "it is precise, it increases acceptance of [pay for performance] programs by physicians, and it ameliorates perverse incentives to refuse care to "difficult" patients." (Doran et al., 2008) A recent study conducted by the PCPI in 47,075 outpatients with coronary artery disease seen during 2006 and 2007 in 5 medical practices that used electronic health records, reported that the overall exception percentage for all 4 measures studied was 3.5%. The vast majority (92.6%) of those exceptions were confirmed during manual review. (Kmetik et al., 2011)

- Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients’ medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician’s exceptions data to identify practice patterns and opportunities for quality improvement.

References:

Committee response: The Committee acknowledged the comments, but agreed they had already discussed these issues and they did not wish to “let the perfect be the enemy of the good” as the commenter stated. They did not change their recommendation for the measure.
<table>
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<tr>
<th><strong>0659 Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps- Avoidance of Inappropriate Use</strong></th>
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<tr>
<td><strong>CSAC Review (July 10, 2013): Y-7; N-7; A-0</strong></td>
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<tr>
<td><strong>Decision:</strong> Tie: Not recommended for endorsement</td>
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<td><strong>Rationale:</strong> The CSAC noted the lack of consensus for this measure in the member voting results, particularly from the consumers and purchasers. Commenters had noted that although the intent of the measure – reducing overuse – is strong, there were several significant technical issues such the broad exclusions that may allow for provider manipulation of results, and the possibility of hiding poor care by not including information from prior colonoscopies. CSAC members noted that the tie vote would place the final decision with the Board of Directors.</td>
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| **Board Review (September 20, 2013)** |
| **Decision:** Approved for Endorsement |
| **Rationale:** Following the CSAC decision, the developer and related specialty societies submitted a letter to the Board requesting their consideration of the measure. Given the general support for the measure during the endorsement process, the NQF Board supported continued endorsement of the measure. However, the endorsement decision was accompanied by a recommendation that efforts to improve the measure continue in an expeditious manner. The NQF Board also emphasized the need to address the use of broad exceptions and exclusions in measures. |
GU Measures Not Recommended for Endorsement

<table>
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<th>Measure Submission Form</th>
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<tr>
<td><strong>0098 Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older</strong></td>
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</table>

**Measure Submission Form**

**Status:** Maintenance, Original Endorsement: May 01, 2007

**Description:** 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.

**Numerator Statement:** This measure has three rates. 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.

**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.

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

**Adjustment/Stratification:** No risk adjustment or risk stratification N/A N/A

**Level of Analysis:** Clinician: Group/Practice, Clinician: Individual, Clinician: Team

**Type of Measure:** Process

**Data Source:** Paper Medical Records

**Measure Steward:** National Committee for Quality Assurance

**STAGE 1**

**STAGE 1 PRE-REVIEW MEMBER COMMENTS (August 7-21, 2012)**

- None

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**NATIONAL QUALITY FORUM**
### 0098 Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

#### STAGE 1 STEERING COMMITTEE MEETING (August 27-28, 2012)

1. Importance to Measure and Report:

   1a. High Impact: **H-15; M-0; L-0; I-0**

   **Discussion:** Similar impact as discussed in #0030. General agreement that incontinence is a high impact area.

   1c. Evidence

   - **13:** Yes, body of evidence meets guidance for quantity, quality, consistency
   - **0:** No, body of evidence does not meet guidance for quantity, quality, consistency
   - **2:** No, inadequate information to rate quantity, quality, consistency of body of evidence

   **Discussion:** The Committee was concerned that the evidence presented by the developer indicated that incontinence should be treated but did not provide evidence that documentation in the medical record improved incontinence. Some expressed concern about the link between this process measure and patient outcomes. However, the Committee ultimately agreed this measure meets the evidence criteria since existing literature does link discussion with the provider about urinary incontinence to improved outcomes.

   1b. Performance Gap: **H-7; M-8; L-0; I-0**

   **Discussion:** While PQRS data does not show a performance gap, the Committee agreed that there is overall low performance and low reporting based on the data submitted.

#### Recommendations to Developer for Stage 2:

- eMeasure specifications are strongly recommended.
- Consider the addition of an option for patient choice of no treatment.
- Expand age group to include commercial and menopausal population.

**Stage 1 Steering Committee Recommendation for Approval of Concept: Y-14; N-1**

#### STAGE 1 MEMBER & PUBLIC COMMENT (September 26 – October 25, 2012)

**Member & Public Comments:**

- Commenters were concerned that this measure was not closely linked to an outcome and would not be meaningful to all stakeholders.
- Suggestions were also made to pair the measure with an outcome measure or create a composite measure that accounts for urinary continence assessment, characterization, and plan of care.
- Commenters also desired a more inclusive age range.

**Committee response:**

- The Committee agrees that measures closely linked to an outcome will provide the most meaningful information to stakeholders. Additionally, the Committee recommended that the measure age range be expanded to include the commercial and menopausal population.

#### STAGE 1 CSAC REVIEW (November 7-8, 2012)

- **Decision:** Concept Approved, with the requirement that the Steering Committee recommendations must be addressed in the stage 2 submission.
# 0098 Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

## STAGE 1 BOD REVIEW (November 29 – December 11, 2012)
- **Decision:** Concept Ratified

## STAGE 2

### STAGE 2 PRE-REVIEW MEMBER COMMENTS (March 4-18, 2013)
- Commenters stated that this measure is a standard of care, and a “check-the-box measure”, and were not supportive.
- Other concerns were raised around the threshold of “any urinary incontinence,” noting that it was too strict, especially in the population of women 65 years and older.
- While commenters noted the clinical importance of this topic, they raised several concerns about the feasibility, stating that it would require significant manual chart review or supplemental codes and suggested an eMeasure may be more feasible.
- Other commenters were concerned about the one measure having three rates, noting that this could be confusing, and that it is not clear how the three rates would be used together to assess provider performance.

### STAGE 2 STEERING COMMITTEE CHECKLIST REVIEW (March 2013):
- Checklist recommendations satisfactorily addressed: **Y-12; N-1; A-1**
- Move forward to full Stage 2 review: **Y-13; N-0; A-1**
  - The Committee had requested the developer add an option for patient choice of no treatment as a response. The developer explained they were unable to make that change in the limited time between the two stages, and also that they did not want to include patient refusal of treatment as a separate option because that can lead to “gaming” of measure reporting; they feel that the option of reassessing at a follow up visit would cover this issue. A Committee member suggested that not doing so meant the measure is not patient-centered and would not change outcomes, and that a patient choosing to opt-out is different than a reassessment and follow up; the developer explained this is consistent with other measures where patient refusal can be abused.
  - The developer did not make additional checklist changes (adding eMeasure specifications and expanding the age group) due to funding and resource constraints. Committee members agreed this was a reasonable response and not a “fatal flaw” to keep the measure from moving forward.

### STAGE 2 STEERING COMMITTEE REVIEW (April 3, 2013)
### 098 Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

#### 2. Scientific Acceptability: The measure meets the Scientific Acceptability criteria

*(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)*

<table>
<thead>
<tr>
<th>2a. Reliability:</th>
<th>H-0; M-12; L-1; I-0</th>
</tr>
</thead>
<tbody>
<tr>
<td>2b. Validity:</td>
<td>H-0; M-11; L-2; I-0</td>
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</tbody>
</table>

- The measure has three different indicators, but it is not a composite measure. Three separate ratings are reported.
- The measure is based on chart review.
- The Committee questioned the definition of assessment, i.e., what are the abstractors looking for? The developer responded that the assessment is just documentation of “yes or no” documented in response to “Have you had any urine leakage?” The characterization rate looks for more detail of the type of incontinence and more of the formal workup of the urinary incontinence.
- The measure was tested for reliability at the data element level (numerator). All three rates had high Kappa scores.
- A systematic assessment of face validity was presented. The developer noted that they also assessed critical data elements of validity during the assessment of reliability.
- The analysis of exclusions indicated a very small number of patients are excluded.
- The measure is not stratified for disparities.

#### 3. Feasibility: H-3; M-10; L-0; I-0

- The required data elements for this measure are routinely generated and used during care delivery and the measure is currently being used in PQRS.
- However, the Committee noted some concern with capture of the data element(s) needed for the numerator.

#### 4. Use & Usability: H-2; M-8; L-3; I-0

- This measure is used in at least one accountability application – in PQRS.
- Committee members noted that the performance data presented indicates little discrimination above the 10-25th percentile.
- The Committee agreed that there is not a lot of room for improvement among the providers currently reporting on this measure; the Committee agreed with the developers that there is likely to be more room for improvement once the measure is in wider use in 2015.

#### 5. Related and Competing Measures

- No related or competing measures noted.

**Stage 2 Steering Committee Recommendation for Endorsement: Y-13; N-0**

**Public & Member Comment**

**Comments received:**

- Six comments were received on this measure. Of those, five were not in support of the measure, noting that it is a “check the box” measure that is a “standard of care process.”
- Commenters noted the limited usability (only in women over 65) and the complexity of the multiple numerators and denominators as additional reasons not to support the measure.
- The measure received one supportive comment from the American Urological Association that the measure was rigorously developed, focuses on an area of importance in an elderly population, and is reliable and valid.
0098 Urinary Incontinence: Assessment, Characterization, and Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

Developer response:
- We agree with the commenter that this measure currently shows "topped out" performance. However, we believe these rates are biased and do not reflect the majority of providers. The PQRS program is currently designed to allow providers to choose which measures to report on and rewards for satisfactory reporting. Fewer than 1% of providers currently choose to report on this measure and it is likely this self-selecting sample does not reflect the broader provider population. In fact, results from other quality measures such as 0030, suggest rates of screening and plan of care for urinary incontinence are much lower (59% and 35% respectively). These rates suggest that when the PQRS program is more widely spread this measure will identify a significant quality gap in the provision of "standard" care.
- We agree with the commenter that this measures is not usable for the commercial population. This measure was designed as part of a measure set focused solely on the geriatric population. Although Urinary Incontinence is prevalent among a younger population, it is more prevalent among older women. We will examine how the age range on this measure can be expanded to include a younger population of women, however this change was not feasible in the timeframe of measure review.

Committee response:
- The Committee agreed that this measure does have the potential to be a “check-the-box” measure, but thought that especially for the assessment portion, further testing and evaluation of the 3 components in a broader population will be important.
- While a urinary incontinence measure does apply to a broader population, older women do have higher rates of incontinence and expanded measures could be developed in the future.
- The Committee agrees with the comment by the developer that the current reported rates from users of the PQRS system may represent a self-selected group and show high rates of meeting the current standard of care. When implemented in a broader setting, this measure may indicate a gap in quality care.
- Committee members reviewed the comments and the developer response and did not wish to change their recommendation.

CSAC Review (July 10, 2013): Y-4; N-7; A-0
Decision: Not recommended for endorsement

Rationale: The CSAC was concerned that this measure is a “borderline useful measure” that does not improve outcomes or the quality of care. During the comment period consumers and purchasers indicated a lack of support for the measure because it is a “check the box measure” that is a “standard of care.” The CSAC was concerned with the lack of true consensus shown in this measure and the strong lack of support from the consumers and purchasers. Both the Steering Committee and the commenters indicated a desire for a better measure in this important topic area.
**GI Measures Not Recommended for Endorsement**

<table>
<thead>
<tr>
<th>Measure Submission Form</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Status:</strong> Maintenance, Original Endorsement: Dec 04, 2009</td>
</tr>
<tr>
<td><strong>Description:</strong> The percentage of patients with in the overall and high risk population with gastroesophageal reflux disease (GERD) with alarm symptoms who have had an upper gastrointestinal study. (2 separate Denominators)</td>
</tr>
<tr>
<td><strong>Numerator Statement:</strong> Patients who have had at least least 1 esophageal procedure, upper GI study (Upper GI radiologic exam with high density barium, with or without delayed films, esophageal or gastric motility study, gastric emptying study, gastric analysis test, upper GI endoscopy, or upper GI series), or gastrectomy or evidence of at least 1 gastric or esophageal cancer diagnosis in the past 12 months. <em>Note-cancer diagnosis implies diagnostic testing was done, and therefore completes numerator</em></td>
</tr>
<tr>
<td><strong>Denominator Statement:</strong> Denominator 1:Patients with a diagnosis of chronic GERD with alarm symptoms (e.g., dysphagia, iron deficiency anemia, weight loss) in the past 12 months. Denominator 2:High risk patients (i.e., obese, male, or age &gt; 50) with a diagnosis of GERD with alarm symptoms (i.e., dysphagia or weight loss) in the past 12 months</td>
</tr>
<tr>
<td><strong>Exclusions:</strong> Specific Exclusions:</td>
</tr>
<tr>
<td>1. Patients with esophageal varices.</td>
</tr>
<tr>
<td>2. Patients with gastric restrictive procedures.</td>
</tr>
<tr>
<td>3. Patients with weight loss surgery.</td>
</tr>
<tr>
<td>4. 1. Patients with a metastatic malignancy, General exclusions:</td>
</tr>
<tr>
<td>1. Evidence of metastatic disease or active treatment of malignancy (chemotherapy or radiation therapy) in the last 6 months</td>
</tr>
<tr>
<td>2. Patients who have been in a skilled nursing facility in the last 3 months</td>
</tr>
<tr>
<td>3. Patients who are terminally ill or in Hospice</td>
</tr>
<tr>
<td><strong>Adjustment/Stratification:</strong> No risk adjustment or risk stratification No risk adjustment or risk stratification This measure is not stratified.</td>
</tr>
<tr>
<td><strong>Level of Analysis:</strong> Population : National</td>
</tr>
<tr>
<td><strong>Type of Measure:</strong> Process</td>
</tr>
<tr>
<td><strong>Data Source:</strong> Other</td>
</tr>
<tr>
<td><strong>Measure Steward:</strong> ActiveHealth Management</td>
</tr>
</tbody>
</table>

**STAGE 1**

**STAGE 1 PRE-REVIEW MEMBER COMMENTS (August 7-21, 2012)**

*America’s Health Insurance Plans* - This measure cannot be easily collected through administrative data and will require burdensome chart abstraction; however, it is a good registry measure. We are also concerned that as written, the “sensitivity” of the measure appears to be problematic (issues with identifying appropriate use) and could therefore falsely suggest overuse.
## 0622 GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms

### STAGE 1 STEERING COMMITTEE MEETING (August 27-28, 2012)

#### 1. Importance to Measure and Report:

1a. **High Impact:** H-2; M-7; L-5; I-1

**Discussion:*
- The Committee discussed the seemingly small number of patients that would be captured in this measure given the measure focus. Based on the data provided, it appears to be a small population of people who actually have alarm symptoms that would be impacted by this measure; patients with GERD and with alarm symptoms are a very small population. Given the severity and implications for treatment of the small population represented by the measure, this measure focus could be impactful. It is potentially a vulnerable population. The Committee also expressed some concerns about physician documentation and capturing dysphagia and weight loss with administrative claims data. It is very difficult to identify these patients.
- These questions around definitions and issues of validity and reliability will become important in stage 2.

1c. **Evidence**

- **4:** Yes, body of evidence meets guidance for quantity, quality, consistency
- **1:** No, body of evidence does not meet guidance for quantity, quality, consistency
- **10:** No, inadequate information to rate quantity, quality, consistency of body of evidence

**Discussion:**
- The sensitivity of the practice to identify cancers in patients with alarm symptom is about 67%, which is equivalent to other cancer screening tests like PSA and mammography.
- *There is general agreement that the quantity, quality, and consistency of the body of evidence meet the NQF guidance: Y-10; N-5*

**Discussion:** The Committee agreed there is significantly more evidence available on this measure focus than was presented in the submission. While the Committee agreed the evidence submitted was insufficient, there was agreement that they would exercise the evidence exception to continue to review the concept, since the quality, quantity, and consistency of the evidence would support this measure focus if provided.

#### 1b. Performance Gap: H-0; M-2; L-13; I-0

**Discussion:**
- Overutilization of esophagogastroduodenoscopy (EGD) is very common so there was some concern on whether there is actually underutilization for this population.
- From the specialist standpoint there is likely not a major performance gap, but for Primary Care Providers (PCP) there may be a larger performance gap.
- This maintenance measure is currently tested only at the population level and the Committee raised concerns on the usability of this measure at that level. This will be discussed in Stage 2.
Recommendations to Developer for Stage 2:

- This measure should include chronic GERD patients.
- The exclusion should be clarified as previous malignancy.
- Barrett’s esophagus should be included.
- The measure should be expanded to include patients under 18 as well; pediatric populations should be included as the same evidence applies.
- Additional evidence should be provided for evidence criterion.
- Additional information on performance gap is needed.
- Define/specify the testing/procedures for the numerator more clearly.
- Consider specifying the numerator in a patient population in which it would have more broadly impact (e.g., obese and/or male patients)

Stage 1 Steering Committee Recommendation for Approval of Concept: Y-14; N-1

Discussion: The concept has been recommended for approval, but will be considered for reserve status in Stage 2 since there was a limited performance gap.

STAGE 1 MEMBER & PUBLIC COMMENT (September 26 – October 25, 2012)

Member & Public Comments:

- Commenters were concerned that measure is not closely link to outcomes and that it is an example of a “check the box” measure.

Committee response:

- Given the severity and implications for treatment, the Committee agreed that this is an important process measure for this population.

CSAC REVIEW (November 7-8, 2012)

- Decision: Approved with the requirement that the Steering Committee recommendations must be addressed in the stage 2 submission.

BOD REVIEW (November 29 – December 11, 2012)

- Decision: Ratification of the concept approval.

STAGE 2

STAGE 2 PRE-REVIEW MEMBER COMMENTS

- This measure received several critical comments. Commenters noted that it is a process measure that is a standard of care, and would not improve the quality of care. They also noted the lack of a performance gap and noted that it would cause a substantial measurement burden.
- Other comments pointed out that the measure specifications do not align with the latest clinical guidelines, and stated that this measure should not be used without pairing with an overuse measure.
- One comment suggested using just the second denominator to simplify the measure, to have providers focus their efforts on high-risk patient populations. Once they have met the goals for this subpopulation, the measure could then be expanded.

STAGE 2 STEERING COMMITTEE CHECKLIST REVIEW (March 2013)

Checklist recommendations satisfactorily addressed: 11 yes, 0 no, 3 abstentions

Move forward to stage 2: 12 yes, 0 no, 2 abstentions

- The Committee suggested several changes to the measure including changes and clarifications to the numerator and denominator, the exclusions, and the population included; additional evidence and information on the performance gap; and additional testing information.
- The developer included chronic GERD patients in the denominator, expanded the age band, added Barrett’s esophagus to the denominator, and clarified the exclusion of metastatic
### 0622 GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms

malignancy as requested by the Committee. They also added additional evidence, gap, and testing information.

- The developer explained they had not been able to test the revised measure due to the limited time available and that the testing results in the form reflect the original measure.
- The Committee agreed that the responses were adequate and that other questions would be addressed in Stage 2 review.

### STAGE 2 STEERING COMMITTEE REVIEW (April 16, 2013)

| 2. Scientific Acceptability: The measure does not meet the Scientific Acceptability criteria |
| (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity) |

#### 2a. Reliability: H-0; M-0; L-7; I-1

- The developer is currently testing the revised measure that includes two denominators. They plan to test the measure with the same methodology as their other measures.
- Similar to the other ActiveHealth measure (0635), this measure uses a proprietary analytic engine. The developers confirmed that the measure is reproducible by others, and that the specifications, code sets, and algorithm are publically available.
- Committee members noted that in the original measure, only 392 patients out of 2.5 million population qualified for the original denominator. The developer estimated the new denominators will each be about half that, approximately 150 people out of the population of 2.5 million.
- A Committee member pointed out that the guidelines cited by this measure are very specific for use of endoscopy in patients with chronic GERD, but the measure includes other tests.
- The Committee noted that while the measure developer is willing to revise the existing measure to answer the Committee’s requests and recommendations, they have not yet been able to do so, nor has that measure been tested. The specifications in front of them are not precisely specified and tested. The Committee decided the measure as it stands did not pass either the reliability or the validity criteria, and encourages to developers to submit a revised measure in the future.

### Public & Member Comment

**Comments received:**

- One commenter state that “patients with GERD and with alarm symptoms are a very small population” and that “The sensitivity of the practice to identify cancers in patients with alarm symptom is about 67%.” I agree with “While the Committee agreed the evidence submitted was insufficient, there was agreement that they would exercise the evidence exception to continue to review the concept, since the quality, quantity, and consistency of the evidence would support this measure focus if provided.” Therefore, I think that this should be further investigated and addressed as soon as possible.

**Committee response:**

- The Committee agrees this measure covers an important aspect of quality of care, and the measure did pass the importance criteria (using the evidence exception). However, the measure as submitted to the Committee for review was not tested, and the specifications were not precisely specified. The measure as submitted did not pass either the reliability or validity criteria, so it did not meet the must-pass criterion of Scientific Acceptability. The Committee encouraged the developers to revise and test the measure and submit it for review in the future.
0635 Chronic Liver Disease - Hepatitis A Vaccination

**Measure Submission Form | Specifications**

**Status:** Maintenance, Original Endorsement: Dec 04, 2009

**Description:** The percentage of adult patients with chronic liver disease who have received a hepatitis A vaccine

**Numerator Statement:** Patients with chronic liver disease who have received a hepatitis A vaccine.

**Denominator Statement:** All patients, ages 18 and older, diagnosed with chronic liver disease

**Exclusions:**
- Specific Exclusions: 1. Patients with a previous history of viral hepatitis 2. Patients who report an allergy to Hepatitis A vaccine
- General exclusions: 1. Evidence of metastatic disease or active treatment of malignancy (chemotherapy or radiation therapy) in the last 6 months; 2. Patients who have been in a skilled nursing facility in the last 3 months (this exclusion is included to avoid holding physicians who care for patients during a transitional period, e.g. temporary SNF placement, for their ongoing care; hence, the time limitation of 3 months).

**Adjustment/Stratification:** No risk adjustment or risk stratification  No risk adjustment necessary None

**Level of Analysis:** Population : National, Health Plan

**Type of Measure:** Process

**Data Source:** Other

**Measure Steward:** ActiveHealth Management

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<tr>
<td><strong>STAGE 1 MEMBER COMMENTS (August 7-21, 2012)</strong></td>
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<tr>
<td>• <em>America’s Health Insurance Plans</em> - While this measure can be calculated using administrative data, there may be challenges with assessing the numerator at the health plan level in instances where patients have received the vaccination but who have also changed health plans.</td>
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**STEERING COMMITTEE MEETING (August 27-28, 2012)**
Chronic Liver Disease - Hepatitis A Vaccination

1. Importance to Measure and Report:

1a. High Impact: H-7; M-8; L-0; I-0

Discussion: The developer cited literature that shows that chronic liver disease is quite prevalent and common, and the patients with chronic liver disease who develop hepatitis A often have higher rates of fulminant hepatitis and mortality.

1c. Evidence

13: Yes, body of evidence meets guidance for quantity, quality, consistency
1: No, body of evidence does not meet guidance for quantity, quality, consistency
1: No, inadequate information to rate quantity, quality, consistency of body of evidence

Discussion: The Committee agreed that the three guidelines cited by the developer were based on a moderate quality, quantity and high consistency level of evidence. The evidence was derived from observational studies, time series studies and expert opinion supporting the guidelines.

1b. Performance Gap: H-11; M-3; L-1; I-0

Discussion: Based on the data provided for this maintenance measure from the ActiveHealth database there is a 64% performance gap. The Committee agrees this is a significant performance gap and an opportunity for improvement.

STAGE 1 STEERING COMMITTEE MEETING (August 27-28, 2012)

Recommendations to Developer for Stage 2:

- The numerator is inconsistent with title of measure; consider changing the title of the measure to more closely align with the measure focus.
- There could be a potential validity issue in stage 2 with the assumption this concept makes that if a person was tested, they were positive and received the vaccination. Consider how to address this issue.
- Understanding there are differences in data sources, harmonize with #0399 under review in the NQF Infectious Disease project
  - Developer Response: Developers acknowledged and agreed to the suggested changes.

Stage 1 Steering Committee Recommendation for Approval of Concept: Y-15; N-0

STAGE 1 MEMBER & PUBLIC COMMENT (September 26 – October 25, 2012)

Member & Public Comments:
- No comments received

STAGE 1 CSAC REVIEW (November 7-8, 2012)

- Decision: Concept Approved with the requirement that the Steering Committee recommendations must be addressed in the stage 2 submission.

BOD REVIEW (November 29 – December 11, 2012)

- Decision: Concept approval ratified

STAGE 2

STAGE 2 PRE-REVIEW MEMBER COMMENTS (March 4-18, 2013)

- Two commenters stated that this is a standard of care process measure, and did not think it was useful to improve health care and outcomes.

STAGE 2 CHECKLIST REVIEW (March, 2013):

Checklist recommendations satisfactorily addressed: Y-11; N-1; A-2

Move forward to full Stage 2 review: Y-12; N-0; A-2
0635 Chronic Liver Disease - Hepatitis A Vaccination

- The Committee requested that the developer work with AMA PCPI on harmonization for a related measure. The two developers have indicated they are working towards this.
- The Committee requested the numerator be changed to no longer allow testing for antibodies to be sufficient. The developer made this change. However, one Committee member suggested they would also need to be removed from the denominator if the results were not available, in order to prevent doctors from being inappropriately penalized.
- The revised measure specifications are not yet tested.

STAGE 2 STEERING COMMITTEE REVIEW (April 8, 2013)

2. Scientific Acceptability: The measure meets the Scientific Acceptability criteria
   (2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
   2a. Reliability: H-0; M-11; L-0 I-0  2b. Validity: H-0; M-8; L-3; I-0

- The developer clarified that that chronic liver disease is defined by the diagnosis codes from claims or health information exchange (HIE) in the past year, and that non-alcoholic fatty liver disease is included as a chronic liver disease. The included codes are provided in a spreadsheet that accompanied the measure submission.
- While the Committee agreed that there are multiple guidelines recommending hepatitis A vaccine in people with chronic liver disease, they were concerned that if the measure is also recommending that people with fatty liver disease receive the vaccination, this would widen the population. Committee members were also concerned that this measure would lead to overuse of the hepatitis A vaccination because while there are no serious adverse effects from the vaccine, the vaccine is less likely to be effective in advanced liver disease. Committee members agreed that despite these concerns the measure was still appropriate.

3. Feasibility: H-2; M-6; L-3; I-0

- The measure is already in use and the submission form included data from this use. The Committee noted the results of this measure are consistent with similar data reported by the Veterans’ Administration.
- The measure uses a proprietary analytic engine, so the Committee questioned whether other organizations would be able to implement it. The developers confirmed that the measure is reproducible by others, and that the specifications and code sets are publically available. Other users may alter the measure, but ActiveHealth reviews all modifications, generally based on data availability, to make sure the measure is aligned with the original intent, and the modified measure would not be considered an NQF-endorsed measure.

4. Use & Usability: H-1; M-8; L-2; I-0

- ActiveHealth reports that they are planning to report yearly, national results on their website.
- The Committee was unsure how useful this measure is as a “national population” measure.
- The Committee noted a potential for over-vaccination of non-susceptible individuals.

5. Related and Competing Measures

- There is one related measure, 0399: Hepatitis C: Hepatitis A Vaccination (AMA-PCPI); the developers are working on harmonization. (See Appendix D)

Stage 2 Steering Committee Recommendation for Endorsement: Y-10; N-1

Public & Member Comment
Comments received:
- This measure received seven comments. Four did not support the measure, noting that it is a “strict process measure” that reflects a “standard of care”. These commenters noted that while
**0635 Chronic Liver Disease - Hepatitis A Vaccination**

it may be feasible, it would not improve care or outcomes. Commenters were also concerned with the usability, noting that it is only submitted as a “national population level” measure and noted the Committee’s uncertainty as to what entity would be accountable with this measure.

- Another comment supported the concept but noted that this measure would be subject to data issues due to incomplete health-plan claim records. Another negative comment also raised the issue of incomplete records for patients who change health plans, as well as noting this measure is subject to a small numbers problem, raising reliability issues. An additional comment supported the concept of hepatitis A vaccination for patients with chronic liver disease, but did not comment on the measure under consideration.

**Developer response:**

- As we move towards a more electronic-data-based healthcare world, the aforementioned gap of data collection should start to diminish. Our algorithms use data from health information exchanges, provider feedback, as well as patient-reported data to help fill this gap.
- The previous version of this measure included Hepatitis A immunity testing in the numerator. This was removed at the request of the NQF due to coding limitations. Because codified HAV antibody results are reported as reactive or nonreactive, as opposed to a numeric value, use of HAV Ab LOINC codes are not possible at this time in the measure algorithm. It would be possible to modify the measure to use feedback or self-reported data indicating immunity to hepatitis A in either the denominator exclusions or as a part of the numerator. However, because such modifications would require retesting of the measure and data elements, further modifications are not possible at this time. AHM remains open to reasonable change requests, given adequate time and notice, during future endorsement maintenance or update cycles.

**Committee response:**

- The Committee discussed the level of analysis and suggested that the measure is used by health plans and the testing data was presented for health plans. The developer agreed to add health plan as a level of analysis.
- The Committee also clarified that this measure is not an eMeasure in HQMF format.
- When asked, the developer was not able to provide any data on the frequency of positive immunity.
- The Committee acknowledges the issues raised in the comments but did not change their recommendation of the measure.

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**CSAC Review (July 10, 2013): Y-0; N-12; A-1**

**Decision: Not recommended for endorsement**

**Rationale:** The CSAC was concerned about both the lack of consensus on this measure and the lack of consumer and purchaser support. Commenters had indicated a lack of support for the measure because of the potential for vaccine overuse because patients with known immunity are not excluded from the measure as well as data issues due to incomplete records of past vaccinations. The CSAC suggested this measure would be better as a part of a composite measure of care for patients with liver disease rather than as a single vaccination measure. CSAC members indicated the data was not “compelling” that this type of measure would improve care.
**Approved Concepts That Did Not Pass Stage 2 Checklist Review**

This measure did not pass the checklist review to enter into Stage 2 review, but remains an approved concept.

<table>
<thead>
<tr>
<th>C 2056 Colonoscopy Quality Index</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measure Submission Form</strong></td>
</tr>
<tr>
<td><strong>Status:</strong> New Submission</td>
</tr>
<tr>
<td><strong>Description:</strong> This is a composite measure of the percentage of patients undergoing screening or surveillance colonoscopy who meet all individual quality elements (Appropriate indication for colonoscopy, standardized assessments of medical risk and bowel preparation, complete examination with photo documentation, free of serious intra-procedural complications, withdrawal time recorded, all essential polyp information recorded if polyp(s) identified, recommendation for follow-up colonoscopy consistent with patient history and examination findings), and the completion rate of each individual quality element.</td>
</tr>
<tr>
<td><strong>Denominator Statement:</strong> All adults undergoing screening or surveillance colonoscopy</td>
</tr>
<tr>
<td><strong>Exclusions:</strong> Patients with a personal or family history of familial adenomatous polyposis, hereditary non-polyposis colorectal cancer or inflammatory bowel disease are excluded from the denominator. Patients assessed as poor or unsatisfactory bowel preparation are excluded from the denominator.</td>
</tr>
<tr>
<td><strong>Adjustment/Stratification:</strong> No risk adjustment or risk stratification N/A - Procedural quality bundled measure. The 7 components related to procedural steps do not need to be risk-adjusted as high quality means that all procedures follow all proper steps. The 2 components related to outcomes (appropriate indication for colonoscopy and free of serious intra-procedural complications) do not need to be risk-adjusted as these outcomes are primarily under the control of the provider. Even so, we recognize that it is not possible to avoid all intra-procedural complications. Patients with a personal or family history of familial adenomatous polyposis, hereditary non-polyposis colorectal cancer or inflammatory bowel disease or patients assessed as poor or unsatisfactory bowel preparation are excluded from the denominator. These situations are excluded because of the need for highly individualized recommendations given the particular patient history and current clinical situation. Therefore, we argue that performing the procedure without appropriate indication is entirely within the control of the provider. None</td>
</tr>
<tr>
<td><strong>Level of Analysis:</strong> Clinician: Individual, Population: Regional</td>
</tr>
<tr>
<td><strong>Type of Measure:</strong> Process</td>
</tr>
<tr>
<td><strong>Data Source:</strong> Electronic Clinical Data, Electronic Clinical Data: Electronic Health Record, Electronic Clinical Data: Laboratory, Other, Paper Medical Records, Electronic Clinical Data: Registry</td>
</tr>
<tr>
<td><strong>Measure Steward:</strong> Quality Quest for Health of Illinois, Inc.</td>
</tr>
<tr>
<td><strong>STAGE 1 PRE-REVIEW MEMBER COMMENT (August 7-21, 2012)</strong></td>
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_American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy – See Letter_
C 2056 Colonoscopy Quality Index

STAGE 1 STEERING COMMITTEE MEETING (August 27-28, 2012)

1. Importance to Measure and Report:
   1a. High Impact: H-15; M-0; L-0; I-0

   Discussion:
   - The focus for impact is on the broad area of colonoscopy screening surveillance.
   - Colon cancer is the 2nd leading cause of cancer in the U.S.
   - From a consumer perspective, the Committee agreed that composites are important and easily understood. There was general agreement that this measure focus addresses a high impact area.

1c. Evidence
   0: 1=Yes, body of evidence meets guidance for quantity, quality, consistency
   12: 2=No, body of evidence does not meet guidance for quantity, quality, consistency
   3: No, inadequate information to rate quantity, quality, consistency of body of evidence

   Discussion by component:
   - 1. Appropriate Indication for Colonoscopy: The Committee agreed that good medical practice should include the indication and thus is not needed as a national consensus standard for quality measurement. The Committee agreed that the evidence submitted is based only on consensus opinion.
   - 2. Standardized Medical Risk Assessment: The Committee reiterated that this is standard clinical practice with evidence that is based only on consensus opinion. Further, as part of a standardized medical risk assessment, a cardiac risk assessment is done. However, documentation of this process as a quality indicator reported by the endoscopist could be problematic as it is frequently completed by the anesthesiologist and the endoscopist and would be difficult to operationalize consistently at a national level.
   - 3. Standardized assessment of bowel prep: The Committee agreed that this is an important component. Members discussed multiple registry/database studies that indicate the quality of the bowel prep results in improved adenoma detection rate; however, this evidence was not provided in the measure submission.
   - 4 & 5 Complete Examination and Cecal Photo Taken: The Committee agreed that these are generally accepted as a standard of practice. These indicators demonstrate that the colonoscopy reached the cecum. The Committee agreed that there is strong evidence in terms of registry/database data and a RCT to support the notion that failure to reach the cecum is associated with a higher risk of having interval cancers but was not discussed on the submission form.
   - 6 & 7 All essential polyp information recorded and withdrawal time recorded: The Committee agreed that there is evidence of endoscopic registry/database studies that demonstrate that if the withdrawal time is greater than 7 minutes, the adenoma detection rate is higher than if the withdrawal time is less than 7 minutes. Therefore, this information may be useful to record. However, Committee members noted that adenoma detection rate is the key quality indicator for colorectal cancer screening with colonoscopy since the purpose of this procedure is to identify and remove adenomas. These two indicators are not sufficiently related to the adenoma detection rate. There is evidence that
endoscopists with withdrawal times of more than seven minutes still have poor adenoma detection rates. The Committee also discussed that those with withdrawal times longer than 10 minutes may also have lower detection rates. This evidence was not provided in the measure submission form. The Committee was also concerned that this component only requires that the withdrawal time is recorded which can be “gamed” by the endoscopist so this may not improve outcomes. Others were also concerned that essential information about the polyp is not included in this measure, including whether pathologic examination of the polyp revealed it to be an adenoma. Low adenoma detection rate (but not short withdrawal time) has been associated with an increased risk of interval colorectal cancers.

- Across components 3-7: There is a focus on the endoscopist's ability to ensure that the entire colon has been examined and all polyps have been removed. The Committee discussed that these components ultimately try to assess whether the colonoscopy is going to minimize or prevent patients from getting colon cancer in the future. The Committee expressed concern that the evidence does not support the link of these processes to the outcome of interest, specifically the adenoma detection rate.

- 8. Free of Serious Complications: In order to identify serious complications, the provider would need to follow up with the patient within a 15 to 30 day time window. The Committee discussed that documenting complications during the time of colonoscopy or in the first 24 hours after colonoscopy as this measure is currently specified would not assess the true rate of complications. While there is no disagreement that any complications experienced during the procedure should also be reported, the most common serious complication, post-polypectomy bleeding, usually does not occur until 2-14 days after colonoscopy and would not be captured by this indicator. The Committee was concerned that inclusion of only patients free of serious complications at the time of colonoscopy or in the first 24 hours after colonoscopy would not be an accurate representation of all complications that could occur.

- 9. Appropriate follow-up recommendation: The Committee generally agreed that the desired outcome should be to determine whether a quality colonoscopy is done. Each of these process components should demonstrate how they improve outcomes, specifically the adenoma detection rate. The identification of an adenoma can be determined within 72 hours of the procedure.

The developer was asked to submit evidence for each of the nine composite components; however, the evidence submitted for most of the components was insufficient and repeated for each component. The Committee therefore voted on the evidence for all components of the composite in a single vote and agreed that the evidence submitted was insufficient.

- The evidence submitted does not exist to support the measure focus (i.e., no empirical evidence) for all components of the composite.

**1b. Performance Gap:**

*There is an exceptional and compelling reason that the measure should be considered further (i.e., benefits outweigh the harms): Y-0; N-15*
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**Discussion:** There was no discussion of gap as the measure did not pass evidence.

**Recommendations to Developer:**
- Consider weighting for certain components of the composite based on severity of complications associated with that component.
- Future submissions should reference evidence that is specific to each of the components.
- Consider developing a composite that is a hybrid of process and outcome measures that includes component measures on the on the most important outcomes related to the colonoscopy.
- Consider a composite that includes components with the highest evidence and impact, including a standardized assessment of bowel prep and completeness of colonoscopy including cecal photo taken that would indicate a failure to reach the cecum. Withdrawal time and serious complications within 14 days of colonoscopy should also be included.
- Consider which process components might link closer to the desired outcome of increasing the adenoma detection rate.
- An adenoma detection rate would be important to include in future composites.

**Stage 1 Steering Committee Recommendation for Approval of Concept:**

**Discussion:**
- The purpose of the composite is to allow consumers and purchasers to determine whether the colonoscopist is doing a quality job.
- The desired outcome of a colonoscopy should be to detect cancer (i.e. adenoma detection) and there is concern that this measure does not focus on processes that significantly impact that outcome.
- This concept is not recommended for approval. The concept did not pass the evidence criterion.

**STAGE 1 MEMBER & PUBLIC COMMENT (September 26 – October 25, 2012)**

**Member & Public Comment included:**
- Multiple commenters submitted comments in support of this concept.
- Due to the length and volume of comments submitted, specific comments can be found in the table of submitted comments.

**CONCEPT RECONSIDERATION (October 31, 2012)**

The developer requested that the Committee reconsider the concept in light of additional evidence provided to support the components of the composite. ([Letter](#)).

**Committee Reconsideration:**
The Committee re-evaluated the evidence for each component of the Colonoscopy Quality Index based on the information submitted by the developer subsequent to the Committee’s first evaluation of the concept. (*Composite elements recommended by the Committee)

1. *Appropriate Indication for Colonoscopy*
   - This component is supported by multiple medical specialty society guidelines. There is substantial evidence to show there is variability in the adherence to these guidelines and would therefore be an appropriate part of a quality index.

2. Standardized Medical Risk Assessment
   - This component only requires that the colonoscopist documents the American Society of Anesthesiology (ASA) score. This component within the composite as defined does not provide the documented score. Ultimately, the Committee agreed this assessment is standard medical practice and does not represent whether or not an endoscopist has
## C 2056 Colonoscopy Quality Index

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<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Colonoscopy was performed for colorectal cancer screening or colon polyp surveillance. Further, there is no evidence submitted by the developer or known by the Committee, which shows that performing a colonoscopy procedure on a patient with an ASA greater than three, for example, leads to poor outcomes.</td>
</tr>
</tbody>
</table>
| 3. | **Standardized Assessment of Bowel Prep**  
- The Committee agreed that poor bowel preparation is associated with lower adenoma detection rates and that adequate bowel preparation is essential to performing a high quality colonoscopy. There is high quality and consistent evidence to support this. However, as specified this measure within the composite only requires that the colonoscopist documented that they assessed the quality of the bowel preparation. Similar to the previous component, this component has no bearing on whether the colonoscopy had to be rescheduled due to poor bowel preparation; the colonoscopist could get credit even if they documented that the patient had poor bowel preparation, which is not a signal of performing a quality colonoscopy. |
| 4. | **Complete Examination**  
- There is sufficient evidence to support that failure to reach the cecum has been associated with a higher risk of interval cancers and that this is an essential component to performing a high quality colonoscopy (e.g., diagnosing a colon cancer in a patient within 5 years after a normal screening colonoscopy). |
| 5. | **Cecal Photo Taken**  
- While the Committee agreed that photo-documentation of the ileocecal valve and appendiceal orifice is not perfect documentation that the cecum was reached as there is variability in the skills to capture the appropriate structures, it is the best measure at this point in time. |
| 6. | **All Essential Polyp Information Recorded**  
- The Committee recognized that based on how the composite is structured to collect data for the other components, it is not possible to satisfy Item 9 if these data are not included in the endoscopy report. There was a recommendation to improve this component by including the pathology results regarding adenoma detection. |
| 7. | **Withdrawal Time was Recorded**  
- There is sufficient evidence that has shown that mean withdrawal time of > 6 minutes has been associated with higher adenoma detection rates compared to individuals with mean withdrawal time of < 6 minutes. In this component of the index, endoscopists are graded based upon whether or not they record and document their withdrawal time. Similar to components 2 & 3, documentation of the withdrawal time is not an indication of a quality colonoscopy as the colonoscopist could get credit for a withdrawal time that is outside of the timeframe shown to produce the highest adenoma detection rates. The Committee acknowledged that a key indicator for identifying quality colonoscopist is the adenoma detection rate, which cannot be applied to an individual colonoscopy and incorporated into a composite such as this. Further, the Committee believes withdrawal time is most helpful when assessed in combination with adenoma detection rates. For example, if an endoscopist has a mean withdrawal time < 6 min (e.g., 5 minutes), but has a high adenoma detection rate (e.g., 35% of screening colonoscopy patients are found to have at least one adenoma), then withdrawal time is not a helpful indicator of quality. Similarly, if an endoscopist has a mean withdrawal time > 6 min (e.g., 9 minutes), but his/her adenoma detection rate is only 10%, then withdrawal time again is
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8. *Free of Serious Complications
   - Sufficient evidence has shown that most complications associated with colonoscopy (e.g., post-polypectomy bleeding) occur 1-14 days after the colonoscopy and are not captured by intra-procedural complication category. However, capturing complications that occur in the short period following the colonoscopy is also an important indicator of quality. In order to more accurately represent what this component measures, the Committee recommended that the title should be renamed to “Free of Serious Intra-Procedural Complications”.

9. *Appropriate Follow-up Recommendation
   - The Committee agrees this is an important indicator of a quality colonoscopy. Multiple randomized control trials and endoscopic registry studies support current guideline recommendations for a repeat colonoscopy in the appropriate timeframe. Some studies have indicated that patients frequently get recommendations for a repeat colonoscopy that is not consistent with guidelines. It should be further addressed in the specifications when submitted for stage two review that recommendations for a repeat colonoscopy may not be provided to the patient at the time of the colonoscopy as it is often dependent on the results of the pathology results, which are usually available days after the procedure.

They further recommended that this composite be renamed to: Colonoscopy Quality Index for Colorectal Cancer Screening and Polyp Surveillance to better reflect its intent.

**Final Committee Votes:**

**Evidence:**
- 6: Yes, with only these components included:
  - Item 1: Appropriate Indication for Colonoscopy
  - Item 4: Complete Examination
  - Item 5: Cecal Photo Taken
  - Item 6: All Essential Polyp Information Recorded
  - Item 8: Free of Serious Complications
  - Item 9: Appropriate Follow-up Recommendation
- 5: Yes, as specified
- 3: No

**Performance Gap:** H-9; M-2; L-1; I-2

**STAGE 1 CSAC REVIEW (November 7-8, 2012)**

**Decision:** Approved as recommended by the Committee during the reconsideration and the requirement that the Steering Committee recommendations must be addressed prior to stage 2 submission. The concept for this composite was approved as follows:
- Item 1: Appropriate Indication for Colonoscopy
- Item 4: Complete Examination
- Item 5: Cecal Photo Taken
- Item 6: All Essential Polyp Information Recorded
- Item 8: Free of Serious Complications
- Item 9: Appropriate Follow-up Recommendation

**BOD REVIEW (November 29 – December 11, 2012)**

- **Decision:** Ratification of the concept approval.
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#### STAGE 2

##### STAGE 2 PRE-REVIEW MEMBER COMMENT (March 4-18, 2013)

- This measure received both supportive and critical comments. Supportive comments noted that it fills a measurement gap, and that measures that determine whether colonoscopies are high-quality, effective, and necessary are both patient-centered and important.
- Negative comments noted that several of the elements of the measure have not been shown to improve performance or outcomes; nor is there a demonstrated performance gap. The commenters were also concerned that the developer did not make the changes recommended by the Committee in Stage 1.

##### STAGE 2 STEERING COMMITTEE CHECKLIST REVIEW (March 2013)

Checklist recommendations satisfactorily addressed: **Y-3; N-9; A-2**  
Move forward to full Stage 2 review: **Y-2; N-10; A-2**

- The Committee had requested a number of changes and recommendations for this measure before it moved to Stage 2 (see above). The developer made one change, updating the timeframe in the title of component 8.
- The Committee agreed that the developer had not completed the checklist items, so the measure did not move forward to Stage 2 review. It remains an approved concept and can be brought back for review within 18 months of the original approval date.
### Endorsed Maintenance Measure, Approved in Stage 1, Not Reviewed in Stage 2

<table>
<thead>
<tr>
<th>Measure</th>
<th>Reason</th>
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<tbody>
<tr>
<td>0030: Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment – A patient reported measure (NCQA)</td>
<td>This maintenance measure was approved as a concept in Stage 1 and passed the Importance criteria. However, it was not reviewed in Stage 2. They are currently developing a new measure that will replace this measure and elected to keep the maintenance concept approved in the interim. The developers have 22 months from the Board’s 12/5/12 approval of the concept to bring the measure revision forward for endorsement. It will be reviewed in Phase 2 of the Person and Family Centered Care Project, scheduled to begin in late 2014.</td>
</tr>
</tbody>
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Appendix A: Measure Specifications

2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18) ................................................................. 47

0658 Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients ........................................................................................................................................... 52

0659 Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps- Avoidance of Inappropriate Use ............................................................................................................................... 55
### 2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18)

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<tr>
<th>Status</th>
<th>New Submission</th>
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<tbody>
<tr>
<td>Steward</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>Description</td>
<td>Percent of discharges with an in-hospital death among cases with a principal diagnosis of gastrointestinal hemorrhage</td>
</tr>
<tr>
<td>Type</td>
<td>Outcome</td>
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<td>Level</td>
<td>Facility</td>
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<tr>
<td>Setting</td>
<td>Hospital/Acute Care Facility</td>
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<tr>
<td>Numerator Statement</td>
<td>Number of in-hospital deaths among cases meeting the inclusion and exclusion rules for the denominator</td>
</tr>
<tr>
<td>Numerator Details</td>
<td>All discharges with a Disposition of Patient (DISP) coded as &quot;died&quot; (20)</td>
</tr>
<tr>
<td>Denominator Statement</td>
<td>All discharges, age 18 years and older, with a principal diagnosis code for gastrointestinal hemorrhage OR a principal diagnosis of predisposing condition for esophageal varices and a secondary diagnosis of esophageal varices in condition classified elsewhere with bleeding (456.20)</td>
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<tr>
<td>Denominator Details</td>
<td>ICD-9-CM principal diagnosis code of Gastrointestinal hemorrhage (see below for detail). According to the ICD-9-CM Official Guidelines for Coding and Reporting (<a href="http://www.cdc.gov/nchs/data/icd9/icd9cm_guidelines_2011.pdf">http://www.cdc.gov/nchs/data/icd9/icd9cm_guidelines_2011.pdf</a>), the principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as “that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care.” The UHDDS definitions are used by hospitals to report inpatient data elements in a standardized manner. These data elements and their definitions can be found in the July 31, 1985, Federal Register (Vol. 50, No. 147), pp. 31038-40. The time window may be determined by the user, but is generally a calendar year. ICD-9-CM Gastrointestinal hemorrhage diagnosis codes: 4560 ESOPHAG VARICES W BLEED 5307 MALLORY-WEISS SYNDROME 53021 ULCER ESOPHAGUS W BLEED 53082 ESOPHAGEAL HEMORRHAGE 53100 AC STOMACH ULCER W HEM 53101 AC STOMAC ULC W HEM-OBST 53120 AC STOMAC ULC W HEM/PERF 53121 AC STOM ULC HEM/PERF-OBS 53140 CHR STOMACH ULC W HEM</td>
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<td>2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18)</td>
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### 2065 Gastrointestinal Hemorrhage Mortality Rate (IQI #18)

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<td>5781</td>
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<td>GASTROINTEST HEMORR NOS</td>
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#### Exclusions

Exclude cases:
- transferred to another short-term hospital
- with MDC 14 (pregnancy, childbirth, and puerperium)
- with missing discharge disposition, gender, age, quarter, year or principal diagnosis

#### Exclusion Details

- transfer to another short-term hospital (Disposition of Patient (DISP) coded as Transfer to Short-term Hospital (2))
  - Major Diagnostic Category 14 (pregnancy, childbirth, and puerperium) - note that this exclusion is implied by the fact that the denominator is limited to patients with a principal diagnosis code for gastrointestinal hemorrhage, which maps to MDC 6 (digestive)
- missing discharge disposition (DISP=missing)
- missing gender (SEX=missing)
- missing age (AGE=missing)
- missing quarter (DQTR=missing)
- missing year (YEAR=missing)
- missing principal diagnosis (DX1=missing)

#### Risk Adjustment

Statistical risk model

The predicted value for each case is computed using a two-stage hierarchical model (the first stage is a logistic regression using Generalized Estimating Equations (GEE) to account for clustering of patients within hospitals; the second stage is a reliability weight). The covariates in the logistic regression include age (in 5-year age groups pooled), APR-DRG and APR-DRG Risk of Mortality subclass, MDC and transfer-in status. The reference population used in the regression is the universe of discharges for states that participate in the HCUP State Inpatient Data (SID) for the years 2008, a database consisting of 42 states and approximately 30 million adult discharges. INTERCEPT
<table>
<thead>
<tr>
<th>AGE</th>
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<tr>
<td>AGE</td>
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<tr>
<td>APR-DRG</td>
<td>'2201' (e.g., APR-DRG 220, Risk of Mortality level 1)</td>
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<td>APR-DRG</td>
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<td>MDC</td>
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Detailed risk model available at [http://www.qualityindicators.ahrq.gov/Downloads/Modules/IQI/V44/Risk%20Adjustment%20Tables%20IQI%204.4.pdf](http://www.qualityindicators.ahrq.gov/Downloads/Modules/IQI/V44/Risk%20Adjustment%20Tables%20IQI%204.4.pdf)


Available in attached Excel or csv file

**Stratification**
The denominator may be stratified into two groups: 1) esophageal varices and 2) all other cases. Esophageal varices includes all discharges for patients age 18 years and older, with a principal diagnosis code for gastrointestinal hemorrhage and a secondary diagnosis of esophageal varices with bleeding (456.0 and 456.20), OR a principal diagnosis of predisposing condition for esophageal varices and a secondary diagnosis of esophageal varices in condition classified elsewhere with bleeding (456.20), OR a principal diagnosis of esophageal varices with bleeding (456.0).

**Type Score**
Rate/proportion  better quality = lower score
### Algorithm

The indicator is expressed as a rate, is defined as outcome of interest / population at risk, or numerator / denominator. The AHRQ Quality Indicators (AHRQ QI) software performs six steps to produce the rates. 1) Flag discharge-level records to identify the outcome of interest and 2) the population at risk. 3) Calculate observed rates as the sum of the records flagged in the numerator divided by the sum of the records flag in the denominator for user-specified combinations of stratifiers. 4) Calculate expected rates. Regression coefficients from a reference population database are applied to the discharge records to compute a predicted value. For indicators that are not risk-adjusted, this is the reference population rate. The expected rate is computed as the sum of the predicted value for each record divided by the number of records flagged in the population at risk for the unit of analysis of interest (i.e., hospital). 5) Calculate risk-adjusted rate using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate. For indicators that are not risk-adjusted, this is the same as the observed rate. 6) Calculate smoothed rate using an Empirical Bayes shrinkage estimator (W) as the weighted average of the risk-adjusted rate and the reference population rate. The shrinkage estimate reflects a reliability adjustment unique to each indicator.

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Not applicable

Not applicable
<table>
<thead>
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<th><strong>0658 Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients</strong></th>
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<tbody>
<tr>
<td><strong>Status</strong></td>
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<td><strong>Steward</strong></td>
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<tr>
<td><strong>Risk Adjustment</strong></td>
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</tr>
</tbody>
</table>
Stratification
We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

Type Score
Rate/proportion  better quality = higher score

Algorithm
To calculate performance rates:
1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).
2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.
3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator.
4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception when exceptions have been specified [for this measure: medical reason(s) (eg, above average risk patient, inadequate prep)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. Although the exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.
If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.
Calculation algorithm is included in attachment 2a1.30. Included in attached appendix.

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<td><strong>EHR Specifications:</strong></td>
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4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator when exceptions have been specified [for this measure: medical reason(s) (eg, patients with high risk for colon cancer, last colonoscopy incomplete, last colonoscopy had inadequate prep, piecemeal removal of adenomas, or last colonoscopy found greater than 10 adenomas) or system reason(s) for an interval of less than 3 years since the last colonoscopy (eg, unable to locate previous colonoscopy report)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.  
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Appendix B: Project Steering Committee and NQF Staff

STEERING COMMITTEE

Andrew Baskin, MD (Co-Chair)
Aetna, Blue Bell, PA

Christopher Saigal, MD, MPH (Co-Chair)
UCLA Medical Center, Los Angeles, CA

Liliana Bordeianou, MD, MPH
Massachusetts General Hospital, Cambridge, MA

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Medisolv Inc., Columbia, MD

Robert Ellis
Consumers' Checkbook, Ashburn, VA

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Performance Measures

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Senior Director
Performance Measures

Taroon Amin, MA, MPH
Senior Director
Performance Measures

Ashlie Wilbon, RN, MPH
Senior Project Manager
Performance Measures

Suzanne Theberge, MPH
Project Manager
Performance Measures

Evan M. Williamson, MPH, MS
Project Analyst
Performance Measures
Appendix C: Measures Endorsed in GI/GU since March 1, 2007

GU Measures

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<td>0030</td>
<td>Urinary Incontinence Management in Older Adults - a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment – A patient reported measure</td>
<td>National Committee for Quality Assurance</td>
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<td>0684</td>
<td>Percent of Residents with a Urinary Tract Infection (Long-Stay)</td>
<td>Centers for Medicare and Medicaid Services</td>
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<tr>
<td>0685</td>
<td>Percent of Low Risk Residents Who Lose Control of Their Bowels or Bladder (Long-Stay)</td>
<td>Centers for Medicare and Medicaid Services</td>
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<tr>
<td>0686</td>
<td>Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (Long-Stay)</td>
<td>Centers for Medicare and Medicaid Services</td>
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<tr>
<td>NQF Number</td>
<td>Title</td>
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<tr>
<td>0034</td>
<td>Colorectal Cancer Screening</td>
<td>National Committee for Quality Assurance</td>
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<tr>
<td>0223</td>
<td>Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer</td>
<td>American College of Surgeons</td>
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<tr>
<td>0225</td>
<td>At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer</td>
<td>American College of Surgeons</td>
</tr>
<tr>
<td>0392</td>
<td>Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade</td>
<td>American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)</td>
</tr>
<tr>
<td>0460</td>
<td>Risk-Adjusted Morbidity and Mortality for Esophagectomy for Cancer</td>
<td>The Society of Thoracic Surgeons</td>
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<tr>
<td>0572</td>
<td>Follow-up after initial diagnosis and treatment of colorectal cancer: colonoscopy</td>
<td>Health Benchmarks-IMS Health</td>
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<tr>
<td>0658</td>
<td>Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients</td>
<td>American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)</td>
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<td>American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)</td>
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<td>0727</td>
<td>Gastroenteritis Admission Rate (pediatric)</td>
<td>Agency for Healthcare Research and Quality</td>
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<td>1617</td>
<td>Patients Treated with an Opioid who are Given a Bowel Regimen</td>
<td>RAND Corporation</td>
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<td>1854</td>
<td>Barrett’s Esophagus</td>
<td>College of American Pathologists</td>
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