

Public Comment Summary Report

Measure Name:

Hospital Visits after Hospital Outpatient Surgery

Date of Report:

September 19, 2014

Contractor (Measure Developer) Name:

Yale New Haven Health Services Corporation — Center for Outcomes Research and Evaluation (CORE)

Introduction

Dates of public comment period:

Wednesday, July 16, 2014 through Sunday, August 3, 2014

Web site used:

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>

Methods used to notify stakeholders and general public of comment period:

- Email notification to the Centers for Medicare & Medicaid Services (CMS) listserv groups
- Email to relevant stakeholders and stakeholder organizations, including:
 - Business and consumer advocacy organizations
 - Electronic Health Record (EHR) vendors
 - Healthcare quality focused organizations
 - Insurance and purchaser organizations
 - Medical associations and societies
 - Research organizations
 - Topic knowledge-related organizations
- Posting on CMS Public Comment website

Volume of responses received:

We received comments from five commenters during the public comment period; specifically:

- Four professional societies (American Academy of Ophthalmology [AAO], American Urological Association [AUA], American Society of Plastic Surgeons [ASPS], and American College of Surgeons [ACS])
- One healthcare improvement company (Premier Healthcare Alliance)

Stakeholder Comments—General

Summary of general comments:

We received comments from five commenters on various aspects of the measure of hospital visits following outpatient surgery conducted in hospital outpatient departments (HOPDs). Comments focused on the measure's objective and methodology, including the cohort, outcome, and risk adjustment.

Several commenters were supportive of the measure's objective to measure risk-standardized, all-cause, unplanned hospital visits following same-day outpatient surgery and the measure's potential impact on health outcomes and quality improvement. However, all five commenters conveyed concern about specific aspects of the measure methodology.

Proposed action(s):

See proposed action under the measure-specific comment summaries below.

Measure-Specific Comment Summaries

Measure name:

Hospital Visits after Hospital Outpatient Surgery

Summary of comments:

General comments

There were six general comments about the measure's focus.

- Four commenters expressed support for the measure's focus on assessing patient outcomes after surgery in the outpatient setting and its potential impact on health outcomes and quality improvement. However, one commenter noted in expressing this support that additional work remains in specifying the measure and testing it for reliability and validity.

Response: We appreciate the commenters' support for the measure's focus. We have not yet completed testing and agree with the need for further testing. Public comment is generally sought during measure development, rather than once the measure is finalized, to allow for concerns or issues raised during the public comment period to be incorporated into the measure development and testing.

- Two commenters recommended measuring procedures occurring at ambulatory surgery centers (ASCs) in addition to HOPDs in order to capture all outpatient surgery complications.

Response: For technical reasons, we have not combined ASC and HOPD surgeries into a single measure. In particular, the wide variation in the type and number of outpatient surgeries

conducted at ASCs makes them more difficult to measure. Many ASCs serve only a single subspecialty (e.g., orthopedics or urology) and perform relatively few procedures compared to HOPDs. Our analysis showed that 75% of substantive same-day surgeries were performed at HOPDs, and thus there would be adequate volume for reliable estimates. We agree that quality measurement following outpatient surgery at ASCs is an important goal.

Cohort

Six comments addressed the cohort's inclusion and exclusion criteria.

- One commenter expressed support for defining the measure cohort using the substantive surgeries included in Medicare's list of covered ASC procedures.

Response: We appreciate the commenter's support for the current approach.

- One commenter expressed support for the proposed inclusion of patients who undergo a cystoscopy with intervention.

Response: We appreciate the commenter's support for the current approach.

- One commenter recommended not including cystoscopy with intervention in the measure cohort. The commenter explained that standard risk-adjustment methodologies will not sufficiently account for unique urologic factors that can lead to complications in otherwise healthy patients.

Response: In our data we observed that cystoscopy with intervention (i.e., treatment) was a common procedure in the outpatient setting and had a similar outcome profile to other included surgeries. Specifically, we observed an unplanned hospital visit rate of 8.8% at 7 days for this procedure. The causes of hospital visits, such as urinary retention, hemorrhage complicating the procedure, and urinary tract infection, were similar to other urology surgeries included in the measure. Therefore, we proposed including cystoscopy in the measure cohort. The majority of the measure Technical Expert Panel (TEP) members and other commenters during the public comment period supported this approach.

We agree that adequate risk adjustment is critical. We have reviewed the issue and have concluded we are adequately risk adjusting for cystoscopy. The measure adjusts for age and a range of comorbidities including the presence of prior history of urinary tract infection and other urinary tract disorders. In addition, we adjust for procedural complexity using two variables. First we adjust for the anatomical body system (e.g., urology, musculoskeletal, etc.) to account for potential organ specific procedural factors. Because range of procedures for a given organ vary, we further adjust for the procedure (CPT code) specific Work Relative Value Unit (RVU) as a surrogate for procedural complexity.

Factors such as voiding status, prostate size, or tumor size matter as it may affect procedural complexity. However, much of this information is captured by the individual CPT codes used and the associated RVU. For example, Table 1 below indicates the typical CPT codes used for

cystoscopy with removal of bladder tumors and their associated Work RVUs. The tumor size is incorporated into the coding and as the size increases (and therefore the surgical complexity increases) the RVU increases. Similarly, CPT codes do take into account location of lesions, specific types of intervention(s), and potential indications (e.g., cystoscopy with intervention for bladder tumor versus cystitis versus stricture etc.).

Table 1. Typical CPT codes for cystoscopy with removal of bladder tumors and their associated Work RVUs

CPT Code	Procedure Description	Work RVU
52224	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of minor (less than 0.5 cm) lesion(s) with or without biopsy	3.14
52234	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; small bladder tumor(s) (0.5 up to 2.0 cm)	4.62
52235	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; medium bladder tumor(s) (2.0 to 5.0 cm)	5.44
52240	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; large bladder tumor(s)	9.71

In summary, the proposed approach risk adjusts for the procedural risk of cystoscopy with intervention and does take into consideration potential urology specific factors. In view of the comment, we re-examined our approach with the TEP. The TEP continued to support the inclusion of cystoscopy with the intervention in the measure cohort.

- Two commenters expressed support for the proposed exclusion of eye surgeries from the measure cohort. Of these, one commenter recommended creating a separate measure to assess eye surgery outcomes.

Response: We agree with the commenters' support for not including eye surgery in the measure. The outcome of hospital visits may not be a good measure of the quality of eye surgery. There is a very low rate of unplanned hospital visits following eye surgery, and our analysis of Medicare data suggests many unplanned hospital visits occurring following surgery are unrelated to eye surgery.

- One commenter recommended excluding patients who are treated urgently in the hospital outpatient setting for wound debridement, drainage of an abscess, or infection from the measure cohort. The commenter explained that these cases are common and during the procedure providers may identify an appropriate reason (e.g., pain control, observation for hemorrhage) for admitting the patient on the day of surgery. The commenter expressed concern that including these cases in the cohort may have the unintended consequence of driving these patients towards inpatient admission to avoid the impact of measurement, resulting in therapy delay and more costly care.

Response: The measure cohort is limited to surgeries on Medicare's list of covered ASC procedures which does not include high risk surgeries or those that are considered emergent or life-

threatening in nature. Ultimately these claims are those billed as an outpatient and the expectation is for the patient to be discharged home from the HOPD facility.

We agree that some admissions following surgery are appropriate admissions for reasons such as unexpected findings as the commenter has noted. Accordingly, we do not expect the rate of hospital visits (outcome) to be zero. The primary role of this measure is to assess the relative performance of HOPDs for outpatient surgery. In other words, the aim is to identify facilities that have a significantly higher than expected rate of hospital visits, adjusted for the case and procedural mix of patients, relative to other facilities to facilitate quality improvement. The appropriate rate of hospital visits following outpatient surgery is unknown but the observed rate of hospital visits following same-day surgery (10% at 7 days) does suggest substantial room for improvement.

Outcome

Seven comments addressed different aspects of the measure outcome as follows below:

There were two comments about the measure's outcome definition.

- One commenter agreed with the outcome definition captured.

Response: We appreciate the commenter's support for the current approach.

- One commenter recommended including observation stays in the measure outcome. The commenter expressed concern that the measure may provide misleading data since it does not include observation stays thus the outcome does not reflect all outpatient surgery complications. The commenter is concerned that surgeons may begin to treat more patients in the inpatient setting or keep patients under observation status in order to avoid inclusion in this measure; this may increase overall health costs.

Response: We include observations stays in the outcome if a patient is discharged from an HOPD and experiences an observation stay during the return hospital visit, because the return for hospital care would be an unexpected adverse event.

However, we do not count in the outcome observation stay use immediately following surgery. Clinicians may use observations stay immediately following surgery to appropriately assess a patient who requires a longer period of evaluation (but not warranting an inpatient admission) or to treat pain, treat nausea and vomiting, or allow for recovery from anesthesia.

Medicare does not typically reimburse additional payments for use of observation stays immediately following outpatient surgery. Therefore, we do not believe the use of observation stay will lead to higher costs.

There were three comments about the measure's outcome timeframe.

- Two commenters supported the proposed 7-day post-surgery outcome timeframe. One commenter recommended reevaluating the outcome timeframe in the future if there are significant changes to the measure specifications following the comment period.

Response: We appreciate the commenter's support for the current approach.

- One commenter expressed concerns regarding the outcome timeframe, suggesting that the proposed 7-day timeframe does not provide enough time to adequately evaluate post-surgery admission to a hospital or an emergency department (ED). The commenter recommended a longer timeframe, such as 30 or 45 days, in order to ensure measurement of postoperative admissions to a hospital or visits to an ED.

Response: We recognize that adverse events of surgery, such as postoperative infection and venous thromboembolism, may occur after 7 days. However, selection of the outcome timeframe is a tradeoff between competing concerns. On the one hand, the outcome timeframe must be sufficiently long to ensure capture of hospital visits related to the surgery, and we observed that the vast majority of hospital visits occur during the first 7 days after surgery. On the other hand, in this elderly Medicare population, hospital visits also occur for reasons unrelated to surgery which do not reflect the quality of surgical care. By extending the outcome timeframe to 30 or 45 days we are likely to capture more adverse events related to surgery. However, we will also capture a greater number of hospital visits unrelated to the surgery. In essence, the 'quality signal to noise' ratio in our measure diminishes as we move the outcome timeframe further away from the day of the surgery.

Therefore, we limited the outcome of hospital visits to 7 days to ensure the hospitals visits captured in the outcome predominantly reflect hospital visits related to the quality of the surgery.

There was one comment about outcome attribution.

- One commenter stressed the importance of ensuring that any readmission to another facility is linked back to the facility where the original surgery was performed

Response: We agree and ensure that all hospital visits within 7 days to another facility are linked back to the original facility that performed the surgery to ensure the outcome is attributed to the facility performing the surgery.

There was one comment regarding the two-midnight policy's potential impact on the measure outcome.

- One commenter recommended considering how Medicare's "two-midnight" payment policy might affect a facility's performance on the measure and how to ensure outcomes are counted consistently across providers.

Response: We agree that the disposition of the two-midnight policy could affect the measure, and CORE and CMS staff are communicating about the link between the two. CMS will consider whether the measure specifications need revision once the two-midnight policy is finalized.

Risk model

Four comments addressed the measure's approach to risk adjustment:

- Two commenters supported risk adjusting the measure to account for differences in case mix and procedure mix across HOPDs. One commenter recommended continuing to assess risk model variables to ensure the strongest risk model in order to alleviate unintended consequences such as providers avoiding certain patients and procedures in order to improve performance on this measure. Another commenter noted that patient severity and other risk factors are outside of a provider's control and the performance measures should be adjusted for these factors.

Response: We appreciate the commenters' support for the current approach. If the measure is implemented CMS will continue to assess the risk model. CMS also routinely monitors for unintended consequences of quality measures.

- One commenter recommended the risk model be further developed to incorporate adjustments for social determinants of health, in particular socioeconomic status (SES). The commenter expressed concern regarding comparing facility performance without adjusting for SES of the populations served since there is a substantial body of evidence that sociodemographic factors, such as patients' income, housing, education, and race, influence a variety of patient outcomes and processes out of a provider's control. The commenter cited that the National Quality Forum's (NQF's) *Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors, Technical Report* recommended adjusting for sociodemographic factors for performance measures used to determine provider payment; the NQF Board of Directors approved a trial period for assessing the impact of risk adjusting relevant quality measures for sociodemographic factors.

Response: CMS is reviewing the NQF report and will consider it in its approach to reporting the measure. CMS is evaluating the effect of the inclusion of SES in the model on the measure score and will include the results in the final measure technical report and NQF application.

- One commenter recommended that the risk-adjustment methodology incorporate a ranking of complication severity rather than treat all complications equally. The commenter argued that counting a minor complication such as hematuria with the same weight as a death is inappropriate.

Response: We use a broad patient-centered outcome to capture the entire range of hospital visits following surgery. This includes hospital visits due to complications, social reasons (such as lack of transport home), and logistical reasons (delayed start of surgery resulting in an inpatient admission). We use this outcome as it is well defined, easy to measure, and widely accepted for assessing outpatient surgery quality.

While ranking these outcomes based on severity is a worthwhile consideration, there is currently no widely accepted method developed to use with claims data. Severity of a presentation is also difficult to accurately assess retrospectively from patient claims.

Please note that death (in the absence of a hospital visit) is not included in the measure outcome, as our preliminary analysis indicated the rate of death is exceedingly rare (0.01% at 7 days in our cohort) with no observable variation between facilities.

Proposed action(s):

We plan to address the comments received during public comment. Specifically:

- CORE reviewed with the TEP the comments received and CORE's proposed responses.
- CMS will continue to evaluate the measure if it is implemented in order to identify unintended consequences.
- CMS is reviewing NQF's *Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors, Technical Report* and will consider it in its approach to finalizing the measure specifications. CMS is evaluating the effect of SES on the measure score. CMS will share the results of these analyses in the final measure technical report and NQF application.
- CORE and CMS staff are communicating about the potential impact of Medicare's two-midnight payment policy on hospital performance. CMS will consider whether the measure specifications need revision once the two-midnight policy is finalized.

Overall Analysis of the Comments and Recommendations to CMS

The feedback on the measure focus and the measure's proposed use for facility-level reporting overall was positive. Commenters identified several methodological issues that we will reevaluate and review with our TEP and clinical experts.

Measure of Hospital Visits after Hospital Outpatient Surgery

Public Comment Verbatim Report

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
7/28/14	<p><i>Comments from American Academy of Ophthalmology:</i></p> <p>The Academy supports the exclusion of eye surgeries from this measure’s covered procedures. We agree with the rationale provided in the report for removing eye surgery, including that although eye surgery is substantive surgery, it has a low rate of complications requiring hospitalizations. Admission to a hospital following eye surgery is rare, especially within a timeframe of 7-14 days. The Academy agrees that hospital visits post-surgery would not be a good measure of quality of eye surgery. The Academy would not support the inclusion of eye surgeries for this measure.</p> <p>The Academy sees no reason to not apply this measure to both ambulatory surgical centers (ASCs) and hospital outpatient departments (HOPDs). During its discussions, the TEP explored measuring the outcome of hospital visits for both HOPDs and ASCs. However, as proposed, the preliminary measure would only apply to HOPDs. The Academy believes this measure is applicable to HOPDs as well as ASCs.</p> <p>The Academy does not support the timeframe proposed for this measure, as it does not provide enough time to adequately evaluate post-surgery admission to a hospital or an emergency department visit. A longer timeframe, such as 30 or 45 days, would provide a more appropriate period of time to ensure that post-operative admissions to a hospital or visits to an emergency department are measured.</p> <p>Additionally, the Academy agrees that this measure should include risk adjustment to account for variances in case mix across providers. Patient severity and other risk factors are outside of a provider’s control, and the Academy believes that performance measures should be adjusted for these factors.</p>	Rebecca Hancock (Manager of Quality and HIT Policy) on behalf of American Academy of Ophthalmology	rhancok@aaodc.org	Professional Society

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
7/31/14	<p><i>Comments from Drs. David Penson and J. Stuart Wolf, Jr.:</i></p> <p>The AUA agrees it is important to assess care in the outpatient setting. , Nonetheless, while supportive of the measure, the AUA has the following concerns and recommendations for strengthening the measure:</p> <p>•Recommendation: Ambulatory care clinics (ASC’s) and observation stays should be included in the measure.</p> <p>Rationale: As currently specified, the measure will not capture all outpatient surgery complications in total and as such may provide misleading data. In addition, some procedure-associated complications will lead to an observation status stay that will not be captured by the measure. The above factors create opportunities to “game the system.” Poorly performing surgeons may begin to treat more patients in the inpatient setting or to keep patients under an observation status in order to avoid this measure; thus increasing overall health costs. The AUA feels this must be remedied in order to strengthen the measure and truly capture performance.</p> <p>•Recommendation: The risk adjustment methodology must be clearly delineated to ensure appropriate adjustment.</p> <p>Rationale: Currently, all complications are treated equally. The AUA feels strongly that a ranking of severity of complications is needed. For example, to count a minor complication such as hematuria as an “event” with the same weight as death is inappropriate.</p> <p>•Recommendation: Cystoscopy with intervention should not be included in the measure cohort (Appendix A).</p> <p>Rationale: First, the point noted above regarding risk adjustment applies here, in that standard risk adjustment methodologies such as NSQIP’s do not consider unique urologic factors that influence complications, such as prostate size and preoperative voiding</p>	Suzanne Pope, MBA (Senior Manager of Quality) of American Urological Association on behalf of Drs. David Penson and J. Stuart Wolf, Jr.	spope@auanet.org	Professional Society

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	<p>status. Some patients who are otherwise healthy are at increased risk for complications solely on the basis of unique urology specific factors.</p> <p>The AUA supports the proposal of a 7 day outcome timeframe and agrees that this should capture most procedure-related complications.</p>			
7/31/14	<p><i>Comments from Premier Healthcare Alliance:</i></p> <p>The Premier healthcare alliance is a healthcare improvement company uniting an alliance of more than 2,900 U.S. hospitals and nearly 100,000 other providers to transform healthcare. Premier, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the views of our owner hospitals and health systems, which, as service providers, have a vested interest in the development of sound quality measures, especially those that will be ultimately used by the Centers for Medicare & Medicaid Services (CMS).</p> <p><u>Overarching Comments</u></p> <p>Premier supports the concept underlying the measure and agrees that it would fill an important gap in quality measurement, although additional work remains in specifying the measure and testing it for reliability and validity. Measuring patient outcomes after outpatient surgery is an important contribution in understanding variation in the quality of care provided in HOPDs. We agree that defining surgeries as those substantive surgeries on Medicare's list of covered ambulatory surgery center procedures is a reasonable way of narrowing the focus to substantive, yet lower-risk surgeries. We also agree with the inclusion of cystoscopies with intervention. Based on the data shown in the technical report for public comment, a 7-day post-surgery window seems appropriate for capturing most associated hospital visits. To the extent that as the</p>	Seth Edwards, MHA (Manager, Federal Affairs) of Premier Healthcare Alliance	seth_edwards@PremierInc.com	Healthcare Improvement Company

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	<p>measure is fully developed other aspects of the measure specifications are changed, the time frame should be re-evaluated.</p> <p>We recognize that the decision to exclude from the measure eye surgeries, which are high volume and stated to be low-risk of post-surgery hospital visits, is intended to avoid swamping the variation in hospital performance on other outpatient surgeries. However, we are not comfortable with the initial decision to completely ignore these procedures. Instead, we believe it would be better to consider having a separate measure that would assess eye surgery outcomes. Initially, the eye surgery outcome measure could be a parallel measure of post-surgery hospital visits for eye surgery only.</p> <p>In considering the hospital visit outcomes, we agree that the measure should include inpatient admissions directly following surgery as well as post-discharge unplanned admissions, emergency department visits, and observation days. A patient may be admitted to an inpatient stay immediately after a scheduled outpatient surgery because something went awry during the procedure or because that patient was not a good candidate for a pure outpatient surgery. Holding HOPDs accountable for both is appropriate. As the measure specifications are further developed, consideration needs to be given to how Medicare’s “two-midnight” payment policy might affect a hospital’s performance on the measure. The measure should be specified in a way that ensures outcomes are counted consistently across providers.</p> <p>Premier agrees that this measure should be risk-adjusted to account for different mix of patients and procedures across hospital outpatient departments. The proposed patient demographic and comorbidity variables should continue to be assessed to ensure that to the greatest extent possible the risk adjustment used for this measure captures these differences. Insufficient risk adjustment may lead to unintended consequences if providers have incentives to avoid certain patients and procedures in order to improve performance on this measure.</p> <p>In addition to the risk adjustment developed to date, the measure should be further</p>			

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	<p>developed to incorporate adjustments for social determinants of health, in particular socioeconomic status (SES), into the risk adjustment methodology. Comparing hospital performance between markets of widely varying SES, without taking the SES of the populations served into account, is flawed. Social determinants play a major role in influencing health and wellness. There is a substantial body of evidence that sociodemographic factors— such as patients’ income, housing, education and race— influence a variety of patient outcomes and some processes that are out of a provider’s control. The National Quality Forum Board (NQF) of Directors voted on July 23, 2014 to initiate a trial period for assessing the impact and implications of risk adjusting relevant quality measures for sociodemographic factors. This vote follows an NQF technical report that recommends adjusting for sociodemographic factors the performance measures used to determine provider payment.¹ A robust risk-adjustment approach would strengthen the value of this measure in understanding variation in outcomes after hospital outpatient surgery and would help to minimize the potential for unintended consequences.</p> <p>¹National Quality Forum, <i>Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors</i>, Technical Report, July 2, 2014, and July 23, 2014 press release available at: http://www.qualityforum.org/Press_Releases/2014/NQF_Board_Approves_Trial_Risk_Adjustment.aspx</p>			
8/4/14	<p><i>Comments from American Society of Plastic Surgeons:</i></p> <p>The Quality and Performance Measurement Committee of the American Society of Plastic Surgeons appreciates the opportunity to submit public comments to the Technical Expert Panel. The Committee notes that while this is a reasonable measure, it is important to ensure that any readmission to another facility will be linked back to the facility where the original surgery was performed.</p>	Diedra D. Gray, MPH (Sr. Manager of Quality and Health Policy) of American Society of Plastic Surgeons	dgray@plasticsurgery.org	Professional Society

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
8/11/14	<p><i>Comments from American College of Surgeons:</i></p> <p>The American College of Surgeons reviewed the Yale-developed measure entitled <i>Hospital Visits after Hospital Outpatient Surgery</i>. Overall, we agree with the measure concept, though we have one major concern. Our concern relates to patients who are treated urgently or emergently in hospital outpatient settings for wound debridement, drainage of an abscess, or infection, all of which are typically for exam under anesthesia. These scenarios are not uncommon and the situation during the operation could identify something worse than expected. In this instance, it would be appropriate to admit the patient on the day of surgery, not 7 days after. To this end, we recommend the exclusion of urgent or emergent cases that involve those three scenarios because those patients may need pain control, observation for hemorrhage, or more intensive treatment of the underlying condition. Without these exclusions, we could create an unintended consequence that would drive these patients toward admission to avoid the impact of measurement which would result in a delay in therapy and more costly care.</p>	Jill Sage, MPH (Quality Affairs Manager) of American College of Surgeons, Division of Advocacy and Health Policy	jsage@facs.org	Professional Society