CBE ID

2539

Title

Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

Project

Cost and Efficiency

Endorsement Status

Endorsed with Conditions

E&M Committee Rationale/Justification

When the measure returns for maintenance, the committee would like to see:

- Consider additional approaches for the reliability assessment that inform the reliability-validity (e.g. shrinkage) and reliability- usability (e.g. stability) tradeoffs

Is Under Review

No

Next Maintenance Cycle

Spring 2029

Previous Endorsement Cycle

Spring 2024

Steward

Centers for Medicare & Medicaid Services

1.0 New or Maintenance

Maintenance

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

This measure was developed to improve the quality of care delivered to patients undergoing outpatient colonoscopy procedures. The Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure, estimates a facility-level rate of risk-standardized, all-cause, unplanned hospital visits within seven days of a colonoscopy procedure performed at a hospital outpatient department (HOPD) or ambulatory surgical center (ASC) among Medicare Fee-for-Service (FFS) patients aged 65 years and older. An unplanned hospital visit is defined as an emergency department (ED) visit, observation stay, or unplanned inpatient admission. The measure is calculated separately for HOPDs and ASCs. The measure is also reported stratified by

dual eligibility for the HOPD setting.

1.7 Composite Measure

No

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Ambulatory Surgery Center, Hospital: Outpatient

1.10 Measure Rationale

The Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure (CBE #2539) (hereafter “Colonoscopy measure”) captures unplanned hospital visits 7 days after a colonoscopy procedure performed at an HOPD, or separately, at an ASC. The measure focuses on the outcome of unplanned hospital visits because this is a broad, patient-centered outcome that captures the full range of hospital visits resulting from adverse events or poor care coordination following the procedure. By providing HOPDs and ASCs with detailed information about patients who have an unplanned hospital visit, this measure supports quality improvement at facilities, and through public reporting of the measure allows for assessment and illumination of the variation in risk-adjusted hospital visits following colonoscopy.

Colonoscopy is a common and costly procedure performed at outpatient facilities and is frequently performed among relatively healthy patients to screen for colorectal cancer (CRC). Given the widespread use of colonoscopy, understanding and minimizing procedure-related adverse events is a high priority. These adverse events, such as abdominal pain, bleeding, and intestinal perforation, can result in unanticipated hospital visits after the procedure. Furthermore, physicians performing colonoscopies may be unaware that patients seek acute care at hospitals following the procedure and thus underestimate such events. This risk-standardized quality measure addresses this information gap and promotes quality improvement by providing feedback to facilities and physicians, including patient-level details for each post-procedure visit. Public reporting transparency for patients on the rates of and variation across facilities in unplanned hospital visits after colonoscopy.

Patients may experience a range of potential adverse events after an outpatient colonoscopy, which could lead to unplanned hospital visits, including ED visits, observation stays, and unplanned inpatient admissions. This measure provides the opportunity to improve the quality of care and to lower rates of adverse events leading to hospital visits after an outpatient colonoscopy. Below we describe the complications that patients may experience; pathways for

improvement by measured entities, and improvement through public reporting.

Colonoscopy Complications

Gastrointestinal complications are common and range from severe to mild. Complications such as colonic perforation and gastrointestinal (GI) bleeding are relatively rare but severe adverse events; other GI complications are considerably more common (Olaiya et al., 2020; Kothari et al., 2019). A recent meta-analysis found that perforation rates ranged from 1.6 to 11.9 per 10,000 procedures and that the risk of perforation was not associated with age; study authors suggested that characteristics of the procedure itself were underlying this adverse event (Kothari et al., 2019). Other adverse events are more common but less severe; among surveyed patients, the reported frequency of complications was 25% by the second day following the procedure (Sewitch et al., 2018). These complications include abdominal pain, abdominal distension, nausea, vomiting, and other nonspecific symptoms. In addition, the overall risk of a complication is higher in older adults (Causada-Calo et al., 2020).

Cardiopulmonary complications are rare (Kothari et al., 2019) but can occur as a complication of the sedation given at the time of the procedure. It has been shown that aspiration is more common with deep sedation with anesthesia assistance (0.14% in Medicare-aged patients) compared to moderate sedation without anesthesia assistance (0.10%) (Cooper et al., 2013).

Post-procedural infection can also occur as a result of a colonoscopy. For example, a 2018 study found rates of infection within 7 days of a screening colonoscopy performed at an ASC to be 1.1 per 1,000 colonoscopies (Wang et al., 2018). Furthermore, the study authors found that the rates of infection varied widely by ASC, from 0 to 115 per 1,000 colonoscopies. Infection can occur due to lapses in infection control procedures, as well as defective equipment (Petersen et al., 2017).

Hospital visits following colonoscopy

The symptoms described above can result in the need for acute care. A 2018 retrospectively review of 50,319 colonoscopies performed on 44,082 individuals (47% male, median age 59 years) reported an ED visit rate within 7 days of a colonoscopy of 0.76% (Grossberg et al., 2018), and a claims-based analysis found an average 7-day hospital visit rate (defined as an ED visit, observation stay, or inpatient hospitalization) of 1.63% (Ranasinghe et al., 2016). A recent study found that older patients are more likely to experience a hospital visit after colonoscopy and reported a rate of inpatient admission or an ED visit within 30 days of 6.8% in people aged 75 and older (Causada-Calo et al, 2020). The rate of hospitalization varies by type of complication; hospitalization rates were nearly 100% among patients who developed perforation and between 50.8% and 70.7% among patients who developed lower GI bleeding (Wang et al., 2018). In

contrast, hospitalizations among patients with abdominal pain or nausea diagnosis were less common.

Studies have shown that many of the reasons for post-procedural hospital visits are related to the colonoscopy. For example, a 2018 single-center study examined the medical records (including medication information) of patients who experienced an emergency department (ED) visit within 7 days of an outpatient colonoscopy (Grossberg et al., 2018). The study authors extracted patients' chief complaint from medical records, assigned the chief complaints as related or unrelated to the colonoscopy, and found that 68% of the reasons for the ED visit were due to the colonoscopy. The most common reasons for related ED visits were abdominal pain (38.2%), gastrointestinal bleeding (29.7%), cardiopulmonary disorders (12.7%), and nausea/vomiting (4.2%). In another study, the authors examined the most frequent diagnoses in claims data associated with an unplanned hospital visit within 7 days, which included hemorrhage (6.4% of all unplanned visits), accidental operative laceration (3.0%), abdominal pain (3.0%), GI hemorrhage (2.7%), chest pain (1.9%), and urinary tract infection (1.8%) (Ranasinghe et al., 2016). CORE's updated analysis (see Section 4.3, Validity) shows a similar pattern of complications 7 days following a screening colonoscopy, with recent data.

Pathways for improvement

Provider- and facility-level factors can affect the outcome of complications and hospital visits related to a colonoscopy. For example, provider-level factors such as low provider volume and fellow involvement in the procedure were significantly associated with a higher risk of an ED visit in one study (Grossberg et al., 2018), and another study found that low procedure volume was associated with a higher risk of infection (Wang et al., 2018), suggesting facilities can influence the patients' outcome through these modifiable pathways.

Providers may be unaware of complications for which patients visit the hospital, leading to understated complication rates and suggesting the need for better measurement to drive quality improvement. Both patients and providers can benefit from outcome measures that capture the full range of adverse experiences associated with outpatient colonoscopy and illuminate quality differences.

Public reporting and facility feedback

CMS provides the public with data to help people make more informed decisions about their healthcare. As of December 2017, measure results have been publicly available; results have been available to facilities since 2015 in the form of facility-specific quality reports. Thus, it is important to continue to make this information transparent to patients choosing among providers who offer

this elective procedure, and to facilities that can use the detailed feedback for quality improvement.

Importantly, providing outcome rates to providers will make meaningful quality differences visible to clinicians, thus incentivizing improvement. In this submission we show improvement across the five performance periods captured by this measure since it was implemented. For example, the national rate of hospital visits per 1,000 colonoscopies among HOPDs declined from 16.4 in 2018 reporting to 14.8 in 2019 reporting, and 13.2 for 2023 reporting, and the distribution of risk-standardized rates also declined.

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1.11 Measure Webpage

https://qualitynet.cms.gov/outpatient/measures/colonoscopy/resources

1.13 Data Dictionary

Not attached. I attest that all information will be provided where codes and/or value sets are needed (1.14a - 1.15c).

1.13a Attach Data Dictionary

2023_ClnscpyMeas_DD_ASCQR_OQR.xlsx

1.14 Numerator

The outcome for this measure is all-cause, unplanned hospital visits within seven days of a qualifying outpatient colonoscopy. The measure defines a hospital visit as any emergency

department (ED) visit, observation stay, or unplanned inpatient admission.

1.14a Numerator Details

The measure defines the outcome as any (one or more) hospital visit for acute care within seven days of an outpatient colonoscopy. A hospital visit includes any ED visit, observation stay, or unplanned inpatient admission. If more than one unplanned hospital visit occurs, only the first hospital visit within the outcome timeframe is counted in the outcome.

The measure defines ED visits and observation stays using billing codes or revenue center codes identified in Medicare Part B outpatient hospital claims. The data dictionary (tab "Colonos Outcome ED Obs Stay") provides the specific codes used to identify ED visits and observation stays.

Outcome Time Frame

The measure limits the outcome of hospital visits to seven days, as existing literature suggests that the vast majority of adverse events after a colonoscopy occur within the first seven days following the procedure, and our empirical analyses during measure development indicated that the highest rates of hospital visits were within seven days of colonoscopy. Thus, based on existing literature and empirical findings, as well as input from the TEP and public comment, the measure development team concluded that unplanned hospital visits within seven days is the optimal outcome to ensure capture of procedure-related adverse events and to minimize capture of hospital visits unrelated to the procedure.

Identification of Planned Admissions

Inpatient admissions within the first 7 days after the colonoscopy are included unless the admission is deemed a "planned" admission as defined by the measure's Planned Admission Algorithm (PAA). The Centers for Medicare & Medicaid Services (CMS) seeks to count only unplanned admissions in the measure outcome, because variation in "planned" admissions does not reflect quality differences. We based the PAA on the CMS Planned Readmission Algorithm (PRA), which CMS created for its hospital-wide readmission measure. The measure does not consider observation stays or ED visits as planned.

In brief, the algorithm identifies admissions that are typically planned and may occur after the patient's index event. The algorithm always considers a few specific, limited types of care planned (e.g., major organ transplant, rehabilitation, or maintenance

chemotherapy). Otherwise, the algorithm defines a planned admission as a non-acute admission for a scheduled procedure (e.g., total hip replacement or cholecystectomy), and the algorithm

never considers admissions for acute illness or for complications of care planned. For example, the algorithm considers hip replacement unplanned if hip fracture (an acute condition) is the discharge diagnosis but planned if osteoarthritis (a non-acute condition) is the discharge diagnosis. The algorithm considers admissions that include potentially planned procedures with acute diagnoses or that might represent complications of a colonoscopy unplanned and thus counts these admissions in the measure outcome.

For more information about the PAA, please see the Facility 7-day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure 2023 Measure Updates and Specifications Report.

Also see sheets 'PAA1 Always Planned Px', 'PAA2 Always Planned Dx', 'PAA3 Post Planned Px', and 'PAA4 Acute Dx' in the attached Data Dictionary for the most up-to-date sets of codes in the algorithm for 'always planned procedures,' 'always planned diagnoses,' 'potentially planned procedures, and 'acute' diagnoses.

1.15 Denominator

The target population for this measure includes low-risk colonoscopies performed in the outpatient setting (HOPD or ASC) for Medicare FFS patients aged 65 years and older. The measure is calculated separately for procedures performed at HOPDs vs ASCs and reported stratified by dual eligibility for HOPDs.

1.15a Denominator Details

The denominator includes colonoscopies performed at hospital outpatient departments (HOPDs) and (separately) ambulatory surgical centers (ASCs) for Medicare FFS patients aged 65 years and older.

The target population is patients aged 65 years and older who have a colonoscopy, to screen for colorectal cancer, biopsy or remove pre-cancerous lesions, or evaluate non-emergent symptoms and signs of disease. We limited the measure cohort to patients who are 65 and older, enrolled in Medicare FFS, and have been enrolled in Part A and Part B Medicare for the 12 months prior to the date of procedure since national data linking risk factors, procedures, and outcomes across care settings are only available for this group.

Eligible colonoscopies were identified using specified Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) procedure codes in the Medicare professional claims (Part B Physician). Specifically, we identified outpatient colonoscopies using physician claims from ASCs, HOPDs and physician office settings. For ASCs, the facility claim (with a unique facility identifier) is included on the professional (physician claim). Physician

claims for colonoscopies performed at HOPDs were linked to the corresponding facility claim.

The CPT and HCPCS procedure codes that define the cohort are in the attached Data Dictionary, sheet “Colonos Cohort.”

We considered all colonoscopy codes during development of the measure cohort. We did not include in the measure colonoscopy CPT procedure codes that reflected fundamentally higher-risk or different procedures. Those procedures billed with a qualifying colonoscopy procedure code and a high-risk colonoscopy procedure code (see attached Data Dictionary, sheet “Colonos Exclusions”) were not included in the measure.

Colonoscopy is not possible among patients who have had a prior total colectomy. Any claim for a colonoscopy in a patient with a prior total colectomy is therefore likely to be a coding error. We perform an error check to ensure the measure does not include these patients with a total colectomy recorded in their prior medical history. The CPT and HCPCS procedure codes and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes that define the total colectomy data reliability check are in the attached Data Dictionary, sheet “Colonos Exclusions.”

Capture of Colonoscopies Affected by the Medicare 3-Day Payment Window Policy:

Colonoscopies performed at HOPDs can be affected by the Medicare 3-day payment window policy. The policy states that outpatient services (including all diagnostic services such as colonoscopy) provided by a hospital or any Part B entity wholly owned or wholly operated by a hospital (such as an HOPD) in the three calendar days preceding the date of a beneficiary’s inpatient admission are deemed to be related to the admission. For outpatient colonoscopies affected, the facility claim (for the technical portion of the colonoscopy) is bundled with the inpatient claim, although the Medicare Part B physician claim for professional services rendered is still submitted. This policy has implications for the measure because it may lead to: (1) failure to completely capture outpatient colonoscopies performed at HOPDs; and (2) underreporting of outcomes for colonoscopies performed in the HOPD setting. To ensure the capture of HOPD colonoscopies, we identify physician claims for colonoscopy in the HOPD setting from Medicare Part B claims, which had an inpatient admission within three days and lacked a corresponding HOPD facility claim. We then attribute the colonoscopies identified as affected by this policy to the appropriate HOPD facility using the facility provider ID from the inpatient claim.

1.15b Denominator Exclusions

A diagram showing the inclusion and exclusion criteria for this measure is shown in Figure 1A (HOPDs) and 1B (ACSs) (see attachment).

We established the following exclusion criteria after reviewing the literature, examining existing measures, discussing alternatives with the working group and technical expert panel (TEP) members, reviewing feedback from the national dry run held in July 2015, and public reporting in 2018 and 2019, and annual re-evaluation of the measure. The goal was to be as inclusive as possible; we excluded only those high-risk procedures and patient groups for which risk adjustment would not be adequate or for which hospital visits were not typically a quality signal. The exclusions, based on clinical rationales, prevent unfair distortion of performance results.

Colonoscopy Measure Exclusion Criteria:

1) Colonoscopies for patients who lack continuous enrollment in Medicare FFS Parts A and B in the 7 days after the procedure.

Rationale: We exclude these patients to ensure full data availability for outcome assessment.

2) Colonoscopies that occur concurrently with high-risk upper gastrointestinal (GI) endoscopy procedures.

Rationale: Patients undergoing concurrent high-risk upper GI endoscopy procedures, such as upper GI endoscopy procedures for the control of bleeding or treatment of esophageal varices, and have a higher risk profile than typical colonoscopy patients. Therefore, these patients have a disproportionally higher risk for the outcome.

3) Colonoscopies for patients with a history of inflammatory bowel disease (IBD) or diagnosis of IBD at time of index colonoscopy or on the subsequent hospital visit outcome claim. Rationale: We exclude these patients because:

• IBD is a chronic condition; patients with IBD undergo colonoscopy both for surveillance due to increased cancer risk and for evaluation of acute symptoms. IBD is likely to be coded as the primary diagnosis prompting the procedure irrespective of whether the patients are undergoing a screening procedure or a diagnostic procedure in the setting of an acute exacerbation of IBD. Therefore, we may not be able to adequately risk adjust for these patients, as we cannot identify relatively well versus acutely unwell patients among visits coded as IBD.

• Our aim is to capture hospital visits which reflect the quality of care. Admissions for acutely ill IBD patients who are evaluated with an outpatient colonoscopy and are subsequently admitted for medical treatment of an IBD flare do not reflect the quality of the colonoscopy. During measure development (see the 2014 Facility 7-day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure Technical Report we found that more than one-third of IBD patients admitted to the hospital with colonoscopy had a discharge diagnosis of IBD, indicating their admission was for medical treatment of their IBD. We therefore excluded this group so that

providers who treat a disproportionate number of IBD patients will not be disadvantaged in the measure.

• A post-index diagnosis of IBD, which represents a very small fraction of cases (less than 0.5% of the cohort) in the measure population, indicates that the condition was likely present at the time of the index colonoscopy but not coded.

4) Colonoscopies for patients with a history of diverticulitis or diagnosis of diverticulitis at time of index colonoscopy or on the subsequent hospital visit outcome claim.

Rationale: We exclude these patients because:

• It is unclear what the health status is of patients coded with a history or current diagnosis of diverticulitis, making it difficult to fully risk adjust for patients' health. Colonoscopies performed on patients with a history or current diagnosis of diverticulitis are likely to be coded as diverticulitis as the primary diagnosis irrespective of whether the patients are undergoing a screening procedure or a diagnostic procedure (i.e., are acutely unwell with active disease). Furthermore, the codes for diverticulitis and diverticulosis may not be consistently used; patients with diverticulosis may be erroneously coded as diverticulitis. Therefore, we may not be able to adequately risk adjust as we cannot identify relatively well versus acutely unwell patients among visits coded as diverticulitis.

• Admissions for acutely ill patients with a history or current diagnosis of diverticulitis who are evaluated with an outpatient colonoscopy and are subsequently admitted for medical treatment of do not reflect the quality of the colonoscopy. During measure development (see the Facility 7-day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure Technical Report) we found that more than one-quarter of patients with a history or current diagnosis of diverticulitis admitted to the hospital post colonoscopy had a discharge diagnosis of diverticulitis, indicating they were admitted for medical treatment of the condition. These admissions are likely unrelated to the quality of the colonoscopy. We therefore excluded this group so that providers who treat a disproportionate number of diverticulitis patients will not be disadvantaged in the measure.

• A post-index diagnosis of diverticulitis, which represents a very small fraction of cases (less than 0.5% of the cohort) in the measure population, indicates that the condition was likely present at the time of the index colonoscopy but not coded.

5) Colonoscopies followed by a subsequent outpatient colonoscopy procedure within 7 days.

Rationale: In these situations, the two colonoscopies are considered part of a single episode of care, for which the subsequent colonoscopy is considered the index procedure.

In addition, for colonoscopies performed at HOPDs, we exclude:

6) Colonoscopies that occur on the same day and at the same hospital as an emergency department (ED) visit that is billed on a different claim than the index colonoscopy, unless the ED visit has a diagnosis indicative of a complication of care.

Rationale: It is unclear whether the colonoscopy or ED visit occurred first. If the ED visit is coded with a diagnosis indicative of a complication of care, the measure assumes the ED visit occurred after the colonoscopy procedure and is counted in the measure. It is unlikely that a patient would experience an ED visit for an acute diagnosis at 1 facility and then travel to another facility for a routine colonoscopy on the same day. Accordingly, ED visits billed on the same day as a colonoscopy but at a different facility are included because they likely represent a routine procedure followed by a complication of care.

7) Colonoscopies that are billed on the same hospital claim as an ED visit and that occur on the same calendar day, unless the ED visit has a diagnosis indicative of a complication of care.

Rationale: In these situations, it is not possible to use claims data to determine whether the colonoscopy was the cause of, subsequent to, or during the ED visit. However, if the ED visit is coded with a diagnosis for a complication, the assumption is that it occurred after the colonoscopy procedure.

8) Colonoscopies that are billed on the same hospital outpatient claim and that occur after the ED visit.

Rationale: In these situations, we assume that the colonoscopy was subsequent to the ED visit and may not represent a routine colonoscopy procedure. Timing of the ED visits is determined using revenue center dates from the outpatient claim.

9) Colonoscopies that are billed on the same hospital outpatient claim as an observation stay.

Rationale: In these situations, it is not possible to use claims data to determine whether the colonoscopy was the cause of, subsequent to, or during the observation stay.

1.15c Denominator Exclusions Details

1) Colonoscopies for patients who lack continuous enrollment in Medicare FFS Parts A and B in the 7 days after the procedure. Lack of continuous enrollment in Medicare FFS for 7 days after the procedure is determined by patient enrollment status in FFS Parts A and B using the Medicare Enrollment Database. The enrollment indicators must be appropriately marked for the month(s)

which fall within 7 days of the procedure date.

2) Colonoscopies that occur concurrently with high-risk upper GI endoscopy procedures. The list of the CPT codes for the upper GI endoscopy procedures identified as “high-risk” are in attached Data Dictionary, sheet “Colonos Exclusions”

3) Colonoscopies for patients with a history of IBD or diagnosis of IBD at time of index colonoscopy or on the subsequent hospital visit outcome claim. The ICD-10-CM codes that define IBD are in the attached Data Dictionary, sheet “Colonos Exclusions.”

4) Colonoscopies for patients with a history of diverticulitis or diagnosis of diverticulitis at time of index colonoscopy or on the subsequent hospital visit outcome claim. The ICD-10-CM codes that define diverticulitis are in the attached Data Dictionary, sheet “Colonos Exclusions.”

5) Colonoscopies followed by a subsequent outpatient colonoscopy procedure within 7 days. For cases in which a colonoscopy is followed by another colonoscopy within 7 days, the measure will use the subsequent colonoscopy as the index colonoscopy.

The following are in addition to those above, but only for HOPDs:

6) Colonoscopies that occur on the same day and at the same hospital as an ED visit that is billed on a separate claim than the index colonoscopy, unless the ED visit has a diagnosis indicative of a complication of care. The billing and revenue center codes that define ED visits are in the attached Data Dictionary, sheet “Colonos Outcome ED Obs Stay.” The same facility is defined as having the same CMS Certification Number (CCN). Complications of care codes are shown in tab “Colonos Exclusions ED CoC” include the CCS categories such as “Complications of surgical procedures or medical care,” “Adverse effects of medical care,” and others.

7) Colonoscopies that are billed on the same hospital claim as an ED visit and that occur on the same calendar day, unless the ED visit has a diagnosis indicative of a complication of care.

The billing and revenue center codes that define ED visits are in the attached Data Dictionary, sheet “Colonos Outcome ED Obs Stay.” Complications of care codes are shown in tab “Colonos Exclusions ED CoC” include the CCS categories such as “Complications of surgical procedures or medical care,” “Adverse effects of medical care,” and others.

8) Colonoscopies that are billed on the same hospital outpatient claim and that occur after the ED visit. The billing and revenue center codes that define ED visits are in the attached Data Dictionary, sheet “Colonos Outcome ED Obs Stay.”

9) Colonoscopies that are billed on the same hospital outpatient claim as an observation stay.

The billing and revenue center codes that define observation stays are in the attached Data Dictionary, sheet “Colonos Outcome ED Obs Stay.”

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

The measure is calculated separately for HOPDs and ASCs.

The measure uses a two-level hierarchical logistic regression model to estimate facility-level risk-standardized hospital visit rates (RSHVRs). This approach accounts for the clustering of patients within facilities and variation in sample size across facilities The RSHVR is calculated as the ratio of the predicted to the expected number of post-procedural unplanned hospital visits among a facility’s patients, multiplied by the national observed rate of unplanned hospital visits. For each facility, the numerator of the ratio is the number of hospital visits predicted for the facility’s patients, accounting for its observed rate and case mix. The denominator is the number of hospital visits expected nationally for the facility’s case mix. As noted above, to calculate a facility’s predicted-to-expected (P/E) ratio, the measure uses a two-level hierarchical logistic regression model. The log-odds of the outcome for an index procedure is modeled as a function of the patient demographics, comorbidities, procedure characteristics, and a random facility-specific intercept. A ratio greater than one indicates that the facility’s patients have more post-procedural hospital visits than expected, compared to an average facility with similar patients. A ratio less than one indicates that the facility’s patients have fewer post-procedural hospital visits than expected, compared to an average facility with a similar patient mix. A facility’s P/E ratio is then multiplied by the overall national rate of unplanned hospital visits to calculate the facility-level RSHVR. This approach is analogous to an observed-to-expected ratio, but accounts for within-facility correlation of the observed outcome and sample size differences, accommodates the assumption that underlying differences in quality across facilities lead to systematic differences in outcomes, and is tailored to and appropriate for a publicly reported outcome measure as articulated in published

scientific guidelines (Normand and Shahian, 2007; Krumholtz et al., 2007).

Below we outline the steps to calculate the measure score:

1. Identify colonoscopies meeting the inclusion criteria described above.

2. Exclude procedures meeting any of the exclusion criteria described above.

3. Identify and create a binary (0/1) flag for an unplanned hospital visit within 7 days of the colonoscopy.

4. Use patients' historical and index procedure claims data to create risk adjustment variables.

5. Fit a hierarchical generalized linear model (HGLM) to produce a ratio of the number of "predicted" hospital visits to the number of "expected" hospital visits for each facility, given its case mix. The HGLM is adjusted for clinical risk factors that vary across patient populations, are unrelated to quality, and influence the outcome.

6. Multiply the ratio estimated in step 3 by the observed national 7-day hospital visit rate, and then by 1,000 to obtain a risk-standardized hospital visit (RSHV) rate per 1,000 colonoscopies for each facility.

7. Use bootstrapping to construct a 95% confidence interval estimate for each facility's RSHV rate.

For more information about the measure methodology, please see the Facility 7-day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy 2023 Measure Updates and Specifications Report for HOPDs and ASCs.

HOPDs: https://qualitynet.cms.gov/files/651b5fb570a30f001c388004?filename=2023...

ASCs: https://qualitynet.cms.gov/files/651b5f9970a30f001c388001?filename=2023...

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1.19 Measure Stratification Details

The HOPD version of this measure is currently stratified by dual eligibility (DE), reported confidentially to hospitals.

In the Calendar Year (CY) 2022 OPPS Proposed Rule, CMS described a plan to stratify reporting using two disparity methods, described below, in the HOPD setting and have identified the colonoscopy measure as one of six priority measures included in the Hospital Outpatient Quality Reporting (OQR) program for confidential disparity reporting stratified by patient DE.

The two stratification methods are:

1. The Within-Facility Disparity Method, highlights differences in outcomes for patient groups based on social risk factors within an HOPD, and

2. The Across-Facility Disparity Method, illuminates variation in healthcare quality for patients with social risk factors across facilities.

The two methods are described in more detail below and visually shown in Figure 2 (see attachment with tables and figures). Details of the methodology can be found here: https://qualitynet.cms.gov/files/652fd45a8be3e0001c0b5141?filename=CY23...;

The **Within-Facility Disparity** Method reports differences in health outcomes between patient populations in the same facility. The goal of this method is to assess the difference in outcomes for two patients with the same condition and medical history but with different social risks. This method can answer the question: “Does a patient with a social risk factor experience similar health outcomes as a patient without that social risk factor when cared for at the same facility?”

The **Across-Facility Disparity** Method reports facility outcome rates for one patient population with a particular social risk factor across facilities. This method can answer the question: “How does the outcome rate for patients with a social risk factor at a specific facility compared to the outcome rate for patients with that social risk factor at an average facility?”

Please see Section 5, Equity, for results for the HOPD colonoscopy method when applying these two disparity methods.

1.20 Types of Data Sources

Administrative Data, Claims Data

1.25 Data Source Details

To calculate the measure score CMS uses final-action claims for Medicare FFS Part A and B and the Medicare Enrollment Database.

This is a claims-based measure and the measure score is calculated automatically from 100% final-action claims; claims data are routinely generated during the delivery of care. We did not encounter any difficulties with respect to data feasibility, reliability, or validity.

1.26 Minimum Sample Size

Not applicable. This measure is not based on a sample.

2.2 Evidence of Measure Importance

Below we review the evidence that supports our logic model (see Figure 3 in attachment) for the connection between both structure and process, outcomes (complications), and post-procedural acute hospital visits, the outcome captured by the Colonoscopy measure. Please see the “measure rationale” section for additional information.

Processes related to the procedure, such as adhering to clinical best practices for the procedure itself, and adhering to evidence-based infection control processes, are tied to outcomes such as complications. More common complications such as nausea and vomiting, as well as more rare complications such as cardiovascular complications, and pneumonia, can be related to anesthesia; excessive sedation may lead to hypoxia, hypotension, respiratory arrest, and aspiration pneumonia (Bielawska et al., 2018). For example, a 2018 retrospective claims-based analysis of more than 3 million outpatient colonoscopies found that the use of anesthesia assistance (sedation with agents that result in deeper sedation, such as Propofol, rather than conscious sedation), resulted in increased risk of aspiration pneumonia (OR, 1.63; 95% CI, 1.11–2.37) (Bielawska et al. 2018). Post-procedural infections can be caused by improper infection

control processes as well as defective equipment, and ASCs have admitted to lapses in infection control procedures (Petersen et al., 2017). Facilities ensure that providers follow best practice guidelines for the procedure, outlined within practice guidelines of professional societies (ASGE, 2018a; ASGE 2018b).

Processes before, during, and after discharge can reduce complications and hospital visits following a procedure. For example, identifying patients at higher risk for a complication, good patient communication, medication reconciliation, and providing access to non-acute care, can reduce post-discharge complications and the need for hospital-based acute care. (Kothari et al., 2022; Thompson et al., 2016; Padmanabhan et al., 2016; Grossberg et al., 2018). Interventions around post-discharge communication have been shown to reduce post-discharge hospital care and improve patient satisfaction (Becker et al., 2021).

Structural (provider- and facility-level) factors can affect the outcome of complications and hospital visits related to a colonoscopy. For example, provider-level factors such as low provider volume and fellow involvement in the procedure were significantly associated with a higher risk of an ED visit in one study (Grossberg et al., 2018), and low procedure volume was associated with a higher risk of infection in another study (Wang et al., 2018), suggesting that facilities can influence patient outcomes through these modifiable pathways. Additionally, endoscopists trained as gastroenterologists and endoscopists with higher colonoscopy volumes have lower complication rates compared to non-gastroenterologists or low-volume endoscopists, respectively (Bielawska et a., 2014).

There is clear evidence that complications related to the processes and structures (or lack of those processes and structures) described above, are linked to post-procedural hospital visits. As described in more detail in the “measure rational section” and summarized here. A 2018 study that categorized chart-abstracted chief complaints from ED visits within 7 days after a hospital visit found that most (68%) were related to the colonoscopy (Grossberg et al., 2018). Other studies, and our own analysis of principal discharge diagnosis codes show that the most frequent reasons for a hospital visit are complications related to the procedure (Ranasinghe et al., 2016; see section 4.3, Validity in this submission).

Providers may be unaware of complications for which patients visit the hospital, leading to understated complication rates and suggesting the need for better measurement to drive quality improvement.

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2.4 Performance Gap

There remains variation in measure scores among facilities. Below we provide the distribution of measures scores, as well as evidence of variation through the median odds ratio. We have seen improvement in this measure score, for both HOPDs and ASCs, over time. Please see Section 6.2.4 on improvement for more information.

Measure score distribution

Tables 1A and 1B, and 2A and 2B, shows the distribution of measure scores, the risk-standardized hospital visit rate, or RSHVR, using the most recent testing data (2024 EM Dataset; July 1, 2020-December 31, 2022) for HOPDs, and ASCs (per 1,000 colonoscopies). Histograms are presented in Figure 4A (HOPD) and 4B (ASC), in the attachment.

For HOPDs, RSHVRs range from 9.13 to 18.14; the median is 13.13; the 25th percentile is 12.74 and the 75th percentile is 13.61. This indicates that the best performer (9.13 per 1,000 colonoscopies) is performing about 30 percent better than the median, and the worst performer (18.14) is performing about 38 percent worse than the median.

For ASCs, RSHVRs range from 6.29 to 14.16; the median is 9.85; the 25th percentile is 9.42 and the 75th percentile is 10.37. This indicates that the best performer (6.29 per 1,000 colonoscopies) is performing about 36 percent better than the median, and the worst performer (14.16) is performing about 44 percent worse than the median.

Median odds ratio

We provide further evidence of variation by calculating and interpreting the median odds ratio (MOR) (Merlo, et al., 2006). The MOR represents the median increase in odds of a hospital visit if a procedure on a single patient was performed at a higher risk facility compared to a lower risk facility. It is calculated by taking all possible combinations of facilities, always comparing the higher risk facility to the lower risk facility. The MOR is interpreted as a traditional odds ratio would be.

The median odds ratio for this updated analysis for HOPDs is 1.19 and for ASCs is 1.21. The median odds ratio suggests a meaningful increase in the risk of a hospital visit if a colonoscopy was performed at a higher risk facility compared to a lower risk facility. A value of 1.19 for HOPDs and ASCs indicates that a patient has a 19 percent increase, or a 21 percent increase in the odds of a hospital visit if the colonoscopy was performed at higher risk facility compared to a lower risk facility (for an HOPD and ASC, respectively) indicating the impact of quality on the outcome rate is meaningful.

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Table 1. Performance Scores by Decile

Performance Gap

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean Performance Score	13.18	9.13	11.56	12.40	12.74	12,94	13.07	13.18	13.38	13.63	14.02	14.93	18.14
N of Entities	3,775	1	377	378	377	378	377	378	378	377	378	377	1
N of Persons / Encounters / Episodes	1,747,993	3,606	506,806	210,522	151,798	101,998	63,409	83,284	131,654	123,112	153,100	222,250	1,303

2.6 Meaningfulness to Target Population

This measure includes colonoscopies performed to screen for colorectal cancer (in addition to other qualifying colonoscopies). Screening for colorectal cancer is a U.S. Preventive Services Task Force (USPSTF) “A” recommendation for adults aged 50-75 and a “B” recommendation for adults aged 45-49 (Lin, JS et al., 2021), and millions of colorectal cancer screenings (a large proportion of them colonoscopies) are performed each year.

A hospital visit following a colonoscopy is an unexpected, undesired, and potentially preventable outcome that is important to patients and providers. Providers may be unaware of their patients’ hospital visits after surgery because patients often present to the ED or to different hospitals, leading to understated adverse event rates and suggesting the need for better measurement to drive quality improvement. Therefore, both patients and providers benefit from outcome measures

of hospital visits – a broad, patient-centered outcome that reflects the full range of reasons leading to hospitalization among patients undergoing a colonoscopy.

Colorectal cancer screenings are elective, so patients must choose to receive the screening. However, due to patient concerns about the procedures (related to anticipated discomfort of the preparation or the procedure itself), efforts have been made to better understand the patients' perspective related to screening. A 2022 study aimed to identify quality domains that map to patients' experiences and concerns around colonoscopy; study authors found that, among other domains, "information" as a concept that fit within the model describing patients' experiences and needs (Rosvall et al., 2022). Information about colonoscopy could include instructions on the preparation prior to and care after a colonoscopy, but also could include information on the quality of care provided by the facilities (and their providers) performing the service. In a study of patient self-reported complications, patients with complications rated the information they received about their surgery lower compared with patients who did not experience a complication. In addition, patients who reported experiencing a complication were more likely to experience post-operative pain, and lower quality of life (Woodfield et al., 2019).

The Colonoscopy measures is part of the Hospital Outpatient Quality Reporting (HOQR) and the Ambulatory Surgical Center Quality Reporting (ASCQR) programs; both pay-for-reporting programs (not pay-for-performance). Currently, there are no other publicly available quality reports related to this procedure which underscores the measurement gap that would exist without this measure. Thus, this measure addresses an important quality measurement area and enhances the information available to patients choosing among HOPDs/ASCs that provide screening colonoscopies. Furthermore, providing outcome rates to HOPDs and ASCs makes visible to clinicians and facilities meaningful quality differences and incentivizes improvement.

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3.1 Contributions Towards Closing Care Gaps

At the patient level, we know that patients with social risk factors (present in our conceptual model) may have higher unadjusted outcomes (hospital visit rates) following an outpatient colonoscopy, but differences vary depending on the social risk factor. For example, at the patient level, for HOPDs we found that patients with dual eligibility (DE) have an unadjusted hospital visit rate of 23.8%, compared with 12.6% for patients without DE. Patients with high ADI, however, have unadjusted hospital visit rates of 17.0%, vs. 12.7% for patients without high ADI. A similar pattern is observed for patients who received their colonoscopies at ASCs (see Table 12 in the attachment).

Measure Stratification

Due to these observed disparities in outcomes and the desire to shed light on and improve outcomes for all patients, CORE has developed for CMS (as described in the "stratification" section of this CBE submission) a disparities stratification methodology. Please see Section 1.19, "Measure Stratification Details," for more information about the methodology; here we provide the most recent results for both the within-facility disparities method (which compares care within a hospital, comparing their DE with non-DE patients) and the across-facility method (which compares facility-level outcomes for DE patients to the national average for all DE patients). The full methodology and results are available in more detail in this report:

https://qualitynet.cms.gov/files/652fd45a8be3e0001c0b5141?filename=CY23...

For the disparities analysis described below, we used data from July 1, 2019 through June 30, 2021.

For the within-hospital approach, we found that more hospitals have worse outcomes for their DE patients compared with their non-DE patients. In these analyses, there were 1,736,193 procedures overall; 86,620 (5%) of patients were dual eligible (DE); 976 of 3,379 facilities (29%) had sufficient volume for reporting. Eligible hospitals are defined as hospitals with at least one patient with DE and one patient without DE. Reporting HOPDs must have at least 25 patients with DE and 25 patients without DE.

We characterized performance using the within-facility approach at the facility level, using rate difference cutoffs of: "better" outcomes as rate differences of less than -1%; "worse" outcomes as rate differences of >1%, and "similar" outcomes for rate differences between -1% and +1%. Using these categories, we found that 151 hospitals (4.5%) were characterized as "better," 275 hospitals (8.1%) were characterized as "worse" and the remaining 550 (16.3%) were characterized as

"similar" for their outcomes for DE patients compared with non-DE patients. Most hospitals (71.1%) had too few cases to be evaluated. There was a 1.8 percent rate adjusted rate difference (mean facility difference between DE and non-DE patients) indicating overall worse performance for DE patients.

For the **across-facility disparities** approach, we found only one facility had outcomes for DE patients that were performed better than the national rate, and 2 facilities that were worse; 513 (15.1%) were no different than the national rate and most hospitals (84.8%) did not have sufficient number of DE patients. In this analysis there were 86,648 DE procedures, 3,392 eligible facilities (with at least one DE patient), and 516 facilities eligible for reporting (those with at least 45 DE patients) (15.2%).

Publicly reported measure

The version of the Colonoscopy measure that is publicly reported is not adjusted for social risk factors. We performed two analyses to explore the impact of adding either of two social risk factors (DE, and ADI) to the model, on measure scores. We found that adding either social risk factor to the model did not result in meaningful impacts on measure scores, suggesting that the variables in the risk model account for most of the differences we see in unadjusted patient-level outcome rates. Therefore, in this pay-for-reporting program, providers will not be unfairly profiled when assessed by the Colonoscopy measure as specified for public reporting. We describe the analyses and results below. All analyses described below used the 2024 EM Dataset.

To examine the impact of social risk factors on measure scores, we first examined correlations (Pearsons) between measure scores with and without either social risk factor and found that correlations were near 1 (HOPDs: 0.997, and 0.997, for DE and high ADI, respectively; ASCs: 0.996, and 0.998, for DE and high ADI, respectively) (Figures 7A, 7B, and 8A, 8B in attachment of tables/figures).

Second, we examined the association (Spearman) between the facility proportion of patients with each social risk factor and measure scores, focusing on the quartile of facilities with the highest proportion of patients with social risk factors (Figures 9A, 9B, and 10A, 10B in the attachment of tables/figures). We found that for HOPDs there no significant correlation (r=-0.024, p=.51) between the proportion of patients with DE and the measure score for the fourth quartile of facility-proportion of patients with DE, and no significant correlation for the high ADI variable (r=-0.02, p=.63). We found similar results for ASCs (r=-0.056, p=.22; r=0.014, p=.77).

We concluded therefore, that there is little to no impact of adding social risk factors on measure scores for this HOPD Surgery measure. As described above, however, CMS has implemented confidential reporting of the measure, stratified for DE.

4.1 Feasibility Assessment

This is a claims-based measure and as mentioned above, the measure score is calculated automatically from claims data which are routinely generated during the delivery of care. No data

are collected by facilities; therefore, this measure imposes no burden on measured entities, and no implementation effort. CMS monitors feedback from the public and measured entities through CMS's Q&A portal on *QualityNet*; there have been no concerns about burden related to this measure. There are no concerns about patient confidentiality because the measure is based on claims data submitted by facilities to CMS, and CMS then uses that data for both payment and calculation of the measure score.

We did not perform an analysis of missing data for the measure because it is based on a 100% sample of paid, final action claims submitted by facilities for payment. To ensure complete claims, we allow at least 3 months of time between accessing the data and the end of the performance period.

4.3 Feasibility Informed Final Measure

Because this is a claims-based measure the is no burden on the facility; rates are automatically calculated by CMS based on claims data submitted by facilities for payment.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

5.1.1 Data Used for Testing

We use paid, final action Medicare claims to identify colonoscopies performed in the outpatient setting at Hospital Outpatient Departments (HOPDs) and Ambulatory Surgical Centers (ASCs), including subsequent hospital visits. In addition, we use the Center for Medicare and Medicaid Services (CMS) enrollment and demographic data to determine inclusion and exclusion criteria. Patient history is assessed using claims data collected in the 12 months prior to the colonoscopy procedure. The measure is calculated separately for HOPDs and ASCs, and the results in this form are presented separately by facility type. Please see the numerator and denominator details sections for additional information. Please see Table 3 (attachment) for details on the different datasets used for testing (original development, and this endorsement maintenance submission).

5.1.2 Differences in Data

Please see Table 3 (attachment) for details.

5.1.3 Characteristics of Measured Entities

Please see Table 3 (attachment) for details.

5.1.4 Characteristics of Units of the Eligible Population

Please see Table 3 (attachment) for details.

5.2.1 Level(s) of Reliability Testing Conducted

Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

We tested facility-level measure score reliability using the signal-to-noise method, using the formula presented by Adams and colleagues (Yu et al., 2013; Adams et al., 2010). Specifically, for each facility we calculate the reliability as:

Reliability=(σ_(facility-to-facility)^2)/(σ_(facility-to-facility)^2+ (σ_(facility error variance)^2)/n)

Where facility-to-facility variance is estimated from the hierarchical logistic regression model, n is equal to each facility's observed case size, and the facility error variance is estimated using the variance of the logistic distribution (pi^2/3).

Signal-to-noise reliability scores can range from 0 to 1. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real difference in performance.

We calculated the measure score reliability (using the 2024 EM Dataset) for all facilities, and for facilities with a volume cutoff of 30 procedures. Our rationale for this is described below.

In general, CMS sets the volume cutoff for publicly reporting facility measures scores based on two considerations. CMS considers the empiric results of reliability testing conducted on the dataset used for public reporting. CMS also considers the volume cutoff for score reporting used for related measures. CMS has empirically determined that measure scores for facilities with 30 or more procedures are reliable. Regardless of the score reporting volume cutoff, all facilities and their cases are used in calculating the measure scores. In the dry run and in public reporting CMS typically reports scores for facilities with fewer procedures than the volume cutoff as having "too few cases" to support a reliable estimate. In summary, the measure specifications do not prejudge the ideal volume cutoff. The minimum sample size for public reporting is a policy choice that balances considerations such as the facility-level reliability testing results on the reporting data and consistency across measures for consumers.

References

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5.2.3 Reliability Testing Results

The distribution of measure score reliability (signal-to-noise reliability) for HOPDs and ASCs is shown in Table 4 and Table 5 (see attachment).

HOPDs: Using three years of performance data, the median facility-level reliability score is 0.748 (IQR, 0.555 - 0.872) for HOPDs with at least 30 cases (the public reporting threshold) representing moderate reliability (Table 4 and Table 6A in the attachment).

ASCs: Using three years of performance data, the median facility-level reliability score for ASCs is 0.822 (IQR, 0.752 - 0.948) for ASCs with at least 30 cases (the public reporting threshold) representing moderate reliability (Table 4 and Table 6B in the attachment).

We note that there is only one embedded table in the Battelle form, which we used for the HOPD data. The ASC results can be found in Table 6B in the attachment.

5.2.4 Interpretation of Reliability Results

HOPDs

Using three years of performance data, the median facility-level reliability score is 0.748 (IQR, 0.555 - 0.872) for HOPDs with at least 30 cases (the public reporting threshold) representing moderate reliability.

At the current public reporting threshold, most facilities (about 75 percent of facilities with at least 30 cases) fall above the 0.6 minimum threshold stated in Battelle's current CBE guidebook. If CMS were to increase the case volume minimum so that all facilities exceeded this threshold, it would remove publicly available information from about 205 facilities that are currently publicly reported.

We believe that median reliability of 0.6 (signal to noise) is sufficiently high for a facility-level publicly reported measure in a pay for reporting program. Increasing the minimum case volume for HOPDs has the tradeoff of removing important information available to the public on *Care Compare*.

ASCs

Using three years of performance data, the median facility-level reliability score for ASCs is 0.822 (IQR, 0.752 - 0.948) for ASCs with at least 30 cases (the public reporting threshold) representing moderate reliability.

At the current public reporting threshold of at least 30 cases, most facilities (all but the first decile) meet the 0.6 minimum threshold stated in Battelle's current CBE guidebook.

Table 2. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Accountable Entity-Level Reliability Testing Results

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Reliability	0.700	0.314	0.314	0.446	0.552	0.636	0.714	0.778	0.829	0.872	0.909	0.953	0.992
Mean Performance Score	13.18	13.24	13.24	13.27	13.28	13.27	13.31	13.39	13.22	13.24	13.09	12.52	13.45
N of Entities	3,270	16	329	320	329	330	327	327	328	325	328	327	1
N of Persons / Encounters / Episodes	1,741,827	480	14,554	24,790	38,896	55,511	78,332	109,905	153,040	212,800	318,259	735,740	11,595

5.3.1 Level(s) of Validity Testing Conducted

Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.3 Method(s) of Validity Testing

For this endorsement maintenance submission, we provide evidence of validity through: face validity conducted during measure development, validation of the outcome, empiric validity through associations with volume, and evidence of improvement in the measure score. Below we describe the methodology; the results are provided in the subsequent section.

Face validity

We assessed measure validity through systematic assessment of measure face validity by a technical expert panel (TEP) of national experts and stakeholder organizations.

To convene the TEP, we released a public call for nominations and selected individuals to represent a range of perspectives including clinicians, patients, and individuals with experience in quality improvement, performance measurement, and healthcare disparities. We held three structured TEP conference calls consisting of presentation of key issues, our proposed approach, and relevant data, followed by open discussion among TEP members.

The TEP, made up of 17 members including patient representatives, expert clinicians, methodologists, researchers, and providers, were asked to formally assess the measure's face validity. We systematically assessed the face validity of the measure score as an indicator of quality by soliciting TEP members' agreement with the following statement: "The risk-standardized hospital visit rates obtained from the colonoscopy measure as specified can be used to distinguish between better and worse quality facilities."

The 14 TEP members who responded to the survey indicated their agreement with the face validity of the measure on a six-point scale:

1=Strongly disagree

2=Moderately disagree

3=Somewhat disagree

4=Somewhat agree

5=Moderately agree

6=Strongly agree

List of TEP Members

1. Joel Brill, MD; Predictive Health LLC (Chief Medical Officer); Fair Health (Medical Director)
2. Zahid Butt, MD; Medisolv Inc. (CEO)
3. David Chang, PhD, MPH, MBA; University of California San Diego (Director of Outcomes Research, Assistant Professor, Department of Surgery)
4. Richard Dutton, MD, MBA; Anesthesia Quality Institute (Executive Director)
5. Brian Fennerty, MD; Oregon Health and Science University (Professor of Medicine, Department of Internal Medicine, Section of Gastroenterology)
6. Terry Golash, MD; Aetna, Inc. (Senior Medical Director)
7. Claudia Gruss, MD; Arbor Medical Group, a division of ProHealth (Physician Partner)
8. Cynthia Ko, MD, MS; University of Washington (Associate Professor, Division of Medicine; Adjunct Associate Professor, Department of Health Services)
9. David Lieberman, MD; Oregon Health and Science University (Professor of Medicine; Chief, Division of Gastroenterology and Hepatology)
10. Keith Metz, MD, JD, MSA; Great Lakes Surgical Center (Medical Director)
11. Michael Morelli, MD, CPE; Indianapolis Gastroenterology and Hepatology (President)
12. Philip Schoenfeld, MD, MSEd, MSc; University of Michigan (Professor of Medicine, Division of Gastroenterology)
13. Anthony Senagore, MD, MS, MBA; Central Michigan University, School of Medicine (Chair, Surgical Disciplines)
14. Joan Warren, PhD; Applied Research Program, NIH, National Cancer Institute (Epidemiologist)
15. Jennifer Weiss, MD, MS; University of Wisconsin School of Medicine and Public Health (Assistant Professor, Department of Medicine – Division of Gastroenterology & Hepatology)
16. 16, 17) Two patients

Validation of the Outcome

The outcome of an unplanned hospital visit following a low-risk elective procedure such as a colonoscopy, is intended to capture adverse events that occur as part of the care received before, during, and after the procedure. To validate the outcome, we examined identified the most commonly occurring principal discharge diagnosis codes associated with the post-procedure hospital visit. (For any hospitalization, a claim for the hospital visit is submitted to CMS that indicates the main reason for the hospitalization; there is only one such main reason, called the "principal diagnosis code" that is used to capture this information.) Based on previous research to validate the outcome during measure development, we know that the most frequent reasons for a post-colonoscopy hospital visit are complications from the procedure. We updated this analysis for this endorsement maintenance submission.

External Empiric Validity

One approach for assessing the validity of a quality measure is to show that performance on the test measure is associated with another quality measure in the same causal pathway. To do this, we needed to identify a comparator measure, however, as summarized below, we did not identify a suitable measure with currently publicly available data.

We first considered CMS's two related CBE-endorsed measures, Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at ASCs (ASC General Surgery), and Hospital Visits after Hospital Outpatient Surgery (HOPD Surgery). The outcome of both measures is nearly identical to that of the colonoscopy measure; an unplanned hospital visit is defined as an emergency department (ED) visit, observation stay, or unplanned inpatient admission. Hence, the measures target the same quality domains as the CMS colonoscopy measure. The patient cohort is also somewhat similar in that the measures target Medicare Fee-For-Service (FFS) patients aged 65 years and older. The cohorts, however, have no overlap with the colonoscopy measure, because they include patients undergoing general surgery, not colonoscopy procedures. Furthermore, the clinicians performing the procedures across the different cohorts are unlikely to be the same individuals, and in addition, most ASCs (about 70% as of 2022) subspecialize (MedPAC, 2024).

To identify non-CMS measures against which to validate, we first searched Battelle's website for measures related to colonoscopy specified for the HOPD or ASC level and identified only one measure: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients. This measure identifies the percentage of patients who have received a screening colonoscopy and have a regular recommended follow-up of ten years. This measure excludes patients who are older than 66 or who have a life expectancy of fewer than ten years, as the follow-up colonoscopy is no longer deemed beneficial. This measure is also not risk-adjusted. Because this follow-up measure does not assess the domains of quality measured by the CMS colonoscopy measure we would expected it to correlate with facilities' 7-Day Risk-Standardized Hospital Visit rate we therefore did not use it to externally validate the CMS measure.

In summary, none of the measures that we identified meet the criteria for a comparator measure that could be used for external validation.

Association with volume

Although the evidence is inconsistent, studies have shown a volume outcome relationship between colonoscopy volume (at the clinician level) and complications (Grossberg et. al., 2018; Wang et. al., 2018, Forbes et. al., 2020). We therefore assessed if higher facility colonoscopy volume was associated with the Colonoscopy measure score. We hypothesized that there would be a weak to moderate, negative relationship between facility procedural volume and colonoscopy measure scores, with higher volumes being associated with better (lower) Colonoscopy measure scores.

Evidence for improvement

The majority of hospitals download their facility-specific reports and claims-detail reports when they are released (three times per year). We also receive specific questions from facilities about these reports, so we know they are using them. As a result, we expect that hospitals, through their work with CMS's Quality Improvement Organizations (QIOs) and their own internal quality improvement, have put in place processes and procedures to improve the quality and coordination of care following outpatient colonoscopy, resulting in improvement in outcome rates. To empirically examine changes in risk-adjusted outcomes over time, we provide density plots (histograms, but without the bars) for the risk-standardized outcomes for each reporting period, comparing the current data used for this endorsement maintenance submission (July 1, 2020-December 31, 2022) with prior reporting periods.

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5.3.4 Validity Testing Results

Face Validity

The distribution of the responses is shown below:

- Mean rating=4.6.
- Frequency of Ratings of Agreement
- Rating, # (%) of Responses:
    - 1 (Strongly disagree): 0 (0)
    - 2 (Moderately disagree): 1 (7.1)
    - 3 (Somewhat disagree): 1 (7.1)
    - 4 (Somewhat agree): 2 (14.3)
    - 5 (Moderately agree): 8 (57.1)
    - 6 (Strongly agree): 2 (14.3)

Of the 14 TEP members who responded to the survey, 12 (86%) indicated they somewhat, moderately, or strongly agreed with the validity statement. In addition, one TEP member somewhat disagreed, and one TEP member moderately disagreed. The TEP member who moderately disagreed did not provide a reason. The reason for the other TEP member's disagreement can no longer be accessed due to software restrictions.

Validation of the Outcome

Tables 7A and 7B show the most frequent (the top 25) principal diagnosis codes associated with the outcome (unplanned hospital visits within 7 days of a qualifying colonoscopy). For example, For HOPDs, the top four principal diagnoses are "Post procedural hemorrhage….," "Hemorrhage of anus and rectum," "Gastrointestinal hemorrhage, unspecified," and "Urinary tract infection, site not specified." Many of the codes in the list in Table 7A (see attachment) indicate a complication from the procedure.

External empiric validity

As noted above, we did not identify any measures that were suitable for comparison with the colonoscopy measure, therefore we examined the association of the measure score with facility volume. Pearson's correlation coefficient for the association between measure scores and facility procedural volume was -0.224 for HOPDs; and -0.132 for ASCs.

Evidence of improvement

The colonoscopy measure went into public reporting in December 2017. Since that time, both the HOPD and ASC colonoscopy measures have shown improvement. For example, the national rate of hospital visits per 1,000 colonoscopies among HOPDs declined from 16.4 in 2018 reporting to 14.8 in 2019 reporting, and 13.2 in 2023 reporting (current data). The distribution of risk-standardized rates also show improvement; Figures 5A and 5B (see attachment) show this improvement graphically as density graphs (histograms without bars), showing an improvement in performance (current data shown in red solid line) in the distribution of risk-standardized rates (narrowing of the range of performance and a shift of performance to the left), for HOPDs (Figure 5A), and to a lesser extent for ASCs (Figure 5B). We note that in Figure 5A the results for 2016-2018 and 2017-2019 almost perfectly overlap so they appear superimposed.

5.3.5 Interpretation of Validity Results

Our results, shown above, demonstrate validity of the Colonoscopy measure at several levels for both ASCs and HOPDs: face validity as assessed by experts; validity of the outcome, shown by analysis of ICD-10 codes associated with the outcome; validity of the measure score as shown by association (in the expected direction) with procedural volume; and finally, evidence of improvement over five performance periods.

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis), Systematic assessment of face validity of the measure's performance score as an indicator of quality or resource use

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

Description of Risk Adjustment Method

We use a two-level hierarchical logistic regression model to estimate risk-standardized hospital visit rates (RSHVRs). This approach accounts for the clustering of patients within facilities and variation in sample size.

The risk-adjustment model includes 15 patient-level variables, including age, concomitant upper GI endoscopy, polypectomy during procedure, and 12 comorbidity variables obtained from inpatient, outpatient, and physician claims 12 months prior to index procedure. The 2023 Colonoscopy Measure Data Dictionary tab "Colonos Risk Factor CCs" presents the definition of these variables, based on CMS's hierarchical CCs. The measure does not include certain diagnoses that occur only at the time of the colonoscopy procedure toward risk adjustment because these diagnoses may represent complications of care; see the 2023 Colonoscopy Measure Data Dictionary tab "Colonos CoC CCs" for a summary of these diagnoses.

Selection of Risk-Adjustment Variables during Measure Development

Candidate risk-adjustment variables were patient-level risk adjustors that are expected to be predictive of hospital visits following colonoscopy, based on prior literature, clinical judgment, and empirical analysis. We limited our initial selection of candidate variables for inclusion in our preliminary colonoscopy-specific risk-adjustment model to variables with a strong clinical rationale for inclusion as identified in the literature and through clinical expert input. These variables include age, sex, indicators of comorbidity and disease severity, and two procedural factors associated with an increased risk of adverse outcomes following colonoscopy (concomitant upper GI endoscopy and polypectomy during the procedure).

Variable Selection

To select the final variables to include in the risk-adjustment model, using Dataset #1, we fitted a logistic regression model to predict the outcome with the candidate variable set. To develop a parsimonious model, we then removed non-significant variables from the initial model using a

stepwise purposeful selection method described by Hosmer and Lemeshow (2000). Our goal was to minimize the number of variables in the model while preserving model performance (as measured by the c-statistic). During this process, the least significant variable in the model was removed one at a time until only statistically significant ($p<0.05$, assessed using a likelihood ratio test) variables remained in the model. Interaction terms between variables were tested and were only retained in the model if significant at a level of $p<0.01$. The higher threshold for statistical significance ensured that only interactions that have a higher likelihood of being true interactions were included.

More detail about risk adjustment variable selection, including a list of candidate risk adjustment variables, can be found in the "Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy Measure Technical Report," 2014: https://www.qualitynet.org/files/5d0d37ae764be766b010196e?filename=Clns....

Social Risk Factors for Disparities Analyses

We selected variables representing social risk factors based on a review of literature, conceptual pathways, and feasibility. Below, we describe the pathways by which social risk factors may influence risk of the outcome.

Causal Pathways for Social Risk Variable Selection

Our conceptualization of the pathways by which patients' social risk factors affect the outcome was informed by the literature and IMPACT Act–funded work by the National Academies of Sciences, Engineering and Medicine (NASEM) and the Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) (ASPE, 2016; NASEM, 2016).

Literature Review of Social Risk Variables and Ambulatory Surgery Post-Procedure Hospital Visits

To inform a conceptual model for the relationship of social risk factors to the outcome we performed a literature search during development of the related Hospital Visits After Outpatient Surgery measure, which included articles that contained key words in the title or abstract related to outpatient surgeries or procedures, socioeconomic and sociodemographic disparities, and hospital visits (emergency department, observation, or hospital admission). A total of 176 studies were reviewed by title and abstract. There were no studies that addressed colonoscopy specifically, therefore we did not find any studies that suggested that variation in patients' social risk factors affected variation in colonoscopy outcome risk across facilities.

For this 2024 submission we have reviewed our original conceptual model related to social risk factors and have determined that the original conceptual model remains valid. We note that for colonoscopy, which is a screening procedure, it is well documented that there are disparities for patients with social risk factors related to access and use of screening colonoscopy, in addition to higher mortality rates for colorectal cancer (Warren Andersen et al, 2019).

Regarding the outcome of hospital visits following a screening colonoscopy, we performed an updated focused literature search and found additional evidence for the impact of social risk factors on outcomes for patients undergoing outpatient procedures, but no studies specific to

colonoscopy. For example, a 2019 study found that while patients with low income undergoing colectomy had higher rates of surgical-site infections compared with higher-income patients, there was no difference in surgical-site infection rates based on income for patients undergoing hysterectomy (Qi et al., 2019). A 2023 study in cancer patients undergoing surgery found that patients with psychosocial risk factors were more likely to experience complications following surgery (Leeds et al., 2019). Finally, a 2021 study found that for some procedures, people living in counties with high social vulnerability (SVI) were more likely to experience complications compared with patients who live in low SVI counties (Diaz et al., 2021).

We note that ASCs serve a low proportion of patients with social risk factors therefore there are disparities in access to care at ASCs, with Black patients and patients with public insurance being less likely to receive care at an ASC compared with others without those social risk factors (Janeway et al., 2020). A recent study found that there are disparities in the geographic distribution of ASCs, with counties with higher socioeconomic status having more ASCs per capita compared with counties with lower socioeconomic status (Chatterjee, Amen, & Khormaee, 2022).

Conceptual Pathways for Social Risk Factor Variable Selection

Although there is limited literature linking social risk factors and adverse outcomes for colonoscopy, we identified the following potential pathways through which social risk factors may influence the outcome of 7-day visits following a colonoscopy, based on the specific clinical consideration of the procedure and the broader social risk factor literature:

1. **Differential care within a facility or unmet differential needs.** One pathway by which social risk factors may contribute to hospital visit risk is that patients may not receive equivalent care within a facility (Trivedi et al., 2014; ASPE, 2016). However, as noted above, studies of colonoscopy in the HOPD and ASC setting are lacking. Moreover, patients with social risk factors, such as lower education, may require differentiated care – e.g., provision of information at a lower health literacy level – to achieve outcomes comparable to those of patients without social risk factors. Facilities that do not identify the need for and provide such care could have worse outcome rates for their patients with social risk factors.
2. **Use of lower-quality facilities**. Patients may differentially obtain care in lower quality facilities. With respect to inpatient hospital care, patients of lower income, lower education, or unstable housing have been shown not to have equitable access to high-quality facilities because such facilities are less likely to be found in geographic areas with large populations of poor patients (Jha et al. 2011). Thus, patients with low income may be likely to be seen in lower-quality facilities, which can contribute to increased risk of adverse outcomes following hospitalization. While analogous data for patients undergoing colonoscopies at HOPDs and ASCs is lacking, a similar pattern may exist, leading to higher (worse) outcome rates for patients with social risk factors. As described above, patients with social risk factors are less likely to have access to care at ASCs, in general (Chatterjee, Amen, & Khormaee, 2022; Janeway et al., 2020).
3. **Influence of social risk factors on hospital visit risk outside of facility quality.** Some social risk factors, such as income or wealth, may affect the likelihood of post-procedure hospital visits without directly being associated with the quality of care received at the facility. For instance, while a colonoscopy provider and/or a facility may make appropriate care decisions and provide tailored care and education, we hypothesized that a lower-

income patient may still have a worse outcome post-procedure due to their approach to preparation for the procedure, a limited understanding of the discharge plan, or a lack of home support, transportation or other resources for following discharge instructions. These factors, however, can be anticipated and addressed for outpatient elective procedures more readily than in more emergent care contexts.

4. **Relationship of social risk factors with patients' health at admission.** Patients with lower income/education/literacy or unstable housing may have a worse general health status and may present for their procedure with greater severity of underlying illness (ASPE, 2016). This causal pathway should be largely accounted for by current clinical risk-adjustment.

As indicated in the Section 5, Equity, the social risk variables that we examined are:

- **Dual-eligible status (DE)**

Dual eligibility for Medicare and Medicaid is available at the patient level in the Medicare Master Beneficiary Summary File. The eligibility threshold for over 65-year-old Medicare patients considers both income and assets. For the dual-eligible (DE) indicator, there is a body of literature demonstrating differential health care and health outcomes among beneficiaries, and the DE variable allows us to examine some of the pathways of interest (Department of Health and Human Services, 2016)

- **Area deprivation index (ADI)**

Area Deprivation index (ADI): The ADI, initially developed by Health Resources & Services Administration (HRSA), is based 17 measures across four domains: income, education, employment, and housing quality (Kind et al., 2018; Singh, 2003).

The 17 components are listed below:

- Population aged ≥ 25 y with < 9 y of education, %
- Population aged ≥ 25 y with at least a high school diploma, %
- Employed persons aged ≥ 16 y in white-collar occupations, %
- Median family income, $
- Income disparity
- Median home value, $
- Median gross rent, $
- Median monthly mortgage, $
- Owner-occupied housing units, % (home ownership rate)
- Civilian labor force population aged ≥16 y unemployed, % (unemployment rate)
- Families below poverty level, %
- Population below 150% of the poverty threshold, %
- Single-parent households with children aged < 18 y, %
- Households without a motor vehicle, %
- Households without a telephone, %
- Occupied housing units without complete plumbing, % (log)
- Households with more than 1 person per room, % (crowding)

ADI scores were derived using beneficiary's 9-digit ZIP Code of residence, which is obtained from the Master Beneficiary Summary File, and is linked to 2017-2021 US Census/American Community Survey (ACS) data. In accordance with the ADI developers' methodology, an ADI score is calculated for the census block group corresponding to the beneficiary's 9-digit ZIP Code using 17 weighted Census indicators. Raw ADI scores were then transformed into a national percentile ranking ranging from 1 to 100, with lower scores indicating lower levels of disadvantage and higher scores indicating higher levels of disadvantage. Percentile thresholds established by the ADI developers were then applied to ADI percentile to dichotomize neighborhoods into more disadvantaged (high ADI areas=ranking equal to or greater than 85) or less disadvantaged areas (Low ADI areas= ranking of less than 85).

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5.4.3 Variable Distribution Across Measured Entities

Table 8A and 8B (see tables/figures attachment) shows the distribution of social risk factors identified in the conceptual model for the Colonoscopy measure. Across all HOPDs with at least one procedure during the performance period, the facility median proportion of patients with the DE and ADI variables is 3.9% and 9.1%, respectively (Table 8A). For ASCs, the facility median proportion of patients with the DE and ADI variables is 1.6% and 2.6%, respectively (Table 8B).

Tables 9A and 10A show the frequency of risk variables in the final Colonoscopy measure risk model (see attachment) for HOPDs and ASCs, respectively.

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

Tables 9B and 10B (see attachment) provide risk variable names, definitions, and odds ratios for the HOPD and ASC risk models, respectively. Codes that define the risk variables can be found in the attached data dictionaries for each measure (HOPD, ASC).

During risk variable selection, we iteratively removed non-significant variables from the initial model using a step-wise purposeful selection approach until only statistically significant ($p<0.05$, assessed using a likelihood ratio test) variables remained in the model. Interaction terms between variables were tested and were only retained in the model if significant at a level of $p<0.01$.

The final risk-adjustment model has 16 variables (age categories, age categorized x arrhythmia interaction, twelve comorbidity variables, and two surgical variables). With the exception of concomitant endoscopy and polypectomy during procedure, which we define using individual CPT® codes, we define comorbidity variables using CMS Condition Categories (CCs), which are clinically meaningful groupings of thousands of ICD-10 diagnosis codes, maintained by CMS.

See Tab 5, “Colono Risk Factor CCs” and Tab 6, “Colonos Risk Factor Codes” in the attached Data Dictionary for the list of CC and CPT codes used to define the colonoscopy model risk variables.

Final Model Variables:

1. Age Categorized (years 65-69; 70-74; 75-79; 80-84; 85+)
2. Concomitant Endoscopy
3. Polypectomy during Procedure
4. Congestive Heart Failure (CC 85)
5. Ischemic Heart Disease (CC 86-89)
6. Stroke/Transient Ischemic Attack (CC 99-101)
7. Chronic Lung Disease (CC 111-113)
8. Metastatic Cancer (CC 8-11)
9. Liver Disease (CC 27-32)
10. Iron Deficiency Anemia (CC 49)
11. Disorders of Fluid, Electrolyte, Acid-Base (CC 24)
12. Pneumonia (CC 114-116)
13. Psychiatric Disorders (CC 57-59, 61-63)
14. Drug and Alcohol Abuse/Dependence (CC 54-56; 202-203)
15. Arrhythmia (CC 96-97)
16. Age Categorized x Arrhythmia Interactions

The frequencies and odds ratios for each risk variable for HOPDs and ASCs are shown in Tables 9A, 9B, 10A and 10B in the attachment.

Our approach to risk adjustment is tailored to, and appropriate for, a publicly reported outcome measure as articulated in published scientific guidelines (Krumholz et al., 2006; Normand & Shahian, 2007). For example, we only adjust for risk factors that are present at the start of care. We do not risk adjust for conditions that are possible adverse events of care and that are only

recorded at the time of the procedure. We do not adjust for factors related to the delivery of care that may reflect care quality.

The measure employs a hierarchical logistic regression model (a form of hierarchical generalized linear model [HGLM]) to calculate the measure score. This approach to modeling appropriately accounts for the structure of the data (patients clustered within facilities), the underlying risk due to patients' procedures/comorbidities, and sample size at a given facility when estimating hospital visit rates. In brief, the approach simultaneously models two levels (patient and facility) to account for the variance in patient outcomes within and between facilities (Normand & Shahian, 2007). At the patient level, the model adjusts the log-odds of hospital visits within 7 days after the procedure for selected demographic, clinical, and procedure risk variables. The second level models the facility-specific intercepts as arising from a normal distribution. The facility intercept, or facility-specific effect, represents the facility contribution to the risk of 7-day hospital visits, after accounting for patient risk and sample size, and can be inferred as a measure of quality. If there were no differences among facilities, then after adjusting for patient risk, the facility intercepts would be identical across all facilities. We provide additional details in the attachment in 4.4.4a

References

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5.4.4a Attach Risk/Case-mix Adjustment Modeling and/or Stratification Specifications

CBE_2539_4.4.4a_attachment.pdf

5.4.5 Calibration and Discrimination

CORE's measures undergo an annual measure reevaluation process, which ensures that the risk-standardized models are continually assessed and remain valid, given possible changes in clinical practice and coding standards over time. Modifications made to measure cohorts, risk models, and outcomes are informed by a review of the most recent literature related to measure conditions or outcomes, feedback from various stakeholders, and empirical analyses, including assessment of coding trends that reveal shifts in clinical practice or billing patterns. Input is solicited from a workgroup composed of up to 20 clinical and measure experts, inclusive of internal and external consultants and subcontractors.

To assess model performance, we computed three summary statistics to demonstrate model discrimination and calibration, and we provide risk-decile plots to demonstrate additional evidence of calibration. We describe the approach and results below; related tables and figures

are in the attachment.

Discrimination statistics (c-statistic and predictive ability)

1.C-statistic: Area under the receiver operating characteristic (ROC) curve (the c-statistic) indicates the probability that predicting the outcome is better than chance, which is a measure of how accurately a statistical model can distinguish between a patient with and without an outcome. Potential values range from 0.5, meaning no better than chance, to 1.0, meaning perfect discrimination. The 2024 EM Dataset was used for this analysis. The c-statistic of 0.679 for HOPDs, and 0.638 for ASCs, respectively, indicates good model discrimination. Results are similar to the c-statistics submitted for initial CBE endorsement, and in line with readmission-type measures. **2.Predictive ability**: Discrimination in predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects; therefore, we want to see a wide range between the lowest decile and highest decile. Predictive ability was 0.47-3.66 for HOPDs, and 0.47-2.34 for ASCs; results are similar to those provided to support initial CBE endorsement.

Calibration statistics (overfitting)

3. Overfitting: Over-fitting refers to the phenomenon in which a model accurately describes the relationship between predictive variables and outcome in the development dataset but fails to provide valid predictions in new patients. Estimated calibration values of γ0 close to 0 and estimated values of γ1 close 1 provide evidence of good calibration of the model. We used Dataset 1a and 1b for this analysis, which were performed during initial measure development. Our results below show a calibration value of close to 0 at one end and close to 1 to the other end indicating good calibration of the model.

Results from original model/measure development:

2010 Medicare 20% FFS Development Sample (Dataset #1a):

Calibration: (0,1)

2010 Medicare 20% FFS Validation Sample (Dataset #1b) results:

Calibration: (-0.03, 0.99)

CORE notes that after initial measure development we do not re-test our risk models for overfitting using a dataset that is external to the testing sample. In our risk models, coefficients are updated each time the measure is calculated; we refit the model with new data each time the measure is calculated. Therefore, random statistical fluctuations in model coefficients across repeated reporting cycles are part of the overall random error in the facility performance estimates.

Risk-decile Plots

Risk decile plots assess calibration of the risk model by examining the alignment between predicted and observed outcomes across deciles of predicted risk. Risk-decile plots (Figures 6A and 6B in the attachment) show good calibration for both the HOPD and ASC models.

5.4.6 Interpretation of Risk/Case-mix Factor Findings

We describe the approach to risk variable selection in Section 4.4.2, and analysis and rationale for not including social risk factors in the final model in Section 5.1. In this section we provide the interpretation of the risk model testing results described in section 4.4.5.

The following results demonstrate that the risk-adjustment model adequately controls for differences in patient characteristics:

Discrimination Statistics

The calculated c-statistics were 0.670 (HOPD) and 0.638 (ASC), which indicates good model discrimination. The models also predicted a wide range between the lowest decile and highest decile, indicating the ability to distinguish high-risk subjects from low-risk subjects.

Calibration Statistics

The calibration values were consistently close to 0 at one end and close to 1 to the other, indicating good calibration of the models.

Risk Decile Plot

Higher deciles of the predicted outcomes are associated with higher observed outcomes, which show a good calibration of the models.

Overall Interpretation

Interpreted together with information provided in the aforementioned sections, our diagnostic results demonstrate the risk-adjustment model adequately controls for differences in patient characteristics (case mix).

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors

6.1.1 Current Status

In use

6.1.3 Current Use(s)

Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

6.1.3 Program Details

Name of the program and sponsor
Hospital Outpatient Quality Reporting (Hospital OQR) Program, CMS
URL of the program
https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/ho...
Purpose of the program

https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initi...
Geographic area and percentage of accountable entities and patients included
The HOQR program is a national program. For the final cohorts from July 1, 2020 – December 31, 2022, there were 1,747,933 colonoscopies performed in 3,775 HOPDs, representing about 90% of all eligible colonoscopies.
Applicable level of analysis and care setting

The level of analysis is the hospital outpatient department, and the care setting is hospital outpatient.

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Name of the program and sponsor
Ambulatory Surgical Center Quality Reporting (ASCQR) Program, CMS
URL of the program
https://www.cms.gov/medicare/quality/initiatives/asc-quality-reporting
Purpose of the program
The ASCQR Program is a national pay-for-reporting, CMS quality data program under which ASCs report quality of care data for standardized measures to receive the full annual update to their ASC annual payment rate. Measured entities include all ASCs with
Geographic area and percentage of accountable entities and patients included
ASCQR is a national program. For the final cohort from July 1, 2020 – December 31, 2022 there were 2,076,667 procedures performed across 2,152 ASCs, representing 93.4% of all eligible colonoscopies.
Applicable level of analysis and care setting

The level of analysis is facility level, and the care setting is ambulatory surgery centers.

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Name of the program and sponsor
Rural Emergency Hospital Quality Reporting (REHQR) Program, CMS
URL of the program
https://www.cms.gov/medicare/health-safety-standards/guidance-for-laws-regulati...
Purpose of the program
Rural Emergency Hospitals (REHs) are a new entity type, effective January 1, 2023. In the CY2024 Final Rule, CMS finalized the REHQR Program that requires REHs to submit quality data to CMS.
Geographic area and percentage of accountable entities and patients included
The REHQR Program is a national program but REHs are in rural areas; there are currently about 20 facilities that have converted to REH status. The colonoscopy measure will first be reported by REHs in the CY2024 reporting period.
Applicable level of analysis and care setting

The level of analysis is the rural emergency hospital, and the care setting is outpatient.

6.2.1 Actions of Measured Entities to Improve Performance

As described earlier in Section 2, provider- and facility-level factors can affect the outcome of complications and hospital visits related to a colonoscopy. For example, provider-level factors

such as low provider volume and fellow involvement in the procedure were significantly associated with a higher risk of an ED visit in one study (Grossberg et al., 2018), and low procedure volume was associated with a higher risk of infection in another study (Wang et al., 2018). In addition, the specialty of the provider performing the procedure was associated with outcomes; surgeons' or endoscopists' outcomes have been shown to be worse than gastroenterologists' outcomes (Mazurek et al., 2022). These studies suggest that facilities can influence the patients' outcome through these modifiable pathways.

In addition, processes that can be influenced by the facility or providers at the facility can improve patient outcomes. For example, the providers' choice of sedation may influence complication rates as it has been shown that anesthesia assistance (sedation with agents that result in deeper sedation, such as Propofol, rather than conscious sedation) was associated with an increased risk of aspiration pneumonia (OR, 1.63; 95% CI, 1.11–2.37) (Bielawska et al., 2018). Another study found that patients who were taking more classes of medications were at higher risk of an ED visit or hospitalization within 7 days of a colonoscopy, suggesting that properly managing patients' medications may improve outcomes (Grossberg et al., 2020).

Facilities and providers may be unaware of complications for which patients experience a post-procedural hospital visit, leading to understated complication rates and suggesting the need for this type of measure to drive quality improvement. To support quality improvement, CMS shares reports with measured entities that include measure results benchmarked against the state and nation ("facility-specific reports"), as well as reports that provide claim-level details for each claim that meets numerator and denominator criteria ("claims-detail reports"). These reports include, among other details, the principal diagnosis code associated with the post-procedure hospital visit, which allows facilities to tie their quality improvement efforts to the specific complications that are occurring.

References

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Grossberg LB, Vodonos A, Papamichael K, Novack V, Sawhney M, Leffler DA. Predictors of post-colonoscopy emergency department use. Gastrointest Endosc. Feb 2018;87(2):517-525.

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Wang P, Xu T, Ngamruengphong S, Makary MA, Kalloo A, Hutfless S. Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut. 2018;67(9):1626–1636.

6.2.2 Feedback on Measure Performance

CMS shares reports with measured entities that include measure results benchmarked against the state and nation ("facility-specific reports"), as well as reports that provide claim-level details for each claim that meets numerator and denominator criteria ("claims-detail reports). For the reporting period covered with data in this submission (July 1, 2020-December 31, 2022), facilities received two claims-detail reports (released in September 2022 with data on colonoscopies performed from July 1, 2020, through May 31, 2022; and one released in March 2022 with data on colonoscopies performed from July 1, 2020, through November 30, 2022) and one facility-specific report (for this data, released in the fall with data on colonoscopies performed from July 1, 2020, through December 31, 2022.

Stakeholders can submit questions and issues to CMS through an online tool (Q&A tool) available to the public on QualityNet. CMS responds to each question submitted by stakeholders. We describe how we consider this, and other feedback, in the next section.

6.2.3 Consideration of Measure Feedback

Each year, issues raised through Q&A or in the literature related to this measure are considered by measure and clinical experts. Any issues that warrant additional analytic work due to potential changes in the measure specifications are addressed as a part of annual measure reevaluation. If small changes are indicated after additional analytic work is complete, those changes are usually incorporated into the measure in the next measurement period. If the changes are substantial, CMS may propose the changes through rulemaking and adopt the changes only after CMS received public comment and finalizes those changes in the OPPS or other rule. Each year we also review and consider changes to HCPCS and ICD-10 codes that are then incorporated into the measure. Those code set files are made available to the public on QualityNet.

During the time between the last maintenance submission and the measure's re-endorsement in 2020 and this current submission, we have made no major changes to the Colonoscopy measure based on stakeholder feedback.

We note that data used in this endorsement maintenance submission CMS reduced the performance period to approximately 29 months (from the typical 36 months) in response to the COVID-19 public health emergency, which included a CMS decision to exclude claims data for January 1, 2020 – June 30, 2020 (Q1 and Q2 of 2020) from quality measurement. This also impacts the 12-month look-back period for risk adjustment. Consistent with this policy, the final performance period for the results in this report included procedures between 7/1/2020 – 12/31/2022, and the data period used for risk adjustment included claims from 1/1/2019 – 12/31/2019 and 7/1/2020 – 12/31/2022.

6.2.4 Progress on Improvement

As shown in the section above (see section 4.3, Validity), for both the HOPD and ASCs versions of this measure, we have seen improvements in performance in both national unadjusted outcome rates as well as the risk-adjusted measure score. Please see Figures 5A and 5B in the attachment for histogram-like plots that show how facility-level performance has improved between 2016 and 2022, across five performance periods.

6.2.5 Unexpected Findings

There have been no negative unexpected findings during or following implementation of this measure. Please see Section 4.3 (Validity) for a description of improvements we have seen for this measure over time.

7.1 Supplemental Attachment

CBE_2539_Colonoscopy_Attachments_Spring_2024.zip

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The measure developer is different from the measure steward

Yes

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