**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 2539

**Measure Title**: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: Click here to enter a date

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: All-cause, unplanned hospital visits within 7 days. We define a hospital visit as any emergency department (ED) visit, observation stay, or unplanned inpatient admission *Health outcome includes patient-reported outcomes (PRO, i.e., HRQoL/functional status, symptom/burden, experience with care, health-related behaviors)*

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Click here to name what is being measured

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

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| The conceptual model for colonoscopy quality, shown below, shows the pathway by which facilities can modify the outcome. For example, the model identifies that patient-level factors, such as comorbidities, increase the risk of unplanned hospitals visits [1]. Better management of the risk associated with these comorbidities may be a potential avenue for facilities to reduce unplanned hospital visits. Provider-level factors (technical quality of the procedure, post-procedure provider accessibility), and facility-level factors (such as the anesthesia, pre- and post-discharge patient communication, other post-procedural processes) may also contribute to the risk of unplanned hospital visits. Therefore, facilities may have opportunities to lower their unplanned hospital visit rates through quality-improvement efforts focused on patient, provider, and facility factors [1].  Citation:   1. Ranasinghe I, Parzynski CS, Searfoss R, Montague J, Lin Z, Allen J, Vender R, Bhat K, Ross JS, Bernheim S, Krumholz HM, Drye EE. Differences in Colonoscopy Quality Among Facilities: Development of a Post-Colonoscopy Risk-Standardized Rate of Unplanned Hospital Visits. Gastroenterology. Jan 2016;150(1):103-13. |

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

Not applicable.

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

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 quality of care and to lower rates of adverse events leading to hospital visits after an outpatient colonoscopy.

**Complications**

Gastrointestinal complications from colonoscopy are common and range from severe to mild. Colonic perforation and gastrointestinal (GI) bleeding are relatively rare but severe adverse events reported after colonoscopy. A meta-analysis of 20 published studies of complications among patients aged ≥65 years in all care settings suggested these occur at a rate of 0.10% (95% confidence interval [CI] 0.09-1.50%) for colonic perforation and 0.63% (95% CI 0.57-0.70%) for GI bleeding [1]. Other GI complications after colonoscopy are considerably more common. Among surveyed patients, the reported frequency of complications ranges from, 20-34% [2,3]. These complications include abdominal pain, abdominal distension, nausea, vomiting, and other nonspecific symptoms.

Cardiovascular and pulmonary complications are the most frequent non-GI complications reported after colonoscopy. Pulmonary complications generally occur as a complication of the sedation given at the time of the procedure [4,5]. Excessive sedation may lead to hypoxia, hypotension, respiratory arrest, and aspiration pneumonia [4,5]. Cardiovascular complications may be attributed to many factors, including the effects of the anesthesia. The rates of cardiovascular and pulmonary complications reported in individual studies included in our review of the literature ranged from 0.012-1.94%. This range may reflect variation in definition of these events and differences in data sources used to capture these complications [6-9].

Post-procedural infections also occur following colonoscopy. For example, a 2018 study found rates of infection within 7 days of a screening colonoscopy performed by at an ASC to be 1.1 per 1000 colonoscopies [10]. Furthermore, the study authors found that the rates of infection varied widely by ASC, from 0 to 115 per 1000 colonoscopies.

**Hospital visits following colonoscopy**

The symptoms described above can result in the need for acute care. Overall, reported rates of post-procedure hospital use, as measured by inpatient admissions or a combination of admissions and ED visits, range from 1-2.4% within 30 days [3,6]. A more recent 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% [13], 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% [11]. 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 [12]. In contrast, hospitalizations among patients with an abdominal pain or nausea diagnosis were less common [12].

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 [13]. 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%) [11]. (Please note the measure developer plans to update this analysis in ICD-10 data and have the results on hand for review by the Standing Committee in June.)

**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 [13], and low procedure volume was associated with a higher risk of infection in another study [10], suggesting facilities can influence the patients’ outcome through these modifiable pathways. In addition, the choice of sedation may influence complication rates. For example, in a 2018 retrospective claims-based analysis of more than 3 million outpatient colonoscopies, researchers 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) [14].

Providers are often 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 [15]. 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**

The Hospital Outpatient Quality Reporting Program (HOQR) provides CMS with data to help Medicare beneficiaries make more informed decisions about their healthcare. As of December 2017, this measure has been publicly available on Hospital Compare, and since July 2015, results have been available in the form of facility-specific quality reports that conduct outpatient colonoscopies. Thus, it is important to continue to make this information transparent to patients choosing among providers who offer this elective procedure.

Importantly, providing outcome rates to providers will make meaningful quality differences visible to clinicians, thus incentivizing improvement. The national rate of hospital visits per 1,000 colonoscopies among HOPDs declined from 16.4 in 2018 reporting (2017 data) to 14.8 in 2019 reporting (2018 data), and the distribution of risk-standardized rates also declined (the interquartile range of rates for 2019 is completely below the 2018 interquartile range). This decline may reflect quality improvement as there were no specification changes to the measure for 2019 reporting that would impact rates, nor were there noticeable differences in patient mix. (Note that the 2020 national rate was 16.4, however this difference compared to 2019 can be attributed to a change in the measures’ specifications that result in the use of three years of performance data that overlap with 2018 and 2019 performance periods.)

Citations

1. Day LW, Kwon A, Inadomi JM, Walter LC, Somsouk M. Adverse events in older patients undergoing colonoscopy: a systematic review and meta-analysis. *Gastrointest Endosc.* Oct 2011;74(4):885-896.

2. Baudet JS, Diaz-Bethencourt D, Aviles J, Aguirre-Jaime A. Minor adverse events of colonoscopy on ambulatory patients: the impact of moderate sedation. *Eur J Gastroenterol Hepatol.* Jun 2009;21(6):656-661.

3. Ko CW, Riffle S, Shapiro JA, et al. Incidence of minor complications and time lost from normal activities after screening or surveillance colonoscopy. *Gastrointest Endosc.* Apr 2007;65(4):648-

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4. Ko CW, Dominitz JA. Complications of colonoscopy: magnitude and management. Gastrointestinal endoscopy clinics of North America. Oct 2010;20(4):659-671.

5. Committee ASoP, Fisher DA, Maple JT, et al. Complications of colonoscopy. *Gastrointest Endosc.* Oct 2011;74(4):745-752.

6. Warren JL, Klabunde CN, Mariotto AB, et al. Adverse events after outpatient colonoscopy in the

Medicare population. Ann Intern Med. Jun 16 2009;150(12):849-857, W152.

7. Crispin A, Birkner B, Munte A, Nusko G, Mansmann U. Process quality and incidence of acute complications in a series of more than 230,000 outpatient colonoscopies. *Endoscopy.* Dec 2009;41(12):1018-1025.

8. Radaelli F, Meucci G, Minoli G. Italian Association of Hospital G. Colonoscopy practice in Italy: a prospective survey on behalf of the Italian Association of Hospital Gastroenterologists. Nov 2008;40(11):897-904.

9. Singh H, Penfold RB, DeCoster C, et al. Colonoscopy and its complications across a Canadian regional health authority. *Dig Liver Dis.* Mar 2009;69(3):665-671.

10. 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.

11. Ranasinghe I, Parzynski CS, Searfoss R, Montague J, Lin Z, Allen J, Vender R, Bhat K, Ross JS, Bernheim S, Krumholz HM, Drye EE. Differences in colonoscopy quality among facilities: Development of a post-colonoscopy risk-standardized rate of unplanned hospital visits. *Gastroenterology*. Jan 2016;150(1):103-13.

12. Wang L, Mannalithara A, Singh G, Ladabaum U. Low rates of gastrointestinal and non-gastrointestinal complications for screening or surveillance colonoscopies in a population-based study. *Gastroenterology*. Oct 2018;154:540-555.

13. 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.

14. Bielawska B, Hookey LC, Sutradhar R, et al. Anesthesia assistance in outpatient colonoscopy and risk of aspiration pneumonia, bowel perforation, and splenic injury. Gastroenterology. 2018;154(1):77–85.e3.

15. Leffler DA, Kheraj R, Garud S, Neeman N, Nathanson LA, Kelly CP, Sawhney M, Landon B, Doyle R, Rosenberg S, Aronson M. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med.* 2010;170:1752-1757.

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

Not applicable. This is an outcome measure.

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Not applicable. This is an outcome measure.

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Not applicable. This is an outcome measure. |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Not applicable. This is an outcome measure. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Not applicable. This is an outcome measure. |
| Provide all other grades and definitions from the evidence grading system | Not applicable. This is an outcome measure. |
| Grade assigned to the **recommendation** with definition of the grade | Not applicable. This is an outcome measure. |
| Provide all other grades and definitions from the recommendation grading system | Not applicable. This is an outcome measure. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Not applicable. This is an outcome measure. |
| Estimates of benefit and consistency across studies | Not applicable. This is an outcome measure. |
| What harms were identified? | Not applicable. This is an outcome measure. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Not applicable. This is an outcome measure. |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

Not applicable. This is an outcome measure.

**1a.4.2 What process was used to identify the evidence?**

Not applicable. This is an outcome measure.

**1a.4.3.** **Provide the citation(s) for the evidence.**

Not applicable. This is an outcome measure.