



August 21, 2012

National Quality Forum
1030 15th St, NW
Suite 800
Washington, D.C. 20005

Re: Colonoscopy Quality Index (NQF# C 2056)

The American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), and American Society for Gastrointestinal Endoscopy (ASGE) welcome the opportunity to comment on the National Quality Forum (NQF) Gastrointestinal/Genitourinary Measure Concepts. Together, our three societies represent virtually all practicing gastroenterologists in the United States.

We appreciate that the NQF has included gastrointestinal measures in its pilot of the redesigned two-stage process. Our societies have been involved in the development of many of the measures being presented to the Gastrointestinal/Genitourinary Steering Committee and look forward to participating in their discussions later this month.

We would like to take this opportunity to comment on the Colonoscopy Quality Index composite measure submitted by Quality Quest for Health of Illinois. The submitting organization proposes a composite measure that requires the reporting physician to “meet all quality parameters”, namely the following elements¹:

- Appropriate indication
- Complete exam
- Photo-documentation of the cecum
- No serious acute complications
- Cardiac risk assessment
- Bowel preparation assessment (excellent/good/fair/poor/unsatisfactory)
- Polyp information complete or no polyp (#/size/location/morph/removal/method)
- Withdrawal time recorded
- Appropriate follow-up recommendation

Our societies have great concern that this measure was developed without input from the specialty societies that perform this procedure – the gastroenterology societies (ACG, ASGE or AGA), surgical societies (American College of Surgeons, Society of American Gastrointestinal and Endoscopic Surgeons, American Society of Colon and Rectal Surgeons) and primary care societies (American Academy of Family Physicians, American College of Physicians, American Osteopathic Association). As we describe below, several of the proposed “measurements” have not been shown to be associated with an improvement in procedural performance or health outcomes.

¹ Lieberman D, Nadel M, Smith R, et al: [Standardized colonoscopy reporting and data system \(CO-RADS\): Report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable](#). *Gastrointest Endosc* 2007; 65:757-766

Our societies strongly support the concept of measuring colonoscopy performance and identifying high-quality colonoscopies. The proper preparation of the patient and performance of colonoscopy to ensure a high-quality examination, accompanied by recommendations based on findings from a high-quality examination, can diminish risks to patients, avoid the need for unnecessary interval examinations, and improve continuity of care. The collective efforts of our societies to develop the PCPI/AGA/ASGE 2008 PCPI Endoscopy and Polyp Surveillance Measure Set and a recent colonoscopy composite measure submitted by the ACG, AGA, and ASGE to the Centers for Medicare and Medicaid Services (CMS) for the Physician Quality Reporting System (PQRS) 2014 reflect that commitment. The elements of our proposed composite measure are:

- Documentation of assessment of bowel preparation
- Photodocumentation of completeness of colonoscopy including cecal intubation or ileocolonic anastomosis.

The three GI societies carefully reviewed each of the elements in this composite measure from Quality Quest and found a lack of evidence for several of the elements. In view of such, we determined that it would not be appropriate to include them in the composite measure that we submitted to CMS. We plan to continue the development of that measure, including a public comment period, over the coming months.

We are concerned that the proposed measure is extremely complicated to implement, limiting its usability and feasibility by practices, small or large, community or academic, gastroenterologist, internist, family practitioner or surgeon. The AGA, which sponsors the AGA Digestive Health Outcomes Registry, has met with Quality Quest and determined that it would be extremely difficult for practices to report the proposed data from this measure into a registry. Our specific comments on the elements of the measure follow.

1. Appropriate indication for colonoscopy

For over 20 years, the American Society for Gastrointestinal Endoscopy² has published standards of practice on the appropriate use of colonoscopy and other endoscopic procedures, which have been incorporated into coverage determinations from Medicare contractors³ and commercial payors⁴. Our societies fail to see the improvement in health outcomes that would result from an exercise in documentation that is more appropriately characterized as a utilization management determination.

2. Standardized medical risk assessment

In the 2008 PCPI Endoscopy and Polyp Surveillance Measure Set the evidence for this element as part of the Comprehensive Colonoscopy Documentation measure was Grade 1C (intermediate-strength recommendation; may change when stronger evidence is available). We are not aware of any new evidence in the past four years which would change this recommendation.

3. Cardiac risk assessment

Several studies have noted a shift in the performance of colonoscopy where the provision of sedation is increasingly being provided by anesthesia professionals.^{5,6} It would be inappropriate to include cardiac risk assessment that is provided by a different health professional within a colonoscopy composite measure for the endoscopist.

² Early DS, Ben-Menachem T, Decker GA, et al. Appropriate use of GI Endoscopy. A consensus statement from the American Society for Gastrointestinal Endoscopy. *Gastrointest Endosc* 2012; 75: 1127-31

³ Wisconsin Physicians Service Local Coverage Determination L30304 GI-006 Colonoscopy and Sigmoidoscopy Diagnostic. Effective date 07/16/2012

⁴ Empire BlueCross BlueShield Clinical UM Guideline CG-SURG-01 Colonoscopy. Effective date 07/10/2012.

⁵ Liu H, Waxman DA, Main R, Mattke S. Utilization of Anesthesia Services During Outpatient Endoscopies and Colonoscopies and Associated Spending in 2003-2009. *JAMA*. 2012;307(11):1178-1184.

⁶ Inadomi JM, Gunnarsson CL, Rizzo JA, et al. Projected increased growth rate of anesthesia professional-delivered sedation for colonoscopy and EGD in the United States: 2009 to 2015. *Gastrointest Endosc*. 2010;72(3):580-586

4. Assessment of bowel preparation

Poor bowel preparation is a major impediment to the effectiveness of colonoscopy, affects the ability to detect polyps, and influences the timing of repeat examinations. Given the increased premalignant potential of advanced adenomas, suboptimal bowel preparation may cause an unacceptably high failure rate at identifying these important lesions, thereby compromising the effectiveness of the colonoscopy. Adenoma miss rates in the context of suboptimal bowel preparation are as high as 42%.⁷ To decrease the risk of missed lesions when the bowel is poorly prepared, a follow-up or repeat colonoscopy should be recommended at a significantly shorter interval than if the bowel was well prepared. Current literature shows great variability in recommendations for follow-up in this circumstance, presenting an opportunity for improvement. Although there is relative uniformity in surveillance intervals when bowel preparation is optimal, there is considerable variability when bowel preparation is suboptimal.^{8 9}

In view of the opportunity for improvement and the desire to ensure a high-quality colonoscopy, the ACG, AGA, and ASGE are supportive of an element on *Documentation of Assessment of Bowel Preparation*. In our submission to CMS for PQRS 2014, we saw the need to include this element as part of a Colonoscopy Quality Composite measure.

5. Complete examination

Based on element six (6) below this seems redundant.

6. Cecal photo taken

While the definition of a colonoscopy is examination of the colon proximal to the splenic flexure, a high-quality evaluation of the colon consists of examination of the entire colon – from the rectum to the cecum or ileo-colonic anastomosis. A significant fraction of colonic neoplasms are located in the right colon, hence successful cecal intubation should be specifically noted with recommended cecal intubation rates of $\geq 95\%$ in healthy adults.^{10 11} Knowing the completeness of the examination can inform physicians whether an imaging procedure or repeat colonoscopy is necessary, and influences the timing of follow-up examination

Our societies are supportive of an element on *Photodocumentation of Completeness of Colonoscopy including cecal intubation or ileocolonic anastomosis*. In our submission to CMS for PQRS 2014, we saw the need to include this element as part of a Colonoscopy Quality Composite measure.

7. All essential polyp information recorded (including size, morphology, location, method of removal)

This measure is an important process measure that for purposes of quality improvement at the individual endoscopist and practice level. However, we question its strength as an accountability measure.

8. Withdrawal time recorded

Despite the positive correlation between withdrawal times and detection of adenomatous lesions¹² withdrawal times fail to correlate with 5-year interval neoplasia¹³ and withdrawal time

⁷ Chokshi RV, Hovis CE, Hollander T, et al. Prevalence of missed adenomas in patients with inadequate bowel preparation on screening colonoscopy. *Gastrointest Endosc* 2012;75:1197-203

⁸ Ben-Horin S, Bar-Meir S, Avidan B. The impact of colon cleanliness assessment on endoscopists' recommendations for follow-up colonoscopy. *Am J Gastroenterol* 2007;102:2680-5

⁹ Lebowitz B, Kastrinos F, Glick M, et al. The impact of suboptimal bowel preparation on adenoma miss rates and the factors associated with early repeat colonoscopy. *Gastrointest Endosc* 2011;73:1207-14.

¹⁰ Imperiale TF, Wagner DR, et al. Risk of advanced proximal neoplasms in asymptomatic adults according to the distal colorectal findings. *N Engl J Med* 2000; 343(3): 169-74.

¹¹ Rabeneck, L, Rumble RB, et al. Cancer Care Ontario Colonoscopy Standards: standards and evidentiary base. *Can J Gastroenterol* 2007; 21 Suppl D: 5D-24D.

¹² Barclay RL, Vicari JJ, Doughty AS, et al. Colonoscopic Withdrawal Times and Adenoma Detection during Screening Colonoscopy. *N Engl J Med* 2006; 355:2533-2541

¹³ Gellad, ZF, Weiss DG, et al. Colonoscopy withdrawal time and risk of neoplasia at 5 years: results from VA Cooperative Studies Program 380. *Am J Gastroenterol* 2010; 105(8): 1746-52

can be reduced safely with the use of wide angle endoscopes.¹⁴ The expert panel that reviewed these measures determined there was a significant potential that this measure could be gamed without any appreciable improvement in polyp detection or outcomes.

9. Free of serious complication

While complications such as perforation or bleeding following the procedure should be monitored and documented to allow identification and correction of any systematic errors, the rate of complications is quite uncommon¹⁵. Attribution of the delayed complications to individual endoscopists may be difficult as such patients may present to health care facilities with which the endoscopists is not associated.

10. Appropriate follow-up recommendation

Endoscopists should adhere to the recommended surveillance guidelines post-resection or post-polypectomy, which make the assumption of cecal intubation, adequate bowel preparation and careful examination. Now that CMS has included PQRS measures for prospective surveillance interval after a normal screening examination and retrospective interval for those with adenomatous polyps¹⁶, including such within a colonoscopy composite measure would be duplicative.

The measure developer has interpreted the recommendations for appropriate follow-up indications for colonoscopy and surveillance colonoscopy in an incorrect manner. According to the measure developer, proper follow-up indications would be based upon a finding of adenomas or neoplasia greater than 1 centimeter (cm). In fact, the authors made recommendations on the appropriate follow-up on patients with finding of adenomas or neoplasia **greater than or equal to** 1 cm.¹⁷

In conclusion, the ACG, AGA, and ASGE believe that the composite measure proposed by Quality Quest for Health of Illinois requires the collection of data elements that, in total, have not been shown to lead to the identification of a high-quality colonoscopy, improvement in health outcomes, or reduction of waste and unnecessary procedures.

In comparison, the composite measure proposed by our societies to CMS for incorporation in PQRS 2014 - *Documentation of Assessment of Bowel Preparation and Photodocumentation of Completeness of Colonoscopy including cecal intubation or ileocolonic anastomosis* – achieves the goals of allowing the physician, patient, purchaser and payor to identify a high-quality colonoscopy and, when deficiencies are seen, providing a pathway for remediation and quality improvement.

Our organizations appreciate the opportunity to provide our comments on the Colonoscopy Quality Index composite measure. Any questions or requests for more information can be directed to Debbie Robin, Senior Director for Quality, AGA, at drobin@gastro.org or 301-941-2615; Brad Conway, Vice President, Public Policy, ACG, at bconway@gi.org or 301-263-9000; or Eden Essex, Quality and Health Policy Manager, ASGE, at eessex@asge.org or 630-570-5646.

Sincerely,

¹⁴ Deenadayalu, VP, Chadalawada V, et al. 170 degrees wide-angle colonoscope: effect on efficiency and miss rates. Am J Gastroenterol 2004; 99(11): 2138-42.

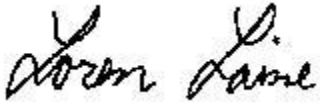
¹⁵ Ko CW, Riffle S, et al. Serious complications within 30 days of screening and surveillance colonoscopy are uncommon. Clin Gastroenterol Hepatol 2010; 8(2): 166-73.

¹⁶ [CMS-1590-P](#): Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B for CY 2013 (Including DME Face-to-Face & Non-random Prepayment Review) Publication Date: July 30, 2012

¹⁷ Lieberman D, Nadel M, Smith R, et al: [Standardized colonoscopy reporting and data system \(CO-RADS\): Report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable](#). Gastrointest Endosc 2007; 65:757-766



Lawrence R. Schiller, MD, FACG
President
American College of Gastroenterology



Loren Laine, MD, AGAF
President
American Gastroenterological Association



Thomas M. Deas, Jr., MD, MMM, FASGE
President
American Society for Gastrointestinal Endoscopy