March 18, 2013

Gastrointestinal and Genitourinary Steering Committee
National Quality Forum
1030 15th St, NW, Suite 800
Washington, D.C. 20005

Dear Steering Committee:

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 (GI/GU) Measures advancing to Stage 2 of committee review. As active members of the NQF, our societies represent virtually all of the practicing gastroenterologists in the United States and have been involved in the development of many of the measures being presented to the GI/GU Steering Committee.

Our comments focus on the Colonoscopy Quality Index composite measure submitted by Quality Quest for Health of Illinois. Specifically, our societies offer comments in the following areas:

1. Measure Harmonization
2. Significance of the Proposed Measure

Measure Harmonization

Because lack of measure harmonization has been identified throughout the measure development lifecycle and across NQF consensus development projects, our societies share NQF's commitment to identifying measure overlap and achieving appropriate levels of measure harmonization within NQF consensus projects.

Our societies strongly support the concept of measuring colonoscopy performance and identifying high-quality colonoscopies. To reflect that commitment, our societies submitted a colonoscopy quality composite measure to the Centers for Medicare and Medicaid Services (CMS) for the 2014 Physician Quality Reporting System (PQRS) with the following elements, which have high impact relative to detecting adenomas or other colorectal cancer precursor or colorectal cancer during screening or surveillance colonoscopy:

- Documentation of assessment of bowel preparation[1]
- Photodocumentation of completeness of colonoscopy including cecal intubation or ileocolonic anastomosis[2]

[1] 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.
[2] Baxter NN, Sutradhar R, Forbes SS, et al. Analysis of administrative data finds endoscopist quality measures associated with post colonoscopy colorectal cancer. Gastroenterology 2011: 140(1):65-72.

During the reconsideration of the Colonoscopy Quality Index measure concept, our societies voiced our desire to collaborate with Quality Quest for Health of Illinois on a colonoscopy quality composite measure in the hopes of reaching consensus on elements associated with improvement in procedural performance of colonoscopy or health outcomes. Our societies remain concerned that the Colonoscopy Quality Index composite measure submitted by Quality Quest for Health of Illinois was again developed without any sincere attempt to integrate input from the specialty societies that perform this procedure – the gastroenterology societies (ACG, AGA or ASGE), and other stakeholder organizations.

Significance of the Proposed Measure

As outlined in a letter from our societies dated August 21, 2012, which is appended, several of the proposed "measurements" contained within the proposed Colonoscopy Quality Index measure have not been shown to be associated with an improvement in procedural performance or health outcomes, nor is there a demonstrated performance gap based on the data supplied by the developer.

It is our understanding that NQF-endorsed measures must have a clear evidence base of the highest quality in addition to evidence that highlights a current performance gap. A measure without evidence of a performance gap has little capability in differentiating high-quality performers. Specifically, an established standard of practice is not an ideal NQF-endorsed measure if it appears that nearly 100 percent of practitioners are compliant. It is with this understanding that we do not understand the developer's insistence on keeping "composite measure 2" regarding standardized medical risk assessment despite the committee's recommendation to remove it. We agree that colonoscopy is an invasive procedure and that a standardized medical risk assessment is necessary prior to starting the procedure, but we are not aware of evidence highlighting a performance gap as it pertains to the colonoscopy procedure itself.

Importantly, merely requiring documentation of specific aspects of care (e.g., standardized medical risk assessment, bowel preparation) does not equate with performance of high-quality colonoscopy. Rather we wish to document aspects of care that predict a higher-quality colonoscopy. For example, documenting that assessment of bowel preparation was performed does not impact colonoscopy quality, while documentation that bowel preparation was adequate to allow proper examination for polyps does predict a higher quality colonoscopy. [3] [4] We agree with the developer that failure to follow standard medical practice is poor quality, but merely documenting a process as required in "composite measure 2 and 3" also does not correlate with high quality. For example, a practitioner could document the wrong ASA score and document a poor bowel preparation, and by the standards set by this proposed measure, the practitioner would be consistent with practicing high-quality care. We do not believe this meets the measure development standards established for NQF endorsement.

Additionally, the developer has chosen to keep documentation of a withdrawal time as part of the composite measure despite the committee's recommendation to remove it. The fundamental purposes of performing colonoscopy for colon cancer prevention are detecting and the removing pre-cancerous polyps before they become cancer. The outcome measure of ultimate interest is the number of interval cancers that develop for an individual endoscopist.[5] Since this is currently not feasible to do, surrogate process measures such as withdrawal time and adenoma detection rate are needed and have been proposed in the medical literature.[6] However, the literature has also demonstrated that a good correlation exists between withdrawal time and adenoma detection rate. We believe that with improved feasibility, adenoma detection rate is a superior surrogate measure as it more closely relates the outcome of interest (cancer

[3] 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

[4] Lebwohl 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.

[5] Farrar WD, Sawhney MS, etal. Colorectal Cancers Found After Complete Colonoscopy. Clin Gastroenterol Hepatol. 2006 Oct;4(10):1259-64. Epub 2006 Sep 25.

[6] Rex DK, Petrini JL, Baron TH, et al. Quality Indicators for Colonoscopy. Am J Gastroenterol 2006;101:873–885.

prevention and development) and stronger evidence that links adenoma detection rates to interval cancers and mortality.

In addition to being an inferior (but valid) surrogate measure, this measure merely defines quality by the documentation of any withdrawal time, and not a time greater than six minutes as suggested in the literature.[4] Again, a practitioner could document a withdrawal time of one minute and merely doing so would meet this composite measure's definition of quality.

Conclusion

ACG, AGA and ASGE appreciate the opportunity to offer comments. We sincerely appreciate and genuinely support Quality Quest's initiative in developing this composite measure to identify high-quality colonoscopy practice. We hope that our shared concerns are perceived in a constructive and harmonizing spirit. These comments have been raised, again, with the intent to preserve the high bar of quality associated with being an NQF-endorsed measure. In summary, this measure, as currently articulated, includes components that do not assist our members in discriminating quality and, consequently, does not advance the needle in ensuring the delivery of high quality patient care for performing colonoscopy for colon cancer prevention.

Should you desire additional information or have any questions, please contact Eden Essex, ASGE manager of quality and health policy at (630) 570-5646 or eessex@asge.org, Brad Conway, ACG vice president of public policy at (301) 263-9000 or bconway@gi.org, or Anushree Vichare, AGA director of quality, at (301) 941-2615 or avichare@gastro.org.

Sincerely,

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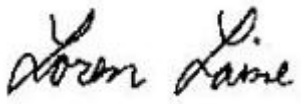

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