Quality Quest *for* Health of Illinois

October, 2, 2012

Dear Helen and Andy,

Thank you for the opportunity to discuss the process and the GI/GU Steering Committee determination, regarding the Colonoscopy Quality Index.

I strongly dispute the Steering Committee's conclusion that there is a lack of evidence to support the Colonoscopy Quality Index – measure #2056. There is solid evidence for each of these elements, and for the composite measure. Each of the elements is part of the complex process of performing colonoscopy. They ALL have an integral role in high quality colonoscopy. Taken together, a high Colonoscopy Quality Index score reflects high process reliability. This is analogous to Atul Gawande and Peter Provonost's work on surgical checklists to improve the reliability of surgical processes that has demonstrably saved lives and decreased costs. See excerpt below and SSSL Checklist attached.

Semel, ME, et al, Adopting A Surgical Safety Checklist Could Save Money And Improve The Quality Of Care In U.S. Hospitals; Health Aff September 2010 29:1593-1599

> "…Atul Gawande, an associate professor at HSPH and a surgeon at Brigham and Women's Hospital (BWH), and colleagues demonstrated that when surgical teams use a simple checklist, avoidable complications plummet and lives are saved. In a new study, Gawande and colleagues have found that using a checklist can also save hospitals money. Their research is published in the September issue of Health Affairs."

A high reliability colonoscopy avoids exposing patients to a procedure they don't need – overuse (appropriate indication and appropriate follow-up recommendation) – and, it ensures that the procedure, when needed, is done safely and well. I posit that, each one of us, if we understood the Colonoscopy Quality Index fully, would expect our doctor to track and follow each of these parameters.

Item 1. Appropriate indication for colonoscopy. The letter from the GI societies states, "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***." The evidence base to support this element was included in the original submission and is reiterated in the attached document, Evidence *Base for Quality Quest Colonoscopy Quality Index*.
If it is agreed that colonoscopy is a commonly overused procedure, this statement cannot possibly be accurate. Five years of experience, and data on over 20,000 colonoscopies, confirms its inaccuracy. One in five colonoscopy procedures is performed at too short an interval (overuse) when practices begin measuring and reporting their results. Data available publicly at www.qualityquest.org

When considering measure# 0659, the Committee states, "There is general agreement this measure focus addresses a high impact area as it is one of the most overused procedures." My jaw literally dropped when I read, "The Committee agreed that good medical practice should include the indication and thus is not needed as a national consensus standard for quality measurement," when considering measure# 2056. These statements are in direct conflict.

RESPONSE: Measure #2056 incorporates personal and family history into the determination of appropriateness of THE CURRENT colonoscopy.
The table below is from Rex DK, et al. (2006) Quality indicators for colonoscopy from ASGE/ACG Taskforce on Quality in Endoscopy. Am J Gastroenterol. 2006 Apr;101(4):873-85. PMID: 16635231. One of the following conditions must be met to be scored appropriate:

SCREENING			
CRC Risk	**Age to Start Screening**	**Personal and Family History**	**Comments**
Average risk	Age 50	No personal history or family history of CRC or adenomas and no colonoscopy in previous 10 years	A colonoscopy performed before age 50 fails.
Increased risk due to family history	Age 40 or 10 years before youngest affected relative	Two or more SDR with CRC and no colonoscopy in previous 10 years One or more FDR with adenoma(s) before age 60 and no previous colonoscopy in previous 5 years One FDR with CRC before age 60 or two or more FDR with CRC at any age and no previous colonoscopy in previous 5 years One FDR with CRC or adenoma age 60 or older and no previous colonoscopy in previous 10 years History of FAP, HNPCC, IBD, HPS per special counseling recommendations	One of these conditions must be met for a colonoscopy to be appropriate prior to age 50. If none are met the procedures fails.
SURVEILLANCE			
Personal History	**Pathology**	**Frequency (if bowel prep adequate & complete exam)**	
Prior colon cancer		Clearance colonoscopy around time of surgery, 1 year, 4 years, then every 5 years	Follow up recommendations at intervals longer, or shorter, than specified, fail.

Prior rectal cancer		Clearance colonoscopy around time of surgery, 1 year, 4 years, then every 5 years	Follow up recommendations at intervals longer, or shorter, than specified, fail.
Prior rectal cancer with low anterior resection without pelvic Radiation and without mesorectal resection		Clearance colonoscopy around time of surgery, 1 year, 4 years, then every 5 years AND flexible sigmoidoscopy every 3-6 months for 2-3 years	Follow up recommendations at intervals longer, or shorter, than specified, fail.
Previous non-cancerous polyp(s)	Hyperplastic polyp(s) excluding HPS	10 years	A colonoscopy performed sooner than 10 years fails; Follow up recommendation at greater than 10 years fails.
	$\leq$ 2 small (<1 cm) tubular adenomas	5 to 10 years	A colonoscopy performed sooner than 5 years fails; Follow up recommendation at greater than 10 years or less than 5 years, fails
	3 – 10 adenomas	3 years	A colonoscopy performed sooner than three years fails; Follow up recommendation longer, or shorter, than three years, fails.
	Advanced Neoplasia (adenoma $\geq$1 cm; villous histology; high-grade dysplasia; or CRC)	3 years	A colonoscopy performed sooner than three years fails; Follow up recommendation at an interval longer, or shorter, than three years, fails.
	More than 10 adenomas or serrated adenoma	1 year	A colonoscopy performed sooner than one year fails; Follow up recommendation at an interval longer, or shorter, than one year, fails.
	Sessile adenoma with incomplete excision	2-6 months	A colonoscopy performed sooner than two months fails; Follow up recommendation at an interval longer, or shorter, than 2-6 months fails.

	Negative complete surveillance colonoscopy	5 years	A colonoscopy performed sooner than five years fails; Follow up recommendation longer, or shorter, than five years fails.

These same algorithms, and the findings and pathology from THE CURRENT procedure, are used to determine the appropriateness of the recommended follow up interval. These elements are evidence based and more strongly identify overuse (common) AND underuse (uncommon but does happen) than measures #0658 and #0659.

Complexity: The GI Society letter states, "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."

RESPONSE: In fact, the AGA registry contains all elements necessary to reporting measure 2056 with the exception of a limited number of family and personal history elements:

Personal Hx CRC: Y/N
PHx Villous Adenoma: Y/N
PHx Severe Dysplasia: Y/N
PHx Serrated Adenoma: Y/N
PHx Incomplete Polyp Removal: Y/N
PHx Adenoma(s) # last exam: none/1-2/3-9/ten or more
Size (mm) of largest Previous Adenoma
Age Youngest FDR with CRC
FDR CRC: 0/1/2/3/etc.
SDR CRC: 0/1/2/3/etc.
FDR Adenoma: Y/N
Age Youngest FDR with Adenoma
Colonoscopy: None/ Y (Year &Polyp Info Known/ Y (Polyp info Unknown)/ Y (Year or Polyp Info Unknown)/ Y (Last Colonoscopy Unsatisfactory)
Year of Previous Colonoscopy
Endoscopy Facility ID
Endoscopist First Name
Endoscopist Last Name
Endoscopist NPI #

These data elements are part of a careful and complete patient history. They are clinically important, as they are necessary to determining, if the colonoscopy, being performed on the patient, is indeed, indicated (appropriate). We have had several discussions with AGA about measure harmonization. There was agreement that these family and personal history elements are clinically important. Logistic

barriers related to the registry developer were cited for not incorporating them into the AGA registry at this time.

Item 2. Standardized Medical Risk Assessment: The letter from the GI societies states, "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." The Steering Committee records state, "…this is standard clinical practice with evidence that is based only on consensus opinion. Further, as part of a standardized medical risk assessment, a cardiac risk assessment is done."

RESPONSE: The ASA score is a structured, evidence-based risk assessment system, developed and used widely in anesthesia. There is strong evidence that this scoring system predicts procedural risk. It is *consensus* that this proven risk prediction algorithm is also predictive of risk for patients that undergo colonoscopy procedures. Patients with an ASA score of 3 or higher are at greater risk of suffering a medical complication from the procedure and additional precautions are recommended. Thus, it is imperative that the ASA score be assessed for every patient. ***Both the AGA and the ASGE registries consider ASA Class sufficiently important to include it in their colonoscopy registry systems.*** Also note, the ASA score is part of the Gawande surgical checklist, **"ANAESTHESIA SAFETY CHECK COMPLETED."**

Item 3. Standardized assessment of bowel preparation: The record states, "The Committee agreed that this is an important component. Members discussed multiple registry/database studies that indicate the quality of the bowel prep results in improved adenoma detection rate; however, this evidence was not provided in the measure submission.

RESPONSE: The following was cited in the submission: "In a US study of 9 hospitals, adequacy of preparation of colonoscopy was noted in only 45% of procedures (range 14.6% to 86.1%) and cecal landmarks were documented in 62.7% of procedures (range 11.6% to 90%), Mehrotra, A., et.al. (2012). " Also cited, "Rex DK, et al. (2006) Quality indicators for colonoscopy from ASGE/ACG Taskforce on Quality in Endoscopy. Am J Gastroenterol. 2006 Apr; 101(4):873-85. PMID: 16635231. Rex states, "In each colonoscopy, the colonoscopist should document the quality of the bowel preparation." "Poor bowel preparation is a major impediment to the effectiveness of colonoscopy. Poor preparation prolongs cecal intubation time and withdrawal time and reduces detection of both small and large polyps." (Harewood 2003; Froelich 2005) "In every colonoscopic practice, some colonoscopies must be repeated at intervals shorter than those recommended in Table 3 because of inadequate preparation. The task force recommends that the procedure be considered adequate if it allows detection of polyps 5 mm or larger." (Rex 2002) "The economic burden of repeating examinations because of inadequate bowel preparation is substantial." (Rex 2002) No thresholds are recommended by the committee for the percentage of examinations that are repeated for poor preparation because the percentage of patients requiring repeat examination may depend mostly on patient population characteristics." (Rex 2002) However, measurement of individual practitioner's percentage of examinations requiring repeat because of preparation is recommended."

Bowel preparation assessment is necessary to determining the adequacy of the colonoscopy and establishing the evidence-based interval for the next examination. It is imperative that bowel preparation be routinely assessed to ensure the patient has an appropriate evidence-based follow-up recommendation. ***Both the AGA and the ASGE registries consider assessment of bowel preparation sufficiently important to include it in their colonoscopy registry systems.***

Item 4 & 5: Complete examination and cecal photo: The record states, "The Committee agreed that these are generally accepted as a standard of practice. These indicators demonstrate that the colonoscopy reached the cecum. The Committee agrees that there is strong evidence in terms of registry/database data and a RCT to support the notion that failure to reach the cecum is associated with a higher risk of having interval cancers but was not discussed on the submission form."

RESPONSE: These citations are included in our submission: Pignone 2002; Rex 2006; Whitlock 2008; Winawer 2003; and Zauber 2008. Per Rex: "In the United State, colonoscopy is generally undertaken with the intent to intubate the cecum. Cecal intubation is defined as passage of the colonoscopy tip to a point proximal to the ileocecal valve so that the entire cecal caput, including the medial wall of the cecum between the ileocecal valve and appendiceal orifice, is visible. The need for cecal intubation is based on the persistent finding that a substantial fraction of colorectal neoplasms are located in the proximal colon, including the cecum." (Rabeneck 2003)

"Effective endoscopists should be able to intubate the cecum in $\geq$ 90% of all cases (Marshall 1993) and in $\geq$ 95% of cases when the indication is screening in a healthy adult." (Johnson 1990; Foutch 1991; Lieberman 1991; Rogge 1994; Rex 1993; Kadakia 1996; Lieberman 2000; Imperiale 2000; Imperiale 2004; Schoenfeld 2005) "Cases in which procedures are aborted because of poor preparation or severe colitis need not be counted in determining cecal intubation rates." **This is the basis for excluding patients with 'poor' or 'inadequate' prep from the Quality Quest Colonoscopy Quality Index.**

Also per Rex: "Photography of the cecum is also recommended. Still photography of the cecum may not be convincing in all cases because of variations in cecal anatomy." (Rex 2000) "… however, still photography is convincing in a substantial majority of cases," "Rate of photo-documentation of cecal landmarks allows an external objective metric of subjective reporting of *complete examination*" "Also allows for external blinded judging of adequacy of proximal laxative colon preparation"

Items 6 & 7: All essential polyp information recorded and withdrawal time recorded: The record states, "The Committee agreed that there is evidence of endoscopic registry/database studies that demonstrate that if the withdrawal time is greater than 7 minutes, the adenoma detection rate is higher than if the withdrawal time is less than 7 minutes. Therefore, this information may be useful to record. However, Committee members noted that adenoma detection rate is the key quality indicator for colorectal cancer screening with colonoscopy since the purpose of this procedure is to identify and remove adenomas. There were concerns that these two indicators are not sufficiently related to the adenoma detection rate. The Committee noted evidence that endoscopists with withdrawal times of greater than seven minutes may still have poor adenoma detection rates. This evidence was not provided in the measure submission form. The Committee was also concerned that this component only requires that the withdrawal time is recorded which can be "gamed" by the endoscopist so this may not improve outcomes."

RESPONSE re: polyp information: The requirement to record all essential polyp information includes: number of polyps, estimated size, anatomic location, morphology (pedunculated, sessile, flat), method of removal, and completeness of removal. These are all integral to determining the appropriate follow up interval. ***The AGA and ASGE registries consider these descriptors of sufficient importance that, with the exception of completeness of removal, they include them in their registries***. Incomplete removal is essential information, as a 2-6 month interval follow up for incomplete sessile polyp removal, is the evidence-based standard.

RESPONSE re: withdrawal time: Withdrawal time of 6 minutes, or greater, has been proven to correlate with adenoma detection rates. Gameable measures are those open to interpretation by the data submitter. This is a yes/no element and, thus, non-gameable. Either the withdrawal time was recorded or it was not. ***The ASGE registry considers withdrawal time sufficiently important that they include it in their colonoscopy registry system.***

Additionally, the record states: "Others were also concerned that essential information about the polyp is not included in this measure, including whether pathologic examination of the polyp revealed it to be an adenoma."

RESPONSE: This is a factual misstatement. Evaluation of the appropriateness of follow-up recommendations incorporates the following data elements as per the submitted materials:

# Polyp(s) removed	Largest polyp (mm) removed this exam; size estimated by colonoscopist	Any adenomatous polyp(s) this exam	Total # of confirmed adenomas this exam	Additional findings/ characteristics noted by the pathologist (Histopathology)	Any serrated adenomas this exam

Item 8 Free of Serious Complications: The record states: "In order to identify serious complications, the provider would need to follow up with the patient within a 15 to 30 day time window. The Committee discussed that documenting complication during the time of colonoscopy or in the first 24 hours after colonoscopy as this measure is currently specified would not assess the true rate of complications. While there is no disagreement that any complications experienced during the procedure should also be reported, the most common serious complication, post-polypectomy bleeding, usually does not occur until 2-14 days after colonoscopy and would not be captured by this indicator. The Committee was concerned that inclusion of only patients free of serious complications at the time of colonoscopy or in the first 24 hours after colonoscopy would not be an accurate representation of all complications that could occur. "

RESPONSE: We do not disagree that complications can occur after the first 24 hours following colonoscopy. This window of time was selected due to the difficulty of collecting data on all patients over a longer time period. With greater availability of electronic health records and health information exchange this time window could be expanded in future. It is important that immediate complications be included and scored as a procedural quality failure.

IN SUMMARY: There is no element in the composite that could be jettisoned by a physician performing high quality procedures. They all add value. When one constructs a composite one has the opportunity to include elements that cumulatively add value to the care for individuals. Some add greater value than others.

COMPARISON TO MEASURES 0658 and 0659

The Colonoscopy Quality Index (2056), as submitted, incorporates, in one measure, the two separate patient populations in measures 0658 and 0659, plus, all other screening and surveillance colonoscopies, with the exception of a small number of patients with personal or family history of

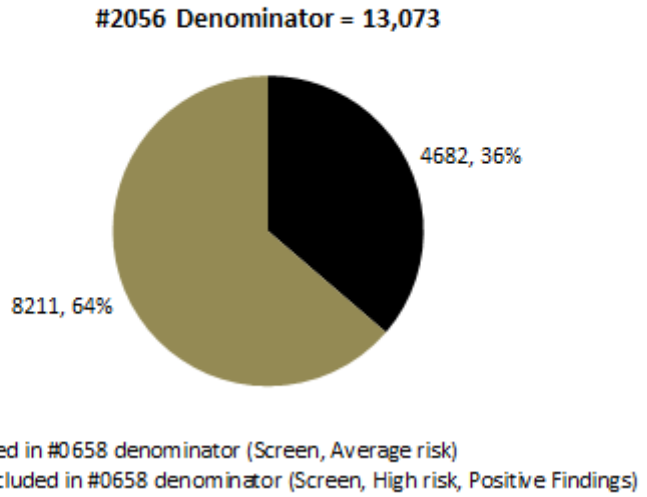
familial adenomatous polyposis, hereditary non-polyposis colorectal cancer, or inflammatory bowel disease. Smaller, separately reported denominators limit the number of physicians with a sufficient number of colonoscopies to report results. Our data show that of 13, 073 patients undergoing screening and surveillance colonoscopy from Q1 2012 through Q2 2012, 4,682 are eligible for the measure #0658 and 8,211 are ineligible for measure #0658.

Specification Comparison: Measures #0658 vs. #2056

Measure # 0658	Measure # 2056
Description: Recommendation for appropriate follow-up interval for normal colonoscopy in average risk patients	Description: Recommendation for appropriate follow-up interval for all screening and surveillance colonoscopies
Denominator: All patients aged 50 years and older receiving screening colonoscopy without biopsy or polypectomy	**Denominator: All adults undergoing screening or surveillance colonoscopy**
Numerator: Patients with recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report	Numerator: All patients age >18 undergoing screening or surveillance colonoscopy with recommended follow-up interval consistent with patient history and examination findings.
Exclusions: Documentation of medical reason(s) for not recommending at least a 10 year follow-up interval (eg, above average risk patient, inadequate prep)	Exclusions: Patients with a personal or family history of familial adenomatous polyposis, hereditary non-polyposis colorectal cancer or inflammatory bowel disease, and patients assessed as poor or unsatisfactory bowel preparation.

Comparison #0658 vs. #2056

Based on Quality Quest data 2010-2012



In conclusion, the Committee erred in its evaluation and assessment of measure 2056. Measure 2056 is a stronger measure than either #0658 or #0659, or both combined. Measure #2056 should advance in to stage 2 of the NQF measurement endorsement process.

Respectfully,

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