Quality Indicators for Inflammatory Bowel Disease: Development of Process and Outcome Measures

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Introduction: Variation in adherence to management guidelines for inflammatory bowel disease (IBD) suggests variable quality of care. Quality indicators (QIs) can be developed to measure the structure, processes, and outcomes of health care delivery. The RAND/UCLA appropriateness method was used to develop a set of process and outcome QIs to define quality of care for IBD.

Methods: Guidelines and position papers for IBD published from 2006 to 2011 were reviewed for potential QIs, which were rated by a multidisciplinary panel. Potential process and outcome QIs were discussed at 3 moderated in-person meetings, with pre-meeting and post-meeting confidential electronic voting. Panelists rated the validity and feasibility of QIs on a 1 through 9 scale; disagreement was assessed using a validated index. QIs rated above 8 were selected for the final set.

Results: More than 500 potential process QIs were extracted from guidelines. Following ratings and discussion by the first panel, 35 process QIs were selected for literature review. After the second panel, 10 process QIs were included in the final set. Candidate outcome QIs were then derived from physician, nurse, and patient input and ratings, in addition to outcomes associated with candidate process QIs. None of the top QIs exhibited disagreement.

Conclusions: A set of QIs for IBD was developed with expert interpretation of the literature and multidisciplinary input. Outcome QIs focused largely on remission and quality of life, whereas process QIs were aimed at therapeutic optimization and patient safety. Evaluation of these QIs in clinical practice is needed to assess the correlation of performance on process QIs with performance on outcome QIs.

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Inflammatory bowel disease (IBD) refers to idiopathic chronic intestinal inflammation classified as Crohn’s disease or ulcerative colitis, which are prevalent and expensive conditions1,2 and significantly impact health-related quality of life.3 Numerous guidelines have been published detailing evidence-based and opinion-based recommendations for the diagnosis, treatment, and...
management of these diseases, many of which are considered “best practice.” However, there is considerable variation in processes of care for patients with IBD, both when comparing care processes of “experts” with community practitioners as well within each group of practitioners. This variation in the process of care indicates possible overuse, underuse, or misuse of medical services and is prevalent across many facets of IBD management including treatment recommendations, use of diagnostic tests, knowledge of preventive care recommendations, and appropriate cancer surveillance practices.

Importantly, variation in care processes may be associated with poor outcomes in IBD as has been demonstrated with increased morbidity and mortality among centers performing fewer colectomies for ulcerative colitis. Furthermore, lack of adherence to various IBD guidelines has been demonstrated in the majority of patients referred to a tertiary care IBD center.

Guidelines differ from quality indicators (QIs), in that explicit QIs (which may be based on guidelines) include defined clinical circumstances for which specific care may be indicated. They may relate to the structure, process, or outcomes of care and can be used to develop standards by which the quality of care can be assessed and measured. Common measures of quality can include process measures (e.g., checking for Clostridium difficile in a patient with diarrhea) that directly assess provider practices and outcome measures (e.g., hospitalization rates and mortality), which may take more time to assess.

Explicit process and outcome QIs for adult patients with IBD are important for several reasons: (1) to better understand where deficiencies in quality care exist, and thus help direct and prioritize improvement efforts; (2) to establish goals for performance competency in IBD care; (3) to create physician-established measures in anticipation of mandated QI development by third party payers; (4) to define outcome measures for future quality-of-care initiatives; and (5) to ultimately improve patient care. In 2011, the American Gastroenterological Association (AGA) Institute developed 10 performance measures, 8 of which were subsequently included in the Centers for Medicare and Medicaid Physician Quality Reporting System in 2012. Process and outcome measures for pediatric IBD care are currently implemented and used in collaborative quality improvement programs through the ImproveCareNow consortium of over 35 pediatric IBD centers.

We aimed to develop a set of process and outcome QIs for Crohn’s disease and ulcerative colitis using standardized, validated methodology that incorporates both content validity (evidence-based methodology) and face validity (consensus panel ratings of QIs) and has previously been used to develop QIs in multiple chronic medical conditions as well as within the field of gastroenterology.

METHODS

We used the RAND appropriateness method to develop both process and outcome measures for IBD. The methods used to develop both measure sets are shown in Figures 1 and 2.

The RAND appropriateness methodology has been shown to be reliable and has been demonstrated to have content, construct, and predictive validity. This approach involves anonymous ratings by a multidisciplinary panel using a standardized Likert scale by an expert panel before and after face-to-face moderated meetings.

We also developed a conceptual model of IBD management to summarize the potential nodes at which quality of care could be impacted, and into which various indicators of quality might fit (Fig. 3). This model was referenced at several of the in-person discussions to inform a perspective of quality of care measurement.

Process Measures

Phase 1: Preliminary QIs

We performed a comprehensive literature review to identify all position statements and guidelines relevant to IBD since 2006 using PubMed and Internet-based searches of North American and European gastroenterology medical societies (AGA, the American College of Gastroenterology, the Crohn’s and Colitis Foundation of America [CCFA], the British Society of Gastroenterology, and the European Crohn’s and Colitis Organization). We also searched all titles published in the “Guidelines” section of the IBD Journal since 2006. We reviewed titles and relevant
process of care to be performed by health care providers, and the “because” component provides the rationale and/or summary of evidence that links the process measure to an outcome of interest.

These 537 preliminary QIs were then each discussed among the QI Task Force and reduced to 100 potential QIs through consensus agreement to remove duplicates or overlapping QIs, outdated practices, structure measures, and QIs, where either the “if” statement was not specific enough or the “then” statement was not a measurable process.

Phase 2: The IBD Process Indicators Advisory Panel Meeting

We convened a 12-member advisory panel comprising the 3-member QI Task force and 9 IBD clinical and health services research and patient care experts from the AGA, American College of Gastroenterology, CCFA, a colorectal surgeon, and pediatric gastroenterologists involved in the ImproveCareNow initiative. Physicians included on the panel represented both academic and community-based practice and were geographically diverse within the United States.

After an introductory teleconference, the panel members independently and anonymously rated the 100 potential QIs electronically for “validity” in advance of a moderated in-person meeting. Ratings were performed on a 1 through 9 scale, with anchors at 1 (“not valid”) and at 9 (“extremely valid”). These initial ratings were compiled, discussed, and confidentially re-rated during a moderated 1-day in-person meeting. At this meeting, discussions were targeted toward clarification of wording for highly rated QIs, and toward items associated with significant disagreement (measured by the disagreement index).24 During the meeting, additional QIs were solicited from the panel that had not been included on the original list of 100. At the in-person meeting, QIs were then rated a second time anonymously, now for both validity and feasibility, each on a 1 through 9 scale.

Panelists were asked to rate validity based on criteria used for QI development for systemic lupus erythematosus17 as follows:

1. Is there adequate scientific evidence or professional consensus to support the indicator?
2. Are there identifiable health benefits to patients who receive care specified by the indicator?
3. Based on your professional experience, would you consider physicians with significantly higher rates of adherence to the indicator higher quality providers?
4. Are the majority of factors that determine adherence to the indicator under the control of the physician (or are they subject to influence by the physician)?17

For feasibility, panelists were asked to consider:

1. Is the information necessary to determine adherence possible to find in an average medical record (or is failure to document such information inherently an indicator of poor quality)?
2. Is the estimate of adherence to the indicator based on medical record data likely to be reliable and unbiased?17

Following this meeting and confidential re-ratings, a total of 35 candidate QIs were found to be rated 7 or higher for both validity and feasibility and thus selected to undergo comprehensive literature review.

Phase 3: Literature Reviews

Each of the 35 candidate QIs was subjected to a comprehensive literature review, to identify any evidence linking that process of care to an outcome of interest. Literature searches were conducted by a committee of 21 physicians, and formal search strategies were developed using PubMed with the help of a professional research librarian. More than 2100 titles were screened, after which selected abstracts were reviewed in detail, and full-length manuscripts were obtained of studies with potential information linking the process of care promoted by the QI to patient outcomes. The resulting tables and literature summaries for each candidate QI were compiled into a 132-page monograph (Supplemental Digital Content 1, http://links.lww.com/IBD/A76). This was distributed to the participants before the second face-to-face (multidisciplinary) meeting and served as the evidence base for discussion at this second moderated meeting.

Phase 4: The Multidisciplinary Advisory Meeting

For the multidisciplinary advisory meeting, we again used the modified RAND/UCLA Appropriateness Method to generate a final process indicator set for IBD. This 11-member panel included the 3 members of the QI Task Force, clinicians from the initial meeting, representing both academic and private practice,
and leadership from the AGA, the American College of Gastroenterology, and the CCFA. In addition, this panel also included representation from European Crohn’s and Colitis Organization, and a patient with IBD. One month before the meeting, all panelists had the opportunity to review the literature compendium and electronically rate the 35 candidate QIs. At the face-to-face meeting, panelists received an anonymous summary of the electronic round of ratings and their own individual ratings. A moderated discussion focused on the highest rated QIs and those found to have high disagreement scores, and wording of select QIs was fine-tuned. Agreement was not required. Panelists then confidently re-rated the 35 candidate QIs for validity. Those QIs with a mean rating of at least 8.0 were then included in the final Process Measures Set. This set was then circulated to all members of both panels for comment and minor editing before finalizing the measures.

Outcome Measures

Phase 1: Preliminary Outcome Measures

Development of the outcome measure set was initiated at the second face-to-face process measure QI meeting. A list of preliminary outcome QIs was generated from 3 sources. First, the 11-member multidisciplinary panel at the second face-to-face meeting was queried during a moderated 2-hour discussion for potential outcome measures. Second, we considered each of the “because” statements from the 35 candidate process measures to represent a potential distinct outcome measure. Finally, members of the QI Task Force proposed additional potential outcome measures, including previously published outcome measures from ImproveCareNow. A total of 73 preliminary outcome measures in 4 categories (healthcare utilization, treatment emergent adverse events, preventable complications, and health-related quality of life) were then presented to a multidisciplinary panel for rating and discussion.

Phase 2: Candidate Outcome Measures

We convened a third multidisciplinary meeting to discuss and rate the preliminary outcome measures. This group of panelists was distinct from the previous 2 groups, and in addition to academic and community-based gastroenterologists, also included a gastroenterology nurse practitioner, a registered nurse, and 2 patients with Crohn’s disease. Each outcome measure was confidentially re-rated after the meeting, and the 10 most highly rated outcome QIs were then circulated for final comment and approval before finalizing the measures.

Statistical Analysis

Summary statistics were calculated for each measure after each round of ratings. The RAND/UCLA Disagreement Index was calculated for each measure for each round of ratings, using a standard formula. A Disagreement Index greater than 1.0 indicates “extreme variation” in ratings, whereas a lower Disagreement Index reflects increasing agreement. Discussion at the in-person meetings highlighted areas of disagreement and highly rated measures. During the meetings, all panelists had the opportunity to propose changes or add to the candidate measures.

RESULTS

Our finalized measure sets include 10 process measures and 10 outcome measures (Tables 1 and 2). These measures were developed, discussed, rated, and refined through a systematic method that incorporated expert opinion at 3 moderated in-person sessions and a comprehensive literature review. The finalized measures were rated 8.0 or higher on a 1 through 9 scale of importance. No measures were excluded on the basis of disagreement because no significant disagreement was noted for any of the highly rated measures.

The final list of highly rated process measures includes processes that relate to treatment, surveillance for colon cancer, and health care maintenance. Process measures relating to treatment include pretreatment screening for important latent infections (tuberculosis, hepatitis B), checking for enteric infections (C. difficile and cytomegalovirus) in severe steroid-refractory colonic disease, and avoidance of long-term corticosteroids. Measures relating to cancer surveillance include appropriate colonoscopy screening for those with longstanding colonic inflammation, and appropriate management of low-grade dysplasia. Measures relating to health care maintenance include patient education regarding appropriate and inappropriate vaccinations, particularly among those who are receiving systemic immunosuppressive therapies.

Highly rated outcome measures included measures relating to the avoidance of long-term corticosteroid use (steroid-free clinical remission and current corticosteroid use), assessments of general health state (anemia, malnutrition), health care utilization (hospitalization days and emergency visits) and health-related quality of life (work/school absence, symptoms of incontinence).

DISCUSSION

Quality improvement efforts for IBD have been underway for several years in the United States and abroad. The British Society of Gastroenterology published a recommended set of IBD Standards that are intended to serve as the basis of quality care for IBD. These comprehensive standards provide a framework for optimal care in IBD, and go well beyond defining minimal basic care. Our intent however in defining indicators of quality for IBD was to present measurable basic processes and outcomes of care that could be used as a basis for limiting variation and improving care. The ImproveCareNow network has developed pediatric-specific process and outcome measures and has been collecting data from several pediatric IBD centers across the United States for several years through a quality improvement collaborative. Through this iterative process, they have reported outcomes data, center variation, and changes over time and have demonstrated improvement in key outcomes such as remission and use of corticosteroids. Given the differences in several aspects of care specific to children (e.g., growth and development) and adults (e.g., emphasis on cancer screening), we developed new measure sets for adult
TABLE 1. Ten Most Highly Rated Process Measuresa

| Measure                                                                 |
|-------------------------------------------------------------------------|
| Treatment                                                               |
| IF a patient with IBD is initiating anti–tumor necrosis factor therapy, THEN tuberculosis risk assessment should be documented, and tuberculin skin testing or interferon gamma release assay should be performed |
| IF a patient with IBD is initiating therapy with anti-TNF, THEN risk assessment for hepatitis B virus should be documented |
| IF a patient with IBD requires at least 10 mg prednisone (or equivalent) for 16 weeks or longer, THEN an appropriately dosed steroid-sparing agent or operation should be recommended |
| IF a hospitalized patient with severe colitis is not improving on intravenous steroids within 3 days, THEN sigmoidoscopy with biopsy should be performed to exclude cytomegalovirus, AND surgical consultation should be obtained |
| IF a patient in whom a flare of IBD is suspected with new or worsening diarrhea THEN the patient should undergo *Clostridium difficile* testing at least once |
| IF a patient with IBD is initiating 6 MP/AZA, THEN TPMT testing should be performed before starting therapy |
| Surveillance                                                            |
| IF a patient with ulcerative colitis is found to have confirmed low-grade dysplasia in flat mucosa, THEN proctocolectomy or repeat surveillance within 6 months should be offered |
| IF a patient with extensive ulcerative colitis or Crohn’s disease involving the colon has had their disease for 8 to 10 years, THEN surveillance colonoscopy should be performed every 1 to 3 years4 |
| Health care maintenance                                                 |
| IF a patient with IBD is on immunosuppressive therapy, THEN patients should be educated about appropriate vaccinations, including (1) annual inactivated influenza, (2) pneumococcal vaccination with a 5-year booster, and (3) general avoidance of live virus vaccines |
| IF a patient with Crohn’s disease is an active tobacco smoker, THEN smoking cessation should be recommended, and treatment should be offered or suitable referral provided at least annually |

6MP, 6-mercaptopurine; AZA, azathioprine; TPMT, thiopurine methyltransferase; PSC, primary sclerosing cholangitis.

aAll measures had median ratings of 8 or higher on a 1 through 9 rating scale.

b6-mercaptopurine, 1.0 to 1.5 mg/kg daily; azathioprine, 2.0 to 2.5 mg/kg daily (if normal TPMT metabolism); methotrexate 25 mg injected subcutaneously weekly, or appropriately dosed biological therapy.

cLeft-sided for ulcerative colitis, or 1/3 or more for Crohn’s disease.

dIf a patient with ulcerative colitis has co-existing PSC (of any duration), THEN surveillance colonoscopy should be performed every 1 to 3 years.

TABLE 2. Ten Most Highly Rated Outcome Measuresa

| Measure                                                                 |
|-------------------------------------------------------------------------|
| Steroid Use                                                             |
| Proportion of patients with steroid-free clinical remission for > 12 month period |
| Proportion of patients currently taking prednisone (excluding those diagnosed within the last 112 days) |
| Number of days per month/year lost from school/work attributable to IBD |
| Number of days per year in the hospital attributable to IBD |
| Number of emergency room visits per year for IBD |
| Proportion of patients with malnutrition |
| Proportion of patients with anemia |
| Proportion of patients with normal disease-targeted health-related quality of life |
| Proportion of patients currently taking narcotic analgesics |
| Proportion of patients with nighttime BM’s or leakage |
| Proportion of patients with incontinence in the last month |

aAll measures had median ratings of 8 or higher on a 1 through 9 rating scale.

Care although some QIs do intersect between pediatric and adult IBD care. The AGA has publicized quality measures for IBD that underwent public comment, and 8 measures received approval by Centers for Medicare and Medicaid and are presently under review by the National Quality Forum. These measures are now available for 2012 Physician Quality Reporting System reporting and incentive program and must be reported as a group through either a claims-based process or a certified registry. Although our process for defining QIs for adults overlapped somewhat with this endeavor, the AGA measure set was primarily intended to define quality for purposes of accountability and reimbursement using a proscribed methodology. Although the CCFA measures were developed without those constraints, and despite somewhat different methodologic approaches to defining quality measures, several process QIs are common to both sets, providing further validity to the results of both efforts.

We have developed process and outcome QIs for adults with IBD using validated methodology. To develop these measures, we conducted an extensive literature review to cull from hundreds of potential measures and narrowed down the candidate measures using a modified Delphi panel of content experts who were provided with summaries of the available evidence in support of given candidate QIs. The expert panels were multidisciplinary, with attempts to obtain representation from academic, community, international, and pediatric gastroenterologists as well as allied health care professionals and the patient perspective.
The development of QIs is a step toward quality improvement, by providing assessment tools to determine and measure basic processes and outcomes for the treatment of adults with IBD. This is in contrast to guidelines, which may guide us toward important processes but do not necessarily address outcomes and may not necessarily be related to improved patient care. These measures still require implementation and operationalization for “real-world” testing. However, they do provide a framework around which quality initiatives can be developed and structured for adults with IBD. As was the case with the ImproveCareNow pediatric IBD network, initial implementation of these measures for quality improvement will likely warrant pilot testing in varied clinical settings to optimize the measures and fully assess their feasibility of measurement and potential impact on quality of care.14

Our QI measure set has limitations. First, given the paucity of evidence linking processes to outcomes, the ratings were largely influenced by the experience and preferences of the individual panel members. Thus, highly rated processes may not necessarily translate into improved outcomes. However, we used rigorous methodology that incorporated stakeholders from various practices settings and geographic locations to broadly capture and discuss a wide range of candidate QIs. Second, QI measures were not all fully defined for practical implementation. For example, the outcome of “malnutrition” was thought to be important by all the panelists, yet its definition (serum albumin, percent body fat, etc..) was not specified. Third, some measures may already be ubiquitous in practice, and may therefore suffer from a “ceiling effect” for which there is little room for improvement. For example, documentation of previous tuberculosis assessment is required by most third party payers when anti-TNF therapy is ordered; thus compliance with this QI may already be close to 100%. Fourth, process measures may prove to be unfeasible for documentation and reporting. Although all process QIs underwent rating for feasibility, it is conceivable that with “real-world” implementation some may simply prove too difficult, time-consuming, or expensive to measure and/or report. We attempted to include a variety of practice settings, providers, and representative patients, to optimize the generalizability of the measures for key stakeholders. However, we did not include third party payors, generalists, or specialists who care for patients with other chronic illnesses, given the highly specialized nature of the management of IBD and the desire to initially avoid considerations of cost in the determination of quality of care for IBD. Finally, it remains to be clarified what is truly a good outcome measure for patients with IBD. Each of the top-rated outcomes could arguably be only an inaccurate surrogate of disease activity, and that without a “hard” outcome (such as survival, an important quality outcome measure for conditions such as cystic fibrosis and cancer) or a valid and reliable “surrogate” outcome (such as radiologic joint deformity in rheumatoid arthritis), IBD lacks a well-defined agreed-upon outcome measure that clearly demonstrates good quality of care.

Despite these limitations, we used rigorous methodology with input from multiple stakeholders to develop a set of process and outcome QIs for IBD. The intent of these measures is to establish an initial foundation of measurable quality processes and outcomes for the care of adults with IBD for the purpose of initiating an iterative quality framework. Over time, we expect these measures to be adapted to suit the feasibility and financial realities of measuring and reporting these QIs. Furthermore, the implementation of these QIs must be flexible to be consistent with best available evidence in support of their validity. Ultimately, quality improvement requires the ability to measure basic indicators of quality care, and limit the variation in care thought to be associated with poor quality of care. Our hope is that these measures will provide that basis for quality improvement programs for adults with inflammatory bowel disease in all settings, ranging from small groups to large academic practices.

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