

# Quality Improvement in Inflammatory Bowel Disease

Gil Y. Melmed, MD, MS, and Corey A. Siegel, MD, MS

Dr. Melmed is a Clinical Assistant Professor of Medicine in the Division of Gastroenterology in the Department of Medicine at Cedars-Sinai Medical Center in Los Angeles, California. Dr. Siegel is an Associate Professor of Medicine in the Section of Gastroenterology and Hepatology in the Department of Medicine at Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire.

Address correspondence to:  
Dr. Gil Y. Melmed  
8635 W. 3rd Street #960-W  
Los Angeles, CA 90048;  
E-mail: melmedg@cshs.org

**Abstract:** Chronic illnesses such as inflammatory bowel disease (IBD) present a unique opportunity to define and improve the quality of care. Processes of care can be complex, and outcomes of care may vary across different healthcare delivery settings. Patients with IBD are managed over long periods of time and often by the same physician within a single care delivery system. Both patients with Crohn's disease and ulcerative colitis have variable courses of disease progression that require changes in therapy over time. These factors necessitate multiple areas of potential assessment and improvement of processes and outcomes of care. A current initiative is the development of quality measures. The American Gastroenterological Association has developed accountability measures for the Physician Quality Reporting System, and the Crohn's and Colitis Foundation of America has developed a set of top 10 recommended processes and outcomes of measurement for high-quality care of patients with IBD. In addition, the pediatric ImproveCareNow collaborative network has collected improvement data from dozens of pediatric centers over the past 5 years and has demonstrated improvement in overall disease activity in their cohort through iterative quality improvement processes. Future directions for quality indicators for adults with IBD will involve implementation of quality-measure reporting, both for purposes of reimbursement as well as improvement of care. These strategies will need to be closely monitored to evaluate the effect of improvement programs on outcomes.

## Keywords

Inflammatory bowel disease, quality of care, quality measures, quality indicators

Quality in healthcare has been defined by the Institute of Medicine (IOM) as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."<sup>1</sup> Assessment of the quality of care in the United States healthcare system has recently been pushed to the forefront of the healthcare agenda, spurred by IOM reports published in 2000 and 2001, including *To Err Is Human*<sup>2</sup> and *Crossing the Quality Chasm*.<sup>1</sup> In these reports, significant deficits in the quality of US

healthcare were identified, including preventable errors in care that led to the deaths of “tens of thousands of Americans” each year and “hundreds of thousands” more who “suffer or barely escape nonfatal injuries.”<sup>1</sup>

Studies show that only about half (55%) of adult outpatients receive recommended care, regardless of whether the medical setting is chronic, acute, or preventative<sup>3,4</sup> or whether care involves screening, diagnosis, treatment, or follow-up.<sup>5</sup> This is also demonstrated in hospitalized patients across multiple disciplines.<sup>5</sup> Overuse, underuse, and misuse of healthcare resources are at issue. In regard to management of inflammatory bowel disease (IBD), one study reported that an estimated 11% of patients receive care that is not recommended in relation to practice guidelines and is potentially harmful.<sup>6</sup> An earlier study reported that it took an average of 17 years before knowledge gained from randomized controlled trials was incorporated into clinical practice, and even then, application of the information was highly variable.<sup>7</sup>

These studies and others highlight the need for improved quality of care for patients through timely and explicit processes. Quality measures, or indicators, differ from practice guidelines in that guidelines provide statements of best care, whereas explicit quality indicators (QI) provide a measurable standard of performance that can be used to assess the basic quality of care.

## Burden of Inflammatory Bowel Disease

IBD is generally classified as either Crohn's disease (CD) or ulcerative colitis (UC) and refers to chronic, idiopathic intestinal inflammation. IBD leads to symptoms and signs that are morbid, expensive to treat, and impair quality of life. Furthermore, IBD has been associated with preventable complications, including infections, thromboembolic events, and cancer.

Symptoms of IBD include diarrhea, gastrointestinal blood loss, weight loss, and abdominal pain. Signs of IBD include anemia, malnutrition, and bone density loss. IBD significantly impacts health-related quality of life relative to a healthy US population,<sup>8</sup> leads to loss of work and work productivity,<sup>9</sup> and results in increased hospitalizations and surgeries.<sup>10</sup> In the United States, these conditions are prevalent and expensive to treat. Kappelman and colleagues recently assessed a medical claims database of over 9 million persons across 33 states and estimated that the prevalence of CD and UC in adults is 201 per 100,000 persons (95% confidence interval [CI], 197–204) and 238 per 100,000 persons (95% CI, 234–241), respectively.<sup>11</sup> These figures are higher than previously estimated.<sup>12,13</sup> The cost of management of CD is estimated to be \$2 billion annually, and it is likely to rise in light of

the increasing use of new biologic therapies.<sup>14,15</sup> Recent estimates show that direct costs of CD diagnosis and treatment may exceed \$8,000 annually per patient.<sup>16</sup> Although the cost of treating UC is lower than for CD, UC still represents a significant societal financial burden, with mean direct costs of over \$5,000 annually per patient.<sup>16</sup> In addition to this burden of disease, patients with IBD may be at increased risk for expensive and morbid complications as a consequence of the disease or immunosuppressive therapies. These complications include infections and malignancies such as colon cancer, cervical cancer, and nonmelanoma skin cancer.

## Defining and Measuring Quality

A major challenge to the implementation of quality improvement programs for IBD is the difficulty of measuring quality, which is a prerequisite for any quality initiative. Quality measures, or indicators, are explicitly defined and measurable items that allow for quality to be assessed and quantified. A major influence on the development of QI is the perspective of stakeholders involved in developing the QI. Stakeholders include healthcare providers, patients, and third-party payers, but they may value different aspects of care as measures of high-quality healthcare. For example, physicians may emphasize health outcomes, patients may value communication skills, and payers may have an interest in cost-effectiveness. Although all of these issues may be deemed relevant, priorities in relation to these indicators may differ depending on who is involved in the QI development process. Arguably, all stakeholders should be represented in the development of comprehensive QI.

Quality measures can be assessed based on the structure of care, the process of care, or outcomes thereof.<sup>17</sup> An example of a structure measure is the number of hospital beds per given population. There is limited evidence, however, to link structures with outcomes, which are ultimately what matter most to patients and providers.<sup>18</sup> Outcome measures (eg, hospitalization rates and mortality) may optimally represent measures of success or failure of a medical intervention or policy, but outcome measures generally take more time to assess and are thus less practical for quality improvement efforts. Process measures reflect the processes of medical care, including the specifics of diagnosis, treatment, referral, and prescribing. Measures of structure, process, and/or outcome are all valid measures for quality assessment; however, each type of measure has distinct advantages and disadvantages. For chronic illnesses such as IBD, process measures may be optimally suited to address quality improvement efforts to allow for more immediate opportunities for quality

assessment, and they are generally considered a more sensitive measure of quality.<sup>18</sup>

In 2011, the American Gastroenterological Association (AGA) endorsed a set of IBD-specific process measures after a public reporting period of select candidate measures. These measures are currently being incorporated into the federally funded Physician Quality Reporting System, a vehicle through which financial incentives can be obtained for adherence to quality reporting if measures are reported through a registry (Table 1).

### Quality of Care in Inflammatory Bowel Disease Is Suboptimal

Numerous evidence-based and consensus-based societal and international guidelines and recommendations representing best practices exist for patients with IBD.<sup>19-22</sup> Although the degree of variability across guidelines has not been assessed, all guidelines attempt to build upon available evidence, and all rely on essentially the same body of published literature. The care of the patient with IBD is complex. Treatment options may equally allow for differing treatment strategies. Continuing evolution regarding our understanding of risk and benefit trade-offs in the treatment of IBD confounds the absolute standardization of care. For example, the use of concomitant immunomodulator therapy with anti-tumor necrosis factor biologic treatments remains a clinical dilemma for many patients, and individualized treatment decisions are made in the absence of guidelines.<sup>23,24</sup> However, despite these grey areas, there are many facets of IBD care that can be subject to standardization, such as colon cancer surveillance in patients with chronic colitis, minimization of steroid use, monitoring of bone health, and prophylactic immunization of immunosuppressed patients against vaccine-preventable infections.

Variation in care has been used as a surrogate marker to represent poor quality of care. A high degree of variation may represent overuse, underuse, or misuse of healthcare resources. In IBD, there is evidence of a high degree of variation of care for both UC and CD. Two studies explored differences among experts and community providers using clinical vignettes.<sup>25,26</sup> The studies found significant differences between experts and community providers as well as variation within both groups for clinical scenarios involving treatment for CD and UC. For CD, there was a general consensus for the approach to diagnosis but not treatment. In UC, the variation was most pronounced in the areas of cancer surveillance, drug dosing, drug monitoring, and the management of severe UC. In a pediatric study that assessed the care of newly diagnosed IBD in children, significant practice variation was noted across

**Table 1.** Inflammatory Bowel Disease (IBD) Quality Measures Eligible for the 2012 Physician Quality Reporting System<sup>51</sup>

|   |
|---|
| Documentation of IBD type, anatomic location, and activity  |
| Documentation that corticosteroid-sparing therapy was recommended for patients unable to taper off corticosteroids        |
| Documentation that bone loss assessment was recommended for patients at risk for corticosteroid-related iatrogenic injury |
| Documentation that influenza immunization was recommended   |
| Documentation that pneumococcal immunization was recommended  |
| Documentation of screening for latent tuberculosis before initiating anti-tumor necrosis factor (TNF) therapy             |
| Documentation of assessment of hepatitis B virus status before initiating anti-TNF therapy                                |
| Documentation of screening for tobacco use and cessation if relevant  |

10 centers for the prescription of various treatments.<sup>27</sup> In a follow-up study, clinical outcomes varied widely up to 12–18 months (range, 38–76%;  $P=.02$ ) after diagnosis across centers.<sup>28</sup> This variation appeared to be independent of disease severity or variation in prescribed therapies. Reddy and colleagues assessed adherence to optimal care by looking at patients referred to a tertiary referral center for a second opinion.<sup>6</sup> The investigators found significant deficits in the quality of care, including suboptimal dosing of mesalazine and immunomodulators, deficiencies in referral for colorectal cancer screening in eligible patients, prolonged use of corticosteroids, and lack of attention to the risk of metabolic bone loss.<sup>6</sup>

The variation in the care of patients with IBD may potentially explain variation in outcomes. An example of this is illustrated in a study of annual colectomy rates in US hospitals in which it was observed that the mortality rates in high-volume hospitals (more than 10 colectomies per year) were less than half of those of low-volume hospitals.<sup>29,30</sup> Taken together, these studies provide evidence that the quality of care of patients with IBD is variable, leading to unintended suboptimal care.

### Preventable Complications

In addition to variation in care, another area in need of quality improvement is the prevention of complications. This has recently become apparent in 3 specific areas: infection prevention through prophylactic vaccinations, recognition of the risk for thromboembolic events (venous thromboembolism [VTE]), and recognition of the risks of (preventable) nonmelanoma skin cancer among thiopurine recipients.

In a survey of nearly 200 patients with IBD, less than half of patients who were eligible for the influenza vaccine had received it within the prior year, and less than 10% of eligible patients had ever received the pneumococcal vaccine.<sup>31</sup> Furthermore, deficiencies in vaccination rates for hepatitis B, varicella, and tetanus were noted. Other studies from the United States, Canada, Europe, and Australia have identified similar gaps in care or in provider knowledge, suggesting that these deficiencies are widespread and not confined to a specific geographic region.<sup>32-35</sup>

The risks of venous and arterial thromboembolic events in patients with active IBD and hospitalized patients with IBD have been identified in several population-based studies and are 2–3-fold higher than those of hospitalized controls who do not have IBD.<sup>36-38</sup> This relative risk is also increased among outpatients with IBD.<sup>39</sup> Furthermore, the risk of dying from a VTE is higher among those with IBD, as is the risk of recurrent VTE.<sup>38-40</sup> Because of the potentially devastating consequences of thromboembolic events, prophylaxis against VTE has been advocated.<sup>19</sup> However, a recent survey found that nearly 30% of gastroenterologists were unaware of any recommendations that addressed pharmacologic prophylaxis among hospitalized patients with UC.<sup>41</sup>

The risk of nonmelanoma skin cancer has been demonstrated in both large retrospective administrative claims cohorts and the prospective CESAME registry in France.<sup>42-44</sup> In CESAME, which includes nearly 20,000 French patients with IBD followed for over 3 years, the risk of development of nonmelanoma skin cancer (basal cell carcinoma or squamous cell carcinoma) was significantly higher in patients currently or previously exposed to thiopurines compared with those patients who had never taken them. This increased risk was seen even in patients younger than age 50 years and persisted across all age groups. Fortunately, these malignancies rarely metastasize and are readily preventable through sun exposure precautions.

## Current Quality Initiatives for Inflammatory Bowel Disease

Several initiatives that aim to assess and ultimately improve quality of care for patients with IBD are currently underway. In the United Kingdom, unacceptable variation in quality of care was noted in 2006. A multidisciplinary task force was convened to define minimum standards for IBD care. The task force involved representatives from various societies, including physicians, surgeons, nurses, nutrition specialists, and primary care specialists. The result of their efforts is a set of standards across 6 domains that encompass IBD care, including clinical care, access to care, nutritional and social support services, use of information technology, research, and

ongoing quality improvement efforts (see <http://www.ibdstandards.org.uk>). In a 23-page document, each of these standards is broken down into multiple subdivisions with specific guidelines.<sup>45</sup> Although these standards may not necessarily represent evidence-based medicine, they clearly represent consensus among providers of care for those with IBD in a multidisciplinary effort to achieve high-quality clinical care. Historical audits of IBD care in the United Kingdom suggest that, with this initiative in place, adherence to these standards will become part of routine quality assessment and improvement efforts.

In the United States, the Quality Assurance Task Group of the National Colorectal Cancer Roundtable has published continuous quality improvement recommendations for colonoscopy.<sup>46</sup> Included in the recommendations are surveillance colonoscopy for chronic UC that includes documentation of risk factors; description of a surveillance protocol; reporting of polyp morphology, withdrawal time, and follow-up, including confirmation of dysplasia by an experienced gastrointestinal pathologist; and appropriate notification of patients.

Quality improvement efforts for IBD in pediatric patients have been undertaken in recent years through the ImproveCareNow network.<sup>28</sup> Through this collaboration, 50 pediatric sites across the United States and 1 site in the United Kingdom are involved in assessing and improving the quality of care that is delivered to pediatric patients with IBD. Quality process and outcome indicators are measured and compared across sites, with shared learning across the network to facilitate quality improvement.<sup>47,48</sup> Using this forum, the proportion of patients in remission (as determined by physician global assessment) has steadily increased over the past 5 years. This suggests that dynamic QI efforts are indeed worth the effort of identifying variation in processes of care to facilitate improvement.

The AGA has developed a set of process QI that have undergone public comment. Data collection for these IBD quality measures can be facilitated through the AGA's Digestive Health Outcomes Registry.<sup>49</sup> The registry is designed to allow multiple interfaces for data input (including electronic record platforms and manual data entry) and facilitates reporting to Centers for Medicare & Medicaid Services for the purposes of accountability and payment incentives. Interested practitioners can log onto the AGA website and download the measures and instructions for participation in the registry to facilitate quality reporting (at <http://www.gastro.org/practice/digestive-health-outcomes-registry> and/or <http://www.gastro.org/practice/quality-initiatives/cms-physician-qualitative-report-initiative>).

The Crohn's and Colitis Foundation of America (CCFA) has, in parallel, methodically defined process

**Table 2.** Crohn's and Colitis Foundation of America's Top 10 Quality Process Indicators for Inflammatory Bowel Disease<sup>50</sup>

| Treatment   |
|---|
| 1. IF a patient with IBD is initiating anti-TNF therapy, THEN tuberculosis risk assessment should be documented and tuberculin skin testing or interferon gamma release assay should be performed.  |
| 2. IF a patient with IBD is initiating therapy with anti-TNF therapy, THEN risk assessment for hepatitis B virus should be documented.  |
| 3. IF a patient with IBD requires at least 10 mg of prednisone (or equivalent) for 16 weeks or longer, THEN an appropriately dosed corticosteroid-sparing agent* or operation should be recommended.  |
| 4. IF a hospitalized patient with severe colitis does not improve within 3 days of treatment with intravenous corticosteroids, THEN sigmoidoscopy with biopsy should be performed to exclude cytomegalovirus AND surgical consultation should be obtained.  |
| 5. IF a patient in whom a flare of IBD is suspected with new or worsening diarrhea, THEN the patient should undergo testing for <i>Clostridium difficile</i> infection at least once.   |
| 6. IF a patient with IBD is initiating azathioprine/6-mercaptopurine, THEN TPMT testing should be performed before starting therapy.  |
| Surveillance  |
| 7. 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.   |
| 8. IF a patient with extensive** ulcerative colitis or Crohn's disease involving the colon has had disease for 8–10 years, THEN surveillance colonoscopy should be performed every 1–3 years. <sup>†</sup>  |
| Healthcare maintenance  |
| 9. IF a patient with IBD is on immunosuppressive therapy, THEN patients should be educated about appropriate vaccinations, including <ul style="list-style-type: none"> <li>– annual inactivated influenza</li> <li>– pneumococcal vaccination with a 5-year booster</li> <li>– general avoidance of live virus vaccines</li> </ul> |
| 10. 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.  |

IBD=inflammatory bowel disease; TNF=tumor necrosis factor;  
TPMT=thiopurine S-methyltransferase.

\*6-mercaptopurine, 1.0–1.5 mg/kg daily; azathioprine, 2.0–2.5 mg/kg daily (if normal TPMT metabolism); methotrexate, 25 mg injected subcutaneously weekly; or appropriately dosed biologic therapy.

\*\*Left-sided colitis or greater involvement for ulcerative colitis, or 1/3 of the colon or greater involvement for Crohn's disease.

<sup>†</sup>If a patient with ulcerative colitis (of any duration) has coexisting primary sclerosing cholangitis, THEN surveillance colonoscopy should be performed annually.

**Table 3.** Crohn's and Colitis Foundation of America's Top 10 Quality Outcome Indicators for Inflammatory Bowel Disease<sup>50</sup>

|   |
|---|
| 1. Corticosteroid use <ul style="list-style-type: none"> <li>– Proportion of patients with steroid-free clinical remission for a 12-month period</li> <li>– Proportion of patients currently taking prednisone (excluding those who received a diagnosis within the past 112 days)</li> </ul> |
| 2. Number of days per month and year lost from school or work because of IBD  |
| 3. Number of days hospitalized per year because of IBD  |
| 4. Number of emergency room visits per year for IBD   |
| 5. Proportion of patients with malnutrition   |
| 6. Proportion of patients with anemia   |
| 7. Proportion of patients with normal disease-targeted health-related quality of life   |
| 8. Proportion of patients currently taking narcotic analgesics  |
| 9. Proportion of patients with nighttime bowel movements or leakage   |
| 10. Proportion of patients with incontinence in the past month  |

IBD=inflammatory bowel disease.

and outcome measure sets. Using the RAND Appropriateness Panel methodology (incorporating expert opinion with extensive literature review), sets of top 10 process and outcome indicators were developed (Tables 2 and 3). The processes of care identified for quality improvement include efforts aimed at diagnosis, treatment (appropriate pre-immunosuppressive screening, recommendations for appropriately dosed corticosteroid-sparing medications), and recommendations for preventive care, including influenza and pneumococcal vaccination.<sup>50</sup> In addition, colorectal cancer and dysplasia screening with appropriate intervals for UC and Crohn's colitis are recommended. The top 10 outcome measures relate to the avoidance of corticosteroids and narcotics, assessment of hospitalization and surgery, aspects of impaired quality of life and work productivity, and signs of anemia and malnutrition.

The CCFA measure set is currently in the process of pilot testing in select clinical environments. Results from these pilot sites will optimally shape a larger rollout of measure implementation as part of a wider quality improvement collaboration with continuous refinement of the measures and continuous quality improvement to achieve them.

## Conclusions

Quality of care for patients with IBD is highly variable, which suggests that there is significant room for quality improvement. As adult centers and practices imple-



ment and utilize accountability and improvement measures—ideally through continuous quality improvement initiatives—the IBD community will learn where to best focus its efforts toward quality improvement. These efforts will include education and dissemination of recommended interventions to improve the quality of care for adults with IBD.

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