

Chapter 1

Barriers to Successful Outcomes in Patients with Inflammatory Bowel Diseases

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Definitions of Successful Outcomes

Before embarking on discussion of obstacles in the care of inflammatory bowel disease (IBD) patients, it is important to establish appropriate endpoints for their care. For ulcerative colitis (UC), the disease can be deemed cured after colectomy; however, most patients with UC do not need or desire surgery. Therefore, goals include inducing and retaining remission with medication and/or surgical intervention. For Crohn's disease (CD), neither medical nor surgical therapy is curative and goals also include inducing and retaining remission. Practice guidelines from the American College of Gastroenterology (ACG) note that the overall goal of care for patients with CD is remission that can include clinical remission, endoscopic remission, or surgical remission. Clinical remission is further defined to include a patient who has no symptoms and is not on steroids [1]. In UC, endpoints in care include remission of symptoms, reduction in need for long-term corticosteroids, and minimization of cancer risk [2].

In research trials, remission is often defined on the basis of a composite index such as the Mayo Clinic Score (MCS) or Modified Baron Score (MBS) in UC or the Crohn's Disease Activity Index (CDAI) in CD [3]. Some indices unfortunately do not combine clinical and endoscopic findings, can be time consuming, and the usefulness of these composite indices in clinical care can be limited. There is a developing concept that our goals for therapy in IBD should be based on resolution of symptoms as well as resolution of inflammation of the mucosa. Damage of the

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R. K. Cross, A. R. Watson (eds.), *Telemangement of Inflammatory Bowel Disease*,
DOI 10.1007/978-3-319-22285-1_1

Table 1.1 Inflammatory bowel disease (IBD) quality measures eligible for Physician Quality Reporting System (PQRS) reporting, 2014

Measure description
Documentation of IBD type, anatomic location, and activity
Percentage of patients prescribed corticosteroid-sparing therapy
Bone loss assessment in patients who have been on corticosteroid therapy
Influenza immunization
Pneumococcal immunization
Testing for latent tuberculosis before starting anti-TNF therapy
Assessment of hepatitis B virus status before starting anti-TNF therapy
Tobacco use screening and counseling for cessation in tobacco users
<i>anti-TNF</i> anti-tumor necrosis factor

intestinal epithelial cells disrupts the intestinal barrier function, and this has been shown to be a factor in the pathogenesis of IBD [4]. Studies on mucosal healing have been undertaken, and mucosal healing has been shown to predict sustained clinical remission as well as resection-free survival [5].

Day-to-day determination of remission and success of IBD treatment in clinical practice is left up to the practitioner; however, in the USA, there are systems in place that hold practitioners accountable for some of their outcomes. A group of more specific endpoints in IBD has been determined by the Centers for Medicare and Medicaid Services (CMS) with help from the American Gastroenterological Association (AGA). The CMS Physician Quality Reporting System (PQRS) defines eight quality measures that are eligible for reporting to CMS. These measures are listed in Table 1.1 and range from documenting IBD type, activity, and anatomic location to immunizations and evaluation for corticosteroid-related iatrogenic bone loss [6]. It is important to note that these indicators of quality of care in IBD do not only involve disease-specific treatment but also revolve around prevention of overall health complications for the patient. Providers who reported to the PQRS in 2012–2014 were eligible for a 0.5% incentive bonus on reimbursements for Medicare Part B patients [7]. Importantly, in 2015, there will also be a “payment adjustment” of –1.5% for Medicare Part B reimbursements for providers who do not satisfactorily report data [8]. Overall, it is important to consider these types of endpoints when managing IBD patients and subsequently determining suboptimal outcomes.

Patient-Related Barriers to Success

Patients are complex human individuals, and IBD is a complex disease process. Therefore, it is no surprise that specific patient components can contribute to undesired outcomes in IBD. Taking these issues into account is important when treating patients and predicting patients’ needs.

Because IBD is such an intricate disease process, it is a priority to teach patients about their disease. Ideally this education should occur during office visits with the provider and/or staff. Unfortunately, it has been shown that patients do not know as much about their IBD as providers would expect or hope. In a study of 70 newly diagnosed IBD patients who underwent a 30 min consultation with a nurse providing education on medication adverse events, medication names, and medication administration, patients only recalled 52.6% of information initially and 53.8% of information after 3 weeks [9]. This confirms that it is prudent to provide continued education to patients during every encounter. Even with education, patients can glean erroneous information about their disease and medications. For example, when 165 patients with established IBD were asked to complete a survey regarding the risks and benefits of the anti-tumor necrosis factor (anti-TNF) medication, infliximab, patients were found to overestimate the benefit of infliximab and to not know or underestimate the risks of infliximab including the lymphoma risk. When asked on the survey to indicate whether they would take a hypothetical drug (with same risks of infliximab), the majority indicated they would not take it and 30% of these patients actually had taken infliximab or were taking it at the time of the survey [10]. Although much medical information is readily available on the Internet, several studies have shown widely varying quality of information available [11–13]. For example, a recent systematic review found that when a Google search was performed for “Crohn’s disease” and “Ulcerative colitis,” a marked variation of the quality of information was found, and high-quality websites were often low on the list of websites generated, making it more difficult for patients to find and discern correct information [12]. Therefore, it is important for physicians and teams to provide patients with high-quality Internet resource tools for patients.

Common mistakes made by physicians in educating patients include the framing effect, numeracy, and relying on verbal labels [14]. The framing effect refers to the choice providers make to present information in a certain format. This format can influence a patient’s decision. For example, presenting a relative risk statistic in regard to an adverse drug reaction versus presenting absolute terms to a patient can affect the patient’s decision to be adherent to the medication. Physicians also assume a patient’s ability to understand numbers. For example, a physician often assumes that a patient has the ability to interpret the term “0.2%” to be 2 in 1000 people; however, this may not always be the case. This can lead to altered patient perception of risk and subsequent changes in adherence. Finally, providers tend to rely on verbal labels such as “very common” and “very rare” when explaining disease and consequences. Patients often do not interpret the actual meaning of this and should be counseled in more specific terms. Tools to help educate patients appropriately include always providing absolute risk numbers, avoiding small percentages, focusing on shorter time intervals (as opposed to lifetime risk), and rounding numbers [7]. Overall, education of patients has been shown to be best presented by the use of decision aids [15]. A decision aid is a balanced presentation of particular treatment options that can be as simple as a paper presentation or as complex as a video. An

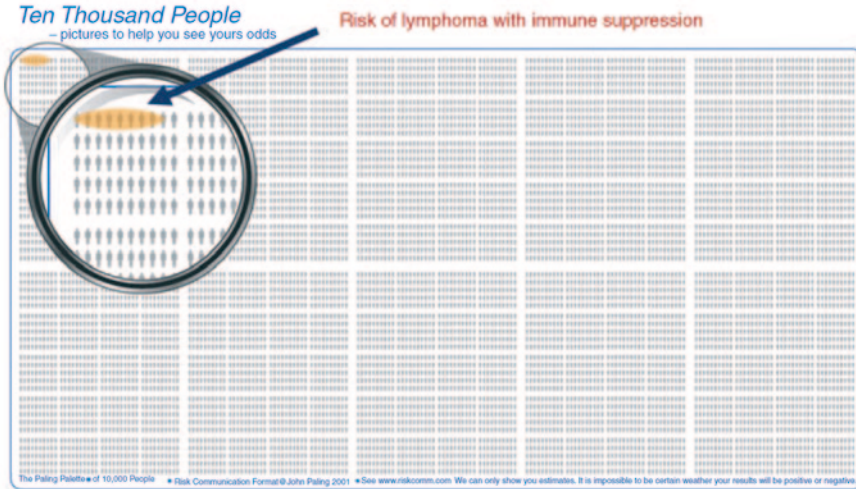


Fig. 1.1 Decision aid in explaining risks of lymphoma in inflammatory bowel disease (IBD) therapy. (Adapted from Ref. [70] with permission)

example of a decision aid is presented in Fig. 1.1. The picture displays the risks of lymphoma and certain IBD treatments. It illustrates 10,000 silhouettes of individual people and highlights nine of these silhouettes to illustrate the numerical risk of 4–9 per 10,000 patients who may develop lymphoma. The goal of using a decision aid is to enhance the physician–provider discussion. The educated patient in turn is then better able to participate in shared decision-making, which is simply the process of including patients in their medical decisions. Patients want to be involved in decision-making. When 1061 IBD patients were asked how important it is for them to be involved in medical decisions, 98% responded that it was important [16].

When involving patients in their care, it is important to estimate a patient’s acceptance of risk as this will translate to their perception of their disease in the context of their entire life. Risk is the probability of an event occurrence and the consequence if it occurs. It is incumbent on the practitioner to disclose these risks to patients prior to starting treatment and patient’s acceptance of these risks will affect their willingness to comply with therapy. When assessing middle-aged and older patients, gastroenterologists have an overall higher acceptance of risk than their patients, so it is important to keep the practitioner bias in check when prescribing and discussing therapy [17]. In assessing patient’s views on medication risks, studies have shown that patients are willing to accept a higher level of risk if they perceive a greater benefit from therapy. It is very important to delineate the risk compared to benefit ratio. For example, discussing the high percentage of steroid-free remission using anti-TNF therapy in a patient with CD can help the patient understand why a medication is recommended despite the risks of therapy. In one recent clinical trial by Colombel et al. [18], greater than 50% patients were in steroid-free remission on azathioprine and infliximab. This is compared to the extremely rare risk of

a complication such as lymphoma (4–6 in 10,000 patients per year). Patients also tend to be more risk averse to unfamiliar risks. For example, in a web-based survey of 600 CD patients who were presented with a series of tasks to determine their maximum acceptable risk of side effects including sepsis, lymphoma, progressive multifocal leukoencephalopathy (PML) in exchange for remission or response, the survey found that patients were more risk averse to adverse events such as PML which were less familiar to them than sepsis or lymphoma [19]. Risk assessment in IBD includes discussions about surgery as well as medications. Bewtra et al. [20] explored patient preferences for surgical and medical therapy in 300 UC patients and found that patients were willing to accept a high risk of complications (including lymphoma and infection risk) from medical therapy to avoid surgery with an ostomy. If the surgery would not involve an ostomy (ileoanal anastomosis), patients considered surgery equivalent to incompletely effective medical therapy.

Studies evaluating if demographic factors including race and socioeconomic status have consistently altered outcomes in IBD such as medical therapy utilization, utilization of surgery, and medication adherence have not been conclusive. In a recent review of 40 studies on this matter, authors concluded that surgical care utilization was the only significant category affected by patients' race [21]. In a large population study using the National Inpatient Sample, Nguyen et al. [22] discovered that when compared to Caucasians, minorities were much less likely to undergo bowel resection for active disease. Specifically, African Americans were 32% less likely to undergo bowel resection, Hispanics were 30% less likely to undergo surgery, and Asians were 69% less likely to pursue an operation. There are conflicting data in regard to medication utilization between different races. In the review, race was a predictor of medical therapy utilization, albeit less drastic [21]. Caucasians were treated more overall with immunomodulators and anti-TNF medications, but the reasons for this were not explored. In contrast, a recent study of over 26 million office visits in the USA for patients with IBD that examined race and use of immunomodulators and anti-TNFs found no evidence of disparities over a 13-year time period [23]. In regard to medication adherence, multiple studies have shown that minorities are less likely to adhere to their medication regimen due to decreased trust in their provider, younger age, and perceived improvement in disease [21]. Racial differences between patients' knowledge and perceptions also exist and minorities have been found to have lower IBD-specific knowledge and perceived greater intrusiveness of IBD on their lives compared with Caucasians [21]. Socioeconomic status such as race has not been shown to consistently affect outcomes in IBD. In the abovementioned study by Nguyen et al. [22] regarding bowel resection for CD, patients with Medicaid coverage were 48% less likely to undergo bowel resection than privately insured patients, and CD patients with an income below the median were associated with 29% increased risk of in-hospital mortality. Contrasting this, a French study of 200 patients with CD failed to show differences in disease severity recurrence, steroid use, infliximab use, and immunomodulator use across deprived and non-deprived populations [24].

Depression and anxiety are common in patients with IBD. Prevalence ranges from 11 to 41% in different cohort assessments [25–27]. Depression in IBD is most

common in younger, female patients and in patients with pain and functional limitations [26]. Anxiety is associated with more severe disease, flares, being disabled or unemployed, and socioeconomic deprivation [27]. When gaging nonadherence to treatment and poor outcomes in IBD, psychiatric disease is often shown to be an associated factor. For example, when asked about adherence and reasons for nonadherence, a survey of 1600 IBD patients performed by Nahon et al. [28] revealed that factors associated with nonadherence were being a smoker, having concerns related to their treatment, anxiety, and moodiness. In a review of adherence to oral medications in IBD, psychiatric factors including depression, chronic stress, or a psychiatric diagnosis were consistently associated with nonadherence [29]. Finally, in patients with CD on infliximab, depression was shown to be a risk factor for lower remission rate and a need for earlier re-treatment with the anti-TNF [30]. Outcomes including surgical utilization are also affected by psychiatric diagnoses of depression or anxiety. When looked at directly, CD patients with a diagnosis of depression or anxiety were 28% more likely to require surgery than patients without these diagnoses [31]. It is therefore important to assess for depression and anxiety in clinical practice and provide support and referral for these diseases if they coexist in the IBD patient.

Patient Adherence

Medication Adherence

Promoting adherence in the IBD patient population is a challenge for health-care providers and nonadherence is certainly a contributor to poor outcomes in IBD. Nonadherent adults are 5.5 times more likely to experience a flare of their disease than their adherent counterparts [32]. Patient adherence is defined as “the extent to which a person’s behavior coincides with medical or health advice” [33]. Exploring patient adherence in IBD patients involves examining medication adherence, adherence to screening and surveillance colonoscopy, and strategies to improve adherence.

Adherence to medications in IBD consists of patient compliance with taking oral medications as well as injectable therapies or medications given by infusion. Nonadherence to oral medications ranges from 7 to 72% with the majority of assessments reporting a 30–45% nonadherence rate [29]. Specifically for aminosalicylate medications (5-ASAs, 5-aminosalicylic acids), adherence ranges from 50 to 68% [34]. Much investigation has been undertaken to identify predictive factors of patient nonadherence to 5-ASA medication as this is one of the mainstays of treatment in IBD. When asked to identify barriers to adherence to taking 5-ASA, patients responses aligned into themes including competing priorities, social stigma, refill inconvenience, cost, doubts about efficacy or need for daily medication, side effects, size of the pill, and frequency of administration [35]. When evaluating adherence to 5-ASAs during the first 3 months of therapy, predictors of lower persistence

with therapy included psychiatric diagnoses, mail order prescription of the index prescription, female gender, and co-pay amount. In this same population of patients, at 12 months, predictors of lower persistence with therapy included more comorbid illnesses, patients who received a mail order prescription for a 90-day supply, and patients who were hospitalized for a gastrointestinal (GI) condition [36]. Taking these predictors into account with prescribing 5-ASAs can help to target and improve nonadherence rates. For example, it may be helpful to investigate a patient's co-pay and provide hard copy or local prescription for the index prescription of the drug. It is also important to provide consistency in prescribing for patients taking 5-ASAs as there are many formulations of ASA medications. In a large study in the UK, when patients were switched between two different formulations of 5-ASA, these switches led to a 3.5-fold greater risk of relapse in disease [37]. The thiopurine drug class, consisting of the oral drugs 6-mercaptopurine and azathioprine, is another common and effective therapy for both CD and UC. Adherence rates for the thiopurine drug class have been reported to be 50–93% [38]. In a study of 144 patients with IBD in England, nonadherence with thiopurines was associated with younger age, lower socioeconomic status, and depression [39]. These factors mirror factors for nonadherence with the 5-ASA class of drugs.

Anti-TNF therapy has become the mainstay of treatment for moderate-to-severe CD and UC. The most commonly used drugs in this class for IBD currently are adalimumab, infliximab, certolizumab pegol, and golimumab. Infliximab is given via an intravenous infusion while adalimumab, certolizumab pegol, and golimumab are administered via self-injection. Overall adherence to the anti-TNFs adalimumab and infliximab has been shown in a recent review to be 82.6% [40]. For both drugs, factors associated with overall nonadherence were female gender, active smoking, and having anxiety or self-reported moodiness. When looking at adalimumab alone, the adherence rate was 83.1% and predictors of nonadherence were every-other-week dosing, syringe use (vs. preloaded pen), prescription by an internist (vs. a gastroenterologist), use of retail pharmacy (vs. a specialty pharmacy), and being a new user [40]. Translating these predictors into clinical practice means that when prescribing adalimumab, it may be important to provide patients with medication reminders, preloaded pens, and specialized education for the new user. Infliximab seems to be an easier anti-TNF for which to measure adherence as patients are required to report to an infusion center to receive the drug. In 2006, Kane et al. [41] assessed adherence to induction and maintenance infliximab in 274 patients (greater than 1000 scheduled infliximab infusions) over 1 year as well as patient characteristics associated with nonadherence. Only 4% of the infusion appointments were classified as “no-show” appointments in this group making the adherence rate 96%. This differs from reported rates in other studies of 30–70% [40]. Risk factors for nonadherence in Kane's study [41] were patients who were female, had Medicaid, and patients who had gone >18 weeks from their initial infusion. Kane et al. [42] then evaluated adherence to maintenance therapy alone in 571 patients with CD on infliximab. The nonadherence rate was 34.3% over 1 year. Risk factors for nonadherence to maintenance infliximab included patients with recent hospitalizations. A cost analysis of adherent and nonadherent patients with CD on maintenance

infliximab in this study showed that all-cause medical costs by nonadherent patients were 81 % greater [42]. In clinical practice, therefore, when prescribing infliximab, it is important to consider closer monitoring of patients > 18 weeks into their therapy and patients with recent hospitalizations.

Measuring adherence to medication regimens for patients in itself is difficult to accomplish. Adherence can be monitored via self-report, tablet counts at clinic visits, pharmacy records, analysis of drug metabolites, and even electronic monitoring systems. All of these methods have their own flaws; however, overall an objective approach to measuring adherence is preferred. In one study of 60 UC patients, electronic monitoring systems were used to evaluate adherence to 5-ASA medications and compared to self-report and tablet counts. The medication event monitoring system records the date and time of bottle cap openings and uploads the data to the physician. Over the 12-month study period, self-reported adherence was 89.3%, tablet count adherence was 96.7%, and electronic adherence was 89.2% [43]. Taking this into account, it is likely important to incorporate some sort of medication adherence measure into clinic visits with IBD patients.

Patient Adherence to Health Maintenance

Not only medication adherence is important but also preventative care is extremely important for patients. For example, patients with UC and CD who have extensive or left-sided colitis are at increased risk for developing colorectal cancer. The AGA has published guidelines regarding surveillance colonoscopy in an attempt to detect early neoplastic lesions. Current guidelines advise a screening colonoscopy at a maximum of 8 years after the onset of IBD symptoms with multiple biopsy specimens obtained throughout the colon to assess true microscopic extent of inflammation [44]. Patients with extensive or left-sided UC are recommended to start surveillance 1–2 years after the initial screening, endoscopy, and after two negative examinations, this interval may be extended to every 1–3 years. Patients with UC and primary sclerosing cholangitis are recommended to have yearly screening starting at diagnosis of UC. IBD patient compliance with screening and surveillance colonoscopy has not been studied extensively. In an older study, Woolrich et al. [45] followed 121 patients with UC for 7 years. Seven patients developed cancer over this time and two of the seven patients had been noncompliant with colonoscopy recommendations. These patients had quiescent disease, and the authors concluded that asymptomatic patients were likely to have decreased adherence with screening and surveillance recommendations. In a larger and more recent cohort study involving three tertiary IBD centers, 400 patients with IBD were followed, and 25 % of patients were found to be nonadherent to recommendations for surveillance colonoscopy [46]. The majority of patients (80%) were aware of the recommended interval. When asked why they did not follow the recommendation, they identified logistics, stress, health perception, and the procedure itself as reasons for postponing.

Another important preventative care measure in patients with IBD involves vaccinations. Often, IBD patients are immunosuppressed, and there are clear current

guidelines regarding appropriate vaccinations (more details given below in the Sect. 1.5). Unfortunately, patients with IBD who are on immunosuppressive medications often are not getting correct vaccinations. A recent large national Internet-based cohort survey of patients with IBD in the Crohn's and Colitis Foundation of America (CCFA) Partners program was evaluated regarding vaccination status and beliefs [47]. Vaccination rates in this patient population remained suboptimal. Of the population, 81.5% had received the influenza vaccine, but only 42.6% had received the pneumococcal vaccine. Only 3.5–19.1% had received counseling about the avoidance of live vaccinations while on immunosuppression. Patients with a primary care physician and who were on immunosuppression were more likely to get the influenza vaccine. Of the patients who avoided the vaccine, concerns about side effects, effectiveness, and worsening their IBD were cited as reasons for refusal. Those who refused the vaccine had a lower education level, were younger, and were not immunosuppressed.

Factors Associated with Improving Patient Adherence

Enhancing the patient–provider relationship can influence adherence, and therefore, cultivating this relationship should be a top priority. A prospective study of 153 IBD patients showed that 2 weeks after a clinic visit, 41% of patients were nonadherent to a medication and that 81% of these patients were intentionally nonadherent. Physician–patient discordance was one of the factors associated with intentional nonadherence [48]. The therapeutic relationship can be cultivated by giving time for patients to discuss concerns and ask questions. Physicians should not over- or underestimate patient understanding and use open questions during encounters. Interventions to improve adherence have been studied and can be grouped into broad categories including educational strategies, behavioral interventions, multifaceted interventions, and finally individual assessment [49].

Educational intervention has been studied in adult populations and aims to achieve patient “buy in” in regard to their disease. Patients do not know as much about their disease as physicians believe. In a study by Martin et al. [50] of 100 IBD patients, 62% of UC patients and 78% of CD patients reported feeling insufficiently informed about their disease in regard to etiology, diet, symptoms, treatments, treatment risks, cancer, and cancer risk. This makes educational intervention an attractive area for improving adherence. For example, a group of 70 IBD patients underwent a total of 12 h of instruction over 4 weeks by a gastroenterology nurse practitioner. Their adherence was compared to a standard care group of patients who had received educational pamphlets and physician education only. The educated group demonstrated a trend towards improved adherence over time [51].

Behavioral interventions with patients and providers can promote adherence by attempting to improve the logistics of taking a medication and by providing cognitive therapy. In regard to 5-ASAs, simplifying a regimen from multiple doses to daily dosing initially improves adherence as shown by Kane et al. [52] who studied

adults with UC. At 3 months, there was 100% adherence in the daily dosed group versus 70% in the multiply dosed group. Cognitive behavioral therapy in IBD has not been specifically evaluated, however, potentially can be implemented to improve behavioral patterns to support adherence and alter thinking patterns that support nonadherence [49]. Practically speaking, providing patients with simple behavior interventions such as reminder systems (visual or auditory) and pillbox use can also improve adherence.

Multicomponent interventions are package interventions that combine strategies to enhance adherence. These are valuable in that they give patients the “best shot” at improving adherence; however, separating out specific interventions within the package that improve adherence can be difficult. For example, Cross et al. [53] intervened on UC patients with the UC Home Automated Telemangement (HAT) program which consisted of providing patients with education, feedback on symptoms, self-management, and follow-up phone contact to change regimens based on symptoms. Adherence in the intervention group was higher at 12 months. Another example of packaged intervention comes from a web-based intervention developed by Elkjaer et al. [54]. UC patients were provided with disease-specific web-based education, feedback, and medication adjustment based on symptoms and additional interaction with providers via electronic messaging in the intervention group. Over 4 weeks, adherence to 5-ASAs was improved by an average of 37% compared to the standard care group. There were also less outpatient clinic visits in the intervention group which translated into calculated monetary savings.

More recent strategies for improving adherence focus on the individual rather than assessing risk factors across large populations. Figure 1.2 displays the emerging concept of individualized assessment of nonadherence [55]. After assessment of the

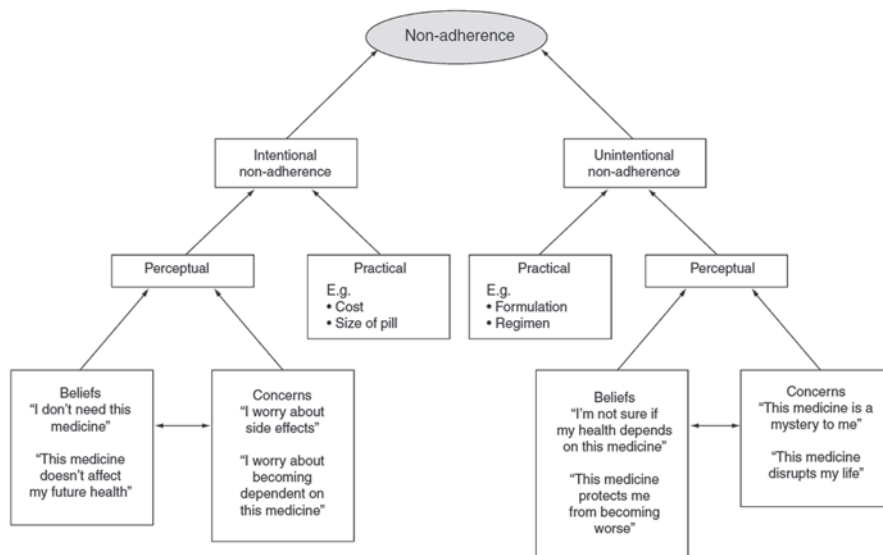


Fig. 1.2 Emerging concepts in nonadherence. (Adapted from Ref. [55] with permission)

individual attitudes and beliefs of a patient, the physician can then focus interventions on the underlying causes for nonadherence and hopefully improve outcomes.

Improving Quality of Care in IBD: A Physician and Community Effort

Successful outcomes in patients with IBD encompass much more than patient adherence. It also involves preventative care which has been increasingly recognized by gastroenterologists, societies, and health-care systems as an area of importance. There is an increasing emphasis on “quality of care” in chronic diseases, and this includes IBD. Quality of care, as defined by the Institute of Medicine, is “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” [56]. The concept of the “Triple Aim” in the area of quality of care involves believing that providing quality care will lead to improved individual outcomes, an overall improvement of health in the population, and reduced costs [57]. To interpret this into clinical practice, it is useful to assess concrete elements of quality, which are quality of care indicators. These indicators have been modeled in the Donabedian model into three categories: structural indicators (context in which care is delivered), process of care indicators (transactions between patients and providers), and outcomes indicators (effects of care on patients and populations) [58]. Specific examples of quality of care indicators in IBD include the measureable elements providers can report to CMS, which are listed in Table 1.1. Unfortunately, physicians often fail to give quality care. A 2005 study by Reddy et al. [59] evaluated 67 IBD patients who were getting care from a gastroenterologist and then sought a second opinion at a tertiary care hospital. Investigators found that many patients were not getting recommended therapy or appropriate medication dosing. In the previously mentioned National Inpatient Sample study, besides looking at race and surgical utilization, authors also investigated geographical patterns of care. Variation between colectomy rates was found. The northeast had lower colectomy rates than other regions of the country [22]. This may signify differences in practice patterns versus failure of providers to recommend appropriate surgical care. Because variation of care exists in the USA, it is possible that some of these variations could be leading to suboptimal care and outcomes within the IBD population.

The IBD community is working very hard to improve quality of care within IBD, and multiple societies are supporting initiatives. The AGA, as mentioned at the beginning of this chapter, has worked with the National Quality Strategy (NQS) framework to develop the quality indicators that have been incorporated into federal programs such as the PQRS. The CCFA has also initiated a quality improvement program with the hopes to integrate the program into both community and academic practices [7]. The CCFA first supported an initiative to identify the ten most important quality indicators in IBD [60]. Many of the measures are similar to the indicators reportable in the PQRS that were developed with the AGA and the NQS framework.

The quality indicators in Table 1.1 are goals that every practitioner should strive to achieve in IBD care. Vaccinating IBD patients is extremely important, and unfortunately, many IBD patients are not being vaccinated appropriately [61]. A survey of almost 1000 patients with IBD found vaccination rates for vaccines including zoster, human papilloma virus (HPV), meningococcal, pneumococcal, varicella, hepatitis B, and hepatitis A below 50%, with the exception of the influenza vaccine which had a vaccination rate around 80% [47]. Many patients with IBD are on corticosteroids, immunomodulators, and/or biologics, and use of these medications places this population at increased risk for infection. These patients are also considered to have altered immunocompetence, and this label may cause errors in physician recommendation for immunization. The Centers for Disease Control (CDC) has clear recommendations for immunization in patients with altered immunocompetence, including those on immunosuppression [62]. These patients should be given vaccines based on the Adult Immunization Schedule with a few important caveats. Unfortunately, gastroenterologists often have poor knowledge in regard to the appropriate vaccination guidelines for patients, as demonstrated in recent studies [63, 64]. For example, IBD patients receiving immunosuppressive agents should receive yearly inactivated influenza vaccine and should not receive the live intranasal influenza vaccine as live vaccines are contraindicated in patients who are immunosuppressed [61]. A recent survey showed nearly one third of gastroenterologists would mistakenly have recommended a live vaccine to a patient on immunosuppressive medications [64]. These patients should also receive vaccination for prevention of streptococcal pneumonia. As of 2012, the Advisory Committee on Immunization Practices at the Centers for Disease Control recommends that the vaccination should extend beyond the pneumococcal polysaccharide vaccine (PPSV23) and that the pneumococcal 13-valent conjugate (PCV13) vaccine should be administered as well, both are inactivated [65]. The abovementioned survey revealed that one half of gastroenterologists would withhold inactivated vaccines in their immunosuppressed patients. Therefore, it is important for gastroenterologists who care for patients with IBD to be adequately informed of the correct vaccine guidelines and ensure this is correctly discussed with the patient. Often, the patient will look to their gastroenterologist to help with these preventative care measures. There are other important vaccine caveats to remember as well. HPV vaccination is recommended by the CDC for females and males aged 9–26, and administration should be emphasized in the appropriate population of IBD patients on immunosuppression as immunosuppression can increase the risk of cervical dysplasia. In IBD patients who are not currently on immunosuppressive medications, it is important to think ahead and plan vaccinations if they are going to receive or expected to receive immunosuppression at any point during their disease course. Specifically, it is important to think about the zoster vaccine. This vaccine is currently approved for those over age 50 and recommended by the CDC for all patients over age 60. It is a live vaccine so it cannot be given to patients on immunosuppression. The biologic must not be started for a minimum of 1–3 months after the vaccine is given [61].

Another example of a quality of care component in IBD is regarding bone health, again an area not directly related to the gastrointestinal tract, but deemed an important component of quality of care. Patients with IBD have a higher risk of

osteoporosis and fracture [66]. The etiology of bone disease is thought to be complex including factors such as corticosteroid use as well as increased bone resorption from inflammatory cytokines and decreased osteocyte viability [67]. The AGA published a position statement in 2003 [68] recommending a dual energy x-ray absorptiometry (DEXA) scan for postmenopausal women, men > 50, patients with prolonged corticosteroid use, patients with a history of fracture associated with low trauma, and hypogonadism. They also recommended considering DEXA in IBD patients with risks such as use of methotrexate (MTX), cyclosporine, poor nutritional status, low body weight, smoking, excess alcohol use, and risk of falling. Some data are starting to emerge that in patients with IBD and low bone mineral density, medical therapy may be improving patient outcomes. A meta-analysis and systematic review showed that bisphosphonate therapy in this population was effective and well tolerated and reduced the risk of vertebral fractures [69].

It is important for gastroenterologists who routinely care for patients with IBD to understand that quality of care now extends beyond medications and into overall health including vaccine-related, bone health-related, smoking cessation, and cancer screening-related issues. It is important to educate patients, and now, increasingly, ensure that appropriate documentation regarding these health issues is recorded. There are increasing options to assist gastroenterologists and health-care teams in ensuring their patients are adherent to quality of care guidelines. For example, authors have generated worksheets to help practitioners ensure patients are getting the appropriate preventative care and that this is recorded properly. In an area of electronic medical record, many practitioners are adding documentation of items such as vaccine history and colon cancer screening into their patient's chart routinely to ensure it has been addressed appropriately. Gastroenterology societies have developed tools to help practitioners document and follow their adherence to quality of care guidelines. For example, the AGA along with the ACG and the American Society of Gastrointestinal Endoscopy (ASGE) has developed slides and webinars available to help practitioners navigate through the new quality reporting system in the USA, available on their website (<http://www.gastro.org/practice/practice-management/aga-think-tank/preparing-gi-ascs>). Also, qualified clinical data registries (QCDRs) have been developed as new reporting mechanisms for PQRS, an example has been developed through the GI Quality Improvement Consortium (GIQuIC), a project recently taken over by the ACG and ASGE (<http://giquic.gi.org/pqrs.asp>). All of these measures and more will help practitioners and health-care teams ensure patients are getting appropriate preventative and current standard of care to hopefully improve outcomes in patients with IBD.

Conclusion

Many factors are associated with barriers to successful outcomes in patients with IBD. Patient's understanding of their disease and risks and benefits associated with medications is very important and an issue that physicians and teams can continue to work on to improve. Patient medication adherence can be a huge hindrance to

appropriate care in IBD and many often widely varying factors are associated with this. It can make improving patient adherence difficult, but several strategies can be considered, including education, behavioral interventions, multifaceted interventions, and finally individual assessments. Also, successful outcomes in IBD are no longer being measured simply by medication adherence. Preventative care has become a large component of quality in IBD as society and health care systems have shifted to focus on the comprehensive care of each patient. Physicians are increasingly becoming aware of the importance of preventative health assessments in patients with IBD, including things like vaccine-related issues, bone health, cancer prevention, and smoking cessation education. Improving physician awareness of preventative care, patient education, and documentation of these issues are increasingly important caveats as successful outcomes in IBD continue to evolve. Physicians, health-care teams, and patients will continue to work together to lead to successful outcomes in IBD.

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