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## Self-Management in Pediatric Inflammatory Bowel Disease: A Clinical Report of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

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### Abstract

This clinical report aims to review key self-management and adherence issues in pediatric inflammatory bowel disease (IBD) and to provide recommendations for health care providers regarding evidence-based assessment and treatment approaches to promote optimal self-management. Self-management difficulties in the form of nonadherence to treatment regimens are common in pediatric IBD and are influenced by various disease-related, individual, family, and health-professional relationship factors. To promote adaptive self-management, health care providers are encouraged to adopt a long-term preventive orientation which includes routine screening of barriers to self-management and nonadherence in the context of routine clinic appointments. The use of a multimethod approach to assessment which incorporates objective measures (e.g., pill counts or bioassays) may be particularly advantageous. Individualized treatment approaches that incorporate evidence-based practices, such as providing written treatment plans and offering opportunities to practice and receive feedback on skills may help to ameliorate minor self-management concerns; however, more severe or chronic self-management problems may require a referral for behavioral health intervention. Additional research to broaden our understanding of self-management in domains beyond medication adherence and to evaluate the impact of clinic-based interventions is imperative.

### Keywords

Self-Management; Adherence; Compliance; Inflammatory bowel disease; Psychosocial; Treatment

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## Introduction

Pediatric inflammatory bowel disease (IBD) is a challenging condition from both medical and behavioral perspectives. Symptoms including diarrhea, rectal bleeding, abdominal pain, fatigue, growth failure, and delayed puberty present unique psychosocial challenges<sup>1</sup>. This is particularly true for adolescents, who make up the majority of diagnosed pediatric cases<sup>2</sup> and are faced with learning to manage a chronic condition that is difficult to discuss with others while attempting to maintain a typical adolescent lifestyle and negotiate normal developmental issues. Treatment for IBD is complex with regard to the number of medications/supplements and their varying dosing regimens. The episodic, variable, and unpredictable disease exacerbations often result in at least temporarily changing drug therapies. Moreover, this unpredictable natural disease course can be discouraging to patients and may set the stage for poor self-management and nonadherence. While the research on self-management in pediatric IBD is still relatively new, there is increasing evidence of the magnitude and scope of the problem as well as how best to promote self-management in clinical practice. A summary of this evidence and recommendations for clinicians at this juncture can facilitate and guide research and clinical practice in the most prudent directions.

The objective of this consensus statement is to provide a review of self-management and adherence issues in pediatric IBD, factors associated with self-management, and approaches to the measurement of self-management. Additionally, this statement provides empirically-supported recommendations for clinicians regarding assessment and treatment approaches to promote self-management.

## Definitions and Conceptualization

The terms “self-management”, “adherence”, and “compliance” have often been used interchangeably. However, there are important conceptual differences that have implications for both clinical intervention and clinical research. “Compliance” has been used commonly, though it has fallen out of favor due to the connotation of patient obedience and blame associated with the term (i.e., patients do or do not follow directions). The term “adherence” has become more widely used and accepted in the past several years as it suggests a more positive interpretation of patient behavior, reflects patient-clinician concordance in treatment planning, and implies a continuum of patient behavior related to medication taking or other treatments. Adherence is defined as “the extent to which a person’s behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice”<sup>3</sup>. Importantly, adherence is a quantification of self-management behaviors and thus, conceptualized as an outcome or mediator of disease outcomes. The term “self-management” is defined as “the interaction of health behaviors and related processes that patients and families engage in to care for a chronic disease”<sup>4</sup>. Thus, self-management behavior results in the extent to which patients are adherent, and this may impact disease outcomes. The term “self-management support” focuses on the clinician’s role in patient self-management and refers to “the care and encouragement to people with chronic conditions and their families to help them understand their central role in managing their illness, make informed decisions about care, and engage in healthy behaviors”<sup>5</sup>.

While this report focuses on self-management in IBD, we discuss adherence considerations and research data throughout, as this is the most proximal and most often used outcome of self-management behavior. Moreover, adherence/nonadherence is an issue of primary clinical concern for practitioners. In order to provide guidance for clinical practice and research, we provide an overview of factors associated with self-management, review strategies for assessing self-management in research and clinical practice contexts, and

discuss opportunities for integrating self-management into clinical care. We conclude with a discussion of future directions for self-management research and practice.

### Factors Associated with Self-Management Behavior

The majority of research examining factors associated with self-management behavior has focused on correlates or predictors of oral medication adherence in pediatric IBD. Studies have generally grouped youth with CD and UC together and have examined cross-sectional rather than longitudinal associations in combined samples of children and adolescents. A number of factors have been examined including sociodemographic factors, disease or disease regimen factors, individual factors, family factors, social factors, and health care system factors.

**Sociodemographic Factors**—Among pediatric IBD patients, sociodemographic factors including age, sex, and ethnicity have not been associated with an increased risk of nonadherence to medication regimen. However, among adults with IBD, full time employment status, higher education level, being single, male sex, and African American ethnicity have each been associated with medication nonadherence<sup>6-11</sup>.

**Disease or Disease Regimen Factors**—Aspects of IBD and the disease-management regimen may adversely influence adherence. Among preadolescents and adolescents with IBD, regimen factors associated with nonadherence include perceived negative side effects associated with medication use<sup>12,13</sup>, greater perceived regimen complexity<sup>13</sup>, and objective reports of regimen complexity (e.g., multiple daily dosing versus once daily dosing<sup>12,14</sup>). Other patient-reported barriers to adherence related to the disease management regimen include large pill size, difficulty swallowing the medication, and unpleasant taste of the pill<sup>13,14</sup>.

Disease activity has been the disease-related factor most often studied in relation to nonadherence in pediatric IBD. Although some studies have found higher rates of medication nonadherence among those with less disease activity<sup>15</sup>, other studies have found an opposite pattern of association. Specifically, Greenley and colleagues found that youth with any disease activity were 3.5 times more likely to be nonadherent<sup>12</sup>. Similarly, not feeling well was reported as a barrier to adherence in one recent study<sup>16</sup>. Additionally, Schurman and colleagues found that high disease activity was associated with volitional nonadherence, but that disease activity was unrelated to accidental nonadherence<sup>13</sup>.

**Individual Factors**—Developmental, cognitive, and psychological factors may either facilitate or serve as barriers to adherence. Regarding developmental factors, adolescence is regarded universally as a time of poor adherence across chronic medical conditions<sup>17</sup>. The developmental changes of adolescence include a greater desire for autonomy, more time spent outside of the home, and an increased need to “fit in” with peers<sup>18</sup>. These normative changes are at odds with completion of disease management tasks and the need to incorporate management of a chronic disease into one’s social routine. In support of this, Hommel and Baldassano as well as Ingerski and colleagues have reported that interference with activities and not being home are barriers to adherence among adolescents with IBD<sup>14,16</sup>.

Cognitive factors such as knowledge, beliefs, and planning/organizational skills also influence adherence. Knowledge of one’s disease and regimen is a necessary but not sufficient condition for adherence, as youth and families must understand what the treatment regimen is and how to carry out illness self-management tasks before they are able to follow the regimen<sup>19</sup>. Recently, less sophisticated knowledge related to supplements used in IBD

was associated with poorer adherence to supplements in a preadolescent and adolescent IBD sample<sup>20</sup>. Additionally, beliefs of lack of medication efficacy or that the medication is unnecessary have been documented as barriers to adherence in pediatric IBD<sup>12,16</sup>. Finally, planning and organizational difficulties have been identified as barriers to adherence. Specifically, reports of forgetting to take medication, failing to plan ahead, and forgetting to get the prescription filled on time have been reported as adherence barriers in pediatric IBD<sup>14,16</sup>.

Patient psychological functioning may also serve as a barrier to adherence. Depressive symptoms have been associated with nonadherence in youth with IBD<sup>21</sup>. In addition, child oppositional behavior has been reported as a barrier to adherence in teens with IBD<sup>14,16</sup>. Finally, Mackner and Crandall documented a relationship between avoidant coping strategies and nonadherence in children with IBD<sup>22</sup>.

**Family Factors**—Family factors influence adherence among children and adolescents with IBD. Mackner and Crandall documented a relationship between higher levels of family dysfunction and nonadherence in pediatric IBD<sup>22</sup>. Similarly, Hommel and Baldassano noted that family or parent-child conflict about taking medications is an adherence barrier<sup>14</sup>. In addition, data suggest that both high adolescent and parent involvement in disease management are associated with better adherence<sup>23,24</sup>.

**Social Factors**—Among adolescents with IBD, social factors such as a wish for friends not to know about the patient's IBD or a refusal to take medication in public may be barriers to adherence<sup>13</sup>. Similarly, a belief that medication interferes with activities is another potential barrier to adherence<sup>13,14,16</sup>.

**Health Care System Factors**—In one recent study, adherence to oral thiopurine medications was significantly higher in the three days before, the day of, and the three days after a pediatric GI specialty appointment among youth ages 11–18 with IBD, indicating that more frequent provider contact may have enhanced accountability and encouraged improved adherence, at least in the short term<sup>25</sup>.

Other health professional relationship factors have been associated with adherence in multiple pediatric populations<sup>26,27</sup> and among adults with IBD<sup>28</sup>. Specifically, among adults with IBD, low trust in physician<sup>29</sup>, working with the treating physician for less than one year<sup>30</sup>, and discordance between patient and physician on perceptions of patient health status<sup>30</sup> have all been associated with nonadherence. Additionally, pediatric patients who are more satisfied with their medical care are more likely to follow treatment recommendations<sup>26</sup>. Similarly, provider verbal support, continued contact with the same provider, perceptions of provider empathy and support, and trust in one's provider have also been associated with higher adherence in pediatric samples<sup>7,26,27</sup>. Although such factors are likely to influence adherence in pediatric IBD, they have yet to be systematically examined.

## **Nonadherence: Scope of the problem and relation to outcomes**

**Prevalence and Frequency of Nonadherence**—All of the aforementioned factors influence self-management behavior and the extent to which an individual adheres to prescribed treatment. Nonadherence to medical treatment is an important, but under-recognized, clinical issue affecting the care and well-being of children and adolescents with pediatric IBD. Although overall adherence to the IBD treatment regimen is suboptimal, adherence varies widely based on the type of medication (e.g., specific medication and prescription vs. non-prescription), specific adherence behavior examined (e.g., oral medication vs. dietary modifications), and how adherence is measured (e.g., patient report

vs. pill count). In general, adherence to prescription medications is over 20% higher than adherence to over-the-counter medications such as multivitamins, calcium, and iron<sup>24</sup>. Among prescription medications, nonadherence significantly differs between immunomodulators and aminosalicylates. Nonadherence prevalence for 5-aminosalicylate (5-ASA) is as high as 88% whereas 6-MP/azathioprine (AZA) nonadherence prevalence is 64%<sup>31</sup>. Higher rates of nonadherence to 5-ASA is not surprising as adolescents with IBD are much more likely to experience barriers to adherence when treatment involves more than once daily medication administration<sup>12</sup>.

Diet is another important component of IBD management<sup>32</sup>. However, adherence to dietary recommendations has been understudied due to the absence of standard recommendations for dietary management of IBD. In addition, variability across patients regarding dietary contributors to IBD symptomatology and limited methods of assessing adherence to dietary recommendations (i.e., self-report) make it difficult to gauge how common dietary nonadherence is among the broader pediatric IBD population. In one of the few studies examining dietary adherence in IBD, 25% of adolescents prescribed gastrostomy tube feedings were nonadherent to treatment<sup>33</sup>. However, given the small sample of this study, further examination of dietary adherence in IBD is needed.

#### **Relation of Nonadherence to Disease and Psychosocial Outcomes—**

Nonadherence is a concern for several reasons. Numerous studies have reported an association between nonadherence to IBD treatment and negative health and psychosocial outcomes. Not surprisingly, patients who are nonadherent are more likely to have greater disease severity<sup>21,23,24</sup>, potentially necessitating the need for more aggressive medical treatment, such as increased corticosteroid use or surgery. Patients with IBD who are nonadherent to treatment also have increased health care costs<sup>34</sup> and have a higher risk of disease recurrence<sup>35</sup>. In addition to these medical consequences, nonadherence is linked to poorer psychosocial functioning. Specifically, children and adolescents who are less adherent to their prescribed treatment regimen are more likely to experience poorer quality of life<sup>36</sup> and greater anxiety/depressive symptoms<sup>21</sup>. Given the severe and potentially irreversible nature of these medical and psychosocial consequences of nonadherence, early intervention with patients who are nonadherent is important. Identifying nonadherence through use of one or more assessment methods is an important first step in improving self-management.

#### **Measurement of Adherence**

There is no “gold-standard” of adherence assessment. Each method has strengths and limitations (see Table 1). A multi-method adherence assessment approach that draws on the strengths of different assessment methods is recommended.

**Patient/Parent-report of adherence—**Patients/parents are ideally-suited to report adherence as they are responsible for following the treatment regimen on a daily basis. They can provide information regarding barriers to adherence as well as adherence to other aspects of the treatment regimen, such as dietary habits, that cannot be measured using other assessment methods. This information may inform clinical decision-making and the delivery of targeted interventions. Accuracy is a major concern with patient/parent-report as poor memory of missed doses and the desire to be viewed favorably by others (e.g., social desirability bias) leads to inflated estimates. For example, patient/parent-report of nonadherence prevalence is 10% for 6-MP/azathioprine (AZA) and 2% for 5-aminosalicylates (5-ASA). However, pill count estimates suggest much higher estimates of nonadherence (64% for 6-MP/AZA and 88% for 5-ASA)<sup>23,31</sup>.

Accuracy of patient/parent-report can be improved by refining how adherence is assessed. How providers ask about nonadherence impacts patient/parent responses. For example, a question such as “You’re taking all of your medicine, correct?” is likely to result in higher patient/parent-report of adherence than “How many doses of your 6-MP did you miss over the past week?” Brief structured interviews/questionnaires (e.g., Medication Adherence Measure<sup>37</sup>, Morisky Medication Adherence Scale<sup>38,39</sup>) can also improve the accuracy of patient/parent report and have been previously used in patients with IBD<sup>16,24,31,40</sup>.

**Clinician-estimate**—In general, clinicians are very good at identifying adherent patients but they are much less accurate at identifying nonadherence and their estimates of adherence are not associated with health outcome<sup>41–43</sup>. Clinician estimates are influenced by unreliable factors such as patient/parent-report (which overestimates adherence), the patient’s current health status (which is influenced by other factors such as sub-therapeutic dosing, illness, pharmacokinetic variability), and their knowledge of the patient’s history of adherence/nonadherence (i.e., “this patient is typically adherent/nonadherent”). As a result of these limitations, clinician-estimate is not considered a reliable and valid method of assessing adherence<sup>44</sup>.

**Direct observation**—Direct observation can confirm ingestion of medication but is time- and labor-intensive as another individual (e.g., reliable family member, inpatient hospital staff) must be present to observe each medication administration. Although accurate, the resource-intensive nature of this approach limits its feasibility in clinical practice and research.

**Pill count**—Pill counts compute an adherence rate based on: 1) the number of pills a patient has initially, 2) the number of pills the patient is expected to have consumed over a pre-determined period of time, and 3) the number of pills remaining at the end of this time. This low-cost method is more accurate than patient/parent-report<sup>31</sup> but can be cumbersome and time consuming, particularly if patients have more than one medication. Missing data is possible as two data points (i.e., number of pills patient has initially, number of pills remaining) are needed to compute adherence and patients may forget to bring in their pill bottles. , Pill counts can also be positively or negatively manipulated. Medication can be discarded or lost. Families may combine old and new medication bottles, resulting in underestimates of adherence or unusual pill count data (i.e., increasing rather than decreasing number of pills) that are difficult to interpret without complementary data (i.e., pharmacy refill data).

**Pharmacy refill**—Pharmacy refill data does not estimate adherence, but rather provides data on refill *behaviors* that are believed to correspond to how well a patient takes his/her medicine. There are no data examining the validity of pharmacy refill data as a measure of adherence in pediatric IBD. A study comparing pharmacy refill data to other objective methods of assessing adherence (e.g., pill count, electronic monitoring) in IBD is needed. This approach may be less desirable when working with patients who: 1) receive their prescription in multi-month supplies, 2) have their medication on an automatic refill schedule, or 3) often switch between multiple pharmacies. Privacy regulations to protect patient health data and fees that some pharmacies are now charging prior to releasing their records may also make use of refill records unfeasible.

**Electronic monitoring**—Electronic monitors record the date and time that medication was accessed from the container and compare this to the prescribed regimen to produce an overall adherence estimate (For a review of existing technologies, please see Ingerski et al.<sup>45</sup>). Electronic monitors provide valuable information on medication-taking patterns (e.g.,



patient is inconsistent with evening doses or takes weekend medications much later than prescribed) that are not otherwise available using other assessment methods. This information may guide the delivery of targeted intervention efforts. Electronic monitors have several limitations. In addition to specialized equipment and software, each electronic monitor may cost several hundred dollars. Monitors tend to be bulky and difficult to transport. They are not compatible with all forms of medication (e.g., liquid medicine) and they may interfere with current adherence routines (e.g., patients used to using a pill box may experience declines in adherence when asked to switch to an electronic pill bottle). Monitors can also malfunction, get damaged/lost or be used incorrectly, resulting in incorrect estimates or complete data loss<sup>45</sup>.

**Bio-assay metabolite monitoring**—Bioassays can indicate whether or not medication has been recently taken and can assist in treatment decision-making to ensure patients stay within a specified therapeutic range. However, not all medications have an associated bioassay available or established therapeutic levels to guide interpretation of data. Pharmacokinetic variations in an individual's drug absorption, metabolism, and excretion<sup>46</sup> as well as the patient's recent medication-taking behavior may influence results. Thus, patients who are generally nonadherent but tend to take their medicine just prior to a medical appointment (e.g., white coat compliance<sup>47</sup>) appear to be more adherent than they truly are. However, bioassays are helpful in identifying extreme cases of nonadherence (i.e., patient has little-to-no medication in their blood).

## Practice Recommendations for Clinicians (see Table 2)

**Routine Adherence Screening**—Adherence assessment, via reliable assessment tools (e.g., pill count, electronic monitoring, pharmacy refill data), should be implemented as part of pediatric IBD standard clinical care. The benefits of routine assessment are multifold. Routine assessment improves early detection of nonadherence and, thus, poor self-management behaviors. In turn, clinical care can focus on primary prevention (clinically significant nonadherence is not present) rather than secondary (clinically significant nonadherence is identified early) or tertiary prevention (an ongoing pattern of clinically significant nonadherence and poor self-management)<sup>48</sup>. Early detection can lead to interventions to improve adherence. As nonadherence is associated with increased disease severity<sup>21,23,24,49</sup>, early detection and intervention of nonadherence may prevent declines in the health and well-being of young patients with IBD. Routine assessment of adherence can also be used to identify patients and families in need of clinical intervention aimed at improving self-management behavior. Since the level and type of clinical intervention can become more complex and time-consuming as nonadherence worsens, proactive assessment can drastically cut down on the time spent addressing issues related to nonadherence during clinical visits.

**Promotion of Self-Management**—The aforementioned assessment tools are powerful agents of change in the clinical care of youth with IBD. They can guide treatment planning and be used to determine the type and level of intervention needed to improve adherence and self-management behaviors. A recent meta-analysis of adherence-promoting interventions revealed that behavioral and multi-component interventions show greatest promise for improving adherence among youth with chronic medical conditions<sup>50</sup>. Behavioral interventions emphasize behavior change to improve self-management behaviors, and include goal setting, reward systems, and adherence monitoring among other techniques. Multicomponent interventions combine various treatment approaches including behavioral, educational, organizational, and family-centered components. Among youth with IBD, emerging evidence suggests that multicomponent interventions tailored to the unique adherence needs of adolescents of IBD may result in substantial improvements in oral

medication adherence<sup>51</sup>. Yet, across adherence-promoting interventions, improvements have been shown to diminish over time<sup>50</sup>. This suggests that improvements in adherence and self-management behavior are most likely to be maintained with ongoing intermittent intervention. Adherence intervention needs to become part of a patient's ongoing clinical care, rather than a one-time treatment approach, as this is mostly likely to capture adherence barriers as they occur in closer proximity to real-time.

For example, forgetfulness has been identified as a key barrier to adherence among youth with chronic medical conditions, including IBD<sup>14,16</sup>. Targeting this barrier might include the following treatment components: 1. Increased monitoring by the youth and caregivers (e.g., keeping daily logs on the refrigerator and checking off when a particular medication has been taken, checking pill containers); 2. Auditory/visual reminders (e.g., setting a cell phone/watch alarm that goes off at the time medication is supposed to be taken, making visual reminder signs); 3. Behavior contracting (e.g., youth earns points, incentives, or privileges for remembering to take medication a specified number of times each week). Sometimes, patient adherence is low due to pill swallowing difficulties or palatability/taste issues<sup>52</sup>. In such cases, adherence can be targeted by modeling and teaching appropriate pill swallowing methods or by modifying how pills are taken (e.g., eating something immediately before/after, putting the pill in ice cream, applesauce, or pudding).

**Clinic-Based Intervention**—Adherence interventions are not routinely integrated into patients' usual care, and clinic-based interventions are lacking<sup>53</sup>. Thus, it is unclear whether empirically-supported treatments for nonadherence can be implemented in a medical clinic setting. It is also unclear whether components of these interventions can be feasibly implemented by medical providers in clinical settings. Regardless, one size does not fit all in adherence-promoting intervention – what works for one patient may be unsuccessful for another patient. Clinicians are encouraged to individualize an intervention to the specific adherence needs and barriers experienced by a particular patient, as there is likely to be great variability across patients. To further improve self-management among young patients with IBD, clinicians should provide written treatment plans and instructions to families to reinforce information given verbally. In-clinic modeling, rehearsal, and practice of various disease-management tasks (e.g., taking medication, administering injections, filling a pill box, selecting healthy food choices) can also be helpful with young patients<sup>54</sup>. Clinicians should also consider including parents/caregivers in self-management interventions, as they often manage the patient's illness and treatment on a daily basis.

**Referral for Treatment**—In some cases, a referral to another provider with expertise in behavioral health interventions may be warranted. Many youth with IBD experience internalizing (e.g., anxiety, depression) or externalizing (e.g., acting out, oppositional behaviors) difficulties<sup>55</sup> that may impact their self-management behavior. Family stressors or parent mental health may also be comorbid with nonadherence, and these issues may cause, exacerbate, or maintain poor adherence. Under such circumstances, referral for behavioral health services and/or additional support services for the patient, parent, and/or family may be necessary before or during efforts to address poor self-management.

## Future Directions

**Broadening self-management focus**—Given the long-term complexities of chronic conditions, medical management is viewed by some as only one aspect of a broader conceptualization of self-management. Lorig and Holman conceptualize self-management as maintaining a wellness perspective in the context of a chronic condition, and they describe three components: Medical management, social/role management to create new behaviors or life roles to adapt to a chronic condition, and emotional management of the psychosocial



sequelae of having a chronic condition<sup>56</sup>. In contrast to acute illnesses, chronic conditions are more likely to evolve over time, have multiple etiological factors that may also change over time, have a waxing and waning course, uncertain prognosis, and require changing management over time<sup>57</sup>. They often result in continuous medication use, behavior change, changed social circumstances and emotional distress<sup>57</sup>.

This broader view of self-management fits well with current perspectives on defining the concept of “health.” Prior definitions of health were developed when acute diseases were more common than chronic conditions<sup>58</sup>. A recent multidisciplinary, international oanel recommended a conceptualization of health that focuses on resilience, or maintaining and restoring “one’s integrity, equilibrium and sense of well-being”<sup>58</sup>. Specifically, they defined health as “the ability to adapt and to self-manage” in physical, mental and social domains. The focus on wellness and the three domains map well onto the conceptualization of self-management described by Lorig and Holman<sup>56</sup>. Given the complexities of chronic conditions such as IBD and the evolving definitions of health and self-management, an important future direction is to broaden our self-management focus in pediatric IBD.

**Measurement Considerations**—As our conceptualization of self-management broadens, we must also strive toward improving our assessment and measurement of self-management behaviors. As Table 1 illustrates, there are a number of options for measurement of adherence; however, none are perfect or 100% accurate and reliable. Much work is needed, particularly in the areas of electronic monitoring and algorithmic assessment approaches. Many electronic monitoring devices have been developed, but have fallen short of providing a user friendly product for patients with IBD. One of the more common problems with these is many of these devices do not accommodate large pills well. Other persistent issues involve reliability and data capture and transfer<sup>45</sup>. In addition, the testing and validation of algorithms using combined adherence assessment methodology is necessary. There has also been little done to standardize approaches to combining adherence measures reliably. For example, an algorithm using self/parent-report, pill counts, and 6-TGN/6-MMPN bioassay data would be feasible and very useful in the IBD population. Finally, measurement needs to focus more on self-management behavior itself rather than solely on adherence. It will be important to clearly define the most critical self-management behaviors and develop measurement tools that are clinically useful and feasible. This will be challenging, but the utility of such tools may prove equally or more beneficial than adherence assessments as they may define a broader range of behavior that impacts health and well-being.

**Clinical Effectiveness, Comparative Effectiveness, and Quality Improvement**—Comparative effectiveness research that tests the relative impact of efficacious interventions for improving self-management in IBD will allow us to identify the most beneficial components. Similar to this, interventions themselves will need to be optimized by determining the most effective components of treatment and designing programs that incorporate only the critical pieces of treatment protocols. In addition, a disadvantage of the relatively sterile environment in which well-controlled behavioral research is conducted is that there may be limited clinical utility of the intervention. Psychological and disease comorbidities that introduce complexity to behavioral functioning and prescribed treatment regimens may present unforeseen difficulties to the success of efficacious interventions. Thus, it will be imperative that the clinical effectiveness of efficacious self-management interventions be carefully evaluated via testing with patients presenting with complex medical conditions and behavioral comorbidities. Finally, many self-management and self-management support interventions can be delivered in clinics. Challenges exist with this type of approach, however, including logistical processes, adoption of new practices, clinic flow issues, and so on. A quality improvement approach is ideal for identifying practice-

level challenges and developing methods to overcome them, determining what existing local conditions will hinder or facilitate certain interventions, and establishing a culture of continuous improvement in self-management provision from both the clinician and patient/family perspective. In conclusion, a well-planned and implemented approach that incorporates comparative effectiveness, clinical effectiveness, and quality improvement research methodologies will significantly advance and accelerate our knowledge and provision of self-management interventions in the pediatric IBD population.

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**Table 1**

Overview of strengths and limitations of adherence assessment approaches

<b>Assessment Method</b>	<b>Strengths</b>	<b>Limitations</b>
<b>Patient- and/or Parent-Report or Interview, Diet Records or Recall</b>	Easy, inexpensive to obtain, provides patient and/or parent perceptions of adherence behavior and barriers to adherence	Can overestimate adherence, subject to patient recall bias and social desirability
<b>Provider Estimates</b>	Easy, inexpensive to obtain	Poor reliability and validity, often based on disease status rather than perceived adherence behavior
<b>Direct Observation</b>	Accurate, only method that can confirm medication consumption frequency	Resource-intensive, limited feasibility in routine clinical care and research
<b>Pill Counts</b>	Easy, inexpensive to obtain, fairly accurate	Can be cumbersome to collect and calculate, requires patients bringing medications to appointments, can be manipulated positively or negatively
<b>Pharmacy Record Data</b>	Provides objective data on refill behavior, can easily assess multiple medications	Assesses refill behavior not consumption, may be difficult or costly to obtain
<b>Electronic Monitoring</b>	Wealth of data, objective, fairly accurate	Expensive, may not be feasible for patients with multiple medications, may not be acceptable to patients, equipment may malfunction
<b>Biological Assays</b>	Confirms consumption but not timing or amount of doses	Expensive, subject to pharmacokinetic variation and metabolism, can be manipulated by recent dosing depending on medication, not available for all medications

**Table 2**

## Recommendations for Clinical Providers

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**WHO:**

- 1 Seek out multiple reporters of adherence (e.g., patient and caregiver)
- 2 Involve caregivers in adherence-promoting interventions; improves generalizability to home environment

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**WHEN:**

- 1 Utilize routine screening of adherence as part of standard of care
- 2 Maintain ongoing monitoring of adherence behaviors

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**WHAT:**

- 1 Target multiple adherence and self-management behaviors (e.g., medication-taking, exercise, diet, and clinic attendance)
- 2 Identify barriers to adherence and self-management. For example:
  - Patient/family-specific factors (e.g., adolescent age, knowledge of disease and treatment, psychological functioning, family conflict, parent involvement)
  - Disease-specific factors (e.g., disease activity)
  - Treatment-specific factors (e.g., cost, complexity, perceived side effects)

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**HOW:**

- 1 Use at least two separate measures of adherence; one objective measure is recommended (e.g., drug assays, pill counts, pharmacy records)
- 2 Give patients feedback on adherence data, and engage them in change and intervention
- 3 Adherence-promoting intervention should be individually tailored to each patient's needs
- 4 Behavioral and multi-component interventions show greatest promise for improving adherence. For example:
  - Setting goals around adherence and self-management
  - Developing behavior contracts, reward systems
  - Adherence monitoring
- 5 Consider clinic setting as an excellent teaching and learning environment (e.g., role-play and behavioral rehearsal of disease management tasks)
- 6 Use multimodal approach to education (e.g., supplement verbal instructions with written treatment plans and instructions)
- 7 Consider referral to other subspecialties, including psychology and psychiatry, social work, patient financial assistance

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