



Special Section on Contemporary Practice in Colon and Rectal Surgery by Dr. Matthew Wilson

## Patient reported outcome measures (PRO) in colorectal surgery



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### ABSTRACT

Patient reported outcomes refer to, “Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else” (US Food and Drug Administration, 2009) [1]. These outcomes can include anything that matters to patients including quality of life, pain, number of bowel movements. Patient reported outcome measures refer to tools or instruments that help to measure these outcomes. These measures can be done using validated tools, those that have undergone rigorous testing and psychometric validation, and non-validated tools such as may exist in a practice to rate practice or physician/staff care quality. For this paper, we will discuss the role of patient reported outcomes measures in colon and rectal surgery.

### Background

Patient reported outcomes refer to, “Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.” [1]

Clinically, patient reported outcome measures are important in colon and rectal surgery as diseases of the colon, rectum, and anus have the potential to greatly affect patients treated with observation, dietary modification, medical therapy, office procedures, or operations. Moreover, there are often several treatment options for colon, rectal, and anal disease with different risks, benefits, and patient-oriented effects. PROs can help assess patients to guide personalized decision making. For example, there is need to understand baseline patient measures such as bowel function, continence, and pain to tailor treatment and counsel patients to achieve the best possible outcome based on available options. The addition of longitudinal measure collection allows for repeat measures to inform disease status, response to treatment, and overall quality of life changes. In addition to patient counseling and tracking, patient reported outcome measures allows for shared decision making when measures are used that help identify what matters most to people.

PRO collection is important in research especially in tracking patient-specific outcomes relating to study interventions. PROs can provide more detail and color to the granular outcomes of survival, recurrence, and utilization outcomes. PROs have aimed for both

ecological evaluation of colon and rectal disease and treatment as well as comparative effectiveness of treatments, predominantly surgical. PRO research has also been used to study the effects of new treatments and technology over status quo [2–4].

In this paper, we will provide a broad overview of the status of patient reported outcomes in colon and rectal surgery. We introduce existing measures and their use. We will discuss how PROs can be collected and used. We will provide some examples of research that has used PRO. Finally, we will discuss future direction for PROs in both research and clinical practice.

### What measures exist

Patient reported outcome measures exist in generic, symptom specific, and disease-specific formats. For the most comprehensive assessment, different PROs are often combined, given the multifaceted nature of symptoms that exists with colorectal disease.

General measures most commonly assess a comprehensive view on the quality of life. This can be general quality of life or health-related quality of life. These measures aim for consistent evaluation across different populations and patient groups to facilitate comparisons within and between populations and to the public [5]. Often, these measures are validated in the general population to ensure diverse psychometric testing and can be used for any person, disease, or condition. General

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measures not measuring quality of life exist and encompass a constellation of related symptoms or conditions such as physical functioning or bowel function. General PRO examples are shown in Table 1.

Disease specific PRO measures are measures that have questions specifically related to disease or condition. For example, the LARS score is a five-item PRO measure that encompasses symptoms specific to patients who have undergone a low anterior resection. These questions are specific to Low Anterior Resection Syndrome, a condition of bowel dysfunction from a low pelvic anastomosis. Disease specific measures may not be usable for all patients but are valuable for comparing patients with the same disease and accurately benchmarking patients with accepted measure norms or the average patient. Disease-specific measures are often developed and validated for use within specific patient demographics depending on disease prevalence [8]. Table 2 summarizes several colorectal disease-specific PRO measures.

Symptom-specific PRO measures assess specific symptoms that affect patients' daily lives. These tend to be measure meaningful symptoms such as pain and fatigue. In colorectal surgery, many of these symptoms occur preoperatively, through the perioperative period and beyond, making their measurement valuable. Symptom specific measures are best used through repeated measurement to monitor for changes over time [7]. Additionally, repeated measurement of symptom specific measures can identify changes in symptoms that may facilitate early intervention. Table 3 summarizes several symptom-specific PRO measures.

### How to collect PRO in CRS

PRO measurement is already being done in most clinical areas. The measurement of inpatient pain scores between 0 and 10 is an example of PRO collection. Similarly, PRO measurement for depression and anxiety occurs frequently in primary care offices by using measures such as the PHQ-9 and GAD. Therefore, PRO collection is not as big of an undertaking as it may seem initially to most practices.

The most important part of PRO collection is to measure things that

**Table 1**  
General PRO measures examples.

Target population	PRO measure	
General	PROMIS Global-10	10-Item questionnaire that evaluates patients' overall physical and mental health [6,9].
General	Euroqol EQ-5D	5-Item questionnaire that measures mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Can be used to compare conditions and populations [10].
General	RAND Short Form 12-General Health Status Survey (SF-12)	36-Item questionnaire that measures the patient's overall quality of life [11].
Cancer	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC WLW-CR30)	30-Item instrument that generally assesses quality of life aspects in cancer patients [12].
Function and Disability	Late-Life Function & Disability Instrument (Late-Life FDI)	Assess functional limitations (32 different activities of daily life) and disability (16 different socially defined tasks) in older adults [13].
Bowel Function	Colorectal Functional Outcome Questionnaire (COREFO)	27-Item questionnaire intended to evaluate the degree of complaints from patients who have undergone colorectal surgery. The questions measure incontinence, social impact, stool-related aspects, and need for medication [14].

**Table 2**  
Colorectal disease-specific PRO measures.

Disease	PRO measure	
Hemorrhoid Disease and Anal Fissure	Hemorrhoid and Fissure Quality of Life Questionnaire (HEMO-FISS-QOL)	38-Item questionnaire measuring disease burden and impact on daily life to assess symptoms of patients with protological ailments [15].
Hemorrhoid Disease	PROM-Hemorrhoidal Impact and Satisfaction Score (PROM-HISS)	Hemorrhoidal disease-specific 7-item questionnaire, measuring symptoms (blood loss, pain, prolapse, itching, and soiling), impact on daily activities, and satisfaction with treatment [16].
Inflammatory Bowel Disease (IBD)	Inflammatory Bowel Disease Stress Index (IBDSI)	38-Item questionnaire measuring bowel symptoms, abdominal discomfort, fatigue, bowel complications, and systemic complications in patients with IBD [17].
Inflammatory Bowel Disease	Inflammatory Bowel Disease Questionnaire (IBDQ-32)	32-Item questionnaire including the most important and frequently reported IBD problems experienced by patients to measure quality of life in patients with IBD [18].
Fecal Incontinence	Wexner Score AKA Cleveland Clinic Fecal Incontinence Severity Scoring (CCIS)	5-Item questionnaire measuring gas, liquid and solid stool, and the need for lifestyle modifications and pad usage to score continence on a 0 (perfect continence) to 20 (complete incontinence) scale [19].
Fecal Incontinence	Fecal Incontinence Severity Index (FISI)	4-Item questionnaire assessing the frequency of gas, mucus, liquid, and solid fecal incontinence [20].
Colorectal Cancer	The European Organization for Research and Treatment of Cancer - Colorectal Cancer Specific Quality of Life Questionnaire EORTC-QLQ-CR38	38-Item questionnaire, covering symptoms and side-effects related to treatment, body image, sexuality, and future perspective for colorectal cancer patients [21].
Colorectal Cancer	Functional Assessment of Cancer Therapy- Colorectal Questionnaire (FACT-C)	9-Item questionnaire, measuring well-being on physical, social, family, emotional and functional scales specific to colorectal cancer concerns [20].
Inflammatory Bowel Disease - Ulcerative colitis	Social Impact of Chronic Conditions - Inflammatory Bowel Disease (SICC-IBD)	34-Item questionnaire, measuring the social dysfunction of patients with IBD through measures of education, work, earnings, and relationships [22].
Low Anterior Resection Syndrome (LARS)	LARS-scoring system	5-Item instrument, measuring frequency, urgency, clustering, gas incontinence, and incontinence of liquid stools. Scores are used to classify patients with LARS, minor LARS, or major LARS [23].

are meaningful to clinical team and patients. Quality of life and pain are common areas to measure as they are very impactful to nearly all patients. Bowel function, stigma, and incontinence are meaningful measures specific to colon and rectal surgery. Utilization measures such as emergency care visits may be meaningful to certain practices such as

**Table 3**  
Symptom-specific PRO measures.

Symptom	PRO measure	
Fatigue	Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)	40-Item questionnaire that measures the impact of fatigue on daily activities and function among patients [24].
Pain	PROMIS Short Form v1.0 – Pain Interference	Measures effects of pain on engagement with social, emotional, cognitive, physical, and recreational activities and how pain affects sleep and enjoyment in life. Child and adult instruments of varying length are available [25].
Sleep	Pittsburgh Sleep Quality Index (PSQI)	19-Item questionnaire that assesses sleep quality and disturbances over a 1-month time interval to generate seven different sleep-related scores and one global score [26].
Anxiety and depression	Hospital Anxiety and Depression Scale	14-Item questionnaire intended for the general patient population that measures anxiety and depression [27].

inflammatory bowel disease programs. Measures do not need to be complicated and overly clinical. A simple measure, such as asking “what matters most to you”, may elicit important and meaningful information.

As with any new outpatient clinical workflow, implementation can be a challenge but does not have to take large amounts of time and resources. To start, practices can collect measures on paper. This minimally adds to the workflow as many practices collect patient intake information on paper through new and established patient forms. A practice can also limit the measures collected. Survey fatigue is a major barrier so higher impact, low question number measures are key. If a practice has technological expertise, it can use electronic tablets for collection and responses can be integrated into the electronic health record for real-time scoring. There are also commercial PRO platforms available for collection should a practice desire an electronic approach for PRO collection.

If a practice is collecting PRO for patient counseling, the surgeon or clinician must address measure result at the time of the visit as best practice. Patients will otherwise question the relevance of answering PRO queries in subsequent visits. Addressing PRO at the time of the visit also allows a practice to understand the limitations of the collection process, sets the stage for longitudinal collection, and allows the clinic staff to know why it matters. PRO for patient counseling also facilitates a more accurate conversation. For example, we have found patients initially say that everything is fine when their PRO score says otherwise. Noting the PRO score, we have had a higher quality conversation and subsequent treatment plan that is goal aligned and clinically relevant. Longitudinal collection helps identify new symptoms not present at baseline or persistent symptoms after treatment. Many patients like seeing their PRO score trajectory with longitudinal collection and electronic PRO collection can facilitate PRO plots.

If a practice is collecting PRO for research, it is important to make this clear to patients as well. We have found that the primary use of PRO for patient counseling with a secondary use for research is the best approach given the high benefit of PRO in patient counseling. In some cases, this secondary use is designated as quality improvement. If using PRO for research only, a group should anticipate possible lower completion rates as there is no feedback loop for scores as in use with patient counseling. As with any investigation, a practice must ensure compliance with its local IRB and typically falls under expedited review.

### What studies have been done in CRS

PRO have been widely employed in colon and rectal surgical research, particularly with clinical trials in oncology [28]. To

demonstrate the potential for PRO measures in colorectal surgery, we will present three representative studies that have utilized generic, symptom-specific, and disease-specific measures.

A retrospective study from MSKCC evaluated 165 consecutive patients with locally advanced rectal cancer who were treated with chemoradiotherapy with or without induction chemotherapy [29]. The authors used a symptom-specific measure, the 7-item Bowel Problems Scale, and a generic measure, the National Cancer Institute's PRO-CTCAE modules [29,30]. The treating physician collected these measures weekly during routine clinic visits during radiation therapy. Patients with four or more completed assessments were included. Results from this investigation determined that patients who had received induction chemotherapy had overall lower odds of experiencing significant urgency, bleeding, and tenesmus, compared to patients treated with upfront chemoradiation [29].

In another retrospective study of a prospectively maintained database, investigators evaluated distress, pain, and quality of life among patients with radiated, non-repairable rectourethral fistula who underwent pelvic exenteration. The authors used a symptom-specific PRO measure, the Numeric Pain Intensity Rating Scale (NRS) [31], and two generic measures, the National Comprehensive Cancer Network (NCCN) Distress Thermometer [32] and Short Form-12 questionnaire (SF-12) [33]. Investigators collected PRO in clinic or by a phone survey in the preoperative, postoperative, and long-term periods. In 11 included patients, investigators found that there was decreased pain and distress with quality of life like the general US population at one-year following pelvic exenteration [34]. The authors concluded that pelvic exenteration may be a reasonable treatment for people with radiated, non-repairable rectourethral fistulae.

In another retrospective study of a prospectively collected database of PRO measures for patient counseling, researchers evaluated the longitudinal change in bowel function during multimodal rectal cancer treatment with restorative reconstruction. The researchers used the Colorectal Functional Outcome (COREFO) [14] questionnaire as a global bowel function measure validated in diverse colorectal diseases. The questionnaire was administered predominantly using electronic tablet at time of clinical visit. The researchers evaluated bowel function at baseline, following neoadjuvant therapy, after TME/adjuvant therapy/ileostomy reversal, and at six-months following ileostomy reversal. The results demonstrated that restorative reconstruction was associated with significant worsening of bowel function compared to baseline bowel function that persists at six-months after ileostomy reversal. The authors concluded that restorative reconstruction after total mesorectal excision is associated with worsening of bowel dysfunction when compared to baseline that is persistent [35].

These studies exemplify use of PRO to assess patient perspective within colon and rectal surgery. Each use validated measures for the target cohort and assess changes longitudinally with repeated measurement. As demonstrated, there is valuable information that is gained through PRO collection that supplements traditional research outcomes such as mortality and disease-free survival.

### Future directions for PRO and CRS

Future direction of PRO and CRS lies in universal measures/measures that have a low question burden, favorable psychometric properties, free to use, and relevant to what matters most to colon and rectal surgical patients. We should have a standardized approach to PRO collection and analysis for research. Many studies do not collect measures at baseline, which is a major current limitation. It is important to use appropriate statistical tests for comparison and be aware of regression to the mean when aggregating cohorts. PRO for research must be validated in the study population. If the PRO is not valid in the general population and is disease specific, researchers should not use them in a non-validated cohort [36]. Although there will likely clinical overlap, there is not a scientific validity with this approach. The use of the LARS

score in patients prior to LAR or in non-rectal cancer populations is the most common example.

Ultimately, the holy grail is a frugal PRO that achieves both a quantitative and qualitative characterization of the patient's status. We suggest that colorectal surgeons consider: "What is your goal for this visit/disease/treatment/life?" This will allow for tailored treatment that achieves goal-oriented treatment for patients for the multiple options for the colorectal disease that they face.

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### CRediT authorship contribution statement

**Kathia E. Nitsch:** Data curation, Writing – original draft, Writing – review & editing. **Srinivas J. Ivatury:** Conceptualization, Data curation, Formal analysis, Supervision, Validation, Writing – original draft, Writing – review & editing.

### Declaration of competing interest

None.

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