Adherence to Clinical Care Protocols for Inflammatory Bowel Disease and Evaluation of a Clinical Decision Support System to Improve Adherence

by

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A thesis submitted in partial fulfillment of the requirements for the degree of

Master of Science

Department of Medicine

University of Alberta

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ABSTRACT

Clinical care pathways have been developed with the goal to standardize and improve quality of care. At the University of Alberta, clinical care pathways have been developed, and are currently in use, for inflammatory bowel disease patents experiencing disease flare. However, there is limited literature available regarding the level of adherence of IBD practitioners to the published guidelines or best practices, such as those implemented through these clinical care pathways.

The first part of this thesis is a retrospective, single-center chart review of 207 inflammatory bowel disease receiving steroid dispensations from inflammatory bowel disease specialists at the University of Alberta. Adherence to best practices for flaring IBD patients were determined by dividing the number of adherent encounters over the total number of encounters. Key gaps in care were found: documenting of clinical scores (33.5%), completion of standard flare lab tests (63.3%), testing for *Clostridium difficile* toxin (65.5%), testing for fecal calprotectin (17.6%), 2-4 week follow-up (22.2%), documentation of steroid consenting (24.6%), and provision of osteoprotective therapy (29.9%).

Electronic clinical decision support systems (CDSS) have been shown to have potential to improve adoption of clinical guidelines. The second part of this thesis details the development, two-phase implementation, and evaluation of a CDSS integrated into the electronic medical record system, for inflammatory bowel disease patients suspected of having disease flares. In Phase 1, before-and-after analysis demonstrates an increase in documentation of clinical scores from 3.5% to 24.1% ($p<0.001$), which also showed a

significant level change on interrupted time series analysis (p=0.028). In Phase 2, before-and-after analysis showed increases in ordering of flare lab tests (47.6% to 65.8%, p<0.001), fecal calprotectin (27.9% to 37.3%, p=0.028), and stool culture testing (54.6% to 66.9%, p=0.005). Interrupted time series analyses did not reach statistical significance in Phase 2. The overall system adoption rate was moderate at approximately 25%, with greater adoption by nurse providers than physicians. This study is one of the first to investigate the implementation of an Epic EMR-based CDSS in IBD and prompts many areas for future investigation, such as the effect of CDSS on outcomes, or how to design CDSS that have greater utility for physicians. Future iterations of CDSS for IBD should be evaluated on a larger scale, which can be facilitated by Connect Care, the coming provincial clinical information system for the province of Alberta.

PREFACE

This thesis is an original work by Reed Taylor Sutton (RTS). Two research projects, which are part of this thesis, both received ethics approval from the University of Alberta Health Research Ethics Board. Chapter 2 encompasses “Adherence to Guidelines and Best Practices for IBD Flare Management and Corticosteroid Administration in Ambulatory Setting: A Retrospective Study”, Pro00064139, approved May 30, 2016. Chapter 3 encompasses “The Effect of an Inflammatory Bowel Disease Clinical Decision Support System on Compliance with IBD Flare Management and Corticosteroid Prescribing Guidelines: An Interrupted Time Series”, Pro00083538, approved July 25, 2018.

Chapter 2 is the basis for a pending original research manuscript, “Adherence to Guidelines and Best Practices for Outpatient IBD Flare Management and Corticosteroid Administration: A Retrospective Cohort Study”, authored by RT Sutton, E Lytvyak, RN Fedorak, and KI Kroeker. RTS contributed to study design, data collection, analysis, manuscript drafting and editing. EL contributed to study design. KIK and RNF were co-primary investigators, contributing to study design and manuscript input.

Chapter 3 is the basis for a pending manuscript, “The Effect of an Inflammatory Bowel Disease Clinical Decision Support System on Compliance with IBD Flare Management Corticosteroid Prescribing Guidelines: An Interrupted Time Series Analysis Study”, co-authored by RT Sutton, E Lytvyak, RN Fedorak, and KI Kroeker. RTS contributed to study design, data collection, data analysis, and manuscript drafting and editing. EL contributed to protocol development. KIK and RNF were co-primary investigators, contributing to study design and manuscript input.

ACKNOWLEDGEMENTS

I am extremely grateful to my supervisor Dr. Karen Kroeker, for always lending her time, expertise, and support, throughout my degree. I am also grateful to Dr. Richard Fedorak, for seeing something in me and motivating me to pursue graduate studies. Thank-you to the other members of my supervisory committee, Dr. Dan Sadowski, Dr. Daniel Baumgart, and David Pincock, for your guidance and feedback both within and outside of our many committee meetings.

Thank you to the Canadian Institute of Health Research (CIHR), to Alberta Innovates, and to the University of Alberta Faculty of Medicine and Dentistry for funding support. I would also like to thank the Centre of Excellence for Gastrointestinal Inflammation and Immunity Research (CEGIIR), who provided an ideal environment and space for me to work and learn. Thank you to Sandee Tocheniuk for her excellent administrative support, references, and generally looking out for me these past two years.

I would also like to thank the many fellow students I was able to work with get to know over the course of my degree. Thank you to Candace Beilman, Nathan Stern, Tyler Cookson, Alexandra Dittrich, Natalie Klostermann, Matt Reeson, and Melissa Silva. A big thank-you to Nathan Stern for helping me with tedious chart review during the second part of my thesis.

Finally, I would like to thank my family, including my parents for their constant and unconditional support.

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LIST OF SYMBOLS, ABBREVIATIONS, and DEFINITIONS

α	alpha
ADA	Anti-drug antibodies
CCP	Clinical care pathway(s)
CD	Crohn's disease
CDI	*Clostridium difficile* infection
CDS	Clinical decision support
CDSS	Clinical decision support system
CPM	Critical Path Method
CPOE	Computerized physician order entry
CQI	Continuous Quality Improvement
CRP	C-reactive protein
CRXO	Cluster randomized crossover trial
CS	Corticosteroids
DDSS	Diagnostic Decision Support System
DRG	Diagnosis Related Group(s)
EBM	Evidence-based Medicine
EHR	Electronic health record
EMR	Electronic medical record
FCP	Fecal calprotectin
FHIR	Fast Healthcare Interoperability Resources
GI	Gastrointestinal
HL7	Health Level 7
HREB	Health Research Ethics Board
IBD	Inflammatory bowel disease
IBD-U	Inflammatory bowel disease, unclassified
ICD	International Statistical Classification of Diseases
ICD-9-CM	International Classification of Disease, 9th Revision, Clinical Modification
ICD-10-CA	International Classification of Diseases and Related Health Problems, 10th Revision

ICPAT	Integrated Care Pathway Appraisal Tool
ITS	Interrupted time series
mHBI	Modified Harvey-Bradshaw Index
PERT	Program Evaluation and Review Technique
PHN	Personal health number
PHR	Personal health record
pMAYO	Partial Mayo Score
QI	Quality improvement
RCT	Randomized controlled trial
SD	Standard deviation
SMART	Substitutable Medical Applications, Reusable Technologies
SS	Six Sigma
TDM	Therapeutic Drug Monitoring
ToC	Theory of Constraints
UC	Ulcerative colitis
VR	Visit Reason / Reason(s)-for-visit

1 BACKGROUND

1.1 Clinical Care Pathways

Although there are no universally agreed upon definitions for what constitutes a clinical care pathway (CCP), the European Pathways Association (EPA) defines a 'care pathway' as "a complex intervention for the mutual decision making and organization of care processes for a well-defined group of patients during a well-defined period".[1] One of the purposes of care pathways is the translation of national or higher level guidelines into local practice[2]. They are designed to be more actionable and prescriptive than guidelines themselves, which is often only achieved by customization to the local context[3]. It is thought that through the standardization of care in accordance with guidelines, there will be improved patient outcomes and safety, as well as reduced cost. However, standardization is not meant to come at the expense of individualization of care[4,5]. Care pathways should be flexible and not dogmatic or a substitute for professional judgement on unique or atypical cases.

CCPs are increasingly and primarily developed internally by hospital providers, individual practices, and academic medical centers, although venders and payers can be more involved in marketing and deployment[6]. Typically, the first step in developing CCPs (assuming the area of practice has been chosen) is to garner higher management or organizational support[7], and convene an expert group or 'panel' of healthcare staff with expertise in the area of interest[6]. The expert panel needs to decide on the scope of the

pathway, defining the diagnosis it concerns, and what patients it will be designed for (inclusion criteria)[7]. From there, literature reviews of the current evidence relevant to the pathway must be completed, starting with recent international/national clinical practice guidelines (if available) and working down to less consensus-established aspects of care. Based on the review, a preliminary draft of the care pathway process, action steps, and decision points can be created by members of the panel. If there are cases of ambiguity, where available evidence does not provide a clear guide, consensus methods can be employed to help the panel decide (such as the Delphi or modified Delphi) [8,9]. Following development, pilot-testing can be conducted to help refine the pathway. This can include the use of auditing tools, and having frontline staff test the pathway on actual patients and give feedback via qualitative methods[10]. This process should be iterative until the pathways are ready for validation on a larger scale.

1.1.1 Clinical Care Pathways for Inflammatory Bowel Disease at the University of Alberta

Between 2014 and 2016, the University of Alberta Division of Gastroenterology and other collaborators developed a set of care pathways and protocols for Inflammatory Bowel Disease. The details of these pathways relevant to this Thesis, are detailed below.

1.1.1.1 Setting of the Pathways

The primary, initial setting of the IBD Clinical Care Pathways (IBD CCP) was **the IBD Unit** (University of Alberta Hospital, Edmonton, Alberta, Canada). The IBD Unit (www.ibdunit.ca) is a specialized division, affiliated with the University of Alberta Hospital, providing long-term IBD care to over 5,300 (and counting, as of 2016) IBD patients from

the Edmonton region, Northern Alberta, Northwest Saskatchewan, Eastern British Columbia, and the Northwest Territories. The IBD Unit encompasses an outpatient clinic, academic, research, and educational facilities.

The IBD Unit integrates a coordinated network of various specialists and services (IBD-specialists, IBD-nurses, weekly IBD flare clinic run by the Nurse Practitioner, dietitians, colorectal surgeons, hepatologists, a family physician with special interest in IBD, and more). This multi-disciplinary team provides routine and semi-urgent coordinated care to all IBD patients.

1.1.1.2 Development: Digestive Disease Summit and IBD Retreats

The idea to develop the IBD CCPs as a province-wide initiative was conceived during a provincial conference hosted by the Alberta Society of Gastroenterology (http://www.albertagastro.ca/) called the Alberta Digestive Disease Summit (ADDS). At this conference, there were over 200 attendees, including a large number of providers from across the province. During a subsection of the event, Dr. Richard Fedorak and Dr. Ellina Lytvyak of University of Alberta, with Dr. Remo Pannaccione of University of Calgary, led a series of 'breakout sessions'. These were 15-20 person groups consisting of IBD nurses, infusion nurses, community gastroenterologists, local Crohn's and Colitis Canada (CCC) representatives, and many others. These groups conducted facilitated discussions of the need for standardized pathways across the province, who would be interested in using them, what topics they should cover, how people from throughout the province could access them easily, what form they would take, and so on. These sessions ultimately served as an informal needs assessment, as well as initial planning for the IBD

CCPs.

Following the initial conception, a dedicated ‘IBD Retreat’ was held in June of 2014. This brought together various IBD physicians, nurses, administrative and clerical staff, researchers, clinical trial staff, and industry and patient representatives from Edmonton, Calgary, and the community. Significant pre-work and drafting of preliminary documents was completed prior to the retreats, and shared with participants. Breakout sessions were conducted to further refined and develop standardized, best practice protocols for each area (clerical/administrative, nursing, and clinical).

Following the session, tasks were delegated to various individuals and groups to finalize the protocols and associated documents on paper. This was conducted over the Fall of 2014, with the protocols being launched into production in late 2014 / early 2015.

1.1.1.3 Pilot Testing

The IBD CCP were developed largely in an academic environment, although members were the community were part of the IBD Retreats and Digestive Disease Summit. Therefore, a small pilot was conducted as part of early validation of the pathways, to confirm that they were transferable from the academic to community health care setting. The pilot involved disseminating the early IBD pathways to the small, remote communities of Fort McMurray, Grande Prairie, and Peace River, for trial use. Verbal feedback from the IBD physicians and nurses in this community confirmed that the pathways were appropriate and applicable to the community.

1.1.1.4 Current Status

Appendix 0 contains current versions of two IBD Clinical Care Pathways relevant to this thesis (CCP #1 and CCP #6). They contain structured, standardized, evidence-based multidisciplinary management protocols, identifying an appropriate sequence of diagnostic and clinical interventions and timeframes for IBD patients. They contain recommended diagnostic tests, medications with dosing, requisitions, and follow-up appointment intervals, tailored to the patient' disease activity, clinical status and tests results, admission orders and discharge planning interventions specific to IBD patients. They are also comprised of algorithms, and checklists that help to harmonize clinical and administrative aspects and ensure continuity of IBD care in outpatient settings.

The IBD CCP were initially introduced in a paper-based format, followed by electronic fillable PDF documents. They were also made publicly available in a web-based format on the University of Alberta IBD clinic's website (http://www.ibdclinic.ca/ibd-ccp), and via a link accessible from the web viewer within Edmonton's local EMR, eCLINICIAN.

1.2 Clinical Decision Support Systems

1.2.1 What is a Clinical Decision Support System?

A clinical decision support system (CDSS) is intended to improve healthcare delivery by enhancing medical decisions with targeted clinical knowledge, patient information, and other health information[11]. A traditional CDSS is comprised of software designed to be a direct aid to clinical-decision making, in which the characteristics of an individual patient are matched to a computerized clinical knowledge base and patient-specific assessments or recommendations are then presented to the clinician for a decision[12]. CDSSs today are primarily used at the point-of-care, for the clinician to combine their knowledge with information or suggestions provided by the CDSS. CDSS often make use of web-applications or integration with electronic health records (EHR) and computerized provider order entry (CPOE) systems. They can be administered through desktop, tablet, smartphone, but also other devices such as biometric monitoring and wearable health devices. These devices may or may not produce outputs directly on the device or be linked into EHR databases.[13]

Today, CDSS are ubiquitous in healthcare systems, including diagnostics, alarm systems, disease management, prescription (Rx), drug control, and more[14]. They can manifest as computerized alerts and reminders, computerized guidelines, order sets, patient data reports, documentation templates, and clinical workflow tools[15]. They have been shown to contribute positively to many aspects of clinical care, from patient safety, where reduction in medication errors can be achieved through drug-drug interaction (DDI) alerts[16], to improving diagnostics through diagnostic decision support systems (DDSS).[17]

One important goal many CDSS' are tasked with is improving adherence and adoption of clinical guidelines, similar to CCPs.[18] This is significant because traditional clinical guidelines and care pathways have been shown to be difficult to implement in practice with low clinician adherance[19,20]. The assumption that practitioners will read, internalize, and implement new guidelines does not always hold true[21]. However, the rules implicitly encoded in guidelines can be literally encoded into CDSS. This can take a variety of forms, from standardized order sets for a targeted case, alerts to a specific protocol for the patients it pertains to, or reminders for laboratory testing. Furthermore, CDSS can assist with managing patients on research/treatment protocols[22], tracking and placing orders, follow-up for referrals or patients who have not followed management plans[23], as well as ensuring preventative care[24].

1.2.2 Problems with Clinical Decision Support Systems

There is a body of literature which shows that, in certain instances, CDSS can have negative consequences to patient care and on providers who use them. Two of the most notable problems discussed are alert fatigue, and workflow disruption.

1.2.2.1 Alert fatigue

If healthcare providers are presented with excessive/unimportant alerts, they can suffer from alert fatigue, whereby they learn to disregard all alerts. This results in providers potentially losing the positive effect of alerts which are justified and clinically important in the ruck of those that are inconsequential.[25]

Unfortunately, this is becoming a digital epidemic, with studies finding that up to 95% of CDSS alerts are inconsequential, and often times physicians disagree with or distrust

alerts[26]. Other times they just do not read them. Therefore, *disruptive* alerts should be limited to more life-threatening or consequential contraindications, such as serious allergies.

1.2.2.2 Workflow disruption or lack of integration

CDSS can disrupt clinician workflow, especially in the case of stand-alone systems (many of the early CDSS were standalone). Disrupted workflow can lead to increased cognitive effort, more time required to complete tasks, and less time face-to-face with patients. Even when CDSS are well integrated within existing information systems, there can be disconnect between face-to-face interactions and interaction with a computer workstation. Furthermore, CDSS can disrupt workflows by disrupting a provider's normal flow of information processing. In response, CDSS have been designed using the 'think-aloud' method to model practitioners' workflow and create a system with better usability[27].

1.2.3 Clinical Decision Support System for Inflammatory Bowel Disease at the University of Alberta

In March of 2014, a new electronic medical record (EMR) built by Epic Systems Inc, was launched in the Edmonton zone and made live to the GI division for outpatient services. The general-purpose Epic EMR software allows for rich clinical decision support functionality. This provided the opportunity to automate and create electronic versions of the CCPs as CDS tools. The IBD group engaged and met with the Ambulatory EMR team for Alberta Health Services (AHS) to begin working on the clinical improvement project.

The CCPs chosen to be converted first were: CCP #1: Suspected IBD Outpatient Flare

(Including Patients on Biologic) and CCP #6: Initiation and Maintenance of Corticosteroids (see Appendix 0). They were iteratively developed through the Epic CDS functionality: flowsheets, best practice advisories (alerts), and smartsets (grouped sets of orders), through consultations with AHS analysts, and the IBD team, which consisted of one research associate, IBD nurse, and IBD physician.

The full details and functionality of the current live version (Version 2) of the CDS tool is detailed in Chapter 3. Importantly, the first version (Version 1) was modelled after an algorithm for the IBD Flare encounter, which included a stepwise approach with three smartsets: (1) Suspected flare, (2) 2-4 weeks' Mid-flare, and (3) 16 weeks' Post-flare assessments.[28] This version required manual activation of the BPA alert for each SmartSet. It was launched September of 2017, to be piloted primarily by the IBD unit nursing staff. Over the next few months, feedback was gathered and compiled based on preliminary use. The IBD CDS group met and discussed solutions and steps to improve the CDS tool further, and then submitted an improvement request to AHS. In August 2018, the group met again with the AHS analyst to implement improvements to the CDS tool. Feedback and changes implemented are compiled in *Appendix: CDSS Version 1 - Feedback from IBD Staff.*

There were two primary changes implemented in Version 2, aside from minor enhancements and modifications outlined in the Appendix. One, the consolidation of the three separate grouped order sets into a single order set for the initial flare encounter. Feedback from users revealed that having multiple grouped order sets made it difficult to ascertain when it was appropriate to use each one. In addition, the mid-flare and follow-up assessments are highly variable between providers and depending on the patient and

treatment. The initial flare was the most important encounter, and therefore became the main target going forward.

Second, the method of activation of the order sets was changed. In Version 1, this involved manually typing in a specific visit diagnosis. Instead, with the AHS analyst, we designed the order set alert to be automatically activated by the presence of any IBD-associated diagnosis in the problem list (ie. Crohn's disease, ulcerative colitis, IBD-unclassified). This did not mean that every IBD patient presenting to clinic would enter the flare pathway, but that the pathway would be easily available for activation by a provider should the presenting IBD patient be suspected of having a disease flare.

Version 2 changes were made live on October 10, 2018 and pushed out to both IBD nurses and physicians. This change was accompanied by in-person user training and educational materials, and communications to raise awareness of the CDS tool to users, thus constituting a practice 'interruption' or intervention. Further details and an interrupted time series study of the intervention comprise Chapter 3 of this thesis.

Table 1-1 History of the Alberta IBD Clinical Care Pathways and Clinical Decision Support Project

April 2013	**IBD Retreat** UAH / RAH / GNH staff meet at Saorsa Business Center Development of Edmonton-specific best practice IBD protocols
June 2013	**Initial Concept, Needs Assessment for Alberta-wide protocols** Alberta Digestive Disease Summit, Lake Louise, Alberta
June 2014	**IBD Standardized Care Protocols Retreat**
Fall 2014	**IBD Standardized Care Protocols Development**
2015-2016	**Launch and Further Development of IBD CCPs**
2016-2017	**CDS Tool Conception and Design** AHS eCLINICIAN Ambulatory Team and Analysts
September 11, 2017	**CDS Tool Version 1 In Production**
August-September 2018	**Design of CDS Tool Version 2** AHS eCLINICIAN Ambulatory Team and Analysts
October 10, 2018	**CDS Tool Version 2 In Production**
December 2018	**IBD Pathways Breakout Groups Feedback** Digestive Health SCN Core Committee Meeting

1.3 Research Aims

1.3.1 Aim I and Research Study I

The first aim of this research was to determine the current level of adoption of best practices and evidence–based guidelines for IBD flare management and corticosteroid administration, using retrospective chart review. This aim is addressed in *Chapter 2: Adherence to Guidelines and Best Practices for IBD Flare Management and Corticosteroid Administration by IBD Specialists: A Retrospective Study*.

1.3.2 Aim II and Research Study II

The second aim of this research was to prospectively evaluate the impact of the developed clinical decision support system for IBD on level of adoption of best practices and evidence-based guidelines for IBD flare management and corticosteroid administration. This aim is addressed in *Chapter 3: EHR-integrated Clinical Decision Support System for IBD Flare Management and Corticosteroid Administration: An Interrupted Time Series.*

2 ADHERENCE TO GUIDELINES AND BEST PRACTICES FOR IBD FLARE MANAGEMENT AND CORTICOSTEROID ADMINISTRATION BY IBD SPECIALISTS: A RETROSPECTIVE STUDY

2.1 Introduction

Inflammatory bowel disease (IBD) is a chronic inflammatory condition characterized by periods of active and inactive intestinal inflammation. A lifelong disease, IBD often begins in young adulthood and, when active, includes symptoms such as diarrhea (with or without blood), weight loss, abdominal pain, and fatigue[29]. IBD is sub-classified into Crohn's disease (CD), Ulcerative colitis (UC), and IBD-unclassified (IBD-U) or indeterminate colitis (IC). Although IBD currently has no known etiology or a cure, it can be managed with medications and, in some cases, surgery.

Corticosteroids are key pharmaceuticals that provide rapid relief from the most dramatic IBD-flare-related gastrointestinal symptoms due to their strong non-specific systemic immunosuppressant effect. However, they fail to demonstrate substantial efficacy in maintaining IBD remission and are therefore only recommended for induction[30,31,32].

In the modern IBD era, newer classes of drugs like immunomodulators and biologics play a key role in maintaining and even inducing remission in IBD patients, with better safety profiles than steroids. Consequently, a primary treatment target in IBD is not just clinical remission (CR), but 'steroid-free' clinical remission (SFCR).

There is limited literature available regarding the extent IBD specialists are being

adherent to the published evidence–based guidelines and best practices in terms of CS use for the induction and maintenance of remission in IBD[33]. The aim of this study was to assess the level of adherence to best practices and evidence–based guidelines regarding CS prescription practices and IBD flare management. A secondary aim was to assess whether patients had better outcomes when their care was conducted in accordance with clinical guidelines.

2.2 Methods

2.2.1 Study Design, Setting, and Data Sources

This retrospective, single center cohort study was performed using data collected from IBD outpatients of the University of Alberta Inflammatory Bowel Disease Consultation and Research Clinic (Edmonton, Alberta Canada), receiving at least one dispensation of corticosteroids between March 1, 2014 and March 1, 2016. Patients were identified from the Division of Gastroenterology IBD Electronic Database. Data for corticosteroid and narcotic dispensations, emergency department visits, and hospital admissions (including surgeries) was extracted from the Pharmaceutical Information Network (PIN), National Ambulatory Care Reporting System (NACRS), and Canadian Institute for Health Information Discharge Abstract Databases (CIHI-DAD), respectively. These three databases were all accessible through the Alberta Health Services Data Repository for Reporting (AHSDRR), which captures 42 diagnostic codes (based on International Classification of Disease, 10th Revision, Clinical Modification, (ICD-10-CA)) and 25 procedural codes (based on Canadian Classification of Health Intervention (CCI) coding).

2.2.2 Patient Population

Patients were eligible for inclusion if they met the following criteria: (1) confirmed CD or UC with a diagnosis established by either endoscopy or histology. For those without this data available in the electronic health record, the diagnosis recorded in the majority of the last 9 IBD clinic visits was used (validated by Benchimol et al. [34]). Diagnosis was also cross-checked with ICD-10-CM codes from emergency visits and hospitalizations (validated by Ma et al. [35]). Any entries with both UC (K51.X) and CD (K50.X) entered in

the same visit were excluded. (2) Dispensed corticosteroids (oral prednisone or budesonide, methylprednisolone) prescribed by an IBD practitioner during an outpatient encounter at the University of Alberta Inflammatory Bowel Disease Consultation and Research Clinic. Patients were excluded if they were (1) less than 18 years of age, (2) pregnant or breastfeeding, (3) suffering from concomitant autoimmune, autoimmune-related, or other diseases requiring indefinite CS use (eg. Ankylosing spondylitis, rheumatoid arthritis, systemic lupus, idiopathic pulmonary fibrosis) diagnosed before the index CS dispensation, and (4) moved out of province or completely lost to follow-up before the end of the study period (incomplete data).

2.2.3 Description of Dataset

The first CS dispensation within the study period (March 2014 – March 2016) was considered the index dispensation and index date for derivation of outcome measures. Additional corticosteroid dispensations up to 18 months after the index dispensation were included in the dataset. It was assumed that dispensations would continue for the stated duration and dosing (including taper) provided by the PIN database and confirmed via manual EHR review. It was assumed that dispensations occurring with 14 days of estimated cessation of a previous dispensation were bridged (common with budesonide prescriptions), unless manual EHR review suggested otherwise.

Data from emergency department visits, hospitalizations, and IBD-related surgeries occurring within 18 months from the index dispensation were included in the dataset. Surgeries were identified using validated Canadian Classification of Health Interventions (CCI) codes linked to the CIHI-DAD (see Appendix: Intervention Codes used to Identify

Inflammatory Bowel Disease-related Surgery in the CIHI-DAD).[36,37] Emergency department visits and hospitalizations were sub classified as IBD-related if UC or CD was recorded as the most responsible diagnosis (MRDx), or if a complication or symptom of IBD (including but not limited to: abdominal pain, anal or rectal abscess or fissure, ankylosing spondylitis, epigastric pain, gastroenteritis unspecified, fistula, hemorrhage of anus or rectum, nausea, intestinal obstruction, joint pain, peritonitis) was the MRDx along with UC or CD as the 2nd or 3rd diagnosis code.

2.2.4 Manual Data Collection

Data not acquirable by database extraction was manually extracted by author R.T.S. using a standardized case report sheet, from the region-specific electronic health record: eCLINICIAN (Epic Systems, Verona, WI). eCLINICIAN includes inpatient and outpatient laboratory investigations, diagnostic imaging, histology and pathology reports, hospital admission and discharge summaries, and operative procedures including endoscopic procedures.

Patient data collected included gender, DOB, year of diagnosis, type of IBD (UC or CD), Montreal Classification of IBD[38], and IBD-specific surgical history. The following was collected at encounters corresponding with the index CS prescription and post-flare clinic visit (if done): Modified Harvey-Bradshaw (mHBI) or partial Mayo (pMAYO) clinical symptom scores completed and result, flare laboratory tests completed, CRP (if done), FCP (if done), Calcium and Vitamin D prescribed, patient information sheets given, current and any modifications to IBD treatment.

2.2.5 Outcomes and Variables

The primary objective of this study was to assess the level of adherence to best practices and evidence–based guidelines regarding clinical management of IBD flares and use of corticosteroids. The variables of interest were selected from the established IBD flare and corticosteroid administration protocols at the University of Alberta, which were largely based on interpretation of published ECCO clinical guidelines, Crohn's and Colitis Foundation of America (CCFA) quality indicators,[39] and later the Crohn's and Colitis Canada PACE quality indicators.[40]

Table 2-1 Variable definitions for IBD flare and corticosteroid prescribing guidelines

Dimension	**Published Guideline or Quality Indicator**	**Local Best Practice (University of Alberta CCPs)**	**Variable Definition**	**Data type and possible values**
IBD Flare Management				
Symptom investigation	Detailed questioning re. onset of symptoms, particularly bloody stool, urgency, abdominal pain et al. Clinical indices not validated (ECCO 3C[41])	Modified Harvey Bradshaw Index (mHBI)[42] and Partial Mayo Score (pMAYO)[43]	Clinical score completed and documented in chart (note, clinic letter, or flowsheet)	Numerical; 0 or 1 (dummy)
Laboratory investigation (bloodwork)	Full blood count, serum urea, creatinine, electrolytes, liver enzymes, iron studies, CRP (ECCO 3F[41])	CRP, CBC, ferritin, creatinine, albumin, alkaline phosphatase, ALT, AST, sodium, potassium, chloride	For each lab item, ordered at encounter or within 1 month.	Numerical; 0 or 1 (dummy)
Laboratory investigation (stool)	C. difficile if patient has diarrhea (PACE PQI 1, ECCO 2E[44]) Fecal calprotectin (for initial diagnostic investigation, ECCO 2E[44])	C. difficile, stool culture and sensitivity having if diarrhea, stool for fecal calprotectin [45], ova and parasite if recent travel / camping.	For each test, if ordered at encounter or within 1 month.	Numerical; 0 or 1 (dummy)
Provision of steroid-sparing therapy	PACE PQI 7[40], various ECCO guidelines, CCFA QPI 3[39].	Steroids prescribed in conjunction with 'maintenance agent': 5ASA, antiTNF, or immunosuppressant	Therapy modified or added at index encounter Type of modification and medication	Numerical; 0 or 1 String

Table 2-1 Variable definitions for IBD flare and corticosteroid prescribing guidelines				
Dimension	**Published Guideline or Quality Indicator**	**Local Best Practice (University of Alberta CCPs)**	**Variable Definition**	**Data type and possible values**
Corticosteroid Administration				
Steroid dosing and tapering	Standard taper (ECCO 5.4.3)	40 mg prednisone, taper 5 mg every week until 20 mg, then 2.5 mg until off. 9 mg budesonide, taper 3 mg every 4 weeks until off	Taper inferred from tablet tab size, quantity and days supply.	Numeric; continuous
Consenting, patient information, and documentation	IBD patients directed to educational information (PACE PQI 22)	Steroid patient information sheet, tapering instructions, and taper calendar	Any documentation in chart of information provided, counselling of side effects, etc.	Numeric; 0 or 1 (dummy)
Bone prophylaxis / preventative care	Calcium and vitamin D if duration>6 weeks (ECCO 5.4.3) [44] Recommended for all systemic steroid (PACE PQI 27)	Calcium 500mg po BID, Vitamin D 1000 po QD for duration of therapy	1. Vitamin D prescribed or recommended at index. 2. Calcium prescribed or recommended at index. 3. Patient already taking vitamin D / calcium.	Numeric; 0 or 1 (dummy)
Repeated long-term use of steroids	Steroid sparing therapy for patients with ≥2 courses in 12 months (PACE PQI 7[40])	Instruction to not prescribe for >3 months.	Number of additional dispensation by PRACID, other practitioners, date, quantity, supply, and DINs.	

2.2.6 Statistical Analysis

Patient demographics and disease characteristics were tabulated. Median and interquartile range (IQR) were calculated for continuous variables, including age and disease duration (non-normal distribution, Shapiro-Wilk test). For categorical variables, frequency distributions of categories were tabulated. Demographics and disease characteristics were compared across subgroups. Medians were compared using the Kruskall-Wallis test. Proportions of categorical variables were compared using the $\chi 2$ test,

or Fisher's exact test where cell counts were less than 5, with null hypothesis that distributions did not differ. Statistical analysis was performed with SPSS 23.0 software (Armonk, NY: IBM Corporation).

2.2.7 Ethical Considerations

The study's design, protocol, and materials were approved by the Health Research Ethics Board of the University of Alberta. IBD practitioner consent was attained. IBD patient consent was not required. Identifying data was amassed collectively and analyzed in aggregate.

2.3 Results

2.3.1 Study Population and Demographic Data

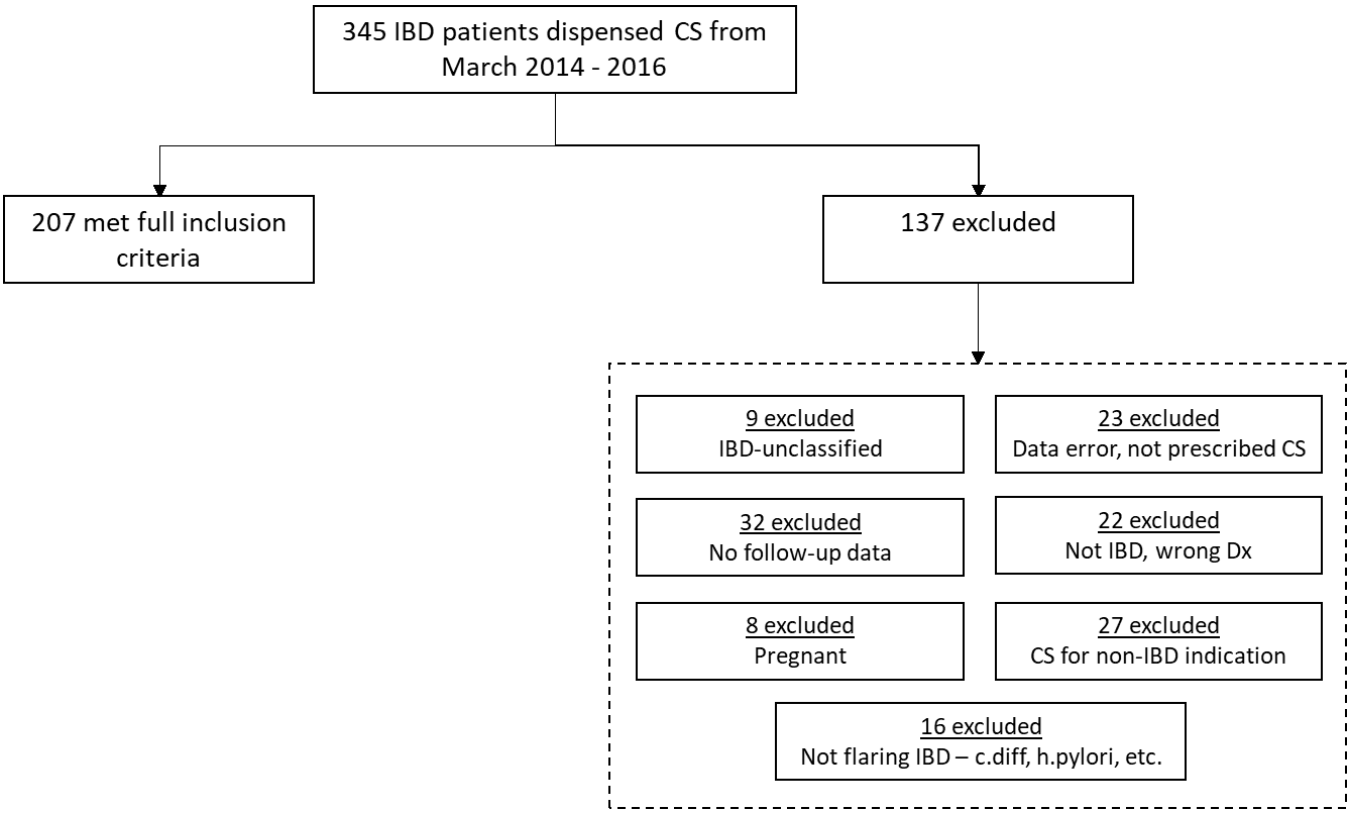

Figure 2-1 Flow diagram of included and excluded patients

After removing patients who did not meet inclusion criteria or did meet exclusion criteria, there were 207 patients in the primary dataset. *Figure 2-1* shows the various reasons for exclusion. Demographic data is displayed in **Table 2-2**. Of importance, 64% of patients resided in Greater Edmonton, 40% of patients were on no IBD maintenance therapy at presentation, even though only 15% were diagnosed at the index encounter (in hospital). Crohn's patients had several differences from ulcerative colitis, including older age, longer disease duration, lower use of 5-ASA therapy, and greater use of budesonide.

Table 2-2 Demographics of IBD, CD, and UC patients in the retrospective cohort at index dispensation

Characteristic	All patients	Crohn's disease (CD)	Ulcerative colitis (UC)	P-value [b]
N (%)	207 (100.0)	135 (65.2)	72 (34.8)	-
Age in years, median (IQR)	42.3 (29.9-57.0)	43.5 (31.9-58.9)	35.9 (28.5-51.5)	0.037
Sex, n (%)				
Female	92 (44.4)	61 (45.2)	31 (43.1)	0.883
Residing in Greater Edmonton	133 (64.3)	89 (65.9)	44 (61.1)	0.543
Smoking Status				
Never	98 (49.5)	59 (45.7)	39 (56.5)	0.009
Current	41 (20.7)	35 (27.1)	6 (8.7)	
Former	59 (29.8)	35 (27.1)	24 (34.8)	
IBD Phenotype, n (%)				
Ileal CD	41 (19.8)	41 (30.4)	-	-
Colonic CD	18 (8.7)	18 (13.3)	-	-
Ileocolonic CD	70 (33.8)	70 (51.9)	-	-
Upper disease	12 (5.8)	12 (8.9)	-	-
Proctitis	0 (0.0)	-	0 (0.0)	-
Left-sided UC	14 (6.8)	-	14 (19.4)	-
Pancolonic UC	58 (28.0)	-	58 (80.6)	-
Years since dx, median (IQR)	7 (1-17)	10 (1-21)	4 (0-11)	<0.001
Current IBD therapy, n (%)				
None	83 (40.1)	59 (43.7)	24 (33.3)	0.180
5-ASA only	50 (24.2)	21 (15.6)	29 (40.3)	<0.001
IMM	30 (14.5)	20 (14.8)	10 (13.9)	0.857
Biologic	45 (21.7)	36 (26.7)	9 (12.5)	0.021
Monotherapy	27 (60.0)	22 (61.1)	5 (55.6)	0.081
Combotherapy	18 (40.0)	14 (38.9)	4 (44.4)	0.306
CRP (mg/L, median (IQR) †	9.0 (2.8-22.4)	8.6 (2.2-23.3)	9.1 (3.6-21.3)	0.429
Clinical Activity, n/N (%) [a] †				
Remission	10 (16.7)	9 (24.3)	1 (4.3)	0.128
Mild disease	22 (36.7)	12 (32.4)	10 (43.5)	
Moderate / severe disease	28 (46.7)	16 (43.2)	12 (52.2)	
Index dispensation				
Prednisone	162 (78.3)	93 (68.9)	69 (95.8)	<0.001
Initial dose: 40 mg	145/162 (87.7)	84/93 (90.3)	61/69 (88.4)	(prednisone
30 mg	3/162 (1.9)	2/93 (2.2)	1/69 (1.4)	vs.
20 mg	14/162 (8.6)	7/93 (7.5)	7/69 (10.1)	budesonide)
Budesonide (9mg)	44 (21.4)	42 (31.1)	2 (2.8)	
Diagnosed at index, n (%)	31 (15.1)	18 (13.5)	13 (18.1)	0.418
Encounter type at index, n (%)				
Clinic visit	92 (44.4)	64 (47.4)	28 (38.9)	0.491
Endoscopy	55 (26.6)	33 (24.4)	22 (30.6)	
Hospital	42 (20.3)	25 (18.5)	17 (23.6)	
Telephone	18 (8.7)	13 (9.6)	5 (6.9)	

a Clinical definitions of disease activity: remission (mHBI < 5, pMS 0–1), mild disease (mHBI 5–7, pMS 2–4), moderate-to-severe disease (HBI ≥ 8, pMS ≥ 5). N = total number of clinical scores completed and documented in chart.

b Fisher's test used for cell counts < 5, Mood media, Mann-Whitney U test used to compare medians

† Variations in sample size among some variables due to missing or unavailable (eg. not done) values: n = 179 (114 CD, 65 UC) for CRP, n = 60 (37 CD, 23 UC) for clinical activity.

2.3.2 Exploratory Analysis: Compliance with Guidelines for IBD Flare Management

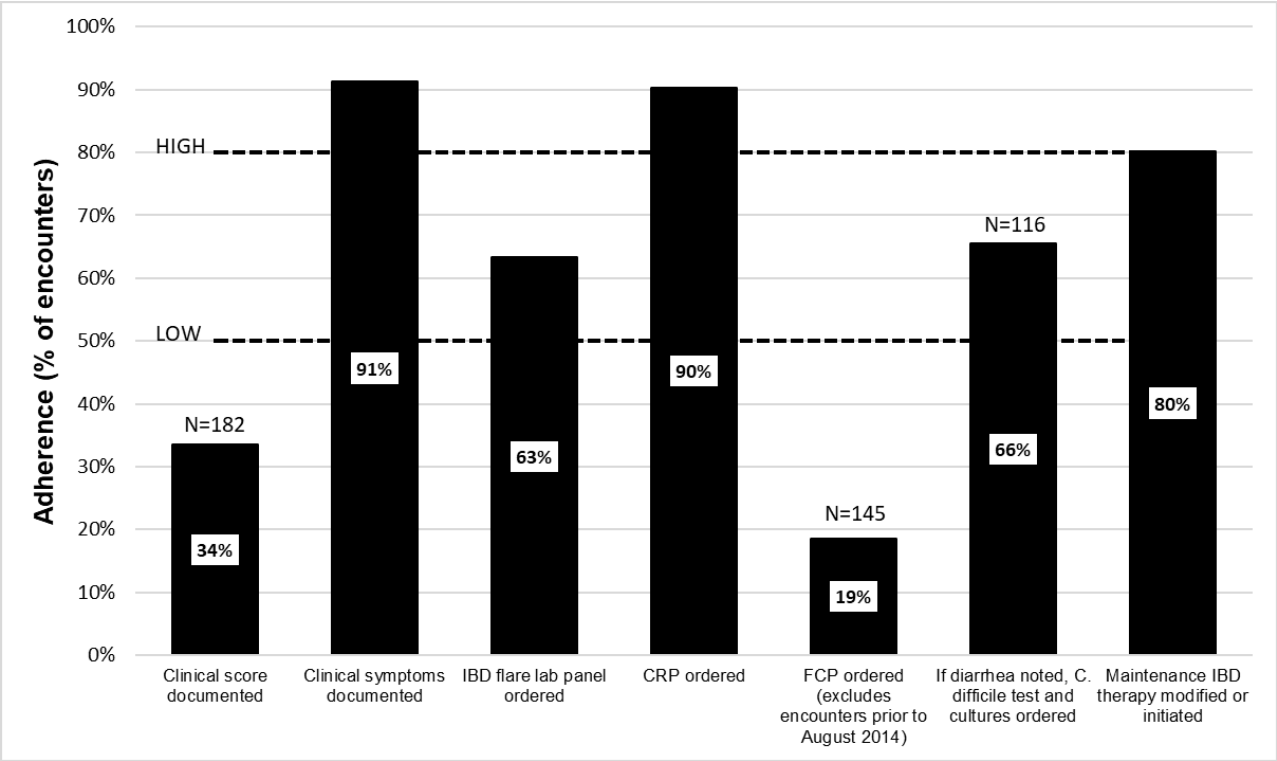

Figure 2-2 Adoption of guidelines and best practices for IBD flare management by practitioners at the University of Alberta, displayed as percent (%) of encounters, n=207 unless otherwise indicated.

2.3.2.1 Symptom documentation: index

Of 182 patients where clinical scores (mHBI/pMAYO) were appropriate (primarily those without pouch, short bowel, or newly diagnosed at the index dispensation), 61 (33.5%) had clinical score completed and documented in their chart at the index dispensation. However, of all 207 patients, 189 (91.3%) had symptoms (abdominal pain, number of stools, presence of blood) documented in their chart by the provider.

2.3.2.2 Symptom documentation: mid-flare

According to the IBD CCP #6 (see Appendix: Clinical Care Pathways (PDF Versions), clinical scores and assessment for treatment response should be done 2-4 weeks after the commencing of steroids (index). There were 46/207 (22.2%) encounters where contact was made with the patient in this time frame (2-4 weeks, or 14-28 days following the date of steroid prescription). Clinical scores (pMAYO or mHBI) were completed in 9 (19.6%) of those 46 encounters.

When expanding the analysis to include mid-flare contact made with the patient outside of the 14 to 28 day window, but prior to 16 weeks, there were 126/207 (60.9%) encounters, 33 (26.2%) of which had completed clinical scores. This means that overall, clinical scores were completed in 33/207 or 15.9% of cases overall at the 'mid-flare' timepoint.

2.3.2.3 Laboratory investigations: index

A total of 127/207 (61.4%) of patients had hepatitis B testing done at the index dispensation or done previously and available in their chart. However, hepatitis B testing is not recommended at all flares. Of 31 patients who were newly diagnosed at the index dispensation, 27 (87.1%) had hepatitis B testing completed.

Similarly, a total of 138/207 (66.7%) of patients had Hepatitis C testing done at the index dispensation or done previously and available in their chart. Of the 31 patients who were newly diagnosed at the index dispensation, again 27 (87.1%) had hepatitis C testing completed.

Full flare lab panels (including CBC, ferritin, electrolytes, creatinine, albumin,

alkaline phosphatase, ALT AST and CRP) were ordered for 131 / 207 (63.3%) of patients. However, 192 / 207 (92.8%) had at least a partial lab panel done (most commonly the regular follow up lab work). A total of 178/207 (86.0%) of patients had both CBC and CRP labs ordered. A total of 187 /207 (90.35) of patients had CRP ordered.

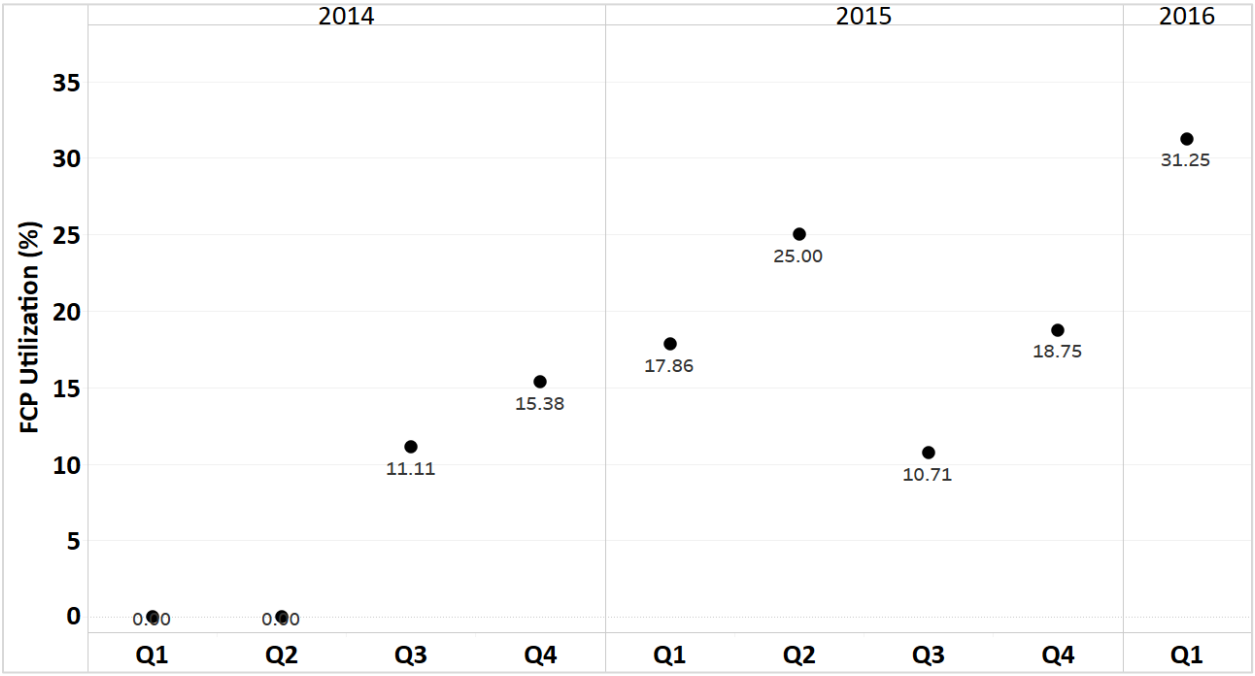

Figure 2-3 Utilization of fecal calprotectin testing, shown as percentage (number of encounters where FCP was ordered over total encounters) for each quarter of 2014-2015 and Q1 of 2016.

Fecal calprotectin was only completed in 29 / 207 (14.0%) of patients in the study. However, when excluding patients with index dispensations prior to September 1, 2014 (FCP was made available in August 2014), then 27/145 (17.6%) of patients had FCP completed. **Figure 2-3** shows that the utilization of FCP was consistently increasing over the study period.

Testing for *Clostridium difficile* infection was done in 100/207 (48.3%) patients at the index dispensation. However, in 116 patients where liquid stool or diarrhea was

mentioned in the note, 76 (65.5%) had *C.difficile* testing completed. On the other hand, stool culture testing was completed in 99/207 (47.8%) of patients at index dispensation. Testing for both *C.difficile* and stool cultures was comparable for patients newly diagnosed at index encounter, with 19/31 (61.3%) completed.

2.3.2.4 Laboratory investigations: 14-16 weeks

An encounter was conducted at sixteen weeks (±1 month) with the patient in 69 / 207 (33.3%) of cases. This was a clinic visit in 56 (81.2%) and a remote (telephone) encounter with the IBD nurse (patient or provider initiated) in 13 (18.8%). However; there was contact made with the patient outside of ±1 month window in 173 (83.6%) patients.

Up to one month prior to the 16 week visit, full flare lab panels were ordered for 83 / 207 (40.1%) of patients. However, 168 / 207 (82.2%) had at least a partial lab panel done (most commonly the regular follow up lab work).

Fecal calprotectin was only completed in 36 / 207 (17.4%) of patients at or 1 month prior to their 16 week encounter.

2.3.2.5 Provision of steroid-sparing therapy

Overall, maintenance IBD therapies (including 5-ASA, immunomodulatory agents (IMM) or biologics) were adjusted or added (or both) in 166 / 207 (80.2%) patients. Of 166 medication changes, 123 (74.1%) involved adding a new medication, 31 (18.7%) changes to dose or frequency of a pre-existing medication, and 12 (7.2%) involved both.

Maintenance IBD therapy was added for 27/32 (84.4%) patients newly diagnosed at

index, and for 72/83 (86.7%) patients not on any maintenance medication at index.

Initiation of maintenance therapy was similar between patients with prior steroid exposure documented (80/100, 80%) and those without (87/107, 81.3%), with p=0.812.

2.3.3 Exploratory Analysis: Compliance with Guidelines for Corticosteroid Administration

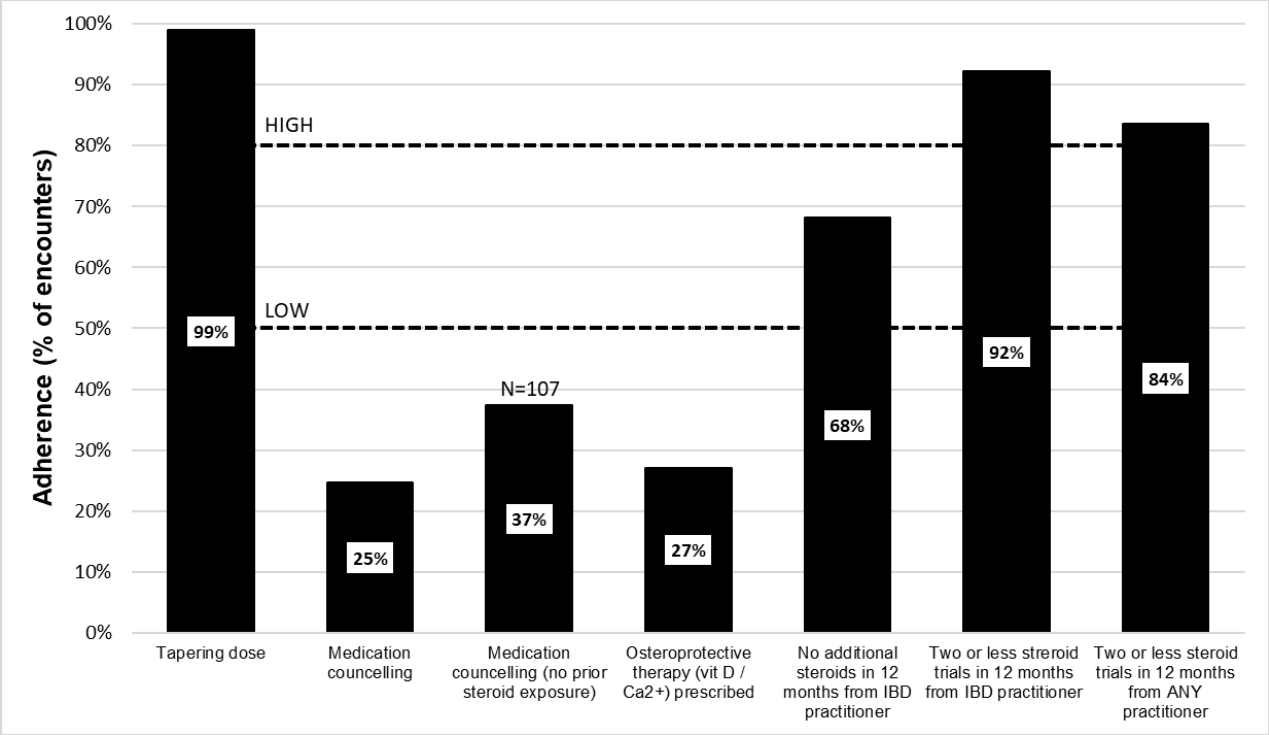

Figure 2-4 Adoption of guidelines and best practices for corticosteroid prescribing by practitioners at the University of Alberta displayed as percent (%) of encounters, n=207 (unless otherwise indicated)

2.3.3.1 Steroid dosing and tapering

Steroid dosages for the patient population are shown in **Table 2-2**. All but 2/207 (0.97%) of steroid prescriptions were administered as tapers. Of the non-tapers, one was a 'short course' of 20 mg prednisone administered for 8 weeks, the other was a patient who was

steroid-dependent, taking 15 mg indefinitely.

ECCO Statement 5B states that budesonide (Entocort®) is favored in patients with mild ileocaecal Crohn's[46]. While we did not have reliable data on disease severity, we did have data on localization: 12/41 (29.3%) of patients with ileal CD (L1), were prescribed budesonide. This is compared with 31/166 (18.7%) of those who were not L1, given budesonide (p=0.134, chi-squared). Only one of 18 (5.6%) patients with colitis (L2) were prescribed budesonide.

2.3.3.2 Consenting, patient information, documentation

In 51/207 (24.6%) of encounters, there was provision of steroid information or consenting documented in the chart. This could include mention of discussion of side effects, mention or attachment of patient information sheets given (including tapering calendars).

When excluding 100 patients who had been documented on steroids previously (past 2 years), 40/107 (37.4%) encounters had provision of steroid information / consenting process.

2.3.3.3 Bone prophylaxis

In 56 /207 (27.1%) encounters, vitamin D or calcium were prescribed or recommended to patients by the provider (and documentation of doing so). When excluding 43 patients who were already reported taking vitamin D or calcium supplementation in the chart, this number was similar with 49/164 (29.9%) prescribed or recommended to take vitamin D / calcium.

2.3.3.4 Repeat steroid-use

A total of 66 (31.9%) patients were prescribed and dispensed an additional steroid course within 12 months of the index dispensation from an IBD practitioner. However, only 16 (7.7%) were given two or more courses within 12 months from an IBD practitioner.

Dispensations from providers other than the UAH IBD practitioners (type unknown) were also collected in this dataset. Observing dispensations from other providers, a total of 38 (18.4%) patients were prescribed and dispensed an additional steroid course within 12 months of the index dispensation, and 7 (3.4%) were given more two or more courses.

Looking at overall dispensations from any provider (IBD and 'other'), 86 (41.5%) were prescribed and dispensed an additional steroid course within 12 months of the index dispensation, and 34 (16.4%) were given two or more additional course within 12 months.

Inversely, there was 83.6% compliance with recommended maximum steroid dosage if we include all providers in the analysis.

2.3.3.5 Predictors of repeat corticosteroid use

Greater than two steroid courses from any provider

Shown in Table 2-3, demographics and disease characteristics were regressed against the likelihood of having greater than 2 steroids courses in a 12 month period, from any provider. Only 'visit type' reached significance at p=0.05, with an odds ratio (OR) of 0.150

(95% CI: 0.032-0.710) for endoscopy compared to telephone encounter. In other words, patients with the index dispensation occurring at an endoscopy visit were less likely to receive repeat courses of steroids. On multivariate analysis, endoscopy remained significant with an OR of 0.137 (95% CI: 0.026-0.735). Patients having flare lab testing completed at the index encounter was also protective, with an OR of 0.385 (95% CI: 0.160-0.931).

Table 2-3 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of guideline adherence, patient demographics and disease characteristics, on having >2 steroid courses in 12 months following index dispensation from any provider.

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Exp(B) / OR	95% CI	*P* value	Exp(B) / OR	95% CI	*P* value
Demographics and disease characteristics						
Disease type						
Ulcerative colitis	ref					
Crohn's disease	0.973	0.451-2.102	0.945			
Sex						
Female	ref.					
Male	0.664	0.318-1.389	0.277			
Age in years	1.010	0.987-1.034	0.403			
Years since diagnosis	1.009	0.977-1.042	0.583			
Residing in Greater Edmonton	1.024	0.475-2.209	0.952			
Smoking status						
Never	ref					
Current	0.769	0.260-2.275	0.634			
Former	1.413	0.610-3.270	0.420			
BMI[1]						
Normal weight	ref.					
Underweight	1.125	0.117-10.852	0.919			
Overweight	0.621	0.243-1.587	0.320			
Obese	1.031	0.430-2.472	0.945			
Visit type						
Telephone	ref.			ref		
Clinic	0.722	0.230-2.268	0.577	0.675	0.186-2.455	0.551
Endoscopy	0.150	0.032-0.710	**0.017**	0.137	0.026-0.735	**0.020***
Hospital	0.433	0.113-1.664	0.223	0.542	0.114-2.587	0.442
C-reactive protein						
<7 or not done	ref.					

Table 2-3 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of guideline adherence, patient demographics and disease characteristics, on having >2 steroid courses in 12 months following index dispensation from any provider.

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Exp(B) / OR	95% CI	*P* value	Exp(B) / OR	95% CI	*P* value
>7	0.619	0.288-1.300	0.201			
Medications at index						
None	ref.			ref.		
5ASA only	1.473	0.563-3.854	0.430	1.436	0.509-4.054	0.494
IMM	1.007	0.295-3.442	0.991	0.995	0.271-3.651	0.994
Biologic	1.870	0.726-4.820	**0.195**	2.121	0.737-6.105	0.163
IBD Flare Guidelines						
Clinical score documented	0.934	0.409-2.131	0.871			
Flare labs - index	0.518	0.246-1.087	**0.082**	0.385	0.160-0.931	**0.034***
FCP – index	1.070	0.377-3.036	0.898			
Diarrhea noted	1.541	0.717-3.309	0.268			
C.difficile tested	0.942	0.451-1.967	0.873			
Stool culture	0.964	0.461-2.013	0.922			
Maintenance therapy modified	0.909	0.365-2.267	0.838			
Clinic at 16 weeks	2.006	0.784-5.133	**0.147**	2.063	0.713-5.968	0.181
Flare labs – 16 week	1.852	0.883-3.884	**0.103**	2.032	0.881-4.687	0.096
FCP – 16 week	0.790	0.283-2.202	0.652			
Corticosteroid Use and Guidelines						
Previous steroid use	1.661	0.788-3.500	**0.182**	1.251	0.558-2.807	0.587
Steroid type						
Budesonide	ref					
Prednisone	1.057	0.427-2.619	0.904			
Steroid consenting / patient info	1.590	0.714-3.542	0.256			
Vitamin D / Ca2+ prescribed or taking	1.307	0.626-2.729	0.477			

1. Normal weight: 25-30; underweight: <25; overweight: >30

***** significant at the 0.05 level.

One or more additional steroid courses from IBD provider

We also examined impact of demographics and disease characteristics on the likelihood of having one or more steroid courses in a 12 month period, specifically from IBD providers. These univariate and multivariate analyses are shown in Table 2-4 below. Here, patients having flare lab testing completed at the index encounter was protective, after adjusting for multivariate effects. However, patients who were seen in clinic at 16 weeks follow-up had an increased likelihood of being dispensed additional steroids from an IBD provider.

Table 2-4 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of guideline adherence, patient demographics and disease characteristics, on having one or more additional steroid courses in 12 months from index from IBD practitioner.

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Exp(B) / OR	95% CI	*P* value	Exp(B) / OR	95% CI	*P* value
Demographics and disease characteristics						
Disease type Ulcerative colitis Crohn's disease	 ref 0.820	 0.446-1.506	 0.523			
Sex Female Male	 ref. 0.787	 0.438-1.415	 0.424			
Age in years	1.015	0.996-1.034	**0.126**	1.009	0.989-1.029	0.373
Years since diagnosis	1.013	0.987-1.040	0.324			
Residing in Greater Edmonton	0.657	0.360-1.200	**0.172**	0.731	0.384-1.391	0.373
Smoking status Never Current Former	 ref 1.221 1.564	 0.552-2.699 0.785-3.114	 0.622 0.204			
BMI[1] Normal weight Underweight Overweight Obese	 ref. 0.000 8.41 1.237	 0.000-xx 0.411-1.719 0.607-2.519	 0.999 0.635 0.558			
Visit type Telephone	 ref.					

Table 2-4 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of guideline adherence, patient demographics and disease characteristics, on having one or more additional steroid courses in 12 months from index from IBD practitioner.

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Exp(B) / OR	95% CI	*P* value	Exp(B) / OR	95% CI	*P* value
Clinic	1.010	0.358-2.847	0.985			
Endoscopy	0.486	0.157-1.511	0.213			
Hospital	0.491	0.150-1.605	0.239			
C-reactive protein						
<7 or not done	ref.					
>7	0.589	0.325-1.066	**0.080**	0.700	0.367-1.336	0.279
Medications at index						
None	ref.			ref		
5ASA only	1.870	0.876-3.992	**0.106**	1.518	0.680-3.390	0.308
IMM	0.899	0.337-2.394	0.831	0.831	0.298-2.319	0.724
Biologic	2.158	0.998-4.666	**0.051**	2.277	0.989-5.243	0.053
IBD Flare Guidelines						
Clinical score documented	0.952	0.495-1.830	0.882			
Flare labs - index	0.581	0.319-1.058	**0.076**	0.466	0.239-0.910	**0.025***
FCP – index	0.955	0.409-2.229	0.916			
Diarrhea noted	1.316	0.726-2.384	0.366			
C.difficile tested	1.010	0.563-1.813	0.972			
Stool culture	1.040	0.579-1.866	0.897			
Maintenance therapy modified	0.733	0.357-1.505	0.397			
Clinic at 16 weeks	2.890	1.355-6.166	**0.006**	2.843	1.252-6.453	**0.012***
Flare labs – 16 week	2.483	1.361-4.531	**0.003**	1.941	1.014-3.714	**0.045***
FCP – 16 week	1.936	0.928-4.039	0.078			
Corticosteroid Use and Guidelines						
Previous steroid use	1.104	0.615-1.982	0.739			
Steroid type						
Budesonide	ref					
Prednisone	0.985	0.481-2.014	0.966			
Steroid consenting / patient info	1.092	0.557-2.141	0.798			
Vitamin D / Ca2+ prescribed or taking	1.162	0.646-2.089	0.617			

1. Normal weight: 25-30; underweight: <25; overweight: >30
*=significant, final model

2.3.4 Outcome Analysis

At 12 months, 125/196 (63.8%) patients were in clinical remission, according to clinical scores (or provider sentiment where clinical scores were not completed). Furthermore, 92 (46.9%) were in complete steroid free, clinical remission. There were 11 patients where clinical remission status was unable to be determined (no follow-up).

2.3.4.1 Clinical remission

The impact of demographics and disease characteristics on the likelihood of clinical remission status at 12 months was investigated using univariate and multivariate regression, shown in Table 2-5. After adjusting for significant covariates, those with a diagnosis of Crohn's disease, and those patients who were steroid free at 12 months were more likely to be in clinical remission at 12 months.

Table 2-5 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of guideline adherence, patient demographics and disease characteristics, on attainment of clinical remission at 12 months (n=196, 11 cases unable to determine status).

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Exp(B) / OR	95% CI	*P* value	Exp(B) / OR	95% CI	*P* value
Demographics and disease characteristics						
Disease type Ulcerative colitis Crohn's disease	 ref 1.774	 0.970-3.247	 **0.063**	 ref 1.801	 0.942-3.370	 **0.070**
Sex Female Male	 ref. 1.397	 0.778-2.508	 0.262			
Age in years	1.006	0.987-1.024	0.559			
Years since diagnosis	0.999	0.973-1.026	0.951			
Residing in Greater Edmonton	1.467	0.802-2.685	0.214			
Smoking status Never Current Former	 ref 0.993 1.387	 0.461-2.140 0.684-2.814	 0.986 0.364			

Table 2-5 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of guideline adherence, patient demographics and disease characteristics, on attainment of clinical remission at 12 months (n=196, 11 cases unable to determine status).

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Exp(B) / OR	95% CI	*P* value	Exp(B) / OR	95% CI	*P* value
BMI[1]						
Normal weight	ref.					
Underweight	0.000	0.000-	0.999			
Overweight	1.104	0.546-2.232	0.783			
Obese	0.989	0.482-2.033	0.977			
Visit type						
Telephone	ref.					
Clinic	1.185	0.415-3.385	0.751			
Endoscopy	1.000	0.335-2.987	1.000			
Hospital	1.227	0.390-3.863	0.726			
C-reactive protein						
<7 or not done	ref.					
>7	0.821	0.458-1.472	0.509			
Medications at index						
None	ref.					
5ASA only	0.808	0.380-1.715	0.578			
IMM	0.981	0.386-2.491	0.967			
Biologic	0.855	0.399-1.831	0.687			
IBD Flare Guidelines						
Clinical score documented	0.696	0.360-1.345	0.281			
Flare labs - index	1.317	0.723-2.399	0.369			
FCP – index	1.093	0.478-2.502	0.833			
Diarrhea noted	0.569	0.313-1.033	**0.064**	0.591	0.311-1.121	0.107
C.difficile tested	0.733	0.409-1.316	0.299			
Stool culture	0.710	0.396-1.275	0.252			
Maintenance therapy modified	1.254	0.603-2.609	0.545			
Follow-up at 16 weeks	1.151	0.600-2.206	0.672			
Flare labs – 16 week	0.586	0.324-1.059	**0.077**	0.671	0.353-1.275	0.223
FCP – 16 week	0.699	0.316-1.417	0.294			
Corticosteroid Use and Guidelines						
Previous steroid use	0.927	0.517-1.659	0.798			
Steroid type						
Budesonide	ref					
Prednisone	1.155	0.561-2.374	0.696			
Steroid consenting / patient info	0.736	0.378-1.433	0.368			

Table 2-5 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of guideline adherence, patient demographics and disease characteristics, on attainment of clinical remission at 12 months (n=196, 11 cases unable to determine status).

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Exp(B) / OR	95% CI	*P* value	Exp(B) / OR	95% CI	*P* value
Vitamin D / Ca2+ prescribed or taking	1.457	0.804-2.639	0.214			
Steroid-free at 12 months	4.336	2.311-8.135	**<0.001**	4.190	2.201-7.977	**<0.001***
>2 steroid courses in 12 months	0.181	0.080-0.410	**<0.001**			
1. Normal weight: 25-30; underweight: <25; overweight: >30 *=significant, final model						

2.3.4.2 Steroid free clinical remission

The impact of demographics and disease characteristics on the likelihood of steroid-free clinical remission status at 12 months was investigated using univariate and multivariate regression, shown in Table 2-6. After adjusting for significant covariates, those with diarrhea noted at their index encounter, and those with flare lab testing completing at 16 week follow-up encounter, were less likely to be in steroid-free clinical remission at 12 months.

Table 2-6 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of guideline adherence, patient demographics and disease characteristics, on attainment of *steroid-free* clinical remission at 12 months.

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Exp(B) / OR	95% CI	*P* value	Exp(B) / OR	95% CI	*P* value
Demographics and disease characteristics						
Disease type Ulcerative colitis Crohn's disease	 ref 1.789	 0.983-3.256	 **0.057**	 ref 1.572	 0.799-3.096	 0.190
Sex Female Male	 ref. 1.367	 0.777-2.408	 0.278			
Age in years	0.997	0.980-1.015	0.782			
Years since diagnosis	0.992	0.967-1.017	0.516			
Residing in Greater Edmonton	1.488	0.822-2.692	**0.189**	1.331	0.694-2.552	1.331
Smoking status Never Current Former	 ref 1.017 1.144	 0.481-2.150 0.587-2.227	 0.966 0.693			
BMI[1] Normal weight Underweight Overweight Obese	 ref. 3.469 1.268 0.760	 0.344-35.019 0.643-2.500 0.374-1.542	 0.292 0.493 0.447			
Visit type Telephone Clinic Endoscopy Hospital	 ref. 1.609 2.154 2.100	 0.551-4.696 0.706-6.574 0.661-6.669	 0.384 **0.178** 0.208	 ref 1.599 2,569 2.264	 0.501-5.101 0.774-8.525 0.636-8.059	 0.428 0.123 0.207
C-reactive protein <7 or not done >7	 ref. 1.080	 0.616-1.893	 0.788			
Medications at index None 5ASA only IMM Biologic	 ref. 0.589 0.614 0.612	 0.282-1.229 0.251-1.503 0.292-1.281	 **0.158** 0.285 **0.192**	 ref 0.778 0.633 0.730	 0.342-1.772 0.239-1.673 0.326-1.636	 0.550 0.356 0.445
IBD Flare Guidelines						
Clinical score documented	0.702	0.366-1.344	0.286			
Flare labs - index	0.714	0.398-1.283	0.260			
FCP – index	0.905	0.410-1.999	0.805			
Diarrhea noted	0.463	0.261-0.821	**0.008**	0.461	0.245-0.867	**0.016***
C.difficile tested	0.849	0.484-1.488	0.567			

Table 2-6 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of guideline adherence, patient demographics and disease characteristics, on attainment of *steroid-free* clinical remission at 12 months.

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Exp(B) / OR	95% CI	*P* value	Exp(B) / OR	95% CI	*P* value
Stool culture	0.813	0.463-1.425	0.469			
Maintenance therapy modified	1.823	0.867-3.833	**0.113**	1.600	0.690-3.709	0.273
Modification type No change Added new Modified existing Both	 ref. 2.411 2.036 1.091	 1.085-5.359 0.735-5.645 0.270-4.408	 **0.031** 0.172 0.903			
Follow-up at 16 weeks	0.842	0.453-1.566	0.587			
Flare labs – 16 week	0.469	0.261-0.843	**0.011**	0.479	0.256-0.898	**0.022***
FCP – 16 week	0.407	0.183-0.904	**0.027**	0.469	0.198-1.114	0.086
Corticosteroid Use and Guidelines						
Previous steroid use	0.882	0.503-1.546	0.661			
Steroid type Budesonide Prednisone	 ref 0.978	 0.494-1.937	 0.949			
Steroid consenting / patient info	1.314	0.684-2.523	0.412			
Vitamin D / Ca2+ prescribed or taking	1.353	0.768-2.384	0.295			

1. Normal weight: 25-30; underweight: <25; overweight: >30

2.4 Summary and Discussion

In this study, we have benchmarked several important process indicators of quality of care for inflammatory bowel disease outpatient flares and use of corticosteroids. Important findings were a lack of standardized documentation of symptoms, and underutilization of fecal calprotectin testing (although increasing). Documentation of steroid and medication consenting (or provision of patient information sheets – a local

best practice) was low, as was provision of osteoprotective therapy. However, encouraging findings were the use of repeated steroid courses in <10% of cases, and a change in medication (dose adjustment or addition of new therapy) in over 80% of steroid prescriptions.

While quality indicators have been developed for IBD in Canada[40], there have been few studies evaluating the uptake of these process measures in IBD clinics. Jackson et al. (2017) evaluated 288 patient encounters with gastroenterologists and compared quality of care with ECCO guidelines[47]. They found an overall adherence of 71%, however major gaps included prescribing of 5ASA to small bowel Crohn's patients (42%), and, in line with our findings, osteoprotective care (bone scan) undertaken in only 21% of patients. Reinglas et al (2019) have also examined quality indicators in 1357 patients at McGill University Health Center, specifically at pre- and post-referral (not necessarily flaring patients). They too found underutilization of fecal cal (37%). Similar but lower rates were observed for HBV/HCV and clostridium difficile testing (~18%). However; appropriateness was not mentioned in their analysis.

We were largely unable to link process indicators with specific patient outcomes (repeated steroid courses, clinical remission). To our knowledge, this has not been done before in IBD, as these process measures are so infrequently evaluated in the first place. However adherence to guidelines have been shown to directly improve outcomes in diabetic patients by Oh et al (2011)[48]. They were able to include almost 5000 patients in their dataset however, where we are limited by the lower volume of IBD flares and lower disease prevalence. Future studies should seek to expand to multiple centers and locations through the province, however this will require a standardized health record to

obtain data automatically.

There are several limitations to our findings worth noting. For one, we were only able to observe precise or intended durations associated with dispensations. It is not known if the patient was compliant, or other instructions or changes were implemented later. Furthermore, even with chart review, many of the more subjective process measures (steroid consenting, documentation of clinical scores), can only determine if the process was documented, not if it was completed but not recorded in the chart.

We were unable to determine full extent of disease activity in patients. This impacts the appropriateness of evaluation of certain guidelines. For example, budesonide is recommended by ECCO for *mild* ileal Crohn's disease.

The differences in the CS prescribing practices provided by IBD and non-IBD specialists remain unclear. Furthermore, this study took place at a major academic center, and was largely a sampling of convenience. It is of great interest to evaluate these process measures on a larger scale and devise large-scale interventions to systematically improve them as well.

3 EHR-INTEGRATED CLINICAL DECISION SUPPORT SYSTEM FOR IBD FLARE MANAGEMENT AND CORTICOSTEROID ADMINISTRATION: AN INTERRUPTED TIME-SERIES

3.1 Introduction

As demonstrated and discussed in the previous study, there are gaps in adoption of clinical care guidelines and best practices for inflammatory bowel disease, including medication management, preventative care, and bone health. This lack of care being given according to established guidelines is not new, and not limited to IBD [19,49]. In fact, as of 2007, it was taking 17 years on average for only 14% of new evidence to be translated into clinical practice [50]. One purported reason for this is the fact that clinical guidelines by themselves are not actionable, because they largely describe what to do, but not how to do it [21,51].

The “Flare Management” and “Initiation and Maintenance of Corticosteroids” CCPs have been implemented in the IBD clinic, University of Alberta, Edmonton, Canada. To increase adoption of these pathways, a clinical decision support project was undertaken to integrate the pathways into electronic and automated form within eCLINICIAN, the local electronic medical record (EMR). There is little guiding literature for these types of integrations, and even fewer formal evaluations of EMR-based CDS implementations in IBD. This is despite the fact that thousands of these tools and been built within commercial EMRs and are currently in use. [52]

This pilot study aims to evaluate the developed electronic CDS tools for effectiveness and

appropriateness. If successful, it will set a precedent for further development and integration into Connect Care, a coming Alberta-wide Provincial EHR initiative capable of reaching over 10,000 physicians.

3.2 Methods

3.2.1 *Organizational Setting*

The study was conducted in an IBD outpatient clinic at the University of Alberta Hospital, which provides care for IBD patients in the Greater Edmonton, rural, and remote communities across Alberta. It also serves a small number of IBD patients from Saskatchewan, Northwest Territories, and BC.

3.2.2 *System Details and System in Use*

The pre-existing system in use by the clinic was an enterprise EMR based on the 2014 version of the Epic EMR system EpicCare (Epic Systems Corporations, Verona, WI), being used in Edmonton, Alberta for outpatient medical care. Medication lists, allergies, and health problems are recorded and shared between users as part of clinical documentation and order entry and planning. The system went live for gastroenterology outpatient care March 2014, branded as eCLINICIAN.

As Epic is a general-purpose EMR, clinical decision support (CDS) functionality is built in. Generic functionality such as alerting the user when duplicate orders exist, are pre-existing in the system. More specialty specific CDS functionality are often customized at

the request and guidance of end-users (healthcare providers).

Functionality can be administered through a number of tools, including those coined by Epic as ‘Flowsheets’, ‘Best Practice Advisories’, and ‘SmartSets’.

- *Flowsheets:* documentation tool used in specialties that need to capture certain information discretely and want it laid out in table format. Can automatically be programmed to perform calculations and pulled into other areas of the medical record as discrete data.

- *BestPractice Advisory (BPA)*: an alert/notification that presents targeted patient-specific guidance to users [53]. BPA can be active (disruptive popups) or passive (navigation workflow) and can link to actions such as placing orders, ordersets/ smartsets, initiating a care plan, sending a message, etc.

- *SmartSet (SS):* collect related orders, diagnoses, and clinical content appropriate for a specific patient, simplifying the ordering process [54]. Busy clinicians don't need to search for every order they want to place.

These tools, particularly BPAs and SSs, are data-driven, and can be triggered by unique combinations of provider characteristics, patient demographics, test results, clinical problems, and current and requested medications.

3.2.3 *System Interruption / Intervention*

The system interruption / intervention was a BPA which appeared in the clinician’s navigator workflow, triggered by the existence of IBD in the patient problem list or

diagnosis fields. The BPA prompted the clinician to complete mHBI or pMAYO clinical scores for the patient, and if the score is indicative of flaring, to activate a corresponding Smart Set, all from within the BPA.

The Smart Set offers one-click ordering (and printing) of appropriate lab panels, stool cultures, and other investigations, including imaging, procedures, and medication prescriptions. All recommendations were designed to be consistent with established IBD care guidelines. For example, during a flare encounter, the IBD flare lab panel and fecal calprotectin tests are automatically checked for ordering (but can still be deselected by the clinician).

The intervention was implemented and evaluated in two phases:

Implementation Phase 1: Activation of the CDSS

The first preliminary version of the CDSS was piloted by IBD nurses. This version included 3 Smart Sets available within the BPA, corresponding to different positions along the care path of a flaring IBD patient; (1) Suspected flare, (2) 2-4 weeks' Mid-flare, and (3) 16 weeks' Post-flare assessments. Feedback was gathered informally from providers (see Appendix for a summary of feedback) to inform further improvement to the CDSS.

Implementation Phase 2: Major changes to the CDSS into production

Based on feedback from Phase 1, and in consult with AHS analysts, further changes were made to the CDSS. Aside from minor modifications to update included lab tests, the major change was to consolidate three separate Smart Sets into one, targeting the "Suspected Flare" or initial position in the care pathway. The activation of the BPA in Version 1 was

entirely manual and dependent on the provider entering a specific visit diagnosis. In Version 2, the BPA is automatically triggered by the presence of an IBD diagnosis in the patient problem list. This was expected to improve adoption and ease of use of the SmartSet for flare encounters.

3.2.4 *Study Design*

The study employs a pre- and post-implementation two-phase interrupted time-series (ITS) design. The interruption was the enhanced CDSS system layer on top of the pre-existing commercial EMR. The Quality Criteria for Interrupted Time Series (ITS) Designs checklist was used in study design and assessment of appropriateness[55], as well as the STARE-HI guidelines for health informatics evaluations [56,57].

We hypothesized the intervention impact model will produce a level change following the intervention period [58]. When the CDSS is used, we predict each outcome will experience a percentage increase in occurrence. However; this may differ between outcomes and over the actual intervention impact period, there may be an uptake period as users adjust to the tool, which may produce a temporary slope change leading to a new level. Intervention impact models will be confirmed post-hoc.

3.2.4.1 Interrupted Time-series Design

The ITS design is like before-and-after (BA) design, but tracks outcome measures at multiple time points (‘data points’) throughout the study period, both before and after the intervention (‘interruption’). A minimum of three time points before and three after must

occur to be considered a true ITS by EPOC [59]. The ITS is useful for interventions that produce rapid, sustained impact on outcomes.

3.2.4.2 Justification

ITS design is considered the most rigorous quasi-experimental design. It provides an advantage over the BA design since secular trends can be accounted for, which might otherwise confound the analysis and weaken the ability to make conclusions[60].

For this evaluation, we considered an experimental cluster randomized design (C-RCT), as well as variations such as the cluster randomized crossover, but did not select them for several reasons;

I. The intervention is currently limited by the availability of the EpicCare EMR to only one gastroenterology clinic, meaning the clusters would be physician practices at a single site. While clustering by physicians is logical (since the intervention is ultimately targeting their behavior), cluster randomized studies already struggle to ensure balance across participant characteristics. The chance of high variability between clusters with such a small sample (<8) is high.

II. Balance between clusters in terms of individual N is also unlikely, as a nurse practitioner sees most flaring patients under the care of all the physicians.

III. Furthermore, the setup of the clinic may predispose a C-RCT to contamination. Often during a patient's encounter in clinic, they will see both a physician and

IBD specialist nurse. It would be infeasible to ensure that physicians randomized to one treatment were not seeing patients then seen by an IBD nurse randomized to the other treatment.

IV. Finally, it was determined that there would not be enough IBD flare encounters to reach the required sample size for a C-RCT (which require large sample sizes) with 7-8 clusters.

3.2.4.3 *Limitations of the ITS Design*

One limitation of the ITS design is the need for a significant number of repeated data points[61]. For this reason, the design lends itself to routinely measured data. In the case of our study, this data is already recorded in the medical record database automatically.

Two other limitations of this design are the lack of a true experimental control group, and the inability to draw inferences regarding individual level outcomes [61]. The former has already been discussed, and the latter is acceptable, since the goal of the assessment is to validate the intervention for use at other clinics and practices throughout the province.

There are several biases that can occur in health technology interventions and assessments. One is the 'Hawthorne effect', which is the tendency for humans to improve their performance when they know their behavior is being studied [62]. This is a possibility we could not rule out in this study. However, a Waiver of Consent was requested and approved by the University of Alberta Health Research Ethics Board (HREB), which should minimize any potential impact.

Another confounder and data collection bias is the 'checklist effect', where improvement can occur due to better structured data collection (which often occurs when computerized systems are implemented) [62]. For our study, we are not particularly concerned with separating these issues. We consider potentially improved and better structured documentation to be both part of the intervention as well as an acceptable outcome.

Finally, the data completeness effect may occur since the intervention itself collects data on the measures of interest. However; the EMR ultimately logs the same data as collected by the intervention, and so, where possible, data will be extracted from the EMR system log and not the log produced by the CDSS (which would only be available for the post-implementation period).

3.2.5 Participants

Participants were selected based on sampling of convenience. All IBD care practitioners were invited to participate in the study, including 7 IBD specialists (a gastroenterologist completing Advanced IBD Clinical Research Fellowship for at least 2 years whose clinical practice consists mostly of IBD patients), 1 IBD nurse- practitioner (NP), and 4 IBD nurses. The term "IBD practitioner" will be used to collectively refer to IBD specialist physicians and IBD NPs.

3.2.5.1 Inclusion Criteria

(1) IBD healthcare providers:

- IBD physician practitioners , IBD nurse practitioner, or IBD nurse

- Faculty members of the Division of Gastroenterology, Department of Medicine, Faculty of Medicine & Dentistry, University of Alberta in 2016 and following at least 25 IBD patients in their routine clinical practice

(2) Patients with IBD who are cared for by the IBD providers:

- Adults (age ≥ 18 years)
- Diagnosis of Crohn's disease, or ulcerative colitis confirmed by imaging, pathology, or endoscopy reports
- Experiencing a flare of the disease during the included encounter, as defined by clinical score (HBI $\geq$ 5, PMS $\geq$ 2) or noted symptoms in combination with physician judgement.

Specifically, the extracted encounters were flagged as 'flares' through manual chart review. Flares had to be acute outpatient encounters (in person clinic visits or remote contact with patient via telephone). Symptoms of active IBD, or clinical scores indicative of active disease needed to be noted, along with (or superseded by) sentiment from the provider that a flare was suspected. Additionally, only initial encounters in an acute flare episode were included. If a patient had ongoing disease for a long period of time or was known to have active disease and the encounter or communication was specifically initiated to change management of the disease, then the encounter was not included. These types of encounters where the disease status was already confirmed through testing, were not as appropriate for activation of the flare protocol.

3.2.5.2 Exclusion Criteria

(1) IBD healthcare providers: None

(2) Patients:

- Age < 18 years
- Pregnant and breastfeeding women
- Concomitant autoimmune, autoimmune–related, or other diseases requiring intermittent or indefinite corticosteroids use (e.g., ankylosing spondylitis, asthma)
- Specific reasons-for-visit (VR) were excluded from being manually reviewed and assumed unlikely to constitute a flare. These were decided upon based on the results of Section 3.3.2.2.

3.2.6 Study Flow and Procedures

A diagram of the study procedures, data points (D1-D18), and pre- and post-implementation periods are outlined in the diagram below.

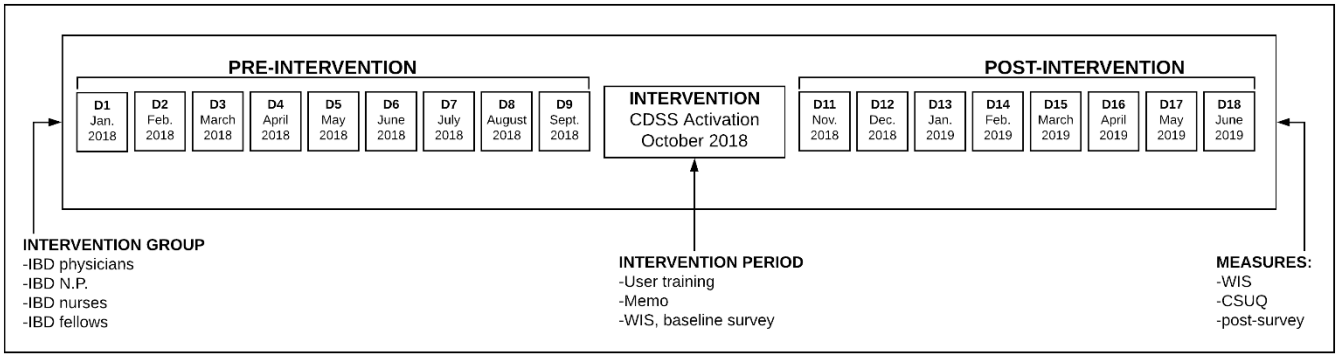

Figure 3-1 Diagram of study flow and procedures for version 2 of the CDSS intervention (Implementation Phase 2)

The primary intervention period began October 10, 2018, at which time the new IBD flare-specific CDSS changes went live in eCLINICIAN, and an instructional memo with paper-based workflow and educational material were sent to each provider (Appendix: Materials Distributed to Providers). Over the course of one month, each participant was given an opportunity to ask questions about use of the system, and access to use the system in the sandbox environment.

A demonstration of the system was presented at weekly clinical rounds, with an opportunity to ask questions. IT support will be available immediately upon request at any time during the study.

Each data point corresponded to one month of clinical encounters. There was a total of 18 data points, 9 before and 9 after the intervention. This frequency was chosen based on the expectation that not enough individual encounters (IBD flares) would occur on a weekly basis, and physician service rotation means not every physician has outpatient clinic every week, which would lead to larger variation between data points, if done weekly.

Data was extracted retrospectively and compiled into each respective month. This approach is made possible by the automatic, passive data collection capabilities of eCLINICIAN (see 3.2.8 Methods for Data Acquisition and Measurement).

3.2.7 Outcome Measures

(1) Primary

The primary outcomes of interest were process measures, used to identify an increase in the proportion of IBD practitioner flare encounters adherent to published evidence– based guidelines and best practices outlined in the Consensus Guidelines by 20%. These include:

1 Clinical scoring (mHBI or pMAYO) completed and documented

2 IBD Flare labs ordered

3 Fecal calprotectin ordered

4 Stool culture and *C..difficile* toxin ordered, if diarrhea present

5 Vitamin D and Calcium ordered with CS

6 CS Patient information given and documented

7 Modification of maintenance therapy following flare and course of CS

These outcomes are deemed to be easily available from a common source (eCLINICIAN) across both the pre- and post-intervention periods. These outcomes are also directly measured by the CDSS system itself.

(2) Secondary

1 Adoption/acceptance of system measured by application rate (ratio of CDSS applied to CDSS available for activation)

2 Usability of system (Computer System Usability Questionnaire, CSUQ)

3 Integration with practitioner's workflow (Workflow Integration Survey, WIS)

3.2.8 Methods for Data Acquisition and Measurement

Potential encounters in the pre- and post-intervention period were identified by querying the eCLINICIAN EMR database for encounters by the included IBD providers, where patients had a documentation of IBD in their problem list or diagnosis field (ICD coding). Encounters were then screened for inclusion and exclusion eligibility manually by RTS.

The filtering logic to identify IBD patient encounters in the system was identical for pre- and post-implementation periods. Each encounter was classified as an IBD-flare (the initial onset or re–appearance of the gastrointestinal symptoms in the setting of IBD without evidence of gastrointestinal infections), as defined by Harvey Bradshaw index >5 or partial Mayo score >1, and physician sentiment.

Data for primary outcome measures were also queried and extracted from the EMR database, in collaboration with the eCLINICIAN Reporting Team, Alberta Health Services. The various database codes and IDs, as well as the final SQL queries used to extract data are included in 0 Appendix: eCLINICIAN .

Secondary outcome measures for usability and practitioner workflow integration were assessed by the IBM Computer Usability Satisfaction Questionnaire (CUSQ) [63]and Workflow Integration Survey (WIS) [64], respectively. Both questionnaires have been extensively validated, although not specifically in the IBD patient population.

Table 3-1 Measures of Success for IBD Clinical Decision Support Intervention

Measure	Definition	Measurement Method / Source	Metric Source
Adoption*	CDS intervention is used	Application Rate (SmartSet activations / eligible encounters)	EMR data
Acceptance*	Compliance with CDS recommendations	Flare guideline procedures followed	EMR data
Usability		IBM Computer System Usability Questionnaire (CSUQ)	Qualitative questionnaire
Workflow Integration		Workflow Integration Survey (WIS)	Qualitative questionnaire
Changes in Behavior*	Changes in process of care	IBD process indicators (e.g. tests ordered, patient instructions given)	EMR data, chart review
Clinical Outcomes**	Demonstrable (statistically significant) changes in patient outcomes	*Not measured*	n/a

* Adapted from Kannry et al.[65]
** Not measured, as not within the scope of the thesis.

3.2.9 *Methods for Data Analysis*

Descriptive statistics were calculated to determine patient characteristics, with data presented as counts and proportions for categorical variables, mean±standard deviation for normally distributed continuous variables, and ($\tilde{X}$, median and IQR) for non-normally distributed continuous variables. Proportions were compared by using Pearson's chi-squared test.[66]

A segmented regression analysis was performed for each primary outcome variable, to determine the level and slope in the pre-intervention phase and the change in level and slope in the post-intervention phase on the mean percentage of adherent encounters.

Regression equation for various outcome measures (Y):

$$Y_t = \beta_0 + \beta_1 * time_t + \beta_2 * intervention_t + \beta_3 * time\ after\ intervention_t + e_t$$ (Wagner et al, 2002)[67]

The full regression model includes changes in slope in the pre- and post-intervention phase and changes in level after the introduction of the CDSS. To analyze the difference between the pre- and post-intervention phase, the regression was tested for autocorrelation (phenomenon where consecutive observations are more similar to one another than those that are further apart) in the residuals using the Durbin-Watson test.

The level of statistical significance will be set to $P < 0.05$. Data analysis will be performed using SPSS (IBM Corp., Version 23.0, 2013) and R/RStudio (various packages, including r/segmented[68]), as required.

3.2.10 Sample Size Determination

The sampling unit was the IBD clinic, University of Alberta, Edmonton, Canada. Sample size was first calculated for pre- and post-implementation cohorts based on logistic regression. Due to the multi-component nature of measurement of physician guideline adherence, it is expected that there will be various effect sizes, with small (OR=1.68[69]) or medium (OR=3.47[69]) being most common. With power equal to 0.80, Type I error set to 5%, the sample size required is approximately 634 for small effects, and 145 for medium

effects. This assumes equal N in the comparison groups, and an initial proportion of adherence to each guideline component of approximately 70%, which was chosen based on a recent study by Jackson et al [47]. This sample size calculation was determined using G*Power. 3.2.9.2 [70].

Power calculation is difficult to approximate accurately in time series, and currently there are no standardize methods or established best practices. It is generally accepted that the more data points and observations within each data point is better. A power calculation from a simulation study does offer some guidance here. [71] The simulation-based power calculation displayed that with N of 16 (8 data points in the pre-intervention period and 8 data points in the post-intervention period), there is 70% chance to detect an effect size of 0.5 or more, and over 90% chance to detect an effect size of 1 or more, at alpha=0.05. For example, a level change of 0.20 from a baseline level of 0.5 is approximately 80% powered.

It is also generally recommended in the literature to have over 100 observations per data point.[67,72] The power is also inversely proportional of the degree of auto correlation.[71]

3.3 Results

3.3.1 General Description of Dataset

The complete, extracted dataset includes 31,726 encounters, covering the date range of January 1, 2017 to June 30, 2019. When only clinic visits (7,655), orders only (16,485), and telephone (5,220) encounter types are included, the dataset totals 29,360 (92.5%)

encounters. There was an average of 998 encounters occurring per month, with the minimum at 735 (December 2018), and maximum at 1202 (May 2017). See Appendix 0 for the full SQL query used to extract the data.

3.3.2 Data Pre-processing and Validation

3.3.2.1 Analysis of encounters with specific visit reasons

Upon initial inspection of the extracted dataset produced from EpicCare, the Reason for Visit (VR) field provides insight into the nature of each encounter. The top ten most common VRs over the entire date range (January 1, 2017 to June 30, 2019) are as follows, shown in **Table 3-2**.

Table 3-2 Top 12 visit reasons for IBD encounter dataset, January 2017 to June 2019

REASON FOR VISIT	# ENCOUNTERS
NULL*	18,294
FOLLOW-UP	4,356
INFLAMMATORY BOWEL DISEASE	3,186
MEDICATION MANAGEMENT	1,879
MEDICATIONS REFILL	1,014
REFERRAL	752
MEDICAL INSURANCE COVERAGE	510
LABS ONLY	266
REVIEW RESULTS	247
DISEASE FLARE-UP	221
APPOINTMENT	201
SUSPECTED IBD FLARE	179

* NULL means no Reason for Visit (RV) was entered.

Furthermore, the proportion of encounters with the most common RVs are graphed longitudinally by month in **Figure 3-2**.

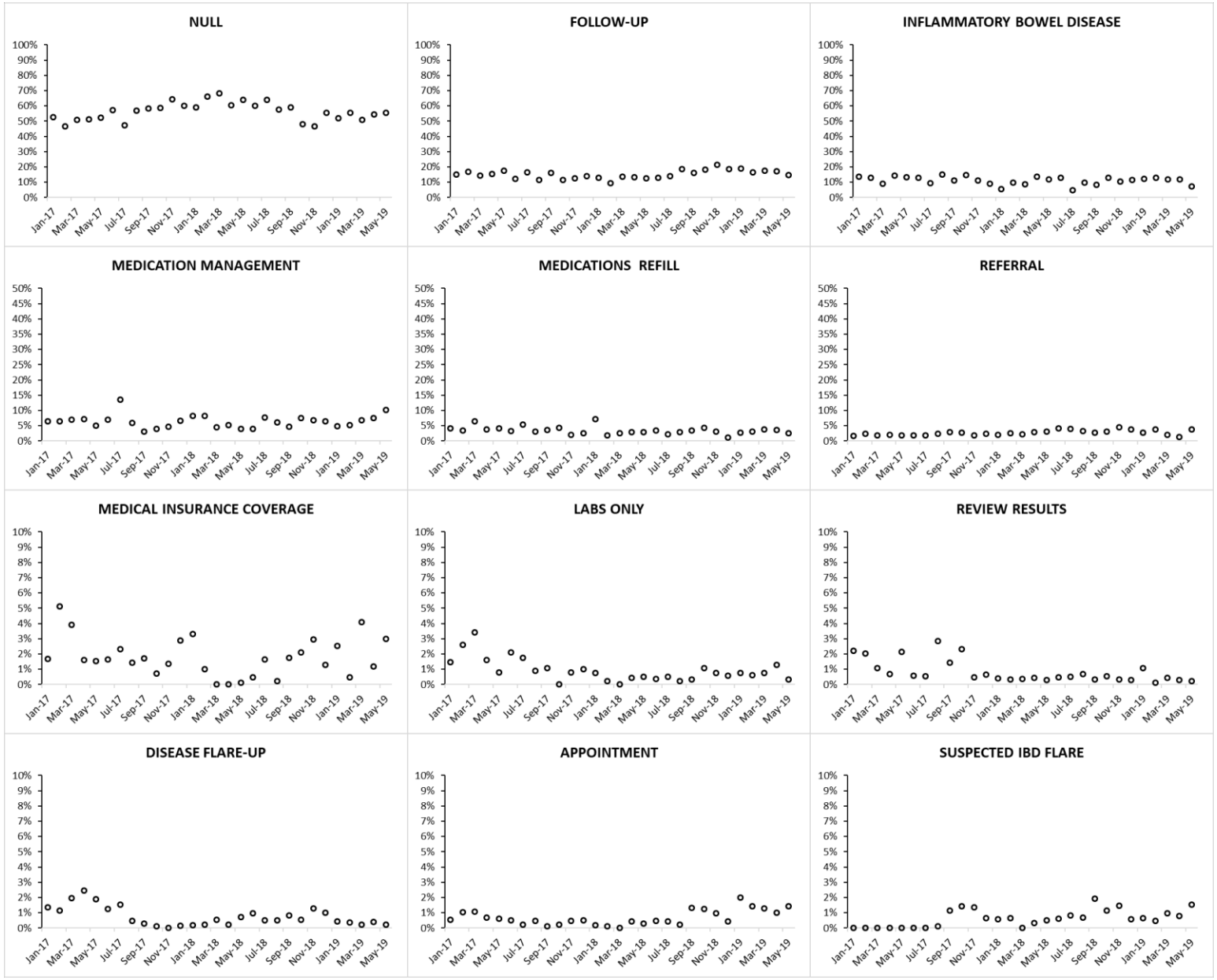

Figure 3-2 Scatterplots showing proportion (%) of total encounters for each visit reason, by month/year on the x-axis.

3.3.2.2 Exclusion of Encounters with 'NULL' Reason-for-visit

The number of encounters extracted from the EMR was deemed too time-consuming for complete manual review (30,000+encounters). In order to select an appropriate sampling method, a full review of one month of data (April 2019) was conducted. This included 1065 encounters, a total of 39 (3.67%) were flares (characteristics described in Tables **Table 3-3**, **Table 3-4**, **Table 3-5** below).

Table 3-3 Visit type name for IBD flares in April 2019	
Null	28
IBD follow-up	9
IBD new	2

Table 3-4 Encounter reason for IBD flares in April 2019	
Inflammatory bowel disease	14
Null	9
Suspected IBD flare	8
Follow-up	3
Disease flare-up	2
Abnormal lab finding	1
Medication change	1
Medication problem	1

Table 3-5 Encounter type for IBD flares in April 2019	
Telephone	24
Clinic visit	11
Orders only	4

Importantly, excluding the most common encounter reason ('null', ie. no encounter reason entered), would have resulted in only 409 charts being reviewed to document 30 flares (9 missed), equating to a yield of 76.9%.

Based on these results, and assuming the reviewer was 100% accurate in applying the study's inclusion criteria, the following encounter reasons encounter reasons (reasons-

for-visit) were included in the chart reviewing methodology: Abdominal cramping, abdominal pain, abnormal lab finding, anemia, bloated, constipation, diarrhea, disease flare-up, epigastric pain, fatigue, follow-up, GI bleeding, inflammatory bowel disease, joint pain, joint swelling, knee pain, medication change, medication management, medication problem, melena, mid-flare IBD assessment, nausea, rash, rectal bleeding, referral, suspected IBD flare, vitamin D deficiency, weight loss.

Other than ‘null’, all excluded reasons were chosen based on having no relevance to IBD disease flare and having no or low expected impact on the number of flare encounters captured by the dataset based on the April 2019 results, as discussed above.

Furthermore, to attempt to elucidate any potential bias that would result from excluding this visit type, we have included an analysis below (Table) which compares, with chi-square p-values, the characteristics of flare encounters with and without (‘null’) a reason for visit entered, from the complete dataset.

Table 3-6 Characteristics of encounters, using chi-squared test to compare encounters with and without ('null') a reason for visit (VR) entered.

Parameter	Total encounters n (% of N)	VR Entered n (% of N)	No VR Entered ('null') n (% of N)	p-value (chi^2)
Provider characteristics				
Provider Type				
IBD nurse	17806 (52.2)	9053 (65.3)	8753 (43.3)	**<0.001***
IBD practitioner	16283 (47.8)	4813 (34.7)	11470 (56.7)	
Provider ID (nurse)				
2	3506 (10.3)	2420 (17.5)	1086 (5.4)	**<0.001***
3	1608 (4.7)	931 (6.7)	677 (3.3)	
4	3582 (10.5)	2457 (17.7)	1125 (5.6)	
5	3987 (11.7)	777 (5.6)	3210 (15.9)	
8	5123 (15.0)	2468 (17.8)	2655 (13.1)	
Provider ID (practitioner)				
1	2520 (7.4)	1023 (7.4)	1497 (7.4)	
6	564 (1.7)	353 (2.5)	211 (1)	
7	883 (2.6)	365 (2.6)	518 (2.6)	
9	3279 (9.6)	680 (4.9)	2599 (12.9)	
10	2577 (7.6)	831 (6)	1746 (8.6)	
11	2542 (7.5)	871 (6.3)	1671 (8.3)	
12	3918 (11.5)	690 (5)	3228 (16)	
Patient characteristics				
Sex				
Female	17549 (51.5)	7332 (52.9)	10217 (50.5)	**<0.001***
Male	16540 (48.5)	6534 (47.1)	10006 (49.5)	
Age, median (IQR)	43 (31-57)	41 (30-56)	43 (31-58)	**<0.001* †**
Tobacco Status				
Never	17222 (50.6)	7400 (53.5)	9822 (48.7)	**<0.001***
Null / not asked	3388 (10.0)	792 (5.7)	2596 (12.9)	
Quit	8423 (24.8)	3547 (25.6)	4876 (24.2)	
Current	4993 (14.7)	2104 (15.2)	2889 (14.3)	
Encounter Characteristics				
Encounter type				
Clinic visit	7984 (26.3)	4558 (33.8)	3426 (20.3)	**<0.001***
Orders only	17030 (56.1)	3608 (26.7)	13422 (79.6)	
Telephone	5346 (17.6)	5334 (39.5)	12 (0.1)	
Visit type name				
IBD - follow-up	6352 (18.8)	3670 (26.7)	2682 (13.4)	**<0.001***
IBD - new	1102 (3.3)	699 (5.1)	403 (2.0)	
IBD – urgent	152 (0.5)	77 (0.6)	75 (0.4)	
Null	26104 (77.4)	9307 (67.7)	16797 (84.2)	

* significant at p=0.05

† Kruskall-Wallis median test

3.3.3 Exploratory Analysis: SmartSet Flare Encounters

The following are exploratory analyses which examine characteristics of IBD flare encounters where the CDSS (SmartSet) was activated. This does not include any comparative analysis of flare encounters where the CDSS was not used.

3.3.3.1 Overall Adoption and Demographics of Use

From September 2017 to June 2019, the CDSS was activated a total of 214 times across 214 encounters with 207 patients. Of these, 16 encounters were excluded from analysis due to, upon review, not being utilized appropriately for a flare or suspected flare encounter with an IBD patient.

Table 3-7 Demographics of users and encounters invoking the IBD flare CDSS

Demographic variable	Study population (N=198) n (% of N)
Provider Characteristics	
Provider Type	
IBD nurse	172 (86.9)
IBD practitioner	26 (13.1)
Provider ID (nurse)	
2	17 (8.6)
3	11 (5.6)
4	20 (10.1)
5	40 (20.2)
8	76 (38.4)
13	8 (4.0)
Provider ID (practitioner)	
1	1 (0.5)
6	20 (10.1)
9	2 (1.0)
14	3 (1.5)
Patient Characteristics	
Sex	
Female	113 (57.1)
Male	85 (42.9)
Age, median (IQR)	37.5 (29-49)
Current IBD therapy	
None	37 (18.7)
5-ASA only	53 (26.8)
IMM	18 (9.1)
Biologic	90 (45.5)
Monotherapy	59 (29.8)
Combotherapy	31 (15.7)
Encounter Characteristics	
Encounter type	
Telephone	139 (70.2)
Orders only	32 (16.2)
Clinic visit	27 (13.6)
Encounter Diagnosis (1st)	
None	172 (86.9)
Crohn's disease	11 (5.6)
Ulcerative colitis	10 (5.1)
Bloody diarrhea	2 (1.0)
Inflammatory Bowel Disease	1 (0.5)
Abdominal bloating	1 (0.5)
Ankylosing spondylitis	1 (0.5)

Table 3-8 Visit Reasons for encounters invoking the IBD flare CDSS	
Visit Reason	Study population (N=198)
	n (% of N)
Suspected IBD Flare	113 (57.1)
Inflammatory Bowel Disease	*39 (19.7)*
Disease Flare-up	15 (7.6)
None	9 (4.5)
Referral	9 (4.5)
Follow-up	7 (3.5)
Diarrhea	3 (1.5)
Medication Change	1 (0.5)
Medication Problem	1 (0.5)

3.3.3.2 Compliance with Clinical Guidelines and Best Practices

Symptom documentation

Of 192 patients where clinical scores (mHBI/pMAYO) were appropriate (those without pouch, short bowel, or newly diagnosed), 133 (69.3%) had clinical score completed and documented in their chart at the index dispensation. Of all 198 patients, 196 (99.0%) had symptoms (abdominal pain, number/characteristics of stool, presence of blood) documented in their chart by the provider.

Laboratory investigations

Full flare lab panels (including CBC, ferritin, electrolytes, creatinine, albumin, alkaline phosphatase, ALT AST and CRP) were ordered for 109 / 198 (55.1%) of patients exactly at the encounter. Including orders up to one-month prior, full panels were ordered for 183/198 (92.4%) of patients. However, 113 / 198 (57.1%) had at least a partial lab panel

including CBC and CRP ordered at the encounter, and 193/198 (97.5%) including up to one month prior to the encounter.

Fecal calprotectin was ordered at the encounter for 147 / 198 (74.2%) patients. 36 / 198 (18.2%) had FCP results available from within 1 month at the encounter, leaving only 15 (7.6%) who had no evaluation of FCP at all. Furthermore, testing for *Clostridium difficile* infection was done in 164/198 (82.8%) patients and for stool cultures in 160 /198 (80.8) patients. In 138 patients where liquid stool or diarrhea was mentioned in the progress note, 127 (92)% had *C.difficile* testing ordered and 123 (89.1%) had stool cultures ordered.

Provision of steroid-sparing therapy and osteoprotective therapy

In this dataset, only 12 (6.1%) patients were prescribed steroids at their encounter. Of these, 6 (50%) had maintenance IBD therapy was adjusted of added. This is compared with 37 (20%) of the 185 patients who were not prescribed steroids (p=0.015*, chi-squared).

Vitamin D or calcium supplementation was recommended for 8/12 (66.7%) patients. When excluding patient with vitamin D / calcium supplementation documented in their medication list (patient reported), this improves to 8/10 (80%).

3.3.4 Implementation Phase 1

Implementation Phase 1 includes data from January 2017 to June 2018 (18 months), where September 2017 and beyond were labelled as the active intervention months.

3.3.4.1 Before-and-after Analysis

Table 3-9 Before and after comparison of process measures from Implementation Phase I, chi-squared.

Parameter	**Pre-intervention n (% of N) N = 228**	**Post-intervention n (% of N) N = 274**	**p-value (chi^2)**
CDSS Activated	0 (0.0)	66 (24.1)	**<0.001***
Clinical score completed	8 (3.5)	66 (24.1)	**<0.001***
Flare labs ordered	124 (54.4)	132 (48.2)	0.327
C-reactive protein ordered	156 (68.4)	178 (65.0)	0.563
Fecal calprotectin ordered	38 (16.7)	74 (27.0)	**0.048***
Stool cultures ordered	128 (56.1)	162 (59.1)	0.634
C. difficile test ordered	128 (56.1)	172 (62.8)	0.286

Bold* = significant at p=0.05

3.3.4.2 Interrupted Time Series Analysis

Interrupted time series analysis was conducted on parameters which were significant from before-and-after analysis (Table 3-10), including clinical score completion (Figure 3-3, Table 3-11), and fecal calprotectin testing (Figure 3-4, Table 3-12).

Clinical Score Completed and Documented

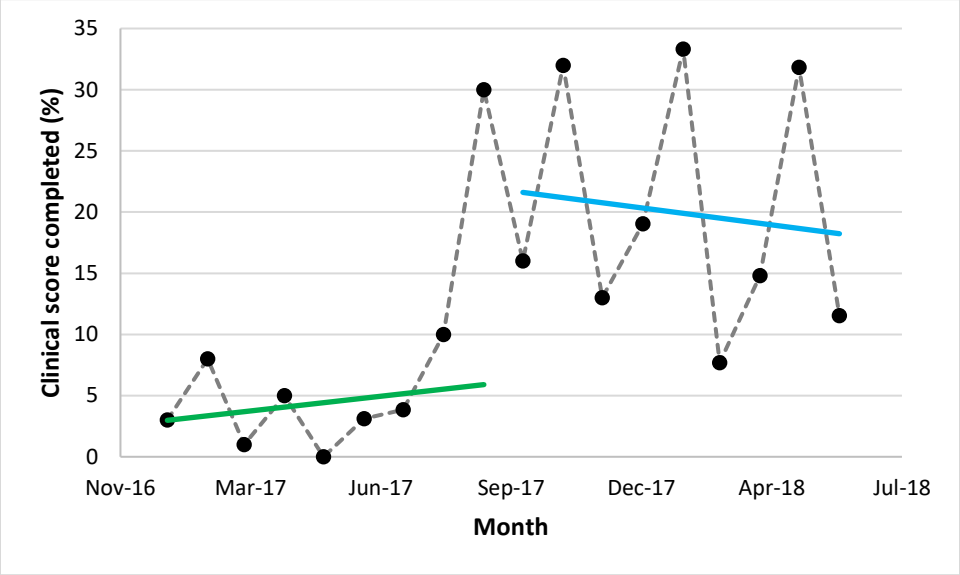

Figure 3-3 Segmented regression of the intervention on rate of clinical score completion, Implementation Phase 1

Table 3-10 Segmented logistic regression analysis of IBD CDSS for clinical score completion, Implementation Phase I

Parameter	Beta	95% CI	p-value
Pre-intervention slope (secular trend, per month)	0.352	-2.273-2.978	0.778
Change in slope (gradual effect, per month)	-1.219	-4.444-2.006	0.431
Change in intercept (immediate effect)	18.992	2.387-35.597	**0.028***

Fecal Calprotectin Ordered

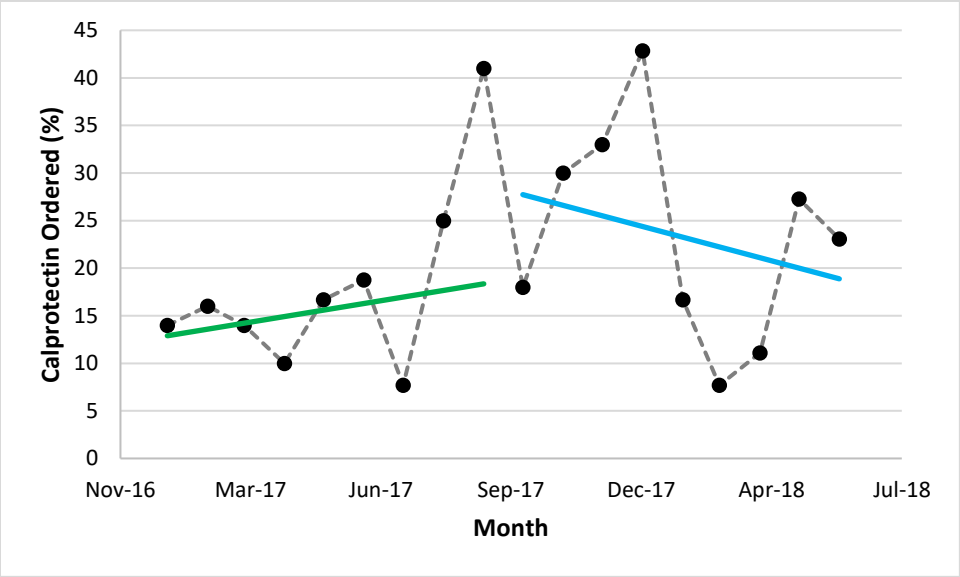

Figure 3-4 Segmented regression of the intervention on rate of fecal calprotectin testing**,** Implementation Phase I

Table 3-11 Segmented logistic regression analysis of IBD CDSS for ordering of fecal calprotectin, Implementation Phase I

Parameter	**Beta**	**95% CI**	**p-value**
Pre-intervention slope (secular trend, per month)	0.671	-2.396-3.738	0.646
Change in slope (gradual effect, per month)	-2.447	-6.214-1.321	0.185
Change in intercept (immediate effect)	14.774	-4.625-34.173	0.125

3.3.5 Implementation Phase 2

Implementation Phase 2 includes data from January 2018 to June 2019 (18 months), where October 2018 and beyond were labelled as the active intervention months.

3.3.5.1 Exploratory Analysis: Adoption of CDS Flare Tool

Demographics

Table 3-12 Characteristics of flare encounters from Implementation Phase II, using chi-squared test to compare encounters with and without CDSS activation

Parameter	**Total flares n (% of N)**	**CDS Activated n (% of N)**	**CDS Inactive n (% of N)**	**p-value (chi^2)**
Provider characteristics				
Provider Type				
IBD nurse	419 (80.1)	128 (94.8)	291 (75.0)	**<0.001***
IBD practitioner	104 (19.9)	7 (5.2)	97 (25.0)	
Provider ID (nurse)				
2	89 (17.0)	8 (5.9)	81 (20.9)	**<0.001***
3	14 (2.7)	5 (3.7)	9 (2.3)	
4	124 (23.7)	21 (15.6)	103 (26.5)	
5	53 (10.1)	35 (25.9)	18 (4.6)	
8	139 (26.6)	59 (43.7)	80 (20.6)	
Provider ID (practitioner)				
1	12 (2.3)	0 (0.0)	12 (3.1)	
6	13 (2.5)	5 (3.7)	8 (2.1)	
7	14 (2.7)	0 (0.0)	14 (3.6)	
9	10 (1.9)	1 (0.7)	9 (2.3)	
10	14 (2.7)	0 (0.0)	14 (3.6)	
11	19 (3.6)	1 (0.7)	18 (4.6)	
12	22 (4.2)	0 (0.0)	22 (5.7)	
Patient characteristics				
Sex				
Female	315 (60.2)	79 (58.5)	236 (60.8)	0.637
Male	208 (39.8)	56 (41.5)	152 (39.2)	
Age, median (IQR)	38 (30-50)	38 (30-48)	38 (30-51.5)	0.678†
Tobacco Status				0.263
Never	277 (53.0)	74 (54.8)	203 (52.3)	
Null	27 (5.2)	5 (3.7)	22 (5.7)	
Quit	143 (27.3)	42 (31.1)	101 (26.0)	
Current	76 (14.5)	14 (10.4)	62 (16.0)	
Encounter Characteristics				
Encounter type				
Clinic visit	100 (19.1)	7 (5.2)	93 (24.0)	**<0.001***
Orders only	73 (7.1)	12 (8.9)	25 (6.4)	

Table 3-12 Characteristics of flare encounters from Implementation Phase II, using chi-squared test to compare encounters with and without CDSS activation				
Parameter	**Total flares n (% of N)**	**CDS Activated n (% of N)**	**CDS Inactive n (% of N)**	**p-value (chi^2)**
Telephone	386 (73.8)	116 (85.9)	270 69.6)	
Visit type name				
IBD - follow-up	72 (13.8)	3 (2.2)	69 (17.8)	**<0.001***
IBD - new	19 (3.6)	4 (3.0)	15 (3.9)	
IBD – urgent	9 (1.7)	0 (0.0)	9 (2.3)	
Null	423 (80.9)	128 (94.8)	295 (76.0)	

* = significant at p=0.05
† Mood median test

Application rate of CDS tool

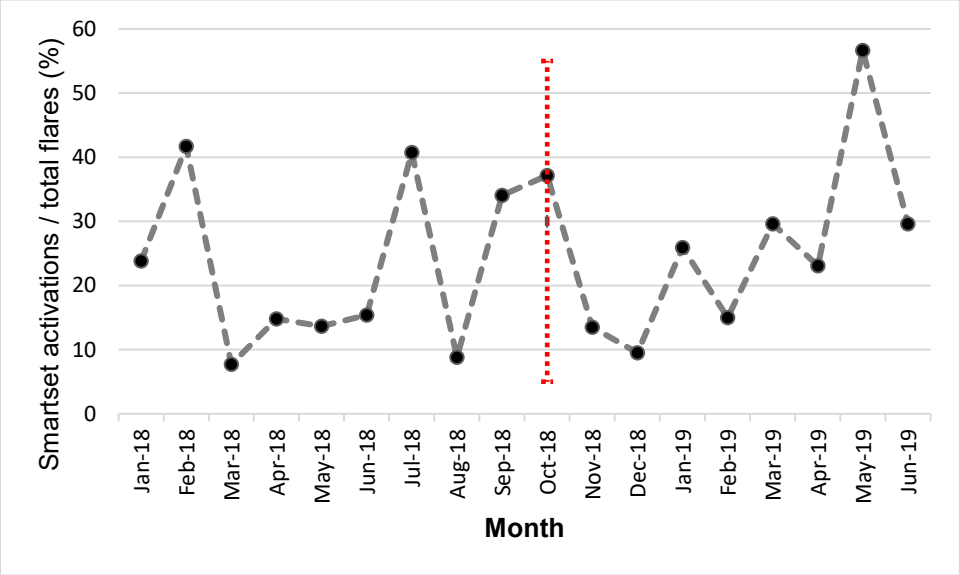

Figure 3-5 Application rate, in %, of the IBD CDSS tool over the study period (Phase 2). Red vertical line represents the implementation of CDSS version 2 changes.

Application rate by provider

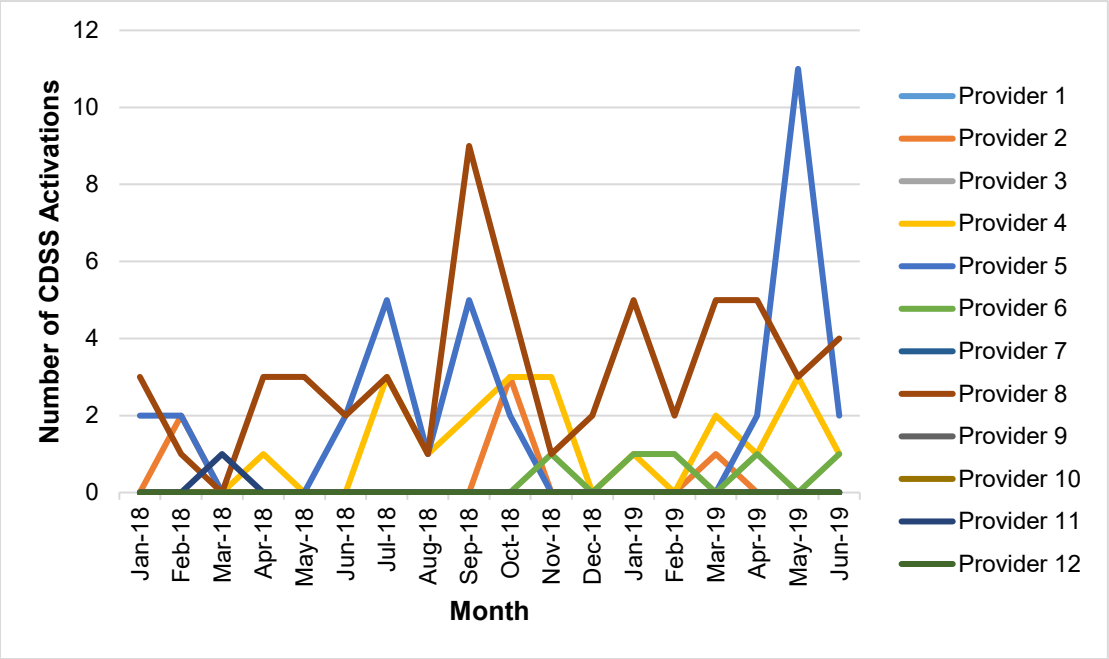

Figure 3-6 Application rate, in number of activations, of the IBD CDSS tool over Implementation Phase 2.

3.3.5.2 Before-and-after Analysis

Table 3-13 Before and after comparison of process measures from Implementation Phase II, chi-squared.

Parameter	Pre-intervention n (% of N) N = 229	Post-intervention n (% of N) N = 263	p-value (chi^2)
Application of smart set	52 (22.7%)	72 (27.4%)	0.234
Clinical score completed	58 (25.3%)	75 (28.5%)	0.427
Flare labs ordered	109 (47.6%)	173 (65.8%)	**<0.001***
C-reactive protein ordered	147 (64.2%)	207 (78.7%)	**<0.001***
Fecal calprotectin ordered	64 (27.9%)	98 (37.3%)	**0.028***
Stool cultures ordered	125 (54.6%)	176 (66.9%)	**0.005***
Clostridium testing ordered	136 (59.4%)	177 (67.3)	0.069

Bold* = significant at p=0.05

3.3.5.3 Multivariate Analysis

Clinical score completed and documented

The impact of study variables on the completion of clinical scores by the provider was analyzed using univariate and multivariate regression, shown in **Table 3-14**. After adjusting for significant covariates, clinical scores were more likely to be completed when the CDSS was activated in the encounter, and less likely when patients smoked, or when the encounter took place outside of the clinic setting (telephone, orders only).

Table 3-14 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of IBD CDSS use and other encounter details on completion of clinical score (mHBI / pMAYO)

Variables	Univariate (unadjusted)			Multivariate (adjusted)		
	Odds Ratio	95% CI	*P* value	Odds Ratio	95% CI	*P* value
Intervention						
CDSS Activated	13.671	8.444-22.136	**<0.001***	16.700	9.774-28.533	**<0.001***
Provider Characteristics						
Provider Type						
IBD nurse	ref.					
IBD practitioner	0.780	0.470-1.296	0.338			
Patient Characteristics						
Sex						
Female	ref					
Male	0.918	0.610-1.381	0.681			
Age	0.985	0.971-0.999	**0.037***		*Not significant*	
Tobacco use						
Never	ref					
NULL	0.655	0.254-1.684	0.380	0.776	0.255-2.366	0.656
Quit	0.850	0.534-1.354	0.494	0.714	0.406-1.255	0.242
Yes	0.458	0.234-0.899	**0.023***	0.419	0.191-0.915	**0.029***
Encounter Characteristics						
Encounter type						
Clinic visit	ref					
Orders only	0.125	0.016-0.972	**0.047***	0.055	0.006-0.496	**0.010***
Telephone	1.303	0.781-2.173	0.310	0.468	0.253-0.866	**0.016***
Visit type name						
Null	ref					
IBD - follow-up	0.820	0.456-1.477	0.509			
IBD - new	1.520	0.583-3.961	0.392			
IBD - urgent	0.000	0.000-	0.999			

Bold = significant at p=0.20, include in preliminary model
Bold* = significant at p=0.05

Flare labs ordered

The impact of study variables on the ordering of flare lab panel by the provider was analyzed using univariate logistic regression, shown in **Table 3-15**. Flare lab testing was more likely to be ordered when the CDSS was activated in the encounter, and less likely when the encounter was with a practitioner (vs. nurse staff). The encounter taking place outside of the clinic setting (telephone, orders only) also increased odds of flare lab testing being ordered. However, when adjusting for CDSS activation, all other covariates were statistically insignificant (not shown in table).

Table 3-15 Results of univariate (unadjusted) logistic regression analysis for the impact of IBD CDSS use and other encounter details on completion of flare lab testing.

Variables	**Univariate (unadjusted)** †		
	Odds Ratio	95% CI	*P* value
Intervention			
CDSS Activated	13.571	6.888-26.739	**<0.001***
Provider Characteristics			
Provider Type			
IBD nurse	ref.		
IBD practitioner	0.108	0.063-0.186	**<0.001***
Patient Characteristics			
Sex			
Female	ref		
Male	1.097	0.761-1.581	0.621
Age	1.002	0.990-1.014	0.760
Tobacco use			
Never	ref		
NULL	0.777	0.351-1.720	0.534
Quit	0.993	0.650-1.516	0.972
Yes	0.902	0.533-1.527	0.702
Encounter Characteristics			
Encounter type			
Clinic visit	ref		
Orders only	9.799	3.718-25.825	**<0.001***
Telephone	10.947	6.140-19.516	**<0.001***

Table 3-15 Results of univariate (unadjusted) logistic regression analysis for the impact of IBD CDSS use and other encounter details on completion of flare lab testing.

Variables	**Univariate (unadjusted)** †		
	Odds Ratio	95% CI	*P* value
Visit type name			
Null	ref		
IBD - follow-up	0.069	0.033-0.144	**<0.001***
IBD - new	0.171	0.060-0.484	**0.001***
IBD - urgent	0.136	0.028-0.666	**0.014***

†All variables insignificant in multivariate preliminary model, except for 'CDS Activation'. No multivariate model.

C-reactive protein ordered

The impact of study variables on the ordering of C-reactive protein (CRP) by the provider was analyzed using univariate logistic regression, shown in **Table 3-16**. CRP was more likely to be ordered when the CDSS was activated in the encounter, and less likely when the encounter was with a practitioner (vs. nurse staff). The encounter taking place outside of the clinic setting (telephone, orders only) also increased odds of CRP being ordered. However, when adjusting for CDSS activation, all other covariates were statistically insignificant (not shown in table).

Table 3-16 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of IBD CDSS use and other encounter details on ordering of c-reactive protein

Variables	**Univariate (unadjusted) †**		
	Odds Ratio	95% CI	*P* value
Intervention			
CDSS Activated	11.000	4.714-25.671	**<0.001***
Provider Characteristics			
Provider Type			
IBD nurse	ref.		
IBD practitioner	0.135	0.084-0.217	**<0.001***
Patient Characteristics			
Sex			
Female	ref		
Male	0.881	0.591-1.314	0.535
Age	1.006	0.993-1.020	0.370
Tobacco use			
Never	ref		
NULL	1.751	0.639-4.795	0.276
Quit	1.114	0.696-1.784	0.653
Yes	0.796	0.455-1.392	0.423
Encounter Characteristics			
Encounter type			
Clinic visit	ref		
Orders only	4.963	1.901-12.957	**0.001***
Telephone	8.188	5.017-13.362	**<0.001***
Visit type name			
Null	ref		
IBD - follow-up	0.118	0.068-0.206	**<0.001***
IBD - new	0.209	0.082-0.532	**0.001***
IBD - urgent	0.066	0.013-0.326	**0.001***

†All variables insignificant in multivariate preliminary model, except for 'CDS Activation'. No multivariate model.

Fecal calprotectin ordered

The impact of study variables on the ordering of FCP by the provider was analyzed using univariate logistic regression, shown in **Table 3-17**. FCP was more likely to be ordered when the CDSS was activated in the encounter, and less likely when the encounter was with a practitioner (vs. nurse staff). The telephone encounter type also increased odds of FCP being ordered (vs. the reference clinic visit type). However, when adjusting for CDSS activation, these covariates were statistically insignificant.

Table 3-17 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of CDSS use and other encounter details on ordering of calprotectin.

Variables	**Univariate (unadjusted)** †		
	Odds Ratio	95% CI	*P* value
Intervention			
CDSS Activated	9.186	5.794-14.561	**<0.001***
Provider Characteristics			
Provider Type			
IBD nurse	ref.		
IBD practitioner	0.210	0.111-0.397	**<0.001***
Patient Characteristics			
Sex			
Female	ref		
Male	1.018	0.93-1.494	0.928
Age	0.995	0.982-1.008	0.441
Tobacco use			
Never	ref		
NULL	1.066	0.460-2.474	0.881
Quit	1.244	0.803-1.928	0.329
Yes	0.878	0.496-1.555	0.656
Encounter Characteristics			
Encounter type			
Clinic visit	ref		
Orders only	2.175	0.728-6.494	0.164
Telephone	4.682	2.471-8.869	**<0.001***
Visit type name			
Null	ref		
IBD - follow-up	0.071	0.022-0.231	**<0.001**
IBD - new	1.458	0.579-3.670	0.423
IBD - urgent	0.000	0.000-	0.999

†All variables insignificant in multivariate preliminary model, except for ‘CDS Activation’. No multivariate model.

Stool cultures ordered

The impact of study variables on the ordering of stool culture testing by the provider was analyzed using univariate and multivariate regression, shown in **Table 3-18**. In multivariate analysis, stool cultures were more likely to be ordered when the CDSS was activated in the encounter, and when the encounter was a telephone encounter, even after adjusting for CDSS activation.

Table 3-18 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of IBD CDSS use and other encounter details on ordering of stool cultures.

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Odds Ratio	95% CI	*P* value	Odds Ratio	95% CI	*P* value
Intervention						
CDSS Activation	5.225	3.045-8.965	**<0.001***	3.992	2.296-6.943	**<0.001***
Provider Characteristics						
Provider Type						
IBD nurse	ref.				Not significant	
IBD practitioner	0.251	0.159-0.397	**<0.001***			
Patient Characteristics						
Sex						
Female	ref					
Male	0.968	0.669-1.402	0.863			
Age	0.997	0.985-1.010	0.676			
Tobacco use						
Never	ref					
NULL	1.558	0.658-3.692	0.314			
Quit	1.241	0.803-1.917	0.331			
Yes	0.733	0.434-1.240	0.247			
Encounter Characteristics						
Encounter type						
Clinic visit	ref			ref.		
Orders only	2.333	0.971-5.609	**0.058**	18.895	0.847-421.394	0.064
Telephone	4.496	2.801-7.215	**<0.001***	31.497	1.392-712.652	**0.030***
Visit type name						
Null	ref				Not significant	
IBD - follow-up	0.209	0.121-0.362	**<0.001***			
IBD - new	0.518	0.205-1.307	**0.164**			
IBD - urgent	0.058	0.007-0.471	**0.008***			

Bold = significant at p=0.20, include in preliminary model
Bold* = significant at p=0.05

Clostridium difficile testing

The impact of study variables on the ordering of *C. difficile* testing by the provider was analyzed using univariate and multivariate regression, shown in **Table 3-19**. In multivariate analysis, *C. difficile* was more likely to be ordered when the CDSS was activated in the encounter, and when the visit type was 'IBD new'.

Table 3-19 Results of univariate (unadjusted) and multivariate (adjusted) logistic regression analysis for the impact of IBD CDSS use and other encounter details on ordering of clostridium difficile test.

Variables	**Univariate (unadjusted)**			**Multivariate (adjusted)**		
	Odds Ratio	95% CI	*P* value	Odds Ratio	95% CI	*P* value
Intervention						
CDSS Activation	4.251	2.501-7.225	**<0.001***	3.640	2.115-6.263	**<0.001***
Provider Characteristics						
Provider Type						
IBD nurse	ref.			Not significant		
IBD practitioner	0.452	0.291-0.702	**<0.001***			
Patient Characteristics						
Sex						
Female	ref					
Male	1.011	0.695-1.472	0.953			
Age	1.003	0.990-1.016	0.648			
Tobacco use						
Never	ref					
NULL	1.460	0.616-3.462	0.390			
Quit	1.380	0.884-2.153	0.156			
Yes	0.813	0.479-1.381	0.444			
Encounter Characteristics						
Encounter type						
Clinic visit	ref			Not significant		
Orders only	1.509	0.631-3.609	0.355			
Telephone	2.394	1.524-3.761	**<0.001***			
Visit type name						
Null	ref					
IBD - follow-up	0.392	0.235-0.654	**<0.001***	2.775	0.538-14.310	0.223
IBD - new	1.034	0.384-2.784	0.947	6.121	0.956-39.201	0.056
IBD - urgent	0.136	0.028-0.666	**0.014***			

Bold = significant at p=0.20, include in preliminary model
Bold* = significant at p=0.05

3.3.5.4 Interrupted Time Series Analysis

Interrupted time series analysis was conducted on all parameters including the application rate of the CDSS, and rates for clinical score completion, flare lab ordering, C-reactive protein ordering, fecal calprotectin ordering, stool culture and *Clostridium difficile* testing.

Interrupted time series graphs with segmented regression lines are displayed for each parameter in Figures 3-7 to 3-13. Tables 3-21 to 3-27 quantify the parameters for each segmented regression, including betas and 95% CIs for the change in slope and in level.

Application Rate

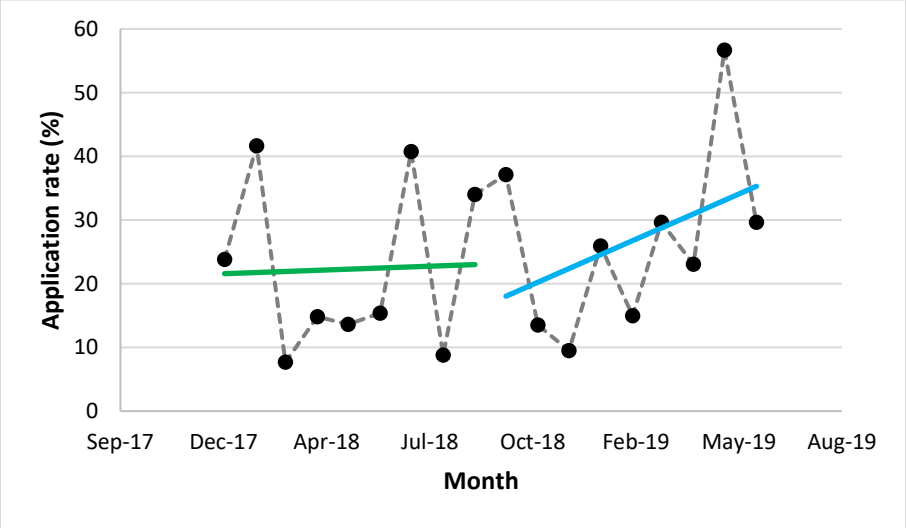

Figure 3-7 Segmented regression of the intervention on application rate of IBD CDSS

Table 3-20 Segmented regression analysis of intervention on application rate of IBD CDSS, Implementation Phase II

Parameter	Beta	95% CI	p-value
Pre-intervention slope (secular trend, per month)	0.151	-3.757 – 4.059	0.935
Change in slope (gradual effect, per month)	2.019	-3.508 – 7.546	0.446
Change in intercept (immediate effect)	-5.048	-33.86 – 23.76	0.713

Clinical score completed and documented

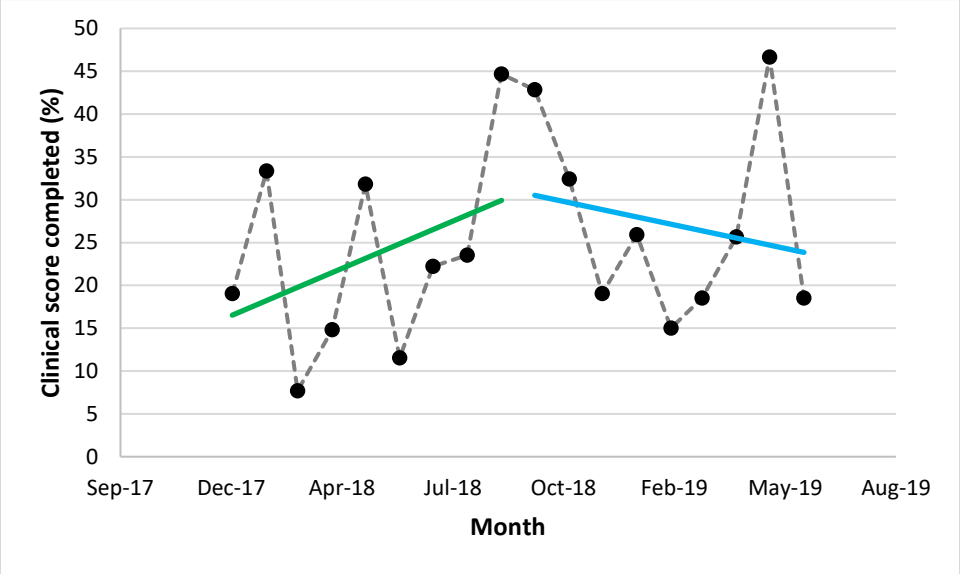

Figure 3-8 Segmented regression of the intervention on rate of clinical score completion.

Table 3-21 Segmented logistic regression analysis of IBD CDSS for clinical score completion, Implementation Phase II

Parameter	Beta	95% CI	p-value
Pre-intervention slope (secular trend, per month)	1.648	-1.596 - 4.893	0.294
Change in slope (gradual effect, per month)	-2.463	-7.051 – 2.125	0.269
Change in intercept (immediate effect)	-0.992	-24.91 – 22.92	0.930

Flare labs ordered

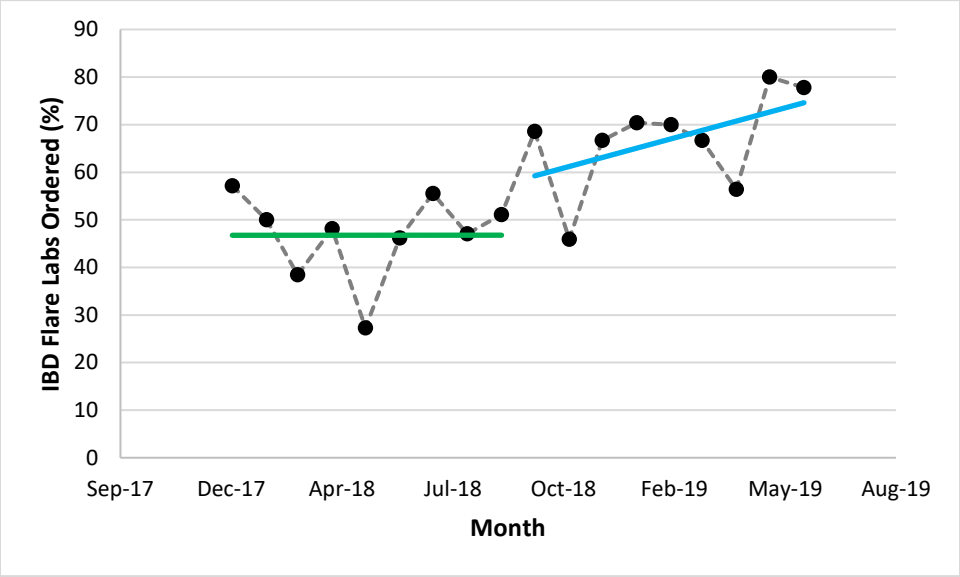

Figure 3-9 Segmented regression of the intervention on rate of IBD flare lab testing.

Table 3-22 Segmented logistic regression analysis of IBD CDSS for ordering of IBD flare labs (CRP, CBC, ferritin, creatinine, albumin, alkaline phosphatase, ALT, AST, electrolytes), Implementation Phase II

Parameter	Beta	95% CI	p-value
Pre-intervention slope (secular trend, per month)	-0.016	-2.693 – 2.662	0.990
Change in slope (gradual effect, per month)	1.929	-1.858 – 5.715	0.293
Change in intercept (immediate effect)	12.60	-7.137 – 32.34	0.193

C-reactive protein ordered

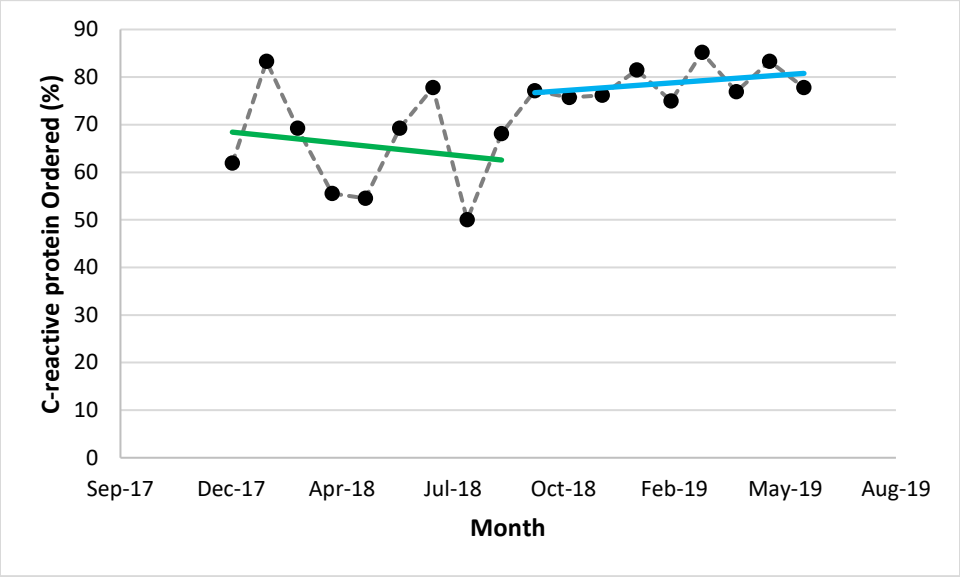

Figure 3-10 Segmented regression of the intervention on rate of c-reactive protein testing.

Table 3-23 Segmented logistic regression analysis of IBD CDSS for ordering of C-reactive protein (CRP), Implementation Phase II

Parameter	Beta	95% CI	p-value
Pre-intervention slope (secular trend, per month)	-0.742	-3.121 – 1.637	0.515
Change in slope (gradual effect, per month)	1.253	-2.111 – 4.618	0.438
Change in intercept (immediate effect)	14.89	-2.645 – 32.43	**0.090***

* = significant at p=0.10 level

Fecal calprotectin ordered

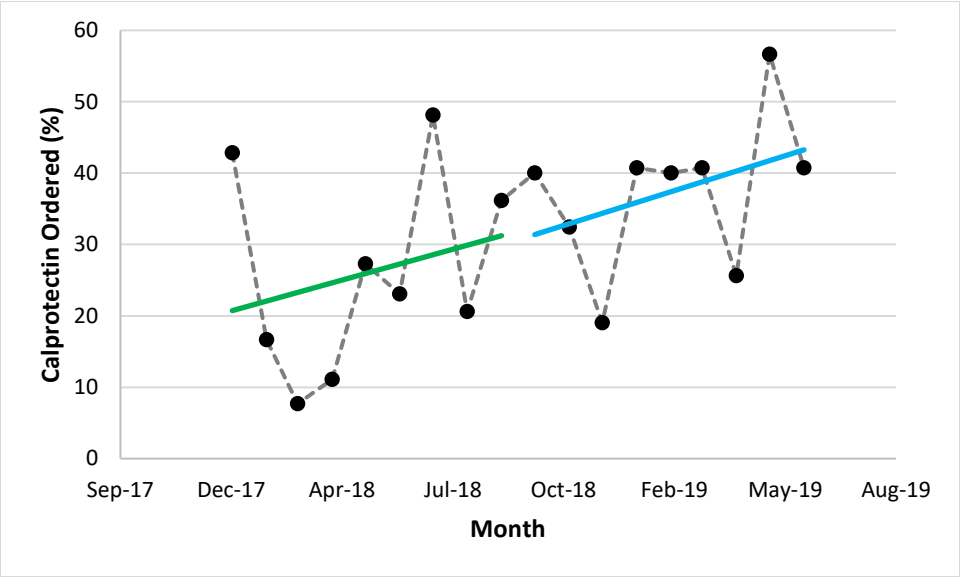

Figure 3-11 Segmented regression of the intervention on rate of fecal calprotectin testing.

Table 3-24 Segmented logistic regression analysis of IBD CDSS for ordering of fecal calprotectin (FCP), Implementation Phase II

Parameter	Beta	95% CI	p-value
Pre-intervention slope (secular trend, per month)	1.298	-2.209 – 4.806	0.441
Change in slope (gradual effect, per month)	0.183	-4.778 – 5.143	0.938
Change in intercept (immediate effect)	-1.034	-26.89 – 24.82	0.933

Stool cultures ordered

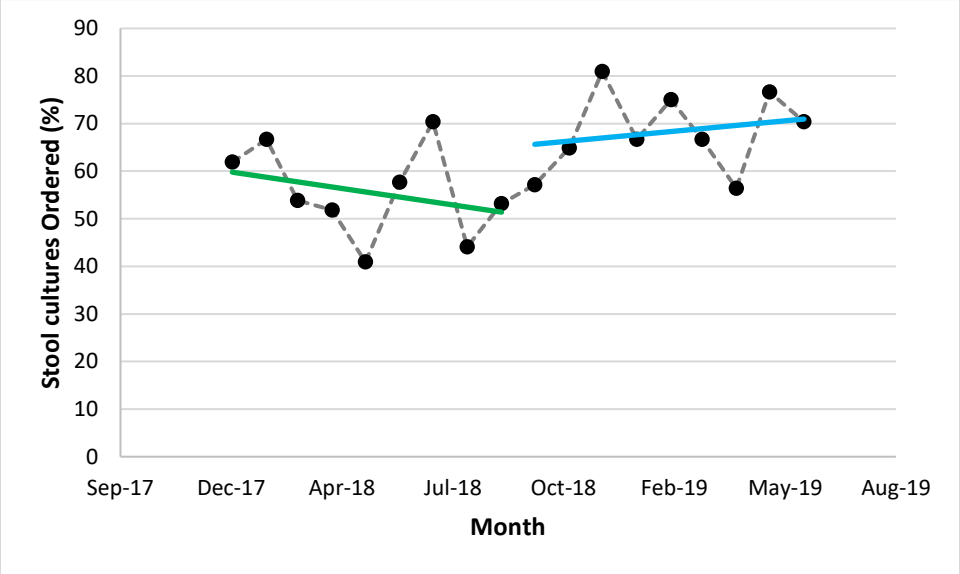

Figure 3-12 Segmented regression of the intervention on rate of testing for stool cultures.

Table 3-25 Segmented logistic regression analysis of IBD CDSS for ordering of stool cultures, Implementation Phase II

Parameter	Beta	95% CI	p-value
Pre-intervention slope (secular trend, per month)	-1.060	-3.650 – 1.529	0.395
Change in slope (gradual effect, per month)	1.714	-1.948 – 5.376	0.332
Change in intercept (immediate effect)	15.37	-3.715 – 34.46	0.106

Clostridium difficile testing

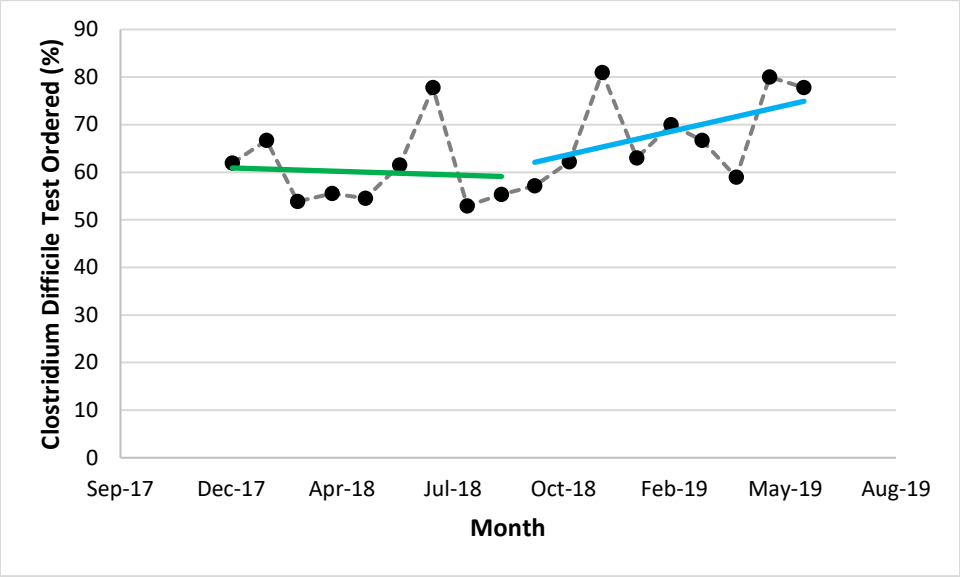

Figure 3-13 Segmented regression of the intervention on rate of testing for clostridium difficile infection.

Table 3-26 Segmented logistic regression analysis of IBD CDSS for ordering of clostridium difficile toxin testing, Implementation Phase 2

Parameter	Beta	95% CI	p-value
Pre-intervention slope (secular trend, per month)	-0.228	-2.613 – 2.158	0.841
Change in slope (gradual effect, per month)	1.825	-1.549 – 5.198	0.265
Change in intercept (immediate effect)	3.258	-14.33 – 20.84	0.697

3.3.6 Questionnaire Responses and Feedback

3.3.6.1 Questionnaire Participants

Table 3-27 Demographics of users (IBD nurses and practitioners) completing Workflow Integration Survey (WIS) and the Computer System Usability Questionnaire (CSUQ).

Demographic variable	Study population n (% of N (11))
Provider Type	
IBD nurse	4 (36.4)
IBD practitioner	7 (63.6)
Sex	
Female	7 (63.6)
Male	4 (36.4)
Length of time as healthcare provider, yrs	
1-2	1 (9.1)
5-6	1 (9.1)
8-10	2 (18.2)
>10	7 (63.6)
Length of time using eCLINICIAN, yrs	
0-1	1 (9.1)
1-2	1 (9.1)
3-4	5 (45.5)
>4	4 (36.4)
Length of time using any EMR, yrs	
3-4	2 (18.2)
5-6	2 (18.2)
7-8	2 (18.2)
>8	5 (45.5)

3.3.6.2 Workflow Integration Survey

Table 3-28 and **Table 3-29** show results from the Workflow Integration Survey, administered to all providers during each implementation phase. **Table 3-29** shows results only for IBD nurses. Scores for each subscale were aggregated and averaged, with means and standard deviations compared using Wilcoxon signed-rank. In both comparisons, there were no statistically significant differences. Looking holistically at the scores, navigation seems to be satisfied by the CDSS, whereas workload may be an area for potential improvement. However, the large standard deviations of some of the scores should be taken into consideration when making conclusions.

Workflow Integration Survey – Aggregate Responses – All Providers

Table 3-28 Means (standard deviations) and p-values from Wilcoxon signed rank tests for the Workflow Integration Survey (WIS) for both versions of the CDSS.

	CDSS Phase I	CDSS Phase II	p-value
WIS Subscale			
Navigation	4.00 (0.64)	4.17 (0.25)	0.480
Functionality	3.29 (0.70)	3.88 (1.39)	0.287
Ease of use	3.46 (0.92)	3.33 (0.62)	0.408
Workload	3.38 (0.88)	2.83 (0.73)	0.125
Addendum			
CDS Functionality	3.75 (0.66)	3.21 (0.35)	0.135

Workflow Integration Survey – Aggregate Responses – IBD Nurses

Table 3-29 Means (standard deviations) and p-values from Wilcoxon signed rank tests for the Workflow Integration Survey (WIS) for both versions of the CDSS; IBD nurses included only.

	CDSS Phase I	CDSS Phase II	p-value
WIS Subscale			
Navigation	3.92 (0.17)	4.25 (0.32)	0.157
Functionality	3.17 (0.88)	3.17 (0.33)	0.713
Ease of use	3.58 (0.83)	3.25 (0.74)	0.180
Workload	3.25 (0.74)	2.83 (0.96)	0.465
Addendum			
CDS Functionality	4.08 (0.69)	3.00 (0.00)	0.066

3.3.6.3 Computer System Usability Questionnaire

Computer System Usability Questionnaire – All Providers

Table 3-30 Results from the CSUQ completed by all providers (practitioners and nurses), ranked on a Likert scale (1-7) and displayed as percentages along with average score.

	DISAGREE						AGREE	AVG
Statement	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Score**
1. Overall, I am satisfied with how easy it is to use this system.		13%		38%	25%	25%		**4.5**
2. It was simple to use this system.			11%	44%	22%	22%		**4.6**
3. I can effectively complete my work using this system.				56%	22%	22%		**4.7**
4. I am able to complete my work quickly using this system.		11%	22%	33%	33%			**3.9**
5. I am able to efficiently complete my work using this system.			22%	33%	22%	22%		**4.4**
6. I feel comfortable using this system.				33%	44%	22%		**4.9**
7. It was easy to learn to use this system.		11%	11%	33%	22%	22%		**4.3**
8. I believe I became productive quickly using this system.		22%	11%	33%	22%	11%		**3.9**
9. The system gives error messages that clearly tell me how to fix problems.		22%		44%	11%	22%		**4.1**
10. Whenever I make a mistake using the system, I recover easily and quickly.		22%		44%	11%	22%		**4.1**
11. The information provided with this system is clear.		11%		56%	11%	22%		**4.3**
12. It is easy to find the information I needed.		0%	22%	44%	22%	11%		**4.2**
13. The information provided for the system is easy to understand.			11%	56%	11%	22%		**4.4**
14. The information is effective in helping me complete the tasks and scenarios.			33%	33%	11%	22%		**4.2**

Table 3-30 Results from the CSUQ completed by all providers (practitioners and nurses), ranked on a Likert scale (1-7) and displayed as percentages along with average score.

	DISAGREE						AGREE	AVG
Statement	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Score**
15. The organization of the information on the systems screens is clear.			11%	56%	11%	22%		**4.4**
16. The interface of the system is pleasant.			11%	56%	11%	22%		**4.4**
17. I like using the interface of this system.				67%	22%	11%		**4.4**
18. This system has all the functions and capabilities I expect it to have.		22%	11%	33%	22%	11%		**3.9**
19. Overall, I am satisfied with this system.				44%	33%	22%		**4.8**
20. The quality of training documents and communications for this SmartSet was adequate.			11%	44%	22%	11%	11%	**4.7**
21. It was easy to prescribe medications with this SmartSet.				44%	33%	11%	11%	**4.9**
22. This SmartSet reflects the current standards of care.				44%	22%	11%	22%	**5.1**
23. It was easy to reach other IBD team members (nurses, admins) using the Follow-up section of the SmartSet.	11%		22%	33%		22%	11%	**4.2**
24. Booking follow-up appointments using the SmartSet was fast.	11%		33%	33%		11%	11%	**3.9**
25. It was easy to complete an IBD flare encounter in a timely fashion using this SmartSet.			22%	44%	11%	11%	11%	**4.4**

Computer System Usability Questionnaire – IBD Nurses

Table 3-31 Results from the CSUQ completed by IBD nurses, ranked on a Likert scale (1-7) and displayed as percentages along with average score.

	DISAGREE						AGREE	AVG
Statement	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Score**
1. Overall, I am satisfied with how easy it is to use this system.		25%		25%	25%	25%		**4.3**
2. It was simple to use this system.			25%	25%	25%	25%		**4.5**
3. I can effectively complete my work using this system.				50%	25%	25%		**4.8**
4. I am able to complete my work quickly using this system.		25%	25%	25%	25%			**3.5**
5. I am able to efficiently complete my work using this system.			25%	25%	25%	25%		**4.5**
6. I feel comfortable using this system.					75%	25%		**5.3**
7. It was easy to learn to use this system.		25%	25%		25%	25%		**4.0**
8. I believe I became productive quickly using this system.		50%		25%	25%			**3.3**
9. The system gives error messages that clearly tell me how to fix problems.		25%		50%		25%		**4.0**
10. Whenever I make a mistake using the system, I recover easily and quickly.		25%		50%		25%		**4.0**
11. The information provided with this system is clear.		25%		50%		25%		**4.0**
12. It is easy to find the information I needed.			50%	25%		25%		**4.0**
13. The information provided for the system is easy to understand.			25%	50%		25%		**4.3**
14. The information is effective in helping me complete the tasks and scenarios.			75%			25%		**3.8**
15. The organization of the information on the systems screens is clear.				75%		25%		**4.5**

Table 3-31 Results from the CSUQ completed by IBD nurses, ranked on a Likert scale (1-7) and displayed as percentages along with average score.

Statement	DISAGREE 1	2	3	4	5	6	AGREE 7	AVG Score
16. The interface of the system is pleasant.				75%		25%		**4.5**
17. I like using the interface of this system.				100%				**4.0**
18. This system has all the functions and capabilities I expect it to have.		50%	25%		25%			**3.0**
19. Overall, I am satisfied with this system.				50%	25%	25%		**4.8**
20. The quality of training documents and communications for this SmartSet was adequate.				50%	50%			**4.5**
21. It was easy to prescribe medications with this SmartSet.				25%	75%			**4.8**
22. This SmartSet reflects the current standards of care.				25%	50%		25%	**5.3**
23. It was easy to reach other IBD team members (nurses, admins) using the Follow-up section of the SmartSet.	25%		25%	25%		25%		**3.5**
24. Booking follow-up appointments using the SmartSet was fast.	25%		50%	25%				**2.8**
25. It was easy to complete an IBD flare encounter in a timely fashion using this SmartSet.		25%	50%	25%				**4.0**

3.3.6.4 Qualitative Feedback

Free text questions and fields were included at the end of the provider questionnaires. Questions asked about whether workflow had to be adjusted, what could be done to improve the CDSS, and for any additional comments. Notable responses mentioned that the flowsheets (for clinical scoring) were difficult to locate during telephone encounters (mentioned by two different providers). Additionally, two providers mentioned that the tool deviates from their normal workflow, and they were comfortable with the standard workflow.

3.4 Summary and Discussion

Clinical decision support systems are being adopted more and more as a tool, by individual healthcare systems and providers, but also through endorsement at the government level. They are especially being utilized in management of several chronic diseases, including diabetes[73]. Unfortunately, there appears to be a relative deficit in published literature on electronic decision support in IBD. This may reflect that CDSS capabilities are being underutilized in IBD or are not being subject to enough formal evaluation and dissemination through scientific literature. In support of the former, a recent review has called for development of CDSS for Crohn's disease[74].

Looking at the Epic software system specifically, there are only a handful of studies validating their clinical decision support features, and none in IBD.[75–77] Nonetheless, a search of Epic's community library (a shared open source library for disseminating implementations of CDSS designed within Epic) for the term inflammatory bowel disease produces over 2000 results. The level of adoption of these tools, and impacts on clinical process and outcomes, remain largely unstudied.

In the present study, we have described the two phase development and implementation of a CDSS designed to standardize protocols for patients experiencing an acute flare of their IBD. We have characterized the adoption of this CDSS measured by the application rate, with an important finding that the CDSS was utilized to a greater degree by IBD nurses than practitioners (physicians or nurse practitioner). This may represent a greater utility of the CDSS to the nurse than the practitioner. In the University of Alberta clinic, patients are instructed to call the IBD nurse flare line if they experience changes in

symptoms, and so the nurse if often the first contact in the flare pathway. This is supported by our data which shows flare encounters are primarily telephone encounters. Other research has shown that flares are unlikely to coincide with scheduled clinic appointments leading the need and current trend towards rapid access clinics.[78–80] Furthermore, the CDSS is partially passive, in that the SmartSet component must be consciously activated by the provider. Therefore, use of the CDSS does require some habit formation, which may be more easily accomplished by nurses who are encountering these *newly* flaring patients more frequently.

Our primary objective was to demonstrate efficacy of the CDSS to improve adoption to clinical guidelines and best practice. Our data does support this hypothesis, as we found both implementation phases to increase utilization of FCP on before-and-after analysis. Completion of clinical scores was also increased during Phase 1 (before-and-after analysis, and ITS analysis) and remained at the increased level through Phase 2. Univariate and multivariate analysis of Phase II data also provides evidence that use of the CDSS significantly increases the odds of clinical score completion, ordering of flare lab tests, including c-reactive protein, FCP, stool cultures, and *Clostridium difficile* toxin. However, neither of these analyses (BA or univariate) provide very strong evidence for causation. Unfortunately, we did not reach significance in slope change or level changes in any ITS analyses in Implementation Phase II. There are however some convincing trends in flare lab testing, CRP ($p<0.10$), and stool cultures. Our lack of significance could be due to a small sample size, which may account for large variances seen in our data points. Conversely, the significance of clinical scoring in Phase I may be due to the larger than anticipated effect size.

In ITS analysis, it is recommended to have a minimum of 16 data points and 100 observations per data point.[71,67,72] While we met the data point requirement, number of flares per month was consistently under 50 (including April 2019). Therefore, it is unlikely we would have been able to reach 100 even without excluding encounters with null VRs. Future studies to aim to include more data points.

The Workflow Integration Survey (WIS) is designed to show specific reasons for why a CDSS may be not well integrated with the existing system. It is to identify not what problems exist, but where they exist.[64] Overall, scores for all providers, and subset by only nurses, tended to lie close to average (3). Navigation was above 4, which may indicate the CDSS was easy enough to work through and access. Functionality trended towards below average, ignoring standard deviation, which is consistent with a desire for greater functionality, indicated by other questionnaire feedback. There were no significant differences observed between Implementation Phases I and II, which is consistent with the fact that major changes were primarily made to the activation of the BPA to prompt SmartSet use. This change might be expected to improve Navigation subscores of the WIS, which did increase although not with statistical significance.

3.4.1 Limitations and potential bias

These research findings come with a few important limitations and caveats. As mentioned, ITS design and especially BA study design, cannot determine absolute causation of an intervention. It is possible that other changes in clinic structure, release or dissemination of guidelines could lead to changes in care. However, apart from the intervention activation, and the released memo and instructions for use that were

disseminated, there were, to our knowledge, no other educational campaigns, institutional changes, or major publications promoting the specific care guidelines investigated by the study. There were subtle changes in staff, for example the joining of a new IBD physician and leaving of another. However, there were no changes in IBD nurse staff, the main user of the intervention.

The EMR data is also not without potential limitations. Data could be absent for various reasons, including patient reported data that may not be captured automatically, such as over the counter supplementation. However, we do not have any reason to believe that this would bias the intervention and control phases unequally.

We only captured data from orders which were tied to the encounter. If a decision was made to not order labs because they were recently completed, this would not be captured by our extraction. This could be possible with more time, but the SQL coding is significantly more complex to achieve this. It is also likely that the inclusion criteria would reduce this possibility, as we selected for new ("suspected") flares of disease, not already known or suspected to be active disease. Since full flare lab panels are not done regularly in follow-up, these patients should still require the full panel.

As with the research study investigating Aim I, with regard to clinical score completion, we can only determine if the process was documented, not if it was completed but not recorded.

4 CONCLUSION & FUTURE DIRECTIONS

4.1 General Summary of Findings

Through this work, we have retrospectively identified several components of inflammatory bowel disease care at an academic center which could be targets for improvement interventions. Key targets related to IBD flare encounters which were under 80% adherence include the documenting of clinical scores (Harvey Bradshaw Index and Partial Mayo Score), completion of flare lab panel, *C. difficile* testing, and fecal calprotectin, as well as 2-4 week follow-up contact. Key targets related to steroid use include documentation of medication counselling and consenting, and provision of osteoprotective therapy.

Furthermore, we have designed and implemented, in two phases, a CDSS for IBD disease flare through existing electronic medical record software and evaluated the CDSS for impact on adoption of clinical guidelines and local best practices. We have shown moderate adoption and acceptance of this system by providers, particularly IBD nurses, as measured by the system application rate. Findings from the first phase support the hypothesis that the CDSS improved utilization of FCP and documentation of clinical scores. Findings from the second phase support further improvement in ordering of flare lab panel, c-reactive protein, and stool cultures, support by before-and-after analysis and multivariate analysis. In addition, areas for improvement in workflow integration were identified through qualitative questionnaires and feedback forms.

4.2 Implications and Future Improvements

Many potential improvements to the CDSS designed in this work stem from the improved functionality available in future versions of Epic (2019 and beyond). Through Connect Care, the province of Alberta will become unified under a single clinical information system (CIS), which be continually updated with the newest Epic software versions.

A usability issue identified in this work was the accessing of flowsheets to complete clinical scores, which required exiting the existing workflow navigator to a separate screen. In later versions of Epic, flowsheets can be embedded within the visit navigation, which should lead to an improved workflow for providers. This should be designed to promote use of clinical scores for all IBD patients, not just those having disease flare.

Another challenge with was identified during earlier iterations of the CDSS was the inability of the current decision support tools in Epic to support complex multi-provider pathways, and to tie together multiple visits along a pathway. A newer type of decision support tool available in Epic 2019 is called “care paths”. Care paths are an episode type in that allow the tracking of a course of diagnosis/treatment across multiple encounters[81]. They visualize a pathway, including branching, where the patient is, what interventions have been tried, and can be linked to Best Practice Advisories. Future work should investigate how these care pathways (if available in Connect Care) could be utilized to design even smarter and comprehensive clinical decision support.

On the other hand, the CDSS may benefit from some compartmentalization and

generalization in design. For example, one objective of our CDSS was to improve the co-prescribing of osteoprotective therapy with corticosteroids. This may be better and more broadly achieved by targeting steroids at the point of ordering, such as a BPA triggered by steroid orders for patients with an IBD Dx, which then recommends the prescribing of vitamin D and calcium or providing of patient education on self-supplementation. Furthermore, this BPA could have exclusionary logic to not activate when patients have osteoprotective therapy documented in their medication list.

The triggering logic for the CDSS could also be refined and more targeted. For example, determining if a patient has had a test done in a certain time span, and if not, prompting the user to order it. The reverse is also possible, if a test has been ordered recently (for example, clostridium difficile which can only be tested once every two weeks), the CDSS could automatically deselect or prompt the user to remove this order to save downstream resources.

4.3 Unanswered Questions and Areas for Further Research

There are two primary avenues to explore from the results of Study I. First, it would be of interest to replicate this study in broader community and non-academic settings. When including steroid dispensations from any provider (in the PIN database), the proportion of patients receiving >2 steroid doses approached 20%. Identifying communities or practices that are not adherent to current guidelines would be of great utility for educational intervention, or interventions using CDSS.

Additionally, Study I only investigated a small portion of the IBD care continuum. The guideline components from Study I are related to 2 of 16 care pathways developed at the University of Alberta. Future work could investigate biologic guidelines, immunosuppressive guidelines, surveillance guidelines, and inpatient care, just to name a few. Again, it would be ideal if these were measured at a provincial level, and set up to be routinely measured, automatically (as opposed to manual chart review). The coming unified clinical information system (CIS) under Connect Care is expected to aid in the capability to measure and analyze granular data at a provincial level.

In Study I, we elucidated that only 22% of IBD flares had a 2-4 week follow up after commencing steroids. This would be an ideal target for a patient-facing CDSS or patient portal, which could be automated to prompt patients to complete symptom scores and other questions at a specified time frame after steroid dispensation. We know that such a portal is being developed in Alberta for the provincial CIS.

A challenge with Study II was identifying flare encounters, which had to be done manually. This stems from a few problems including a lack of discrete data identifying patients with active disease (clinical scores could be used but as shown in both studies, are not regularly documented as discrete data). It would be of interest and utility for future research to develop a case definition for disease flare (and different types of flare) through administrative provincial datasets. This could include quantitative metrics such as CRP, FCP that predict likelihood of flare, but also a case finding algorithm could be developed using natural language processing (NLP) to parse clinical notes. This has been done in several other diseases[82–84], and some work has been done in IBD to identify phenotypic information from clinic notes using NLP.[85]

As with Research Study I, the methodology of Study II should be expanded to investigate the effects of improved versions of CDSS for IBD on other community clinics and non-academic practices throughout Alberta. While answering a broader research question, a provincial study would also be a higher-powered study, better capable of providing evidence for causation. Other study designs could also be explored, such as those discussed in Chapter 3.2.4, since multiple clinics could be randomized to different interventions or control groups.

In Study II, we did not investigate impact on patient outcomes. This would require a longer follow-up period (ideally 2+years) but is of great importance to investigate. We were also not able to determine the impact of the CDSS on provision of osteoprotective therapy with steroid dispensations (only 12 patients were prescribed steroids through a CDSS encounter).

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APPENDICES

Appendix: Clinical Care Pathways (PDF Versions)

Figure 0-1 CCP #1: Suspected IBD Outpatient Flare (Including Patients on Biologic)

Alberta Health Services

IBD CLINIC UNIVERSITY OF ALBERTA

Inflammatory Bowel Disease Standardized Care Protocols

1. SUSPECTED IBD OUTPATIENT FLARE

Physician/Nurse:

1. Gather information using the Inflammatory Bowel Disease Patient Phone Consultation form (#1).
2. Utilize the information collected to complete the Harvey Bradshaw Index (#2) or Partial Mayo (#3) with the patient; if the patient has an undetermined diagnosis, an HBI will be used.
3. Communicate the completed assessment to the most responsible physician /nurse practitioner within the following timelines:

Timeline	Patient Assessment Guidelines	Mode of communication
Urgent/Emergent	Patient requires immediate intervention/investigation or is able to wait only until the next day in the following cases: - abdominal pain that is not relieved with any intervention - profuse rectal bleeding - new fistula with an elevated temperature - elevated temperature, not improved by intervention - elevated temperature while on biologic therapy - sudden/unexplained change in health status - extensive bloating and pain or unable to pass stool for 48 hours (obstruction)	- page and speak with the physician / NP directly - if plan to admit – refer to "14. IBD ADMISSION – PATIENT CARE ORDERS"
Routine	Patient is able to wait for 2-3 days for intervention/investigation in the following cases: -nausea/vomiting -fistula draining – old site - fecal incontinence/urgency - up at night with diarrhea - more frequent diarrhea - bloating - fatigue - change in daily activity	- send email or EMR message to physician / NP

4. Under the direction of the physician process laboratory/diagnostic imaging investigations based on the assessment:
   a. IBD Flare Labs (#4).
   b. Stool C diff and culture and sensitivity (if have diarrhea) (#5).(CCFA QPI 5)
   c. Stool Fecal Calprotectin (#6), if patient is on Humira use specific requisition (#7).
   d. Ova and Parasite should be added if patient has recently travelled or was camping (#8).
   e. Flat plate of abdomen with 3 views if the patient is experiencing bloating, nausea, vomiting (#9).
   f. Hepatitis B and C testing if negative results are not documented (#10)
5. Deliver requisitions to the patient by one of the following methods:
   - fax requisition to the patient's closest laboratory/radiology centre

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Figure 0-2 CCP #6: Initiation and Maintenance of Corticosteroids

Alberta Health Services

IBD CLINIC UNIVERSITY OF ALBERTA

Inflammatory Bowel DiseaseStandardized Care Protocols

6. INITIATION AND MAINTENANCE OF CORTICOSTEROIDS

Nurse:

1. At the initiation of corticosteroid treatment, ensure that the patient is supplied with:
   - Patient information sheets for the corticosteroid he/she is prescribed (#1, #2, #3 & #4)
   - IBD Flare labs to complete at baseline and at 14 weeks (#5)
   - Fecal Calprotectin (#6) or Fecal Calprotectin for patients on Humira (#7) to do at baseline and at 14 weeks
   - Instructions to take calcium 500 mg po BID and vitamin D 1000 po QD for the duration of corticosteroid therapy
   - If the patient is 65 y.o. and older, consider bisphosphonate at commencement of corticosteroids
   - Consider using Prednisone tapering calendar (#10) or Budesonide tapering calendar (#11) to improve adherence and ensure well-timed completion of corticosteroids' course
2. Complete a telephone interview (#6)and HBI (#7) or Partial Mayo (#8) at 2-4 weeks to ensure response:
   - If there is a significant subjective reduction of IBD symptoms and HBI <5 or Partial Mayo <1:
     a. continue with steroids until tapered
     b. send message to support staff to make follow-up appointment at 16 weeks
   - If there is no adequate response, then consult physician urgently

Support Staff:

1. Arrange clinic follow-up at 16 weeks.

Physician:

1. Issue one corticosteroid prescription of three months only. No repeats.
2. To be given in conjunction with a maintenance agent: azathioprine (immunosuppressant), mesalamine (5-ASA), anti-TNF (biologic). (CCFA QPI 3).
3. Initiate planning for post-corticosteroid therapy.
4. If planning to start biologics, send a message to the nurse to begin biologic work up and paper work. (CCFA QPI 3).
5. If there is not adequate response, then optimize therapy.

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Appendix: CDSS Version 1 - Feedback from IBD Staff

SmartSet Affected	Comment / Issue / Problem
☒**SUSPECTED** ☒**MID-Flare** ☒**POST-Flare**	Completely remove ESR – no longer orderable
☒**SUSPECTED** ☐**MID-Flare** ☐**POST-Flare**	Automatically have stool culture, c.diff , FCP checked? For SUSPECTED only
☐**SUSPECTED** ☒**MID-Flare** ☐**POST-Flare**	IBD Flare panel – doesn't need to be auto checked at 2-4 weeks, not necessarily done – case by case.
☒**SUSPECTED** ☒**MID-Flare** ☒**POST-Flare**	Prebiologic panel – not auto checked – not always done – people may accidentally order
☒**SUSPECTED** ☒**MID-Flare** ☒**POST-Flare**	TB Skin Test – Does not print – have link to website form – nurses have to leave encounter to access these on the EPIC front page links
☒**SUSPECTED** ☒**MID-Flare** ☐**POST-Flare**	POST-FLARE has consultations for biologic therapy + others – this should be on SUSPECTED and MID as well.
☒**SUSPECTED** ☒**MID-Flare** ☒**POST-Flare**	CONSULTATIONS dropdown – IBD clinic link – instead of going to resources – have a link also going directly to Biologic page with all Biologic forms
☒**SUSPECTED** ☒**MID-Flare** ☒**POST-Flare**	Referral to Gastro Small Bowel– link to from IBD Clinic website
☒**SUSPECTED** ☒**MID-Flare** ☒**POST-Flare**	Link biologics to biologics summary page Link CS to "online initiation of CS CCP"
☒**SUSPECTED** ☒**MID-Flare** ☒**POST-Flare**	DIARRHEA? • Stool culture • C. difficile test RECENT TRAVEL OR CAMPING? • Ova and Parasite
☒**SUSPECTED** ☒**MID-Flare** ☒**POST-Flare**	Merge to a single BPA as the following: □ "Click to complete HBI or PMAYO Flowsheet" i) SUSPECTED FLARE ii) MID FLARE ASSESSMENT iii) POST-FLARE FOLLOW UP If not possible, remove mid-flare and post-flare based on provider feedback .

Appendix: Retrospective Study: AHS DRR Data elements requested

Field	Field Name	Description/definition	Data source
ULI	ULI	Patient identifier	PIN
Index Dispense Date	DispenseDt_Index	Date of dispensation of first corticosteroid within time period for each patient	PIN
Dispense Date	DispenseDt	Date of dispensations for subsequent corticosteroid dispensations within 18 months (545 days) after index dispensation	PIN
PRID	PRID	Prescribing practitioner ID	PIN
Study physician dispensation	PRID_STUDY	Flag indicating if corticosteroids dispensed within 18 months after index dispensation were prescribed by one of the study physicians	PIN
Dispensed quantity	Dispense_Qty	Quantity of drug dispensed	PIN
Days Supply	Days_Supply	Dispensed days supply	PIN
DIN	DIN	Drug identification number (as per Appendix Table B)	PIN
Corticosteroid within 18 months	FLAG_CS	Flag indicating if patient had any corticosteroid dispensations within 18 months (545 days) after index dispensation	PIN
Hospitalization within 18 months	FLAG_HOSP	Flag indicating if patient had any hospitalizations within 18 months (545 days) after index dispensation	DAD
ED visit within 18 months	FLAG_ED	Flag indicating if patient had any ED visits within 18 months (545 days) after index dispensation	NACRS
Narcotic analgesic within 18 months	FLAG_NARCOTIC	Flag indicating if patient had any narcotic analgesic dispensations within 18 months (545 days) after index dispensation	PIN
Hosp Admit Date	AdmitDt	Hospital admission date within 18 months after index CS dispensation (all hospitalizations)	DAD
Hosp Discharge Date	DischDt	Hospital discharge date	DAD
Hosp Most Responsible Dx ICD-10	MRDx	ICD-10 code corresponding to Most responsible diagnosis of hospitalization	DAD
Hosp Most Responsible Dx Description	MRDx_Desc	Description corresponding to ICD-10 code	DAD
Hosp IBD Dx Position	ICD10_IBD_Position	Position of IBD ICD-10 code on hospitalization abstract. 0=no IBD diagnosis, 1=Most responsible, 2=second Dx field, 3=third Dx field, etc (max 25 diagnosis fields)	DAD
Hosp IBD ICD-10 Code	ICD10_IBD	Full ICD-10 code corresponding to IBD (K50.*, K51.*), if it exists in any of the 25 diagnosis fields.	DAD

Bypass, small intestine	Bypass_SmallInt	Yes/No based on corresponding CCI code (Appendix A) during hospitalization	DAD
Bypass, small intestine CCI Code	Bpass_SmallInt_CCI	Full CCI code corresponding to Bypass, small intestine (if exists)	DAD
Bypass, large intestine	Bypass_LargeInt	Yes/No based on corresponding CCI code (Appendix A) during hospitalization	DAD
Bypass, large intestine CCI Code	Bypass_LargeInt_CCI	Full CCI code corresponding to Bypass, large intestine (if exists)	DAD
Closure of fistula	Fistula	Yes/No based on corresponding CCI code (Appendix A) during hospitalization	DAD
Closure of fistula CCI Code	Fistula_CCI	Full CCI code corresponding to Closure of fistula (if exists)	DAD
Small Bowel Resection	Resection_SmallBowel	Yes/No based on corresponding CCI code (Appendix A) during hospitalization	DAD
Small Bowel Resection CCI Code	Resection_SmallBowel_CCI	Full CCI code corresponding to Small Bowel Resection (if exists)	DAD
Large Bowel Resection	Resection_LargeBowel	Yes/No based on corresponding CCI code (Appendix A) during hospitalization	DAD
Large Bowel Resection CCI Code	Resection_LargeBowel_CCI	Full CCI code corresponding to Large Bowel Resection (if exists)	DAD
Proctectomy	Proctectomy	Yes/No based on corresponding CCI code (Appendix A) during hospitalization	DAD
Proctectomy CCI Code	Protectomy_CCI	Full CCI code corresponding to Proctectomy (if exists)	DAD
Stricturoplasty	Stricturoplasty	Yes/No based on corresponding CCI code (Appendix A) during hospitalization	DAD
Stricturoplasty CCI Code	Stricturoplasty_CCI	Full CCI code corresponding to Stricturoplasty (if exists)	DAD
ICU After surgery	Surg_ICU	Yes/No indicating if patient was admitted to ICU after any of the above surgeries.	DAD
Hosp Resource Intensity Weight	RIW	Resource Intensity Weight (RIW) corresponding to hospitalization	DAD
Hosp Cost	RIW_COST	Approximate cost of hospitalization, calculated by multiplying RIW by the annual provincial adjustment factor	DAD
ED triage date	TriageDt	Triage Date of ED visit	NACRS
ED discharge date	DischDt	Discharge date of ED visit	NACRS
ED Most Responsible Dx – ICD10	MRDx	ICD-10 code corresponding to Most responsible diagnosis of ED visit	NACRS
ED Most Responsible Dx – Description	MRDx_Desc	Description corresponding to ICD-10 code most responsible diagnosis	NACRS
ED IBD Dx Position	ICD10_IBD_Position	Position of IBD ICD-10 codes (K50.*, K51.*) on ED visit abstract. 0=no IBD diagnosis, 1=Most responsible, 2=second Dx field, 3=third Dx field, etc (max 10 diagnosis fields)	NACRS

ED IBD ICD-10 Code	ICD10_IBD	Full ICD-10 code corresponding to IBD (K50.*, K51.*), if it exists in any of the 10 diagnosis fields.	NACRS
ED Complication -K92.2	Compl_K922	Yes/No flag indicating presence of ICD-10 code K92.2 in any diagnosis field	NACRS
ED Complication -K92.9	Compl_K929	Yes/No flag indicating presence of ICD-10 code K92.9 in any diagnosis field	NACRS
ED Complication –K56.6	Compl_K566	Yes/No flag indicating presence of ICD-10 code K56.6 in any diagnosis field	NACRS
ED Complication –K59.0	Compl_K590	Yes/No flag indicating presence of ICD-10 code K59.0 in any diagnosis field	NACRS
ED Complication –K60.0	Compl_K600	Yes/No flag indicating presence of ICD-10 code K60.0 in any diagnosis field	NACRS
ED Complication –K60.3	Compl_K603	Yes/No flag indicating presence of ICD-10 code K60.3 in any diagnosis field	NACRS
ED Complication –K61.2	Compl_K612	Yes/No flag indicating presence of ICD-10 code K61.2 in any diagnosis field	NACRS
ED Complication –K61.3	Compl_K613	Yes/No flag indicating presence of ICD-10 code K61.3 in any diagnosis field	NACRS
ED Resource Intensity Weight	RIW	Resource Intensity Weight (RIW) corresponding to ED visit	NACRS
ED Cost	RIW_Cost	Approximate cost of ED visit, calculated by multiplying RIW by the annual provincial adjustment factor	NACRS
Narcotic Analgesic - Date	dispenseDt	Date of all dispensations corresponding to ATC Code N02A* within 18 months after index CS dispensation.	PIN
Narcotic Analgesic - DIN	DIN	DIN corresponding to dispensations above	PIN

Appendix: Intervention Codes used to Identify Inflammatory Bowel Disease-related Surgery in the CIHI-DAD

Procedure	CCI Codes
Bypass, small intestine	1NK76.xx, 1NK77.xx
Bypass, large intestine	1NM76.xx, 1NM77.xx
Closure of fistula	1NP86.xx, 1NQ86.xx
Small Bowel Resection	1NK87.xx
Large Bowel Resection	1NM87.xx, 1NM89.xx, 1NM91.xx
Proctectomy	1NQ87.xx, 1NQ89.xx, 1NQ90LAXXG
Stricturoplasty	1NK80.xx, INM80.xx

Appendix: Drug Identification Numbers (DIN) for Corticosteroids

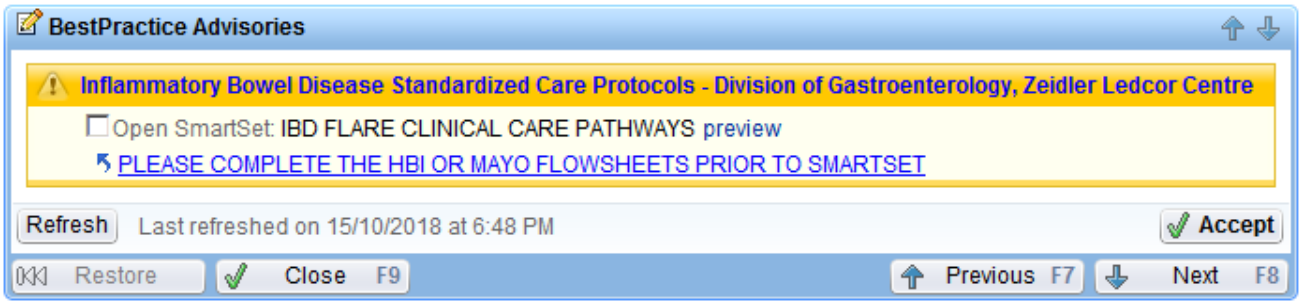
Active Ingredient	Drug	DIN	Strength
PREDNISONE ORAL	APO prednisone tab 50mg	00550957	50 MG
	APO prednisone tab 5mg	00312770	5 MG
	JAA prednisone tab 1mg USP	00868426	1.0 MG
	JAA prednisone tab 50mg USP	00868434	50 MG
	JAA prednisone tab 5mg USP	00868442	5 MG
	Prednisone 50 tab 50mg	00607517	50 MG
	Prednisone tab 5mg	00156876	5 MG
	Teva-prednisone	00021695	5 MG
	Teva-prednisone	00232378	50 MG
	Winpred tab 1mg	00271373	1 MG
BUDESONIDE	Entocort capsule	02229293	3 MG
METHYLPREDNISOLONE	Medrol 16 mg	00036129	16 MG
	Medrol 4 mg	00030988	4 MG

Appendix: Materials Distributed to Providers

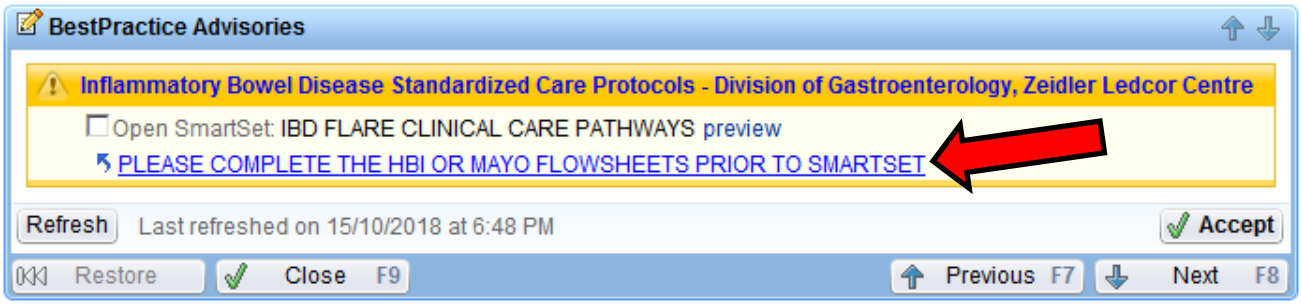
IBD FLARE Clinical Decision Support Tools

The following workflow describes the process for using the IBD Flare CDS Tool in ***eCLINICIAN*** as completed by the GI Physician or Nurse. These tools are designed in accordance with current guidelines and best practices for IBD patients with active disease.

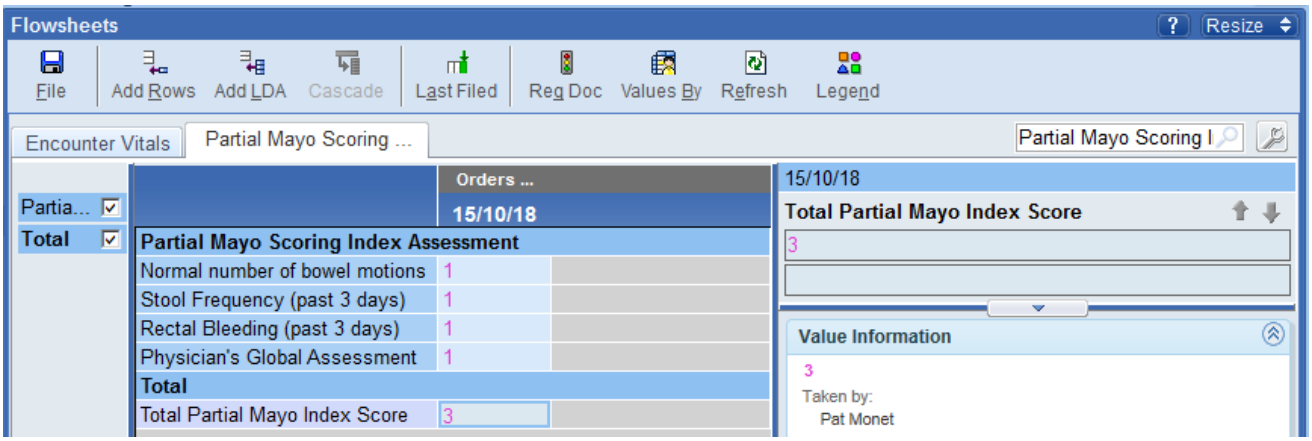
1. In an **Encounter** with *any* IBD patient, a **BestPractice Advisory** will trigger and display as shown:



2. The BPA will prompt you to first complete the mHBI or pMAYO score flowsheet. Click on the blue link as shown:

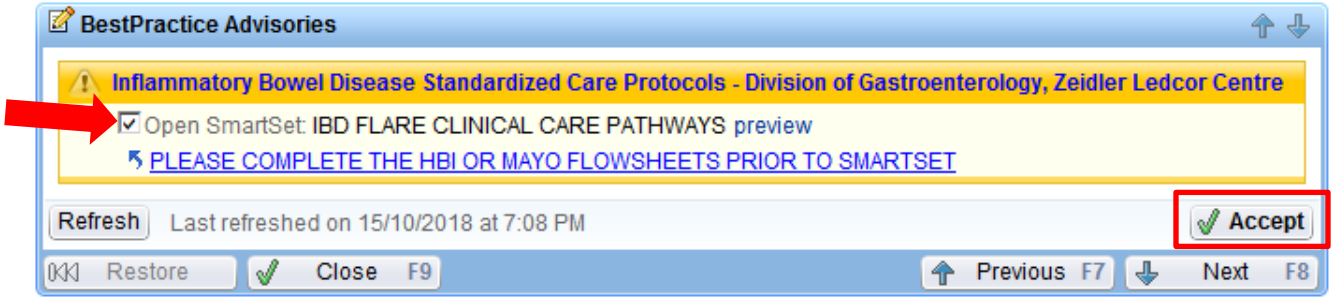


3. The hyperlink takes you directly to the **Flowsheet** activity. Fill out the appropriate clinical scale.
   (These should have been added to your default flowsheet template already, and display automatically).



4. If your patient is suspected to be an IBD flare, return back to the Best Practice Advisory to complete the protocol, via the **Visit Navigator** activity tab.

5. Open the suggested SmartSet under the SmartSet section, by checking the box and then **Accept**.



6. The IBD CLINICAL CARE PATHWAYS **SmartSet** opens. Complete the appropriate **Sections** below:

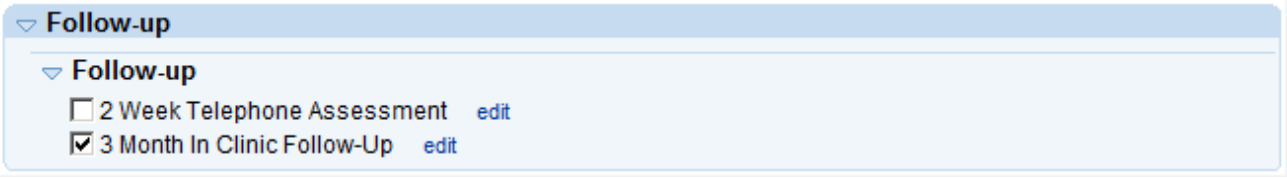
Section I: Labs

Selected by default: IBD Flare Lab Panel, Stool Culture, Clostridium Difficile, Fecal calprotectin

Section II: Imaging, Section III: Procedures, Section IV: Medications, Section V: Consultation (Referrals), Section VI: Billing

Available as needed.

Section VII: Follow-up. Select an option and click **Edit**

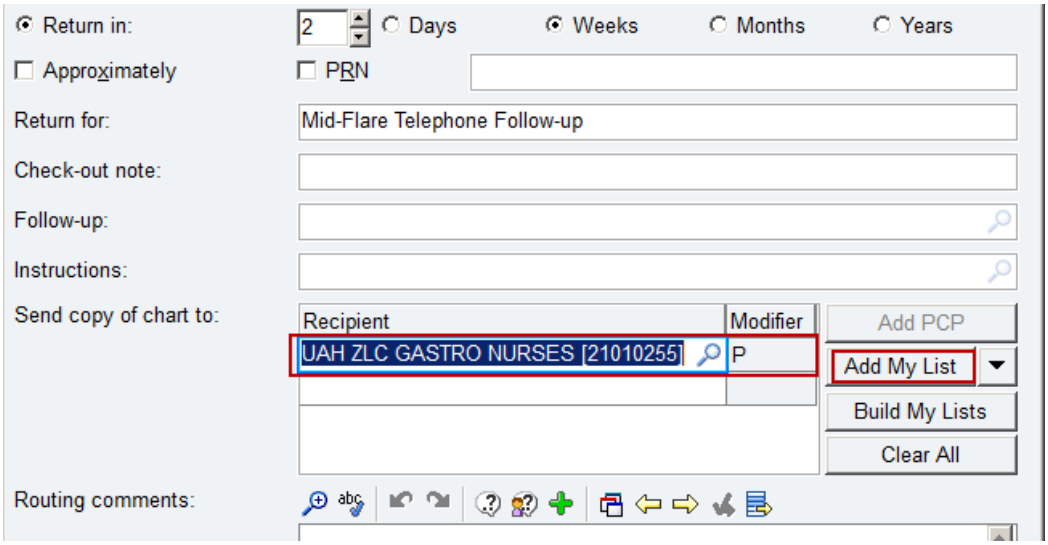


This section is for scheduling follow up encounters:

a) Mid-flare Assessment – Select to request a follow-up call re. the patient's status (following a treatment change, for example).
Use the IBD Nurse Pool, available as **"UAH ZLC GASTRO IBD NURSES"**

b) 3 Month in Clinic Follow-up – Select to request follow-up appointment to be scheduled by your admin.

I. To send an In Basket message (CC'd Chart Message) to an individual or Pool, indicate this in the field below. You can "Personalize" a **quick list** by using the 'Add My List' functionality.



II. Click Accept to return to the **SmartSet**

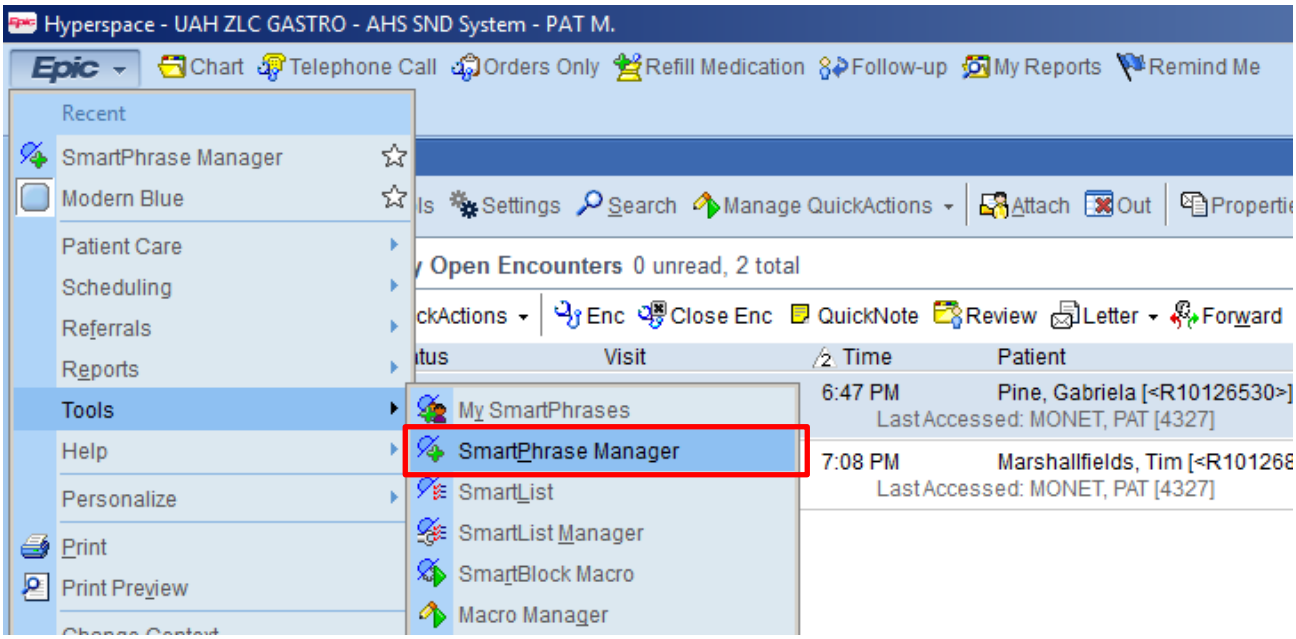
7. Sign and close **SmartSet**
- Any lab tests ordered will print requisition(s) in the exam room (other than FCP, etc).
- Any medications ordered will print prescription(s) in the exam room.
- Billing will be sent automatically to the billing application.
- The Endoscopy procedures will fall on the Schedulable Orders Report.
- Follow Up – In Basket Message will be sent to the recipient(s) you have identified

pMAYO Total Only:	pMAYO Full Sheet:	mHBI Total Only:	mHBI Full Sheet:
.pmayototal	.pmayofull	.hbitotal	.hbifull

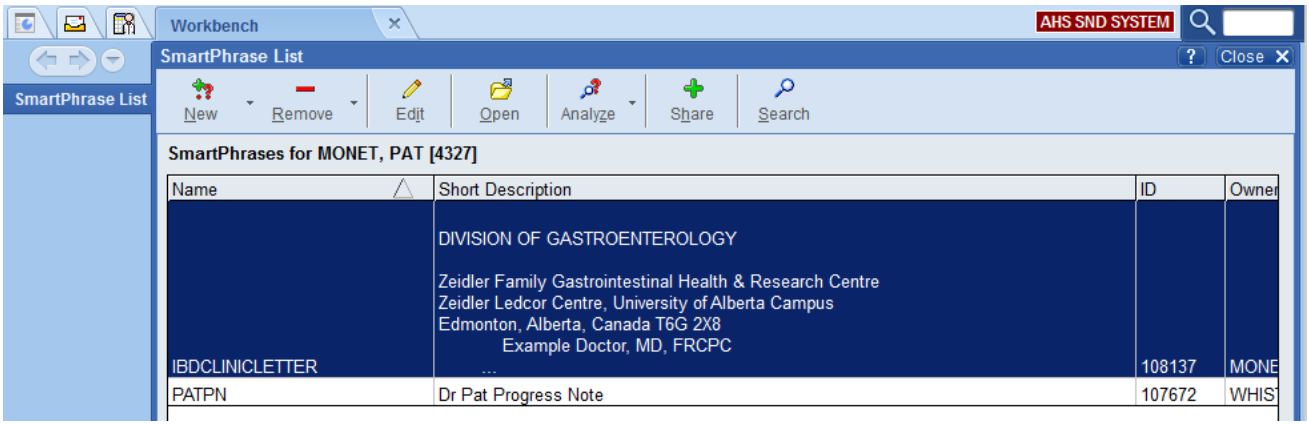
PULLING GI SCALES INTO TEMPLATES

The GI Scales Flowsheets for mHBI and pMAYO, when filled out, collect discrete data that can be pulled in and used in your notes, smartphrases, and templates. The following outlines an example of how to do this.

1. Go to **SmartPhrase Manager:**



2. Your name should already be auto-filled. From there, select **'Go'** and proceed to find your current letter/note that you want to modify:

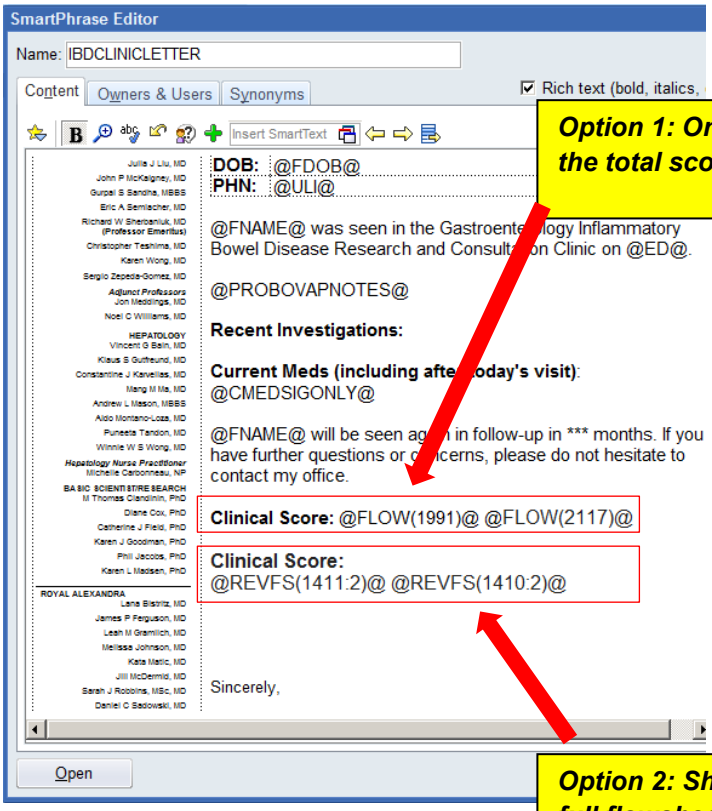


3. Double click and enter the note for editing. From there, you can add in the appropriate **SmartLinks**, which will pull in the flowsheet data from the respective score (mHBI or pMAYO).

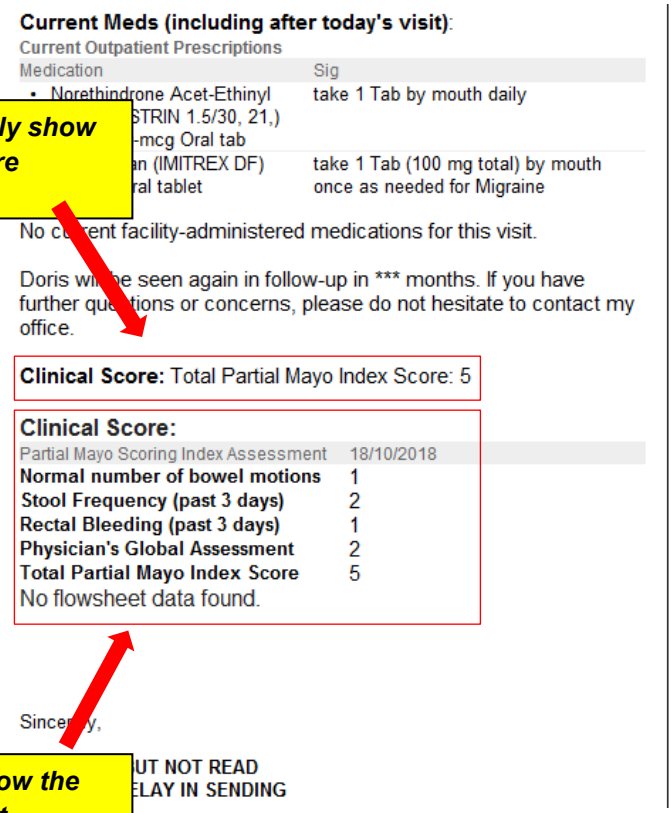
SmartLinks:	**pMAYO Total Only:**	**pMAYO Full Sheet:**	**mHBI Total Only:**	**mHBI Full Sheet:**
	@FLOW(1991)@	**@REVFS(1411:2)@**	**@FLOW(2117)@**	**@REVFS(1410:2)@**

4. Side by side note editing and the result:

Editor



The Output:



Option 1: Only show the total score

Option 2: Show the full flowsheet

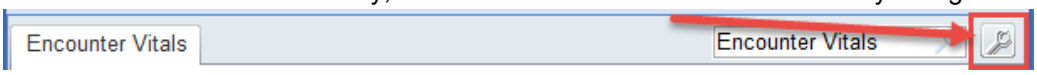
PULLING GI SCALES REAL TIME

We have created and shared 4 *SmartPhrases* to pull in the pMAYO and mHBI scores into *any* note in real time (ie. you do not have to pre-program them into your templates). These can be done using the 'dotphrases' as shown below

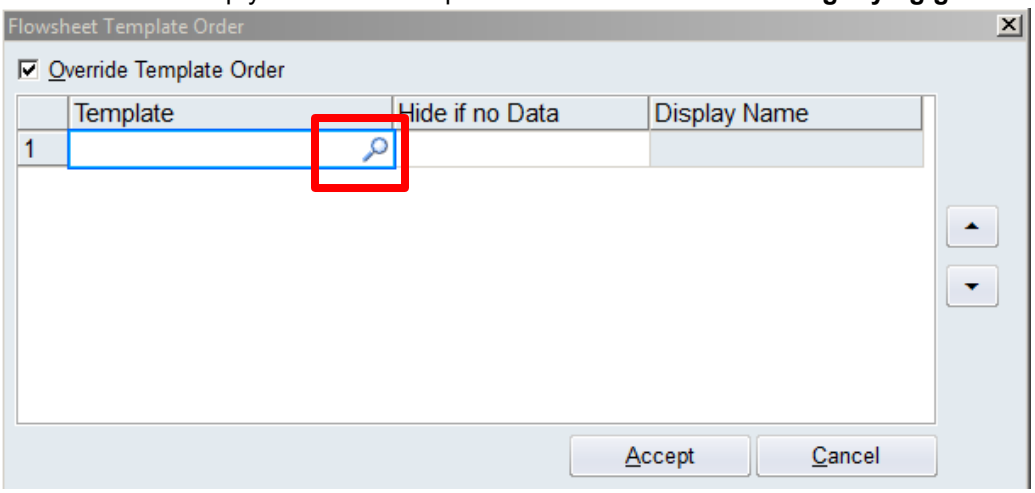
pMAYO Total Only:	pMAYO Full Sheet:	mHBI Total Only:	mHBI Full Sheet:
.pmayototal	**.pmayofull**	**.hbitotal**	**.hbifull**

Personalize! Set the flowsheet to always appear

1. While in the **Flowsheets** activity, click on the **wrench** icon on the very far right.

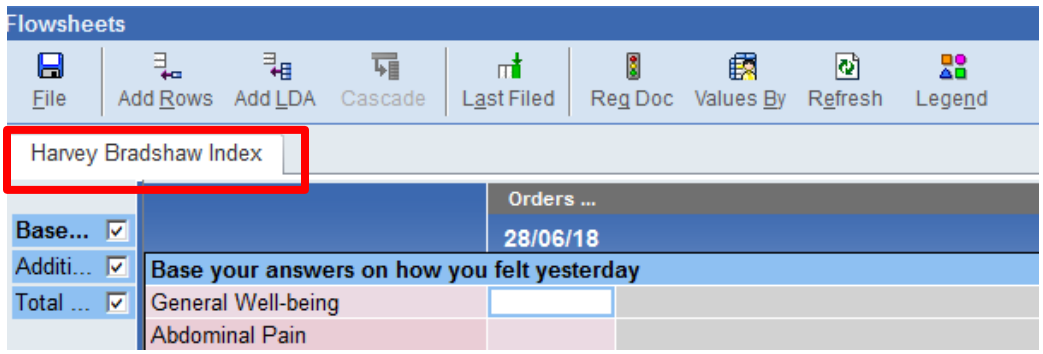


2. Check the checkbox **Override Template Order**.
3. Click in the first empty row in the Template Column and select the **magnifying glass**.

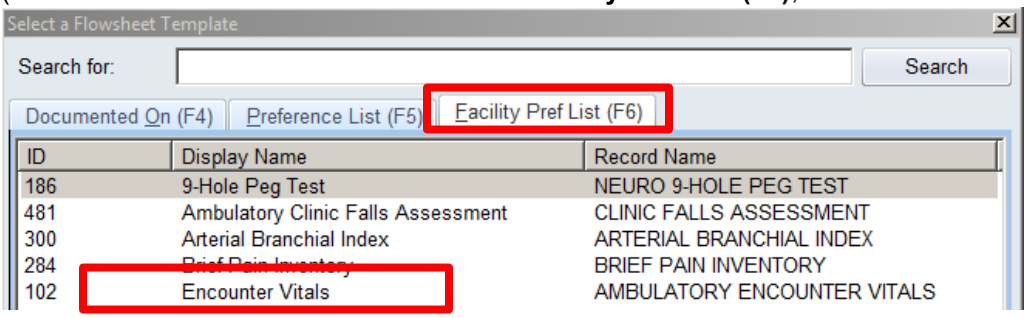


4. Under Preference List (F5), select the flowsheet **Harvey Bradshaw Index**. You may need to search for it.
5. Accept

For all future encounters with any patient, a tab with the **Harvey Bradshaw Index** flowsheet will now be available.



6. You will need to repeat the steps for **Partial Mayo Scoring Index Assessment.**
7. Because we overrode the template, you will also need to add **Encounter Vitals** if you require it (note: Encounter Vitals will be located under **Facility Pref List (F6)**, not **Preference List (F5):**



Appendix: Reasons for Visit Included in Analysis

All Visit Reasons in Dataset	IBD-related Symptoms (Potential)	>70% Yield in Validation Set (April '19)	Included (Final Analysis)
ABDOMINAL CRAMPING	X		X
ABDOMINAL PAIN	X		X
ABNORMAL ECG			
ABNORMAL IMAGING STUDY FINDING			
ABNORMAL LAB FINDING		X	X
ADVICE ONLY			
ANEMIA	X		X
APPOINTMENT			
BACK PAIN			
BLOATED	X		X
CELLULITIS			
CHEST PAIN			
COLON CANCER SCREENING			
COLON POLYPS			
CONSTIPATION	X		X
CONSULT			
DIARRHEA	X		X
DISEASE FLARE-UP	X	X	X
DIVERTICULITIS			
DYSPHAGIA			
ELEVATED LIVER ENZYMES			
EPIGASTRIC PAIN	X		X
ERRONEOUS ENCOUNTER-DISREGARD			
ERROR			
EYE PROBLEM			
FATIGUE	X		X
FEVER			
FOLLOW-UP		X	X
GI BLEEDING	X		X
HEARTBURN			
HEMATEMESIS			
HEPATITIS			

All Visit Reasons in Dataset	IBD-related Symptoms (Potential)	>70% Yield in Validation Set (April '19)	Included (Final Analysis)
HERNIA			
HIP PAIN			
IMMUNIZATIONS			
INFLAMMATORY BOWEL DISEASE	X	X	X
IRRITABLE BOWEL SYNDROME			
IV MEDICATION			
JOINT PAIN	X		X
JOINT SWELLING	X		X
KNEE PAIN	X		X
LABS ONLY			
LEG SWELLING			
LETTER			
LOST REQUISITION			
MEDICAL INSURANCE COVERAGE			
MEDICATION CHANGE	X	X	X
MEDICAITON MANAGEMENT			
MEDICATION PROBLEM	X	X	X
MEDICATIONS REFILL			
MELENA	X		X
MID-FLARE IBD ASSESSMENT	X		X
NASAL CONGESTION			
NAUSEA	X		X
NO SHOW			
NULL			
NURSE PRE-WORK			
ORDERS			
OTHER			
PEER RELATIONS			
PHARYNGITIS			
PHYSICIAN CONSULT			
POST-OP MANAGEMENT			
PREGNANCY PROBLEM			
RASH	X		X
RECTAL BLEEDING	X		X
REFERRAL	X		X
RESEARCH			
RESULTS			

All Visit Reasons in Dataset	IBD-related Symptoms (Potential)	>70% Yield in Validation Set (April '19)	Included (Final Analysis)
REVIEW RESULTS			
ROI OTHER			
SHORTNESS OF BREATH			
SINUSITIS			
SUSPECTED IBD FLARE	**X**	**X**	**X**
TRAVEL CONSULT			
TREATMENT PLAN			
TREATMANT PLAN UPDATE			
VITAMIN D DEFICIENCY	**X**		**X**
WEIGHT LOSS	**X**		**X**

Appendix: Workflow Integration Survey (WIS)

System Evaluation Survey[64]:

Please think about the work involved in using eClinician during IBD flare patient encounters and please rate the extent to which you agree with each of the following statements. Please use the scale below where 1=strongly disagree and 5=strongly agree. Use 'neutral' when you are on the fence between agreement and disagreement, and use 'don't know' when you don't feel the question is relevant or applies to you.

In your assessment, to what extent do you agree that:		**STRONGLY DISAGREE 1**	**DISAGREE 2**	**NEUTRAL 3**	**AGREE 4**	**STRONGLY AGREE 5**	**DON'T KNOW 9**
Navigation	Patient information is easy to find in eClinician.						
	Patient information is easily accessed with eClinician.						
	With eClinician, it is difficult to search for patient information during IBD flare encounters.*						
Functionality	eClinician has all of the functions (e.g., order entry, medication list) needed to complete IBD flare patient encounters.						
	eCLinician helps you perform the tasks (e.g., order entry, progress notes, record review) you need to during IBD flare patient encounters.						
	The same information is entered into eClinician multiple times during IBD flare patient encounters.*						
Usability	eClinician is challenging to use.*						
	eClinician is easy to use.*						
	eClinician is frustrating to use.*						

In your assessment, to what extent do you agree that:		STRONGLY DISAGREE 1	DISAGREE 2	NEUTRAL 3	AGREE 4	STRONGLY AGREE 5	DON'T KNOW 9
Workload	Using eClinician during IBD flare patient encounters adds effort (e.g., typing, clicks).*						
	Using eClinician during IBD flare patient encounters increases workload.*						
	eClinician helps you complete IBD flare patient encounters efficiently.						

Clinical Decision Support (CDS) Addendum Questions[86]

Clinical Decision Support (CDS) is clinical information that is either provided to you or accessible by you, from the EpicCare (eClinician) workstation. We consider enhanced displays such as flow sheets, health maintenance reminders, alternative medication suggestions, order sets or **Smart Sets**, alerts, and access to any internet-based information resources as clinical decision support.

How would you rate the CDS that is currently offered within Epic (eClinician)?		STRONGLY DISAGREE 1	DISAGREE 2	NEUTRAL 3	AGREE 4	STRONGLY AGREE 5	DON'T KNOW 9
Clinical Decision Support	It helps me take better care of my patients.						
	It's worth the time it takes.						
	It reminds me of something I had forgotten about.						

IBD Flare and Corticosteroid Prescribing Guidelines Addendum Questions

To what extent do you agree that:		STRONGLY DISAGREE 1	DISAGREE 2	NEUTRAL 3	AGREE 4	STRONGLY AGREE 5	DON'T KNOW 9
Treating IBD Flares and Prescribing Corticosteroids	With all the steps involved, treating a flaring IBD patient can be very challenging.						
	eClinician sometimes reminds me of something (eg. Test, workup, patient instruction) I had forgotten to do during an IBD flare encounter.						
	With all the steps involved, starting a patient on corticosteroids is a demanding process.						
	eClinician has all of the functions needed to start a patient on corticosteroids effectively.						

Appendix: IBM Computer System Usability Questionnaire (CSUQ)

Computer System Usability Questionnaire (CSUQ)[63,87]

This questionnaire gives you an opportunity to tell us your reactions to the system (eCLINICIAN-integrated IBD flare clinical support system) you used. Your responses will help us understand what aspects of the system you are particularly concerned about and the aspects that satisfy you. To as great a degree as possible, think about all the tasks that you have done with the system while you answer these questions. Please read each statement and indicate how strongly you agree or disagree with the statement by indicating a number on the scale. If a statement does not apply to you, or if you would like to elaborate on your answers, please feel free to indicate in the extra column provided.

	STRONGLY DISAGREE						STRONGLY AGREE	
STATEMENT:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	***COMMENTS:***
1. Overall, I am satisfied with how easy it is to use this system.								
2. It was simple to use this system.								
3. I can effectively complete my work using this system.								
4. I am able to complete my work quickly using this system.								
5. I am able to efficiently complete my work using this system.								
6. I feel comfortable using this system.								
7. It was easy to learn to use this system.								
8. I believe I became productive quickly using this system.								
9. The system gives error messages that clearly tell me how to fix problems.								
10. Whenever I make a mistake using the system, I recover easily and quickly.								
11. The information provided with this system is clear.								

	STRONGLY DISAGREE						STRONGLY AGREE	
STATEMENT:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	***COMMENTS:***
12. It is easy to find the information I needed.								
13. The information provided for the system is easy to understand.								
14. The information is effective in helping me complete the tasks and scenarios.								
15. The organization of the information on the systems screens is clear.								
16. The interface of the system is pleasant.								
17. I like using the interface of this system.								
18. This system has all the functions and capabilities I expect it to have.								
19. Overall, I am satisfied with this system.								
APPENDED ITEMS RELATED TO THE IBD FLARE SMARTSET:								
20. The quality of training documents and communications for this SmartSet was adequate.								
21. It was easy to prescribe medications with this SmartSet.								
22. This SmartSet reflects the current standards of care.								
23. It was easy to reach other IBD team members (nurses, admins) using the Follow-up section of the SmartSet.								
24. Booking follow-up appointments using the SmartSet was fast.								
25. It was easy to complete an IBD flare encounter in a timely fashion using this SmartSet.								

Note: Questions 1-19 comprise the validated Computer System Usability Questionnaire (CSUQ)

Appendix: eCLINICIAN Query Information

Laboratory Testing Identification

ID	Test Name
LAB 2365	TB Skin Test- Does Not Print
LAB472	Hepatitis B Surface Antibody
LAB2271	Thiopurine Metabolites (6-TG and 6-MMP)
LAB2308	Infliximab Antibody Level
LAB258	Ova and Parasite Examination (If patient was traveling or camping recently)
LAB1510	Hepatitis A Immunity (IgG & IgM)
LAB1296	Hepatitis C Antibody
LAB1304	HIV Antibody
LAB2310	Anti-Adalimumab Antibodies
LAB149	C-Reactive Protein
LAB223	Stool Culture
LAB68	Ferritin
LAB294	Complete Blood Count **NO DIFF**
LAB2307	Infliximab Trough
LAB66	Creatinine
LAB112	Alkaline Phosphatase
LAB471	Hepatitis B Surface Antigen
LAB132	ALT
LAB322	ESR-Westergren
LAB2309	Quantitative Analysis of Adalimumab
LAB2366	Fecal Calprotectin - PLEASE provide kit to patient
LAB16	Electrolytes (Na, K, Cl, CO2)
LAB45	Albumin
LAB131	AST
LAB253	Clostridium Difficile Test (Testing will only be performed if stool is not formed)
LAB258	Ova and Parasite Examination (If the patient was traveling or camping recently)

SQL Query for Data Extraction

```
select e.visit_prov_id, s.prov_name, e.enc_type_c, d.NAME enc_name, e.appt_prc_id
 vt_id, vt.prc_name vt_name,
       convert(varchar,e.contact_date,106) enc_date, e.appt_time, e.pat_enc_csn_i
d,
       u.identity_id uli, convert(varchar,p.birth_date,106) DOB, x.NAME Gender,
       EPIC_UTIL.EFN_DATEDIFF('Year',p.birth_date,e.contact_date) age, convert(va
rchar,p.DEATH_DATE,106) deceased,
       g.icd9_code primary_dx, g.dx_name, v.ENC_REASON_NAME,

       stuff(( select ', ' + pl.DX_EXTERNAL_ID from problem_list pl where pl.PAT_
ID = e.pat_id and pl.PROBLEM_EPT_CSN = e.pat_enc_csn_id
             for XML PATH('')), 1, 1, '') list_problems,

       a.bpa, ss.ibd_ss,
       fs1.mayo_score, fs2.hbi_score,
       --e.pat_id,
       t.tobacco_status,  t.tobacco_used_yrs, t.TOBACCO_COMMENT, t.QUIT_DATE
from pat_enc e
left outer join vw_pat_phn_uli u on u.pat_id = e.pat_id
left outer join clarity_prc vt on vt.prc_id = e.appt_prc_id
left outer join patient p on p.pat_id = e.pat_id
left outer join (select u.name tobacco_status, s.TOBACCO_USER_C tobacco_c, s.TOBA
CCO_USED_YEARS tobacco_used_yrs, s.TOBACCO_COMMENT,
                convert(varchar,s.SMOKING_QUIT_DATE,106) quit_date, s.pat_id, s.p
at_enc_csn_id, s.contact_date
                 from social_hx s, zc_tobacco_user u where s.TOBACCO_USER_C = u.T
OBACCO_USER_C) t
                   on t.pat_id = e.pat_id and t.pat_enc_csn_id = e.pat_enc_csn_id
 --and t.contact_date = e.contact_date
--left outer join (SELECT e.PAT_ID, e.pat_enc_csn_id, e.contact_date,
-
-          stuff(( select ', ' + pl.DX_EXTERNAL_ID from problem_list pl where pl.
PAT_ID = e.pat_id and pl.PROBLEM_EPT_CSN = e.pat_enc_csn_id
--           for XML PATH('')), 1, 1, '') list_problems
-
-                  FROM pat_enc e where e.department_id = 1001101210003 and e.con
tact_date >= '2019-03-01' and e.contact_date <= '2019-04-30'
-
-           group by e.pat_id, e.pat_enc_csn_id, e.contact_date) lp on lp.pat_id
= e.pat_id and lp.pat_enc_csn_id = e.pat_enc_csn_id and lp.contact_date = e.conta
ct_date
left outer join (select 'Y' bpa, * from alert where BPA_LOCATOR_ID = 726) a on a.
pat_id = e.pat_id and a.pat_csn = e.pat_enc_csn_id
left outer join (SELECT e.pat_id, e.pat_enc_csn_id, e.contact_date, 'Y' ibd_ss
```

```
                  FROM  pat_enc e where  e.department_id = 1001101210003 and e.c
ontact_date >= '2017-01-01' and e.contact_date <= '2019-05-31'
          and exists (select 'b' from [CLARITY_REPORT].[dbo].[ORDER_SMARTSET] s
where ss_sg_name = 'IBD Flare Labs' and e.PAT_ENC_CSN_ID = s.PAT_ENC_CSN_ID)) ss
          on ss.pat_id = e.pat_id and ss.PAT_ENC_CSN_ID = e.PAT_ENC_CSN_ID and s
s.CONTACT_DATE = e.CONTACT_DATE
left outer join ZC_DISP_ENC_TYPE d on d.DISP_ENC_TYPE_C = e.ENC_TYPE_C
left outer join (select z.dx_name, d.* from pat_enc_dx d, clarity_edg z where PRI
MARY_DX_YN = 'Y' and d.dx_id = z.DX_ID
        and exists (select * from pat_enc x where x.department_id = 1001101210003

        and x.contact_date >= '2017-01-01' and x.contact_date <= '2019-05-
31' and x.enc_type_c in (70,2623,111,50)
        and x.visit_prov_id in (
                                                                        )
        and x.pat_id = d.pat_id and x.PAT_ENC_CSN_ID = d.PAT_ENC_CSN_ID and x.CON
TACT_DATE = d.CONTACT_DATE)) g
          on e.pat_id = g.pat_id and e.pat_enc_csn_id = g.pat_enc_csn_id and e.c
ontact_date = g.contact_date
left outer join (SELECT m.MEAS_VALUE mayo_score, r.PAT_ID, r.INPATIENT_DATA_ID
     FROM [CLARITY_REPORT].[dbo].[IP_FLWSHT_REC] r, IP_FLWSHT_MEAS m where r.FSD_
ID = m.FSD_ID and m.FLT_ID = '145' and m.FLO_MEAS_ID = '1991') fs1
     on fs1.INPATIENT_DATA_ID = e.INPATIENT_DATA_ID and fs1.pat_id = e.pat_id
left outer join (SELECT m.MEAS_VALUE hbi_score, r.PAT_ID, r.INPATIENT_DATA_ID
     FROM [CLARITY_REPORT].[dbo].[IP_FLWSHT_REC] r, IP_FLWSHT_MEAS m where r.FSD_
ID = m.FSD_ID and m.FLT_ID = '149' and m.FLO_MEAS_ID = '2117') fs2
     on fs2.INPATIENT_DATA_ID = e.INPATIENT_DATA_ID and fs2.pat_id = e.pat_id
left outer join (select * from PAT_ENC_RSN_VISIT where line = 1) v on e.pat_id =
v.pat_id and e.PAT_ENC_CSN_ID = v.PAT_ENC_CSN_ID,
clarity_ser s, pat_enc_2 e2, ZC_SEX x
where e.department_id = 1001101210003
  and e.contact_date >= '2017-01-01' and e.contact_date <= '2019-05-31'
  and e.enc_type_c not in (50,109) -- 50 appt, 109 history  --in (70,2623,111,50)
  and e.VISIT_PROV_ID = s.prov_id
  and e.visit_prov_id in (
                                                                        )
  and p.SEX_C = x.RCPT_MEM_SEX_C
  and e.pat_id = e2.pat_id and e.PAT_ENC_CSN_ID = e2.PAT_ENC_CSN_ID
  --
and e.pat_id = v.PAT_ID and e.PAT_ENC_CSN_ID = v.PAT_ENC_CSN_ID and e.CONTACT_DAT
E = v.CONTACT_DATE
order by e.contact_date, e.appt_time
```