Effect of an Electronic Medical Record-Based Clinical Decision Support System on Adherence to Clinical Protocols: An Interrupted Time Series Study in Inflammatory Bowel Disease

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Table of Contents

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Abstract

Background: Electronic medical record (EMR) (also called electronic health record (EHR)) embedded clinical decision support systems (CDSS) have the potential to improve the adoption of clinical guidelines. The University of Alberta Inflammatory Bowel Disease (IBD) Group developed a CDSS for IBD patients with suspected disease flare and deployed it within a clinical information system (CIS) in two continuous time periods.

Objective: This study aims to evaluate the impact of the IBD CDSS on health care provider (physicians and nurses) adherence to institutionally agreed clinical management protocols.

Methods: Two-period interrupted time-series (ITS) design, comparing adherence to a clinical flare management protocol during outpatient visits pre- and post-implementation of the CDSS. Each interruption was initiated with user training and a memo with instructions for use. 7 physicians, 1 nurse practitioner, and 4 nurses were invited to use the CDSS. 31,726 flare encounters were extracted from the CIS database, after which 9,217 were manually screened for inclusion. Each data point in the ITS analysis corresponds to one month of individual patient encounters, with a total of 18 months of data, 9 pre- and 9 post-interruption, for each period. The study was designed in accordance with STARE-HI guidelines for health informatics evaluations.

Results: Following manual screening, 623 flare encounters were confirmed and designated for ITS analysis. The CDSS was activated in 198/623 of the encounters, most commonly in cases where the primary visit reason was a suspected IBD flare. In Period 1, before-and-after analysis demonstrates an increase in documentation of clinical scores from 3.5% to 24.1% (P<.001), which also showed a statistically significant level change on ITS analysis (P=.028). In Period 2, before-and-after analysis showed further increases in ordering of acute disease flare lab tests (47.6% to 65.8%, P <.001), including the biomarker fecal calprotectin (27.9% to 37.3%, P=.028), and stool culture testing (54.6% to 66.9%, P=.005), the latter which is a test used to distinguish a flare from an infectious disease. There were no significant slope or level changes on ITS analyses in Period 2. The overall provider adoption rate was moderate at approximately 25%, with greater adoption by nurse providers (used in 30.5% of flare encounters) than physicians (used in 6.7% of flare encounters).

Conclusions: This is one of the first studies to investigate the implementation of a CDSS for IBD designed with a leading EMR software (Epic Systems, Verona, WI, USA), providing initial evidence of an improvement over routine care. Several areas for future research were identified, notably the effect of CDSS on outcomes, and how to design CDSS with greater utility for physicians. CDSS for IBD should also be evaluated on a larger scale, which can be facilitated by regional and national centralized EMR systems.

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Keywords: Inflammatory Bowel Disease; Decision Support Systems, Clinical; Interrupted Time Series Analysis; Implementation Science

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evaluated on a larger scale, which can be facilitated by regional and national centralized EMR systems.

Introduction

Limited or delayed adoption of professional society developed clinical care guidelines into practice is a common problem in medicine [1,2]. In 2007, researchers estimated that it took 17 years on average for only 14% of published evidence in guidelines to be translated into clinical practice [3,4]. One purported reason is that clinical guidelines by themselves are not actionable, because they largely describe what to do, but not how to do it [5,6].

Clinical decision support systems (CDSS) are tools that can be employed to support provider decision making. CDSS use clinical, patient, and other health information to supply providers with recommendations to assist in a variety of aspects of care, including diagnosis, treatment, and management [7,8]. Recent systematic reviews suggest that the use of CDSS in clinical settings can improve practitioner performance in relation to their adherence to best practice guidelines [7,9].

There are several demonstrated gaps in the adoption of professional society clinical care guidelines and best practices for inflammatory bowel disease (IBD). These include practices in medication management, preventative care, and bone health. [10,11]. The University of Alberta IBD outpatient clinic (Edmonton, Alberta, Canada) has previously developed and implemented several clinical care pathways (CCP) to consolidate best practices for IBD [10,12]. To further increase adoption, a clinical decision support (CDS) project was undertaken to integrate the pathways into the local electronic medical record (EMR). There are thousands of CDS built and deployed within commercial EMRs [13,14], yet there are few published evaluations of EMR-based CDSS' in IBD [15,16]. Consequently, the objective of this pilot study was to evaluate the effectiveness and provider acceptance of an EMR-integrated CDSS in the context of inflammatory bowel disease.

Methods

Organizational Setting

The study was conducted in the Comprehensive Academic Outpatient Center at the University of Alberta Hospital, which provides care for IBD patients in the Greater Edmonton region and rural and remote communities across Alberta, Canada. It also serves a small number of IBD patients from Saskatchewan, Northwest Territories, and British Columbia.

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 Epic EMR (Epic Systems., Verona, WI, USA), being used in Edmonton, Alberta for outpatient medical care (customized

and branded locally as eCLINICIAN). 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.

As Epic is a general-purpose EMR, CDS functionality is built in. For example, generic functionality such as alerting the user when duplicate orders exist. More specialty-specific CDS functionality are often customized at the request and guidance of end-users.

Functionality can be administered through a number of tools, including those referred to by Epic as ‘Flowsheets’ (documentation tables), ‘Best Practice Advisories (BPA)’ (alerts) [17] and ‘SmartSets’ (grouping of orders and clinical content) [18].

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

System Interruption / Intervention

The system interruption / intervention uses a BPA appearing in the clinician’s navigator workflow. The BPA is triggered by the existence of IBD in the patient problem list or visit diagnosis fields. The BPA (Figure 1) prompts the clinician to complete clinical symptom indices (modified Harvey Bradshaw Index (mHBI) [19] for Crohn’s disease or partial Mayo Score (pMAYO) [20] for ulcerative colitis) for the encounter. If the score is indicative of a disease flare, the BPA instructs the user to activate a corresponding SmartSet.

The SmartSet offers 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 and flare protocol for the clinic. For example, during a flare encounter, the IBD flare lab panel and fecal calprotectin tests are automatically selected for ordering (but can still be deselected by the provider). A snapshot of the SmartSet portion of the CDSS is shown in (Figure 2).

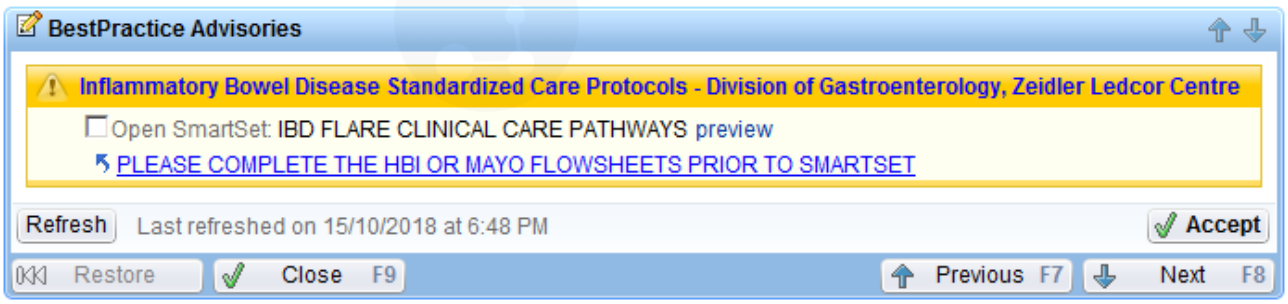


Figure 1: Snapshot of the IBD flare CDSS, showing the initial Best Practice Advisory (BPA). BPAs act as alerts that presents targeted patient-specific guidance to users. They can be active (disruptive popups) or passive (navigation workflow) and can link to actions such as placing orders, order sets, initiating a care plan,

or sending a message. This alert appeared passively in the providers workflow navigation whenever IBD was in the patient problem list.

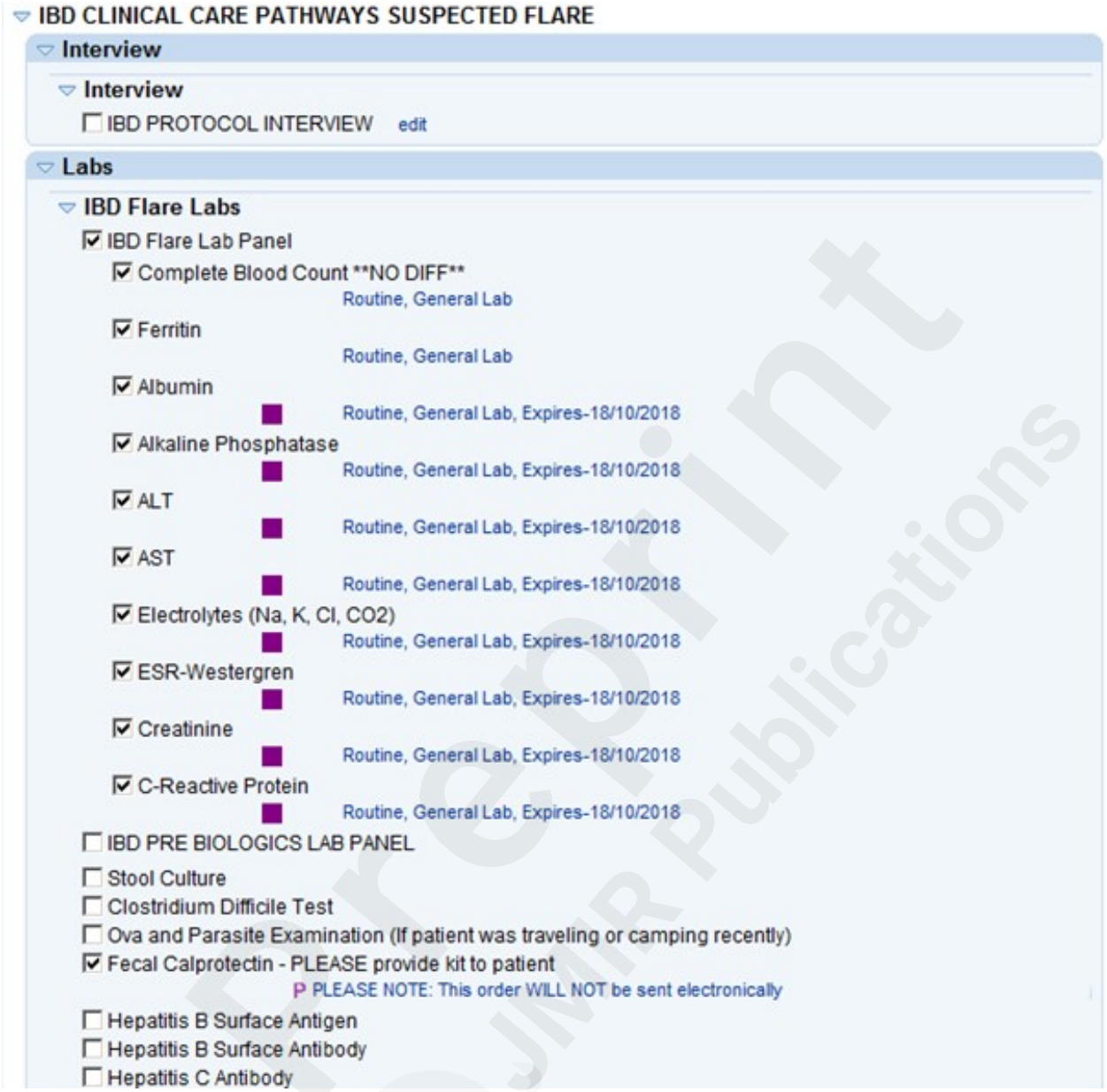


Figure 2. Snapshot of the IBD flare CDSS, showing the SmartSet, which presents after activation by the BPA. Not all sections of the SmartSet shown, including sections for medications, imaging investigations, billing, and follow-up appointment booking.

Study Design

The study used a pre- and post-implementation interrupted time-series (ITS) design, the interruption being the enhanced CDSS used within the EMR. Each data point was chosen to be one month of clinical encounters. For each intervention period there was a total of 18 data points, 9 before and 9 post-intervention. See (Multimedia Appendix 1) for elaboration on the rationale for using ITS design.

Physicians at the participating clinic were not guaranteed to have outpatient clinics on a weekly basis due to their service rotation; therefore, the decision was made to aggregate the data points by month as opposed to by week. This avoided the potential week-to-week variation and ensured an adequate number of individual patient encounters (IBD flares) was achieved for each data point.

The Quality Criteria for Interrupted Time Series (ITS) Designs checklist was used in study design and assessment of appropriateness [21], as well as the STARE-HI guidelines for health informatics evaluations [22,23].

Participants

All IBD care providers at the University-based outpatient clinic were included in the study and invited to use the CDSS, including 7 IBD specialist clinicians1 IBD nurse practitioner (NP), and 4 IBD specialist nurses. The term “IBD practitioner” will be used to collectively refer to IBD specialists and IBD NP.

To be included in the dataset, patients had to be under care of the IBD providers, with age ≥ 18 years, and a diagnosis of Crohn's disease, or ulcerative colitis confirmed by imaging, pathology, or endoscopy report. They also had to be experiencing a flare of the disease during the included encounter, as defined by clinical score (mHBI > 5, pMAYO > 2) or noted symptoms in combination with physician judgement. Only initial encounters in a flare episode spanning multiple encounters, were included.

Study Flow

The intervention was implemented and evaluated in two continuous periods (Figure 3): first a pilot version was trialed by IBD nurses (Implementation Period 1), and then the polished version was implemented across all providers in the division (clinicians, nurse practitioners, and IBD nurses) as Implementation Period 2. The pilot version was trialed beginning in September 2017 and 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 (Multimedia Appendix 2) to inform further improvement to the CDSS.

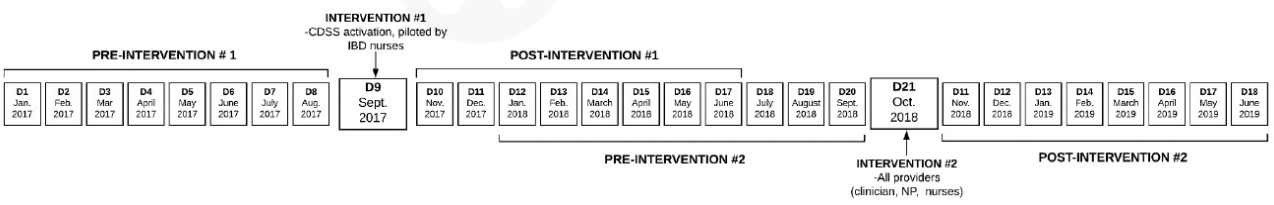


Figure 3. Study design diagram of two-period interrupted time series. First the CDSS was implemented as a limited pilot with IBD nurses (intervention #1), then fully implemented across all providers (intervention #2). Each data point (abbreviated D) corresponds to one month of clinical encounters by study providers.

After collecting feedback on from the pilot, further changes were made to the CDSS. Aside from minor modifications to update included lab tests, the most significant change was the consolidation of the three separate Smart Sets into one, targeting the “Suspected Flare”, the first step in the care pathway. The activation of the BPA in the initial CDSS was entirely manual and dependent on the provider entering a specific visit diagnosis. In the full version, the BPA was set to automatically trigger by the presence of an IBD diagnosis in the patient problem list. With this change, we expected to improve adoption and ease of use of the SmartSet for flare encounters.

The full implementation of the CDSS began October 10, 2018. An instructional memo with paper-based workflow and educational material were sent to each provider (Multimedia Appendix 3). 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 also presented at weekly clinical rounds, with an opportunity to ask questions.

Outcome Measures

Process indicators were used to measure the proportion of adherent IBD practitioner flare encounters. These include completion of clinical score (mHBI or pMAYO), laboratory testing including standard lab panel, fecal calprotectin, stool cultures, *C. difficile* toxin (only if diarrhea present), measurement of vitamin D / calcium in conjunction with corticosteroid prescription, patient information given and documented, and modification of maintenance therapy. A secondary outcome was adoption/acceptance of the CDSS measured by application rate (ratio of CDSS applied to CDSS available for activation).

Methods for Data Acquisition and Measurement

Potential encounters in the pre- and post-intervention periods were initially identified by querying the eCLINICIAN EMR database for encounters with the included IBD providers, where patients had a documentation of IBD in their problem list or diagnosis field (ICD coding). A sampling method was used to exclude encounters with specific reasons-for-visit (VR) deemed unlikely to constitute a flare based on exploratory analysis of the dataset. Examples of excluded VR included ‘medication refill’, ‘medical insurance coverage’, and ‘review results’ (a more detailed description of the sampling method is available in a previous publication [10]). Encounters were then screened for inclusion and exclusion eligibility manually by the study author (RTS) and a research assistant.

Data for primary outcome measures were also queried and extracted from the EMR database, in collaboration with the eCLINICIAN Reporting Team, Alberta Health Services (AHS). The various database codes and IDs, as well as the final structured query language (SQL) queries used to extract data are included in the (Multimedia Appendix 4).

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 median and IQR for non-normally distributed continuous variables. Proportions were compared by using Pearson's chi-squared test [24].

A segmented regression analysis was performed for each primary outcome variable, to determine the level and slope in the pre-intervention period and the change in level and slope in the post-intervention period on the mean percentage of adherent encounters [25]. Autocorrelation was tested for in the residuals using the Durbin-Watson test.

Data analysis was performed using IBM SPSS Statistics 23 (IBM Corp, Armonk, NY, USA) and R 3.5.1 (RStudio Inc, Boston, MA, USA) [26]. A confidence level of 95% was used in all analysis unless otherwise specified.

Sample Size Determination

Sample size was first calculated for pre- and post-implementation cohorts based on logistic regression (Multimedia Appendix 5). With power equal to 0.80, Type I error set to 5%, the sample size required was approximately 634 for small effects, and 145 for medium effects [27]. 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 [28]. Sample size was calculated using G*Power. 3.2.9.2. [29].

There is no standard method for determining power in time series analysis. However, a 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 [30]. It is also generally recommended in the literature to have over 100 observations per data point [25,31].

Results

Initial dataset and pre-processing

(Figure 4) shows the study flow diagram. The complete, extracted dataset includes 31,726 encounters, spanning 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). Of note, there is overlap between both implementation periods (Figure 3), thereby, a number of flare encounters appear in both analyses.

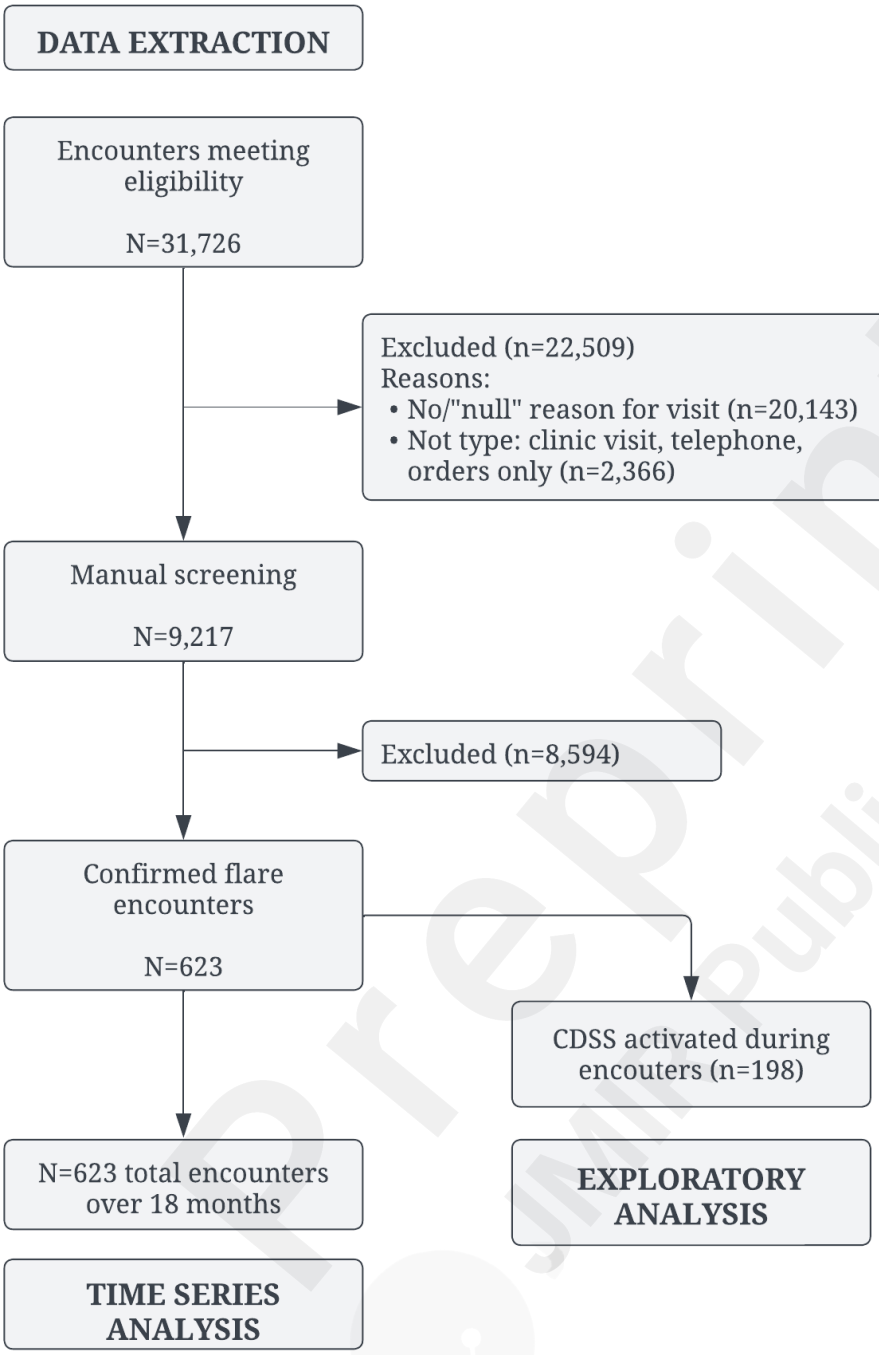


Figure 4: Flow data diagram for data extraction, screening, and analyses.

Demographics of CDSS-enabled encounters

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. This left 198 encounters, which are detailed in (Table 1). More detailed demographics of providers using the system are included in (Multimedia

Appendix 6).

Table 1. 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)
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 monotherapy	59 (29.8)
	Biologic combination therapy	31 (15.7)
Encounter Characteristics		
Encounter Type		
	Telephone	139 (70.2)
	Orders only	32 (16.2)
	Clinic visit	27 (13.6)
First Encounter Diagnosis		
	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)
Visit Reason		
	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)

Demographic variable		Study population (N=198)
	Medication Problem	1 (0.5)

Study findings and outcome data

Exploratory analysis of adherence to clinical protocols

Symptom documentation

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

Laboratory investigations

Full flare lab panels, including complete blood count (CBC), ferritin, electrolytes, creatinine, albumin, alkaline phosphatase, alanine transaminase (ALT), aspartate transaminase (AST), and C-reactive protein (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 (FCP) was ordered at the encounter for 147 / 198 (74.2%) patients, and within 1 month of the encounter for a further 36 / 198 (18.2%). This leaves 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 with liquid stool or diarrhea 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 adjusted or added. In contrast, 37 (20%) of the 185 patients who were not prescribed steroids had maintenance therapy adjusted (P=.015, chi-squared).

Vitamin D or calcium supplementation was recommended for 8/12 (66.7%) patients prescribed steroids and 8/10 (80%) when excluding patient with vitamin D / calcium supplementation documented in their medication list.

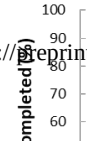
Implementation Period 1: Pilot Version, IBD Nurses

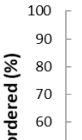
Implementation Period 1 includes data from January 2017 to June 2018 (18 months), where September 2017 and beyond were labelled as the active intervention months (post-intervention). 502/623 of the total confirmed flare encounters occurred during Implementation Period 1 (Figure 3). (Table 2) compares outcome measures between pre- and post-intervention using chi-squared. Notably, there was a substantial increase in the proportion of flare encounters with completed clinical scores from 3.5% (8/228) to 24.1% (66/274) post-intervention. There was also an increase in proportion of flare encounters with fecal calprotectin ordered, from 16.7% (38/228) to 27% (74/274).

Interrupted time series analysis was done for outcomes which were significant on before-and-after analyses (Figure 5). For clinical score completion rates, there was no slope change (estimated beta [95% CI] of -1.22 [-4.44-2.01], *P*=.431) but was a level increase (estimated beta [95% CI] of 19.0 [2.39-35.60], *P*=.028). For calprotectin testing, there was no slope change (estimated beta [95% CI] of -2.45 [-6.21-1.32], *P*=.185) or level change (estimated beta [95% CI] of 14.77 [-4.63-34.17], *P*=.125).

Table 2. Before-and-after of process measures from Implementation Period 1, chi-squared.

Parameter	Pre-intervention N = 228	Post-intervention N = 274	P-value
	n (% of N)	n (% of N)	(chi^2)
CDSS Activated			
	0 (0.0)	66 (24.1)	<.001
Clinical score completed			
	8 (3.5)	66 (24.1)	<.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





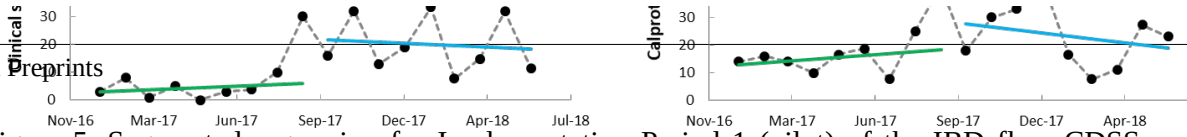


Figure 5. Segmented regression for Implementation Period 1 (pilot) of the IBD flare CDSS on rates of a) clinical score completion and b) calprotectin testing.

Implementation Period 2: Full CDSS, All Providers

Implementation Period 2 includes data from January 2018 to June 2019 (18 months), where October 2018 and beyond were post-intervention months. 492/623 of the total confirmed flare encounters occurred during Implementation Period 2 (Figure 3). (Table 3) compares outcome measures between pre- and post-intervention using chi-squared. There were increases in the proportion of flare encounters with completed flare labs (47.6% (109/229) to 65.8% (173/263)), CRP ordered (64.2% (147/229) to 78.7% (207/263)), calprotectin ordered (27.9% (64/229) to 37.3% (98/263)), and stool cultures ordered (54.6% (125/229) to 66.9% (176/263)).

Table 3. Before and after of process measures from Implementation Period 2, chi-squared.

Parameter	Pre-intervention N = 229	Post-intervention N = 263	p-value
	n (% of N)	n (% of N)	(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%)	<.001
C-reactive protein ordered			
	147 (64.2%)	207 (78.7%)	<.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

Interrupted time series analysis for significant outcomes is shown in (Figure 6), and accompanying betas for slope change and level change with 95% confidence intervals, are shown in (Table 4). For Period 2, there were

no slope or level increases which reached significance at P=.05, although CRP testing and stool culture testing would be significant for a level increase at P=.10.

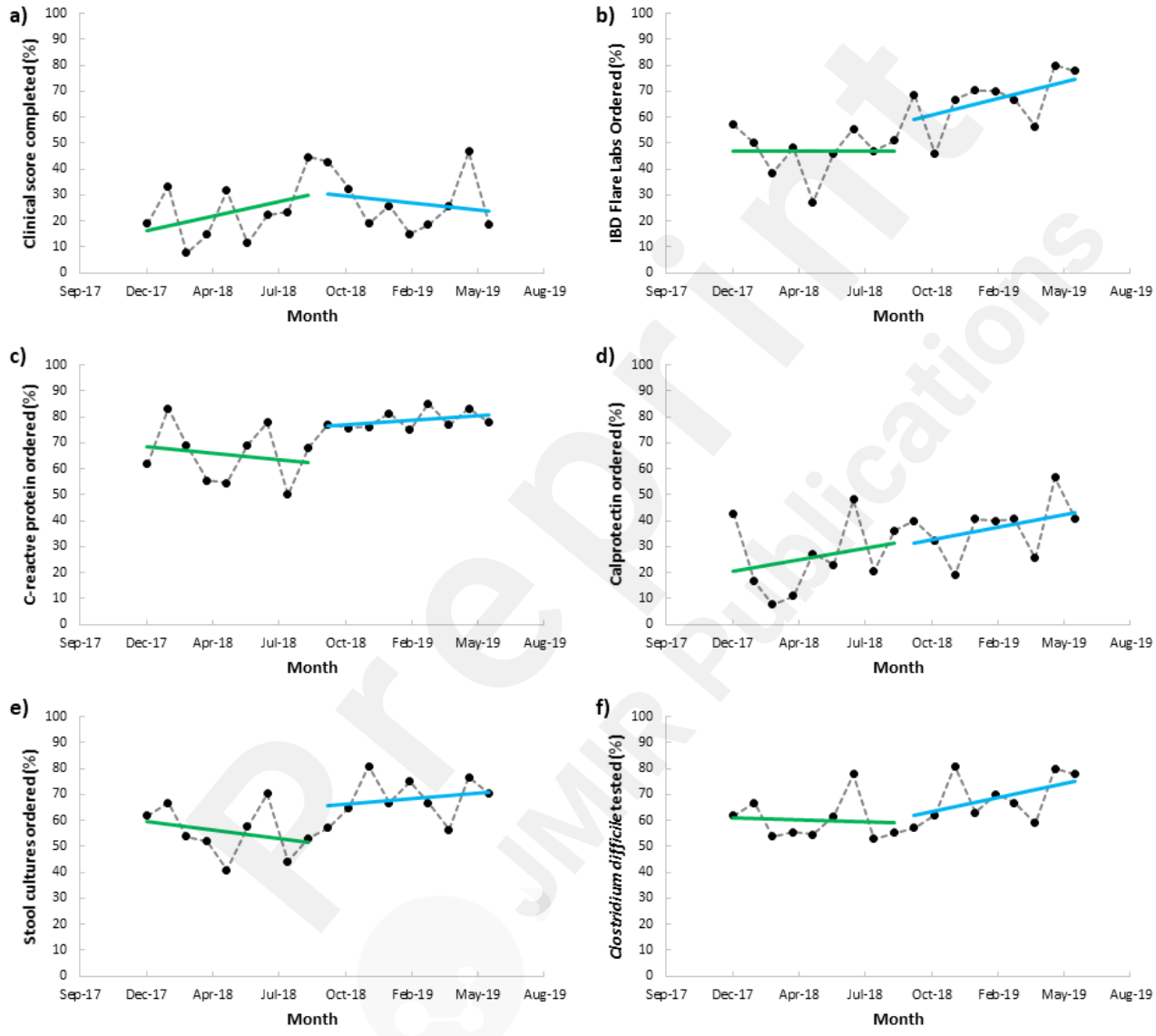


Figure 6. Segmented regression for Implementation Period 2 of the IBD flare CDSS on rates of a) clinical score completion, b) flare lab testing, c) CRP testing, d) calprotectin testing, e) stool culture testing, and f) *C.difficile* testing.

Table 4. Parameters for segmented logistic regression analysis of the IBD CDSS in Implementation Period 2.

Parameter	Beta	95% CI	p-value

Application rate			
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			
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
IBD flare lab tests ordered			
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			
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
Fecal calprotectin ordered			
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			
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* ordered**			
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

Discussion

Answering the study question

In this study, we evaluated the effectiveness of a CDSS which aimed to standardize protocol for IBD patients experiencing an acute disease flare. An increase in several practices was demonstrated following CDSS implementation, including increased utilization of FCP. Completion of clinical scores was also increased during Period 1 of implementation (before-and-after and ITS analysis) and remained increased through Period 2.

We did not reach significance in slope change or level changes in any ITS analyses in Period 2. This could be due to sample size, which may also account for the large variance seen in some data points. There were however some encouraging upward trends in flare lab testing, CRP (P<0.10, ITS analysis), and stool cultures.

In characterizing the adoption of this CDSS by the application rate, an interesting finding was that the CDSS was utilized more by IBD nurses than practitioners. This could represent the nurses' increased experience with the CDSS from the pilot phase and our CDSS focus on decisions related to patients experiencing a disease flare. In the University of Alberta clinic, patients are instructed to call the IBD nurse flare line if they

experience changes in symptoms, and so nurses are often the first contact in the flare clinical 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 which aligns with the current uptake in remote monitoring and rapid access clinics [32-34].

Our observed CDSS use by the specialized IBD nurses is in contrast to several other studies that have demonstrated that nurses are less likely to use CDSS when making decisions about care they are experienced and confident in delivering, especially in the case of telephone triage decisions [35-37]. Our results could be a product of the integration of the nurses' feedback after the pilot phase, a strategy that may have increased the utility of the CDSS for the nurses. This highlights recommendations from other research that emphasizes the importance of engaging all stakeholders, but especially end-users in the design of CDSS [38,39].

Limitations of the study

These are several limitations of this research. While the ITS design allows for better characterization of temporal changes than before-and-after analysis, it is still possible that other changes such as clinic structure, release or dissemination of guidelines could have led to the changes observed. However, apart from the intervention activation and the released memo and instructions for use that were disseminated, to our knowledge there were 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, who were the primary users of the CDSS.

In contrast to the advantage that our two phased design provided regarding the opportunity for feedback from nurses, the design may have hindered our ability to demonstrate change. Because we used the same group of IBD nurses in the pilot (Phase 1) and implementation (Phase 2), our baseline usage prior to the beginning of Phase 2 had already started. This may have accelerated the observed uptake speed of the CDSS by practitioners and could have also led to an underestimation of the changes before and after the Phase 2 implementation.

Sample size is another limitation. In ITS analysis, it is recommended to have a minimum of 16 data points and 100 observations per data point [25,30,31]. While we met the data point requirement, number of flares per month was consistently under 50. Future studies should aim to include more data points, which may require multi-site participation. Unfortunately, at the time of this study, the EMR software was only in deployment at a single site.

We only captured data from orders which were tied to the encounter. If a decision was made to not order labs for any reason (for example, they were recently completed), they would not be captured by our extraction. As

a consequence, estimates of protocol adherence could be deflated.

Finally, it is important to note that for process measures that depend on manual data entry, such as clinical score completion, this research method can only determine that a process was not documented as completed, but not necessarily that it was not completed. This may have resulted in underestimates of protocol adherence.

Future directions

The currently available CDSS system in this study was limited in its ability to support complex multi-provider pathways, and to tie together multiple visits along a pathway. More advanced CDSS workflows should be investigated in future versions of the CDSS software, and evaluated for effectiveness.

Triggering logic for CDSS should also be precisely 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. This was not possible with the resources available in our CDSS environment.

In extracting data for analysis, a significant challenge was identifying flare encounters based on EMR data. The problem stems from a lack of discrete data identifying patients with active disease (clinical scores were not regularly documented as discrete data). Future research should seek to develop a case definition for disease flare through administrative provincial datasets. This could include quantitative metrics such as CRP and FCP that predict likelihood of flare, but also the integration of a case finding algorithm that uses natural language processing (NLP) to parse clinical notes. This strategy has been explored in several other diseases and has been shown to significantly improve case detection [40]. Some work has been done in IBD to identify phenotypic information from clinic notes using NLP [41].

The methodology used in this research should be expanded to investigate the effects of improved versions of CDSS for IBD on other community clinics and non-academic practices throughout Alberta. Cluster-randomized designs or stepped-wedge designs could be explored since multiple clinics could be available for randomization.

This study did not investigate impact on patient outcomes, which would require a longer follow-up period (ideally 2 or more years). Nonetheless, long term patient outcomes for CDSS are of great importance [9] and should be explored in the future.

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Conflicts of Interest

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Author Contributions

RTS contributed to study design, data collection, analysis, and manuscript drafting. KDC contributed to drafting and revision of the manuscript. DP, DCS, DCB contributed to critical revision of the manuscript. KIK contributed to study design, analysis and critical revision of the manuscript. All authors approved the final version. KIK is the guarantor of the article.

Data Sharing Statement

The data and analysis scripts that support the findings of this study are available from the corresponding author, KIK, upon reasonable request.

References

1. Davis DA, Taylor-Vaisey A. Translating guidelines into practice: a systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. Can Med Assoc J. 1997;157(4):408-416.

2. Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH. Why don't physicians follow a framework for improvement. J Am Med Assoc; 1999;Vol 282:1458-1465. doi:10.1001/jama.282.15.1458

3. Westfall JM, Mold J, Fagnan L. Practice-based research - "Blue highways" on the NIH roadmap. J Am Med Assoc; 2007;297(4):403-406. doi:10.1001/jama.297.4.403

4. Balas EA, Boren SA. Managing clinical knowledge for health care improvement. Yearb Med Inform; 2000;09(01):65-70. doi:10.1055/s-0038-1637943

5. Shortliffe T. Medical thinking: what should we do? Published 2006. Accessed February 16, 2018. http://www.openclinical.org/medicalThinking2006Summary2.html

6. Vander Schaaf EB, Seashore CJ, Randolph GD. Translating clinical guidelines into practice: challenges and opportunities in a dynamic health care environment. N C Med J; 2015;76(4):230-234. doi:10.18043/ncm.76.4.230

7. Garg AX, Adhikari NKJ, McDonald H, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: A systematic review; J Am Med Assoc. 2005;293(10):1223–1238. doi:10.1001/jama.293.10.122

8. Sutton RT, Pincock D, Baumgart DC, Sadowski DC, Fedorak RN, Kroeker KI. An overview of clinical decision support systems: Benefits, risks, and strategies for success. npj Digit. Med; 2020;3(17). https://doi.org/10.1038/s41746-020-0221-y

9. Jaspers MW, Smeulers M, Vermeulen H, Peute LW. Effects of clinical decision-support systems on practitioner performance and patient outcomes: A synthesis of high-quality systematic review findings. J Am Med Inform Assoc; 2011;18(3):327-334. doi:10.1136/amiajnl-2011-000094

10. Sutton RT. Adherence to clinical care protocols for inflammatory bowel disease and evaluation of a clinical decision support system to improve adherence. Published online December 2019. https://doi.org/10.7939/r3-exjr-bc17

11. Jackson BD, Con D, Liew D, De Cruz P. Clinicians' adherence to international guidelines in the clinical care of adults with inflammatory bowel disease. Scand J Gastroenterol; 2017;52(5):536-542. doi:10.1080/00365521.2017.1278785

12. Lytvyak E, Sutton RT, Dieleman LA, Peerani F, Fedorak RN, Kroeker KI. Management of inflammatory bowel disease patients with clinical care pathways reduces emergency department utilization. Crohns Colitis 360; 2020;2(4):otaa080. Published 2020 Oct 13. doi:10.1093/crocol/otaa080

13. Epic Community Library [Internet]. Published 2018. Accessed May 8, 2018. https://comlib.epic.com/

14. Pauwen NY, Louis E, Siegel C, Colombel J-F, Macq J. Integrated care for Crohn's disease: a plea for the development of clinical decision support systems. J Crohns Colitis; 2018;12(12):1499-1504.

15. Breton J, Witmer CM, Zhang Y, et al. Utilization of an electronic medical record-integrated dashboard improves identification and treatment of anemia and iron deficiency in pediatric inflammatory bowel disease. Inflamm Bowel Dis; 2021;27(9):1409-1417. doi:10.1093/ibd/izaa288

16. Jackson B, Begun J, Gray K, et al. Clinical decision support improves quality of care in patients with ulcerative colitis. Aliment Pharmacol Ther; 2019;49(8):1040-1051. doi:10.1111/apt.15209

17. Epic. Best Practice Advisories setup and support guide. Published online 2018.

18. Epic. Decision support strategy handbook. Published online 2018.

19. Harvey RF, Bradshaw JM. A simple index of Crohn's-disease activity. *Lancet*.

1980;1(8167):514. doi:10.1016/s0140-6736(80)92767-1

20. Lewis JD, Chuai S, Nessel L, Lichtenstein GR, Aberra FN, Ellenberg JH. Use of the noninvasive components of the Mayo score to assess clinical response in ulcerative colitis. *Inflamm Bowel Dis*. 2008;14(12):1660-1666. doi:10.1002/ibd.20520

21. Ramsay CR, Matowe L, Grilli R, Grimshaw JM, Thomas RE. Interrupted time series designs in health technology assessment: lessons from two systematic reviews of behavior change strategies. Int J Technol Assess Health Care; 2003;19(4):613-623. doi:10.1017/S0266462303000576

22. Talmon J, Ammenwerth E, Brender J, de Keizer N, Nykänen P, Rigby M. STARE-HI-Statement on reporting of evaluation studies in Health Informatics. Int J Med Inf; 2009;78(1):1-9. doi:10.1016/j.ijmedinf.2008.09.002

23. Brender J, Talmon J, de Keizer N, Nykänen P, Rigby M, Ammenwerth E. STARE-HI – Statement on reporting of evaluation studies in Health Informatics. Appl Clin Inform; 2013;4(3):331-358. doi:10.4338/ACI-2013-04-RA-0024

24. Pearson K. X. On the criterion that a given system of deviations from the probable in the case of a correlated system of variables is such that it can be reasonably supposed to have arisen from random sampling. Philos Mag Ser 5; 1900;50(302):157-175. doi:10.1080/14786440009463897

25. Wagner AK, Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther; 2002;27(4):299-309. doi:10.1046/j.1365-2710.2002.00430.x

26. Muggeo VMR. segmented: An R package to fit regression models with broken-line relationships; 2008;8:7.

27. Chen H, Cohen P, Chen S. How big is a big odds ratio? Interpreting the magnitudes of odds ratios in epidemiological studies. Commun Stat Simul Comput; 2010;39(4):860-864. doi:10.1080/03610911003650383

28. Jackson BD, Con D, Liew D, De Cruz P. Clinicians' adherence to international guidelines in the clinical care of adults with inflammatory bowel disease. Scand J Gastroenterol; 2017;52(5):536-542. doi:10.1080/00365521.2017.1278785

29. Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods; 2007;39(2):175-191.

30. Zhang F, Wagner AK, Ross-Degnan D. Simulation-based power calculation for designing interrupted time series analyses of health policy interventions. J Clin Epidemiol; 2011;64(11):1252-1261. doi:10.1016/j.jclinepi.2011.02.007

31. Jandoc R, Burden AM, Mamdani M, Lévesque LE, Cadarette SM. Interrupted time series analysis in drug utilization research is increasing: systematic review and recommendations. J Clin Epidemiol; 2015;68(8):950-956. doi:10.1016/j.jclinepi.2014.12.018

32. Kemp K, Griffiths J, Campbell S, Lovell K. An exploration of the follow-up up needs of patients with inflammatory bowel disease. J Crohns Colitis; 2013;7(9):e386-e395. doi:10.1016/j.crohns.2013.03.001

33. Nene S, Gonczi L, Kurti Z, et al. Benefits of implementing a rapid access clinic in a high-volume inflammatory bowel disease center: Access, resource utilization and outcomes. World J Gastroenterol; 2020;26(7):759-769. doi:10.3748/wjg.v26.i7.759

34. Pure N, Mize C. P193 The development of an IBD specialty clinic within a gastroenterology practice. Gastroenterology; 2018;154(1):S107-S108. doi:10.1053/j.gastro.2017.11.253

35. Dowding D, Mitchell N, Randell R, Foster R, Lattimer V, Thompson C. Nurses' use of computerised clinical decision support systems: a case site analysis. J Clin Nurs; 2009;18(8):1159-1167. doi:10.1111/j.1365-2702.2008.02607.x

36. O'Cathain A, Sampson FC, Munro JF, Thomas KJ, Nicholl JP. Nurses' views of using computerized decision support software in NHS Direct. J Adv Nurs; 2004;45(3):280-286. doi:10.1046/j.1365-2648.2003.02894.x

37. O'Cathain A, Nicholl J, Sampson F, Walters S, McDonnell A, Munro J. Do different types of nurses give different triage decisions in NHS Direct? A mixed methods study. J Health Serv Res Policy; 2004;9(4):226-233. doi:10.1258/1355819042250221

38. Rocque G, Miller-Sonnet E, Balch A, et al. Engaging multidisciplinary stakeholders to drive shared decision-making in oncology. J Palliat Care; 2019;34(1):29-31. doi:10.1177/0825859718810723

39. Daudelin DH, Ruthazer R, Kwong M, et al. Stakeholder engagement in methodological research: Development of a clinical decision support tool. Journal of Clinical and Translational Science; 2020;4(2):133-140. doi:10.1017/cts.2019.443

40. Ford E, Carroll JA, Smith HE, Scott D, Cassell JA. Extracting information from the text of electronic medical records to improve case detection: a systematic review. J Am Med Inform Assoc; 2016;23(5):1007-1015. doi:10.1093/jamia/ocv180

41. South BR, Shen S, Jones M, et al. Developing a manually annotated clinical document corpus to identify phenotypic information for inflammatory bowel disease. BMC Bioinformatics; 2009;10(9). doi:10.1186/1471-2105-10-S9-S12

Abbreviations

AHS: Alberta Health Services

ALT: alanine transaminase

AST: aspartate aminotransferase

BPA: best practice advisory

CBC: complete blood count

CCP: clinical care pathway

CDS: clinical decision support

CDSS: clinical decision support system

CIHR: Canadian Institutes of Health Research

CIS: clinical information system

CRP: C-reactive protein

EMR: electronic medical record

FCP: fecal calprotectin

IBD: inflammatory bowel disease

ITS: interrupted time-series

mHBI: modified Harvey Bradshaw Index

NLP: natural language processing

NP: nurse practitioner

PACE: Promoting Access and Care through Centers of Excellence

pMAYO: partial Mayo score

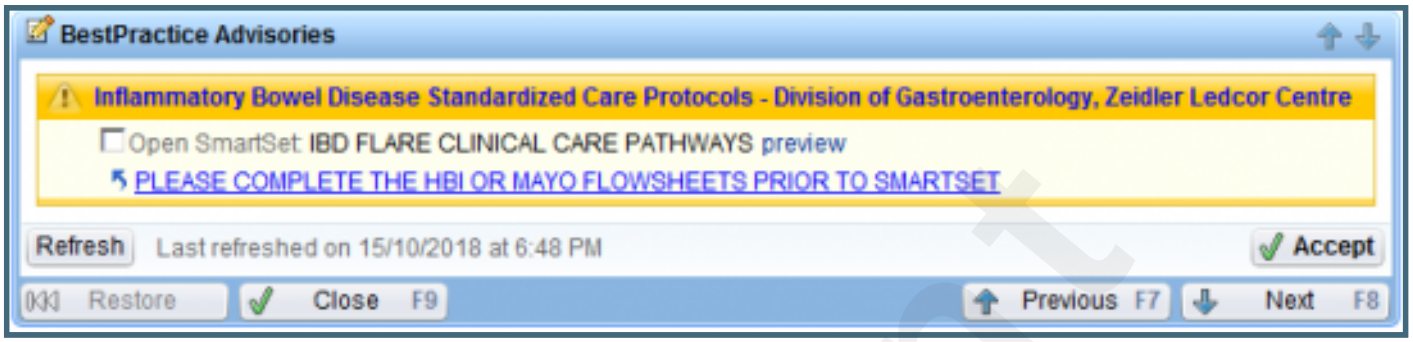
SQL: structured language quarries

VR: reason for visit

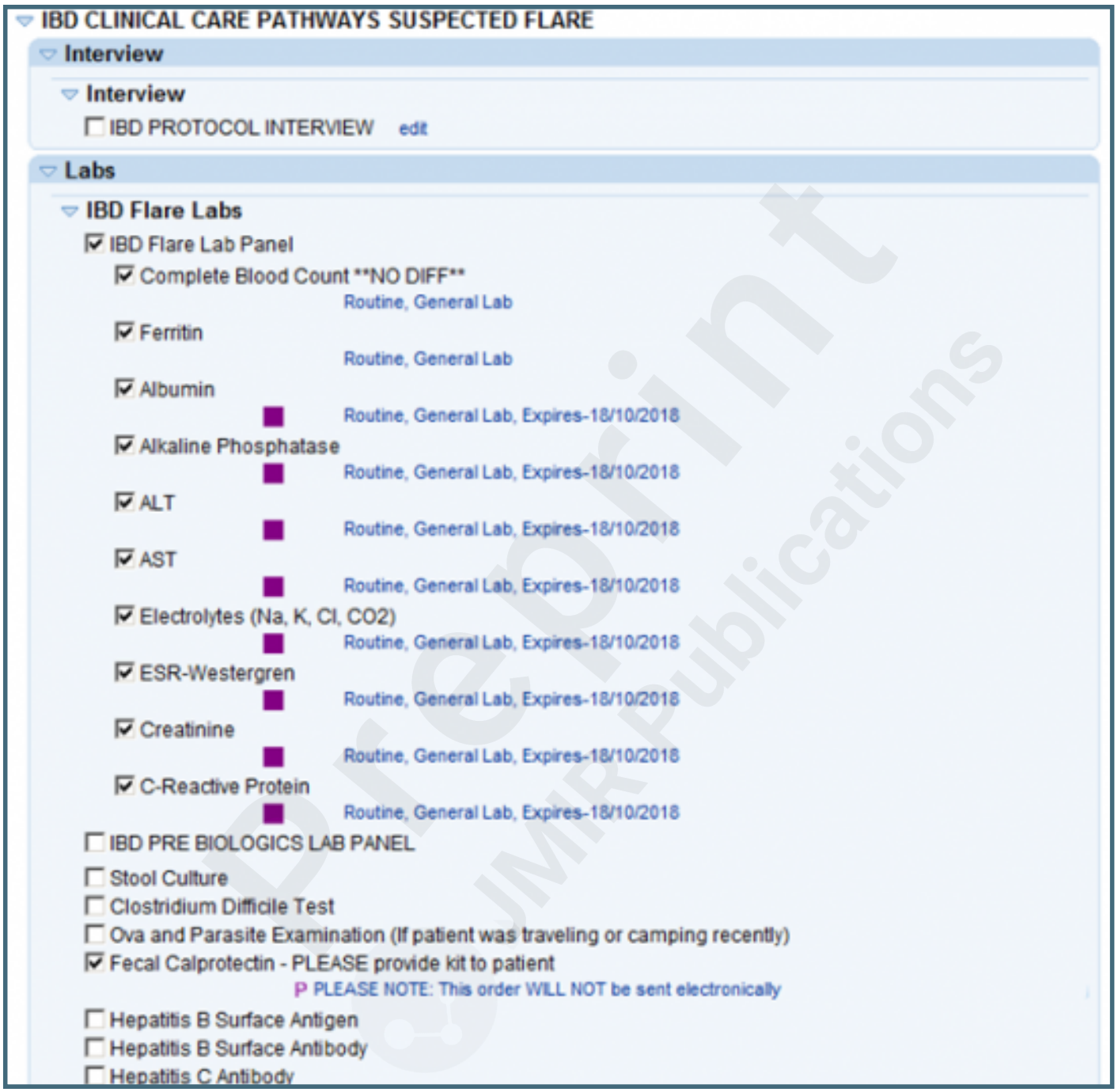
Supplementary Files

Figures

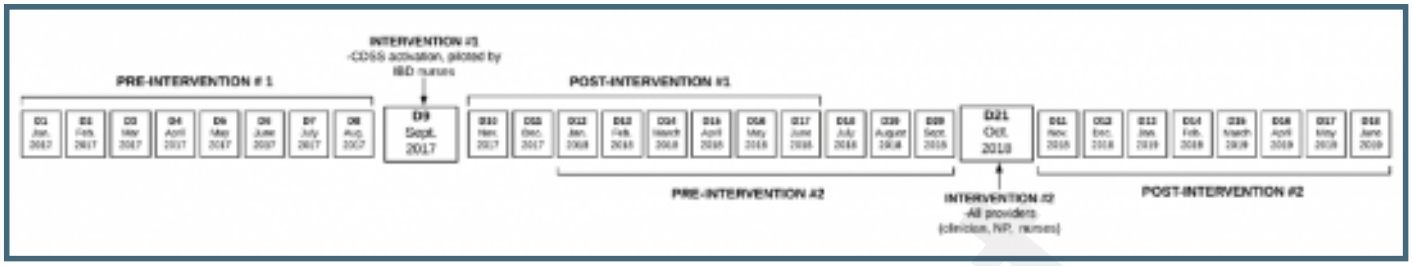
Snapshot of the IBD flare CDSS, showing the initial Best Practice Advisory (BPA). BPAs act as alerts that presents targeted patient-specific guidance to users. They can be active (disruptive popups) or passive (navigation workflow) and can link to actions such as placing orders, order sets, initiating a care plan, or sending a message. This alert appeared passively in the providers workflow navigation whenever IBD was in the patient problem list.



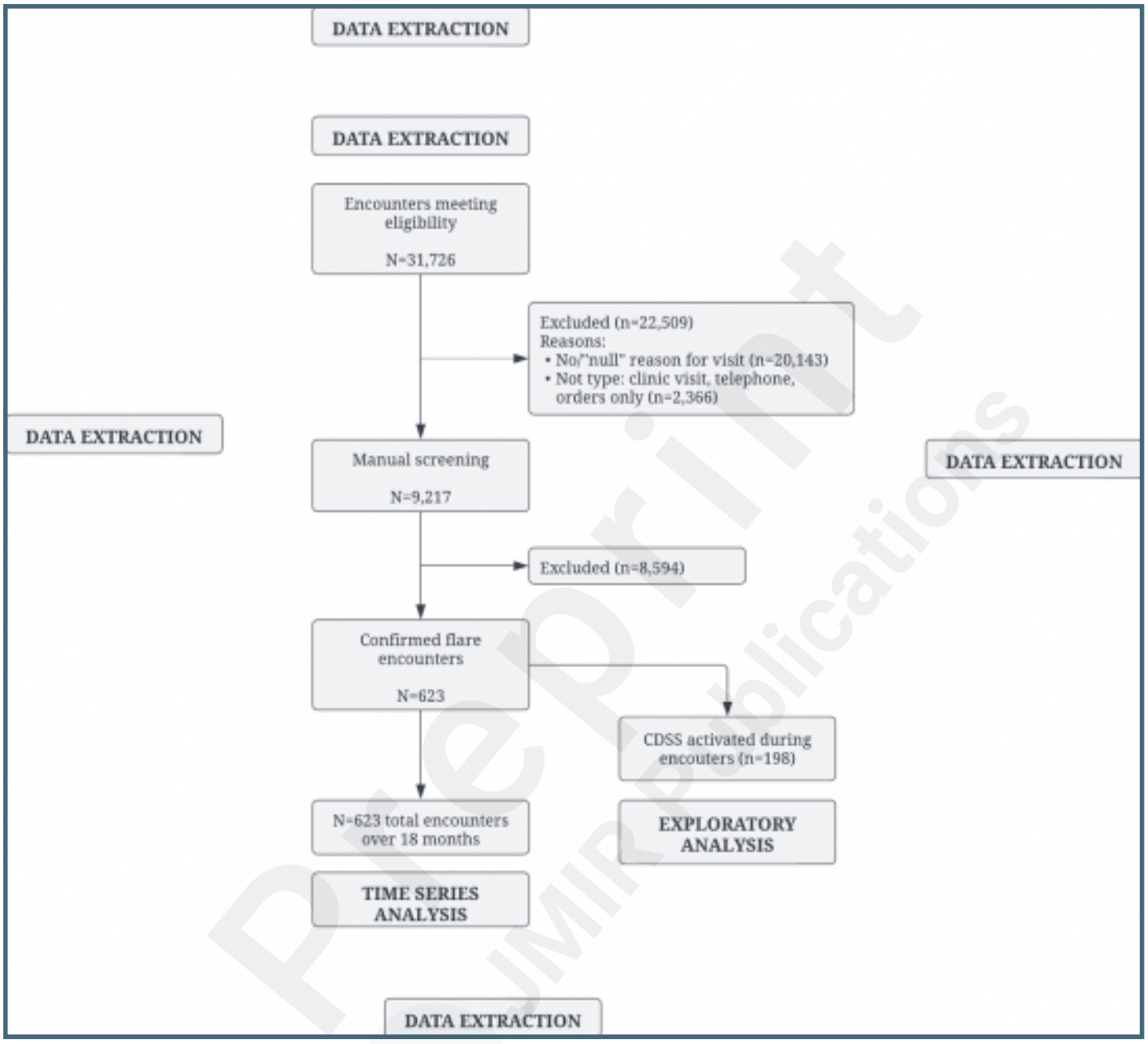
Snapshot of the IBD flare CDSS, showing the SmartSet, which presents after activation by the BPA. Not all sections of the SmartSet shown, including sections for medications, imaging investigations, billing, and follow-up appointment booking.



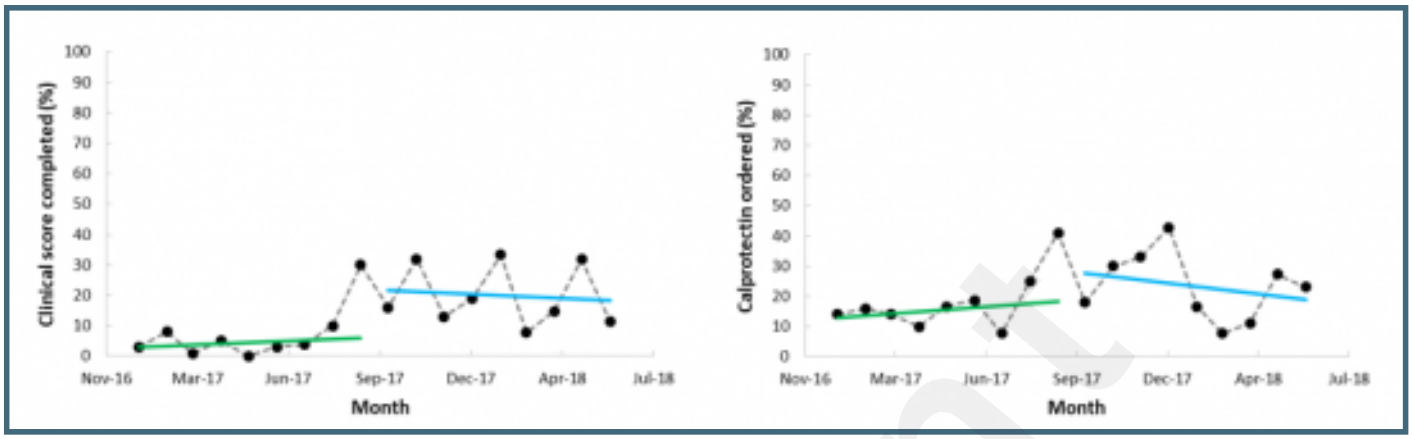
Study design diagram of two-period interrupted time series. First the CDSS was implemented as a limited pilot with IBD nurses (intervention #1), then fully implemented across all providers (intervention #2). Each data point (abbreviated D) corresponds to one month of clinical encounters by study providers.



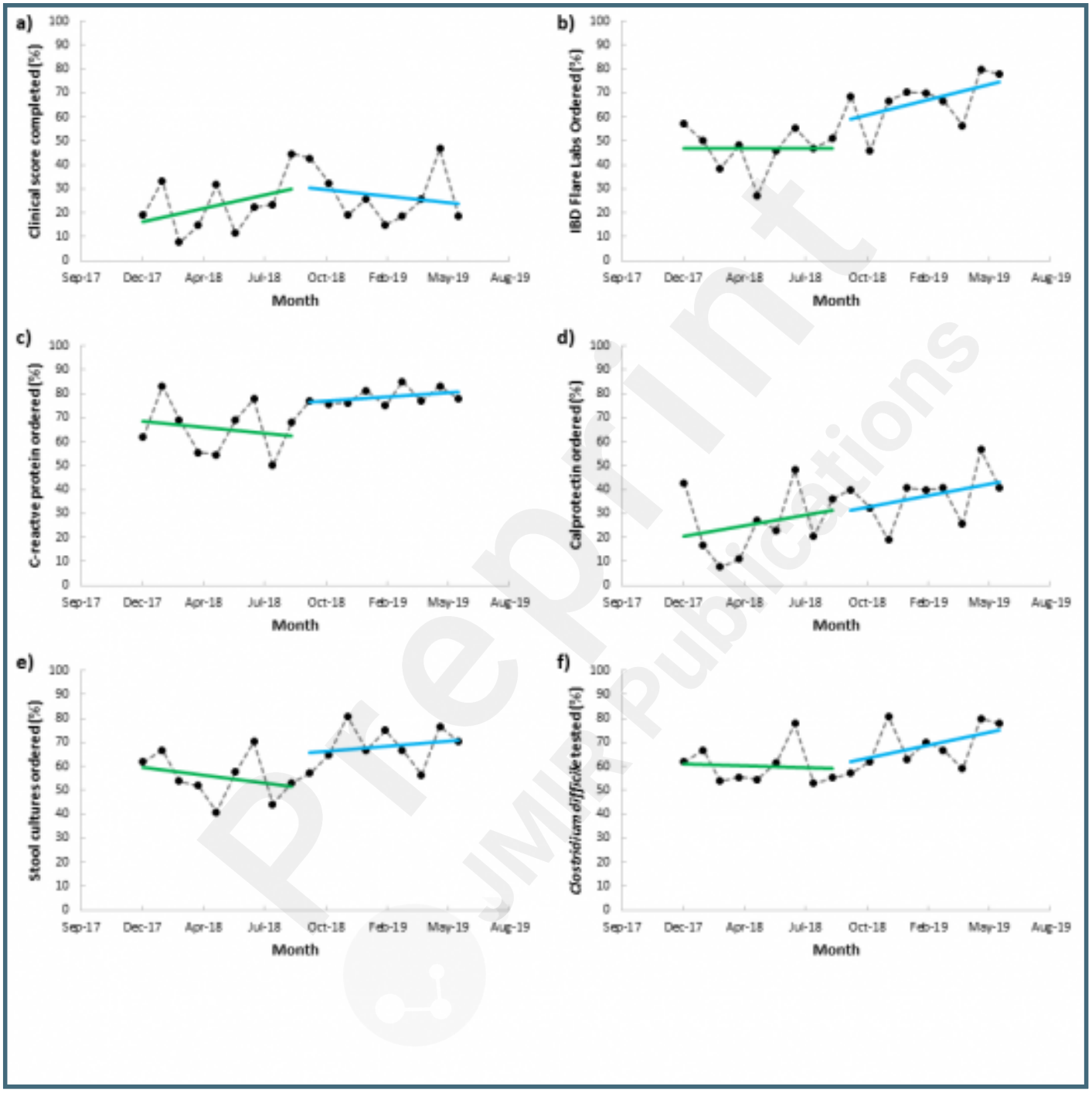
Flow data diagram for data extraction, screening, and analyses.



Segmented regression for Implementation Period 1 (pilot) of the IBD flare CDSS on rates of a) clinical score completion and b) calprotectin testing.



Segmented regression for Implementation Period 2 of the IBD flare CDSS on rates of a) clinical score completion, b) flare lab testing, c) CRP testing, d) calprotectin testing, e) stool culture testing, and f) C.difficile testing.



Multimedia Appendixes

ITS justification.
URL: http://asset.jmir.pub/assets/f25227c74c891702ffea40443858a6d7.docx

Feedback on CDSS pilot version.
URL: http://asset.jmir.pub/assets/a25871ec9d602a3c1685a0c7245544cb.docx

Educational material distributed to providers.
URL: http://asset.jmir.pub/assets/3e7717933df4a673cb874bee8c24daf8.docx

Database codes and queries.
URL: http://asset.jmir.pub/assets/5b7ab50167c237cd63bdb6a5c60dfaac.docx

Sample size determination.
URL: http://asset.jmir.pub/assets/ae95f94891f3d75e7ef185d6c1533bbc.docx

Demographics of users.
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