A Triple Perspective on the Triple Visit: A mixed methods evaluation of the implementation of a paediatric multidisciplinary clinic model for inflammatory bowel disease

Aisling Curtin Wach, Yasmin Lalani, Alexandra Christofides, Pete Wegier, Lara Hart

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Abstract

Background: Given the impact of inflammatory bowel disease (IBD) on both physical health and psychosocial functioning, the management of paediatric IBD requires a multidisciplinary approach that provides holistic care, rapid access, and health education to young IBD patients. Yet despite recommendations, a formalized clinic model for holistic paediatric IBD care remains an unmet need for this population.

Objective: The objective of this study is to comprehensively evaluate the implementation of a new clinic model aimed at providing holistic care, rapid access, and health education for paediatric IBD patients.

Methods: This study employs a multi-perspective mixed methods design, incorporating both qualitative and quantitative data collected simultaneously from clinicians, parents/guardians, and paediatric patients. The quantitative component includes a pre-post implementation chart review, structured observations of clinical practices, and surveys tailored to paediatric patients and parents/guardians. The qualitative aspect encompasses semi-structured interviews with clinicians and parents/guardians, respectively, as well as play-based interviews (PBIs) with patients. Triangulation will be used to converge these different methodologies and to produce a holistic evaluation of the IBD clinic.

Results: This study was approved by the Humber River Health Research Ethics Board on December 23, 2024. Recruitment for this study began on January 30th, 2025, and we anticipate a data collection end date of December 2025.

Conclusions: Given that this clinic model is relatively new, this protocol will provide sound methodological direction for other studies that aim to evaluate or implement this type of model in their setting. The evaluation itself will provide comprehensive insights into both the successes and challenges of implementing a multidisciplinary approach that provides a holistic model of care for paediatric IBD patients. As such, this evaluation will be foundational in providing an applied understanding of the impact and effectiveness of this holistic approach in paediatric IBD patients.

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Given the impact of inflammatory bowel disease (IBD) on both physical health and psychosocial functioning, the management of paediatric IBD requires a multidisciplinary approach that provides holistic care, rapid access, and health education to young IBD patients. Yet despite recommendations, a formalized clinic model for holistic paediatric IBD care remains an unmet need for this population.

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Keywords:

Child-centred methods, Crohn’s disease, Health maintenance, Mental health, Multidisciplinary care model, Paediatric inflammatory bowel disease, Patient perspectives, Parent perspectives, Rapid access clinic, Ulcerative colitis

Introduction

Inflammatory bowel disease (IBD) is a chronic and relapsing inflammatory condition that affects not only the patient’s physical health, but their quality of life and social functioning also.[1,2]. Indeed, patients with IBD reportedly experience increased anxiety and mental health concerns compared to the healthy population,[3] in addition to a disease course that is often unpredictable and marked by a waxing and waning pattern, despite surgical intervention and optimal medication.[4] In children, IBD can also affect growth and pubertal development.[5] As such, they are a challenging patient population to manage which poses a significant burden on healthcare costs and resources. In Canada, specifically, paediatric IBD has been increasing steadily over the past 20 years, [6] and it is expected to exponentially increase in the next 10–20 years.[7]

To facilitate the management of complex IBD patients, recommendations have been put forth to standardize and improve access to IBD subspeciality care. For example, Crohn’s and Colitis

Canada recently supported the “Promoting Access and Care through Centres of Excellence” (PACE) program. PACE included a group of IBD experts, nurses, and patients, who sought to develop a portfolio of quality indicators important for the establishment of an IBD clinic.[8] By using the PACE principles to develop an IBD centre of excellence, clinicians from McGill University reported only 6.6% of patients were steroid dependant and 48.8% of patients were on biologic medications following the IBD centre’s establishment.[9,10] In addition, the implementation of their IBD rapid access clinic improved health care delivery, replaced many invasive investigations (e.g., colonoscopy, endoscopy) with less invasive monitoring methods (e.g., fecal calprotectin, c-reactive protein test) and reduced ED visits and associated costs.[11]. Notably, IBD patients who presented to the hospital first (*n* = 135 patients) during an acute crisis costed healthcare an average of $1,885 CAD per visit, excluding admission costs, and use of cross-sectional imaging occurred in 65.7% of these visits. This contrasts markedly with the $403 CAD average cost for patients who presented to the IBD rapid access clinic first (*n* = 488 patients) and the use of cross-sectional imaging was 6%. Despite the guidance provided by PACE and positive impact of the rapid access IBD clinic at McGill, community IBD clinics with rapid access components, including for paediatric IBD, are still uncommon in Canada.

Beyond proving IBD patients with rapid access, it is important to provide children with IBD, health education, health maintenance checks, and mental health assessments.[12] Education is typically focused on the disease itself, its management, and how to cope with chronic illness.[13] Health maintenance emphasizes ensuring that children with IBD have (1) appropriate growth which is monitored by an IBD nurse and dietician, (2) good nutritional status which includes improving/normalizing vitamin D levels, iron status, and other micronutrients), (3) excellent bone health which includes checking bone age and performing DEXA (dual-energy x-ray absorptiometry scan; measures bone density) if they have been exposed to steroids, and (4) up-to-date vaccines.[14] Mental health status should also be assessed on a regular basis, both at baseline and at routine intervals, to ensure early referrals to appropriate providers and prevent poor outcomes associated with anxiety and depression.[15] By providing such services, a paediatric IBD clinic ensures a holistic approach to the management of IBD, while simultaneously preparing children for managing their disease in the future. Subsequently, this improves patients' management of disease and their self-efficacy, and thus, provides the building blocks and foundation for a successful transition to adult care.[13,16]

To address the significant unmet need of a holistic clinic model of care that provides rapid access to paediatric patients at Humber River Health (HRH), the Outpatient Paediatric IBD Clinic at HRH aimed to achieve several aims within their clinic:

1. Establish a community IBD Centre with a rapid access IBD clinic based on the guidance provided by the PACE quality indicators.
2. Establish a multi-disciplinary community clinic. This provides patients with a biannual visit, referred to as the *Triple Visit*, where patients would be reviewed by the gastroenterologist (GI), nurse practitioner, and dietician during their visit to the clinic.
3. Establish a mental health screening program for paediatric patients within the clinic, to allow for the proactive identification of patients who need additional supports and resources such as social work, psychology, adolescent medicine etc.,
4. Develop a health maintenance checklist with proactive management strategies such as bone health, growth assessment, vaccine status etc.

Aims of the Study

To understand the impact of the newly implemented *Triple Visit* and clinic model of care on HRH's Outpatient Paediatric IBD Clinic, we aim to comprehensively evaluate its implementation from the triple perspective of patients, parents/guardians, and clinicians. We will evaluate the clinic's efficacy in (1) improving access to new or unwell patients, (2) improving health maintenance for children with IBD, (3) effectively identifying mental health concerns in this specific population, and (4) satisfying patients' needs.

Our specific research questions are:

1. What is the impact of the new IBD clinic model of care on patient outcomes such as use the of steroid and biologic medications, health maintenance, and mental health?
2. What is the impact of the new IBD clinic model of care on improving patient access to care and healthcare usage in general?
3. Are patients and their parents/guardians satisfied with this new model of care?
4. What are the barriers and facilitators experienced by different clinician roles in implementing the new clinic model?

Study Design and Procedures

This study is a multi-perspective concurrent mixed-methods design, incorporating both quantitative and qualitative data collected simultaneously from clinicians, parents/guardians, and paediatric patients.[17] Data will be triangulated to integrate these different methodologies to produce a holistic evaluation of the IBD clinic and its newly implemented components (see Figure 1). The quantitative phase will involve a pre-post implementation chart review, structured observations of clinical practices, and surveys tailored to paediatric patients and parents/guardians. The qualitative aspect will encompass semi-structured interviews with clinicians and parents/guardians, respectively, as well as play-based interviews (PBIs) with patients. Qualitative data collection and analysis will be guided by the COREQ standards.[18]

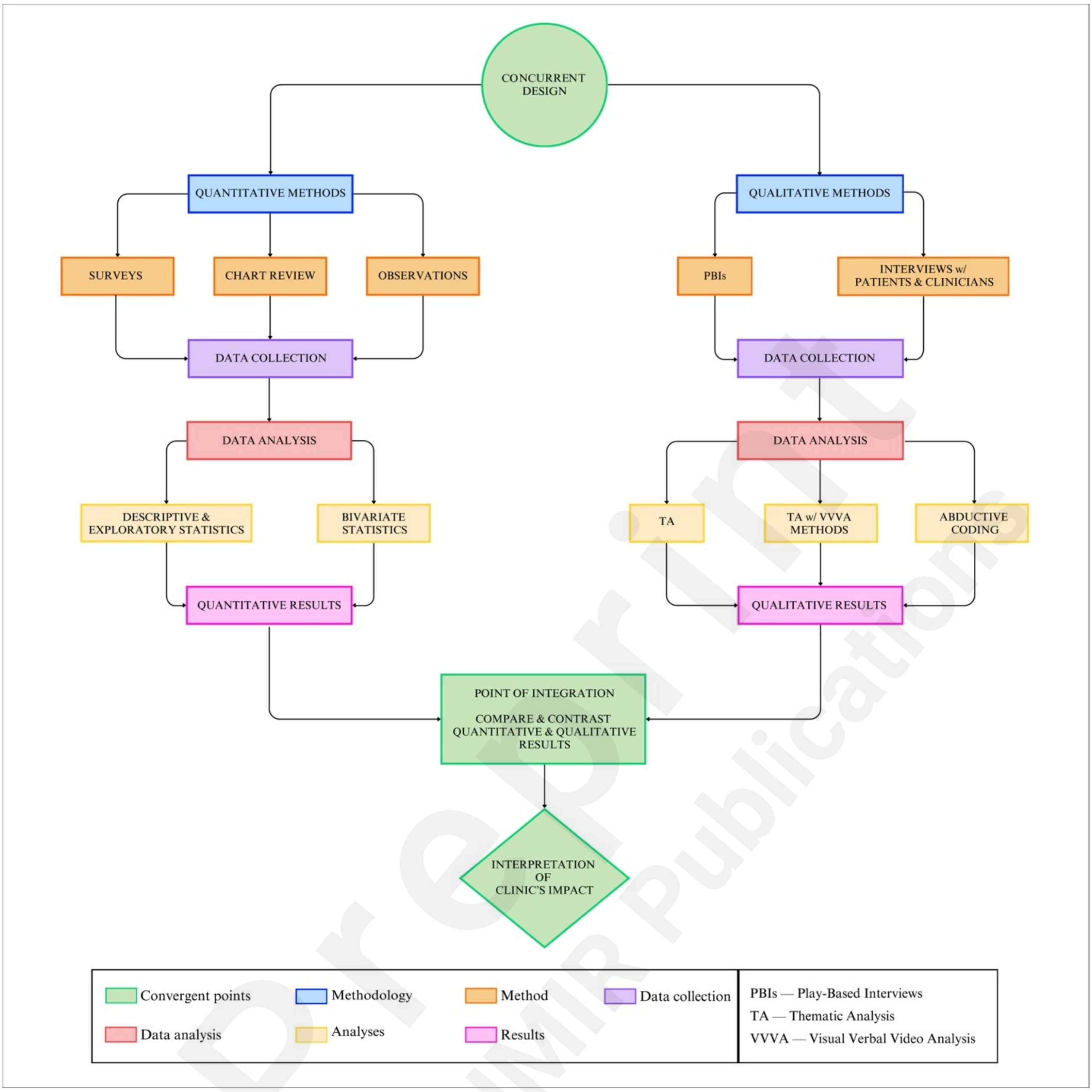

Figure 1. Flowchart illustrating the steps in the convergence model of triangulation design deployed for this evaluation.

By triangulating both qualitative and quantitative methods with an equal weight on each,[19][20]we aim to offer a nuanced portrayal of the IBD clinic's efficacy in achieving its aforementioned aims, in addition to illuminating any of the barriers and facilitators influencing the implementation of the new clinic model. The integration of diverse data sources through triangulation will not only enhance the validity of our findings but also provide a more comprehensive understanding of the clinic's dynamics, ensuring a well-informed basis for future[21] enhancements and improvements to the IBD clinic.

Methods

Participants and Recruitment

To comprehensively evaluate the IBD clinic's new model of care, including the *Triple Visit*, participants will be recruited from three different perspectives: (1) patients, (2) parents/guardians, and (3) clinicians, including GI physicians, nurse practitioner, dietitians, and mental health professionals such as social workers and psychologists. We will deploy a parallel sampling design [22] in that the samples from the quantitative and qualitative components may be different but are drawn from the same database within the IBD clinic. This sampling design was chosen to increase the uptake in recruitment in a small clinic.

Paediatric Patients and Parent/Guardians

During IBD clinic outpatient appointments, all parents/guardians accompanying paediatric patients in attendance at HRH's Outpatient Paediatric IBD Clinic will be asked by the clinic's GI physicians and nurse practitioner, if they consent to being contacted by the hospital's Research Institute in relation to an evaluation of the clinic's *Triple Visit* model of care. Study brochures outlining research activities will be provided to parents/guardians during the appointment, in addition to study information cards tailored to our paediatric population. Subsequently, a research team member will connect with parents/guardians who consent to being contacted via their preferred means of communication (i.e., email and/or phone) and will be invited to take part in research activities evaluating the clinic. Patients and parents/guardians can choose to participate in all, some, or none of the research activities. Moreover, patients and parents/guardians will not be recruited as dyads, and therefore one does not necessitate the other for participation. Participants who participate in, and complete research activities will be compensated with an e-gift card of their choice from a list of available gift cards and the value of the compensation will correspond to the activity completed. Patient and parent/parent survey compensation value will be $10, patient and parent/guardian interview compensation will be $15, and clinician interviews will be $5. Patients and parents/guardians who complete a survey and an interview, will receive a $10 bonus for completing both.

For patients, the inclusion criteria will consist of being 8-18 years old, a patient of the HRH's Outpatient Paediatric IBD Clinic between January 2021 and December 2024, free from cognitive impairment, verbally fluent, and proficient in English. Patients who do not provide assent or whose parents/guardians do not consent to their participation will be excluded. For parents/guardians, the inclusion criteria will consist of being the parent/guardian of a current paediatric patient of HRH's Outpatient Paediatric IBD Clinic, free from cognitive impairment, and proficiency in English. For the quantitative phase, we aim to recruit the maximum number of patients (i.e., ~80) and their parents/guardians (i.e., ~80). For the qualitative phase, we aim to recruit 15 patients, in addition to 15 parents/guardians.

Clinicians

For the semi-structured interviews, we will invite all clinicians who provide direct care to HRH's Outpatient Paediatric IBD Clinic patients to participate. This will include G. I physicians, nurse practitioners, dieticians, and mental health professionals such as social workers and psychologists. We anticipate that the sample size will be approximately 6-8 clinicians. A combination of convenience and purposive sampling will be used,[23] so that all clinician roles in the IBD clinic are represented; the Director of the Maternal Child Health department will send an email to clinicians who provide IBD care, to inform them of the study and the invitation to participate in the interview.

For the structured observations of clinical practices, we will not be recruiting staff or patients per se but rather aiming to observe appointment types such as first visit, last visit/transitioning to adult care, and *Triple Visit*. A memo will be sent from the clinic lead to clinic staff, notifying them that observations will be conducted throughout the study duration. Research staff will work with clinicians to pick appropriate times to observe clinical activities based on appointment type and with the consent of parents/guardians.

Measures and Qualitative Methods

No fixed order will be prescribed for participation in patient- or parent/guardian-facing research activities as this will allow patients and parents/guardians the flexibility to change their mind about what research activities they wish to be a part of. As such, some patients may start with the patient survey, while others may start with the Play-Based Interview (PBI). Similarly, some parents/guardians may begin with the parent/guardian survey, while others may begin with the semi-structured interviews. Direct observations, chart reviews, and clinician interviews will flexibly occur over the course of the study. A battery of quantitative measures delivered via patient and parent/guardian surveys, as well as chart reviews and structured observations, will be deployed to quantify and measure the impact of the new clinic model on patient outcomes, in addition to satisfaction with the model of care. Qualitative methods will be used to collect data from clinicians, parents/guardian, and paediatric patients regarding their experiences and perceptions of the new clinic model, including the *Triple Visit,* as well as their recommendations for improvement. Semi-structured interviews will be conducted with clinicians and parents/guardians and a PBI framework method will be used with patients

Demographics

Patient and disease related demographics, as well as parent/guardian demographics will be collected once, at the time of first participation. Parents/guardians will be responsible for completing demographic information on behalf of themselves and their child via a link sent to them for a demographics survey in Qualtrics. Demographic questions include but are not limited to age, sex, and gender for both the patient and parent/guardian, as well as the first three characters of their postal code so that researchers can map how far patients travel to receive this speciality care.

Chart Review

To understand the impact of the new clinic model of care, including the *Triple Visit*, on patient outcomes and healthcare usage (e.g., number of contacts with nurse practitioner and tests/procedures ordered), as well as ascertaining whether new clinic components that follow PACE guidelines are being consistently implemented, health maintenance processes are followed, and identified concerns addressed, a pre-post implementation chart review will be undertaken. As the IBD clinic's new model of care began January 2023, the pre-implementation chart review will capture patients who attended the clinic in January 2021 to December 2022 which will then be compared to the post-implementation chart review of patients who attended the clinic from January 2023 to December 2024. Electronic medical records (EMRs) in Meditech will be accessed to complete this review. Variables of interest include prescribed steroid and biologic medications (including dosage), height and weight, and ordered tests.

Paediatric Patient and Parent/Guardian Surveys

Paediatric Patient Survey

To reduce the time and logistical burden of visiting HRH outside of their IBD clinic appointments, participants will be invited to take part in an online survey to assess their satisfaction with the new model of care in the IBD clinic, as well as the impact the clinic has had on patients' knowledge of IBD, transition readiness, self-efficacy, mental health, and health-related quality of life. The online survey will be conducted in real time using Zoom, and participant responses will be captured in Qualtrics. Older teenagers may be given the option to complete the online survey unassisted via a link sent to their parent/guardian's email address. PowerPoint slides will be used to display and support the interactive delivery of survey measures The PowerPoint slides will be appropriately tailored to the age range, as necessary, and measures within the survey will be displayed in an order that places the more difficult questions in the middle ,such as questions pertaining to mental health. This is to help children to finish the survey feeling positive. As we project that the survey will take 20-30 minutes for participants to complete, there is the potential for participants to experience survey fatigue. To mitigate against such effects, participants will be offered breaks at intervals throughout the survey, and they will have the opportunity to watch a short age-appropriate cartoon/tv-show or to do something of their own choosing such as grabbing a snack. Children who complete their survey online via Qualtrics without researcher support, will be prompted within the survey to take a break at the same intervals.

Transition Readiness

Patients' readiness to transition from paediatric to adult care will be assessed using the Self-Management and Transition to Adulthood with Rx = Treatment (STARx) Questionnaire.[24] The STARx Questionnaire is an 18-item questionnaire, targeting the following six subdomains integral to transition readiness: medication management, provider communication, engagement during appointments, disease knowledge, adult health responsibilities, and resource utilization. All questions are presented to patients in Likert scale format. For example, patients will be asked to indicate on a 5-point Likert scale from 1 (never) to 5 (always), "How often do you take your medications on your own?" and on a 5-point Likert scale from 1 (Nothing now) to 5 (A lot), "How much do you know about your illness". For this present investigation, this tool will help identify not only gaps in skills and knowledge in individual patients but gaps across the clinic population or where they are doing well as a whole.

Patient Self-Efficacy

IBD Self-efficacy Scale for Adolescent and Young Adults is a 13-item questionnaire to assess IBD specific self-efficacy among patients.[25,26] The scale touches on four key areas of disease management including managing medical care, managing daily life with IBD, managing emotions, and managing the future with IBD. Patients are asked to rate their agreement with statements such as "I worry about much IBD will affect my future" and "I know what to do when I think a flare is starting," using a 5-point Likert scale from 1 (completely disagree) to 5 (completely agree). As self-efficacy is an important predictor of health outcomes in chronic illness, scores from this scale will be compared to the health-related quality of life (HRQOL) measures, among other measures and variables.

Patient Knowledge of IBD

Patients' knowledge of IBD will be assessed via the Inflammatory Bowel Disease – Knowledge Inventory Device 2 (IBD-KID2) .[27] The IBD-KID2 is a 15-item assessment tool investigating patients' understanding of IBD across various knowledge domains such as general IBD, treatment, and lifestyle/nutrition. The tool consists of six multiple choice questions and nine true/false questions, with each correct answer receiving a score of one, for a maximum total score of 15. Patient knowledge of their IBD is integral to their treatment adherence and development of self-management skills. Thus, similar to the transition readiness scale, the IBD-KID2 will help identify gaps in knowledge among patients of this IBD clinic which could adversely impact their disease trajectory. IBD knowledge scores will also be compared to their transition readiness scores, HRQOL scores, and parents/guardians' knowledge of IBD scores, among other measures.

Patient Service Satisfaction

Paediatric patients' satisfaction with the IBD clinic and its new model of care will be assessed via the Youth Satisfaction Questionnaire (YSQ).[28] The YSQ is a tool that was developed to assess children's general satisfaction with a service, as well as their satisfaction with specific aspects of the service and activities they are involved in.

To measure general service satisfaction respondents are asked to rate their agreement with five statements such as, "Did you get the help you wanted?" and "Have the services helped you with your life?", using the response options, (1) "yes", (2) "somewhat", and (3) "no". Satisfaction with specific service components and activities are measured by asking respondents to assign a grade (A through F) to the specific services and activities they were engaged with. For this project, the specific services and activities list has been generated in collaboration with the research team and IBD clinic care team. Children will be asked to assign a grade to five service aspects such as, “medication management” and “access to clinic.” Results from the YSQ will be compared to scores of HRQOL and parental/guardian satisfaction, in addition to informing how the clinic is doing against the PACE quality indicators.

Patient Health Related Quality of Life

IMPACT-III [29] will be used to assess patient’s health related quality of life (HRQOL). In addition to indicating the impact of disease burden on health, HRQOL is an important measure of assessing the efficacy of medical care. The IMPACT-III is a 35-item questionnaire, that measures patients’ views on their health, including their physical well-being, emotional functioning, social functioning, and body image. Questions include, “How much energy did you have during the week?,” “Are you embarrassed because of your bowel condition?,” and “How much has your stomach been hurting over the past two weeks.” For each question, respondents are provided five possible answers ranging from 1 (e.g., “Not at all”) to 5 (e.g., “Hurting very much”). HRQOL will be used to assess how well patients in the clinic are doing as a whole and compared to their scores on measures related to mental wellbeing, in addition to other measures and variables such as their parents’ scores on the parent version of the measure described in the *patient survey.*

Mental Health and Well-Being

The Child Attitudes Towards Illness Scale (CATIS) [30] will be used to assess patients’ attitudes towards their illness. Paediatric patients’ perceptions of their illness can be pivotal in influencing adjustment to their condition, particularly when there is a stigma attached, as is the case for those with IBD. Negative feelings about a chronic condition can lead a child toward maladaptive coping behaviors, which in turn can lead to a more negative adaption to their condition compared to those with positive attitudes. The CATIS uses 5-point Likert scales ranging from 1 (very sad/never/very unfair) to 5 (very happy/very often/very fair) and includes questions such as, “How good or bad do you feel it is that you have [insert illness, e.g., ulcerative colitis/Crohn’s disease]” and “ How often do you feel sad about being sick?”. Total sores can range from 13-65, with higher scores indicating more positive attitudes. Scores from the CATIS will be compared to other patient measures such as HRQOL.

The Generalized Anxiety Disorder screener (GAD-7)[31] will be administered to patients to screen for anxiety and explore whether the IBD clinic has been achieving its aim of proactively identifying patients who require additional mental health supports. The GAD-7 is a 7-item questionnaire that asks respondents to consider how often over the past two weeks they have been bothered by a particular problem such as, “Feeling nervous, anxious or on edge” and “Trouble relaxing”. Response options include 0 “Not at all”, 1 “Several days”, 2 “More than half the days”, 3 “Nearly every day”. Scores ≥ 10 indicate moderate anxiety.

The Patient Health Questionnaire – 9 (PHQ-9) [32] will also be administered to patients to screen for depressions and similar to the GAD-7, explore whether the IBD clinic has been achieving its aim of proactively identifying patients requiring additional mental health input. The PHQ-9 is a 9-item questionnaire that asks respondents to consider how often over the past two weeks they have been bothered by a particular problem such as, “Feeling down, depressed, or hopeless” and “Trouble concentrating on things, such as reading the newspapers or watching television”. Similarly to the GAD-7, the PHQ-9's response options include “Not at all”, 1 “Several days”, 2 “More than half the days”, 3 “Nearly every day”. At the end of the questionnaire participants are asked to indicate how difficult these problems have made it for them in their daily life. Response options range from “Not difficult at all” to “Extremely difficult.” Scores ≥ 10 indicate moderate anxiety.

Desirable Responding

As this survey is asking children and young adolescents to respond to questions regarding sensitive topics such as their symptoms and experiences of IBD, as well as their mental health, there is the potential for participants to respond in socially desirable ways. Thus, the Short Children's Social Desirability Scale (CSD-S) [33] has been included to identify and control for biased responses in patient self-reports. The CSD-S scale includes 14 questions to which participants can provide a "yes" or "no" response such as, "Have you ever felt like saying unkind things to a person?" and "Do you always listen to your parents?".

Parent/Guardian Survey

Similar to the paediatric patient survey, parents/guardians will be invited to take part in an online survey to assess their satisfaction with the IBD clinic's new model of care, the impact the clinic has had on their knowledge of IBD, as well as the impact the clinic has had on their child's well-being. Unlike the paediatric patient survey, parents/guardians will be sent a link to the online survey in Qualtrics and will be given a two-week window to complete the survey at a time of their convenience.

Parent/Guardian Service Satisfaction

To measure parent/guardian satisfaction with the IBD clinic, the Quality of Care Through the Patient's Eyes – Inflammatory Bowel Disease (QUOTE-IBD) [34] questionnaire developed by The Netherlands Institute for Health Services Research (NIVEL) is being adapted. The QUOTE – IBD is a 23-item questionnaire that contains 10 generic - and 13 disease-specific questions assessing the following eight dimensions of care: accessibility, costs, accommodation, continuity of care, courtesy, information, competence, and autonomy. Participants are asked to rate the importance of each aspect of care using a 4-point scale (1 "No", 2 "Not really", 3 "On the whole, yes", 4 "Yes") and then, to rate the performance of the medical setting and workers based on their experience using the same 4-point scale. Subsequently, a Quality Impact Index (QI) is derived for each item which combines the effect of importance and performance. Note, a QI score of < 9 is considered suboptimal patient satisfaction as it is widely held that 90% of patient populations are satisfied with quality of care. To fit the parent format, question structure has been modified as necessary to replace items such as "my" with "me and my child" or "my child's." For example, the statement, "Doctors, nurses, and other care works should have a good understanding of my problems" will be modified to read, "Doctors, nurses, and other care workers should have a good understanding of my child's problems." Similarly, questions have been edited to reflect the IBD clinic, thus, some statements have either been removed or modified. For example, in the original version, participants are asked to respond to questions about their GP and specialist, respectively. In this survey, questions pertaining to GPs have been removed and questions regarding the patient's specialist are reworded to reflect the IBD specialist team.

Parents/guardians will also complete the same grading activity their children complete from the YSQ,i.e., parents/guardians will assign a grade (A through F) to the specific services and activities their child has engaged with.

Parent/Guardian Knowledge of IBD

Parents/guardians' knowledge of IBD will be assessed via the IBD-KID2 described in *the patient survey.* This measure will allow for comparison between patients and parents/guardians, as well as investigating the relationship between parents/guardians' knowledge of IBD, service satisfaction, parenting stress and so on.

Parent/Guardian Perception of Child's Health Related Quality of Life

The parent IMPACT-III (IMPACT-III-P) [35] will be used in conjunction with the IMPACT-III [29] described in the patient survey to assess patient's health related quality of life (HRQOL). The IMPACT-III-P uses the same 35 items from the IMPACT-III, with personal pronouns modified to fit the parent format. For example, the children's version asks, "How much energy did you have during the week?" whereas the parents' version has been modified to ask, "How much energy does your child have during the week?." Parent scores from the IMPACT-III will be compared to patient scores on the same measure.

Parent/Guardian Perception of Child’s Transition Readiness

The parent STARx Questionnaire (STARx-P) [36] will be used in conjunction with the child STARx Questionnaire described in the *patient survey* to assess patients’ transition readiness, in addition to comparing potential differences and/or similarities in patients and parents/guardians’ perceptions of transition readiness. The STARx-P uses the same 18 questions and Likert-scale response options as the STARx, with the word “you” being replaced as necessary with “your child” to fit the parent format.

Paediatric Parenting Stress

Paediatric parenting stress will be assessed with the Paediatric Inventory for Parents (PIP - Short Form).[37] Across 13 questions parents are asked to consider over the past seven days how often and how difficult they experienced- and -found particular events such as sleeping, attending work, and seeing their child sad. Thus, 13 questions produce 26 responses. A 5-point Likert scale is used for the response options for both “How often” (i.e., from 1 “Never” to 5 “Very often”) and “How difficult” (i.e., from 1 “Not at all” to 5 “extremely”). Parents’ scores on the PIP will be compared to their knowledge of IBD and patient HRQOL, among other measures.

Structured Observation

As the implementation of PACE guidelines in other clinics have resulted in positive patient outcomes,[9,10] a structured observation of clinical practices in this new model of care at HRH’s Outpatient Paediatric IBD clinic will be conducted. The structured observation will involve direct clinical observation of clinical appointments such as a new patient visit, last/transition to adult care visit, and the *Triple Visit*, in addition to the review of specific EMR metrics from patients’ charts, measurement of patient satisfaction as per the patient survey, and consultation with clinical staff, as necessary. The clinic’s paediatric GI has been consulted to determine the applicability of each guideline to the paediatric setting. As such, 42 of 45 indicators which cover structure (the inclusion of particular healthcare professionals in the clinic etc.), process (performing tests and prescribing particular medications based on certain criteria etc.,), and outcome quality indicators (patient healthcare usage, patient satisfaction etc.,) have been included for this structured observation.

Semi-structured Interviews with Parents/Guardians and Clinicians

Parent/Guardian Semi-structured Interviews

Parents/guardians will participate in one virtual or in-person semi-structured interview. Questions will focus on the key elements of evaluation that include their perspectives on accessing the clinic, mental health, their views on how their child's health is being maintained, and more general views on their satisfaction with the new clinic model. To round off the interview, parents/guardians will be asked to provide any recommendations to any aspect of their clinic experience.

Clinician Semi-structured Interviews

For clinicians, the focus will be on garnering their perspectives of how the new clinic model was implemented, paying specific attention to the experiences of the different clinician specialties that comprise the new model. To do so, we will use the Consolidated Framework for Implementation Research (CFIR), a validated two-versioned framework comprised of a taxonomy of constructs that have been shown to be associated with implementation success.[38,39] A defining feature of the *Triple Visit* is its commitment to coordinated care and collaboration amongst a multidisciplinary team; as such, attention will be paid to the *Characteristics of Individuals* domain of the CFIR. This domain aims to uncover contextual information about how those involved in implementing and executing the *Triple Visit* model make sense of the new initiative and the interplay amongst other staff within the purview of the intervention. Other CIFR domains included in the interview guide are Intervention Characteristics, to obtain data about participants' knowledge and perceptions of the new clinic model; Outer Setting which focuses on clinicians' opinions on the patient/parent population, Inner Setting to gather insights on whether the new clinic model is embraced in the hospital context, and Process, to understand clinicians' views on how the new model was implemented. All interview questions aim to uncover the barriers and facilitators associated with implementing the new clinic model and clinicians' insights on how to improve the service.

Paediatric Patients and Play-Based Interviews

We aim to gather insights from IBD patients about their experience of the IBD *Triple Visit* clinic visits. Data collection scripts used with patients will be tailored to their developmental stage, guided by a narrative play-based interview (PBI) framework that incorporates play and/or opportunities for creative expression as a vehicle to elicit their responses from the interview guide.[40–42] Previous research on conducting qualitative data collection with young children and adolescents shows that novel methods such as play, drawing, diary writing, or other forms of creative expression are effective at eliciting responses from children in a supportive setting.[43] These methods reside outside an artificial interview context and instead, are grounded in a "child's perspective"— a perspective that has been methodologically overlooked in studies involving children in hospital settings.[44] Approaching interviews with children in a way that reflects their developmental stage enhances the validity of the data and in turn, its quality.[41,45]

A Certified Child Life Specialist (CCLS) will facilitate the PBIs. CCLS are healthcare professionals who are clinically trained in evidence-based techniques to help children feel emotionally safe and calm in hospital settings when undergoing medical procedures and invasive examinations. Thus, the CCLS is well suited to facilitate the PBIs, as they possess the skill set to understand both children's developmental stage and socioemotional needs. To ensure rigour in data quality, a qualitative methodologist (QM) will also be present to take detailed fieldnotes to compliment the audio and video data from the interviews.

PBI Procedure

For the PBIs, children will be split into their developmental ages: 8 to 12 years, 13 to 15 years, and 16 to 18 years which will determine the age-appropriate interview script to use on the interview guide for the PBI. Sessions will be audio and video recorded in a room within the Maternal and Child clinic; however, parents will have the option on the consent form to not have their child video recorded. The video camera will be attached to a laptop and positioned in a specific area of the clinic room to ensure it does not interfere with the child's activities during their interview with the CCLS. In line with child interview recording, our aim is to ensure the experience remains as unobtrusive as possible.[41]

The QM will obtain consent from parents and assent from the patients prior to the PBI; it will be reiterated to the patient that their participation is voluntary and that they may stop the PBI at any time. The CCLS will use the interview guide using the age-appropriate script that corresponds to the age of the patient. The interview guide will touch on the following topics: what the children like about coming to the clinic, what they do not like, their thoughts about their care team, what they find helpful about the clinic and how they would like their clinic experience to be improved. To elicit responses from the patients, they will be invited to choose one or more items from an activity portfolio [41] located in the interview clinic room to play/engage with. While the patient is occupied with their activity of choice from the portfolio, the CCLS will consult the interview guide and elicit their responses; having the child "busy" with an enjoyable activity allows for a more a natural conversation with the child to unfold.[40,41] At the end of the PBI, the patient will be invited to choose a small gift of appreciation from a "Thank You Bin" in the clinic room. After the CCLS and QM lead the child back to their parents/guardians in the waiting area, the child will also be offered a gift card.

Ethical Considerations

This study received Humber River Health Research Ethics Board approval on December 23rd, 2024 (REB#24-0005). Prior to commencing research activities, a researcher will obtain verbal consent from parents/guardians for the specific research activity being undertaken. Parents/guardians will be responsible for providing consent for their and their child's participation. Although parents/guardians will provide consent for their child's participation, all paediatric patients will also be asked at the time of participation if they assent to participating in the research activity at hand. Age-appropriate assent scripts will be used to describe the specifics of the research activity, including that their participation is voluntary, they have the right to withdraw at any time without penalty, and that their information will be kept private and confidential. If a patient does not assent, they will be withdrawn immediately, thanked for their time, and reassured that this will not impact the care they receive at HRH.

Clinical staff who are interested in participating in research activities will be provided with a consent document to review, followed by a verbal read through with a member of research staff. Ample time will be provided for staff to ask the researcher questions before verbally indicating if they wish to participate. As employees of HRH and the department in which research activities are taking place, some clinicians may feel a sense of pressure to participate, or perhaps even worry about work-related repercussions should they decline an invitation to engage in research activities. Clinical staff will be made aware that their participation is voluntary and not a condition of employment. The possibility of coercion or undue influence will be minimized, as research staff from the hospital's Research Institute, rather than staff from within the IBD clinic, will be responsible for recruiting and consenting clinical staff into the study.

Data Analysis and Sample Size

In line with a concurrent triangulation design, analysis of qualitative and quantitative data will be analyzed separately. Results from both methods will then be integrated and interpreted where appropriate.

Quantitative Analysis

Chart Review

Baseline demographics, clinical history, and outcomes including healthcare usage will be extracted from the electronic medical records for patients that had an IBD clinic visit any time since January 2021 to December 2024. A prospective chart review will also be conducted to extract post-*Triple Visit* patient information for those who had their first *Triple Visit* in 2023/2024. The primary goal of this chart review will be to compare patient outcomes at 6 months before and after their first *Triple Visit,* to understand how the new model of care has affected patient outcomes. The primary analysis will be a matched T-test, with a two-sided $P < 0.05$ as the critical value, effect size of 0.35, and power of 0.8. This estimates a required sample size of at least 67 patients for meaningful analyses.

Patient and Parent/Guardian Survey Data Analyses and Sample Size Calculation

The primary analysis will be a correlation between patient service satisfaction scores from the YSQ and HRQOL from the IMPACT-III, with two-sided $P < 0.05$ as the critical value, a medium effect size of 0.35, and a power of 0.8. This results in a required sample size of 61 patients. Secondary analyses will be descriptive statistics and bivariate statistics using T-tests, chi-squared and Pearson/Spearman correlations to identify relationships between other variables captured in the survey. Identical analyses will be conducted for the parent/guardian survey; thus, we will aim to recruit 61 parent/guardians, also. Once data is collected from both surveys, bivariate statistics will be utilized to compare differences between the patients and parent/guardians for the scales present in both surveys.

Structured Observation

Descriptive statistics will be used to capture the percentage of PACE Quality Indicators that have been implemented by the clinic, as well as the clinics compliance with these implemented measures.

Qualitative Analysis

Semi-structured Interviews with Parents/Guardians

Parent/guardian interview transcripts will be uploaded to NVivo 14 and will be analyzed thematically, primarily drawing on Braun and Clarke's six steps for analysis.[46,47]

Semi-structured Interviews with Clinicians

For clinician interviews, all transcripts will be uploaded into NVivo 14 where codes for each CFIR construct will have already been pre-defined from the CFIR taxonomy;[38] interviews will be coded deductively against the CFIR constructs selected from the interview guide. Interviews will also be coded inductively for relevant data that is not captured by the CFIR framework; the CFIR framework is flexible in that other researcher and project-specific codes that aid or hinder implementation but not captured but the CFIR framework can be developed during analysis. Abductive coding (coding deductively and inductively) thus produces a finely tuned analysis.[48,49]

Paediatric Patients and Play-Based Interviews

Paediatric patient data will be collected in the form of audio and fieldnote data from the play sessions and with video data if the child's parent/guardian had provided consent for their child to be video recorded. If the children created artwork, block towers or drawings, these products will not be analysed as they are not methods per se, but rather the evidence that the child engaged in responses to the interview questions that the child answered during the play session.

For children who were video recorded during their play session, these recordings will be analyzed using the six steps outlined in the Visual Verbal Video Analysis (VVVA)method; the method aligns with a similar approach to classic thematic analysis,[47] with an emphasis on selecting key moments in the video to analyze. The steps involve collecting and reviewing data, transcribing, choosing units of analysis, coding data, organizing, and describing data and reporting the findings.[50] For children whose parents/guardians opted out of video recording, their data will consist of an audio recording of the play-based interview in addition to fieldnotes taken by the qualitative specialist; fieldnotes will be structured using the using the VVVA matrix framework that includes the following topics: general characteristics of the video, multimodal and visual characteristics, participants in the video and content including emotions, gestures and discourses.[50,51] Analytic memos will be written by the CCLS and the QM after each patient interview; writing memos immediately after the data collection session will be critical to enhance validity and facilitate consensus discussions during analysis.[52]

Data Triangulation

We anticipate that the datasets from the qualitative and quantitative components that will intersect at the “point of interface” [53] will be the parent satisfaction survey with the parent interviews and the patient satisfaction survey with the patient interviews. With these datasets, we will be guided by Tashakkori & Teddlie: (1) data reduction (2) data display (3) data transformation (4) data correlation (5) data consolidation (6) data comparison and (7) data integration.[17] . More specifically, themes generated from qualitative results will be transformed into quantitative variables for comparison with the survey items. This comparison will be an iterative process wherein both datasets will be in conversation with each other to produce a consolidated profile of parent and patient satisfaction of the clinic.

Results

Recruitment commenced in January 2025, and we anticipate a data collection end date of December 2025. Thus, results are not yet available.

Discussion

We anticipate that this mixed-methods evaluation of a holistic paediatric IBD clinic model of care that includes a multidisciplinary team *Triple Visit,* as well as a rapid access component, will provide a strong rationale for a multidisciplinary approach to care for children with IBD, a population that is increasingly prevalent in Canada.[7] Our results aim to demonstrate how the clinic's accessibility, processes for health maintenance checks, patient and parent/guardian satisfaction and the monitoring of patients' mental health will enable a more comprehensive and holistic approach to patient care and management of IBD.

Limitations of this study can be pinpointed. First, data integration of mixed-methods concurrent designs is not without flaws.[19] Integrating and interpreting data sources from qualitative and quantitative results may pose challenges as it is possible that not all data sources will be compatible with each other, especially given the chasm between the two paradigms and their respective epistemological assumptions.[54] Consequently, we expect that some findings may exist independently within each paradigm rather than fitting together across both; these discrepancies may require further research to resolve them.[55] However, a benefit of this mixed-methods approach, is where one method has weaknesses or produces a gap in knowledge, the other method will be a strength by filling in those gaps. For example, from a quantitative perspective it is not possible to gather a true measure of pre-post implementation satisfaction among patients and their parents/guardians as satisfaction was not objectively measured prior to the new clinic model's implementation. By triangulating results from measures in the patient and parent/guardian surveys with the patient PBI and parent/guardian interviews, a fuller understanding of satisfaction pre-post implementation can be derived. Finally, the process of integrating and interpreting the data will be time-consuming as integration cannot occur until all data has been analyzed; generally speaking, qualitative data analysis is labour intensive and as such, leads to a longer timeline for completion.[56,57]

This protocol will be instructive for other scholars and clinicians of paediatric IBD. Given that the multidisciplinary clinic model is relatively new, we believe that this protocol will provide sound methodological direction for other studies that aim to evaluate or implement this model in their setting. From an implementation science perspective, qualitative results with clinicians will reveal contextual information about barriers and facilitators of putting the model in place in the clinic;[38] these results will show specific details on what factors led to high or low implementation success—data that may prove useful for other clinics that aim to implement a similar model of care. From the perspective of the paediatric IBD clinic at HRH, we anticipate this evaluation will lay the foundation for further monitoring and improvement of the clinic model, in addition to evaluating this model from a health economist and resource specific lens.

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Author Contributions

All authors contributed to the study conception and design. ACW and YL contributed equally to the methodology and establishing an analysis plan. AC served in a supporting role for patient qualitative methods. ACW served as lead for project administration. YL and PW served in a supporting role for project administration. PW and LH served as leads for supervision. The first manuscript draft was written by ACW, YL, and LH. All authors contributed to writing-review and editing. All authors read and approved the final manuscript.

Conflicts of Interest

The principal investigator, co-investigators, and research staff do not have any conflicts of interest, financial or otherwise, related to this study or its outcomes.

Abbreviations

CCLS: Certified child life specialist

EMRs: Electronic medical records

GI: Gastroenterologist

HRH: Humber River Health

IBD: Inflammatory Bowel Disease

PACE: Promoting Access and Care through Centres of Excellence

PBIs: Play Based Interviews

QM: Qualitative methodologist

TA: Thematic Analysis

VVVA: Visual Verbal Video Analysis

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Supplementary Files