

Shared Decision Making in Pregnancy in Inflammatory Bowel Disease: Design of a Patient Orientated Decision Aid

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Abstract

Objective:

Research has indicated a lack of disease-specific reproductive knowledge among patients with Inflammatory Bowel Disease (IBD) and this has been associated with increased “voluntary childlessness”. Furthermore, a lack of knowledge may contribute to inappropriate medication changes during or after pregnancy. Decision aids have been shown to support decision making in pregnancy as well as in multiple other chronic diseases. A published decision aid for pregnancy in IBD has not been identified, despite the benefit of pre-conception counselling and patient desire for a decision support tool. Development and feasibility testing of a decision aid encompassing reproductive decisions in the setting of IBD

Methods:

The International Patient Decision Aid Standards were implemented in the development of the Pregnancy in IBD Decision Aid (PIDA). A multi-disciplinary steering committee was formed. Patient and clinician focus groups were conducted to explore themes of importance in the reproductive decision-making processes in IBD. A PIDA prototype was designed and tested for feasibility.

Results:

Issues considered of importance to patients and clinicians encountering decisions regarding pregnancy in the setting of IBD included fertility, conception timing, inheritance, medications, infant health, impact of surgery, contraception, nutrition and breastfeeding. Decisions relating to conception and medications were chosen as the current focus of PIDA, however content inclusion was broad to support use across preconception, pregnancy and post-partum phases. Favourable and constructive user feedback was received.

Conclusions:

The novel development of a decision aid for use in pregnancy and IBD was supported by initial user testing.

Key Findings/implications

Initial user testing has supported the novel development of a decision aid for use in pregnancy and Inflammatory Bowel Disease.

Introduction

Inflammatory Bowel Disease (IBD) includes chronic conditions of the intestines namely Crohn’s disease (CD) and ulcerative colitis (UC). IBD is increasingly diagnosed at younger ages and is usually managed

with medications and/or surgery (1). It is known that the lack of IBD-specific reproductive knowledge among patients has been associated with increased “voluntary childlessness”, with reported rates of 18% and 14% in patients with CD and UC respectively compared with 6.2% in the general population (2, 3). Furthermore, a lack of patient and clinician knowledge may contribute to inappropriate medication cessation during attempts at conception or pregnancy and increase the risk of flares, despite the expanding data supporting drug safety in pregnancy (4–7). In particular, there is increasing evidence supporting the safety of biologics. With appropriate information provided to both patients and clinicians, it is anticipated that a greater proportion of patients may receive necessary IBD therapy that has not otherwise been prescribed or adhered to due to misinformation, with resultant optimization of maternal and foetal outcomes (8).

Active IBD during preconception adversely impacts fertility and increases the risk of active disease throughout pregnancy. Thus, it is recommended that patients be in remission before attempting to conceive (9, 10). Several studies have demonstrated that IBD activity during pregnancy can adversely impact outcomes. For example, a prospective Danish cohort study of women with a history of moderate to severely active IBD reported that disease activity was associated with an increased risk of low birth weight (adjusted odds ratio 2.05; 95% confidence interval: 0.37–11.35) and preterm birth (2.64; 1.14–11.36) (11). It is also known that active IBD is associated with an increased risk of miscarriage (12, 13).

A significant proportion of women with IBD are of child-bearing age and therefore, a decision aid focusing on reproductive decisions in the context of having IBD has the potential to have significant impact for both patients and clinicians. A Canadian survey study conducted between 2012 to 2014 of women with IBD and clinicians involved in the treatment of patients with IBD confirmed a lack of reproductive knowledge specific to IBD and a desire for more information (14). While there are existing evidence-based decision aids designed to support decision making in pregnancy in general, as well as in multiple other chronic diseases (15–17), a review of the existing literature has not identified such a resource for pregnancy in IBD. This is despite studies indicating the benefit of pre-conception counselling and patient desire for education and a decision support tool (14, 18–20).

Accordingly, we ascertained issues considered of importance to patients and clinicians encountering decisions regarding pregnancy in the setting of IBD to guide the design of a patient-focused decision aid intended for use in preconception, pregnancy and post-partum phases. Following identification of pertinent issues, an electronic decision aid was created, with the subsequent study aim to evaluate the feasibility of the decision aid using a user-centered approach.

Methods

OVERVIEW

The International Patient Decision Aid Standards (IPDAS) guided the development and evaluation of the Pregnancy in IBD Decision Aid (PIDA) (21). Figure 1 outlines the sequence of events in the design and

evaluation of the decision aid as recommended by IPDAS.

A steering committee was assembled comprising four IBD specialists (Dr Vivian Huang, Dr Astrid-Jane Williams, Dr Yvette Leung, Dr Levinus Dieleman), a general gastroenterologist (Dr Daniel Sadowski), an obstetrician (Dr Flora Fang-Hwa Teng), an obstetric medicine physician (Dr Rshmi Khurana), a paediatric gastroenterologist (Dr Eytan Wine), two patient representatives (Kristen Brooker and Virginia Lewis), a shared decision making expert (Dr Dawn Kingston), an information and knowledge translation specialist (Kathleen Ismond) and a perinatal pharmacoepidemiologist (Mary A De Vera). The steering committee conducted regular meetings by teleconference throughout the development process.

Three study sites were chosen to conduct user testing: 1. Liverpool Hospital (LH); University of New South Wales (UNSW) 2. Pacific Gastroenterology (PG); University of British Columbia (UBC) 3. Mt Sinai Hospital (MSH); University of Toronto (U of T)

Focus groups were conducted to explore patient and clinician views on decisional needs in relation to pregnancy and IBD and to receive feedback regarding methods in which content could be best delivered.

An existing systematic review within the field of pregnancy and IBD(9) was updated to ensure the comprehensive inclusion of current content relevant to the management of pregnancy in IBD. Content was appraised and then organised into themes by the steering committee for allocation of drafting of the individual sections of the decision aid.

An electronic prototype of the decision aid with a focus on (a) desires and 'ideal' timing for conception and (b) medication choices during pregnancy was produced and then evaluated by users for feasibility across the three sites.

PHASE ONE: FOCUS GROUPS

Patient focus group

A patient focus group was conducted at the UBC site to explore issues of concern in pregnancy and IBD. Participants were recruited through social media advertising with Crohn's and Colitis Canada and contacting patients at PG who had previously provided permission to be contacted regarding research opportunities. The focus group was moderated by a clinician and another clinician took fieldnotes to document key discussion items and contextual information, while there was also audio recording and subsequent transcription. Duration of this focus group was one hour and thirty-five minutes.

Clinician focus group

A clinician focus group was conducted at the UBC site to explore issues of concern relevant to clinicians and their patient care. The focus group was moderated by a clinician and another clinician took fieldnotes to document key discussion items. There was also audio recording and subsequent transcription. Duration of this focus group was one hour.

PHASE TWO: REVIEW and SYNTHESIZE EVIDENCE

Evidence based appraisal comprised two components: a systematic literature review and allocation of specific content topics to members of the steering committee as guided by their individual areas of expertise.

Literature review

More recent literature published in addition to that utilised to develop the Toronto Consensus Pregnancy Statements (9) was reviewed with the aim to identify the best available evidence on the management of IBD during the preconception period, pregnancy, and the postpartum period. The same search string and selection criteria for the databases MEDLINE and EMBASE as used in the development of the Toronto Consensus Pregnancy Statements were implemented. The updated search string was for January 1, 2014 to April 29, 2018. The overlap between the 2016 Toronto Consensus Statements (searches completed in MEDLINE from 1946 to Nov 2014 and in EMBASE from 1974 to Nov 2014) ensured completeness. In addition, ClinicalTrials.gov was systematically searched from inception to April 29, 2018. The search strategy used for this additional search is presented in Appendix 1.

Steering committee review of the content topic

The moderator of the steering committee directed allocation of content topics to each member at the initial steering committee teleconference according to member background expertise. Individual members then independently devised content summaries for each topic as guided by the literature and their own experience.

PHASE THREE: DECISION AID DESIGN AND EVALUATION

Prototype Design

Using content resulting from the focus groups, literature review and the review of content topics by the members of the steering committee, the steering committee drafted a paper version of the PIDA prototype, which was subsequently converted into a PowerPoint® version to enable incorporation of clickable logic. This was then used to guide the development of an electronic prototype through utilisation of the digital media company, Tactica. *

The description of the prototype according to the two key decisions is outlined below:

Desires and ideal timing for conception:

The desire to attempt conception and the ideal timing of such was considered in the design of the information presented. Given recognition of the contribution of fears relating to IBD and pregnancy, including the impact of disease activity on pregnancy, concerns regarding medication use, fear of disease

inheritance and concerns surrounding delivery, such topics were given emphasis in the design. In particular, there was a focus placed on the importance of disease remission at the time of conception.

Medication choices during pregnancy:

The decision as to what to do with IBD related medications during pregnancy was presented. This was supported by the rationale that medication management is essential during pregnancy (to maintain disease control given disease activity has been associated with adverse pregnancy outcomes) and specific medication information needs to be tailored to preconception, pregnancy and postpartum stages. The presentation of information included numerical probabilities, such as that relating to the impact of active disease on adverse pregnancy outcomes. Values regarding medication usage during pregnancy were also assessed prior to and following presentation of the aforementioned information.

Steering Committee Feedback

The steering committee subsequently provided feedback regarding the design and content of PIDA. An opportunity was offered to formally critique the comprehensibility, usability and accuracy through completion of the Clinician or Patient Feasibility Questionnaire (See Appendix 2a and 2b). The questionnaire was designed based on tools used in preceding decision aid studies (22–24), with questions pertaining to the time required to review PIDA, perceived readability, content amount, usefulness for the user (if patient user) as well as that anticipated for others, ability to aid with values clarification (if patient user) and accuracy (if clinician user).

With regards to the design, feedback included recommendations to improve clarity of the flow of the decision aid and outlay of text in individual sections. For example, colour coding of medication content according to safety of use was suggested. Content additions included elaboration of the information provided for medications and inheritance.

Four clinicians and two patient representatives from the steering committee provided formalised feedback, including an Obstetric Physician, an Obstetrician and an adult and a paediatric Gastroenterologist. (See Table 1) It is noted that the patients from the steering committee were already well educated on pregnancy and their IBD in the context of previous pregnancies and prior physician education, and hence it was reported that the decision aid did not personally impact their understanding and decision making.

Table 1
Steering Committee Feasibility Responses

CLINICIAN	
(n = 4)	
Question Statement	Response (Median)
Time for review of decision aid (minutes + IQR †)	12.5 (9.5–22.5)
Length* (where 3 indicates adequate, 1 short and 5 excessive)	3
Readability* (where 3 indicates appropriate, 1 simplified and 5 challenging)	3.25
Content Amount* (where 3 indicates appropriate, 1 limited and 5 excessive)	3
Usefulness for patient understanding and decision making * (where 3 indicates no impact on understanding and decision making, 1 confusing and 5 useful)	4.5
Recommending the decision aid to patient* (where 3 indicates suggested, 1 not recommended and 5 highly recommended)	3.5
Patient values* (where 3 indicates adequate assessment of patient values, 1 inadequate and 5 very well)	3
PATIENT	
(n = 2)	
Question Statement	Response (P1, P2) ‡
Time for review of decision aid (minutes + IQR)	17.5, 2.5
Length* (where 3 indicates adequate, 1 short and 5 excessive)	3,3
Readability* (where 3 indicates appropriate, 1 simplified and 5 challenging)	3,3

CLINICIAN	
(n = 4)	
Content Amount*	3,2
(where 3 indicates appropriate, 1 limited and 5 excessive)	
Usefulness for patient understanding and decision making *	3,3
(where 3 indicates no impact on understanding and decision making, 1 confusing, and 5 useful)	
Recommending the decision aid to others in my situation*	5,4
(where 3 indicates suggested, 1 not recommended and 5 highly recommended)	
Patient values*	5,4
(where 3 indicates adequate assessment of patient values, 1 inadequate and 5 very well)	
*Likert scale of 1 to 5	
† IQR: Interquartile range	
‡ P: Patient	

Patient Feasibility Testing

Feasibility testing comprised individual patient interviews and feasibility questionnaire completion to seek user feedback regarding the current PIDA prototype and ensure that content had been saturated with respect to what users considered necessary for inclusion. The concept of feasibility testing and the associated questionnaire was based on preceding publications focussing on the development of exemplary decision aids.(22, 24)

The following criteria was used for recruitment:

Inclusion Criteria: 18 to 45 years of age; confirmed diagnosis of IBD; preconception: (a) with no pregnancy history, however interested in considering issues surrounding pregnancy or prior pregnancy history, OR (b) currently pregnant, OR (c) post-partum (defined as within 12 months of delivery).

Exclusion Criteria: inability to speak or read English sufficiently to complete surveys or use the decision aid; known previous adverse pregnancy outcomes (which could place the participant at risk of emotional or mental health upset generated by pregnancy related discussions).

Patient interviews

Individual patient interviews were conducted by research coordinators or an IBD fellow at one of the three sites. The participant had the opportunity to review the PIDA prototype in the week preceding their interview using the website link. Basic demographic data was collected for each participant at the interview (age, reproductive status and IBD type (UC or CD)). An interview script was designed a priori and implemented during the interview. A template facilitating note taking during the interview was also designed (See Appendix 3). Each interview took approximately 30 minutes.

Feasibility questionnaire

In addition to patient interviews, participants completed a Patient Feasibility Questionnaire (See Appendix 2b). The compiled feedback obtained was then used to make further changes to the PIDA prototype.

Statistical approach

Sample Size

We aimed to have at least four representative participants from each of the reproductive stages of preconception, pregnancy and post-partum across the three sites for the focus group and interviews.

Statistical Methods

Baseline demographic and feasibility questionnaire responses were presented as proportions and medians respectively, depending on whether categorical or numerical distribution.

ETHICAL CONSIDERATIONS

The study had ethics approval from the associated institutions: UNSW (Human Research Ethics Committee number: 2019/ETH00254); UBC (Research Ethics Board Number: H17-02354); U of T (Research Ethics Board Number: 18-0215-E). Informed written consent was obtained from participants involved in the study.

Results

PHASE ONE: FOCUS GROUPS

Patient focus group

Three patients participated in the focus group, while a further seven who were also interested could not attend on the day due to personal or employment reasons. Median age of participants was 32 years, all with CD and in a preconception stage; one had a history of prior surgery (diverting stoma) for perianal

disease and all three were on biologic therapy. Two were currently employed, and the other receiving a disability pension.

Using thematic analysis, the transcript generated from the focus group was analyzed in terms of patient concerns, patient observations as a woman with IBD who is considering pregnancy and patient recommendations for the decision aid and specialist care. Patient concerns regarding conception and pregnancy included (a) the negative impact of active disease on both maternal and fetal/infant health (b) the potential impact of current and past drug therapies on the fetus/infant (c) the ability to care for a child in the setting of being unwell and (d) the ability to conceive, maintain a pregnancy and deliver in the setting of previous abdominal surgery. Recommendations for the design of the decision aid included the ability to facilitate joint decision making (patient and clinician) for decisions surrounding medication management in pregnancy and the promotion of the tool for users at any stage of their reproductive life, including at diagnosis in order for patients to know that pregnancy is an option despite IBD. Exemplary quotes for the expressed concerns and recommendations are shown in Appendix 4a.

Clinician focus group

In attendance at the focus group were two IBD nurses, an obstetrician, neonatal intensivist, two gastroenterologists (IBD Specialists), gastroenterologist (IBD Specialist with expertise in pregnancy) and two IBD fellows.

The transcript generated from the focus group was analysed using thematic analysis and in terms of clinician perception of patient concerns, clinician concerns regarding pregnancy in the setting of IBD, clinician observations as a health care professional for women with IBD and clinician recommendations for the decision aid. Perceived patient concerns included (a) medications in pregnancy, and in particular the potential for birth defects and impact on immunity, (b) infection risk in infants and safety of infant vaccination (c) plan for flares during pregnancy (d) nutrition, (e) contraception and (f) fertility. Recommendations for design of the decision aid included the ability to provide simplified information to patients at multiple stages (for example, preconception and pregnancy) of their reproductive life. Furthermore, the design of the decision aid was perceived as having a role in facilitating discussion with treating specialists, and hopefully promoting opportunities for discussions regarding pregnancy early on in the disease course that may not otherwise have occurred. Exemplary quotes for the expressed concerns and recommendations are shown in Appendix 4b.

PHASE TWO: REVIEW and SYNTHESIZE EVIDENCE

Literature review

The literature review identified 306 articles (290 following duplicate removal), with 104 records retained following title and abstract screening. Of the remaining 104 articles, 29 full text articles were included to

guide the decision aid content beyond what had been utilised to formulate the Toronto Consensus Pregnancy Statements (11, 25–53).

Steering committee review of the content topic

Each member of the steering committee devised a draft document outlining the recommended content for inclusion for the allocated topics of Introduction; Preconception; Pregnancy; Medications including biologic transfer and vaccinations (for example, Nutrition) and Delivery and Breastfeeding. The draft documents were initially reviewed individually by steering committee members followed by teleconference discussions of areas of concern including presentation, language or accuracy until agreement was obtained.

PHASE THREE: DECISION AID DESIGN AND EVALUATION

Prototype

The decision aid was designed to include a broad range of content, extending from fertility concerns through to post-partum issues and accordingly is considered relevant for users regardless of their reproductive stage. However, the steering committee decided that the predominant decision presented in the current version of PIDA would relate to medication choices during pregnancy (cessation, modification or continuation of current IBD medications), given medication concerns were the dominant theme in the patient focus group. The intention behind including information on all stages of pregnancy in the decision aid, however, was that it could also guide decision making with respect to the desire for and/or timing of attempts at conception, as well medication choices in the setting of breastfeeding.

Following several iterations, a prototype was agreed upon which was deemed suitable for alpha testing[^]. (See Appendix 5 for exemplary section of prototype) Reading level was assessed using the Flesch Kincaid index (54). Four representative content sections were chosen from the prototype for testing – disease activity, nutrition, substance abuse and post-partum medications. The obtained reading levels ranged between an average grade level of 13 to 16, deemed able to be read easily by 18 to 19 year olds and 21 to 22-year olds respectively.

Patient Feasibility Testing

Patient Interviews

Thirteen patients across three sites were interviewed, either in person at the institutional site or via telephone. Median age of participants was 31 years (interquartile range (IQR): 30.25-33), six with UC and seven with CD. Three were in preconception, six in pregnant and four in post-partum stages. For nine of these patients, expanded demographic data was available. (See Table 2)

Table 2
Demographic Variables of Feasibility Testing Participants(n = 9)

Demographic Variable	Frequency of Demographic n (%)
Age (median years + IQR [†])	31 (29.5–33.5)
Ulcerative Colitis	4 (44)
Crohn's Disease	5 (56)
Duration of Disease (median years + IQR)	5.5 (3.5–13)
Current Medications	
5-aminosalicylates	3 (33)
Corticosteroids	2 (22)
Immunomodulator (Thiopurine)	4 (44)
Biologics	4 (44)
Anti-Tumour Necrosis Factor	4
Vedolizumab	0
Ustekinumab	0
Surgical History	
Yes	2 (22)
No	7 (78)
Pregnancy Stage	
Preconception	3 (33)
Pregnancy	4 (44)
Post-partum	2 (22)
Currently breastfeeding	
Yes	2 (22)
No	0
Not Applicable	7 (78)
Prior Pregnancies (if pregnant, excludes current)	
Yes	5 (56)
No	2 (22)

Demographic Variable	Frequency of Demographic n (%)
Marital Status	
Married	6 (67)
Common-Law	1 (11)
Single	2 (22)
Highest Level of Education	
High school diploma	2 (22)
Trade, technical, vocational, business school	1 (11)
University Undergraduate Degree	3 (33)
Post Graduate Degree	3 (33)
Total Income (CAD/AUS \$)	
20 000–39 990	1 (11)
40 000–69 900	1 (11)
70 000–99,000	2 (22)
100 000 +	5 (56)
†IQR: Interquartile	

Content discussed during interviews at each site was analysed using thematic analysis. Patients indicated that the most desired content related to medication management during conception, pregnancy and lactation. Additional pregnancy in IBD questions related to other topics such as fertility, inheritance and delivery. Feedback regarding PIDA was predominantly positive, with comments pertaining to adequacy of content coverage, personalization, readability and unbiased information presentation. Suggestions were made for enhancement of design and inclusion of further content. Design related suggestions were the inclusion of visual aids, a summary page and the availability of links to further information, all of which have now been incorporated into the PIDA prototype. Recommendations for content additions which have since been incorporated into the current prototype included statistical representation of inheritance, exercise recommendations, pregnancy related gastrointestinal symptoms and differentiation from IBD symptoms and the timing of recommencement of medications post-partum. Content to be included in subsequent prototype iterations include the impact of IBD on sexual function, expected laboratory changes during pregnancy, and additional post-partum issues including IBD activity and newborn care. The responses to interview questions are summarised and further exemplified in Table 3.

Table 3
Summary of Patient Interview Responses

<p>What were you looking for or most interested in when you were first introduced to the content?</p> <ul style="list-style-type: none">• Health of baby when mothers have IBD[†]• Clear information on IBD drugs in relation to the effect it can have on the baby and on pregnancy• Information regarding breastfeeding while continuing IBD drug (safety)• Information regarding delivery
<p>What were some of the questions you first had about IBD and pregnancy?</p> <ul style="list-style-type: none">• How does my IBD effect my fertility?• Will I be able to breastfeed with IBD?• Can I have a vaginal delivery?• Will I pass IBD or my immune system to my baby?• Will any of my IBD drugs pass through to my baby? (during pregnancy & breastfeeding)
<p>If you had to speculate on what kinds of topics or guidance patients may be looking for when they have access to this info what do you think that would be?</p> <ul style="list-style-type: none">• The impact of drugs on both the pregnancy and the baby• What drugs are considered the safest for pregnancy, breastfeeding and the baby• How to plan drug doses for pregnancy, breastfeeding and baby's health• When is the ideal time to become pregnant
<p>When you first went through the decision aid, what was your first impression...?</p> <ul style="list-style-type: none">• Quantity of information on the slides was not overwhelming• Nothing seemed to be missing or too elaborate• Information was presented in a neutral light

What were you looking for or most interested in when you were first introduced to the content?

- Health of baby when mothers have IBD[†]
- Clear information on IBD drugs in relation to the effect it can have on the baby and on pregnancy
- Information regarding breastfeeding while continuing IBD drug (safety)
- Information regarding delivery

Suggested improvements to presentation or content

- Pictures and diagrams to help visualize information
- Statistics for example, likelihood of IBD inheritance and flares
- Summary page
- Links to further information
- Suggestions how to provide information on the available communication channels between specialists
- Transferability of the data entered in the system: are data provided stored and transferred to the IBD team?
- Information on how to increase chance of getting pregnant with IBD
- Sexual function and how it is impacted by IBD
- Pregnancy related GI symptoms vs IBD related symptoms
- Laboratory changes during pregnancy
- Safety or recommendations for exercise during pregnancy
- Analgesia during delivery
- When should medications be restarted
- What to expect after delivery – flare ups or otherwise
- Any special things for adjusting to home life in the presence of IBD

How did reviewing the decision aid make you feel?

- *It was a positive experience completing the survey and reading the answers*
- *The information presented did not change my opinions about pregnancy*
- *The information presented increased my confidence in women with IBD being able to have children*
- *The information did not result in any new concerns about IBD and pregnancy*

† IBD: Inflammatory Bowel Disease

Feasibility questionnaire

Feasibility questionnaires were completed at two of three sites. Scoring indicated that length was considered adequate, with a median time of 15 minutes (IQR: 10-16.25) for review. Similarly, readability and content amount were both scored as appropriate. Patients reported that the decision aid was useful in terms of obtaining information and decision making and noted that they would recommend to others in their situation. Importantly, it was indicated that PIDA enabled thorough assessment of patient values. Numerically there did not appear to be substantial variation between responses from participants who were pregnant as opposed to preconception or post-partum. Summarised feasibility questionnaire responses are displayed in Table 4.

Table 4
Patient Feasibility Questionnaire Responses (n = 9)

Question Statement	Response (Median)
Time for review of decision aid (minutes + IQR [†])	15 (10-16.25)
Length* (where 3 indicates adequate, 1 short and 5 excessive)	3
Readability* (where 3 indicates appropriate, 1 simplified and 5 challenging)	3
Content Amount* (where 3 indicates appropriate, 1 limited and 5 excessive)	3
Usefulness for patient understanding and decision making* (where 3 indicates no impact on understanding and decision making, 1 confusing, and 5 useful)	5
Recommending the decision aid to others in my situation* (where 3 indicates suggested, 1 not recommended and 5 highly recommended)	5
Patient values* (where 3 indicates adequate assessment of patient values, 1 inadequate and 5 very well)	5
*Likert scale of 1 to 5	
† IQR: interquartile range	

Discussion

There has been increasing recognition of the importance of tailored IBD management during conception, pregnancy and postpartum phases to optimise obstetric and infant outcomes. This has been parallel to the increasing complexity of therapeutic options for IBD. Fortunately, accompanying this is an increasing volume of data providing reassurance for the safety during conception, pregnancy and lactation of most medications prescribed for IBD. However, there remains deficiencies in clinician and patient education regarding the management of IBD during pregnancy. This has been highlighted in previous studies demonstrating high rates of voluntary childlessness, inappropriate medication management and the recognised desire for further education from both interest groups (3, 4, 20, 55).

Accordingly, we have embarked on the development of a personalised decision aid to help meet the aforementioned gap in patient education, which has been further motivated by preceding evidence for the use of decision aids in pregnancy (16). To guide this process, the IPDAS guidelines have been followed²¹. In addition, the Standards for UNiversal Reporting of patient Decision Aid Evaluations (SUNDAE) checklist was utilised to prepare the reporting of the design process and results (21, 56). The novelty of PIDA is that it is the first interactive personalized decision aid for pregnancy in IBD. Other available online resources to date are information presenting, or provide checklists, but none are as interactive or personalized to the extent that PIDA has been designed. We feel this advancement in the field will allow more preconception and pregnant women with IBD to obtain core information that they can use to make informed decisions and/or to stimulate discussion with their clinicians.

Reflecting on discussion and feedback occurring during focus groups and individual patient interviews highlighted the consistent theme of the potential for voluntary childlessness, with contributing factors of fear, limitations in existing knowledge and both individual and community misperceptions. Similarly, another persistent theme was that of medication uncertainty across all stages of reproduction (preconception, pregnancy and post-partum). Accordingly, two key decisions were identified (1) the decision regarding the possibility and timing of conception and (2) the decision around the choice of medications in the peri-partum period. Information relevant to both decisions (such as medication safety in conception, pregnancy and lactation; placental transfer and implication for infant vaccinations and importance of disease activity control) were provided in the decision aid. Questions were incorporated to help assist the individual user to clarify their values with regards to medication related decisions.

While there was an attempt to obtain a broad patient perspective in the design and preliminary evaluation process for PIDA, note is made of certain demographic biases, related to the intrinsic difficulties with recruitment, especially within the cohort of young patients who often have additional time constraints related to family (particularly given the involvement of young mothers with children) or professional commitments. Furthermore, it is acknowledged that the content included intensely personal issues, with discussion potentially being further challenged in the setting of an outpatient clinic location. Accordingly, there was a limitation of the number of participants able to attend the initial patient focus group. Further limitations were the homogeneity of disease type (CD) and preconception status of all participants, however there was inclusion of the impact of a previous IBD surgical history. Given the limitation of focus group size and the desire of participants to be involved in the study at a more convenient location (for

example from home), feasibility testing included the option of telephone interviews conducted by the research team. In the future, there could be consideration of videoconference as an alternative method to enhance participant involvement and comfort. It is also observed that the majority of participants in patient interviews were of a high socioeconomic background, and thus feedback obtained may not have been reflective of the intended overall target audience for PIDA, including those with limited reading skills. Future consideration of the potential influence of religious and cultural beliefs on pregnancy related perceptions is also necessary to enhance the generalisability of the decision aid.

Subsequent iterations of the current prototype will enable further fulfilment of the requirements in the criteria for judging quality of decision aids as listed in the IPDAS guidelines (57). In future prototypes, values questions assisting decision making surrounding the desires and timing of conception will be included. It is also intended that there will be the ability to enable the user to search for keywords, while content will also be presented in additional modes other than written text and graphs (for example, audio or video). Medication content will be expanded, in addition to being colour coded according to compatibility of use in conception, pregnancy and lactation. Additional content inclusion such as the impact of IBD on sexual function and the potential effect of IBD during the post-partum period will occur. Evaluation of the decision aid with patient and clinician alpha testing (including the assessment of the impact of PIDA on the quality of the decision-making process, as well as the decision) will guide future iterations. Furthermore, subsequent beta testing (with a randomised controlled trial) is necessary prior to routine use and promotion of the decision aid. Beyond beta testing, adaptation of the decision aid into different electronic technologies, including that of a mobile applications or video representation, could be considered.

Given the efforts employed to systematically develop the decision aid thus far, and the favourable initial user feedback obtained, we anticipate that PIDA will be able to meet an unmet need in the education of patients with IBD who are encountering decisions regarding conception, pregnancy and post-partum timing and management. We envision that there may be the potential for minimisation of voluntary childlessness, as well as optimization of maternal, foetal and infant outcomes related to the enhancement of pregnancy-specific IBD management through the use of PIDA.

Declarations

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Conflicts of Interest:

Astrid-Jane Williams: Honoraria received from Takeda, Janssen and Abbvie and Honoraria and Grant support from Ferring

Radha Chari: No COI

Susan Connor: Honoraria for Advisory Board participation, speaker fees, educational support and/or research support from Abbvie/Aspen/Celgene/Ferring/Gilead/Janssen/MSD/Novartis/Orphan/Pfizer/Takeda/Vifor

Mary A. De Vera: Canada Research Chair in Medication Adherence, Utilization, and Outcomes; Michael Smith Foundation for Health Research Scholar.

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Ethics Approval:

The study had ethics approval from the associated institutions: UNSW (Human Research Ethics Committee number: 2019/ETH00254); UBC (Research Ethics Board Number: H17-02354); U of T (Research Ethics Board Number: 18-0215-E).

Consent to participate:

Informed written consent was obtained from participants involved in the study.

Consent to publication:

Informed written consent was obtained from participants involved in the study.

Availability of data and material:

Data and material can be made available on reasonable request.

Code Availability:

Not applicable

Authors' contributions:

Astrid-Jane Williams: conception and design of the study; acquisition, analysis and interpretation of data and drafting and revising of the manuscript.

Neda Karimi: acquisition and analysis of data and drafting and revising of the manuscript.

Radha Chari: conception and design of the study; acquisition and analysis of data; drafting and revising of the manuscript.

Susan Connor: design of the study; acquisition of data; revising of the manuscript

Mary A De Vera: conception and design of the study; acquisition and analysis of data; drafting and revising of the manuscript.

Levinus A Dieleman: conception and design of the study; acquisition and analysis of data; drafting and revising of the manuscript.

Tawnya Hansen: design of the study; acquisition and analysis of data; revising of the manuscript.

Kathleen Ismond: conception and design of the study; acquisition and analysis of data; drafting and revising of the manuscript.

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Katie O'Connor: design of the study; acquisition and analysis of data; drafting and revising of the manuscript.

Daniel C Sadowski: conception and design of the study; acquisition and analysis of data; drafting and revising of the manuscript.

Flora Fang-Hwa Teng: conception and design of the study; acquisition and analysis of data; revising of the manuscript.

Eytan Wine: conception and design of the study; acquisition and analysis of data; revising of the manuscript.

Yvette Leung: conception and design of the study; acquisition and analysis of data; revising of the manuscript.

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Virginia Lewis: Contribution to the design and evaluation of PIDA through Steering Committee Role

FOOTNOTE

* Tactica specializes in cross-platform digital media strategy and products for researchers, agencies, and producers. Such products have included numerous health projects, including the HOPE digital platform designed and validated for antenatal and post-partum depression (58).

^ The current PIDA prototype can be found at <http://ibdpregnancyaid.com/>.

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Figures

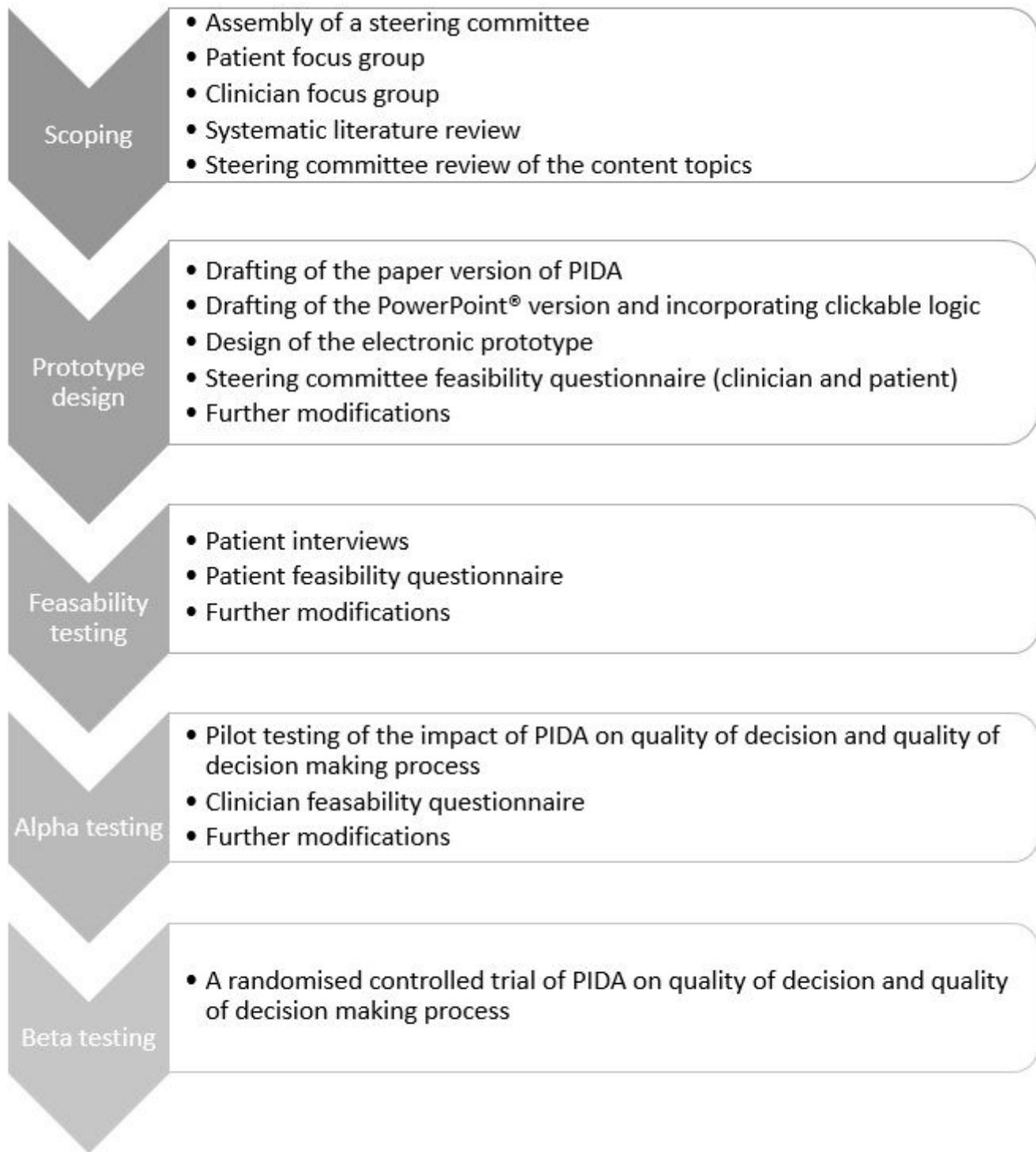


Figure 1

Flow Diagram of Decision Aid Development and Evaluation PIDA: Pregnancy in IBD Decision Aid

Supplementary Files

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