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

**Journal Name:** The Patient

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Appendix 1:

**Search strategy for clinicaltrials.gov**

1. inflammatory bowel disease OR IBD OR crohn\* OR ulcerative colitis
2. pregnancy OR pregnant woman OR prenatal care OR conception OR breast feed\* OR lactation
3. 1 AND 2
4. Limit 3 to Female, Adult (18–64), Trials with Results

Search period: conception to 2018

Number of records: 3

Number of records after abstract and title screening: 1 https://pubmed.ncbi.nlm.nih.gov/28814432/

Clowse ME, Förger F, Hwang C, Thorp J, Dolhain RJ, van Tubergen A, Shaughnessy L, Simpson J, Teil M, Toublanc N, Wang M, Hale TW. Minimal to no transfer of certolizumab pegol into breast milk: results from CRADLE, a prospective, postmarketing, multicentre, pharmacokinetic study. Ann Rheum Dis. 2017 Nov;76(11):1890-1896. doi:

Outline of the systematic review:

• Databases: Embase, MEDLINE, and Clinical Trials

• Total articles retrieved: 306

• Duplicate records removed (-16): 290

• Records retained following title; abstract screening (-186): 104

• Records included in the study following full text review (-75): 29

Appendix 2a:

**Patient Feasibility Questionnaire**

Thank you for your time to review the Pregnancy in Inflammatory Bowel Disease Decision Aid. We value your feedback and would appreciate if you could please complete the questionnaire below by circling which response best describes your rating for each assessment.

1. LENGTH

My review of the decision aid took me ……. minutes

On a scale of 1 to 5, I rate the length as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Too short Adequate Excessive |

1. READABILITY

On a scale of 1 to 5, I rate the ease to read as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Too simplified Appropriate Too challenging |

1. CONTENT AMOUNT

On a scale of 1 to 5, I rate the amount of information provided as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Limited Appropriate Excessive |

1. USEFULNESS (for me)

On a scale of 1 to 5, I rate how well the decision aid helped my understanding and decision making as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| More confusing No difference Useful |

1. USEFULNESS (for others)

On a scale of 1 to 5, this is how I would recommend the decision aid to others in my situation as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Not at all Suggest Highly Recommend |

1. VALUES

On a scale of 1 to 5, I rate how well the decision aid helps me demonstrate what is important to me as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Not at all Adequate Very Well |

Appendix 2b:

**Clinician Feasibility Questionnaire**

Thank you for your time to review the Pregnancy in Inflammatory Bowel Disease Decision Aid. We value your feedback and would appreciate if you could please complete the questionnaire below by circling which response best describes your rating for each assessment with the target patient population in mind.

1. LENGTH

My review of the decision aid took me ……. minutes

On a scale of 1 to 5, I rate the length as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Too short Adequate Excessive |

1. READABILITY

On a scale of 1 to 5, I rate the ease to read as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Too simplified Appropriate Too challenging |

1. CONTENT AMOUNT

On a scale of 1 to 5, I rate the amount of information provided as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Limited Appropriate Excessive |

1. USEFULNESS (for me)

On a scale of 1 to 5, I rate how well I expect the decision aid would help patient understanding and decision making as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| More confusing No difference Useful |

1. USEFULNESS (for others)

On a scale of 1 to 5, this is how I would recommend the decision aid to patients:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Not at all Suggest Highly Recommend |

1. VALUES

On a scale of 1 to 5, I rate how well the decision aid would likely help patients demonstrate what is important to them as:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 |
| Not at all Adequate Very Well |

1. ACCURACY

Please list any concerns regarding the accuracy of data presented in the decision aid:

Appendix 3:

**Patient Interview Script**

|  |
| --- |
| Date:Start Time:Stop Time:Interviewer:Participant Number: |
| Focus question | Responses | Key Issues |
| What were you looking for or most interested in when you were first introduced to the content?” |  |  |
| What were some of the questions you first had about IBD and pregnancy? |  |  |
| If you had to speculate on what kinds of topics or guidance patients may be looking for when they have access to this information, what do you think that would be? What questions would they have?  |  |  |
| “When you first went through the content in Decision Aid, what was your first impression?” * + “Were you overwhelmed by the quantity of information in the slides?”
	+ “Did you feel like anything was missing or too elaborate?”
	+ “Did you feel like the information was presented in a neutral light?”
	+ Is the information presented in the diagrams (inheritance and pregnancy associated risk) easy to understand?
 |  |  |
| How did reviewing the decision aid make you feel?* Was it a positive or negative experience completing the survey or reading the answers?
* Did the information presented change your opinions about pregnancy? For example,

- occurrence and/or timing of pregnancy in setting of IBD- decisions regarding what to do with medications surrounding pregnancy- decisions surrounding breastfeeding* Did the information presented increase your confidence about women with IBD being able to have children?
* Did the information presented result in any new concerns surrounding pregnancy and IBD?
 |  |  |
| Summary and reflections |

Appendix 4a:

**Patient Focus Group Quotations**

|  |  |
| --- | --- |
| Theme | Quotation |
| Voluntary Childlessness | *My mom always says, “I don’t want you to be pregnant. This disease is so stressful. You have stresses” … “Stress is bad for you. Don’t have children. Just live a life without kids and without husband and just be single” … So, to me, pregnancy sounds a little scary thing to do and is it possible?**So, I know having children is possible but then in my head I’m like well maybe her Crohn’s was different and maybe mine is not the right kind for it you know. Maybe the drug I’m on isn’t compatible with pregnancy. I have no idea. So, it’s just a scary sort of concept. But I mean I’d like for it not to be. It never was three years ago. It was eventually get married and have kids. That’s life but now it’s like ugh.* |
| Inflammatory Bowel Disease Medications | *I feel like I’ve heard it here and there that people do continue their IBD drug. But I didn’t know is it all the way through or how long and then what are the risks. Like what are the risks if a little bit is, like you said, there can be a little bit detected. I don’t know enough about the drug and what it does to understand what that could do to the development of the baby like I don’t really know much about that.**I get conflicting messages. I’ve heard women go into remission but then you’re putting drugs into your body and there’s supposed to be a baby in there.**I know every time the doctors say ok let’s try this medication, my first question is it okay to get pregnant on or how is it while you’re pregnant. That’s always my number one concern* |
| Impact of Inflammatory Bowel Disease on Pregnancy | *I think pre-term delivery was the main thing I took away from the discussion with my doctors. And I think they knew. I was concerned with the risk of preeclampsia, but it sounded like that was not particularly increased risk. So that’s great. I think things like a low birth weight if they’re born too early or if they are a little bit malnourished or you’re malnourished during pregnancy is a little bit of a concern.**I guess my concern is, if I were flaring, I know how weak I get myself and then the nutrients wouldn’t get to the baby and then you’d be depriving the baby and all…it’s like you can barely stand and function when you’re going through a flare and how are you supposed to be growing a baby when you’re not even getting the nutrients yourself. So, I think that’s a huge concern.* |
| Impact of Inflammatory Bowel Disease on Ability to Care for a Child | *I worry about parenting with Crohn’s just knowing how much my life revolves around it. Like where’s the bathroom, how quickly can I get to it, that kind of thing when you have a toddler with you and how that would go.* |
| Impact of Previous Surgeries on Pregnancy | *I don’t have an ostomy anymore, but what would it be like, can you be pregnant with an ostomy and do all that? See I don’t even know how that would all kind of come together and the impact of that. And um yah, I really don’t know.* |

Appendix 4b:

**Clinician Focus Group Quotations**

|  |  |
| --- | --- |
| Theme | Quotation |
| Inflammatory Bowel Disease Medications | *So, the kind of things that we hear kind of coming from patients are concerns that the medication is going to the baby obviously and that would be their concerns with continuing their medication after that.**I think birth defects is one thing and then immunity for the baby. So, they feel like oh I’m going to be immunosuppressed so is this baby going to be immunosuppressed as well? Am I going to have to have a bubble child and have lots of restrictions around infection meds, that kind of thing.* |
| Nutrition | *During pregnancy, patients will talk about nutrition, one big thing, because they want to be sure they are helping the baby receive enough nutrients and specifically about supplementation.*  |
| Contraception | *One thing we were going to add that we haven’t talked about yet is contraception so preventing pregnancy until you’re ready. So, drop that in the beginning or post-partum …if you are somebody who actively wants to use contraception because you know that your disease is really active, and it would be the worst case scenario for you to be pregnant in this time frame - that is something that should be included in the Decision Aide as well.* |
| Provision of Inflammatory Bowel Disease Care in Pregnancy | *So, the problem is that the ones who see us are a highly-select group. They are known to us. They are seeing IBD-focused doctors. …. It just really shouldn’t matter where you live or your proximity to IBD pregnancy specialist... We need a way of homogenizing care…. And I guess, in IBD and specifically in pregnancy, which is the area that I’m very passionate about it, we need a way to be able to offer it, at least education homogenously.*  |