MASTER OF SCIENCE BY RESEARCH

A mixed methods exploration of the experiences of women living with inflammatory bowel disease of pregnancy

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MScR

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A thesis submitted in part fulfilment of the University's requirements for the Degree of Masters of Science by Research

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Certificate of Ethical Approval

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Applicant:

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Project Title:

A Mixed Methods Exploration of the Experiences of Women Living with Inflammatory Bowel Disease of Pregnancy

This is to certify that the above named applicant has completed the Coventry University Ethical Approval process and their project has been confirmed and approved as Medium Risk

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Thank you to Crohns and Colitis UK for distributing my survey

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Most of all, thank you to the women, who shared their experiences with me and gave me an incredibly valuable insight into such an important time of their lives, and who without there would be no study

‘I can’t go back to yesterday – because I was a different person then’

Lewis Carroll

Abstract

Inflammatory bowel disease (IBD) is a chronic condition affecting the gastrointestinal system and is an umbrella term for Ulcerative Colitis and Crohns Disease, affecting one in 250 people. Management of symptoms of IBD prior to and during pregnancy is key, with the risk of developing pregnancy complications increasing if there is active disease (Getahun et al. 2014). Literature about IBD and pregnancy is dominated by medicinal safety, with a preliminary literature search highlighting the paucity of evidence about women's experience of pregnancy and IBD

The **aim** of the study was to gain insight into the experiences of women living with IBD of pregnancy. An exploratory, mixed methods design was selected, with data collected using an anonymous online survey containing closed ended questions, open ended questions and agreement scales. This was distributed by Crohns and Colitis UK on their website and social media platforms for six weeks. Women self-selected as fulfilling the eligibility criteria which was diagnosis of IBD prior to or during pregnancy, given birth in the last twelve months and aged 18 years or over.

The quantitative data was analysed using descriptive statistics due to the amount of data obtained and template analysis was used for the qualitative data. The quantitative results of the study identified that women felt that they were not prepared for the unpredictability of the disease activity during their pregnancy whilst the qualitative findings of the study identified concerns about mode of birth for women, with the differences in experience either detracting from or positively contributing to experiences of pregnancy. Advice about medication also varied, despite the literature being dominated by medication and safety efficacy, and therefore this wealth of literature does not appear to be being translated into meaningful information given to women by health professionals. A lack of midwifery knowledge about IBD also emerged and the impact this had on women's experiences of pregnancy.

Whilst a small sample, this study has provided a unique insight into the experiences of pregnancy for women living with IBD and has provided the opportunity to give suggestions about how their pregnancy could have been improved.

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Chapter 1: Introduction and Background to the Study

This is a mixed methods exploration of the experiences of women living with IBD and pregnancy and combines a literature review with original survey data on women's views to support the case for further work into women's experiences, clinical pathways and emotional support.

1.1 Personal Context of the Research

I have been a midwife for 15 years, working in a large acute teaching hospital. After the birth of my second child, I was diagnosed with Inflammatory Bowel Disease (IBD). During my midwifery training, or since qualifying I have received no teaching or training about IBD and therefore not only was it a huge personal learning curve, but on my return to work from maternity leave, it made me aware of the inequalities in care women with IBD have in pregnancy compared to women with other long term conditions such as diabetes or epilepsy who will have a specialist nurse, a specialist midwife, a named consultant and a robust personalised care plan; yet this was not the same for women with IBD. Women with IBD were routinely placed in bays with access to only one toilet, had their dietary choices dictated by the ward waitress' and prescribed medication which was contra-indicated due to their IBD, such as iron preparations. My new-found knowledge made me aware of the additional needs these women had and made me advocate for them to ensure they receive good quality care. However, I was aware that my knowledge had come from my personal experiences and most other midwives would not be privy to this information, therefore how can midwives provide evidence based, high quality care to women with IBD during pregnancy if they have not received any teaching about this topic. The holistic care of women with IBD in pregnancy, from a maternity care provider perspective needs to be more fully understood and this can be achieved through undertaking research in this area.

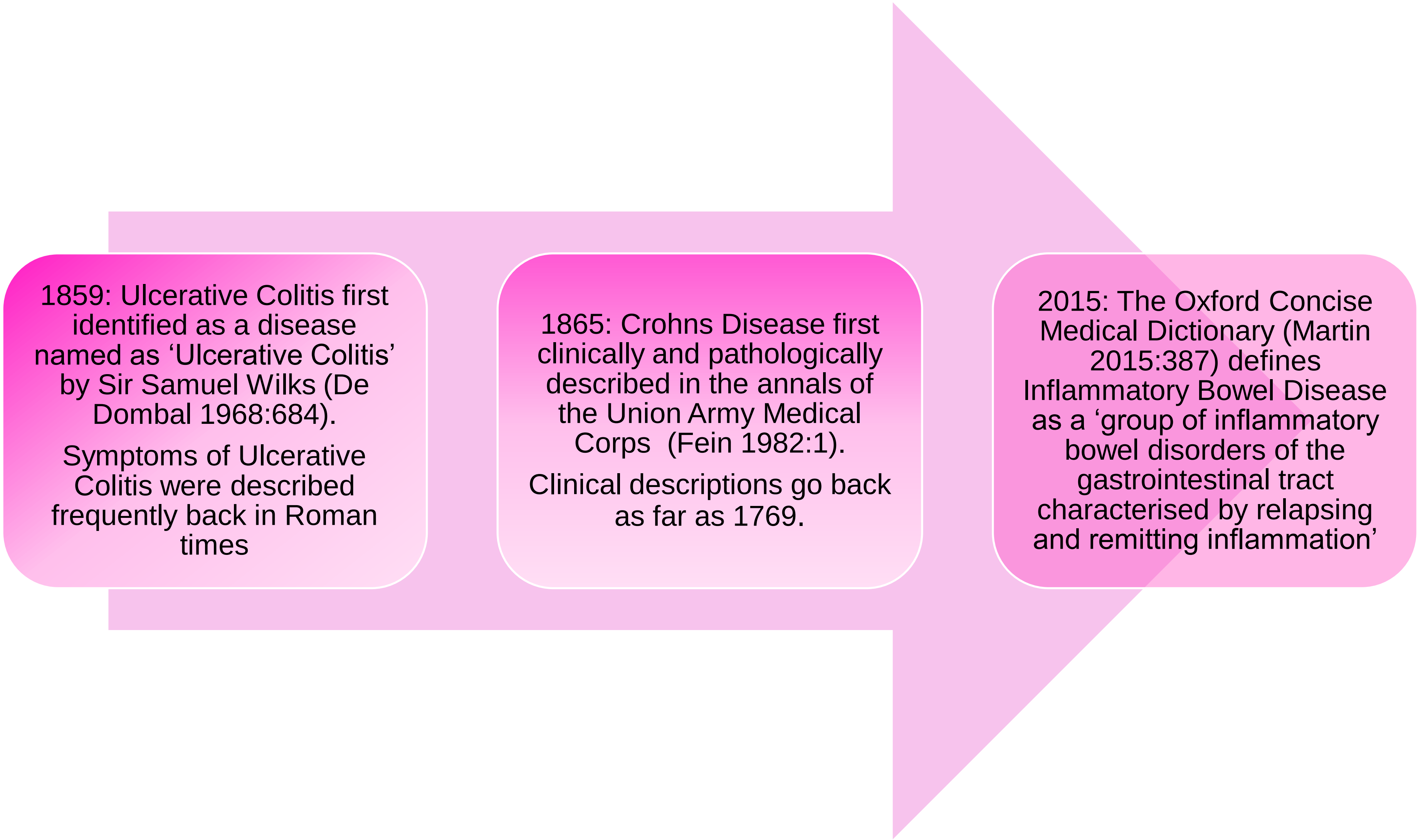
1.2 Background to the Study

IBD is an umbrella term for a chronic disease encompassing two main conditions: Crohns Disease and Ulcerative Colitis, with symptoms including abdominal pain, loss of appetite, anaemia, general fatigue and tiredness and diarrhoea (Crohns and Colitis 2017). Symptoms have a remission and relapse cycle, with a worsening of symptoms during relapse and no symptoms during periods of remission. IBD is not the same as Irritable Bowel Syndrome (IBS) which is a disorder of unknown cause which can result in abdominal pain and alternating diarrhoea and constipation (Youngson 2005).

The history of IBD is outlined in **Figure 1 (page 3**).

There are approximately 300,000 people living with IBD in the United Kingdom, with incidence of Ulcerative Colitis being nearly double that of Crohns Disease. The peak onset of IBD is between 15-30 years of age, however the etiology of IBD is still unknown, and the reason for this peak age of onset also remains unknown. Women with IBD have a similar fertility rate to that of the general population unless they have had pelvic surgery, which can decrease their rate of conception (Kwan and Mahadevan 2010:651). Approximately a quarter of women will get pregnant following their diagnosis of IBD (Riis et al. 2006:1539).

Figure 1: Timeline of IBD



1859: Ulcerative Colitis first identified as a disease named as ‘Ulcerative Colitis’ by Sir Samuel Wilks (De Dombal 1968:684).

Symptoms of Ulcerative Colitis were described frequently back in Roman times

1865: Crohns Disease first clinically and pathologically described in the annals of the Union Army Medical Corps (Fein 1982:1).

Clinical descriptions go back as far as 1769.

2015: The Oxford Concise Medical Dictionary (Martin 2015:387) defines Inflammatory Bowel Disease as a ‘group of inflammatory bowel disorders of the gastrointestinal tract characterised by relapsing and remitting inflammation’

Ulcerative Colitis can be scored using a severity index (**Figure 2**) and outlines the severity of the disease activity.

Figure 2: Reproduction of Truelove and Whitts Severity Index for Ulcerative Colitis

Some materials have been removed due to 3rd party copyright. The unabridged version can be viewed in Lancester Library - Coventry University.

(Truelove, SC and Witts, LJ (1955) Cortisone in Ulcerative Colitis: Final Report on a Therapeutic Trial *British Medical Journal* 1041-8)

Disease activity at conception can be a good indicator of both how the disease will behave during pregnancy, and the risk of pregnancy complications for the mother and the fetus/baby. Abhyankar, Ham and Moss (2013:5) concluded from their meta-analysis that women who become pregnant when there is active disease are more likely to have active disease throughout their pregnancy, compared to those who are in remission at conception. Pregnancy for women with IBD does increase the risks of complications including maternal gestational diabetes, preterm birth (<37 weeks) both spontaneous and iatrogenic, such as preterm prelabour caesarean section or induction of labour, low birth weight (< 2.5kg) and caesarean section and these are discussed in studies by Getahun et al. (2014), Boyd et al. (2015), Shand et al. (2016) and Bortoli et al. (2011). The prevalence of these complications are not conclusive from the available literature, however the increased risk is evident and should therefore be considered and acknowledged.

Women with IBD are considered to have a high risk pregnancy (Ferguson et al. 2008), which Lee et al. (2015:43) describe as a woman with either an obstetric or medical history which could affect the pregnancy and requires referral to an obstetrician. Kapoor et al.(2016:205) recommended that they should ideally be cared for by a specialist multidisciplinary team of an obstetrician and a medical or gastroenterology team, yet the national guidance management of long term conditions in pregnancy varies greatly depending upon the condition, with no clear rationale for this discrepancy.

The National Institute for Health and Care Excellence (NICE 2015) gives clear guidance around the management of diabetes in pregnancy, from preconception right through to the postnatal period. Similarly NICE have guidance around the management of epilepsy in pregnancy and birth (NICE 2018), however there is no specific guidance around the management of IBD during pregnancy or birth despite evidence of adverse outcomes for mothers and babies. The most recent NICE guidance around the management of Ulcerative Colitis (NICE 2013) has a small section about ensuring good communication between health professionals during pregnancy and that the risks of treatment should be discussed with the patient, whilst the NICE guidance (NICE 2012) regarding the management of Crohns disease also only contains a small subsection about conception and pregnancy. NICE offers clear pathways for the management of high risk pregnancies complicated by some long term conditions yet offers no real acknowledgement of the complications IBD may have on a pregnancy. European Crohns and Colitis Organisation (ECCO) offers comprehensive guidance about the care women for women with IBD in pregnancy in their 18 page guidance/consensus paper (van der Woude et al. 2015), with contributions from numerous European countries, yet unfortunately this guidance has not been used in the NICE guidance. As most acute NHS Trusts base their clinical guidance on NICE guidance, it could be argued that the lack of national NICE guidance around the management of IBD in pregnancy, birth and the postnatal period means the risks are not being adequately managed. There are also psychological considerations for women, with Zadeh et al. (2012:110) suggesting that women diagnosed with a high-risk pregnancy are at increased risk of developing anxiety and/or postnatal depression, therefore women with IBD may then not only have the risk of adverse physical outcomes, such as preterm birth as previously discussed, but may also be at increased risk of developing a psychological disorder during or after pregnancy.

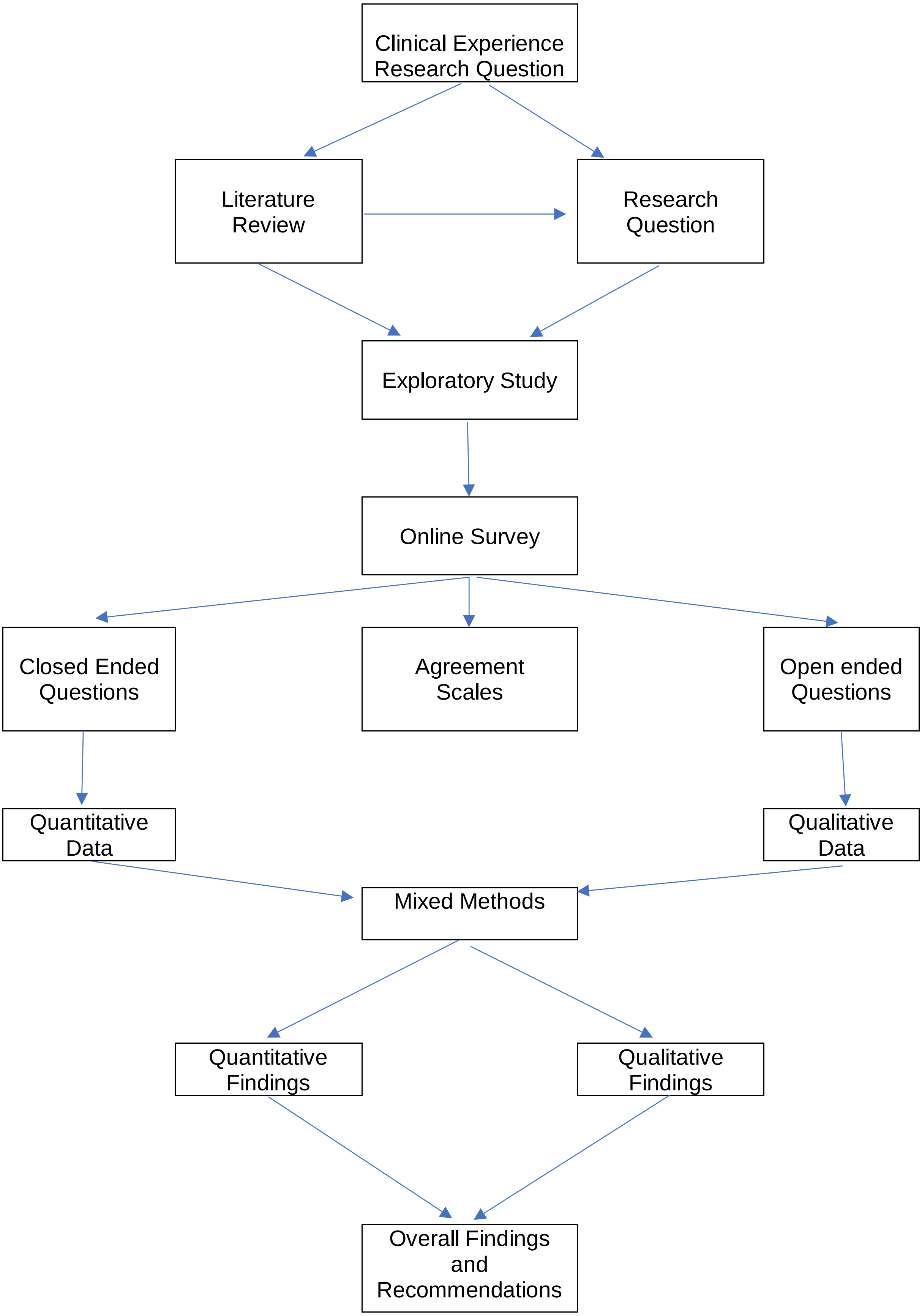
1.3 Chapter Summary

IBD complicates pregnancy for many women, and even those whose pregnancy is not directly affected by IBD, the diagnosis of a high-risk pregnancy can affect a woman's wellbeing. Further exploration of IBD and pregnancy is needed to understand what is already known, what research has already been undertaken and if there is a gap in the existing knowledge which may offer new knowledge or insights when answered.

An exploratory study will be undertaken, to gain insight into the experiences of women living with IBD of pregnancy, to enable to their voices to be heard about what is important to them and to identify any recommendations for clinical practice which will enhance or improve the experiences of pregnancy for women who have IBD. The process in which this exploration will be undertaken is presented in **Figure 3.**

Chapter 2 will now determine and critically analyse the available literature about IBD and pregnancy.

Figure 3: A Diagram to Show the Study Process



Chapter 2: Reviewing the Literature

2.1 Introduction and Aim of the Literature Review

This chapter will explore and critically appraise the existing literature about IBD and pregnancy, to determine what is already known in this research area and to support defining the research question and identifying appropriate research methods.

2.2 Design

A narrative literature review was undertaken as this involves comprehensively assessing and critically appraising the existing literature relating to the area of interest, or research area, and then provides justification for the research question (Bryman 2016:91). A narrative review is often used as the background for empirical study as it provides an overview of the chosen research topic, and then provides a springboard to explore this research topic further through empirical research.

2.3 Search Methods

2.3.1 Key Words/Search Terms

Prior to undertaking the literature review, key words relating to the research topic were identified through undertaking a preliminary literature search, as suggested by (Bryman 2016:110). The key words which were identified in relevant articles were recorded (**Table 1).**

Table 1: Key Words

Ulcerative Colitis	**Crohns Disease**	**Inflammatory Bowel Disease**
IBD	**Childbirth**	**Pregnancy**
Colitis	**Crohns**	**Experience**

These words were then individually entered into the chosen databases to assess their suitability as key words and ensure that appropriate articles were retrieved from the databases.

Once the keywords had been ‘tested’, a combination of words were entered into the databases to ensure that similar articles were obtained, and the best combination of words was then decided as the search terms. Both the title and the abstract were searched individually to ensure that all relevant articles would be identified.

Table 2 summarises the search terms, which electronic data bases were searched, and the number of results generated from the search:

Table 2: Search terms

Search Terms	Searched in:	Database:	Number of results
Inflammatory Bowel Disease AND pregnancy	Title	**Academic Search Complete** AMED – The Allied and Complementary **Medicine Database** CINAHL Complete **GreenFILE** PsycARTICLES **Library, Information Science & Technology Abstracts** MEDLINE **PsycINFO**	304
Inflammatory Bowel Disease AND pregnancy	Abstract	**Academic Search Complete** AMED – The Allied and Complementary **Medicine Database** CINAHL Complete **GreenFILE** PsycARTICLES **Library, Information Science & Technology Abstracts** MEDLINE **PsycINFO**	875
Inflammatory Bowel Disease AND pregnancy AND Experience	Title	**Academic Search Complete** AMED – The Allied and Complementary **Medicine Database** CINAHL Complete **GreenFILE** PsycARTICLES **Library, Information Science & Technology Abstracts** MEDLINE **PsycINFO**	1
Inflammatory Bowel Disease AND pregnancy AND Experience	Abstract	**Academic Search Complete** AMED – The Allied and Complementary **Medicine Database** CINAHL Complete **GreenFILE** PsycARTICLES **Library, Information Science & Technology Abstracts** MEDLINE **PsycINFO**	36

2.3.2 Inclusion/Exclusion

Inclusion and exclusion criteria were developed prior to undertaking the literature search which was structured using the PRISMA Checklist (Liberati et al. 2009). The PRISMA Flow Diagram was to be used to screen the articles from the literature search. The inclusion/exclusion criteria were developed to ensure that the articles to be included were appropriate to the empirical study topic (**Table 3**). The rationale for the inclusion/exclusion of articles was: due to the development of medication for the treatment and management of IBD in the last ten years, articles over ten years old were not included, articles not in English were not included due to the time/resources needed to translate them, and the focus of the article needed to be about women's experiences and perspectives of pregnancy and IBD. The articles also needed to be written about a healthcare system equitable to that of the UK.

Table 3: Inclusion and exclusion criteria

Inclusion Criteria	**Exclusion Criteria**
Article written in English Health care system similar to UK Article published 2008 onwards **Focus on:** Patient perspectives Patient experience	Article not written in English Health care system similar to UK Article published prior to 2008 **Focus on:** Medication safety Medication efficiency Fertility Adverse outcomes for baby Complications for mothers Fathers with IBD Effects of medication on breastfeeding

2.4 Search Outcomes

All abstracts for the articles generated from the literature search were read and the following themes evolved:

Table 4: Search outcomes and themes

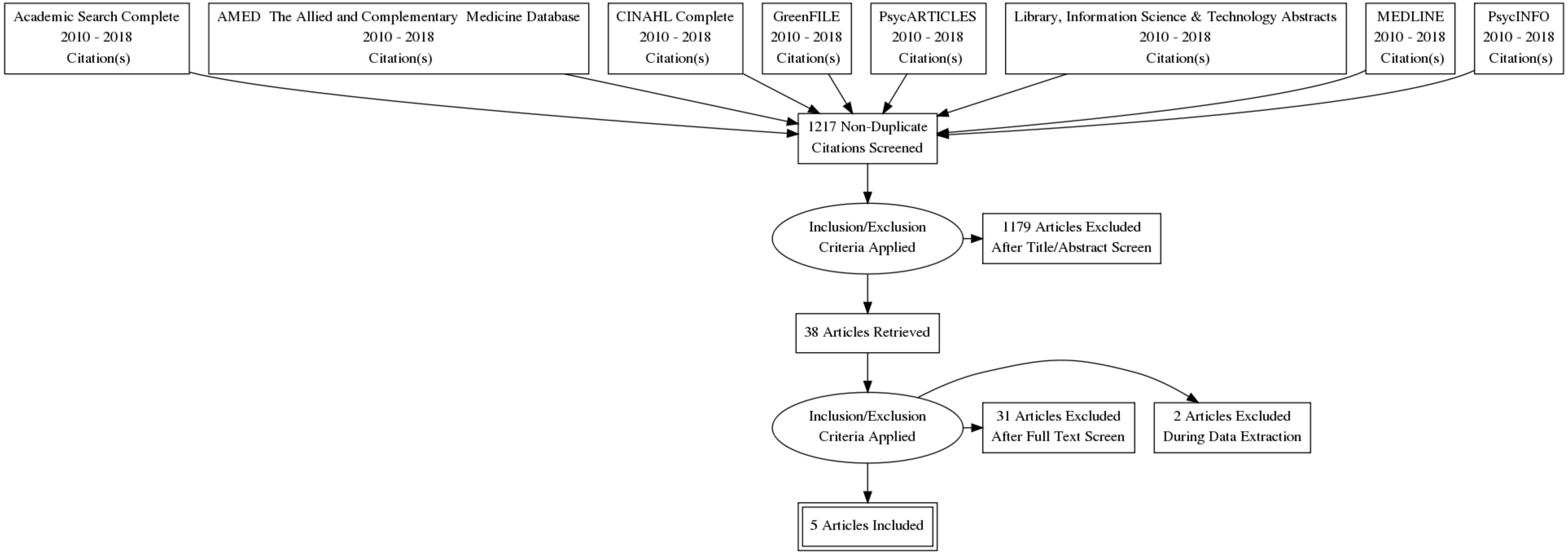
Safety of medication in pregnancy	**Fertility**	**Breastfeeding**
Prophylactic low dose molecular weight heparin Corticosteroids Anti TNF inhibitors Infliximab Adalimumab Allopurinol Ciclosporin Biologics Mercaptopurine azathioprine	Reproductive planning Voluntary childlessness	Role in disease activity Medication use Drug transfer
Outcomes for mother	**Outcomes for baby at birth**	**Knowledge**
Gestational diabetes Seasonal variations – birth month DVT Tuberculosis Placental inflammation Timing of Diagnosis Disease Activity at Conception	Low birth weight Preterm birth Brain injury Disease Activity at Conception	Women’s knowledge Obstetricians knowledge Gastroenterologist knowledge
Fathers	**Children (offspring)**	**Management**
Influence of medication: Thiopurines Preconceptual care IVF Voluntary childlessness	Medications Live vaccines Long Term Follow up	Surgical Endoscopy Care

The 1217 articles were then screened using the inclusion and exclusion criteria. As demonstrated in **Table 4**, medicinal safety dominated the literature, and this reflects the developments in medication used to treat and manage IBD over the last ten years.

Of the 1217 results from the literature search, five fulfilled the inclusion criteria and are detailed in **Table 5**, with the focus of the study or article being on experiences of women during pregnancy.

The PRISMA checklist (Liberati et al. 2009) was used as this facilitates a systematic approach to screening and then selecting or discarding articles generated from the literature review. It provides a step by step approach which then translates to a PRISMA Flow Diagram which illustrates how the articles were screened and selected (**Figure 4**)

Figure 4: A Prisma Flow Diagram to Show Screening of Articles



(Liberati et al. 2009)

Table 5: Articles Selected for Inclusion

Authors	Title	Year published	Journal	Approach	Sampling Technique (Country)	Summary
Mountifield, R.E., Prosser, R., Bampton, P., Muller, K., and Andrews, J.M.	Pregnancy and IBD Treatment: This Challenging Interplay from a Patients	2010	*Journal of Crohn's and Colitis*	mixed methods retrospective study	pregnancy outcome data from women with IBD (Australia)	This study identified risk factors for adverse pregnancy outcomes, and explored patient perceptions of the interaction between pregnancy and IBD medications and if this affected medication taking behaviour.
Cooper, J., Collier, J., James, V., and Hawkey, C	Living with Inflammatory Bowel Disease: Diagnosis during Pregnancy'.	2011	*Gastrointestinal Nursing*	case study	Purposive sampling (UK)	This case study focus is on one participants experience who was diagnosed with IBD during pregnancy.
Selinger, C.P., Leong, R.W.L., and Lal, S	'Pregnancy Related Issues in Inflammatory Bowel Disease: Evidence Base and Patients' Perspective'	2012	*World Journal of Gastroenterology*	Clinical review	Clinical review	This clinical review provided information about the pregnancy related issues in IBD combining both the evidence base and perspectives from women
Selinger, C.P., Eaden, J., Selby, W., Jones, D.B., Katelaris, P., Chapman, G., McDonald, C., McLaughlin, J., Leong, R.W.L., and Lal, S	Patients' Knowledge of Pregnancy-Related Issues in Inflammatory Bowel Disease and Validation of a Novel Assessment Tool ("CCPKnow")'	2012b	*Alimentary Pharmacology & Therapeutics*	survey design	Purposive sampling (Australia)	This study was designed to validate a new tool which assessed women's knowledge of pregnancy related issues in IBD
Ghorayeb, J., Branney, P., Selinger, C.P., and Madill, A	'When Your Pregnancy Echoes Your Illness: Transition to Motherhood With Inflammatory Bowel Disease'	2018	*Qualitative Health Research*	Semi-structured interviews	Purposive sampling (UK)	This study conducted semi-structured interviews with women who have IBD and have a child aged two to seven years to gain understanding of the transition to motherhood

2.5 Quality Appraisal

Critical appraisal is essential as it seeks to highlight methodological flaws in the literature, whilst also looking at the reliability and validity of the studies (Bryman 2016:95). There are numerous critical appraisal tools available depending upon the type of literature being critiqued. There are two main institutes which provide checklists for critically appraising literature: Joanna Briggs Institute (JBI) and the Critical Appraisal Skills Programme (CASP) (**Table 6**).

Table 6: Critical appraisal checklists

JBI	CASP
Checklist for Diagnostic Test Accuracy Studies	Diagnostic Testing Checklist
Checklist for Systematic Review	Systematic Review Checklist
Checklist for Randomised Control Trials	Randomised Control Trial Checklist
Checklist for Case Control Studies	Case Control Checklist
Checklist for Cohort Studies	Cohort Study Checklist
Checklist for Economic Evaluations	Economic Evaluation Checklist
Checklist for Qualitative Research	Clinical Prediction Checklist
Checklist for Prevalence Studies	
Checklist for Quasi-Experimental Studies	
Checklist for Case Series	
Checklist for Case Reports	
Checklist for Test and Opinion	
Checklist for Analytical Cross Sectional Studies	

JBI provide checklists for the seven study designs which CASP provide checklists for, and they also provide a further six checklists for further study designs, so it could be argued that they provide checklists for a more comprehensive range of study designs. There are other available critical appraisal tools.

READER (Relevance, Education, Applicability, Discrimination, Evaluation and Reaction) (MacAuley 1994) was initially developed to assist general practitioners with critiquing literature but has become an accepted a critical appraisal tool and is well suited to the critical appraisal of clinical reviews. SPIDER, (Sample, Phenomenon of Interest, Design, Evaluation and Research Type) (Cooke et al. 2012) was initially developed as a search strategy for qualitative research and has evolved to become a critical appraisal tool and is well suited to mixed method study designs.

It is therefore important to ensure that the correct tool is used to appraise the study depending upon its methodology.

The studies were appraised using the following selected critical appraisal tools (**Table 7**):

Table 7: Selected articles and critical appraisal tool

Authors	Title	Type	Critical Appraisal Tool Used
Mountifield, R.E., Prosser, R., Bampton, P., Muller, K., and Andrews, J.M.	Pregnancy and IBD Treatment: This Challenging Interplay from a Patients Perspective	Mixed methods	SPIDER Tool (Cooke et al. 2012)
Cooper, J., Collier, J., James, V., and Hawkey, C	Living with Inflammatory Bowel Disease: Diagnosis during Pregnancy'.	Case Study	Joanna Briggs Institute Checklist for Case Reports (Joanna Briggs Institute 2016)
Selinger, C.P., Leong, R.W.L., and Lal, S	'Pregnancy Related Issues in Inflammatory Bowel Disease: Evidence Base and Patients' Perspective'	Clinical Review	READER (MacAuley 1994)
Selinger, C.P., Eaden, J., Selby, W., Jones, D.B., Katelaris, P., Chapman, G., McDonald, C., McLaughlin, J., Leong, R.W.L., and Lal, S	Patients' Knowledge of Pregnancy-Related Issues in Inflammatory Bowel Disease and Validation of a Novel Assessment Tool ("CCPKnow")'	Quantitative Survey	CASP Diagnostic Checklist (Critical Appraisal Skills Programme 1994)
Ghorayeb, J., Branney, P., Selinger, C.P., and Madill, A	'When Your Pregnancy Echoes Your Illness: Transition to Motherhood With Inflammatory Bowel Disease'	Qualitive study	Joanna Briggs Institute Checklist for Qualitive Research (The Joanna Briggs Institute 2017)

All the studies fulfilled the relevant checklist and were deemed to be suitable for inclusion in the literature critique.

2.6 Results and Discussion

2.6.1 Study Population

The study population differed in the study with some recruiting women of childbearing age and some specifically targeting women who had experienced a pregnancy. An exception to this is Cooper et al. (2010) who recruited 30-40 year old with IBD for a study and this case study evolved as one participant was diagnosed with IBD during her second pregnancy (Cooper et al. 2010). Selinger et al. (2012b) recruited participants who were women aged 18-45 years, either attending tertiary IBD hospital clinics or who were registered with gastroenterologists not based in a hospital or in-patient setting. It is unclear exactly how many tertiary hospitals were included, only that 44 women were recruited because of attending IBD clinics in tertiary hospitals and 101 women were under the care of a gastroenterologist. This may lead to sample bias, as described by Bryman (2016:174); if all of the participants were receiving care from the same tertiary hospital, then they would have received the same care pathway, including similar patient information. The participants in Sellinger (2012b) had not all experienced pregnancy and it could be argued that this a flaw in the study as women who have experienced pregnancy will have been exposed to more information and therefore have more knowledge about the effects of IBD on pregnancy. Selinger et al. (2012b) appropriately identified pregnancy as a variable which increased knowledge of IBD and pregnancy in their study, and this could be attributed to the information women may acquire during pregnancy or when planning a pregnancy. Women considering a pregnancy, or who become pregnant are more likely to seek out information about the implications their IBD may have on pregnancy, and therefore increase their knowledge about this, as opposed to women who either are voluntary childless or who have not yet considered parenthood.

An alternative recruitment strategy was employed by Mountifield et al. (2010) who surveyed 219 women aged between 18-50 years old who were contactable from a hospital based IBD database. The survey was entitled: *Quality of life, body image, sexual function and pregnancy in IBD – A survey of patients in their reproductive years*. A section of the survey contained 61 questions which explored pregnancy outcomes. Only women who had experienced pregnancy needed to complete this section, with 143 completing the survey.

Ghorayeb et al. (2018) advertised their study via Crohns and Colitis UK, social media and relevant websites, with 98 women enquiring about the study and 22 recruited using purposive sampling to ensure a diverse study population. Eligible women were those with a self-reported diagnosis of IBD, at least 18 years old and having given birth to at least one child aged between two and seven years.

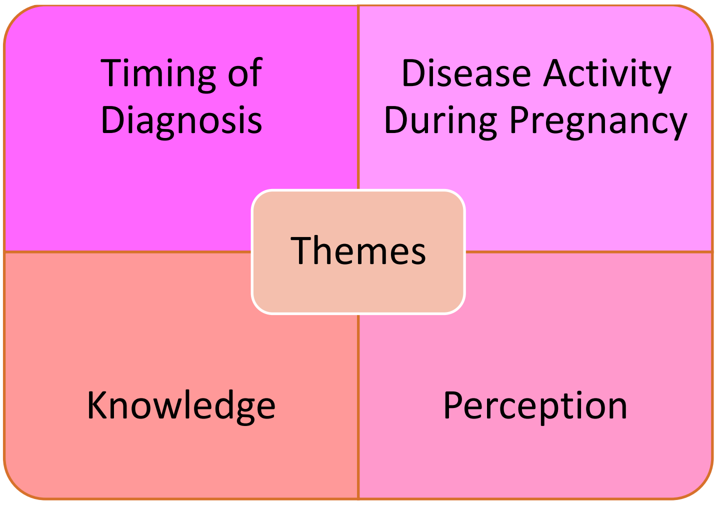
The clinical review by Selinger, Leong and Lal (2012) examined literature from 1980-2010 in relation to IBD and pregnancy and breastfeeding and any data available about patient views about the impact IBD and its treatment in pregnancy. They discussed the literature in relation to fertility and conception, disease behaviour during and after pregnancy including the effects of disease activity on pregnancy, congenital abnormalities in babies born to women with IBD, medication, mode of delivery, breastfeeding and women's beliefs and attitudes.

Whilst two studies did not aim to offer generalisable results from their study; Cooper et al. (2011) and Ghorayeb et al. (2018) offered unique insights into the diagnosis of IBD during pregnancy, whilst Selinger et al. (2012b) and Mountifield et al. (2010) aimed to provide generalisable results from their studies. Mountifield et al. (2010:181) acknowledged they did not achieve this due to several limitations of their study, which included the potential of recall bias due to the respective nature of the study and the reliance of self-reporting without external validation of adverse outcomes. Conversely Selinger et al. (2012b:62) considered the results of their study demonstrated reliable and accurate quantification of women's knowledge of disease activity in pregnancy.

2.6.2 Themes from the Literature

Four themes of timing of diagnosis, disease activity, knowledge and perception emerged whilst critically appraising the selected literature (**Figure 5**):

Figure 5: Emerged themes from the literature review



2.6.2.1 Timing of Diagnosis

Timing of diagnosis was a theme which emerged in all five articles, with the emphasis being greater in some than others. Women were either diagnosed with IBD prior to conception or whilst pregnant. Mountifield et al. (2010:177) states that a quarter of women with IBD will conceive after diagnosis and references this with Ferguson et al. (2008) and Loftus (2004). Interestingly Ferguson et al. (2008) does not reference this figure so it’s origins are unknown and Loftus (2004) makes no reference to this figure in his paper.

This is a commonly used statistic when discussing conception rates in women with IBD but Mountifield et al. does not collect this information from the participants in their study. It seems that there may have been a missed opportunity, as this information could have been easily collected and would have given valuable information as opposed to quoting the accepted rates. Timing of diagnosis had specific implications for women, with Ghorayeb et al. (2018:7) identifying that women who were diagnosed with IBD during childhood relied on their mother and partner for support in pregnancy, and this may be related to the parent/child relationship when the disease emerged, with the parent caring for the child during illness. Selinger et al. (2012b:61) found that women who had given birth since their diagnosis of IBD had better knowledge of pregnancy related issues in IBD than those who had not. As previously discussed, this is likely to be due to the information acquired during pregnancy and highlights a lack of effective pre-conceptual advice. Selinger, Leong and Lal (2012:2600) does not explicitly explore timing of disease but suggests that women's attitudes may influence decision making around having children, with the literature used to formulate the clinical review suggesting that women with IBD are more fearful of fertility problems and concerns about passing on IBD to their children being the main reason given for women with IBD being voluntarily childless (Selinger, Leong and Lal 2012:2605).

Diagnosis during pregnancy also had specific effects on the women, as Ghorayeb et al. (2018:6) discussed the impact of diagnosis of IBD during pregnancy for two participants who blamed their pregnancies for triggering the IBD. Cooper et al. (2011:30) discussed the additional impact that a delay in diagnosis of IBD during pregnancy had on the relationship between the woman and the health care providers and the effects on the mother-baby relationship following birth.

Cooper et al. (2011:33) recommend that further research is needed into the experiences of women who are diagnosed with IBD during pregnancy because this case study evolved from a larger study exploring IBD. Due to the pregnancy of one of the participants an insight was gained. However, this is the experience of only woman, hence the need to explore this further.

2.6.2.2 Disease Activity During Pregnancy

Disease activity during pregnancy and its attribution to adverse outcomes features in all of the articles and is the main focus of many articles relating to IBD and pregnancy. Cooper et al. (2011:30) suggest the delay in diagnosis of IBD of over 4 months may have led to an increase in disease activity. By the time of diagnosis, the disease activity was moderate in accordance to Truelove and Witts Severity Index (Truelove and Witts 1955) (**Figure 2 page 4**) as outlined in NICE (2013) Ulcerative Colitis management guideline. Ghorayeb et al. (2018:6) found that women with IBD often found it difficult to distinguish between IBD symptoms and labour/pregnancy related symptoms. They also found that conversely, maternity care providers often attributed IBD symptoms to pregnancy symptoms, when women feared they were increasing symptoms of IBD. Lack of recognition of symptoms could lead to poor control of disease activity thus increasing the risk of harm for both women and their unborn babies. If the increased symptoms of IBD are attributed to possible complications of pregnancy, women may be subjected to unnecessary interventions including speculum vaginal examination to rule out preterm labour and therefore be exposed to iatrogenic harm. Disease activity may also be allowed to worsen if symptoms are incorrectly attributed to complications of pregnancy, and severe disease activity increases the risk of adverse pregnancy outcomes, with Mountifield et al. (2010:180) arguing that the adverse outcomes of pregnancy, which included stillbirth, preterm birth, developmental delay, congenital abnormality, miscarriage or low birth weight baby, in women with IBD are increased if there is severe disease activity. The risk of adverse outcomes were comparable to those of the general population for women with mild or moderate disease activity, as demonstrated in **Figure 6**, and therefore this level of disease activity does not pose any additional risks to women and their babies. The concern is that if disease activity is not accurately recognised as worsening disease activity and treated accordingly, women may develop severe disease activity which will increase their risks of these adverse outcomes.

Figure 6: Reproduction of Figure 2 from Mountifield et al. (2010:179)

Mountifield et al. (2010:179) explored the effects of maternal steroid use during pregnancy by analysing medication exposure during pregnancies, which included oral or intravenous corticosteroids. Women taking steroid medication, regardless of disease activity, had an increased incidence of major adverse pregnancy outcomes than women not taking steroids, as demonstrated in **Figure 7**. Therefore, this demonstrates that steroid exposure is associated with an increased risk of adverse pregnancy outcome and this presents a challenge for clinical management, as steroids may be required to keep symptoms under control to avoid the risk of severe disease activity, but if disease activity is mild or moderate the steroid treatment may increase risk of adverse pregnancy outcome.

Figure 7: Reproduction of Figure 3 from Mountifield et al. (2010:179)

The correlation between adverse pregnancy outcomes and disease activity are not definite, with Selinger, Leong and Lal (2012:2601) discussing the conflicting results for adverse pregnancy outcomes and disease activity in the population based studies used for the review, with one study finding there was no positive correlation between disease activity and adverse outcomes, whereas another found an increase in preterm birth for women with Crohns Disease and active disease. However, all the studies used to formulate this clinical review used healthy women as controls rather than those with other chronic disease; therefore it is difficult to directly attribute the disease activity of the IBD to any increase in adverse pregnancy outcomes and this is acknowledged by the authors (Selinger, Leong and Lal 2012:2601).

Selinger et al. (2012b) tested women's knowledge of pregnancy related issues in IBD by asking three questions about disease activity and its effects on pregnancy, which then produced a single score to determine knowledge, without identifying the specific areas where knowledge may be deficient. As previously discussed, not all participants had experienced pregnancy and therefore may not have considered the possible adverse effects of disease activity on pregnancy. It may have been useful to have developed inclusion criteria which only included women who had experienced pregnancy. The survey was sent through the post, and therefore again this raises ethical concerns about sending women of childbearing age a survey about pregnancy when their fertility circumstances are unknown. There is an overlap between the theme of disease activity during pregnancy and knowledge, which will be discussed in the following sub section: **Knowledge**.

2.6.2.3 Knowledge

Knowledge encompasses both knowledge of health care providers and women's knowledge and therefore these will be split into two further sub sections.

i) Maternity Care Provider Knowledge about IBD in Pregnancy

With much emphasis being put on the management of IBD with disease activity being so key in predicting the risk of adverse pregnancy outcomes, the knowledge of the health care provider caring for women with IBD during pregnancy is of high importance. NICE Guidance (NICE 2013:22) 'Management of Ulcerative Colitis' recommends that pregnant women with Ulcerative Colitis are given information about the risks and benefits of medications used to manage IBD as well as going without medication, and information should she require hospitalisation due to a severe flare up.

As previously discussed the participant in Cooper et al. (2011) case study was not diagnosed with IBD during her pregnancy until four months after she first complained of symptoms. Furthermore, Cooper et al. (2011:30) attribute the delay in diagnosis to the lack of knowledge about IBD in non-specialist health care providers, in this case, the general practitioners and the midwives. Again, this study by use of in depth case study provided a unique insight into the challenges faced in getting a diagnosis of IBD during pregnancy, without the fortuitous pregnancy which occurred during the main study, this insight would not have been gained, so although this is only the experience of one woman, the potential impact of such insight is high. The participants in Ghorayeb et al. (2018:6) concluded that most general practitioners, midwives and nurses had little knowledge about pregnancy and IBD.

Similarly, Selinger, Leong and Lal (2012:2605) discusses the importance of women with IBD's physician providing advice and counselling before embarking on pregnancy until further research is undertaken exploring women's views and whether their views which are often contrary to medical opinion are due to lack of knowledge. There is no suggestion as to which health care provider would be best placed to offer this advice or counselling. In light of the finding from Cooper et al. (2011:30) where the general practitioner was not sufficiently knowledgeable about IBD and pregnancy, clear, accessible and evidence-based guidance for practitioners to share with women is essential. Selinger, Leong and Lal (2012:2604) also recommend that decisions regarding caesarean section as a mode of birth should be decided on a case by case basis, relying on extensive knowledge of the impact IBD and mode of birth may have on women.

ii) Women's Knowledge about IBD in Pregnancy

Mountifield et al. (2010:179) reported an overwhelming consensus that women would rather put up with symptoms of IBD than take ongoing prophylactic medication, indicating a lack of knowledge about the adverse pregnancy outcomes associated with severe disease activity. Women also identified that family, friends and the internet influenced their decision making about taking medication, as opposed to their health care provider. This is worrying as the correlation between disease activity and adverse pregnancy outcome is widely demonstrated and without sufficient information, women may be unknowingly increasing their risk.

Selinger et al. (2012b:62) concluded that lack of knowledge may contribute to choices being made by women which adversely affect pregnancy outcomes, therefore women's knowledge about IBD and its potential effects on pregnancy are of huge importance to informed decision making. Selinger et al. (2012b:62) also found that women who were members of Crohns and Colitis UK had better knowledge of pregnancy related issues in IBD than those without membership. Crohns and Colitis UK provides comprehensive advice about IBD, including IBD and pregnancy and therefore women who have membership are more likely to have accessed this information through the website. It could also be argued that women who are members or Crohns and Colitis UK are motivated to develop their knowledge about their IBD and will use the available resources. Although Crohns and Colitis UK has an annual membership fee and the information provided on their website is free of charge, not all women may be aware of the organisation or the website and its resources. Women will usually seek information about IBD following diagnosis, and this is reinforced by Cooper et al. (2011:32) who recall the experience of the participant in the case study who had no knowledge about IBD but knew that what she was experiencing was not pregnancy related as she had experienced a pregnancy before. However, the participant was repeatedly told by health care professionals that the symptoms she had were of pregnancy. The case study highlights the importance of listening to women, as the participant knew that the symptoms she had were not related to her pregnancy, yet her concerns were dismissed. This led to a delay in the diagnosis of IBD, which may have increased her risk of adverse pregnancy outcome as disease activity may have increased during this time.

2.6.2.4 Perceptions

Perceptions by women was another theme which ran through the five articles. Perceptions were underpinned by various factors, which included women's personal beliefs, women's views, women's concerns and what knowledge women had. Although there is some overlap with knowledge, as for some women their perceptions develop in the absence of information, perception is more than just knowledge, it is about individual women's views and how this then shapes their experiences. Women may have received comprehensive information about their IBD and pregnancy, yet still do not comply with medication recommendations due to their preconceptions about harm to the baby and this is demonstrated by Mountifield et al. (2010:179) who identified that 28% of women changed their IBD medication without a physician's knowledge once conception had occurred, and that some women ceased taking all medications, instead seeking alternatives such as herbal remedies as these were thought to be safer by women. The lack of knowledge associated with medication use and the risks to the baby may reflect the poor communication these women have received from health care professionals about this topic, or it may be that their preconceptions about medication and the potential risk of harm to their baby was more dominant in their decision making.

Women in this study also raised specific concerns in the free text questions about the risk of congenital abnormalities or 'deformities' caused by IBD medication, but with no apparent concern over the risk of preterm birth or low birth weight. The perceptions of women are that medication is more harmful than the effects of active disease, which Selinger et al. (2012b:62) argues stems from a lack of knowledge, and the generic advice and warnings given to women about taking medication in pregnancy. However, women need to be given information to have knowledge and without knowledge women will form perceptions which may not be accurate.

Cooper et al. (2011:32) provides the unique insight into the perceptions surrounding diagnosis during pregnancy, as the participant thought all the signs and symptoms indicated cancer. For this participant, the diagnosis of IBD actually came as a relief, whereas for women with a diagnosis prior to pregnancy, IBD is often the cause of additional anxiety due to concerns about medications used for IBD. Selinger, Leong and Lal (2012:2605) concluded their clinical review suggesting that the limited data available about women's beliefs demonstrates a contrary view between pregnant women with IBD and the medical evidence. Mountifield et al. (2010:181) however acknowledges the importance of ascertaining the views of the woman. This will ensure that information can be tailored to meet a woman's specific needs and that any preconceptions can be explored. Ghorayeb et al. (2018:7) discussed the perceptions regarding weight gain in pregnancy, and how usually weight gain is associated with positive fetal growth and for women with IBD a period of remission, however the perception of positive weight gain had an upper limit and women were anxious about prolonged weight gain especially if they took steroid medication. However, it is important to remember that accurate monitoring of fetal growth can be more difficult in an overweight mother (RCOG 2010:6), and therefore the notion that weight gain is associated with positive fetal growth may be problematic.

2.7 Recommendations

The literature made recommendations in relation to further research and improvements in maternity care, with Cooper et al. (2011:33) recommending that further research is undertaken into the experiences of women diagnosed with IBD during pregnancy as the experience of one woman has highlighted areas requiring further exploration, whilst Selinger, Leong and Lal (2012:2605) identified a need for further research examining women's views about their beliefs and choices in pregnancy in their clinical review. Ghorayeb et al. (2018:9) concluded that there is a need for better integration of ongoing treatment for IBD and maternity care using a more holistic and multidisciplinary approach, and that health professionals should be more alert to the increased anxiety women with IBD may have regarding their own health, life expectancy and that of their baby.

2.8 Conclusion and Development of the Research Question

The literature review highlighted the four main themes:

Timing of Diagnosis

Disease Activity During Pregnancy

Knowledge

Perceptions

All had an overarching emphasis on women's beliefs and views. Specific recommendations were made to further examine women living with IBD's views, beliefs and experiences of pregnancy.

There is an evident paucity of literature about women's experiences of pregnancy and IBD, yet this cohort of women are identified as having a high risk pregnancy which Zadeh et al. (2012:110) argues increases the likelihood of developing postnatal depression and/or anxiety. The limited literature which has looked at the experiences of women with IBD and pregnancy has highlighted some concerning themes, and further understanding of their experiences are needed to ensure that their physical and psychological needs are understood and cared for. Better Births (National Maternity Review 2016) highlighted the importance of ensuring women's mental wellbeing is considered equitably to their physical wellbeing. To fully understand the holistic needs, the experiences of women living with IBD of pregnancy needs to be explored.

Research Question: What are the experiences of pregnancy for women living with Inflammatory Bowel Disease?

Aim: To gain insight into the experiences of women living with IBD of pregnancy using exploratory research.

2.9 Chapter Summary

The literature about the experiences of women living with IBD of pregnancy is sparse. The risks of adverse pregnancy outcomes are clearly evidenced for women living with IBD, yet women are not equipped with enough knowledge or information to make informed decisions about their pregnancy care. Therefore, research exploring the experiences of women living with IBD of pregnancy is needed, to hear their experiences first hand and to facilitate an opportunity for them to voice what they consider to be important during their pregnancy.

Chapter 3: Theoretical Foundations will discuss the theoretical perspective and methodology used for undertaking this study.

Chapter 3: Theoretical Foundations

3.1 Introduction

This chapter will discuss the theoretical foundations for the study and how they were decided. The theoretical foundations were not decided until the research question had been formulated and this was intentional as the question would influence the theoretical perspective needed for the study's underpinning.

3.2 Epistemology and Ontology Positions

All research is underpinned by theory which may be decided prior to undertaking the research, which will then influence the data collection methods, or decided following the data collection and analysis depending upon the findings. The theory may be either deductive or inductive and this determines the relationship between the theory and research, and this influences the approach used. The deduction approach uses the theory to guide the research and the process is described by Bryman (2016:21), which involves the researcher deciding a theory, creating a hypothesis, collecting data and presenting findings and then either confirming or rejecting the original hypothesis. Inductive theory contrasts to deductive theory and is described by Strauss and Corbin (1998:12) as starting with a research topic to study and allowing the theory to emerge from the findings.

Before deciding on a theory, it is important to consider the ontological and epistemological position, which identifies what is reality and how this is known: is there one single truth, can the reality be measured, does the reality need to be interpreted, does the reality change or is it subjective or is it influenced by other influences. The ontological and epistemological positions lend themselves to particular theoretical perspectives, which are usually either positivism, realism or interpretivism. Flick (2015:20) suggests positivism relies on a belief that new information can only be gathered through facts gathered in an objective manner, which are completely independent of the participant, the researcher and free from any values. Conversely Harvey and Land (2017:39) describe interpretivism as the contrasting epistemology to positivism, where there are multiple truths which are subjectively perceived by the individuals depending upon their understandings generated from their own experiences. For an exploratory study about the potentially sensitive topic of experience of pregnancy, this approach is ideal, as the experiences are unique to individuals and can be influenced by internal and external factors.

Similarly to Positivism, Realism is a philosophical position which also follows the belief that the natural and social sciences should use the same data collection methods and that reality is separate to any descriptions of it. It takes two forms; empirical realism which asserts reality can be understood if the appropriate methods are used to gain understanding, and critical realism which argues that reality is influenced by the natural order and events which displace or change this (Maxwell 2012:6).

As the research question is of an experiential nature an inductive approach was chosen. A hypothesis was not developed, as the study does not aim to prove or disprove anything, but instead aims to explore experiences – whatever they may be. An inductive approach is well suited to the potentially sensitive topic of experience of pregnancy as the participants experiences are to be explored and any themes allowed to emerge, as opposed to predefining responses, through the data collection method, such as a survey with open ended questions as suggested by Lee (1999:76).

The epistemological position is interpretivist as the study does not aim to offer explanation but instead aims to gain understanding and insight of women living with IBD's experiences of pregnancy. The ontological position is constructivism as this position argues that there is no single reality (Bryman 2016:29), and that individual experiences influence their understanding on a continual cycle. Women with IBD will undoubtedly have had different experiences and this will affect their understanding, as demonstrated in the literature review, women did not all have the same views on medication safety in pregnancy, or the effects of disease activity on pregnancy, and knowledge and perception were thought to be influential in these differences. Therefore, further exploratory study needs a constructivist underpinning.

3. 3 Methodology

The research question is of an exploratory nature, as the narrative review (**Chapter 2**) highlighted that little is known about the experiences of women with IBD and pregnancy, and there is no substantial existing literature base. Therefore, exploratory is the most appropriate methodology. Exploratory research is a relatively newly recognised methodology, with Stebbins (2001:2) making reference to the acceptance of it as a methodology in 2001.

Annells (2007:223) observed in 2007 that nurses who presented their qualitative research often considered their studies to have a phenomenological methodology, when in fact they were exploratory, as they only identified, described or explored elements of an event or situation, which the researchers claimed to be ‘experiences’. There was no understanding illuminative of the personal experiences, or the meaning of these experiences which is a fundamental element of phenomenology. Annells (2007b) suggests an exploratory methodology is well placed in nursing and midwifery research as it enables researchers to inquire what is happening in the clinical areas and can assist with positively implementing changes to practice. An experienced, clinically credible midwife, with recognised research skills, is ideally placed to identify areas of practice needing developing, changing or verifying and to undertake the necessary actions to fulfil this. This is the role of the Clinical academic midwife, for which the Masters in Clinical Research is a vital component of training and education.

3.4 Chapter Summary

Following consideration of the methodologies appropriate to this study, an exploratory methodology will be used, as this will enable exploration of the experiences women living with IBD of pregnancy, whilst also having the flexibility needed in the methods of undertaking the research considering the time constraints of this one year Masters in Clinical Research programme. **Chapter 4: Research designs and methods** will discuss the research design and the methods used.

Chapter 4: Research Designs and Methods

4.1 Introduction

This chapter will discuss the research design and methods used to undertake the study. As discussed in **Chapter 3**, the methodology for the study is exploratory and this approach has influenced the study design and the methods used.

4.2 Study Aims and Objectives

As previously outlined the research question is:

What are the experiences of women living with IBD of pregnancy?

The **aim** of the study is:

to gain insight into the experiences of women living with IBD of pregnancy

The **objectives** of the study are:

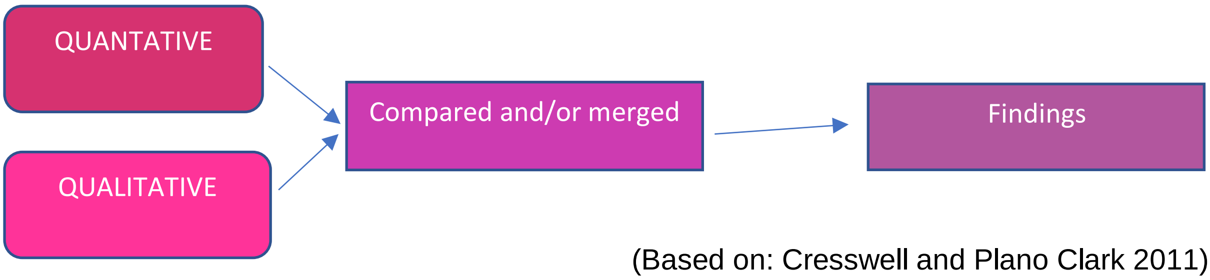
- To collect survey responses to closed questions from women living with IBD about their experiences of pregnancy and care in pregnancy
- To enable free text descriptions via open ended questions from women living with IBD about their experiences of pregnancy and care in pregnancy
- To collect responses using agreement scales about women's experiences during pregnancy

4.3 Mixed methods

The study used a mixed methods design which has become increasingly become more popular in health related research (Doyle et al. 2016:623), as this allows a better understanding of complex phenomena. It is increasingly used in nursing research and mixed methods were chosen for this study, as purely qualitative or quantitative methods alone would not provide the necessary insight.

There are distinguished differences between qualitative and quantitative research, with qualitative research having an emphasis on words (Bryman 2016:694) and is well suited to studies into individual experiences. Quantitative research meanwhile has an emphasis on the quantification of data and data analysis (Bryman 2016:694) and usually involves numbers and statistics. It is well suited to studies which have a positivist approach. Neither approach in isolation would be suitable for the study, as collection of quantifiable data, such as participant characteristics was wanted, in conjunction with an exploration of the individual experiences which required a qualitative research approach including open ended questions for women to input free text responses. Therefore, the rationale for using mixed methods is for completeness, as outlined by Doyle et al. (2016:624) who suggest that using mixed methods ensures a more comprehensive account of the studied phenomena is provided, and Illustration, as outlined by (Bryman 2016:641) as the qualitative data put the 'meat on the bones' on the quantitative data. A convergent parallel design was used, as qualitative and quantitative data are collected simultaneously and have equal priority. The data is then merged or/and compared to give a comprehensive insight and is illustrated in **Figure 8**.

Figure 8: Convergent Parallel Design



(Based on: Cresswell and Plano Clark 2011)

4.4 Ethical Approval

A favourable ethical opinion was sought from Coventry University Ethics Committee prior to the study commencing (P66074). The Study Protocol (**Appendix 1**), Participant Information (**Appendix 2**), Consent Statements (**Appendix 3**) and the survey (**Appendix 4**) were submitted to Coventry University Ethics Committee.

The study protocol was not initiated until a favourable opinion has been granted from Coventry University Ethics Committee.

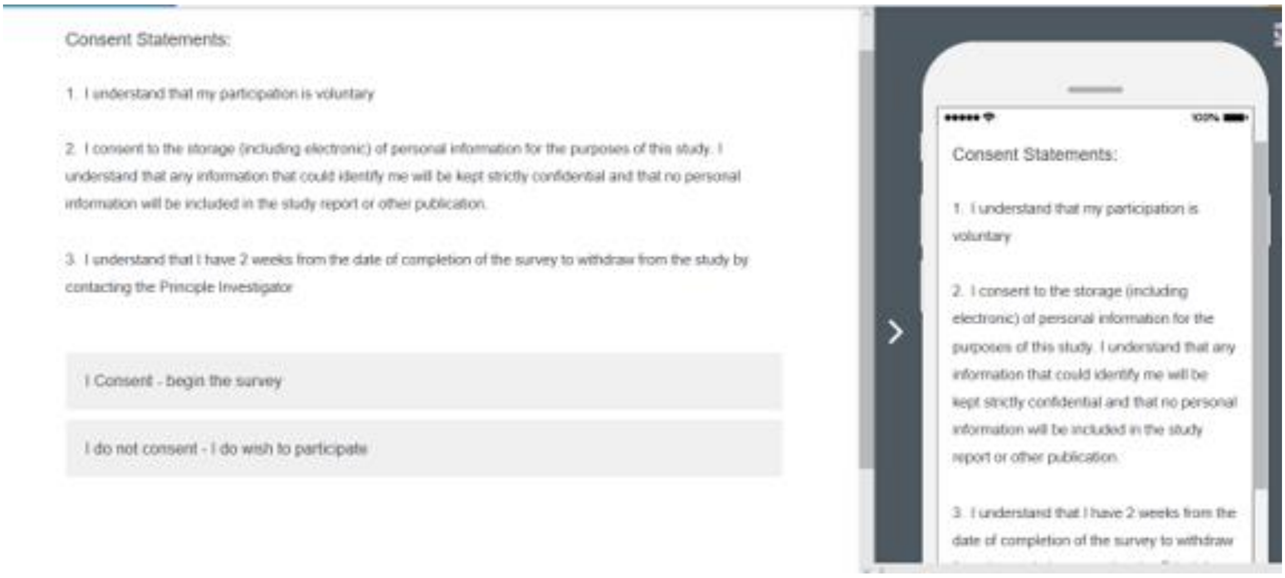
4.4.1 Ethical Considerations

There are four main ethical considerations outlined by Diener and Crandall (1978): lack of *informed consent*, potential *harm* to participants, potential *invasion of privacy* and potential *deception*.

4.4.1.1 Informed Consent

The key components of Informed Consent in healthcare research are outlined by the RCN Research Society (2015) and include the potential participant receiving unbiased information about the study, the purpose of the study, the duration of time of involvement, the right to withdraw from the study at any time, how their confidentiality will be maintained, and how the data will be stored and used. Before any research can be undertaken, a favourable opinion must be gained from the relevant Ethics Committee and these components must be adequately addressed before this will be obtained. Information about the study was displayed for the potential participant to read and there were three statements relating to consent (**Figure 9**).

Figure 9: A screen shot of the consent statements on *Qualtrics*



Consent Statements:

1. I understand that my participation is voluntary

2. I consent to the storage (including electronic) of personal information for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication.

3. I understand that I have 2 weeks from the date of completion of the survey to withdraw from the study by contacting the Principle Investigator

Consent Statements:

1. I understand that my participation is voluntary

2. I consent to the storage (including electronic) of personal information for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication.

3. I understand that I have 2 weeks from the date of completion of the survey to withdraw

This ensured potential participants had enough information to make an informed decision about whether they wanted to participate in the study, and that they were aware their participation was voluntary and that they could withdraw from the study. Information about withdrawal from the study was included and a withdrawal mechanism was built into the study. If potential participants did not click on the ‘I Consent’ then the survey did not open, and a pop-up message thanked them for considering participating, however as they did not consent to take part, they were unable to complete the survey.

4.4.1.2 Risk of Harm

Bryman (2016:126) argues that research which is likely to harm participants is unacceptable, however it is important to ascertain exactly what harm is before steps can be put in place to reduce the risk of harm. Diener and Crandall (1978:19) suggest that ‘harm’ can be used to describe several aspects: physical harm, loss of self-esteem and stress.

The study data collection method was a survey, and Rees (2003:105) suggests that surveys have one of the lowest risk of harm attached and are generally considered an inconvenience as opposed to harmful.   **Table 8** discusses the ethical considerations when undertaking research on sensitive topics and the considerations made within the study.

Table 8: Ethical Considerations when undertaking research on sensitive topics

Ethical Consideration	Considerations within the study
Risk of psychological harm or causing distress when asking women to recall their pregnancy or birth experience as The British Trauma Association (British Trauma Association 2018) have highlighted that 20,000 women per year in the UK suffer from Post-Traumatic Stress Disorder following the birth of their baby.	As women are self-selecting to participate in the study, it could be argued that women are making an informed decision to participate and therefore the risk of potential harm is mitigated. They may also choose not to answer any questions they do not wish to and can also leave the survey at any point. The question which may initiate recall of birth experience or pregnancy is open ended, and Lee (1999:76) suggests that using open questions is preferable when asking about sensitive topics as it enables to participant to describe events using words familiar to them and that this also encourages more frank reporting than using closed questions. Griffin et al. (2003:221) concluded from their study into participation in trauma research that participants who had experienced a traumatic event often found the experience of participating in research about it a valuable experience and even therapeutic.
Risk of psychological harm or emotional distress through the inclusion of women who's pregnancy may not have resulted in a live baby which may cause	Careful consideration was given to including women who may not have had a live baby, however it was felt that additional distress may be caused if these women wanted to participate but were unable to. As women self-selected to participate, this was felt to offer some protection against the risk of harm for this cohort of women, and it was felt to be unethical to exclude these women. Harvey and Land (2017:255) suggest support for participants should be external to the study. Support from Crohns and Colitis UK is readily available for members and as they were the gatekeeper for the study and distributed the link through their website and social medial platforms, participants could seek support if needed.
Risk of psychological harm or distress when asking women about pregnancy loss	Women may choose to not answer this question and may also leave the survey if they do not want to proceed. The question is a closed question, with a multiple choice tick box answer and therefore does not ask for any detail other than gestation of when the loss occurred. Whilst Lee (1999:76) suggests using open ended questions is preferable to researching sensitive topics, the focus of the research is not about pregnancy loss and this question was asked to gain an understanding about the women who participated in the study.
Risk of harm of psychological distress to the researcher when researching sensitive topics	Harvey and Land (2017:256) suggest researchers often concentrate on the possible distress caused to participants and overlook the need for support for themselves as the researcher of sensitive topics which may be emotionally draining. This study, although did focus on sensitive topics, such as birth experiences, pregnancy experience and pregnancy loss was not anticipated to cause the researcher any distress, however the supervisory team would have been ideally placed to provide support should it have been needed.

4.4.1.3 Other Ethical Considerations

The other ethical considerations are in **Table 9**.

Table 9: Ethical Considerations

Ethical Consideration	Considerations within Study
Privacy	As the data collection method was an anonymous online survey generated through *Qualtrics*, the privacy of the participants at the time of survey completion was maintained. Bryman (2016:133) suggests that the use of a survey as a data collection method minimises the risk of an invasion of privacy, as participants can choose whether they want to divulge certain information through answering certain questions. The survey did not have a mandatory response requirement; therefore, participants were free to answer or not answer questions as they desired.
Confidentiality and Anonymity	The survey was anonymous and did not request any identifying information. The withdrawal mechanism required participants to create their own unique identifier, using a combination of the last three digits of their postcode and the last three numbers of their mobile phone number. This does not cause them to divulge any information which could identify them to anyone other than themselves. *Qualtrics* captures IP addresses, and due to the withdrawal mechanism within two weeks of survey completion, the data was considered to be pseudoanonymised and remained in *Qualtrics* until the two week window had closed. The data was then exported from *Qualtrics* and IP addresses were removed and was saved in a fully anonymised form. All data is stored on a password protected memory stick and in accordance to the Data Protection Act 1998.
Deception	There was no deception in the study, and the purpose of the study was accurately detailed in the Participant Information (**Appendix 2**). There were no changes to the way in which the data was used and had there have been this would have required an amendment to the Study Protocol (**Appendix 1**) which would have necessitated further approval from the relevant ethics committee.
Exploitation	There was no exploitation within the study as women were free to take part through anonymous self-selection.

4.5 Sampling selection and recruitment

4.5.1 Sampling

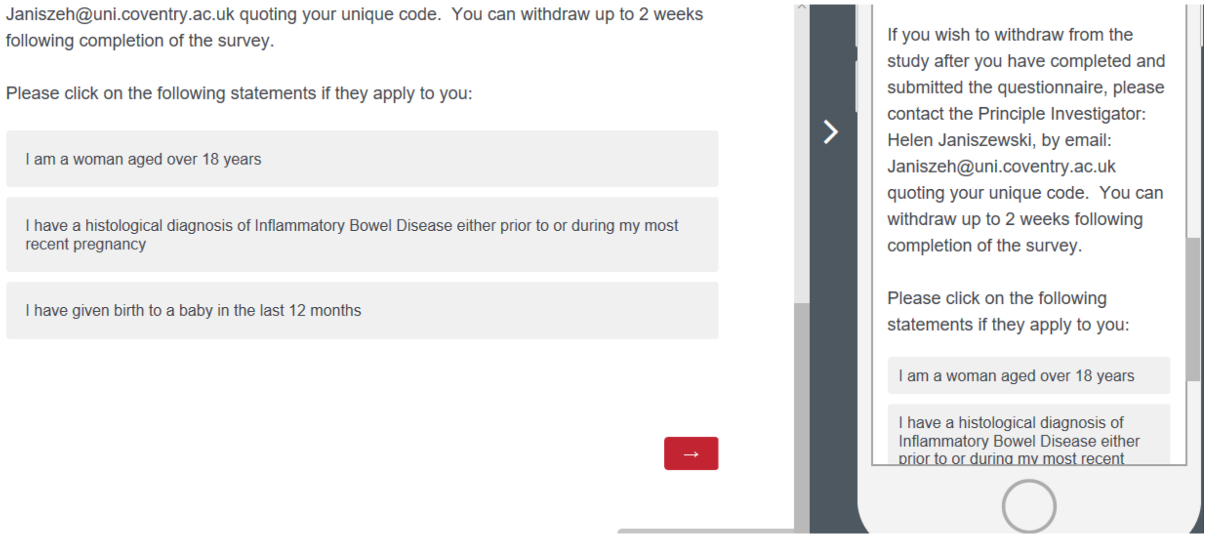
The sample size was influenced by using Crohn and Colitis UK as the gatekeeper, as the link to the survey was distributed through their website and social media platforms. There are approximately 30,500 members of Crohns and Colitis UK, and in 2016 Selinger et al. (2016) identified 4300 women who were members of Crohns and Colitis UK with a diagnosis of IBD and aged between 18-45 years, therefore of childbearing age. The fertility rate according to ONS (2016) was 61.7/1000 women and therefore there were approximately 265 women who could potentially fulfil the eligibility criteria for this study, however actual exposure would depend on how active these women were on Crohns and Colitis UK website and social media platforms over the course of the study period.

4.5.2 Selection

Potential participants were asked to self-identify as being eligible to participate in the study, by ticking three statements on *Qualtrics*. Due to the recruitment strategy used, self-selection was the only feasible method of identifying participants although the limitations of the approach were carefully considered. Khazaal et al. (2014) describe the potential difficulties of self-selection bias including the characteristics of a person may increase their desire to participate and therefore a representative sample is not obtained. However, it is impossible to overcome these difficulties as the characteristics of the people who chose not to participate are not known. The potential issues with self-selection for this study is that ineligible people may complete the survey. Using a gatekeeper goes someway in mitigating these potential issues, and as described by Khazaal et al. (2014) the design of the online web survey and the way in which it is distributed is where the researcher can try and mitigate potential issues.

The screenshot (**Figure 10**) shows the potential participants view of the self-identifying statements on *Qualtrics* which need to be clicked as being correct to progress to the survey:

Figure 10: A Screen shot of the Eligibility Criteria on *Qualtrics*



Janiszeh@uni.coventry.ac.uk quoting your unique code. You can withdraw up to 2 weeks following completion of the survey.

Please click on the following statements if they apply to you:

I am a woman aged over 18 years

I have a histological diagnosis of Inflammatory Bowel Disease either prior to or during my most recent pregnancy

I have given birth to a baby in the last 12 months

If you wish to withdraw from the study after you have completed and submitted the questionnaire, please contact the Principle Investigator: Helen Janiszewski, by email: Janiszeh@uni.coventry.ac.uk quoting your unique code. You can withdraw up to 2 weeks following completion of the survey.

Please click on the following statements if they apply to you:

I am a woman aged over 18 years

I have a histological diagnosis of Inflammatory Bowel Disease either prior to or during my most recent

Once potential participants had clicked the eligibility statements, the survey then commenced.

4.6 Data Collection and Analysis

Data was collected using an anonymous online web survey (**Appendix 4**) generated through *Qualtrics*, which was distributed by a national gatekeeper: Crohns and Colitis UK through social media. The survey contained a combination of closed ended questions, open ended questions and agreement scales. An online anonymous survey was chosen as the data collection method for reasons suggested by Bryman (2016:235) including wider geographical coverage, especially when a national gatekeeper was used, faster response time and a suggestion that there is a better response to open ended questions when using an online survey. A postal survey was not considered to be appropriate due to the sampling method used, although it is acknowledged that this meant that the survey was restricted to those with internet access. However in 2017, the Office for National Statistics (Pollard 2017) divulged that 90% of UK households has internet access at home and that 73% of adults had internet access on a smart device. Therefore, an online web survey was felt to be an appropriate data collection method in view of the recruitment strategy, the time scale of the study and the national gatekeeper being used. The survey was planned to be live for 4 weeks, as this would balance the time needed for responses with the time constraints of the study. The survey went live on the 09 February 2018, and three weeks into the recruitment period, there were only seven responses. Ethical approval was sought and gained for the survey to remain open for an additional two weeks, giving a recruitment period of six weeks in total. Crohns and Colitis UK agreed to this, and the survey remained live until the 18 March 2018. A further five responses were gained during the two-week extension period, giving a total of thirteen responses. The challenges around recruitment are discussed in **Section 6.2.**

4.6.1 Qualitative Data

Qualitative data was collected using two open ended questions, with a maximum word count limit (100 words) for responses (**Appendix 4**). The questions were*: 'What would have improved your experience of pregnancy?'* and '*Any other comments?*'. Open ended questions were used as the study is of an exploratory nature and therefore it would be difficult and inappropriate to pre-empt responses to create multiple choice closed ended questions.

Data from the two open ended questions was analysed using template analysis. Template analysis is one of the most common ways of analysing qualitative data, and involves reading the data, coding the material, arranging the coded data into themes, looking for subthemes and then examining the links between them. The insight gained from data analysis provides a narrative about the data, and justification of the themes is essential (Bryman 2016:588)

As suggested by Brooks et al. (2015:203) themes were allowed to evolve as the qualitative data was analysed, as opposed to using predefined themes, as the study is exploratory and therefore themes could not be predetermined. The data was read repeatedly until an immersive position was reached and then words which seemed to be of significance were highlighted in different colours. These words were written separately, and themes emerged. It became apparent that some themes were part of a larger theme, and so original themes became sub-themes.

4.6.2 Quantitative Data

Quantitative data was collected using dichotomous and multiple choice closed ended questions (**Appendix 4**). Agreement scales were also used, as the study is exploring women's experiences, and Burns and Grove (2001) suggest this increases the sensitivity of closed ended questions. A combination of statements expressed both positively and negatively were used as this reduces the possibility of participants simply ticking the same box for each statement.

The quantitative data provided nominal, ordinal and dichotomous variables and therefore the data was planned to be analysed according to the data type as suggested by (Bryman 2016:335). Due to the small number of responses, data was analysed using only univariate analysis and is presented with descriptive statistics and whole numbers. It was not possible or appropriate to undertake bivariate analysis or look for statistical significance due to the small amount of data obtained.

4.8 Conclusion Summary

Due to the exploratory methodology of the study, the design and methods were tailored accordingly. The ethical considerations were carefully explored in view of the sample of participants and the phenomena being explored. The use of a national gatekeeper helped mitigate against various concerns, including risk of harm, self selection bias, distribution of the survey and other ethical considerations.

The findings of the study will be presented in the next chapter**: Chapter 5: Research Findings**.

Chapter 5: Research Results and Findings

5.1 Introduction

This chapter will present the qualitative and quantitative findings of the study gained from data analysis of the survey responses. Data was collected and analysed using the methods outlined in **Chapter 4**.

5.2 Participants, Recruitment and Characteristics

The link to the anonymous online survey was distributed by Crohns and Colitis UK on their webpage and their social media pages. **Table 10** highlights the number of followers of the official Crohns and Colitis UK social media platforms.

Table 10: Crohns and Colitis UK Social Media

	Social Media Platform	
Crohns and Colitis UK	-	30,504 members
Crohns and Colitis UK	Facebook	176,916 people liking page
Crohns and Colitis UK	Facebook	166,697 followers
Crohns and Colitis UK	Twitter	30,500 followers

Distribution of the link to the survey, by Crohns and Colitis UK ‘Taking Part in Research’ page, and associated activity is shown in **Table 11.**

Table 11: Survey Distribution on Social Media

Social Media Platform	Page	Number of Likes	Number of Shares	Number of Retweets
Facebook	Crohns and Colitis UK	80	17	-
Facebook	Crohns and Colitis UK	81	12	-
Twitter	Crohn's & Colitis UK	-	-	-
Twitter	Crohn's & Colitis Research	37	-	18
Twitter	Crohn's & Colitis Research	1	-	0

The survey was live for six weeks. Comments were made on the Facebook post by two women, stating that they would have liked to have participated but did not meet the inclusion criteria, and two women emailed to say that they would have liked to have participated but did not meet the inclusion criteria because their baby was either too old or they were still pregnant and would not have given birth by the survey closing date.

The characteristics of the participants are displayed in **Table 12**.

Table 12: Participant Characteristics

Characteristic	**Responses**
Number of women who consented to participate	15
Number of women who completed all of the survey	13
Age range at time of completion	24-37 years
Mean age at time of completion	30 years
Age at diagnosis	13 – 31 years
Mean age at diagnosis	20 years
Number of participants diagnosed with Crohns Disease	6
Number of participants diagnosed with Ulcerative Colitis	7
Number of participants diagnosed with IBD prior to pregnancy	13

Women were asked about other aspects of their pregnancy these findings are presented in **Table 13**:

Table 13: Other Pregnancy Characteristics

Other pregnancy characteristics	Number of participants (out of 13)
Pregnancy loss at less than 12 weeks gestation	2
First baby	11
Second baby	2
Attended parent education classes	8

5.3 Quantitative Results

Due to the small sample size, findings will be presented using descriptive statistics and graphs.

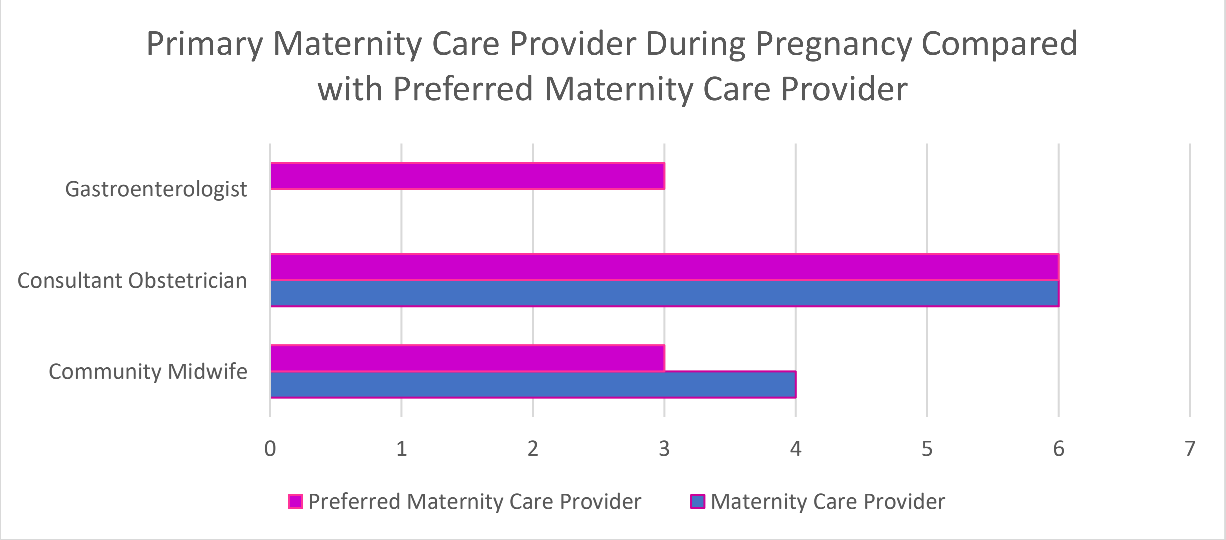
5.3.1 Primary Maternity Care Provider During Pregnancy

Women were asked to select from a multiple-choice list which health professional they most saw during pregnancy. This included Community Midwife, Consultant Obstetrician, Gastroenterologist, IBD Nurse, Practice Nurse or other (and to specify in a free text box).

Women either saw a community midwife (four out of 13), a consultant obstetrician (six out of thirteen) or three women specified ‘other’. The was one woman admitted to hospital during her pregnancy, another woman saw hospital midwives/nurses and another woman saw a ‘high risk’ obstetrician.

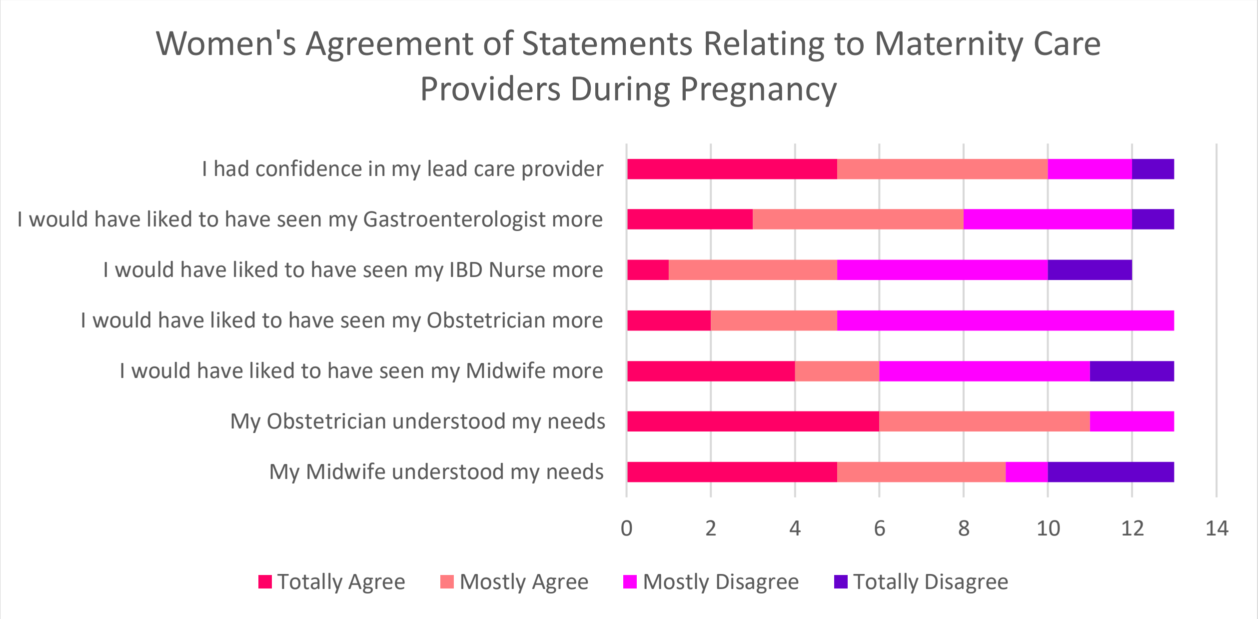
Women were then asked who they would have liked to have led their care during pregnancy, with the same options being given with the exception of the Practice Nurse, as they should not be providing maternity care in isolation. Community Midwife was selected by four out of thirteen women to have led their care during pregnancy, six women would have liked a Consultant Obstetrician to lead their care, three women would have liked a Gastroenterologist and one woman would have like a joint Consultant Obstetrician and Gastroenterologist to have led her care during pregnancy (**Figure 11**).

Figure 11:



Women were given a series of statements and asked to indicate their level of agreement with each statement, either totally agree, mostly agree, mostly disagree or totally disagree. Responses relating to maternity care providers are illustrated in **Figure 12**.

Figure 12:



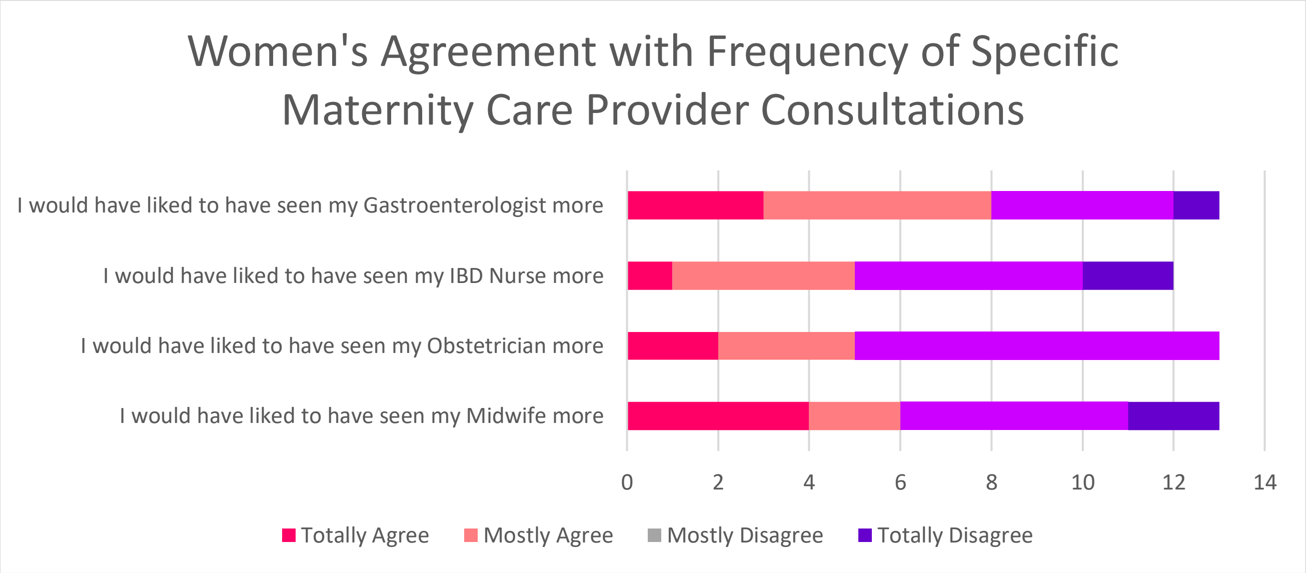
When asked about confidence in their lead care provider during pregnancy, ten out of thirteen women reported they had confidence in them, and nine out of thirteen women felt that their midwife understood their needs, however three women strongly disagreed with the statement that their midwife understood their needs.

When asked about whether they felt that their obstetrician understood their needs, eleven out of thirteen women reported that their obstetrician did understand their needs. The exact nature of these needs were not made explicit, however as the survey was about pregnancy and IBD, it was anticipated that the needs were around these.

Just under half of the women (six out of thirteen) would have liked to have seen their midwife more, whilst seven women did not share this view, and five out of thirteen women would have liked to have seen their obstetrician more.

When asked about contact with their IBD nurse and gastroenterologist, five out of thirteen women would have liked to have seen their IBD nurses more during their pregnancy, and eight out of thirteen women would have liked to have seen their gastroenterologist more (**Figure 13**).

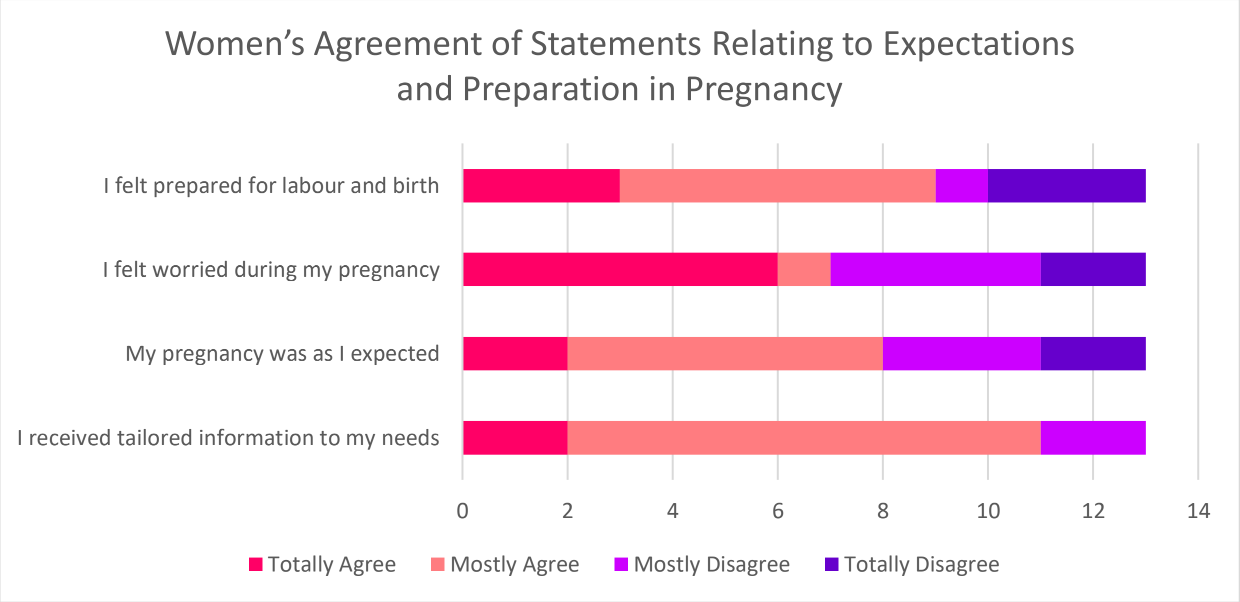
Figure 13:



5.3.2 Preparation and expectations

Within the series of statements for women to indicate their levels of agreement with, were statements which related to their expectations of pregnancy and birth and preparation for labour and birth (**Figure 14**).

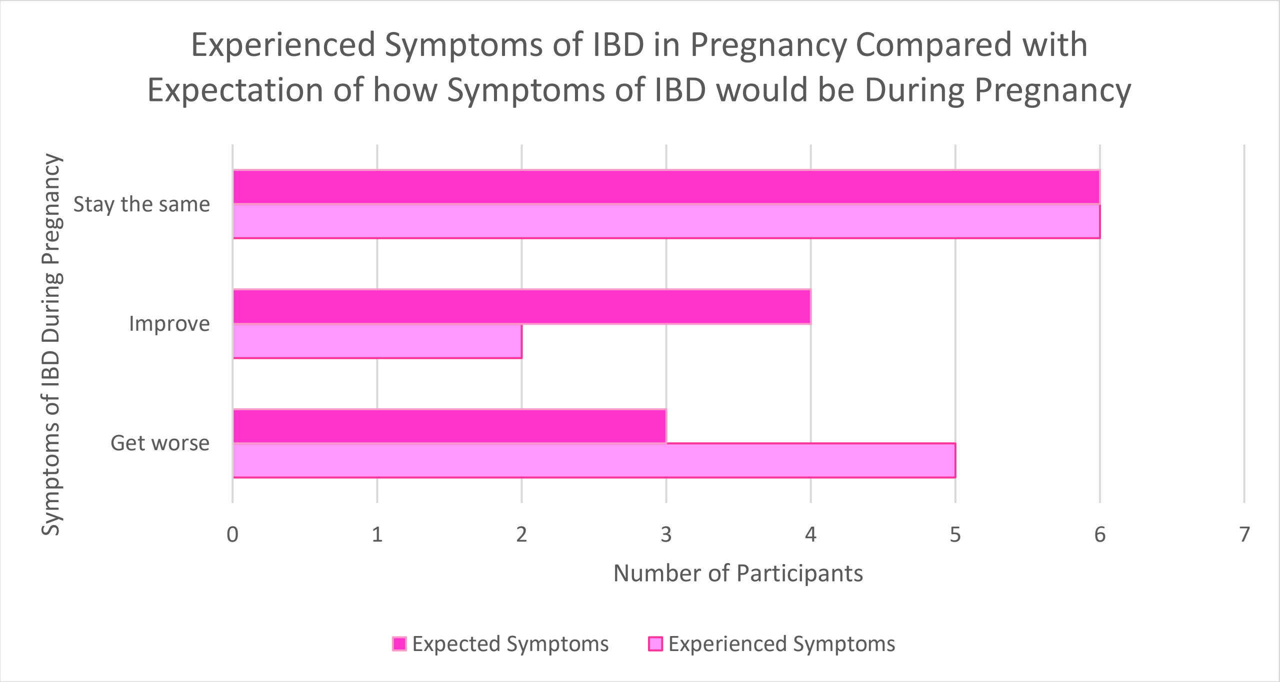
Figure 14:



Most women (eleven out of thirteen) felt that they received tailored information to their needs. Over half (seven out of thirteen) of the women agreed with the statement that they felt worried during their pregnancy, with six women strongly agreeing with this statement and only two women strongly disagreeing with this statement. Most women (nine out of thirteen) felt prepared for labour and birth, however three women strongly disagreed with this statement. Women were asked about their expectation of pregnancy and eight out of thirteen women felt that their pregnancy was as they had expected.

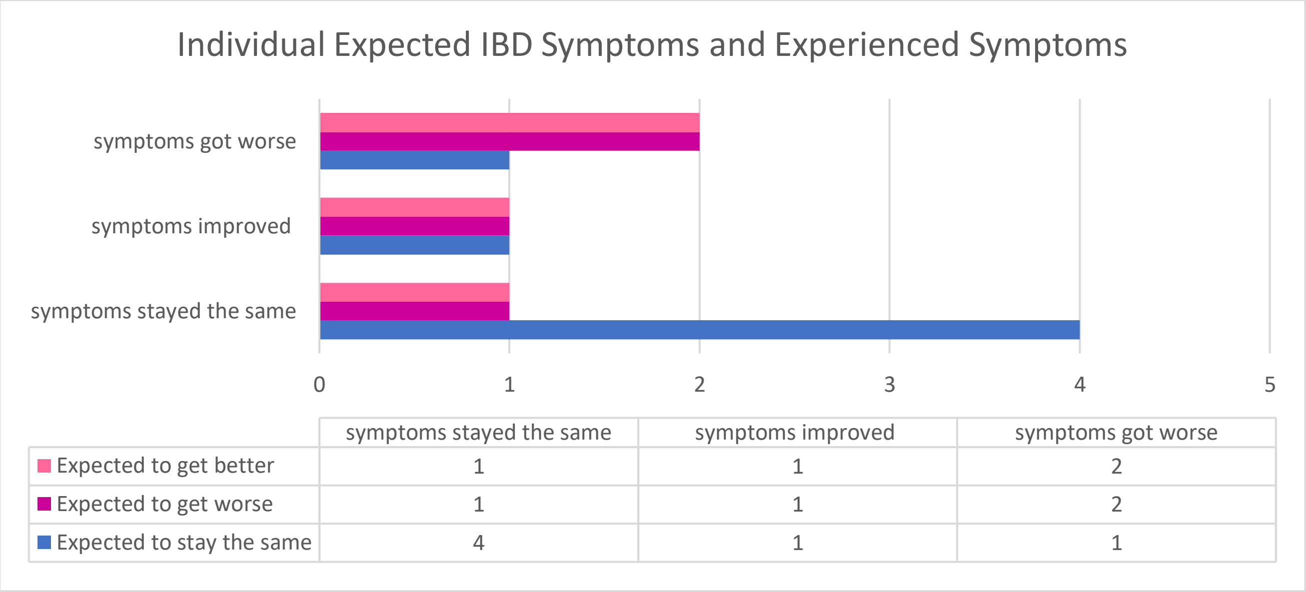
Women were asked about their symptoms of IBD during pregnancy and about their expectations of how their symptoms would be during pregnancy. The options for both questions being: 'get worse', 'improve' or 'stay the same', and five women found that their symptoms got worse during pregnancy, two improved and six stayed the same. With regards to expected symptoms, three women expected their symptoms to get worse, four expected their symptoms to improve and six expected their symptoms to stay the same (**Figure 15**).

Figure 15:



Although this gives an overview of expectations versus experienced, it is useful to look at how individual women’s expectations compared with their experiences of symptoms of IBD in pregnancy (**Figure 16**). Of the six women who expected their symptoms to stay the same, four experienced this, one experienced a worsening of symptoms and one experiences an improvement in symptoms. Of the four women who expected their symptoms to improve, symptoms stayed the same for one woman, got worse for two women and improved for one woman, and for the three women who expected their symptoms to get worse during pregnancy, one woman experienced her symptoms staying the same, two women experienced a worsening in their symptoms and no women experienced an improvement in symptoms.

Figure 16:



	symptoms stayed the same	symptoms improved	symptoms got worse
■ Expected to get better	1	1	2
■ Expected to get worse	1	1	2
■ Expected to stay the same	4	1	1

This concludes the quantitative findings and the next section will focus on the qualitative findings.

5.4 Qualitative Findings

Qualitative findings from the study were gathered from two open ended questions within the survey: ‘*What would have improved your experience of pregnancy?’* and ‘*Do you have any other comments?’.*

There were nine out of thirteen women who provided responses to the question ‘*What Would Have Improved your Experience of Pregnancy?’* and six out of thirteen women provided a response in the ‘*Any Other Comments’* section. Template analysis was undertaken on the questions individually and then merged to give overall qualitative findings.

A word cloud was generated from the text response data to both open ended questions (**Figure 17** and **Figure 18**). The word ‘pregnancy’ was removed from **Figure 16** as this was used in response to the word ‘pregnancy’ used in the question and was not of any significance in terms of the responses given. The word pregnancy was left in **Figure 17**, as this was an opportunity for women to comment about anything they felt was important, and although the survey was about experiences of pregnancy, the word pregnancy was not in the question and therefore if women used the word pregnancy it wasn’t in the context of purely answering the question.

Figure 17: Responses to ‘what would have improved your experience of pregnancy’

Figure 18: responses to ‘do you have any comments’

5.5 Emergent Themes

There were six identified emergent themes from the responses to the open-ended questions, and the responses from both questions were merged (**Figure 19**). The themes had a hierarchy, with some themes being more dominant in the responses than others, and they were discussed in order with the most dominant first. Direct quotes from the participants are also included to help illustrate the findings.

Figure 19: Emergent Themes

5.5.1 Mode of Birth

Mode of birth emerged as an area for concern for women, with two women expressing that they were pressured by their maternity health care professional into having a type of birth they did deem not appropriate for them in view of their IBD as outlined by the following quotes

> *"I had to enforce with them that I was not low risk (they were keen for me to have a homebirth) and had to remind them several times about my multiple surgeries and family history which increased my risk rating"* (P10)

> *"there was a lot of uncertainty about how I would deliver"* (P6)

The uncertainty detracted from her experience of pregnancy, as this comment was made in the response to *'what would have improved your experience of pregnancy'*. However, for one woman mode of birth was determined due to her IBD and disease activity, and this seemed to be the only option as outlined below

> *"due to my IBD I had to have an elective c-section…..a vagina birth wasn't an option in case I tore during labour"* (P11)

The experiences of women regarding decision making about mode of birth was varied with women having very different experiences regarding the advice and information given to them by maternity care providers.

5.5.2 Knowledge

A lack of midwifery knowledge about IBD emerged from the data as evidenced with the following quotes:

> *"my midwife had no idea about Ulcerative Colitis"* (P12)

> *"the midwives had NO idea about my IBD"* (P10)

Awareness of IBD on the maternity wards was also found to be lacking, as outlined below

> *"there needs to me more awareness of IBD in maternity wards".* (P2)

5.5.3 Medication

Experiences around medication varied, with two women having a stark contrast in experiences:

> *"…..wouldn't test on me or change meds, suffered a lot, hated it"*, (P12)

While one woman was unable to access testing in pregnancy, another participant reported having screening tests in pregnancy for suitable medication for once she had given birth to her baby.

> *"I had screening tests for humira during pregnancy and now my baby is born I will be starting this medication promptly"* (P11)

The advice around medication also varied, with one woman identifying a need for clearer guidance about medication which is suitable for use in pregnancy and breastfeeding in response to the question '*what would have improved your experience of pregnancy"*, whilst another woman reported receiving advice about medication and breastfeeding which enabled her to make an informed decision.

> *"Clearer guidance on medication suitable for pregnancy and birth (to enable breastfeeding)"* (P10)

> *"I am disappointed I am not recommended to breastfeed on this medical so I have decided to bottlefeed to ensure I don't compromise my son's immunity"* (P11)

5.5.4 Sharing Information

Women reported that they had seen different maternity health care providers, and although they had seen the same profession, it had not been the same person, and this meant that they had to retell their situation at each interaction as evidenced by the quotes below:

> *"would have been better to have seen the same cons as had to keep explaining my back history "* (P10)

> *"….I seen 12 different midwives".* (P9)

However, one woman experienced her IBD Nurse visiting her on the postnatal ward and found this to be helpful, as outlined by the following quote:

> *"my IBD nurses visited me on the maternity ward the day after birth and this was brilliant and reassuring".* (P11)

5.5.5 Perception of Risk

Increased risk of complications emerged as a theme, with women identifying themselves as being at increased risk of complications during pregnancy and birth. Two women experienced conflict with the maternity health care provider, who felt that they were low risk, whereas the women felt they were high risk and had to articulate their risk factors, in some cases repeatedly and this is outlined by the following quotes

> *"I had to enforce with them that I was not low risk (they were keen for me to have a home birth) and had to remind them several times about my multiple surgeries and family history which increased my risk rating".* (P10)

> *"….if I didn't have the initiative to go through the risks involved if I had given birth naturally then I would have put myself at risk of further complications".* (P4)

5.5.6 Disease Activity

Disease activity during pregnancy and after pregnancy emerged as a theme, with women generally commenting about this in the ‘any other comments’ section. Experiences varied, with one women recalling her symptoms got worse during pregnancy but then dramatically improved after the birth as outlined below

> *“during my pregnancy my symptoms got worse, but now he’s here my symptoms have been non existent! First time since I was 13!”* (P1)

Another woman needed surgery during pregnancy due to worsening symptoms, and one woman when asked what would have improved her experience of pregnancy wanted her IBD to be under control, as outlined below

> *“my IBD being under control, couldn’t leave the house….suffered a lot”* (P12)

A worsening of symptoms in the postnatal period, to the extent that hospitalisation was needed, was experienced by one woman. She had been well during her pregnancy and for some time prior to pregnancy

> *“I was well for 3 years before my pregnancy and well throughout, however had a bad flare 4 months after giving birth. I ended up in hospital very unwell”* (P9)

5.6 Chapter Summary

This chapter has illustrated the findings, following analysis of the quantitative and qualitative data, using direct quotes to support the findings. The findings will be discussed, compared and contrasted with the literature review themes and with recommendations from national maternity guidance **Chapter 6: Discussion.**

Chapter 6: The Discussion

6.1 Introduction

This chapter will discuss the findings in depth in relation to the aim and objective of the study, exploring contrast and comparisons with the information evolved from the narrative literature review and the findings and recommendations, the strengths and limitations of the study and placed in context of national guidance and midwifery policy.

The **aim** of the study was to gain insight into the experiences of women living with IBD of pregnancy.

The **objectives** of the study were to:

- collect survey responses to closed questions from women living with IBD about their experiences of pregnancy and care in pregnancy
- enable free text descriptions via open ended questions from women living with IBD about their experiences of pregnancy and care in pregnancy
- to collect responses using agreement scales about women's experiences during pregnancy

6.2 Participants, Recruitment and Characteristics

The recruitment strategy proved challenging for the study, as the initial proposed recruitment strategy to use purposive sampling was not feasible due to the lack of robust mechanism within the local NHS Trust to identify eligible participants. A strategy of an online anonymous survey distributed by a national gatekeeper; Crohns and Colitis UK was used. Although this relied on participants self-identifying as being eligible to participate and the potential risk of ineligible people completing the study, the use of a gatekeeper does help to mitigate this risk as discussed in **Chapter 5**. The strengths and limitations of the study are discussed in **section 6.5.**

The estimated number of potentially eligible women was calculated to be 265 and this was based on the birth rate and the number of women aged between 18 to 45 years who were members of Crohns and Colitis UK. It was important to calculate the estimated number of eligible women for planning of data analysis.

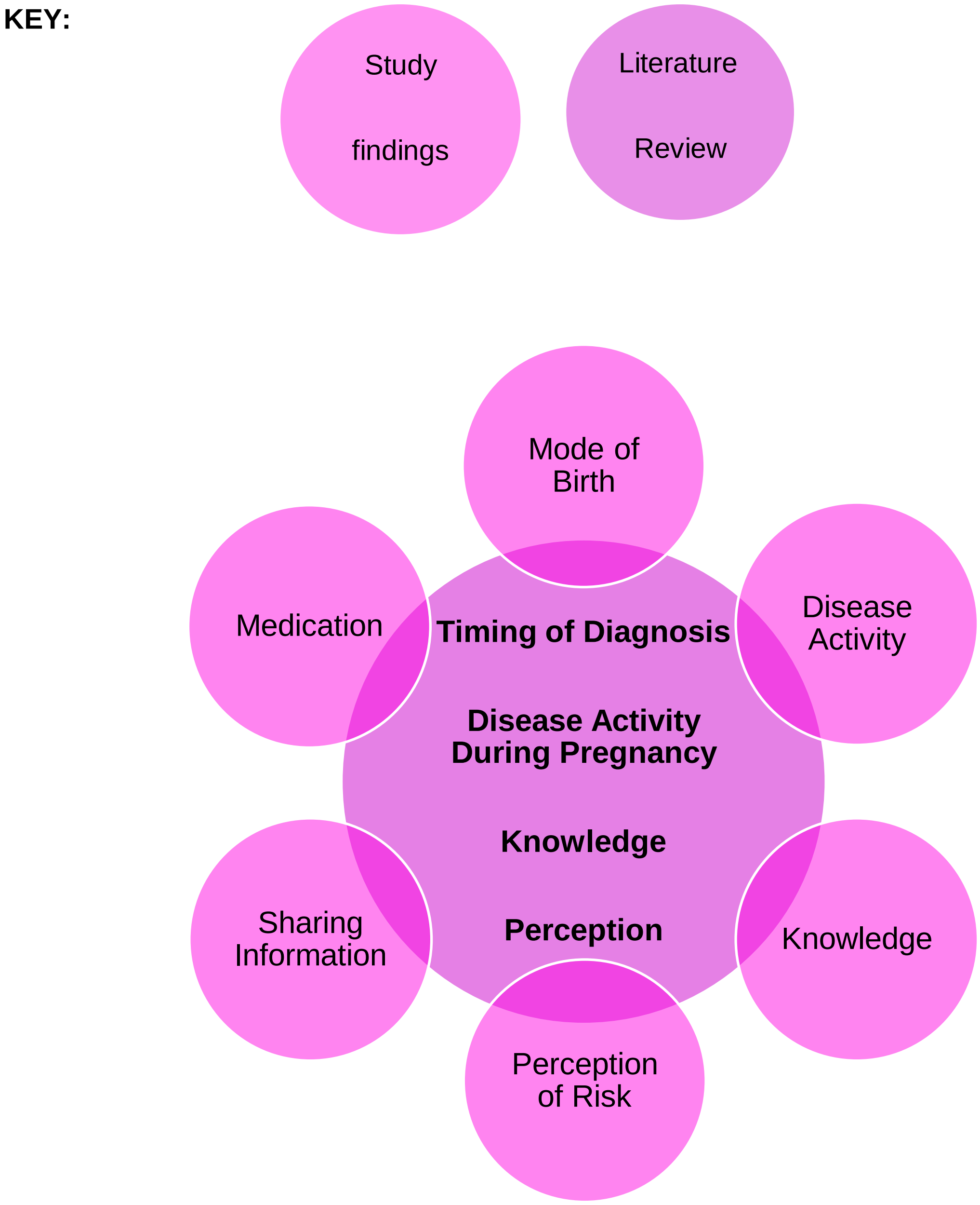
As outlined in **Chapter 5**, and in **Table 10 (page 50)** Crohns and Colitis has a large following on social media and over 30,500 members. It could be suggested that through using a gatekeeper who would distribute the survey through social media and their website, the survey would be widely distributed, however the number of interactions are a small proportion of the number of followers and the number of members of Crohns and Colitis UK. Therefore, despite the large following on social media, the use of a national gatekeeper to distribute the online survey does not guarantee a high response rate, although it does offer many other positive contributions to the research process as previously discussed in **Chapter 4** and **Chapter 5**, such as helping to mitigate the risk of non-eligible participation, offering ongoing support to its members and participants of the study, access to potentially eligible participants and also creating awareness about the research topic. Interestingly, two women commented on the Facebook posts, as they did not fulfil the eligibility criteria (child too old) but would have liked to have participated, and two women used the contact email to express their interest in the study although they were not eligible to participate. Women with IBD wanted to share their experiences and were disappointed that they were not able to, and that expanding the inclusion criteria, in particular to include women who had given birth more than 12 months ago would have given more women this opportunity. The inclusion criteria was restricted to women who had given birth within the last 12 months due to the time constraints of the study as this would create a maximum potential sample of 265 women, and also to help maximise the accuracy of the recall of details women gave, as the pregnancy would be more fresh in their mind. Simkin (1991:209) however found that women were able to recall their birth experiences with complete accuracy 15 to 20 years after and that women were eager to share their experiences. This is reflected in the messages received from women who were not eligible to participate due to their babies being too old for the inclusion criteria, who expressed that their pregnancy was not something they ever would forget.

All, except two women, who participated were aged at least 18 years at the time of diagnosis, which Ghorayeb et al. (2018:7) suggests is positive in terms of women being maintaining independence during pregnancy and birth, as those diagnosed with IBD during childhood were found to be more reliant on others, which may be related to the child/parent relationship when the symptoms first started and they received the diagnosis of IBD.

6.3 Themes

The results and themes from the findings will now be discussed, drawing comparisons and contrasts with the information gathered from the literature review and the recommendations national guidelines and midwifery policy. There were four emergent themes from the literature review and six emergent themes from the study findings, with some overlap (**Figure 20**). The four themes from the literature review were timing of diagnosis, disease activity during pregnancy, knowledge and perception. The themes from the study findings were disease activity, knowledge, perception of risk, sharing information, medication and mode of birth.

Figure 20: Combined themes from the literature review and the study findings



6.3.1 Mode of Birth

Mode of birth emerged as a new theme from the findings of the study and was the most dominant theme, highlighting it’s importance to the women in the study, whilst caesarean section featured as an outcome in the literature review, with Selinger, Leong and Lal (2012: 2604) stating that caesarean section as a mode of birth should be decided on a case by case basis, therefore suggesting that decisions about mode of birth for women with IBD are multifactorial which require individual consideration. Contrary to the literature, mode of birth was not exclusively about caesarean section for women in the study, it was much more than simply if they needed a caesarean section or not. Women in the study were not asked specifically about mode of birth, and this theme emerged from the responses to the open- ended questions which could suggest that this is something women considered to be of great importance to them. Worryingly women in the study had differing experiences regarding decisions about the mode of birth, with one woman reporting that a caesarean section was the only considered mode of birth due to the extent of her disease and she seems quite accepting of this, whilst another woman reporting uncertainty around the mode of birth and expressed that this detracted from her experience of pregnancy. Another woman reported having to take the initiative to explain the risks of further complications, to her obstetrician; whilst another woman reported that her community midwives were keen for her to have a home birth, which she correctly identified as being inappropriate and that she needed to remind them of this. This is not ideal as women look to their maternity care providers for knowledge and expertise and experience conflict over suitability for a particular type of birth will corrode confidence and lead to frustration.

Women in this study considered mode of birth to be an important aspect of their pregnancy, and that discussions and plans relating to mode of birth can make the difference between women having a positive or negative experience of pregnancy. This finding contrasts with findings by Afshar et al. (2018:43) who argued that women with a birth plan were less satisfied with their birth experience than those without a birth plan. This study excluded women who did not have a planned vaginal birth, therefore it could be argued that the findings of this study are not generalisable to women who have uncertainty around their mode of birth.

Some women described a conflict between their views and that of their maternity care giver regarding mode of birth which would not contribute to a positive experience of pregnancy or create a trusting relationship between the pregnant woman and the maternity health care provider. It could be suggested that this conflict is related to the lack of knowledge about IBD and pregnancy of the part of the maternity care provider, and this will be discussed in **section 6.3.3**.

Regardless of the possible reasons for the potential conflict, women need to be listened to, and decisions about mode of birth need to be made collaboratively by the woman and the maternity care provider.

6.3.2 Disease Activity

Disease activity was an emergent theme from both the literature review and the findings of the study, however the context in which they were explored was different. Disease activity within the literature review was very focused on the association of adverse pregnancy outcomes, such as preterm birth and low birth weight, whilst these research findings were concerned with the impact disease activity had the individual women and their expectations and their actual experiences of how the disease would behave during pregnancy.

The symptoms of IBD are unpredictable and whilst the literature offers some suggestion about how disease activity may behave, with Abhyankar, Ham and Moss (2013:5) suggesting that the activity status at conception is key in predicting how the IBD will behave for the pregnancy: if there is active disease at conception there is a higher risk the disease will remain active throughout pregnancy and conversely if the disease is in remission at conception it is likely to remain this way for the pregnancy. It is interesting to note that although this remains the accepted predictor of disease activity during pregnancy, this arose from a meta-analysis which used literature from over 60 years ago. Therefore, either there have been no real developments in disease activity behaviour during pregnancy or it has not been explored again.

The findings of this study not only provided overall numbers of women who experienced an improvement, worsening or symptoms that remained the same throughout pregnancy, but this was explored further, by determining individual experiences compared to their expectations. Women also used open ended questions to make comments about disease activity, which demonstrates the importance of disease activity to women during pregnancy and the impact this has had on them. There is therefore both qualitative and quantitative data albeit with low numbers. The most concerning finding was that of the four women who expected their symptoms to improve during pregnancy, two women experienced a worsening of symptoms, one woman’s symptoms remained the same and only one woman did experience an improvement.

The expectations and experiences were otherwise well matched, with the three women who expected their symptoms to worsen experiencing either a worsening in symptoms (two out of three) or their symptoms remaining the same. Of the six women who expected their symptoms to remain the same, four did experience this, whilst one experienced an improvement and one experienced a worsening. Just under half the women experienced the disease activity they were not expecting, and this illustrates the unpredictable nature of IBD activity during pregnancy.

Ghorayeb et al. (2018:9) found that pregnancy can offer relief from symptoms of IBD and that subsequent pregnancies in quick succession may be ‘used’ by women to keep symptoms at bay. Unfortunately this relies on women having the same experience with disease activity for all pregnancies and as the literature suggests disease activity during pregnancy can be unpredictable and also that pregnancy can be an anxiety inducing time for women, with 13% of women experiencing anxiety in pregnancy (NICE 2007:6) and seven out of thirteen women did identify as feeling worried during pregnancy. It could be suggested that this is considerably more than average, considering the percentage given by NICE, however women were asked about whether they felt worried, not if they felt anxious and it is appreciated that although the two have some commonality, they are different. Women who experience a worsening in symptoms of IBD that they were not expecting, as in the case for two women in the study, may suffer emotional distress as well as a decline in their physical wellbeing. However, for two women, it was also post birth that they noticed the dramatic changes in the disease activity, with one reporting a dramatic improvement in symptoms following the birth and one having a significant worsening in symptoms following birth for which she required hospitalisation. This must have been extremely difficult for the woman and her family, as admission to hospital postnatally for a non-maternity condition usually involves separation of the mother and baby as non-maternity wards do not always offer provision for babies to stay. This can affect breastfeeding as well causing distress to the mother and baby and wider family at an already distressing time due to illness. Unfortunately, the study did not specifically ask about disease activity at conception, and this is a limitation of the study which will discussed in **section 6.4**. This would have been useful information to have gathered, as it would have contributed to the data about expectations and experiences of IBD symptoms during pregnancy and may have offered some further insight into predicating disease activity and women's expectations.

To help prepare women for the unpredictability of IBD activity during pregnancy and crucially in the post-partum period there needs to be personalised multidisciplinary discussions during the early part of pregnancy. This study has heard first-hand the experiences of the effects disease activity has on them and their pregnancy. Due to the unpredictable nature of disease activity in IBD, women cannot adequately prepare themselves and both expected and unexpected worsening of symptoms can have devastating effects on women and their babies, particularly if separation of mother and baby occurs due to hospital admission.

6.3.3 Knowledge

Knowledge emerged as a theme from both the literature review and the research findings and is split into two sub-types: knowledge of the maternity care provider and knowledge held by women. These will be discussed separately.

i) Knowledge of the Maternity Care Provider

Knowledge of IBD and IBD in pregnancy was found to be lacking in midwives in the literature by both Cooper et al. (2011:30) and Ghorayeb et al. (2018:6) with Cooper et al. (2011:30) arguing that the delay in diagnosis was attributable to the lack of knowledge held by midwives and general practitioners about IBD, and therefore increasing the risks associated with active disease.

Before discussing the knowledge of the maternity care provider, it is important to understand who these were for women in this study. Community midwives provided maternity care to four out of thirteen women in the study, whilst six out of thirteen women saw a consultant obstetrician for most of their maternity care, with one woman seeing a combination of hospital midwives, one woman was admitted to hospital in her pregnancy and one woman saw a specialist ‘high risk’ obstetrician for most of her maternity care. There was no elaboration on exactly what a ‘high risk’ obstetrician was. When women were asked who they would have preferred to provide their maternity care six out of thirteen women stated a consultant obstetrician and three stated a community midwife. Despite no women having received maternity care from their gastroenterologist, this was the preferred care giver for three women and eight women reported that they would have liked to have seen their gastroenterologist more in their pregnancy. This may be due to the knowledge and experience around IBD gastroenterologists have, or that women already have established trusting relationships with their gastroenterologists and want this to continue throughout their pregnancy. One woman responded that her preference would have been a joint consultant obstetrician and gastroenterologist, and this is in line with recommendations from Saving Lives, Improving Mothers Care (Knight et al. 2017:v) which recommends women with complex medical problems have their maternity care led by a consultant obstetrician who coordinates care with midwives, other physicians and any other health care professionals needed.

Knowledge about IBD and pregnancy was found to be lacking in this study with three out of thirteen women commenting, unprompted, that their midwives had no knowledge about IBD, and that the knowledge of IBD of the staff on the maternity ward was lacking. For women to comment about this unprompted, highlights the importance of this to them. The lack of knowledge will mean that midwives will not ask women about their IBD, as they do not understand what it is or how it can affect pregnancy, and therefore do not facilitate the platform for discussions about this and equally if women feel that their midwives have no knowledge about IBD they are unlikely to divulge intimate information to them about their IBD.

It was not always a lack of knowledge about IBD which women commented on, two out of thirteen women reported having to explain the implications of their IBD on their pregnancy to their maternity care provider, and the associated risks (which will be discussed in **section 6.3.5**), and this demonstrates the lack of knowledge held by the maternity health care provider, either the midwife or the obstetrician. Despite the apparent lack of knowledge held by midwives, nine out of thirteen women responded positively when asked if their midwife understood their needs, ten out of thirteen women reported having confidence in the lead care provider during their pregnancy and six out of thirteen women stating they would have liked to have seen their midwife more during their pregnancy, however due to the means that data was collected, it is not possible to establish if this means they would have liked to have seen their own named midwife in greater frequency or whether they would have liked to have seen their named midwife more as opposed to seeing other community midwives at their appointments. This is not only related to anticipated increased satisfaction of care in pregnancy but also has safety implications which will explored and discussed in **section 6.3.5**. Sandall et al. (2016:17) concluded in their Cochrane Review, that when women receive antenatal care from the same midwife, or a small team of midwives, the risk of preterm birth is reduced. This is a particularly important finding for when caring for women with IBD, who already have an increased risk of preterm labour. Aside from the reducing the risks of known adverse risk factors for women with IBD, seeing the same midwife would also help reduce the frustrations of having to retell their story at each interaction. Conversely it is also worth appreciating that for some women seeing other midwives may offer some reassurance if their named midwife has no knowledge of IBD and pregnancy and they do not have confidence in them. However, in this case, it is hoped that the woman feels able to request an alternative named midwife.

The literature and findings of the study overwhelmingly demonstrate a lack of knowledge about IBD and pregnancy in maternity care providers, in particular midwives, and women expressed this unprompted. This is concerning as midwives are the first point of contact for most pregnant women. Women need to have confidence in their maternity care provider, and confidence that the correct pathways will be initiated for their care, yet these decisions are being made by maternity care providers who do not always understand what IBD is or the effects it may have on pregnancy. Women expressed that they often compensated for the lack of knowledge held by their maternity care provider and this then relies on them having good knowledge themselves and this is discussed in the next section.

ii) Knowledge held by Women about IBD and Pregnancy

As discussed in the previous section, women in the study reported having to explain the implications of their IBD on their pregnancy to their maternity care provider, which is concerning, as if women do not have this knowledge, there is potential for women with IBD to receive inadequate or inappropriate care during pregnancy. Selinger et al. (2012b:62) suggested that if women have poor knowledge of IBD and pregnancy this may contribute to them making decisions about their pregnancy which may affect the pregnancy outcome, however this knowledge needs to be provided. Women cannot be expected to source their own information about the effects of IBD on pregnancy, therefore, women need to be provided with information ideally before pregnancy occurs, or as soon as possible during the pregnancy. Saving Lives, Improving Mothers Care (Knight et al. 2017:50) recommends that women with medical conditions receive preconceptual counselling, however does not offer any guidance about who is best placed to provide this or indeed at what point to provide this.

Mountifield et al. (2010:179) findings support the lack of information given to women, as women in their study were more concerned about the possible side effects of prophylactic medication for IBD on their pregnancy than they were about the possible effects of active disease, and this will be discussed further in **section 6.3.4**. As previously discussed, disease activity is linked to pregnancy outcome. Therefore, if women are not given knowledge about IBD and pregnancy, and their maternity care provider also does not have sufficient knowledge yet look to the woman for information, decisions could be made which may have a detrimental effect on the pregnancy, such as not taking prophylactic medication.

Knowledge of IBD and pregnancy is an area of concern, both the literature and study findings demonstrated a lack of midwifery knowledge, whilst the literature is also suggesting that if women do not have good knowledge about IBD and pregnancy they may make detrimental choices about their pregnancy. As previously discussed, women must be given information to have good knowledge, so therefore the real concern is that women are not being given adequate information about IBD and pregnancy, and it could be argued that this is due to maternity care providers not having sufficient knowledge themselves. In terms of offering preconceptual advise, not all pregnancies are planned and therefore it may prove challenging to provide this information without counselling all women of childbearing age, which has its own ethical challenges. If women are not given information, this is when preconceptions develop, and this is discussed in **section 6.3.6**.

6.3.4 Medication

Much of the literature about IBD and pregnancy was dominated by medication safety and efficacy and as this was not the focus of the research question, articles predominantly about medications were not included in the literature review. However as previously discussed Mountifield et al. (2010:179) found women were more concerned about the possible effects of prophylactic IBD medication than they were about the effects of active disease on their pregnancy outcome. Women were not explicitly asked about medication, yet this came through as a theme in the free text responses. Findings did not echo that of the literature review, with one woman recounting being supported to make an informed decision about medication and how this would impact on her infant feeding choices, and another woman describing how her medication regime would not be changed due to pregnancy, despite her disease activity being so severe she could not leave the house. The contrasting experiences for these two women are evident, for one woman to be supported in her decision making, yet for the other woman to feel unable to leave her house due to her severity of her IBD symptoms and be offered no solution or support with this. This discrepancy in care is unacceptable and is also not in line with NICE guidance for the management of Ulcerative Colitis (NICE 2013) which states that women should be given information about the risks of medication, and the risks of not taking medication to manage their IBD in pregnancy: interestingly the woman who was denied medication to manage her IBD despite the debilitating level of disease activity during pregnancy had Ulcerative Colitis. A need for clearer advice about IBD medication suitable for use in pregnancy and breastfeeding was identified by one woman. Despite the vast literature relating to IBD medication safety and efficacy, this does not appear to be translating into meaningful information given to women during pregnancy by any professional involved in their maternity care.

6.3.5 Sharing Information

The theme ‘Sharing Information’ is a theme which evolved from another theme ‘Continuity of Care’, however it appreciated that this term is used commonly in midwifery yet the exact meaning and reason why it’s important is not explicit within the term.   Therefore, exploration of what exactly ‘continuity of care’ means was undertaken along with the responses, and the underlying theme was sharing information amongst health professionals involved in the woman’s care.

Better Births (2016:107) discusses the positive impact continuity of care can have on pregnancy outcomes and that through having continuity of carer throughout the pregnancy, the woman will be cared for by someone she has built up a trusting relationship with, although how this will translate into maternity care for women needing multidisciplinary, hospital based care is not specified. Caution is needed when implementing this recommendation to ensure that a two-tier system does not emerge, with women receiving community based care receiving a better package of care than those with additional medical needs necessitating antenatal care in the acute setting.

The recent PICKER Maternity Survey (Quality Care Commission 2018) demonstrated that only 39% of women saw the same midwife for all their antenatal appointments, yet the benefits of continuity of care are well evidenced. Sandall et al. (2016:17) report a reduction in risks of preterm birth, a reduction in assisted vaginal birth using forceps or ventouse and a reduction in the use of regional analgesia for women who had continuity of midwife. Whilst these findings did not include women with pre-existing medical conditions, it is argued that their benefits are transferable, even if not to the degree that they were in the cohort of women without medical conditions. As previously discussed the reduction in preterm birth is of particular importance, given the increased risk associated with IBD. In relation to this study one woman reported seeing twelve different midwives during her pregnancy, and another said that at she was having to re-tell her situation every time she met a new maternity care provider, which must have been extremely frustrating and may have increased her risk of preterm birth. Interestingly the recent PICKER Maternity Survey (Quality Care Commission 2018) highlighted that only 50% of women reported that their midwife was aware of their medical history at each interaction, with 36% of women stating that they were sometimes aware. However, one woman in the study reported that her IBD nurse came to visit her on the postnatal ward and that she found this to be reassuring, and this shows how, if information is shared, multidisciplinary working can work well to enhance experience.

6.4.6 Perceptions

As previously discussed in **section 6.4.1**, women’s perceptions closely link to the notions surrounding mode of birth.

Perception of risk emerged as a theme from the study, with women identifying themselves as being at increased risk of developing complications during pregnancy or birth. Zadeh et al. (2012:110) suggest that women diagnosed with a ‘high risk’ pregnancy are more likely to develop anxiety and/or postnatal depression whilst Better Births (2016:32), suggest women feel resentment when they are labelled as high risk, medium risk or low risk. Therefore, it could be argued that this terminology of high risk, medium risk and low risk is no longer meaningful. Interestingly there is no one recognised definition of what exactly it means to be ‘high risk’ during pregnancy and therefore, individual perceptions around this may well vary.

Women in the study categorised themselves as ‘high risk’, with one woman reporting that she had to remind her midwives that she was not ‘low risk’, and another stating she had to explain the risks of a vaginal birth to her obstetrician to avoid further complications. Women in the study have adopted this terminology around risk and are using almost self-categorising themselves. As previously discussed, women’s knowledge about the effects if IBD on pregnancy can vary, and therefore it is essential that women’s views are listened to, as it may be that their perceptions are not based on accurate information.

Perceptions around medication have been discussed briefly in **section 6.3.4**. The literature suggested that women were more concerned about the effects of prophylactic medical management of IBD than the effects of active disease on the pregnancy. However, this was not echoed in the findings of the study, as women were actively seeking information about medications suitable for use in pregnancy and whilst breastfeeding, and with varying successes in achieving this.

6.4 Strengths and Limitations of the Study

The study used a national gatekeeper, which helped to reduce self-selection bias and provided a platform for distribution of the survey. It also provided support for participants should they require it due to the sensitive topic being researched. Arguably the study is small scale, with only thirteen participants. However, this was an exploratory methodology so the study was not aimed to provide generalisable findings. Instead, it aimed to offer a unique and valuable insight into the experiences of women living with IBD and pregnancy and thirteen women shared their experiences, shared what was important to them and had their voices heard. Without this study, those thirteen voices would not have been heard, and recommendations for improving practice could not be made.

The number of responses could have been improved if the survey was open for longer, however due to the time constraints of the study, the length of time the survey was open was maximised as much as possible, with the two-week extension which still allowed for adequate time for data analysis and completion of the study.

The exclusion of women with a baby over 12 months old also may have reduced the number of responses as women with babies over 12 months expressed their desire to participate in the study. The exclusion of these women gave a predicted eligibility of 265 women, which again within the time constraints of the study would have provided a manageable amount of data, however the response rate was lower than anticipated. Simkin (1992:81) suggests that women’s memories of birth are generally accurate, even after 15-20 years, and this was the message from women who were not eligible to participate in this study. A more purposive sampling technique may have improved the response rate, with women who fulfilled the inclusion criteria being directly sent a survey, however this would rely on women being in contact with the chosen NHS care provider and may exclude women who are not currently needing to receive any care. This supplementary method would have required further ethical approval which may have provided challenging given the time frame of the study.

There was also a missed opportunity to collect data about disease activity at the time of conception within the closed ended questions, and this would have enhanced the data about predicted and experienced disease activity. However due to exploratory nature of the study, this is only considered to be of use due to the other data which emerged, and it is only with the benefit of hindsight it could be considered to be a missed opportunity. It will be key in developing further research designs in this area.

6.5 Recommendations for Future Research

The study was completed in eight months due to the timeframe of the MRes, (as per the Gantt Chart **Appendix 5**) and this meant that the questions were kept focused, however it is apparent that more information could have been gained with additional questions which would have complimented the data already being collected. The survey questions could have been improved, e.g. asking about disease activity at conception, although this has transpired as data analysis took place, and this is the nature of the exploratory study design used and proves extremely valuable when designing subsequent studies in this area. The '*other*' boxes for women to write their responses if their answers did not fall into one of the provided responses meant that sometimes the answer needed further clarify. Therefore, although this proved problematic with data analysis, it has provided an insight which will benefit further research in the area which will be discussed in **Chapter 8**. Purposive sampling is needed, using recruitment through a clinical environment and over a longer period to ensure that an appropriate sample is obtained, including sample size and variation in participant characteristics.

6.6 Chapter Summary

This chapter has discussed the findings of the study whilst comparing them and contrasting them to the themes evolved from the literature review and wider literature, and in context of strengths and limitations. There are areas of discord between the study findings and the literature review, including women's perceptions about medication use in pregnancy, and decisions around mode of birth. However, many of the study findings were echoed by the literature review, which included midwives’ knowledge about IBD and pregnancy and the importance of sharing information between maternity care providers which improves multidisciplinary working.

Chapter 7: Conclusion will draw conclusions from the study findings, the literature review and national guidance and will give recommendations about how the experiences for women with living with IBD during pregnancy can be improved. **Chapter 8**: **Research Implications** will then suggest recommendations about further research.

Chapter 7: Conclusion

The study explored the experiences of thirteen women living with IBD of pregnancy and compared their experiences with the current literature, evidence base around pregnancy and IBD, and national guidance about the management of IBD in pregnancy.

The study findings regarding the perception of risk and women identifying as being at increased risk of complications was of note and may be that women feel this is the most appropriate way to communicate to maternity care providers that they have additional needs. The terminology around risk is well accepted in maternity care, yet there remains to be a universally accepted definition of exactly what high risk is, therefore it may be open to interpretation or misuse.

Improving midwifery knowledge about IBD and pregnancy has been identified by the literature and the findings of the study. There is minimal guidance for maternity care providers about caring for women with IBD. Therefore, the lack of knowledge is compounded by the lack of guidance and the risk of adverse pregnancy outcomes are increased. This is further compounded by a lack of evidence on which to base guidance, particularly evidence that considers women's experiences and preferences.

The current disparity in care that women with IBD currently experience has the potential to impact their experience of birth by either increasing anxiety or failing to ameliorate anxiety. There is the potential that more comprehensive national guidance would help to ensure that women with IBD receive more equitable care.

7.1 Implications for Maternity Care

The findings of the study and the literature review have led to two clear recommendations regarding improvements to maternity care and are show in **Table 14**: Recommendations.

Table 14: Recommendations

Aspect of Maternity Care	Recommendation
Education	Improving maternity care providers knowledge, through education has been highlighted by both the literature and the findings of the study as something which is much needed, and one of the recommendations is that an education package is designed and made available for all maternity care providers. A Specialist Midwife with enhanced knowledge about IBD is also recommended to be a resource for women with IBD during pregnancy and to maternity care providers caring for women with IBD.
Information Sharing	There must be a robust system for health professionals to share information when proving multidisciplinary maternity care, to improve the safety of women with additional medical needs and improve the experience of pregnancy.
Further Research	Both these recommendations would be enhanced if informed by further research

Further research is required to improve knowledge and instigate changes in practice which will further improve the experiences of women through more meaningful discussions. Women ought to be empowered to work in collaboration with their maternity care provider, as opposed to them feeling that they are compensating for care provider lack of knowledge as is currently the case, as indicated by the experiences of some women in this study.

Chapter 8: Research Implications

The findings of the study provided a valuable, unique insight into the experiences of women living with IBD of pregnancy, however, the experiences of women have only really been touched upon, and further research would facilitate further understanding of the experiences of women living with IBD. An immersive exploration of how women living with IBD make sense of pregnancy and the information exploring and seeking to validate the themes emerging from this study would be desirable. A possible methodological approach to apply to such a study is Interpretive Phenomenological Analysis. However further shaping and refining of a specific research question would shape the methodological choice. The researcher is committed to undertaking this research, as they continue their clinical academic journey.

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ehost-live>

Appendix 1: Study Protocol

Study Protocol

FULL/LONG TITLE OF THE STUDY

A Mixed Methods Exploration of the Experiences of Women Living with Inflammatory Bowel Disease of Pregnancy

SHORT STUDY TITLE / ACRONYM

Experiences of pregnancy and IBD

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Helen Janiszewski
Study Co-ordinator	Dr Elizabeth Bailey Midwife Research Fellow Coventry University
Sponsor	Coventry University
Joint-sponsor(s)/co-sponsor(s)	

STUDY SUMMARY

Study Title	**A Mixed Methods Exploration of the Experiences of Women Living with Inflammatory Bowel Disease of Pregnancy**
Internal ref. no. (or short title)	Experiences of IBD in pregnancy
Study Design	Mixed Methods
Study Participants	Women aged over 18 years with a diagnosis of IBD prior to or during pregnancy, who have given birth to a baby in the last 12 months
Planned Size of Sample (if applicable)	265
Follow up duration (if applicable)	None
Planned Study Period	Completion 31 May 2018
Research Question/Aim(s)	**What are the experiences of women living with IBD of pregnancy?**

ROLE OF STUDY SPONSOR AND FUNDER

This research is being undertaken as part of the NIHR HEE Clinical Masters in Research at Coventry University. The study sponsor is the university. The NIHR is funding the Clinical Masters in Research.

PROTOCOL CONTRIBUTORS

This protocol has been developed and approved by the assigned Supervisory Team:

Director of Studies: Dr Elizabeth Bailey – Research Fellow
2nd Supervisor: Collette Clay – Principle Lecturer in Midwifery
3rd Supervisor: Professor Jane Coad – Associate Dean in Research

KEY WORDS:

Childbirth

Crohns Disease

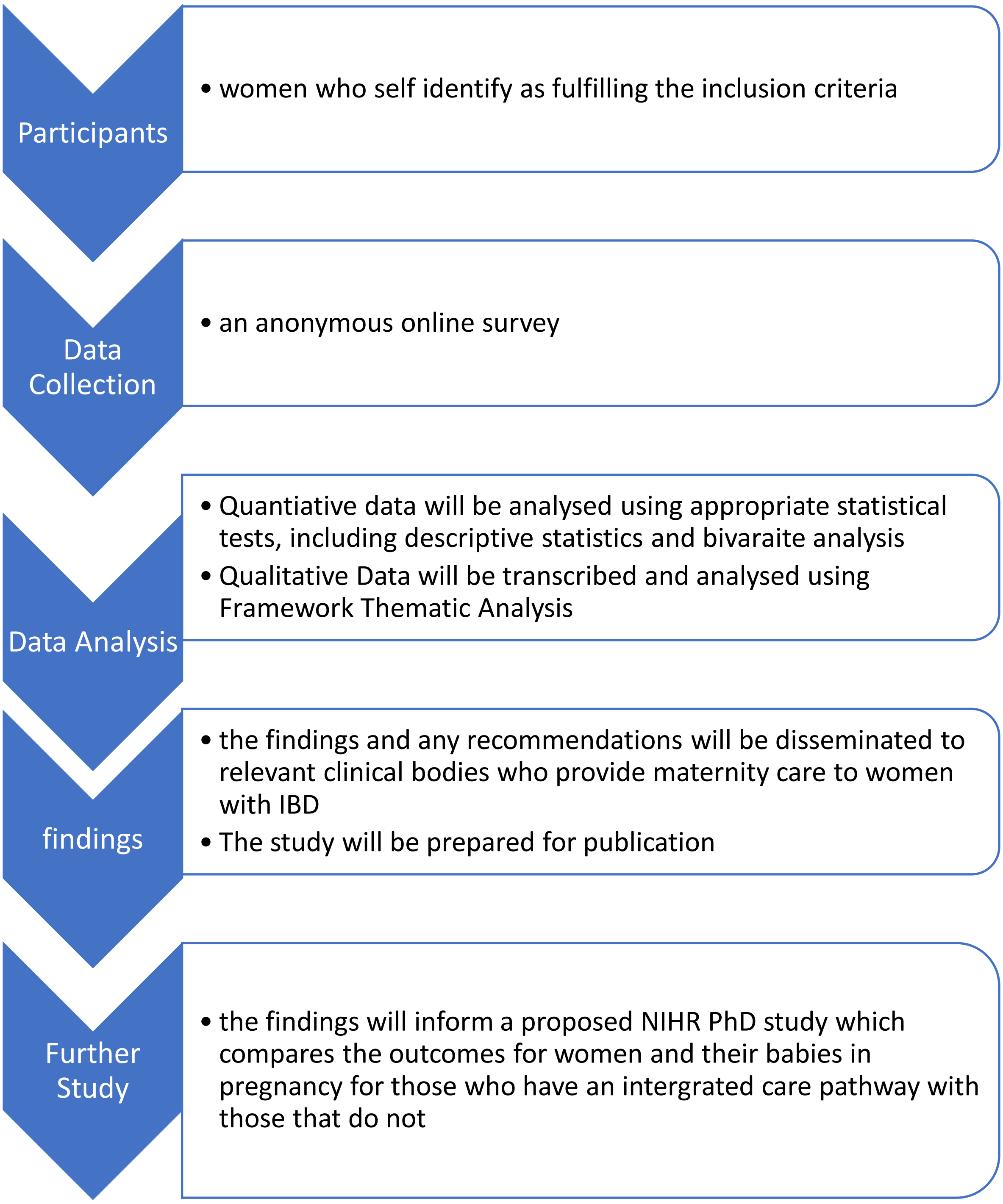
IBD

Pregnancy

Ulcerative Colitis

Care giver

STUDY FLOW CHART



Participants

- women who self identify as fulfilling the inclusion criteria

Data Collection

- an anonymous online survey

Data Analysis

- Quantiative data will be analysed using appropriate statistical tests, including descriptive statistics and bivaraite analysis
- Qualitative Data will be transcribed and analysed using Framework Thematic Analysis

findings

- the findings and any recommendations will be disseminated to relevant clinical bodies who provide maternity care to women with IBD
- The study will be prepared for publication

Further Study

- the findings will inform a proposed NIHR PhD study which compares the outcomes for women and their babies in pregnancy for those who have an intergrated care pathway with those that do not

STUDY PROTOCOL

What are the experiences of women living with IBD of pregnancy?

1 BACKGROUND

Inflammatory Bowel Disease (IBD) is a chronic disease of the gastrointestinal tract, and an umbrella term predominantly used for two distinct conditions; Crohn's Disease and Ulcerative Colitis. There are approximately 10.4 people per 100,000 affected by Ulcerative Colitis and 5.6 people per 100,000 by Crohn's Disease in western populations, with approximately 300,000 people living with IBD in the UK (Crohns and Colitis n.d.). The peak age of onset of IBD is between 15-30 years and a quarter of women will become pregnant after diagnosis. The conception rate for women with IBD is similar to that of the general population, although pelvic surgery can decreases the rate of conception (Kwan and Mahadevan 2010:651) therefore the effects of IBD on pregnancy, childbirth and the postnatal period must be appreciated and appropriate care pathways put in place to help mitigate any identified potentially detrimental consequences to either the pregnant woman or the unborn baby or newborn.

Care of the pregnant woman should include both physical wellbeing and psychological wellbeing, as well as care for the unborn baby, with Better Births (National Maternity Review 2016) outlining the importance of ensuring mental wellbeing is as treated with the same regard as physical wellbeing. Much of the current literature about Inflammatory Bowel Disease in pregnancy focuses on either the physical effects on the mother during the pregnancy, the effects on the unborn baby or newborn, or on the pregnancy outcomes, such as mode of birth. Much of the current evidence is contradictory regarding the risks of developing pregnancy complications such as gestational diabetes, pre-eclampsia or pregnancy induced hypertension and preterm rupture of membranes and/or preterm labour (Shand et al. 2016, Boyd et al. 2015, Bortoli et al. 2011) . The evidence is similar for the outcomes for the baby, such as low birthweight.

Oates(2003:279) discusses the importance of considering the mental wellbeing of pregnant and postnatal women, as between 1997-1999 suicide was the leading cause of maternal deaths in the UK. Therefore, maternal psychological wellbeing should be considered to be an outcome in conjunction with maternal physical wellbeing. Zadeh et al. (2012:110) discuss that women with a high risk pregnancy, or an identified increased risks of adverse pregnancy outcome, may be at increased risk of developing mental health issues such as anxiety or postnatal depression.

The study will involve women providing information about their experience of pregnancy through an anonymous online survey with both open and closed questions.

The population involved is women, who have given birth to a baby, within the last 12 months, who have a diagnosis of prior to or during pregnancy of Inflammatory Bowel Disease.

2 RATIONALE

Much of the existing literature focuses on the maternal physical wellbeing and possible complications during pregnancy and birth, and the possible complications for the unborn baby or newborn. Literature about the experiences for women with IBD can have during pregnancy, is sparse, yet mental health in the perinatal period (pregnancy, birth and postnatal period) is cited in Better Births ((National Maternity Review 2016) as being as important as the physical wellbeing of the woman and baby. Therefore, it is essential that the experiences of women with IBD in pregnancy are understood. The psychological effects of pregnancy, birth and the postnatal period are well researched.

5 THEORETICAL FRAMEWORK

A preliminary literature review has revealed a paucity of published work into women's experience of pregnancy with IBD. Due to this an Exploratory Approach will be used to gain further insight into this issue. By taking this exploratory approach to those who have experienced pregnancy with IBD through the relevant support group, it is expected that a sense of their lived experiences will be gained. This will allow for shaping of further research questions that are relevant to and informed by this particular population.

(Cooke et al. 2012)

Sample	Women who are members of Crohns and Colitis UK who fulfil the inclusion criteria,
Population of Interest	Women living with IBD, experiences of pregnancy
Design	Open and closed questions in an anonymous online survey
Evaluation	Interpretivist Epistemological approach Descriptive statistic and bivariate analysis Framework analysis
Research Type	Mixed methods

4 RESEARCH QUESTION/AIM(S)

What are the experiences of women living with IBD of pregnancy?

To gain insight into the experiences that having IBD may have on women during pregnancy

4.1 Objectives

To collect survey responses to closed questions from women living with IBD about their experiences of pregnancy and care in pregnancy

To enable free text descriptions via open ended questions from women living with IBD about their experiences of pregnancy and care in pregnancy

4.2 Outcome

To explore women with IBD's experiences during pregnancy

The findings will inform a proposed PhD study which may seek to compare outcomes for women and their babies who have an integrated care pathway during pregnancy with those who do not. An Exploratory Approach will be used as this will enable women's experiences and preferences for care provision to be explored using a mixed method study design.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Mixed methods of data collection will be used. A link to an online survey (Appendix 11.1.3) will be available on Crohns and Colitis UK, which will collect data such as incidence, type of IBD, diagnosis prior to or after pregnancy, number of children, satisfaction with primary caregiver during pregnancy and statements about pregnancy which the participants indicates their level of agreement with the statement.

- **Survey**: A survey will be online for women to complete, Quantitative data from the survey will be analysed using descriptive statistics and bivariate analysis. Qualitative data will be analysed using thematic analysis

6 STUDY SETTING

Women will self-identify as to whether they fulfil the inclusion criteria and then complete the online survey through the link on the Crohns and Colitis UK website and through their social media pages, including Twitter and Facebook. The online survey will be generated through Qualtrics. All responses are anonymous.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria.

Women will self-identify via the inclusion/exclusion checklist at the beginning of the online survey, and the survey will then either open (if they fulfil the inclusion criteria) or a comment will pop up which will thank them for considering participating in this study, however they are not eligible to complete the survey.

7.1.1 Inclusion criteria

Women aged over 18 years old, with a clinical diagnosis of Inflammatory Bowel Disease, and who have given birth to a baby within the last 12 months

7.1.2 Exclusion criteria

Women under the age of 18 years, women not self-identifying as having a diagnosis of IBD, not been pregnant in the last 12 months or now has a baby over 12 months old

7.2 Sampling

7.2.1 Size of sample

The fertility rate is 61.7 per 1000 women (ONS 2016) and (Selinger et al. 2016) determined that there were 4300 women who were member of Crohns and Colitis UK who were of childbearing age (18-45 years). which gives an expected sample size of 265 women. Based on an approximate response rate of 30-40% of those eligible, we conservatively estimate the expected completion rate to be around 80-100.

7.2.2 Sampling technique

- Purposive criterion sampling will be used, however is it acknowledged that due to the gatekeeper used to distribute the survey, not all eligible women will have opportunity to participate in the study. However, with over 33,000 members, and the profile of Crohns and Colitis UK on social media and the internet, it is anticipated that this will mean that the survey will be widely available and through sharing may reach non-members.

7.3 Recruitment

7.3.1 Sample identification

Women will self-identify their eligibility for the study and will complete the anonymous online survey.

7.3.2 Consent

The following statements follow the introduction to the online survey:

1. I understand that my participation is voluntary

2. I consent to the storage (including electronic) of personal information for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication.

3. I understand that I have 2 weeks from the date of completion of the survey to withdraw from the study by contacting the Principle Investigator

Potential participants can then tick either:

I Consent – begin the survey

I do not consent – I do not wish to participate

The survey will then either begin or not depending on which statement the participant ticked.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk.

Careful consideration was given to the inclusion or exclusion of women whose pregnancy had not ended in a live birth. The risk of psychological harm to the participant through participating in the study was weighed up against the risk of causing further distress for women who wanted to participate in the study but were told they were not eligible as they had not had a live baby. As women were self-selecting to participate in the study, it was felt to be unethical to exclude these women. As Crohns and Colitis UK is distributing the link, women who choose to participate are members of a supportive recognised organisation should they feel they need any support.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Regulatory Review & Compliance

Before the start of the study, a favourable opinion will be sought from Coventry University Ethics Committee.

Amendments

Any amendments to the study will be submitted to Coventry University Ethics Committee.

8.3 Peer review

The study will be peer review as part of the Ethical Approval process.

8.4 Patient & Public Involvement

Feedback about findings from the study will be discussed with a PPI group as part of consideration and research development into a potential PhD project.

8.5 Protocol compliance

There will be no intentional deviations from the protocol, any accidental deviations will be resolved and reported to Coventry Ethics Committee as necessary.

8.6 Data protection and patient confidentiality

The online survey will be created using Qualtrics, ensuring full confidentiality of the respondents. As Qualtrics captures IP addresses, and allowing for the mechanism for withdrawal the data will be considered pseudoanonymised until such a point as the 2 week withdrawal window is closed and the data is exported from Qualtrics, IP addresses removed and saved in a fully anonymised form. Anonymised data from the online survey will be stored within Qualtrics and then analysed using descriptive statistics.

All data will be stored on a password protected external hard drive/memory stick and in accordance to the Data Protection Act 1998.

8.7 Indemnity

The sponsor of the study is Coventry University and they will provide the Indemnity insurance.

8.8 Access to the final study dataset

The final (anonymised) study data set will be accessed by the PI and the full Supervisory Team as named in this protocol.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

The study will be written up into a thesis for examination as it is a Masters in Clinical Research. Findings from the study may be published in midwifery journals, which usually requires peer review prior to publishing. The findings will also be presented at midwifery and/or research conferences.

10 REFERENCES

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11. APPENDICIES

11.1 Appendix 1- Required documentation

11.1.1 Participant Information
11.1.2 Consent Information
11.1.3 Survey questions which will be used on Qualtrics

11.2 Appendix 2 - Gantt Chart

	November	December	January	February	March	April	May	June
Research Protocol	🟨	🟨						
CU Ethics		🟩	🟩					
Recruitment:			🟥	🟥				
Online Survey			🟦	🟦				
Code Data			🟧	🟧	🟧			
Analyse Data				▨	▨	▨		
Write up		🟪	🟪	🟪	🟪	🟪	🟪	
Disseminate Findings								🟩

11.3 Appendix 3 – Amendment History

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**

Appendix 2: Participant Information Sheet

This will be part of the introduction to the online Qualtrics Survey.

Thank you for considering taking part in this study. This study is being undertaken as part of a NIHR Masters in Clinical Research at Coventry University and is exploring the experiences of women living with Inflammatory Bowel Disease of Pregnancy. You will need to be over 18 years old, have had a baby within the last 12 months and have a diagnosis of IBD during or prior to pregnancy.

It is anticipated it will take no more than 10 minutes to complete the survey.

The benefits to completing the survey are that you will have an opportunity to share your experience of pregnancy to help us understand the needs of pregnant women with Inflammatory Bowel Disease. There are no anticipated disadvantages to completing the study should you wish to participate.

Your responses will be collected anonymously. The findings of the study may be published in relevant journals. There will be no identifiable information shared, all information published will remain completely anonymous.

Participation is completely voluntary, and should you change your mind about participating, you can discontinue before completing and submitting the survey responses. At the end of the study you will be prompted to create your own unique code that can be used to track your responses should you chose to withdraw. If you wish to withdraw from the study after you have completed and submitted the questionnaire, please contact the Principle Investigator: Helen Janiszewski, by email: Janiszeh@uni.coventry.ac.uk quoting your unique code. You can withdraw up to 2 weeks following completion of the survey.

Appendix 3: Consent Statements

The following will be built into Qualtrics and unless the participant selects the 'I Consent – begin the survey' option the study will not start and a pop thanking them for considering the study and explaining that as they do not consent they cannot complete the survey.

Consent – statements below:

4. I understand that my participation is voluntary

5. I consent to the storage (including electronic), of personal information for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication.

6. I understand that I have 2 weeks from the date of completion of the survey to withdraw from the study by contacting the Principle Investigator

Potential participants can then tick either:

I Consent – begin the survey

I do not consent – I do not wish to participate

Appendix 4: Survey questions used in *Qualtrics*

What are the experiences of women living with IBD of pregnancy?

Thank you for considering taking part in this study. This study is being undertaken as part of a NIHR Masters in Clinical Research at Coventry University and is exploring the experiences of women living with Inflammatory Bowel Disease of Pregnancy. You will need to be over 18 years old, have had a baby within the last 12 months and have a diagnosis of IBD during or prior to pregnancy.

It is anticipated it will take no more than 10 minutes to complete the survey.

The benefits to completing the survey are that you will have an opportunity to share your experience of pregnancy to help us understand the needs of pregnant women with Inflammatory Bowel Disease. There are no anticipated disadvantages to completing the study should you wish to participate.

Your responses will be collected anonymously. The findings of the study may be published in relevant journals. There will be no identifiable information shared, all information published will remain completely anonymous.

Participation is completely voluntary, and should you change your mind about participating, you can discontinue before completing and submitting the survey responses. At the end of the study you will be prompted to create your own unique code that can be used to track your responses should you chose to withdraw. If you wish to withdraw from the study after you have completed and submitted the questionnaire, please contact the Principle Investigator: Helen Janiszewski, by email: Janiszeh@uni.coventry.ac.uk quoting your unique code. You can withdraw up to 2 weeks following completion of the survey.

(This will be on line and potential participant select the statements if they are correct. If all selected it will proceed to link for the survey, if not all selected, a pop up which

says, ‘thank you for registering your interest for this study, as you have not answered yes to all of the questions, you do not need to complete the survey’)

I am a woman aged over 18 years

I have a histological diagnosis of Inflammatory Bowel Disease either prior to or during my most recent pregnancy

I have given birth to a baby within the last 12 months

Consent – statements below:

7. I understand that my participation is voluntary

8. I consent to the storage (including electronic), of personal information for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication.

9. I understand that I have 2 weeks from the date of completion of the survey to withdraw from the study by contacting the Principle Investigator

Potential participants can then tick either:

I Consent – begin the survey

I do not consent – I do not wish to participate

---

1. **How old are you?**

2. **What type of IBD do you have?**
    - a. Crohns Disease
    - b. Ulcerative Colitis
    - c. Other – please specify:

3. **How old were you when you diagnosed with IBD?**

4. **Were you diagnosed with IBD prior to your most recent pregnancy?**
    - a. Yes diagnosed prior to pregnancy
    - b. No diagnosed during pregnancy

5. **Have you had any pregnancy losses?**
    - a. Yes at less than 12 weeks
    - b. Yes between 12 – 20 weeks
    - c. Yes between 21-23 weeks
    - d. Yes over 24 weeks
    - e. No

6. **Is this your first baby?**
    - a. Yes
    - b. No

7. **If, no what baby number is this?**
    - a. 2
    - b. 3
    - c. 4+

8. **Who did you see mostly during your pregnancy?**
    - a. Community midwife
    - b. Consultant Obstetrician
    - c. Gastroenterologist

d. IBD nurses

e. Practice Nurse

f. Other – please specify:

9. Who would you have liked to have led your care whilst you were pregnant?

a. Community midwife

b. Hospital midwife

c. Consultant Obstetrician

d. Gastroenterologist

e. IBD nurses

f. Practice Nurse

g. Other – please specify:

10. Did your symptoms of your IBD during pregnancy:

a. Get worse

b. Improve

c. Stay the same

11. Did you expect your symptoms of your IBD during pregnancy to:

a. Get worse

b. Improve

c. Stay the same

12. Please tick one box for each of the statements below, which relates to your pregnancy:

	Totally agree	*Mostly* agree	*Mostly* disagree	*Totally* disagree
My midwife understood my needs				
My obstetrician understood my needs				

I received information tailored to my needs

I would have liked to have seen my midwife more

I would have liked to have seen my obstetrician more

I would have liked to have seen my IBD nurse more

I would have liked to have seen my gastroenterologist more

My pregnancy was as I expected

I felt happy during pregnancy

I felt worried during my pregnancy

I felt prepared for labour and birth

I had confidence in my lead care provider

13. I attended Parent Education Classes during pregnancy:

   a. Yes

   b. No

   c. None were available

14. What would have improved your experience of pregnancy?

   a. Free text answer (max 100 words)

15. Do you have any other comments?

   a. Free text answer (max 100 words)

16. Please enter the last 3 digits of your postcode followed by the last 3 digits of your mobile phone number – this is your unique identifier should you wish to withdraw from the study:

Thank you for taking the time to complete this survey.

If you wish to make a complaint about any aspect of the survey, please contact Professor Oliver Sparagaro (Chair of the University Applied Research Committee) by email: ab8677@coventry.ac.uk

Appendix 5: Gantt Chart

Activity	2017 August	September	October	November	December	2018 January	February	March	April	May	w/c 21 May	June	July	August	September
Literature Review	■	■									S				
Research Protocol		■	■	■	■						U				
Questionnaire			■	■	■						B				
Seek CU Ethical Approval					■	■					M				
Liaise with Crohns and Colitis UK						■	■				I				
Recruit Participants							■	■			S				
Data Collection							■	■			S				
Data Analysis									■		I				
Write Thesis						■	■	■	■	■	O				
Introduction						■	■				N				
Theoretical Foundations						■	■				-				
Reviewing the Literature							■				S				
Research Designs and Methods							■	■			U				
Findings									■		B				
Overall Findings									■		M				
Discussion									■		I				
Conclusions									■		S				
Appendices References										■	S				
Amendments											I			■	■
Publish Literature Review											O		■	■	■
Publish Findings of Study											N		■	■	■
Write PhD Proposal											-		■	■	■
Clinical Portfolio	■	■	■	■	■	■	■	■	■	■	-				