An exploration of the experiences of women living with Inflammatory Bowel Disease and pregnancy

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Award date:
2021

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by

Helen Elizabeth Janiszewski

PhD

September 2021

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September 2021

A thesis submitted in part fulfilment of the University's requirements for the Degree of Doctor of Philosophy

Certificate of Ethical Approval

Applicant:

Helen Janiszewski

Project Title:

An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and 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

Date of approval:

17 January 2019

Project Reference Number:

P80386

Certificate of Ethical Approval

Applicant:

Helen Janiszewski

Project Title:

An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease of Pregnancy using Interpretative Phenomenological Analysis

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 High Risk

Date of approval:

30 January 2019

Project Reference Number:

P76258

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Health and Care Research Wales

NHS
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20 March 2019

Dear Dr Bailey

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and Pregnancy Using Interpretative Phenomenological Analysis
IRAS project ID:	256277
REC reference:	19/NW/0133
Sponsor	Coventry University

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations in England and Wales that are Recruiting sites should formally confirm their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter. You should then work with each organisation that has confirmed capacity and capability and provide clear instructions when research activities can commence.

Participating NHS organisations in England and Wales that are Participant Identification Centres (PICs) will not be required to formally confirm capacity and capability before you may commence research activity at site. As such, you may commence the research at each organisation 35 days following sponsor provision to the site of the local information pack, so long as:

- You have contacted participating NHS organisations (see below for details)
- The NHS organisation has not provided a reason as to why they cannot participate
- The NHS organisation has not requested additional time to confirm.

Certificate of Ethical Approval

Applicant:

Helen Janiszewski

Project Title:

An Exploration of the Experiences of Women Living With Inflammatory Bowel Disease and 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 Low Risk

Date of approval:

29 April 2019

Project Reference Number:

P90195

Acknowledgements

Thank you to Dr Liz Bailey my Director of Studies and my fantastic supervisory team: Professor Jane Coad, Dr Joanne Cooper, Dr Gordon Moran, for their guidance, expertise and advice in supporting me in turning my vision into a study, which enabled women to share their experiences and recommend ways to shape maternity care for women living with IBD.

Thank you to Claire Greenaway, Patient and Public Involvement Representative, for her guidance, advice and support

Thank you to the Inflammatory Bowel Disease specialist nurses at Nottingham University Hospitals NHS Trust and the staff at the Biomedical Research Unit for their support with recruiting women to the study

Thank you to Lee Patterson for his help and expertise in transforming my drawings into a digital reality

Thank you to my husband Ashley, and boys Louie and Theo for their unwavering encouragement and support

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

Alone we can do so little; together we can do so much

Helen Keller

Abstract

Approximately 260,000 people are living in the United Kingdom with Inflammatory Bowel Disease (IBD). IBD is long term condition affecting the gastrointestinal tract and is an umbrella term for two main conditions: ulcerative colitis and Crohns disease.

Women living with IBD have a similar fertility rate as the general population, with a quarter of women becoming pregnant after their diagnosis. IBD increases the risk of pregnancy complications including gestational diabetes, preterm birth (<37 weeks), low birth weight babies (<2.5kg at term) and caesarean section.

A mixed methods study was undertaken to gain an in-depth understanding the experiences of pregnancy for women living with IBD, which encompassed a national online survey and one to one interviews which were analysed using Interpretative Phenomenological Analysis.

The interviews provided qualitative data which was considered to the primary data whilst the survey provided predominantly quantitative data which was considered to be supplementary.

Four main themes emerged as being important to the women: expectations, control, care and information giving. Women described what their expectations were, which mainly focused on their IBD activity and how these expectations were shaped, with any advice they were given being valued. Control emerged as being important, with a lack of control sometimes having positive effects. Women also described the choices they made and what influenced these and how these were sometimes difficult decisions as opposed to choices. Who women wanted to care for them, and the importance of a trusted relationship emerged, with the struggle for information about IBD and pregnancy detracting from experiences.

This small novel exploratory study provided in-depth understanding of the experiences of pregnancy for women living with IBD and recommendations about pregnancy care include a national guideline, a national resource for healthcare practitioners and an online training package caring for women living with IBD. It is also recommended further research into the impact IBD disease activity has on preterm birth and pregnancy loss is undertaken.

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Chapter 1: Introduction and Background

Personal context of the study

Whilst working clinically as a midwife, I became acutely aware of the differences in care provisions and established plans of care for women living with IBD when compared to those with more well-known diseases, such as diabetes mellitus, renal disease, obesity, asthma or cardiovascular disease or disorders (National Alliance Guideline and National Institute for Health and Care Excellence 2019). Women with diabetes mellitus, for example, commonly have care plans, access to a specialist clinic and team caring for them, and national guidance to inform local guidance about care in pregnancy, labour and the postnatal period. This was notably lacking for women living with gastrointestinal diseases, in particular IBD. Very soon after the birth of my second child, I was diagnosed with Inflammatory Bowel Disease and therefore had acquired personal knowledge and information about IBD and how it can impact on life and the postnatal period. This acquired knowledge enabled me to care for pregnant or postnatal women with IBD with more confidence and an ability to advocate for them when care was not evidence based, or when decisions were made about their care without their involvement. However, had I not have had this personal experience, I would not have been in a position to do this, and the apparent paucity of guidance about caring for women in pregnancy with IBD compounded my concern about the disparity and inequity of care this cohort of women received. What remained unclear was whether my perceptions about care inequities were reflected in the experiences of others with IBD, or indeed whether women were happy with the care they received. In 2018, I completed the HEE NIHR Masters in Clinical Research undertaking an exploratory study to explore and describe the experiences of pregnancy for women living with IBD. This was a small study but aimed to explore the experiences of women across the UK and if the lack of national guidance impacted on their care as had been seen in practice locally.

While limited, this study provided valuable insight into the experiences of pregnancy for women living with IBD and although too small to provide any firm conclusions, was able to make recommendations about the need for further research into this area. The findings of the study were published in a midwifery journal and disseminated at a national midwifery conference, raising awareness and knowledge of IBD and pregnancy.

The work presented in this thesis builds on the foundations of the MRes findings to structure the survey. Following feedback from women who wanted to participate in the previous study but were excluded due to time frames in the inclusion criteria, the eligibility was increased by including all women who had experienced pregnancy and been diagnosed with IBD prior to or during pregnancy. I wanted to undertake this PhD to enable women's voices to be heard about their experiences of pregnancy, whilst building on the recommendations for further research into this area and enabling more women to share to their experiences, critiquing the existing evidence and published literature, creating new knowledge which will help reduce the inequity in care faced by women living with IBD during their pregnancy. This will be achieved through a systematic review of the relevant literature and the development of aims and objectives which will enable an in-depth exploration with recommendations for those caring for women living with IBD during pregnancy. This PhD was completed in just over 2 years, due to a successful competitive application to extend the HEE NIHR Masters in Clinical Research (completed in 12 months) and was funded by Coventry University. All of the data presented in this thesis was gained solely from the studies undertaken during the PhD, with the findings of the MRes being used to inform elements of the studies. The PhD was a 24 month programme and was completed in 27 months due to the impact of COVID-19.

1.1 Background

This section will outline the background and context of Inflammatory Bowel Disease and current pregnancy care provided within the NHS in the United Kingdom. **Chapter 2** will present a systematic review of the literature of IBD and pregnancy experiences.

1.1.1 Inflammatory Bowel Disease

Inflammatory Bowel Disease is an umbrella term for a chronic disease encompassing two main conditions: Crohn's disease and Ulcerative Colitis, with symptoms including diarrhoea, rectal bleeding abdominal pain, loss of appetite, anaemia, general fatigue, and tiredness. Approximately 261,000 people are living in the United Kingdom with Inflammatory Bowel Disease (IBD) (Crohns and Colitis UK 2017). Symptoms have a remission and relapse cycle, with a worsening of symptoms during relapse and less or no symptoms during periods of remission. The peak incidence of IBD is between 15-30 years of age, however the aetiology of IBD is still unknown, and the reason for this peak age of onset also remains unclear.

IBD was first identified as a disease in the 1800's and the history of IBD is outlined in **Figure 1.**

Figure 1: Timeline of IBD

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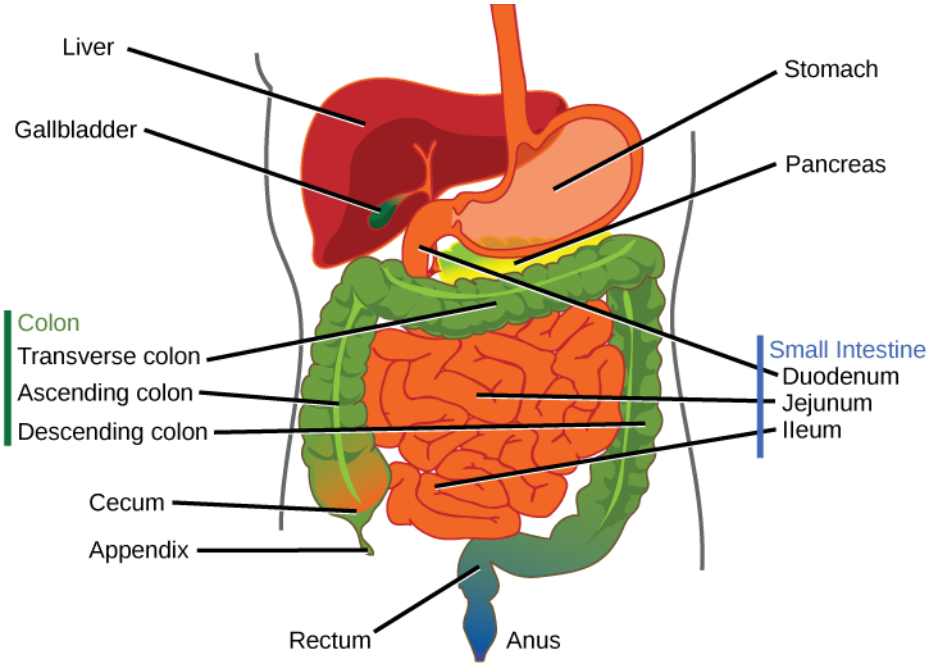
(De Dombal 1968:684) (Wolff 1989) (Fein 1982:1)(Martin 2015:387) (Vilardell 2019)

Figure 2: The Digestive System



1.1.2 Crohn's disease

Symptoms of Crohn's disease include diarrhoea, loss of appetite, anaemia and weight loss. It is only once the disease has become well established that symptoms occur. Crohn's disease causes inflammation of the digestive tract (**Figure 2**) which can lead to the formation of strictures. The location of the disease will dictate the symptoms experienced, with diarrhoea with blood and lower abdominal pain suggesting that the **colon** is involved, and nausea, upper abdominal pain and fever indicating it is **small intestine** involvement (Korelitz 1998:41). Crohn's disease will usually remain in the section of bowel where it was originally discovered, unless surgery has been performed, to remove the affected section of bowel, in which case the disease will almost always extend proximally (Korelitz 1998:40).

Complications of Crohn's disease can include obstruction, which is usually in the small intestine and is caused by inflammation causing scarring which causes narrowing and stops food or gas passing through. Obstruction can occur in the colon, although this is less common. Abscesses and fistulas are another complication, and are considered together, as it is usually the breakdown of the abscess which creates the fistula, which are holes that form between the affected section of bowel and adjoining areas. Malabsorption may occur when larges areas of the small intestine are involved, as this leads to an interference with the absorption of food. Premalignant changes and cancer in the colon and small intestine are another complication of Crohn's disease, as is toxic megacolon which is a dilatation of the colon due to the inflammation spreading through the wall of the colon. It is a symptom of severe disease activity and can lead to perforation of the colon. Perforation of the colon or small intestine can also occur spontaneously although this is rare (Korelitz 1998:46)

1.1.2.1 Management of Crohn's disease and Extraintestinal manifestations

Crohn's disease can be managed using medication, to achieve remission and to maintain remission. Surgery may also be used. Pharmacological interventions may be used to manage and treat Crohn's disease if the disease is refractory to conventual medications (Gomollón et al. 2017:12) or if there is local disease surgery may be considered (Gomollón et al. 2017:13).

Extraintestinal manifestations of Crohn's disease may involve the mouth, skin, eyes, joints, musculoskeletal system, perianal abscesses and Irritable Bowel Syndrome and may present before the gastrointestinal symptoms of Crohn's disease appear. They are most common when the colon is affect by Crohn's disease (Gomollón et al. 2017:9).

1.1.3 Ulcerative Colitis

Ulcerative Colitis differs to Crohn's disease as it only affects the colon and causes inflammation and ulceration. It can affect all, or just sections of the colon (Rood 1998:31). Ulcerative colitis is also contained to the mucosa of the colon, whereas Crohn's disease can affect the whole thickness of the bowel wall. Ulcerative colitis affects the colon in a continuous manner, therefore unlike Crohn's disease it is not characterised by skip lesions sections. Symptoms of Ulcerative colitis include diarrhoea, rectal bleeding and abdominal pain. Depending on where the Ulceration colitis affects, symptoms may vary, with constipation being a symptom if the lower end of the colon is affected and diarrhoea if the colon is more widely affected.

Complications of Ulcerative colitis can include toxic megacolon where the colon becomes extremely distended and there is a risk of perforation. The risk of colon cancer is also increased in the presence of Ulcerative colitis (Rood 1998:36).

1.1.3.1 Management of Ulcerative Colitis and Extraintestinal manifestations

Ulcerative colitis can be managed using medication. Surgery can also be used, as removing the colon will remove the Ulcerative colitis. The most commonly used procedure involves removing the colon and creating an ileal-pouch anal anastomosis.

Extraintestinal manifestations of Ulcerative colitis include anaemia due to blood loss, bone disorders, joint disorders, skin and eye disorders and conditions affecting the liver and gallbladder (Magro et al. 2017:657).

1.1.4 Inflammatory Bowel Disease as a long-term condition

IBD is a long-term condition, with approximately 146,000 people living with Ulcerative Colitis (National Institute for Health and Care Excellence (NICE) 2013) and 115,00 people living with Crohn's disease in the United Kingdom (NICE) 2012).

The Department of Health (2012) defines a long-term condition as being a:

"**condition which cannot be, at present, cured but is controlled with medication and/or other treatment/therapies" (Department of Health 2012:3).**

There are approximately 15 million people living with a long-term condition in England, however IBD is not included as a long-term condition in the long-term condition quality and outcomes framework devised by the Department of Health (2012:5). Long-term conditions have a financial burden both to the individual and to society, with those living with a long-term condition having an increased likelihood of unemployment or working absence. Half of people living with a long-term condition state that their condition is a barrier to the type of work they can do, and this rises to 80% of people who have three or more conditions (Department of Health 2012:15). Approximately 70% of the health care spend in England is attributed to the care of the ~30% of people living with long-term conditions, implying a poor apportioning of an already restricted healthcare budget. This highlights the additional cost of care needed by people living with long-term conditions, including medication, treatments, investigations and some of which require prolonged hospital stays.

Living with a long-term condition may create financial difficulties for individuals in conjunction with the physical and psychological difficulties they may also experience. Two thirds of people living with a long-term conditions also have a co-morbid mental health illness,

predominantly anxiety and depression (NHS England 2020a). NHS England (2014:12) aim is that those living with long-term conditions feel confident and able to self-manage their condition. Self-efficacy is an important factor in how confident and able someone feels to be in control of their condition or disease, as it is the ability to determine what actions are taken when faced with prospective situations and creates a belief of the ability to succeed in a particular situation, in this case a flare up of the condition or disease. There are different elements which influence self-efficacy, which include personal accomplishments which includes if you have been unwell with your disease and subsequently recovered. Vicarious experience is where you have witnessed others with the same disease achieve an event, such as pregnancy, without adverse outcomes and verbal persuasion which relies on others telling you that you will ok and will cope (Bandura 1977:193-198). Therefore, it appears that there may be some benefits associated with supporting people living with IBD to actively participate in how they live with IBD as it may increase their self-efficacy and ability to self-manage and cope with their disease.

1.1.5 Inflammatory Bowel Disease and pregnancy

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, however to what degree is not stated, or chronic disease activity which has resulted in malnourished state (Kwan and Mahadevan 2010:651).

The literature reports that approximately a quarter of women will become pregnant following their diagnosis of IBD (Ferguson et al. 2008:1), however it has not been possible to identify the origin of this statistic. Approximately 50% of people are diagnosed with IBD before they are 35 years old (Ferguson et al. 2008:1) and the average age of women at the birth of their first baby is 28.6 years (Office for National Statisticts 2016). This may suggest that either the

statistic commonly used is outdated, or that a large proportion of women are not having babies following their diagnosis of IBD. As previously discussed, fertility in women with IBD is generally similar to that of the general population. Studies have been untaken exploring what is termed as 'voluntary childlessness' in women with IBD, who are women who feel psychologically unable to have a baby due to their concerns about their IBD. Selinger et al. (2013) undertook a study which assessed the views of women living with IBD on IBD and pregnancy, and reported that there was an associated between 'poor' knowledge and misconceptions about IBD and pregnancy led to an increase in 'voluntary childlessness' and that this could be reduced through education and reassurance about hereditary rates and targeted education for women with particularly poor knowledge (as assessed using the researchers CCPKnow knowledge assessment tool). This suggests that by giving women more information and improving their knowledge they will then feel able to consider a pregnancy. The terminology of 'voluntary childlessness' suggests women have simply chosen not to have children, as opposed to the difficult decisions they may have made in considering a family and is patronising to suggest that this can be overcome by providing more information.

It is often suggested that a third of women living with IBD will experience and improvement in their symptoms, a third will stay the same and third will experience a worsening (Tresca 2019) however disease activity at conception may be a more accurate predictor of disease activity during pregnancy, and the risk of pregnancy complications for the mother and the baby. Abhyankar et al. (2013:5) concluded from their meta-analysis that women who become pregnant with active disease are more likely to continue with active disease throughout their pregnancy, compared to those who are in remission at conception. This meta-analysis drew on data from 14 studies, including controlled trials, observational studies and cohort studies which reported disease relapse rates or clinical outcomes during

pregnancy based on disease activity at conception. The primary outcome measure of the meta-analysis was the proportion of women with active disease during pregnancy, and whether disease was active or inactive at conception. There was not a pre-specified disease activity score used as the researchers did not expect there to be a universal definition of 'active disease' across the studies. If active disease was reported and disease activity at conception was reported within the study, they were included. This has implications for drawing any conclusions as 'disease activity' was subjective. The researchers did acknowledge this limitation. The literature search timeframe was 1966-2013, however three studies from the 1950s were included as deemed to be eligible. This was a reasonable meta-analysis which supports the association with disease activity at conception and disease behaviour in pregnancy, however most of the papers included were retrospective and low quality. They also date back to before recent therapeutics for IBD management. Given the time frames the studies spanned, it is unclear if the findings apply to a contemporary childbearing population.

A more recent meta-analysis of 28 papers (published between 1952 – 2020) was published in 2020 by Kim et al. (2020) reviewed the association between IBD activity at conception and pregnancy outcomes, including preterm birth and pregnancy loss and recommended pregnancies are planned when disease activity is quiescent. Whilst this provides more up to date evidence which includes the current management of IBD, only seven of the 28 papers included were published after 2013, and further demonstrates the limited evidence available about IBD activity at conception and the impact on pregnancy. They concluded that a large prospective study was needed to determine the risk of adverse pregnancy outcome (namely preterm birth, pregnancy loss and low birth weight babies) for women living with IBD.

IBD increases the risk of pregnancy related complications including: maternal gestational diabetes (due to the use of corticosteroids in the treatment and management of IBD) , 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 (Getahun et al. 2014), (Boyd et al. 2015) (Shand et al. 2016) (Bortoli et al. 2011) and severe disease activity during pregnancy further increases the risk of these pregnancy complications. Getahun et al. (2014) reported novel findings from their study which matched hospital records and compared perinatal outcomes with women living with IBD and those without, which were small-for-gestational-age babies, spontaneous preterm birth and premature rupture of membranes. However they did acknowledge that they relied on self-reporting of behaviours such as smoking which may have contributed to adverse perinatal outcomes. Shand et al. (2016) also recognised that there may have been an over representation of women with more severe IBD included in their study as it drew data from hospital admission and compared perinatal outcomes between women diagnosed with IBD and those without IBD and therefore the increase in complications may have been due to the over-representation. The prevalence of these complications is not conclusive from the available literature, however the increased risk is evident and should therefore be considered and acknowledged.

Whilst the evidence suggests women living with IBD are at increased risk of caesarean section as a mode of birth, according to The Second European Evidenced-Based Consensus on Reproduction and Pregnancy in Inflammatory Bowel Disease (van der Woude et al. 2015:109), mode of birth should be based on obstetric necessity, with advice from the gastroenterologist. Vaginal birth should be supported for women with quiescent or mild disease, whilst women who have perianal disease or active disease which affects the rectum a caesarean section is recommended. However it is important to remember than women

who do not have active disease affecting the rectum or perianal disease may request a caesarean section, and this should be respected and undertaken after discussion and an offer of support (National Institute for Health and Care Excellence (NICE) 2011:96). Equally, women with active perianal disease or active disease involving their rectum may not want a caesarean section, and should be supported with their choice, whilst ensuring they have the information they require to make a fully informed decision. Maternity care should be personalised to meet the unique needs of each woman and this is discussed further in **Section 1.1.7**. Therefore, women should be involved in discussions about mode of birth and their preference acknowledged and supported.

The positive effects of preconceptual counselling or information-giving to women living with IBD about pregnancy are frequently referred to, with Pinder et al. (2016:326) summarising that preconceptual counselling about pregnancy and IBD improves pregnancy outcomes, however exactly what these outcomes are is not stated. Hoekstra et al. (2018:704) and Selinger et al. (2012:62)) both discuss the importance of all women living with IBD being given information about IBD and pregnancy, and that this should be routinely provided. The Second European Evidenced Based Consensus on Reproduction and Pregnancy in IBD (van der Woude et al. 2015) argue that 'poor' patient knowledge about IBD and pregnancy increases the number of women who feel psychologically unable to have children due to their concerns about their IBD. This suggests that if women received enough information about IBD and pregnancy, they would be able to overcome their psychological concerns and have children, yet this is extremely controversial as even with extensive information, some women will still feel psychologically unable to have children. However, exactly what and who should provide this much needed preconceptual counselling or information giving to women remains vague, which will undoubtedly impact on the prevalence of this occurring. Preconceptual counselling should also include information about infant feeding, with women

being advised pre-conceptually of the potential protective benefits of breastfeeding. There is a significant association between maternal IBD and changes in the microbiome composition during pregnancy and in the baby as found by Torres et al. (2020:48), who recruited women from a prospective study exploring the mechanisms of disease transmission in utero through the microbiome. A total of 121 pregnant women were included in the study, 40 of which had IBD. Women with IBD were matched with women without IBD and women collected stool and salvia samples at each trimester, along with medication use and disease activity (defined using existing assessment tools). After birth, serial stool samples were collected from the babies. Maternal IBD was found to be the most major consistent factor associated with the baby's microbiome composition, however other factors including mode of birth, feeding, exposure to antibiotics and preterm birth were also found to affect the microbial composition, which may positively influence the development of diseases including IBD (Xu et al. 2017:781). Therefore, through the changes to the baby's microbiome from the maternal IBD, this may increase the risk of the baby developing IBD. Exclusive breastfeeding increases the Bifidobacterium in the baby's gut, which is the earliest gut coloniser and promotes health benefits for the gut (Torres et al. 2020:48), with a strong inverse association between breastfeeding and the development of IBD during infancy and adult onset. The greatest benefit is observed if breastfeeding is continued for at least 12 months, due to the strong influence of breastmilk on the intestinal microbiome of the baby (Xu et al. 2017:785).

Lee et al. (2015:43) describe a 'high risk pregnancy' as a woman with either an obstetric or medical history which could affect the pregnancy and requires referral to an obstetrician. Women with IBD are considered to have a high risk pregnancy (Ferguson, Mahsud-Dornan, and Patterson 2008), which Kapoor et al. (2016:205) recommended should ideally be cared for by a specialist multidisciplinary team of an obstetrician and a medical or gastroenterology

team. However, the UK national guidance on the management of long-term conditions in pregnancy varies greatly depending upon the condition, with no clear rationale for this discrepancy. The need for multidisciplinary or interprofessional working when caring for women with existing medical conditions is well documented throughout the National Institute for Health and Care Excellence (NICE) documents, yet how this integration works in practice is not explained and is based on assumptions rather than direction or advice (Mayer, Bick, and Taylor 2020:9).

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) and hypertension and obesity pregnancy care, having more recently published guidance about intrapartum care for women with existing medical conditions, including heart disease, bleeding disorders, asthma, obesity and kidney disease (National Alliance Guideline and National Institute for Health and Care Excellence 2019). Maternity services often have dedicated clinics and specialist healthcare professionals providing care for women with these conditions, which ensures they have their pregnancy needs and medical needs met simultaneously.

However, there is no specific guidance around the management of IBD during pregnancy or birth, despite evidence linked to adverse outcomes for mothers and babies. The most recent NICE guidance around the management of Ulcerative Colitis (NICE 2019) highlights the importance of effective communication between health professionals during pregnancy and that the risks of treatment should be discussed with the patient. Notably, NICE guidance (NICE 2019) regarding the management of Crohn's disease also only contains a small subsection about conception and pregnancy, outlining the need to ensure effective

communication and sharing of information between specialities including obstetricians and gastroenterologists.

Despite these brief mentions of the potential additional risk to women living with IBD during pregnancy, no specific guidance is provided by NICE. Moreover, 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. In contrast, 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 including the UK, Spain, Belgium, Greece, the Netherlands, Croatia, Israel, Germany and also the USA. This guidance and evidence presented within this has not been used within 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.

Importantly, there are also psychological considerations for women during the perinatal period, with one in five women being affected by depression or an anxiety disorder (Bayrampour et al. 2018:47). People living with a long-term condition are two to three times more likely than the general population to experience mental health problems, including depression and anxiety (Naylor et al. 2012:2) (NHS England 2020a), therefore the combination of living with a long-term condition and experiencing pregnancy may increase the risk of developing a mental health illness, primarily depression or an anxiety disorder. Furthermore, being diagnosed with a high risk pregnancy, increases the risk of developing

anxiety and/or postnatal depression (Zadeh et al. 2012:110). Women with IBD may then not only have the risk of adverse physical outcomes but may be at increased risk of developing a psychological disorder during or after pregnancy. Psychological wellbeing may change throughout the pregnancy, especially if disease activity worsens. Excessive reassurance-seeking is common amongst people living with anxiety, and may involve excessively seeking medical care and internet searching, and quickly diminishes anxiety which leads to immediate relief, however this is relief is short lived and anxiety may increase as the desired reassurance has not been sought (Osborne and Williams 2013:420). This has implications for healthcare professionals, and when caring for women living with a long-term condition and possible mental health issues, it is important to be mindful that if reassurance or information seeking becomes excessive this may be excessive reassurance-seeking which may require strategies to address.

1.1.6 Burden of medication

Medication is used for both maintaining remission in IBD and also for managing active disease, in a variety of forms, including oral medication, intravenous medication, subcutaneous injections, rectal suppositories and topically applied medications. Sawicki et al. (2011:335) undertook a cross sectional, survey based, study which looked at medication use for chronic health conditions by pregnant women. More than one third of the women who responded reported having at least one chronic health condition during their pregnancy It has a response rate of 88% and found that the majority of women had concerns about using any medication in pregnancy, and that many participants had perceived some risks with using medication during pregnancy. It did not distinguish between pre-existing and pregnancy induced conditions (such as gestational diabetes) and it is acknowledged that due to the way data was analysed this may have led to over estimation of prevalence of

chronic conditions. It is not known whether this is unique to women who do not take medications to control long-term conditions or do women in this cohort share a similar view. Horne et al. (2005:53) suggests that 50% of patients with a long-term condition do not take their medication as prescribed, with concerns about the side effects being an influencing factor. This suggests that the perception of harm from medication is not unique to pregnant women. Horne et al. (2005:135) concluded that there appears to be little evidence that adherence to medication use in long-term conditions can be improved in a sustainable way within the clinic setting.

Patel et al. (2012:2529) found that women who needed low-molecular-weight heparin during pregnancy were compliant (97.92%), although acknowledging they had concerns about the possible harm associated with the medication, with 96.8% of women wanting to know the possible side effects and risk of harm to them and their unborn baby. This medication was regarded as being protective for the health of the woman and therefore the unborn baby and it was suggested that this was the reason for the high adherence. This suggests a positive relationship between the information given about the risks and benefits of the medication and adherence of it being taken as prescribed and may be especially important to women during pregnancy given the anxieties they already have about medication. The psychological burden of taking regular medication and the uncertainties about side effects or risk of harm to them or their unborn baby must be acknowledged and factored into antenatal care.

1.1.7 Maternity Transformation

In 2016, The National Maternity Review published 'Better Births Improving Outcomes of Maternity Services in England' (National Maternity Review 2016) sharing a vision for maternity services and maternity care until 2021. It comprised of seven components, all with

measurable outcomes: personalised care, continuity of carer, safer care, better postnatal and perinatal mental health care, multi-professional working, working across boundaries and payment systems. Whilst all have importance to the physical and emotional and psychological wellbeing to women during pregnancy and in the postnatal period, some have more significance for individual cohorts of women. Women living with long-term conditions such as IBD may benefit from having a personalised plan of care for their pregnancy as needs dictate. However, the unpredictable nature of IBD needs to be factored into this plan. Continuity of carer, has demonstrated benefits which included a reduction in preterm birth and a reduction in assisted vaginal births using forceps or ventouse (Sandall et al. 2016:17). Whilst it is important to note that these were findings from a study which included only women without pre-existing medical or obstetric complications. The POPPIE study (Pilot study Of midwifery Practice in Preterm birth Including women's Experiences) (Fernandez Turienzo et al. 2019) is a randomised controlled trial which allocated 334 pregnant women at increased risk of preterm birth to either standard maternity care to midwifery continuity of carer, with the primary outcome ascertaining any difference in the initiation of appropriate interventions for the prevention or management of preterm labour and/or birth. In 2021 the results of the study pertaining to women's experiences were published (Turienzo et al. 2021) which found women who were assigned to the midwifery continuity of carer arm of the study reported higher levels of trust with their midwife and had greater perceptions of safety and quality of care. However, there were no differences reported in social support, bonding, and control in labour or quality of life. The increased trust reported by the women who received midwifery continuity of carer was argued to mean women would be more likely to disclose potentially harmful behaviours such as smoking or drinking, which may enable midwives to provide tailored emotional and mental health support. However, the primary outcome of the study was to determine if women assigned to midwifery continuity of carer were less likely to

have a preterm birth and the results showed that there was no difference in the preterm birth rates for women who were part of a continuity of carer and those receiving traditional antenatal midwifery care. Whilst there are other benefits demonstrated, it could be argued that continuity of carer does not provide transferable benefits in terms of preterm birth to women with high risk pregnancies, or indeed those outside of low risk midwifery care.

The measurable outcome for this component started as 20% of women will receive continuity of carer by 2019. A recent progress report 'Better Births Four Years On: A Review of Progress' (NHS England 2020b) revealed that in March 2019, 17.3% of women were assigned onto continuity of care pathway and therefore not the 20% originally aimed for, with the ambition then being for 35% of all women to be on a continuity of carer pathway by March 2020, and most women being assigned onto one by March 2021. The impact of COVID-19 on maternity care has meant that in some areas continuity of carer schemes have been closed in some areas (Renfrew et al. 2020) and that there has been significant staff shortages which will impact on the delivery of continuity of carer. Therefore, the ambition may well be hindered by the effects of COVID-19 on maternity services. How the women are selected to be on a continuity of carer pathway is decided by the maternity care provider. Some providers have based allocation on postcode, whereas others have created caseloads of women depending upon their needs, such as increased vulnerability or low socio-economic status. Therefore, if there are benefits to be realised of Continuity of Carer for women living with IBD, it may be some time until these are seen or can be evaluated.

However, despite the potential benefits which Continuity of Carer may offer women living with IBD and other medical conditions which may increase their risk of preterm birth, how Continuity of Carer is delivered to women requiring multidisciplinary care is yet to be nationally agreed. There is more opportunity for women who have conditions that have

designated pregnancy clinics and specialist healthcare professionals working collaboratively to receive Continuity of Carer, however for those without such care pathways it will be more challenging to ensure they receive continuity of carer due to the often disjointed multidisciplinary care they receive. How Continuity of Carer is delivered to women with complex health needs remains on ongoing challenge and would benefit from further research about how it can be achieved, in conjunction with an evaluation of whether the benefits seen in low risk women are transferable to this cohort of women.

Safer care relies on midwives, obstetricians and specialists to work in partnership to ensure women receive the right care in the right place, whilst multi-professional working requires midwives, obstetricians and any relevant specialists to work collaboratively. This is of particular significance for women living with long-term conditions, including IBD, as their pregnancy care will encompass management and/or treatment needed for their condition, and that care will not be disjointed. It also provides interventions to ensure that there is risk assessment and management of babies at risk of fetal growth restriction – which the evidence suggests babies born to women living with IBD are, as discussed in **Section 1.1.5**. Better Births also calls for better postnatal and perinatal mental health care with 15-20% of women being affected by anxiety or depression in the first year after giving birth, and as previously outlined, women who are diagnosed with a high risk pregnancy are at increased risk of developing anxiety and/or postnatal depression. Therefore, this is of particular benefit to women living with long-term conditions which translates to their pregnancy being considered as high risk.

1.2 Chapter Summary

Living with a long-term condition such as IBD is multifactorial especially when considering, or during pregnancy, as IBD may physically complicate pregnancy and psychologically affect the experience of pregnancy. Women living with IBD are not currently receiving maternity care equitable to that of other long-term conditions, due to a lack of national guidance, and the impact of this for women is not understood. Before this inequity can be fully addressed, it is important to understand what the experiences of pregnancy are for women living with IBD, both for those diagnosed with IBD prior to pregnancy and for those women who become pregnant after a diagnosis of IBD, and also what current literature is available.

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

Further to this, the subsequent chapters will present the research methods and methodology, the novel mixed methods data collected, which allowed women's voices to be heard about a previously unstudied phenomenon. The mixed methods data synthesis will be presented and then discussed in the wider context of midwifery care, local and national guidance and policy and what novel contribution this study brings. Recommendations and overall conclusions will conclude the thesis.

Chapter 2: Reviewing the literature

2.1 Introduction

This chapter consists of a systematic review and as such is presented according to the PRISMA reporting guidelines which is described in more detail in the methods section: **Section 2.2**. The rationale for the systematic review is discussed below in **Section 2.1.1**.

2.1.1 Rationale

Prior to finalising a research question, it was important to examine the existing evidence base including published literature in relation to IBD and pregnancy, what research methods have been used in this topic, if there are any coherence of consensus or disagreement of evidence and who the key contributors to research in this topic are (Bryman 2016:6). Whilst the research topic had been already identified, the research question will be influenced by the information gained from an initial scoping literature review. Moreover, the research question will influence the research design, data collection methods and data analysis methods. It was important to ascertain a need for the research, which undertaking a critical literature review will determine (Harvey and Land 2017:170).

A narrative review or systematic review may be used to review the existing literature. A narrative review provides an overview of what is known about the area of interest and is often a prelude to research being undertaken in that area (Bryman 2016:91). A systematic review uses a strict approach, comprising of several steps and it this approach which makes it replicable, scientific and transparent (Tranfield et al. 2003:209). Both methods of reviewing the literature require a comprehensive search of the available literature, a critical appraisal and synthesis of the included studies and conclusions.

A systematic review was chosen as the method for reviewing the data, as this facilitates a comprehensive account of the available literature whilst reducing the risk of researcher bias (Bryman 2016:98) .

2.1.2 Objectives

The objectives of this review are to systematically and critically review the existing literature around women's experiences of pregnancy and pregnancy care when living with Inflammatory Bowel Disease. The systematic review in this study did not aim to include purely qualitative research for a meta-analysis or purely quantitative research for a meta-ethnography but provides a narrative synthesis of the results and findings from the included literature.

Table 1 shows the objectives of the Systematic Review using SPIDER (Sample, Phenomenon of Interest, Design, Evaluation and Research Type) (Cooke, Smith, and Booth 2012) which was used as both quantitative and qualitative research is to be included in the review.

Table 1: Study objectives

S	Sample	Women who have experienced pregnancy and have a diagnosis of IBD
P I	Phenomenon of Interest	The experiences of pregnancy care for women living with IBD
D	Design	Mixed methods systematic review
E	Evaluation	Emergent themes from the literature
R	Research	Qualitative, quantitative, mixed methods

2.2 Methods

2.2.1 Protocol and registration

A study protocol was written **(Appendix 2)**, and ethical approval for desk-based research was sought from Coventry University **(Appendix 3)** prior to commencing the systematic review (P90195). The systematic review protocol was registered with PROSPERO (CRD42019134856), the International Prospective Register of Systematic Reviews in Health and Social Care which keeps a comprehensive list of all systematic reviews being undertaken, reducing duplication.

2.2.2 Eligibility criteria

The eligibility criteria for articles inclusion and exclusion in the systematic review is shown in **Table 2**.

Table 2: Inclusion/Exclusion Criteria

Inclusion Criteria	**Exclusion Criteria**
Articles written within the date 2010 - 2020	Articles not written in English
Study undertaken in a country with a healthcare system similar to the United Kingdom, where pregnant women have access to a midwife, obstetrician and gastroenterologist	Study undertaken in a country with healthcare system dissimilar to the United Kingdom, including USA and Turkey
Empirical research	Clinical review, where existing evidence is used to create an overview of management of the condition
Study participants to have experienced pregnancy	Study participants women of childbearing age but none experienced pregnancy
Focus of study about: • perceptions, experiences and perspectives of women who have experienced pregnancy and have Inflammatory Bowel Disease	Focus of study about: • medication safety or efficacy • management of IBD and pregnancy from healthcare professional perspective

The results from the search terms were screened for articles published from 2010 onwards and articles written in English as this was the initial inclusion and exclusion criteria. The year 2010 was selected as this meant that articles would be no older than ten years, and due to the developments in IBD management and biologic treatment over the last 10 years, older articles may not reflect current practice or evidence. Therefore, this timeframe ensured that only studies which use current management and treatments of IBD are included.

The exclusion of articles not written in English was due to the time and resources needed to translate them which were not available. Articles written not in English are also more likely to have been studies undertaken in countries with a non-comparable healthcare system to the UK. It is acknowledged that this will lead to publication bias, as it is solely the management of IBD and pregnancy in the high-income countries that was being explored.

2.2.3 Information sources

A preliminary literature search was undertaken prior to commencing the literature review, and this involved identifying key words relating to the research topic from the preliminary search results as suggested by Bryman (2016:110). The following electronic databases; Academic Search Complete, AMED, CINAHL COMPLETE, PsycARTICLES, MEDLINE, PsycINFO were used for data searches. Papers cited in the results of the preliminary literature review were also accessed and read and this highlighted that some studies had been split into several papers. All papers were accessible through university subscriptions.

2.2.4 Search

Relevant key words were identified, as presented in **Table 3** and were individually entered into the following electronic databases; Academic Search Complete, AMED, CINAHL COMPLETE, PsycARTICLES, MEDLINE, PsycINFO. This ensured the key words were appropriate and that relevant articles were retrieved from database searches.

Table 3: Key words

Ulcerative Colitis	**Crohn's Disease**	**Inflammatory Bowel Disease**
IBD	**Antenatal Care**	**Pregnancy**
Experience	**Perception**	**Perspective**

Combinations of the words, using BOOLEAN terms, were then entered into the selected electronic databases, searching both the title and the abstracts independently to ensure that similar articles were retrieved. These combinations became the search terms. **Table 4** summarises the search terms, the electronic databases searched and the number of results (excluding duplicates) generated.

Table 4: Search terms

Search Terms	Searched in	Databases Searched	Number of Results (excluding duplicates)
Inflammatory Bowel Disease AND pregnancy	Title	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	228
Inflammatory Bowel Disease AND pregnancy	Abstract	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	819
Inflammatory Bowel Disease AND antenatal care	Title	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	0
Inflammatory Bowel Disease AND antenatal care	Abstract	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE**	1

		PsycINFO	
Ulcerative Colitis AND pregnancy	Title	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	132
Ulcerative Colitis AND pregnancy	Abstract	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	176
Crohns disease AND pregnancy	Title	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	147
Crohns disease AND pregnancy	Abstract	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	232
Inflammatory Bowel Disease AND pregnancy AND experience OR	Title	**Academic Search Complete** AMED	0

perspective OR perception		**CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	
Inflammatory Bowel Disease AND pregnancy AND experience OR perspective OR perception	Abstract	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	68
Ulcerative Colitis AND pregnancy AND experience OR perspective OR perception	Title	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	0
Ulcerative Colitis AND pregnancy AND experience OR perspective OR perception	Abstract	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	34
Crohns disease AND pregnancy AND experience OR perspective OR perception	Title	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	0

Crohns disease AND pregnancy AND experience OR perspective OR perception	Abstract	**Academic Search Complete** AMED **CINAHL COMPLETE** PsycARTICLES **MEDLINE** PsycINFO	42

2.2.5 Study selection

Titles and abstracts of studies were retrieved using the search strategy and were screened to identify studies that potentially met the inclusion criteria outlined above. The inclusion criteria as outlined in **Table 2** were used to screen the abstracts to ensure that only articles relevant to the study would be included in the literature review. An independent second reviewer (from outside the supervision team) also reviewed the full text of the 42 potentially eligible studies were retrieved and independently assessed for eligibility as this reduces the risk of researcher bias (Bryman 2016:99). The studies for inclusion in the review were agreed.

Following screening of the full articles using the inclusion/exclusion criteria by two independent reviewers, five articles fulfilled the inclusion criteria and had a focus on the experiences of pregnancy of women living with IBD as shown in **Table 5.**

The PRISMA checklist was used as this provides a systematic tool for screening articles, using the devised inclusion/exclusion criteria and then results in a Prisma Diagram (**Figure 3**) which demonstrates the processes applied from initial searches to the selection of the included articles.

The main reasons for exclusion were that the article did not focus on women's experiences of pregnancy and instead focused on medication use, management of the disease activity or surgical management options, or that the article was an opinion piece or clinical review, which if included could increase the risk of bias (Harvey and Land 2017:188)

Search terms	Searched in	Number of None Duplicate Articles	Number of Articles Excluded After Inclusion/Exclusion Criteria Applied to Title/Abstract	Number of Articles Retrieved for full text screen	Number of Articles Excluded after Full Text Screen	Number of Articles Included
Inflammatory Bowel Disease AND pregnancy	Title	228	202	26	25	1
Inflammatory Bowel Disease AND pregnancy	Abstract	825	819	6	6	0
Inflammatory Bowel Disease AND pregnancy AND experience OR perspective OR perception	Title	0	0	0	0	0
Inflammatory Bowel Disease AND Pregnancy AND experience OR perception OR perspective	Abstract	68	62	6	4	2
Ulcerative Colitis AND pregnancy AND experience OR perception OR perspective	Title	0	0	0	0	0
Ulcerative Colitis AND Pregnancy AND experience OR perception OR perspective	Abstract	34	32	2	1	1
Crohns disease AND pregnancy AND experience OR perception OR perspective	Title	0	0	0	0	0
Crohns disease AND Pregnancy AND experience OR perception OR perspective	Abstract	42	40	2	1	1
		1197	1155	42	37	5

Table 5 article inclusion

Figure 3: Prisma Diagram showing article selection

(Liberati et al. 2009)

2.2.6 Data collection process

Data were collected independently by two reviewers, through reading the articles, and using a data collection sheet to note themes, areas of bias, any quality issues and make comments. As the topic of interest was the phenomenon of experiences of pregnancy, themes were not predetermined as they could not be assumed and nor would this have been appropriate. Therefore, themes were allowed to emerge with a narrative synthesis undertaken of these emergent themes as they originated from both qualitative and quantitative data (Bryman 2016:102).

The data were both qualitative and quantitative. Quantitative data were presented as nominal data, with statistical analyses being used for all quantitative data. This was then presented in graphs and tables. The results were discussed in the discussion of the articles, and this is where the themes emerged, as the results section did not always explicitly outline the context of the results. Qualitative data were presented as quotes and author commentary with the findings being discussed in the discussion section. The emergent themes were identified from both the findings section and the discussion section, as due to the qualitative nature, the findings had context within this section.

For all papers, all data were extracted onto the data collection sheet, and emerging themes were highlighted. The second reviewer used the same process independently as this was decided prior to undertaking the data extraction, and the emergent themes from both reviewers were compared across all of the papers with the themes occurring in at least two papers being included. There was some discrepancy in the titles of the individually identified

themes pertaining to knowledge of the participants and IBD and pregnancy and information given by HCP, and through a discussion between the two reviewers the key concept of the theme was discussed, and an encompassing title was decided. A member of the Supervisory Team was available to solve any discrepancies; however, they were not required.

2.2.7 Data items

All data from papers that fulfilled the inclusion criteria was included.

2.2.8 Risk of bias in individual studies

Critical appraisal involves not only identifying flaws in the study but also identifying any strengths (Harvey and Land 2017:304). Critical appraisal is essential as not all published studies are sound, and critical appraisal enables the methodology, reliability and validity of the study to be examined (Bryman 2016:95). Critical appraisal tools are used to identify flaws within individual studies whereas the risk of bias across the studies is discussed in **Section 2.2.11.** Bias exists in all research and is impossible to completely eliminate. It can occur at any stage of the research process, including the study design, recruitment, data collection or measurement, analysis and publication. Bias impacts the validity and reliability of findings and therefore reducing the risk of bias is essential (Smith and Noble 2014:101). Risk of bias assessment tools or scales are commonly designed for randomised control studies or studies which have cohort comparability within the design. In studies with designs outside of these constricts, critical appraisal tools appropriate to the design of the study were used to critically appraise the quality of the study and the risk of bias. The assessment tools are shown in **Table 6.**

The selected studies were then critically appraised using the appropriate critical appraisal tool by two independent reviewers to reduce the risk of researcher bias.

There are numerous critical appraisal tools which facilitate the systematic appraisal of literature, depending upon the type of literature being appraised. The Joanna Briggs Institute (JBI) and Critical Appraisal Skills Programme (CASP) are the two main institutes which provide critical appraisal checklists, however these do not encompass all types of literature and it is sometimes necessary to seek out other appraisal tools. READER (Relevance, Education, Applicability, Discrimination, Evaluation and Reaction) (MacAuley 1994) was developed to provide support to General Practitioners when critically analysing literature but is now a recognised critical appraisal tool which is well suited to the critical appraisal of clinical reviews. SPIDER (Sample, Phenomenon of Interest, Design, Evaluation and Research Type) (Cooke, Smith, and Booth 2012) is another example of a critical appraisal tool which has evolved, as it was initially designed as an alternative search strategy to PICO (Population, Intervention, Counter Intervention and Outcome) which was a search strategy for systematic reviews and Randomised Control Trials. SPIDER was developed as a search strategy for qualitative or mixed method research and is now an accepted critical appraisal tool well suited to mixed method studies.

As each critical appraisal tool is designed or suited to a study design or methodology, it is important that the correct tool is selected for use. Depending upon the methodology and methods used in a study, there will be different threats to the validity and reliability. Observational studies are pre-disposed to observer bias, in which there is a difference between the actual situation and how it is recorded by the observer due to perceptual differences. Respondents to interviews may be influenced by the interviewer who may consciously or unconsciously influence their answers either through leading questions or

applying social desirability (Bowling 2014:180). Publication bias, recall bias and reporting bias are also important considerations and the use a critical appraisal tool appropriate to the study design will ensure these are considered.

The included studies were appraised according to their design and **Table 7** highlights the critical appraisal tool or checklist used. Critical appraisal tools were independently selected by the two reviewers and were independently critically appraised. All selected tools were the same with the exception of one article which the reviewers selected different, yet appropriate tools.

2.2.9 Summary measures

The data were both quantitative and qualitative with a variety of methods used for data collection as outlined in **Table 6.**

Table 6: Summary measures

Authors	Title	Summary measure
Mountifield, R.E., Prosser, R., Bampton, P., Muller, K., and Andrews, J.M.	Pregnancy and IBD Treatment: This Challenging Interplay from a Patients' Perspective	Quantitative and qualitative data obtained through a postal survey containing closed and opened ended questions
Cooper, J., Collier, J., James, V., and Hawkey, C.	Living with Inflammatory Bowel Disease: Diagnosis during Pregnancy	Qualitative data obtained through a one to one interview case study
Ellul, P., Zammita, S.C., Katsanos, K.H., Cesarini, M., Allocca, M., Danese, S., Karatzas, P., Moreno, S.C., Kopylov, U., Fiorino, G., Torres, J., Lopez-Sanroman, A., Caruana, M., Zammit, L., and Mantzaris, G.	'Perception of Reproductive Health in Women with Inflammatory Bowel Disease'	Quantitative data obtained through closed questions in a postal survey

Ghorayeb, J., Branney, P., Selinger, C.P., and Madill, A	When Your Pregnancy Echoes Your Illness: Transition to Motherhood With Inflammatory Bowel Disease	Qualitative data obtained through one to one interviews
Hoekstra, J., Van Roon, A.H.C., Bekkering, F.C., Van Tilburg, A.J.P., and West, R.L.	Decision Making and Outcome of Pregnancies in Female Patients with Inflammatory Bowel Disease: Findings from a Community-Based Practice	Observational study with quantitative data collected through a postal survey comprising of closed questions, with medical records being used to verify information or obtain further information.

2.2.10 Synthesis of results

The results were obtained through individually reviewing and critiquing each article, using thematic analysis to determine the themes, which involved identifying themes within the data (Bryman 2016:585) . The themes were then compared across all the papers, with recurring themes being included. The variations in methods used and data type did not complicate this, as the themes emerged either through the descriptive statistics presented or the narrative and quotes from the qualitative studies.

2.2.11 Risk of bias across studies

There are several specific risk of bias assessment tools, including ROBINS-1 for intervention studies, RoB2 for randomised controlled trials, Robis for systematic reviews and Newcastle Ottawa for prospective cohort studies or observational studies, most of which were not appropriate for the methodological approaches in the selected studies. The risk of bias across all studies could not be considered using specific risk of bias assessment tools due to the lack of tools available for the differing methodological approaches within the studies (see **Section 2.2.8)** for individual study critical appraisal). Therefore, where available a specific

risk of bias assessment tool was used, and where a specific tool was unavailable, careful consideration of the risk of bias using the methodological appropriate critical appraisal tool was given as outlined in **Table 8** . This included recall bias, the impact of retrospective studies, journals used for publication of the studies, the authors' affiliations and any funding sources.

2.2.12 Additional analyses

There were no additional analyses.

2.3 Results

2.3.1 Study selection

Of the initial 1197 results, all 1197 abstracts were read and screened using the inclusion/exclusion criteria as shown in **Figure 3,** with five articles being included in the systematic review shown in **Table 7**

Table 7: Selected for Inclusion

Authors	Title	Year	Journal	Approach	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' Perspective	2010	*Journal of Crohn's and Colitis*	Mixed Methods retrospective study	Australia	Study explored patient perceptions of the interaction between IBD medication and pregnancy and 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	United Kingdom	Case study about the experience a woman diagnosed with IBD whilst pregnant
Ellul, P., Zammita, S.C., Katsanos, K.H., Cesarini, M., Allocca, M., Danese, S., Karatzas, P., Moreno, S.C., Kopylov, U., Fiorino, G., Torres, J., Lopez-Sanroman, A., Caruana, M., Zammit, L., and Mantzaris, G.	'Perception of Reproductive Health in Women with Inflammatory Bowel Disease'	2016	*Journal of Crohn's and Colitis*	Cross sectional study – survey	Malta Greece Israel Italy Portugal Spain	Survey sent to women aged between 16-50 who were receiving care at any of none IBD centres. Survey questions were based on ECCO guidelines of pregnancy
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*	Qualitative study – semi structed interviews	United Kingdom	Study explored experiences of the transition to motherhood of women living with IBD who have a child aged between 2-7 years
Hoekstra, J., Van Roon, A.H.C., Bekkering, F.C., Van Tilburg, A.J.P., and West, R.L.	Decision Making and Outcome of Pregnancies in Female Patients with Inflammatory Bowel Disease: Findings from a Community-Based Practice	2018	*European Journal of Gastroenterology and Hepatology*	Observational study - survey	Netherlands	Survey sent to all women with IBD who attended one of two gastroenterology outpatient clinics in the Netherlands. Survey asked about pregnancies or reasons for not becoming pregnant and outcomes of pregnancy.

2.3.2 Study characteristics

The study population was similar across all the five studies, with all participants having experienced pregnancy, all having a diagnosis of IBD prior to or during pregnancy and all having received pregnancy care in a health care setting where they had access to a midwife, an obstetrician and a gastroenterologist .

The recruitment strategies varied with Mountifield et al. (2010) undertaking a cross sectional mixed methods study, which involved sending a postal survey to individuals, both female and male, aged between 18 to 50 years who were contactable through an IBD database. The questionnaire had four sections, with one section being focussed on pregnancy and containing 61 questions about pregnancy. A total of 219 women were surveyed, with 143 completing the questionnaire, giving a response rate of 68% and data about 298 pregnancies were obtained. The included article by Mountifield et al. (2010) was the results of the section of the survey about pregnancy, with the other section of results being written as a separate manuscript (Mountifield et al. 2009).

Hoekstra et al. (2018) employed a similar recruitment strategy, sending questionnaires to all women who attended a gastroenterology outpatients clinic at two specified hospitals. 272 women who had experienced pregnancy completed the survey, providing data about 501 completed pregnancies. Hoekstra et al. (2018:705) considered a pregnancy to be complete if it reached 20 weeks gestation, and did not collect data about any occurrences or IBD activity prior to 20 weeks gestation whereas Mountifield et al. (2010) did explore pregnancy loss and IBD activity during the entirety of the pregnancy. Ellul et al. (2016) also sent questionnaires to women under the care of IBD centres who were aged between 16 and 60 years. The questionnaires contained eight sections about pregnancy and fertility. Responses were submitted by 348 women. However, as it was sent to all women of

childbearing age who were under the care of IBD centres, not all women had experienced pregnancy, with 49% of women having experienced pregnancy. The data collected included all women who had experienced pregnancy regardless of the length of pregnancy.

Ghorayeb et al. (2018) meanwhile advertised their study through Crohns and Colitis UK and various relevant websites and social media platforms aiming to recruit women with IBD in the UK, aged at least 18 years old and who had at least one child aged between two and seven years old. Out of the 98 enquiries, 22 women were selected to participate using convenience sampling and then purposive sampling to ensure diversity of geographical location and experiences. As analysis was undertaken, recruitment for women with specific characteristics was undertaken, including single mothers. Participants were interviewed using a semi-structured interview schedule comprising of 23 questions, with 20 interviews being undertaken face to face and two interviews were undertaken over Skype and all were audio recorded. Cooper et al. (2011) also undertook a face-to-face semi-structured interview with a single participant, using the case study of a woman who became pregnant whilst participating in different, larger study exploring the personal beliefs and self-control relating to IBD (Cooper et al. 2010).

Mountifield et al. (2010)**,** Hoekstra et al. (2018) and Ellul et al. (2016) discuss their results as being generalisable to women living with IBD and Mountifield et al. (2010) and Ellul et al. (2016) make recommendations accordingly, which will be discussed in **Section 2.4.2**. Cooper et al. (2011) and Ghorayeb et al. (2018) however did not aim to provide generalisable results, but instead aimed to offer unique personal insights into the lived experiences of living with IBD during pregnancy, which included diagnosis of IBD during pregnancy. Both made recommendations and these are also discussed in **Section 2.4.2.**

2.3.3 Risk of bias within studies

All papers were critiqued using the appropriate risk of bias assessments and critical appraisal tool and were found to be methodologically sound, hence inclusion. Where there was no appropriate risk of bias assessment due to the study design, particular attention was given to the risk of bias when critically appraising the article. The risk of bias assessments and critical appraisal tools are illustrated in **Table 8**

Table 8:Risk of bias assessment and critical appraisal tools

Authors	Title	Year	Journal	Type of Study	Bias Risk Assessment Tool Used Critical Appraisal Tool Used	Specific threats to reliability and validity (Bowling 2014:179)
Mountifield, R.E., Prosser, R., Bampton, P., Muller, K., and Andrews, J.M.	Pregnancy and IBD Treatment: This Challenging Interplay from a Patients' Perspective	2010	*Journal of Crohn's and Colitis*	Mixed Methods	SPIDER Tool (Cooke, Smith, and Booth 2012) Joanna Briggs Checklist for Observational Studies	Acquiescence response set ("yes" saying Random measurement error Recall bias Reporting bias
Cooper, J., Collier, J., James, V., and Hawkey, C.	Living with Inflammatory Bowel Disease: Diagnosis during Pregnancy	2011	*Gastrointestinal Nursing*	Case study	Joanna Briggs Checklist for Case Reports (Joanna Briggs Institute 2016)	Interviewer bias Recall bias
Ellul, P., Zammita, S.C., Katsanos, K.H., Cesarini, M., Allocca, M., Danese, S., Karatzas, P., Moreno, S.C., Kopylov, U., Fiorino, G., Torres, J., Lopez-Sanroman, A., Caruana, M.,	'Perception of Reproductive Health in Women with Inflammatory Bowel Disease'	2016	*Journal of Crohn's and Colitis*	Cross sectional study	Newcastle- Ottawa Quality Assessment Scale Cohort Studies (Wells et al. 2014) Joanna Briggs Checklist of Analytical Cross-Sectional Studies (The Joanna Briggs Institute 2017)	Acquiescence response set ("yes" saying Random measurement error Recall bias Reporting bias

Zammit, L., and Mantzaris, G.						
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*	Qualitative study	Critical Appraisal Skills Programme Checklist for Qualitative research (Critical Appraisal Skills Program 2013)	Interviewer bias Recall bias Mood bias
Hoekstra, J., Van Roon, A.H.C., Bekkering, F.C., Van Tilburg, A.J.P., and West, R.L.	Decision Making and Outcome of Pregnancies in Female Patients with Inflammatory Bowel Disease: Findings from a Community-Based Practice	2018	*European Journal of Gastroenterology and Hepatology*	Observational study	Newcastle- Ottawa Quality Assessment Scale Cohort Studies (Wells et al. 2014) Critical Appraisal Checklist for Cohort Studies (CASP checklist 2018)	Acquiescence response set ("yes" saying Random measurement error Recall bias Reporting bias

The qualitative methodologies of the studies by Mountifield et al. (2010), Ghorayeb et al. (2018) and Cooper et al. (2011) makes them more susceptible to bias due to the potential researcher influence during the recruitment and data collection process (Galdas 2017:1), with Ghorayeb et al. (2018) acknowledging that their sample may have been under-represented by less economically privileged women and women with severe IBD due to recruitment strategy they employed. They also recognised that their sample was dominated by non-single women and this was despite a specific call for single women to participate.

Recall bias was acknowledged as a limitation due to the retrospective nature of their studies (Mountifield et al. 2010), (Ellul et al. 2016) and (Hoekstra et al. 2018), and the retrospective study design may have also meant participants were not answering some questions (Mountifield et al. 2010). Ellul et al. (2016) suggested there may have been an element of anxiety and under-reporting about admitting to medication compliance issues as the survey was not anonymous and participants could be identified as their health records were used to record additional data if needed.

Recall bias may have influenced the responses given by women when asked about their experience of pregnancy, as those who had a difficult experience either due to pregnancy complications or as a result of their IBD may have affected their recall of events. Individuals who have experienced an adverse outcome or difficult experience will usually recall the events surrounding this in greater detail than those who did not have an adverse outcome or difficult experience (Sedgwick 2012:1).

The statistical analysis and presentation of the figures by Ellul et al. (2016) made it difficult to interpret the findings and made their results less representative of a wider and more applicable population, with figures being given about the experiences of pregnancy being based on the entire sample of women. The presentation of the statistics made it extremely

difficult to interpret the findings of the study, as the figures presented are not representative of the sample of women who had experienced pregnancy.

Recruitment varied within the studies, with Ghorayeb et al. (2018) asking eligible women to contact them, Mountifield et al. (2010) and Hoekstra et al. (2018) used an IBD registry or database to send questionnaires to eligible women, Cooper et al. (2011) recruited a woman from their original study which identified eligible women from IBD clinics and Ellul et al. (2016) gave eligible women a questionnaire to complete whilst they were attending an outpatient gastroenterology/IBD clinic. All studies had the relevant ethical approval, however all studies except Ellul et al. (2016) gave women time to consider the study, as they either sent material relating to the study or asked to self identify. Ellul et al. (2016) gave eligible women a questionnaire at the time they attended the IBD/gastroenterology outpatient clinic which "patients had to complete" (Ellul et al. 2016:887).

The dates used for the inclusion criteria were limited to the last ten years to ensure that the findings are reflective of current standard care practice. It was noticed that the literature in latter part of the 10 year search period was dominated by the safety and efficacy of biologic treatments which until recently were not used in pregnancy.

The sample was homogenous in the studies by Cooper et al. (2011), Mountifield et al. (2010) Ghorayeb et al. (2018) and Hoekstra et al. (2018) with the views of women who had experienced pregnancy being sought. Ellul et al. (2016) however sought the views about pregnancy, fertility, consideration of pregnancy, pregnancy and outcomes, delivery, breastfeeding, surgery, contraception and cervical pathology. Women who had not experienced pregnancy were asked about their views about pregnancy, and therefore the results from this study are not solely relating to women who had experienced pregnancy.

Ellul et al. (2016) highlighted that just under half of the respondents (49.1%) had experienced pregnancy and just over half (50.9%) had not. The mean age of the participants was 37.4 years (standard deviation ± 2.1) however the age distribution of the participants was not given, despite participants being asked their age with a free text response option. It may be that the number of women towards the lower end of the age range in the inclusion criteria (16-50 years) and had not considered pregnancy yet makes it difficult to infer the age profile of respondents who had experienced pregnancy within the study. Further detail on age may have provided insight into voluntary or delayed childlessness in this group and any potential relationships with understanding of IBD medication and pregnancy outcomes.

2.3.4 Results of individual studies

The key findings of the individual studies, along with any recommendations are detailed in **Table 9**.

Table 9: Results from individual studies

Authors	Study	Key findings	Recommendations
Mountifield, R.E., Prosser, R., Bampton, P., Muller, K., and Andrews, J.M.	Pregnancy and IBD Treatment: This Challenging Interplay from a Patients' Perspective	Women stopped taking medication to conception as concerned about adverse outcomes 84% women thought IBD medication would harm their baby 28% women changed their medication without their Drs knowledge 19% women concerned about effects of active IBD on pregnancy	recommendations about information giving, in particular the role of the gastroenterologist in providing early evidence-based information, with an emphasis on the importance of disease control prior to and during pregnancy.
Cooper, J., Collier, J., James, V., and Hawkey, C.	Living with Inflammatory Bowel Disease: Diagnosis during Pregnancy	Little known about the impact of diagnosis of IBD during pregnancy Delay in diagnosis affected relationship with healthcare provider	recommend further research is undertaken into the experiences of women who are diagnosed with IBD during pregnancy to help shape the most effective models of care

Ellul, P., Zammita, S.C., Katsanos, K.H., Cesarini, M., Allocca, M., Danese, S., Karatzas, P., Moreno, S.C., Kopylov, U., Fiorino, G., Torres, J., Lopez-Sanroman, A., Caruana, M., Zammit, L., and Mantzaris, G.	'Perception of Reproductive Health in Women with Inflammatory Bowel Disease'	Clinical remission at time of conception associated with clinical remission during pregnancy Women concerned about transmission of IBD to babies during pregnancy and breastfeeding Women concerned about risk of harm or abnormalities in baby with medication during pregnancy and breastfeeding	recommend a change to the way in which current knowledge about IBD and reproductive health is imparted to patients as at present the knowledge is not being adequately transmitted. Better patient education is recommended involving a multidisciplinary team of gastroenterologists, obstetricians, gynaecologists, midwives, IBD specialists nurses and IBD associates to try and improve women's
Ghorayeb, J., Branney, P., Selinger, C.P., and Madill, A	When Your Pregnancy Echoes Your Illness: Transition to Motherhood With Inflammatory Bowel Disease	Little knowledge about IBD and pregnancy in GP's, midwives and nurses Symptom confusion between pregnancy and IBD substantiated in study Disease activity linked to decisions about subsequent babies	recommends a more holistic, multidisciplinary approach to the care of pregnant women living with IBD, which integrates any IBD treatment with maternity care,
Hoekstra, J., Van Roon, A.H.C., Bekkering, F.C., Van	Decision Making and Outcome of Pregnancies in Female Patients with Inflammatory	17% of women reported stopping or altering their IBD medication during pregnancy	No recommendations made

Tilburg, A.J.P., and West, R.L.	Bowel Disease: Findings from a Community-Based Practice	57% of women reported information given to them about IBD and pregnancy as being good or very good 19% women diagnosed with IBD prior to pregnancy had personal doubts about becoming pregnant	

Mountifield et al.(2010) received responses from 143 women after sending surveys to contactable women on an IBD database aged between 28-50 years. The data related to the denominator number of surveys sent is not publicly available. Hoekstra et al. (2018) similarly sent questionnaires to all female patients with IBD who attended gastroenterology out-patients clinics within two identified centres. A total of 760 patients were considered eligible for the study, with 385 women returning the survey, giving a response rate of 51%, which is considered to an adequate response rate for a postal survey (Mangione 1995:61) . Ellul et al. (2016) recruited 348 women from IBD outpatient centres, but again did not specify how many women were eligible for the study.

Ghorayeb et al. (2018) and Cooper et al. 2011) employed different recruitment strategies, with Ghorayeb et al.(2018) advertising their study through Crohns and Colitis UK, with 98 women inquiring about the study. Of the 98 women, 22 were selected to be interviewed, initially using convenience and then purposive sampling, based on their geographical location, diagnosis and experience of surgery. Purposive sampling was used as analysis took place to recruit participants for their particular characteristics such as single mothers. Cooper et al. (2011) focuses of a woman who became pregnant whilst enrolled in the larger study exploring beliefs about personal control and self-management in IBD. The larger study from where the case study emerged from had a total of 24 participants who were recruited directly from an IBD outpatient clinic.

The themes which emerged in each paper are highlighted in **Table 10** and will be discussed in **Section 2.3.5.1.**

Table 10: themes from individual studies

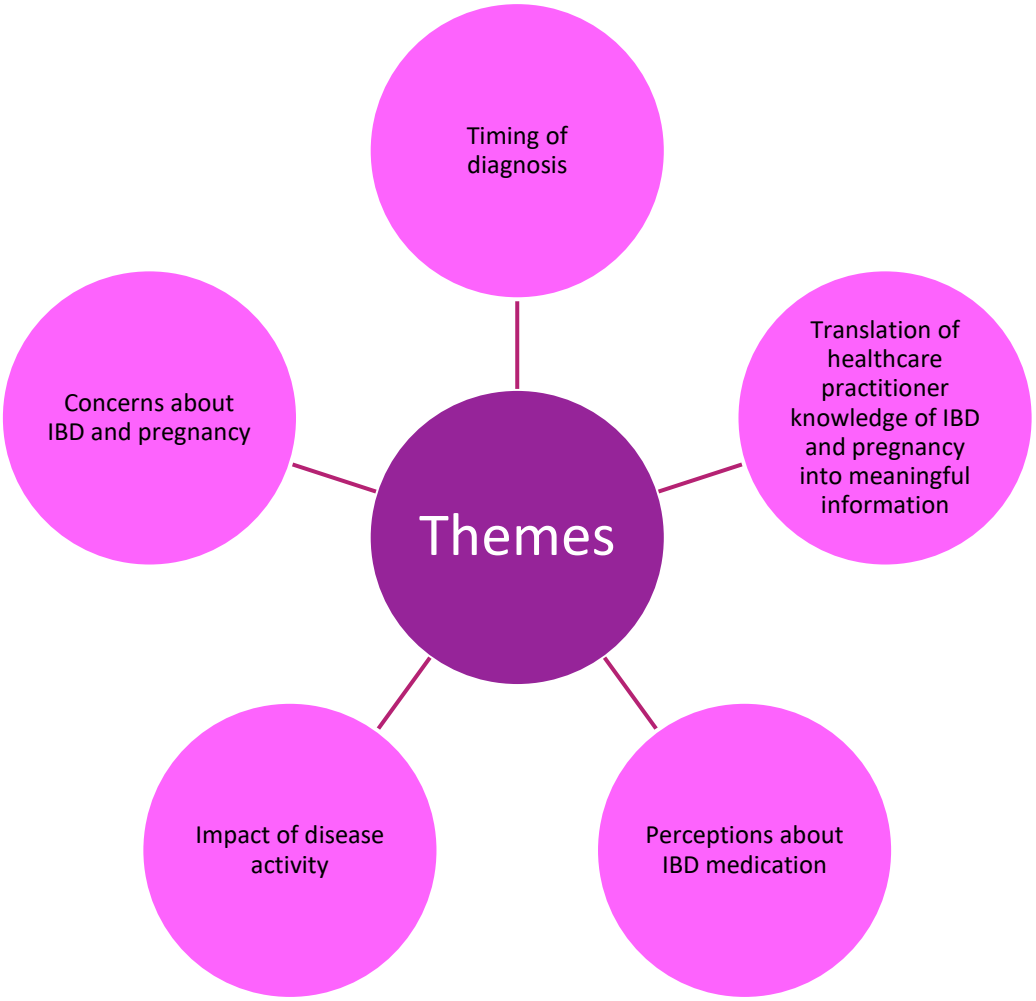
Authors	Concerns about IBD and pregnancy	Perceptions about IBD medication	Knowledge held by women about IBD and pregnancy	Information given to women abut IBD and pregnancy by HCP	Timing of diagnosis	Impact of disease activity
Mountifield, R.E., Prosser, R., Bampton, P., Muller, K., and Andrews, J.M.	✓	✓	✓			✓
Cooper, J., Collier, J., James, V., and Hawkey, C.				✓	✓	✓
Ellul, P., Zammita, S.C., Katsanos, K.H., Cesarini, M., Allocca, M., Danese, S., Karatzas, P., Moreno, S.C., Kopylov, U., Fiorino, G., Torres, J., Lopez-Sanroman, A., Caruana, M., Zammit, L., and Mantzaris, G.	✓	✓	✓	✓		
Ghorayeb, J., Branney, P., Selinger, C.P., and Madill, A	✓		✓	✓	✓	✓
Hoekstra, J., Van Roon, A.H.C., Bekkering, F.C., Van Tilburg, A.J.P., and West, R.L.	✓	✓	✓	✓		

2.3.5 Synthesis of results

2.3.5.1 Synthesised Themes from the Literature

Whilst the two reviewers were independently screening and then critically appraising the literature, five agreed themes emerged: timing of diagnosis, translation of healthcare practitioner knowledge of IBD and pregnancy into meaningful information (merging of women's knowledge and information given by HCP), perceptions about IBD medication, impact of disease activity and concerns about IBD and pregnancy. These are highlighted in **Figure 4.**

Figure 4: Emerged Themes from the Literature



2.3.5.2 Translation of healthcare practitioner knowledge of IBD and pregnancy into meaningful information

Knowledge about IBD and pregnancy by healthcare practitioners varied greatly, with some studies demonstrating the value of healthcare practitioners imparting evidence-based information to women about IBD and pregnancy and others highlighting the apparent knowledge gap for certain healthcare practitioners. How healthcare practitioners' knowledge translated into meaningful information given to women living with IBD also varied.

Lack of knowledge about IBD and pregnancy by health care professionals and how this impacts on care was identified (Cooper et al. 2011) (Ellul et al. 2016) and the apparent lack of knowledge that non IBD specialist staff had about IBD and pregnancy, in particular midwives and General Practitioners (GP) (Cooper et al. 2011:32). This lack of knowledge from non specialist could be attributed to a lack of training, limited experience in caring for women living with IBD during pregnancy, a lack of national guidance about care delivery or as Snow, Humphrey, and Sandall (2013:7) identify healthcare practitioners cannot be experts in all conditions. Therefore, those not specialising in IBD are unlikely to be experts in this field. This would support the findings of the studies by Cooper et al. (2011) and Ellul et al. (2016) as it was non IBD specialist healthcare professionals highlighted as the most deficient in knowledge about pregnancy and IBD.

The lack of knowledge about IBD and IBD and pregnancy led to a delay in recognition of the disease and subsequent management, increasing the associated risks with disease activity. Ghorayeb et al. (2018:6) also discuss the lack of knowledge midwives and GP's had about IBD and pregnancy, which was highlighted by the women in their study. Multidisciplinary classes held by gastroenterologists, obstetricians, midwives and IBD specialist nurses may increase the knowledge women themselves have about IBD and pregnancy, however this relies on the healthcare practitioners having evidence based knowledge (Ellul et al. (2016:890). They suggest that their study demonstrates that the European Crohn's and Colitis Organisation guidance about pregnancy and IBD is not being used effectively when counselling or caring for women with IBD. The authors suggested that lack of knowledge based on incomplete information given may lead to misconceptions developing and incorrect decisions being made. Ellul et al. (2016:890) also reported that it is the gastroenterologist who should be the lead healthcare professional in providing evidence based information to ensure that management decisions around pregnancy are fully informed though the timing of

provision of this patient education is not highlighted. Currently, in the UK, one third of all pregnancies are either unplanned or ambivalent (so neither planned or unplanned) (Health Education England 2018) and therefore may not have actively sought preconceptual counselling, which then leads to the consideration of when and how should preconceptual information be given. Whilst it is acknowledged that women with active IBD receiving treatment or women taking maintenance medication would benefit most from planning their pregnancy, currently there is no data about the number of women within this cohort regarding the planning of pregnancy.

The information given to women living with IBD about IBD and pregnancy by their gastroenterologist was explored (Hoekstra et al. 2018) , whilst Mountifield et al. (2010) predominantly explored how information given to women living with IBD by their physician about IBD medication and pregnancy was utilised. Pregnancy counselling, ideally before conception, is a key component of care for young women with IBD (Hoekstra et al. 2018). However, it is not specified as to who should give this information. The study explored women's satisfaction with the information they were given by their gastroenterologist about pregnancy and IBD, and also explored the timing of these discussions. They found that the younger the woman was when diagnosed with IBD, the more likely she was to receive information from her gastroenterologist. However, for women aged 35 years and over at the time of diagnosis were considerably less likely to receive such information. The gastroenterologist appeared to be the key healthcare professional in giving women information about IBD and pregnancy, and women in their study also commented that should they require any information about IBD and pregnancy then they would ask their gastroenterologist. Although this study was undertaken in the Netherlands and the model of maternity care is different to that of the UK, pregnant women do have midwifery care and for 26% of women, a midwife was their primary care giver, however midwifery knowledge of IBD

and pregnancy was not explored or even commented on. The influence of family, friends and publicly available information was considered to be more influential on medication compliance by women living with IBD when compared to when compared to information provided by a clinical healthcare provider. Women also were less concerned about the effects of disease activity than the perceived effects of IBD medication on their pregnancy and unborn baby, as discussed in **Section 2.3.5.4.** Women in the study also commented that the advice given to them to discuss any medication was vague and women did not always follow this advice but instead stopped their medication without medical supervision.

The importance of the role of the gastroenterologist in providing early, evidence-based information to support the management of IBD and pregnancy, and to also emphasise the importance of good disease control at conception and during pregnancy was highlighted (Mountifield et al. 2010:181). Again it is the gastroenterologist who has been identified as the key health care professional in providing such information, yet this study, and other studies demonstrate that women are either not receiving this information or it is not being given in a way which is meaningful and therefore considered important or reputable.

2.3.5.3 Timing of Diagnosis

Timing of the diagnosis of IBD featured in all five articles. Mountifield et al. (2010:177) refers to the statistic that a quarter of women will conceive after the diagnosis of IBD and references Ferguson et al. (2008) yet the authors do not provide any source data. Data was collected about the timing of diagnosis, and the number of women who conceived prior to and following diagnosis of IBD (Hoekstra et al. 2018) (Ellul et al. 2016), with 42.1% of pregnancies occurred following the diagnosis of IBD (Ellul et al. 2016:889). The impact of diagnosis prior to or after pregnancy on birthweight or gestation of pregnancy was explored, and found that there were no differences. Hoekstra et al.(2018:706) found that 334

pregnancies occurred prior to a diagnosis of IBD, 157 occurred after diagnosis of IBD and in ten cases women were diagnosed with IBD whilst pregnant, which equates to about 2%. Pregnancy both prior to and following diagnosis of IBD was experienced by 22 women. Differences in outcomes for women diagnosed prior to, during or after pregnancy were not explored, instead comparisons were made between pregnancy outcomes for women who had Crohn's disease and Ulcerative Colitis. It was reported that 79% of pregnancies which occurred after diagnosis of IBD were considered to be 'uneventful', with 21% experiencing complications. Complications included preterm birth (n=21), maternal hypertension or pre-eclampsia (n=8), severe hyperemesis requiring hospitalisation (n =1), HELLP Syndrome (haemolysis, elevated liver enzymes, low platelets) (n=1), cholestasis of pregnancy (n=1), threatened preterm labour or vaginal bleeding (n=4), fetal growth restriction (n=2) and intrauterine fetal death (n=2).

A relatively unique insight into diagnosis of IBD during pregnancy was offered by both Ghorayeb et al. (2018) and Cooper et al. (2011). Cooper et al. (2011:32) discusses the battle for recognition and diagnosis, with diagnosis of IBD coming as a relief, whereas Ghorayeb et al. (2018:6) discusses the impact diagnosis of IBD during pregnancy had on two women, who blamed pregnancy for triggering the IBD. One woman considered terminating her pregnancy as she was struggling to cope with the illness.

2.3.5.4 Perceptions about Medication

Despite the inclusion criteria excluding articles which focussed on IBD medication primarily, women's perceptions about IBD medication was an emergent theme, with four out of the five selected manuscripts discussing this to varying depths.

The majority of women (84%) of women were concerned that IBD medication would harm their pregnancy and that 28% of women changed their IBD medication regimen whilst

pregnant without their doctor's knowledge (Mountifield et al. 2010:179) . Another study found 17% of women either stopped their IBD medication (12%) or altered the dose or type of medication (5%) during pregnancy, and that 38% of women requested these changes themselves (Hoekstra et al. 2018:706). Although women were not changing their medication without their healthcare practitioners' knowledge, they were requesting changes to their medication. Similarly Ellul et al. (2016:888) found that women in their study also stopped taking IBD medication of their own accord, although in their study it was reported that this was only 2.1% of the women, with the main reasons given as disease symptom control and concerns about the medication affecting their unborn baby developmentally. Conversely to the findings of Mountifield et al. (2010:179), Ellul et al. (2016:888) found that women were relatively similarly concerned about the effects of IBD medication (73%) and the effects of IBD (63%) causing harm to the baby.

Concerns about medications used to treat IBD, in particular corticosteroid medication, and the side effect of weight gain were identified (Ghorayeb et al. 2018:7). Perceptions about medication use during pregnancy did not emerge in the study by Cooper et al. (2011) as the participant was diagnosed with IBD in pregnancy, and the diagnosis and subsequent treatment of IBD came a relief.

2.3.5.5 Impact of Disease of Activity

The relationship between increased IBD activity and increased risk of preterm birth and low birth weight babies is well evidenced (Getahun et al. 2014)(Boyd et al. 2015)(Shand et al. 2016)(Bortoli et al. 2011), with evidence about the pattern of disease activity during the course of pregnancy being influenced by the disease activity status at the time of conception (Abhyankar, Ham, and Moss 2013). **Section 2.3.5.3** has discussed the timing of diagnosis

of IBD in relation to the literature, however this section will discuss what impact disease activity has on women during their pregnancy.

As previously discussed, a detailed insight into diagnosis of IBD during pregnancy was given in two studies (Cooper et al. 2011) (Ghorayeb et al. 2018). Cooper et al. (2011) found that due to symptoms the participant was experiencing, she feared she had bowel cancer due to the similarities in symptoms. The symptoms from the disease activity had a significant impact on the participant's pregnancy. Women diagnosed with IBD during pregnancy blamed their pregnancy for triggering the IBD, with one woman considering a termination of pregnancy as she was unable to cope with the illness (Ghorayeb et al. 2018). Women who are diagnosed with IBD in pregnancy will invariably have an element of disease activity to trigger symptom generation. The diagnosis of IBD in pregnancy does not only provide the insight into the transition women experience when diagnosed with a long term condition but also provides insight into disease activity and symptoms of IBD for women in pregnancy. Ghorayeb et al. (2018:9) highlighted that a limitation to their study was that women with severe disease activity may not be fully represented due to recruitment methods they used.

Management of severe disease activity was explored by Mountifield et al. (2018) and Hoekstra et al. (2018), which included additional medication use and hospitalisation. Mountifield et al. (2010:178) found that 14 pregnancies in their study were to women who reported severe disease activity during pregnancy, and eight required hospital admission. Hospital admission during pregnancy can have a negative impact not only on the woman's life, but also that of her family. Medication exposure during pregnancy was explored and found that 67/237 pregnancies were exposed to IBD medication, suggesting that these women had active disease and symptoms of IBD which needed treatment (Mountifield et al. 2010:179). Given the perceptions of the women in this study about IBD medication and

pregnancy as discussed in **Section 2.3.5.4.** It could be argued that not only did the disease activity impact on the women but also the medication exposure may have caused them some degree of anxiety if they had perceptions about the harm this may cause. Even for women who did not have the perception that IBD medication posed more of a risk to pregnancy and their baby, they may have had the correct perception that IBD activity has an increased risk of adverse outcomes for their pregnancy which may cause concern and anxiety. Some type of IBD medication was prior to pregnancy in 115 (73%) pregnancies, and IBD medication was used during pregnancy in 96 (61%) of pregnancies (Hoekstra et al. 2018:706). This suggests that a large number of women were experiencing some degree of symptoms indicative of disease activity both prior to and during pregnancy. Given the concerns that women living with IBD have about IBD medication and the perceived risk of harm to their pregnancy or unborn baby, as discussed in **Section 2.3.5.4** which may relate to anxiety inducing for women. Surgery was required by two women due to their IBD during pregnancy and another three had surgery after pregnancy (Hoekstra et al. 2018:706). The level of disease activity which necessitated surgery and the surgery may have affected the experiences of pregnancy. As this study was purely quantitative, the true impact of disease activity and the associated treatment for the women in this study remains unknown.

For other women, pregnancy was associated with a relapse in their condition and this detracted from the decision to conceive further, as they worried about coping with the symptoms of IBD whilst caring for another child. Ghorayeb et al. (2018:6) discuss one participant who had such painful symptoms that she worried she may not be the mother to her child that she felt she should be. It is acknowledged that this is an in-depth qualitative study of 22 women and therefore the findings are not generalisable, however this was not the primary aim of the study. However disease activity did not always worsen during pregnancy, with two woman in the qualitative study by Ghorayeb et al. (2018:6)

experiencing an improvement of their IBD symptoms, and therefore disease activity improved during pregnancy. One woman found that being pregnant offered respite from the symptoms of IBD, so had two children in quick succession to minimise symptoms.

Another study found that only one woman had active disease before conception and that 6.2% (21) women experienced IBD relapse during pregnancy (Ellul et al. 2016:889). Over half (57.4%) of pregnancies were unplanned, and therefore it could be argued that the level of disease activity at conception was fortuitous rather than due to good disease control in anticipation of conception. The level of disease activity for these women is not specified and therefore distinctions between levels of disease activity and the planning of pregnancy cannot be made.

2.3.5.5.1 Symptom Confusion

Both Cooper et al. (2011) and Ghorayeb et al. (2018) specifically discuss symptoms confusion. The rectal bleeding experienced by one pregnant woman was misdiagnosed as of haeamorrhoidal aetiology, a common complaint in the pregnant mother. After initial inconclusive investigations, the patient concluded that her symptoms could have been related to a malignant process (Cooper et al. 2011:32), with the eventual diagnosis of IBD coming as a great relief. As previously discussed in **Section 2.3.5.3** the delay in diagnosis of IBD due to the symptom confusion from the healthcare practitioners may have exposed the pregnant woman to further risks associated with disease activity and pregnancy outcomes. Ghorayeb et al. (2018:7) also discussed the symptom confusion experienced by women in their study and healthcare professionals caring for them; for instance the confusion between labour pains and IBD relapse or the anxiety provoked by rectal bleeding due to haemorrhoids rather than an IBD relapse. Other elements of symptom confusion recalled included musculoskeletal pain, abdominal pain, pelvic pain, sickness and fatigue,

which are all common complaints in pregnancy but are also symptoms of IBD. Uncertainty about the cause of fatigue in particular caused women much anxiety. A failure to listen to women's concerns about symptoms can leave women feeling vulnerable and undermined (Ghorayeb et al. 2018:9).

Improving knowledge of healthcare professionals who care for pregnant women, as discussed in **Section 2.3.5.3** may offer some assistance with improving symptom confusion for health care professionals and reduce the iatrogenic risks to women and their babies as associated with invasive tests. Moreover, raising awareness may alleviate symptom confusion in pregnancy with IBD for both women and healthcare professionals. Both studies highlight the importance of listening to women who present with any complaint, and not assuming or excluding the origin without careful evaluation.

2.3.5.6 Concerns about IBD and Pregnancy

Whilst concerns were predominantly about IBD medications, the women in these studies had other concerns about IBD and pregnancy. Nearly a fifth (30/157) of the women who became pregnant after a diagnosis of IBD had personal doubts about becoming pregnant (Hoekstra et al. 2018:706). It is unclear as to the aetiology of these doubts. However, a diagnosis of IBD does not play a major role in the decision to become pregnant and therefore the personal doubts about pregnancy may be more about the pregnancy as opposed to the ability to conceive. It could be argued that there was a missed opportunity to explore these 'doubts' and this could have been done within the selected study method.

Concerns about medication was most prevalent with 73% of women fearing that IBD medication may harm their baby, however other concerns about the inheritance risk related to IBD (68%), fear of IBD causing harm to the baby (63%), fear of the pregnancy being complicated by the IBD (63%), and fearing not being able to care for the baby (13.1%) (Ellul

et al. 2016:888). Whilst the medication remains the greatest fear for women, this is closely followed by fear about the risk of offspring inheriting IBD. It is estimated that the risk children having IBD increases three to twenty fold if one parent has a diagnosis of IBD (Kevans et al. 2016:210). Therefore, the concerns women have about their children inheriting IBD require preconceptual discussions to ensure women are empowered to make informed decisions about their family.

As Ghorayeb et al. (2018) interviewed the women in their study, they were able to explore any concerns in great detail and provide detailed insights into the concerns women living with IBD have about pregnancy. Women had anxieties about their own mortality, and the impact the surgery for IBD may have on their ability to continue with their pregnancy. Women in the study also worried about their children inheriting IBD. Weight gain was another cause for concern, specifically either directly related to pregnancy, or to IBD medication (namely corticosteroids) used to treat IBD activity during pregnancy. Fatigue was another concern women had, and how this would affect their ability to cope with their children.

Whilst concerns about medication use in pregnancy remains the main concern for women, these studies have provided valuable insights into what else women living with IBD worry about regarding their IBD and pregnancy. As argued by Ellul et al. (2016:890), without the correct information and knowledge, women will develop misconceptions which may lead to ill-informed decisions being made.

2.3.6 Risk of bias across studies

The literature about the experiences of pregnancy for women living with IBD is sparse, with only the five included articles fulfilling the inclusion criteria, which predominantly centred

around the experiences, perceptions and preconceptions of women living with IBD about pregnancy and having experienced pregnancy. The recruitment strategies employed increase the risk of bias, with gatekeepers being used and therefore restricting participation within the studies. The risk of recall bias is high for all studies, with the exception of Cooper et al. (2011) due to the participant electing to participate and therefore may choose to participate if they had an experience of personal significance (Sedgwick 2012:1). There was a dominance of quantitative data obtained through surveys, however the depth of the qualitative data obtained through one to one interviews reduced the risk of bias associated with smaller sample sizes.

As previously discussed, the literature is dominated by articles about IBD medication safety and efficacy which reflects the advances in pharmacology used to treat and manage IBD over the past ten years, and the management of IBD from a clinician's perspective. Therefore, there is an identified need for research which seeks the views and experiences of pregnancy from women living with IBD and this will shape the research question and aims and objectives of the PhD study.

2.3.7 Additional analysis

There was no additional analysis.

2.4 Critical Discussion

2.4.1 Summary of evidence

The literature around the experiences of pregnancy for women living with IBD is sparse, however from the limited literature five themes were evident from the results and findings:

timing of diagnosis, translation of health care professional knowledge about IBD and pregnancy into meaningful information, perceptions about IBD medication, concerns about IBD and pregnancy and the impact of disease activity.

Timing of diagnosis appears to be an important aspect when researching IBD and pregnancy and it is valuable to have some evidence about the number of women who conceive following the diagnosis of IBD with Ellul et al. (2016:889) reporting that 42.1% of their participants and Hoekstra et al. (2018:706) finding that 31% of women in their study conceived following their diagnosis of IBD. Timing of diagnosis, which included the insight into diagnosis of IBD during pregnancy provided, some limited evidence about the impact diagnosis has on pregnancy outcomes. It could be argued that Mountifield et al. (2010) missed an opportunity to collect data about this in their study and provide some evidence base around the number of women conceiving after the diagnosis of IBD as the origin of the statistic used cannot be traced.

The translation of healthcare practitioner knowledge about IBD and pregnancy into meaningful information for women was varied across the studies and the difference on experience of pregnancy depending on the information given was demonstrated. However, the lack of meaningful information could be attributed to the development of incorrect perceptions women developed, and perceptions around IBD medication and pregnancy is an evidenced example of this. Women were generally more concerned about the possible harm their IBD medication may cause their unborn baby than they were about the risk of harm from the effects of disease activity. The studies also highlighted the frequency of women either omitting or reducing their IBD medication without discussion or the knowledge of their healthcare practitioner, which is undoubtedly a cause for concern for healthcare practitioners caring for women with IBD during pregnancy. The healthcare professional giving information

within in the studies differed, and this may also have an effect on the confidence women had in responding to advice given, if they felt their healthcare professional was not an expert in this area they may be less likely to follow advice.

The often debilitating impact of disease activity was evidenced throughout the studies, as well as the impact it has on pregnancy outcomes for women and their babies. Symptom confusion described within the studies provides valuable insight into the challenges pregnant women living with IBD may have encountered during the course of their pregnancy and this should encourage healthcare professionals caring for this cohort of women to consider the causes of symptoms experienced in pregnancy as opposed to making assumptions. Whilst concerns were predominantly about IBD medication, women in the studies were also concerned about the effects of their IBD on their pregnancy, and this compliments previous studies undertaken exploring voluntary childlessness and decisions about starting a family (Selinger, Ghorayeb, and Madill 2016). Concerns included the ability to cope with motherhood, risk of inheritance, IBD causing harm to the baby and the IBD causing pregnancy complications. Whilst the evidence is sparse, these five studies provide valuable insights and create opportunities for healthcare providers to optimise pregnancy care based on these findings and results.

However, due to the retrospective nature of this research, the studies are at high risk of recall bias, and the qualitative methodologies of some included studies also increases the risk of bias. The studies do not aim to provide generalisable results across the entire cohort of pregnant women living with IBD, but instead aim to provide an insight, for which they do.

2.4.2 Recommendations

Four of the five studies made recommendations as outlined in **Table 8**, with three of the studies offering generalisable results, whereas two studies did not aim to provide such results.

Ellul et al. (2016) and Mountifield et al. (2010) both make recommendations about the information given to women living with IBD with regards to pregnancy, and role of health professionals in this. This is well supported by the findings of their studies.

Ghorayeb et al. (2018) and Cooper et al. (2011) made recommendations about the integration of IBD and maternity care, with Cooper et al (2011) suggesting that further research is undertaken in this area. These recommendations are well supported by the findings of their studies, with both studies demonstrating the impact the lack of integrated, multidisciplinary care had on the delivery of care.

Knowledge about the implications of IBD on pregnancy is evidenced as lacking, and these studies demonstrate this. Therefore, recommendations about improving the information, or ensuring that information is given in a meaningful way to women living with IBD prior to or/and during pregnancy are well placed. The recommendation for further research supports the conclusions of this systematic review, that there is a paucity of evidence about the experiences of pregnancy for women living with IBD.

2.5 Limitations

The qualitative studies had small numbers, however the rich data obtained in these offer a valuable insight into the experiences of pregnancy for women living with IBD. All studies relied on retrospective accounts and therefore are at high risk of recall bias. The overall

paucity of literature about the experiences of pregnancy for women living with IBD is considered a limitation of this systematic review, however it has demonstrated a need for further research in this relatively unresearched area.

2.6 Conclusions and chapter summary

The scoping review provided an insight into the available literature about IBD and pregnancy and was instrumental in deciding the research question, however it was the Systematic Review which provided the in-depth knowledge about the literature, and the themes within the articles and was therefore essential. The Systematic Review had five emergent themes: timing of diagnosis, translation of healthcare practitioner knowledge of IBD and pregnancy into meaningful information perceptions about IBD medication, impact of disease activity and concerns about IBD and pregnancy. This led to the development of the aims and objectives of the study which will influence the theoretical foundations of the study and the methods and study design required.

This chapter has reviewed and critically appraised the current literature about IBD and pregnancy and has explored systematically and in the detail the literature available about the experiences or perceptions about pregnancy for women living with IBD. However, the literature around this is sparse, and the literature review has highlighted the need for further, in-depth research around this topic.

Chapter 3 will move the topic further by outlining and discussing the theoretical perspectives and underpinnings of the study and explore the study design used.

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Chapter 3: Methodology, methods and research design

3.1 Introduction

Following the recognition of inequality in care for women living with IBD during pregnancy discussed in **Chapter 1**, and the paucity of literature identified about IBD and pregnancy experiences from the systematic review in **Chapter 2,** further research into this phenomenon is needed. This chapter will discuss the development of the research question, the methodology, methods and ethical considerations used for the design and conduct of the study.

3.2 Research question

As concluded at the end of **Chapter 2**, the literature around the experiences of pregnancy for women living with IBD is sparse, and that there is therefore a need for further research. Due to the paucity of literature around this topic the research question needs to be relatively broad, with more specific aims and objectives.

The research question and study aims are:

Research Question

What are experiences of pregnancy for women living with Inflammatory Bowel Disease?

Study Aims

Aims:

To explore recommendations about a care pathway model for women living with IBD during pregnancy from women living with IBD who have experienced pregnancy

To gain an in depth understanding of the experiences of pregnancy in women living with Inflammatory Bowel Disease using IPA

Study Objectives

- To hear first-hand lived experiences regarding pregnancy from women living with IBD
- To build on the findings of my previous exploratory study: A mixed methods exploration of the experiences of women living with inflammatory bowel disease of pregnancy
- To explore potential components of a care pathway model for women living with IBD during pregnancy from women living with IBD who have experienced pregnancy

3.3 Positionality and Reflexivity

Before undertaking research, it is important to consider one's position. As a researcher, a midwife, a mother, and someone living with Inflammatory Bowel Disease, exploring the experiences of pregnancy, how would I be able to remain completely objective, or was this even necessary? Would personal and professional experiences hinder the objectiveness of the research, or would it enhance the understanding and insight of women's experiences? It was through observations in clinical practice combined with my personal experience of being diagnosed with IBD having just given birth that developed my interest in the research subject, and therefore my position had already contributed to the research. Therefore, to try and remain objective, or ignore my position would be impossible and would probably create difficulties as the research progressed, so it was necessary to find a solution to this and this solution was reflexivity.

Reflexivity has become a key component of qualitative research, with it being accepted that the researcher is a central figure in research (Finlay 2003:5) and the research is therefore co-constituted, produced between the researcher, participant and their relationship. Reflexivity has several variants: introspection, intersubjective reflection, mutual collaboration, social critique and ironic deconstruction.

Reflexivity as introspection embraces the experiences of the researcher which enhances generalised understanding and interpretation (Finlay 2003:8). This enables the researcher and participant to use their personal experiences to provide greater insight and social context to the subject being explored. Intersubjective reflection however involves the researcher exploring the mutual meanings within the relationship within the research (Finlay 2003:8) so within the this study, this would be the mutual meanings resulting from the researcher as a midwife, as the researchers diagnosis of IBD was not disclosed to participants. Mutual collaboration meanwhile requires involvement of the participant in the research process, usually data analysis (Finlay 2003:12) and whilst this approach to research has not been used, the involvement of a patient public participant representative has necessitated reflexivity on her part. The experiences of the Patient Public Representative have been key in the development of the research design and public facing documents and has enabled the experiences of a woman living with IBD to help shape the research project. Reflexivity as social critique relies on the social positions of the researcher and the participants and openly acknowledges the difficulties in potential power imbalances between the two and the tensions which may arise with the differing social positions, in particular race, gender or class (Finlay 2003:12). Ironic deconstruction does not allow power imbalances and instead all voices compete to be heard. The role of the researcher is to enable the multiple voices to be heard whilst exploring the ambiguity of meanings in the language used.

3.4 Theoretical Foundations

All research is underpinned by theory and paradigms help to regulate inquiry undertaken by researchers through shared sets of beliefs and practices (Weaver and Olson 2006:459). Whilst the research topic or phenomena can be decided early in the research process, the paradigm, driven by positionality, should be recognised and reflected upon prior to finalising the research question and aims and objectives as it will frame the theories and principles for study and will also influence data collection and data analysis methods.

Pragmatism facilitates the use of contrasting methodologies, with the epistemological and ontological positions being determined by the studies aims and objectives, not the paradigm (Harvey and Land 2017:75). There were three main influencers for Pragmatism: Charles Peirce, John Dewey and William James, all American philosophers. Charles Peirce (1877) started to question the notion of belief in 1877, which led to the term 'inquiry', used to describe the struggle between doubt and belief which aimed to result in a settlement of opinion. The difficulties with belief, both individual and beliefs within a community led to concerns about 'fixing beliefs' which may lead to institutional authority, and state authority, prohibiting individuals having non-regulated beliefs. Settling of opinions encouraged integrity of belief and consider the concept of truth. In 1907, William James introduced the concept of Pragmatism in a book entitled: *Pragmatism, a new name for some old ways of thinking*. This was a series of lectures given as an alternative philosophy which could satisfy both rationalists and also the empiricists and was a method of settling metaphysical disputes (James 1907:45). James (1907: 47) noted that it was Peirce who first identified the principle of pragmatism in 1904; but pragmatism was not accepted until James applied it to religion (James 1907). Pragmatism was therefore discussed in conjunction with religion and the relationship between the two and as an alternative philosophy. In response to

misunderstandings about Pragmatism, James published a reply which sought to clarify the impact of 'truth' on philosophy, recognising that "truth" may mean different things to different people and this may be influenced by their philosophical stance. James (1908) argues that Pragmatism does not rely on the theory of 'truth' being proven to be a reality or existing but focuses on what 'truth' would signify ideally and "intended to cover the most complete truth that can be conceived of, 'absolute' truth if you like, as well as truth of the most relative and imperfect description" (James 1908)

John Dewey further contributed to Pragmatism in 1929 by re-orientating the philosophy towards human experiences and away from abstract concerns. He raised two key questions: i) what are the sources of beliefs and ii) what are the meanings of actions; with experiences being a fusion of beliefs and actions (Morgan 2014:1046). This was in contrast to the views of established philosophy, which relied on metaphysics – the nature of existence, being and the world. Dewey had an emphasis on human experience which required a different starting point to the typical metaphysical discussions about reality or truth. This meant that rather than a metaphysic philosophy of knowledge, Dewey used inquiry as a process-based approach to knowledge (Dewey 1929:48). The term 'knowledge' was replaced with 'warranted assertions' which were born out of the outcomes of the inquiry, which acknowledged the integral relationship between knowing and doing.

Paradigms are defined by their epistemological and ontological position, and provide set beliefs about truth and reality, often holding contrasting and conflicting views. Pragmatism however as a paradigm accepts the differing views about reality and truth, as the emphasis is about experiences, making all arguments valid and necessitate discussion (Morgan 2014:1048). Pragmatism acknowledges that reality is not static and can be interpreted or be renegotiated depending upon the situation which may be unpredictable.

Despite having being an accepted philosophy since the 1900's, Pragmatism was first adopted as a philosophy into social research in 1989 following the 'paradigm war' which resulted from a critical attack on scientific based studies related to research in teaching, as the critics argued that the attempts to have a scientific foundation for the 'art of teaching' had failed (Gage 2009:4) Pragmatism was adopted as a philosophy in response to the critique of the existing, accepted paradigms by the antinaturalist, the interpretivist and the critical theorists'. It was realised that quantitative and qualitative perspectives did not need to be mutually exclusive as had previously been the perception, and it was appreciated that paradigm differences did not automatically constitute paradigm conflict (Gage 2009:8). The realisation that programmes of research which were concerned with different topics could be undertaken with researchers studying the different elements of the research led to the questioning of whether these programmes of research were actually mutually antagonistic or whether they were simply exploring different topics which required different methodologies to address the research question or research programme (Gage 2009:7). It became understood and accepted that both objective-quantitative and interpretative-qualitative methods could be used harmoniously, and offered greater insights which led in to greater improvements (Gage 2009:7). Pragmatism enables qualitative and quantitative research to be undertaken within one study.

Pragmatism is well suited to nursing and midwifery studies, due to its integration of theory and practice, as pragmatic truth is not based solely on evidence. Instead pragmatism validates new theories through new techniques and enhanced awareness (Eun-ok and Chee 2003:57). Whilst this enables research to be undertaken comprising of multiple methodologies, contrasting epistemologies and ontological positions enabling the strengths of each to be maximised and the weaknesses offset (Bryman 2016:635). However, care must be taken to ensure that the results are integrated appropriately and without

compromising the integrity of the research. The research question must be appropriate for a pragmatic approach, with pragmatism aligning well with the philosophy of nursing and midwifery which relies on a foundation of skills and knowledge which are continually evaluated and developed to ensure that the best care is given (Marshall 2010:7).

This collaborative and understanding paradigm is ideally suited to exploring the experiences of women living with IBD and pregnancy. These approaches will now be explored in detail in the context of the proposed research; the experiences of pregnancy for women living with IBD. Exploration of a subject may require more than one study to be undertaken, which may use more than one methodological approach and/or methods and then integration of the results and therefore pragmatism will facilitate this whilst ensuring the integrity of the different approaches are retained.

The individual objectives will require different ontological and epistemological positioning to ensure that they are met, and to ensure that the research question is answered **(Figure 5).**

The research question: '*What are the experiences of women living with Inflammatory Bowel Disease and pregnancy'* is of an exploratory nature and seeks to gain understanding and insight into these lived phenomena from those experiencing it.

The objectives are:

1. To hear first-hand lived experiences regarding pregnancy from women living with IBD

2. To build on the findings of a previous exploratory study: A mixed methods exploration of the experiences of women living with inflammatory bowel disease and pregnancy (Janiszewski et al. 2019)

3. To explore the potential components of a care pathway model for women living with IBD during pregnancy from women living with IBD who have experienced pregnancy

As previously discussed in **Chapter 2** the current literature is dominated by medical efficacy, medicine safety and outcomes for pregnant women and their baby. There is a paucity of literature about the experiences of pregnancy for women living with IBD and the factors which women considered to affect their experience from a number of viewpoints. The development of the research question evolved from critical appraisal of the available literature and evidence base about IBD and pregnancy, with the paucity of evidence and literature about the experiences of pregnancy for women living with IBD. The experiences of pregnancy have not been specifically explored before, yet the studies into pregnancy and IBD discussed in **Chapter 2** discuss elements which contribute to the experiences of pregnancy.

3.4.1 Pragmatism

Pragmatism as the research paradigm is well suited to the study being undertaken discussed in this thesis, as it facilitates philosophical pluralism (Eun-ok and Chee 2003:58) which is necessary to answer the research question. The phenomena to be explored requires consideration of the ontological and epistemological position as different research subjects often lend themselves to specific positions, and this defines the appropriate methodology needed for the research to be undertaken.

Ontology is concerned with whether entities can exist independently of individual beliefs and attitudes or whether these are an integral part of the entity being researched. There are two ontological positions: objectivism which asserts that phenomena and their meanings exist independently of personal beliefs or attitudes and constructivism which is considered to be

the alternative ontological position to objectivism (Bryman 2016:29). Constructivism asserts that phenomena and their meanings rely on individual attitudes which are continuously revised as experiences contribute to the meaning of the phenomena.

Epistemology is concerned with knowledge and how knowledge is considered to be acceptable (Bryman 2016:690). There are two contrasting epistemological positions: positivism and interpretivism. Positivism asserts that knowledge must be confirmed by the senses if it is to be considered as genuine knowledge, and that knowledge relies on the gathering of facts (Bryman 2016:24). Interpretivism however asserts that knowledge can be achieved through experiences and other influences and does not require tangible evidence. Whilst positivism has an emphasis on explaining a phenomenon, interpretivism aims to understand the phenomenon (Bryman 2016:26).

As the research is focused on experiences, the ontological position is that of constructivism, that reality is influenced by situations, experiences and is unique to individuals. For women living with IBD, there will not be one single reality or truth and that this will be shaped by their own individual experiences, perceptions or beliefs. The epistemological position is interpretivism with new knowledge being gained through interpretation and understanding of the individual world we live in.

As this research is of an exploratory nature and is not aiming to prove or disprove a hypothesis, an inductive approach is needed as this approach allows data collected to develop into new theories. An inductive approach is typically used in qualitative research as it does not require predefined questions or responses for data collection. Instead the responses are free flowing which is of particular benefit when exploring topics of a sensitive nature (Lee 1999:77), such as experiences of pregnancy as it allows women to express their

experience in their own words as opposed to trying to make their experience fit into a predefined response or answer.

This contrasts with a deductive approach which will use a theory to prove or disprove a hypothesis and confirm or refute the original theory posed. A deductive approach shapes the research design as data collection method must be able to disprove or prove the predefined hypothesis and then use this to revise the original theory (Bryman 2016:21).

The research objectives described require different methodological approaches, as both an inductive approach and a deductive approach are needed to fulfil the study objectives. The study objectives could not be achieved using one methodological approach, which a purely deductive approach not allowing for unique in depth lived experiences to be explored and a purely inductive approach not enabling the collective experiences of numerous women to be sought. However, inductive and deductive are fundamentally contrasting it was essential to ensure that their individual relationships between theory and research were acknowledged and protected (Bryman 2016:17) as it is through using these two contrasting approaches that the phenomena can be explored in detail. Care is needed to ensure that different with different methodological approaches are not simply undertaken and then presented together, and this is avoided by using an appropriate paradigm, which enables contrasting methodologies to be used within one study to answer the research question and study objectives.

Pragmatism enables both qualitative and quantitative methodologies to be used within one study which may also include using a mixed methods design which will be discussed in **Section 3.5**. Whilst different methodological approaches are needed to address the study objectives, in order to fully address the research question, two independent studies need to be undertaken using different methodologies and methods. With Pragmatism as the

paradigm and conducting two independent studies, which will be brought together using triangulation, this will ensure that the integrity of the overall research is not compromised and that the philosophical and theoretical clarity within the studies are preserved (Weaver and Olson 2006:466). This is shown in **Figure 5**. Whilst this is imperative, it is also important to determine how the different methodological approaches were integrated in this study.

3.4.2 Theoretical foundations and study objectives

3.4.2.1 Objective one

Objective one aims to understand the phenomena of lived experiences and therefore requires an inductive, interpretivist approach, as women's experiences will be shaped by their perceptions, previous experiences and beliefs. Phenomenology as a philosophical approach is therefore well suited as a methodology for addressing this objective and will form an independent qualitative study which will explore the phenomena of lived experiences in detail.

3.4.2.2 Objective two

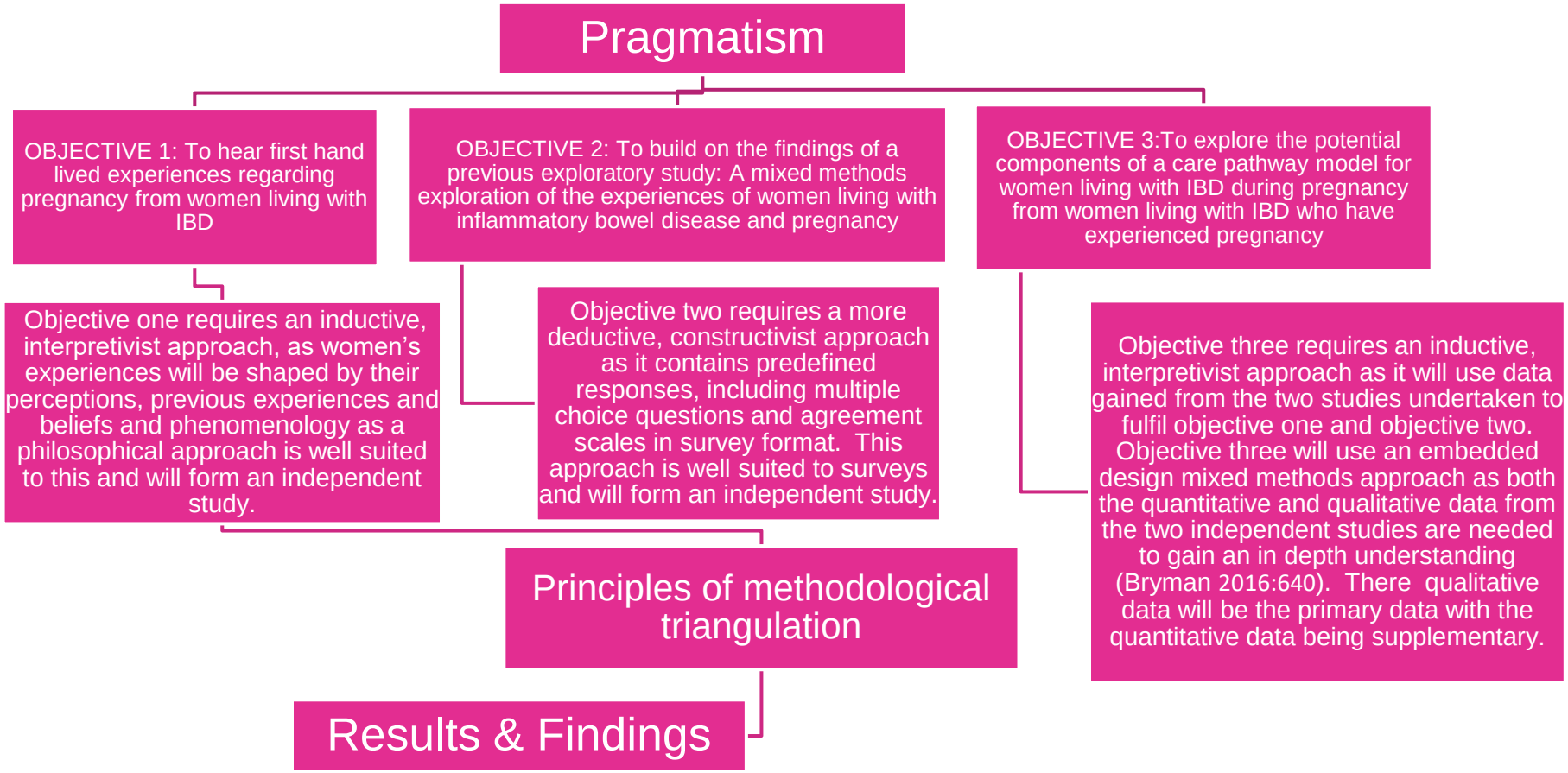
Objective two aims to supplement the findings of a previous exploratory study about IBD and pregnancy and requires a more deductive, positivist approach as it contains predefined responses, including multiple choice questions and agreement scales in survey format. This approach is well suited to surveys and will form an independent predominantly quantitative study.

3.4.2.3 Objective three

Objective three aims to explore the potential components for a care pathway model and requires an inductive, interpretivist approach as it will use data gained from the two studies undertaken to fulfil objective one and objective two. Objective three will use an embedded design mixed methods approach as both the quantitative and qualitative data from the two independent studies are needed to gain an in depth understanding (Bryman 2016:640). The qualitative data will be the primary data with the quantitative data being supplementary.

Due to diverse methods used, the principles of methodological triangulation are needed to combine the findings of the studies and integrate them appropriately. Methodological triangulation will ensure that the individual study designs are safeguarded, as the threats to the rigour for each study are carefully considered (Weaver and Olson 2006:466). Using methodological analysis enables researchers to research subjects which cannot be explored satisfactorily using a single method, as in the case of this study exploring the experiences of pregnancy for women living with IBD.

Figure 5: Ontological and epistemological positions



3.5 Mixed Methods

Using a mixed methods approach is necessary when both qualitative and quantitative data is needed to fully examine a case (Cresswell and Plano Clark 2011:91). Inclusion of quantitative information to validate qualitative finding was first used as early as 1959, with Campbell and Fiske discussing the use of multiple sources of data, during what is considered to be the formative period of development of mixed methods research. The inclusion of qualitative data in quantitative experimental studies was introduced in the late 1970's (Cresswell and Plano Clark 2011:21). By the late 1980's, mixed methods received more attention, with several publications describing and defining an approach, which is now known and accepted as mixed methods and it was during this time that the paradigm debate period of mixed methods research was ongoing. During the 1990's the procedural development period was underway, with various designs being suggested and developed which was followed by the advocacy and expansion period. The reflection period followed, through the 2000's, during which time mixed methods as a methodology was assessed and critiqued (Cresswell and Plano Clark 2011:24). In 2006, Bryman pulled together the previously described integrated approaches with Creswell and Plano Clark creating a list of the classifications of types of design.

Prior to mixed methods being widely recognised and accepted as an approach, evaluations of nursing and midwifery practices would often include both qualitative data measuring the outcome but with a focus also on the patient experience, therefore what could now be considered to be a mixed methods approach. Evidence based nursing followed the movement of evidence based medicine, with medical research usually being scientific and exploring or answering questions around causation, prognosis and effectiveness (Mulhall 1998:5). Whilst this is important to nurses as well as medics, the continual presence of

nurses throughout treatment meaning nurses become concerned with other elements of the patient such as emotions and feeling, which the social and natural sciences find difficult to accommodate (Mulhall 1998:4). With the acceptance and recognition of mixed methods, collaboration using both quantitative and qualitative research designs are now recognised as formal research.

There are many different designs for mixed methods and which one to use may be determined by several factors, predominantly around if there is a hierarchy of data and how the research design will determine data collection.

An embedded design will be used as this is appropriate when there are different objectives which require different types of data or when purely qualitative or quantitative data will not be sufficient in gaining understanding of the chosen phenomena (Bryman 2016:640). The embedded approach requires one data set to be primary, which the qualitative data will be for this study, and the quantitative data is subservient or supplementary. This approach is sometimes used when an emergent issue in the primary research design leads to the development of a secondary research design (Cresswell and Plano Clark 2011:91) however this is not the case for this study as the research questions, aims and objectives were already determined and required a mixed methods design to fully answer them. The quantitative and qualitative data can be collected either simultaneously or sequentially. There are many advantages to using an embedded design, which include the size of the research design due to the supplementary data, and the focus on different questions or objectives means that the different results can be published separately aiding dissemination (Cresswell and Plano Clark 2011:94). However there are also limitations when undertaking mixed methods research and these include difficulties in integrating the results and the

researcher needing expertise in both the qualitative and quantitative design as well as the mixed methods design (Cresswell and Plano Clark 2011:95).

Figure 6 demonstrates the embedded design to be used for this study, which has a quantitative strand embedded within a qualitative study. Quantitative and qualitative data is then integrated to give the findings.

Figure 6: Mixed methods embedded design

Using the embedded design enables different theoretical perspectives to be accommodated within one study providing a more holistic approach to phenomena (Harvey and Land 2017:97), which facilitates a greater depth and breadth of understanding and insight of data collected.

Two studies were undertaken to enable the research objectives to be fully answered, and the embedded mixed methods design enabled data gathered from the separate studies to be brought together to answer the research question.

An anonymous online survey distributed through social media platforms, was used to collect both qualitative and quantitative data using closed questions, multiple choice questions, agreement scales and two open ended questions. This is discussed in detail in **Section 3.7.5** and **Appendix 3.**

A flexible interview tool was used to help structure the semi-structured interviews which consisted of two questions and relevant prompts and probes. This is discussed in **Section 3.8.5** and **Appendix 4.**

3.5.1 Triangulation

Whilst a mixed methods approach enables qualitative and quantitative data to be combined, and in the case of the embedded design, one set of data to be supplementary to the primary data, additional steps are needed to ensure that the combination of the data does not affect its validity.

Triangulation can be used in research to give different perspectives in answering the research question or in issues within the study (Flick 2015:219). There are four different types of triangulation: triangulation of data, investigator triangulation, triangulation of theories and methodological triangulation (Denzin 1970) as outlined in **Table 11**.

Table 11: Forms of triangulation

Form of triangulation	Summary
Triangulation of data	Combines data from different sources, times, places or people
Investigator triangulation	Different observers or interviewers used to collect data
Triangulation of theories	Different theoretical perspectives used within the study
Methodological triangulation	Using different methods within a study

Triangulation is needed to combine the quantitative and qualitative data, which focus' on the results and have three possible outcomes: that the results converge, that the results are complementary or that the results are divergent or contradictory (Flick 2015:220).

Triangulation was initially used in the wider research field to converge or corroborate results from research using different methods and sought to corroborate results from qualitative and quantitative data (Greene et al. 1989:259). However triangulation also provides a process for combining qualitative and quantitative findings to increase validity (Bryman 2006:105).

The principles of methodological triangulation were used, as this enabled the phenomena of pregnancy whilst living with IBD to be explored using the data obtained from the online survey and from the interviews and reducing the potential biases of using a single method (Noble and Heale 2019:67).

A description of how the data will be analysed within the context of the embedded approach is described in **Section 3.8.7**.

3.6 Ethical Considerations

There are four main ethical considerations when undertaking research: informed consent, potential harm to participants, potential invasion of privacy and potential deception (Diener and Crandall 1978). There is guidance available to support researchers in ensuring their research is complaint with ethical standards and the guidance from the Health Research Authority (Health Research Agency 2017) was used.

3.6.1 Ethical approvals

Favourable ethical opinions were sought from Coventry University Ethics Committee for the online survey (P80386) and the interviews (P76258) independently, with additional HRA approval being sought and granted for the interview study (IRAS:256277) prior to either study commencing. HRA approval was needed for the interview study due to the recruitment strategy used.

The study protocols were not initiated until a favourable opinion has been granted from Coventry University Ethics Committee and the HRA for the interview study (Health Research Authority 2017:12). Confirmation of capacity and capability from the Trust Research and Innovation department was sought and gained prior to commencing the interview study also, again due to recruitment strategy employed.

Table 12 shows the variation in documentation required for submission for ethical approval for each of the studies, demonstrating the complexities of the overall study and processes followed.

Table 12: Documents submitted for ethical approval

Document	Online Survey CU ethics	IPA study CU ethics	IPA study IRAS	Appendix
Study protocol	✓	✓	✓	1a systematic review 1b online survey 1c IPA study
Participant information	✓	x	X	5
Participant Information Sheet	X	✓	✓	7
Consent statements	✓	x	X	6
Consent form	X	✓	✓	8
Study advertising material	✓	✓	✓	9
Letter to GP	X	✓	✓	10
Invitation to study letter	X	✓	✓	11
Questionnaire	✓	X	X	3
Flexible interview tool	X	✓	✓	4
HRA Statement of activities	X	X	✓	12
HRA Schedule of events	X	X	✓	13
Indemnity insurance	X	X	✓	14
Sponsor letter	X	X	✓	15
CU ethics certificate	X	X	✓	2a systematic review 2b online survey 2c IPA study

3.6.2 Benefits of participation

Whilst there are many strategies in place to avoid harm to participants during research which are discussed in **Sections 3.7.3.2** and **3.8.3.2**, it is important to acknowledge that there are benefits to participation, particularly in qualitative research (Boeije 2014:51). Benefits include a feeling of relief at being able to talk about experiences which may not otherwise be discussed, a feeling of being worthy and that their opinion counts and that their voice is being heard can lead to a feeling of self-empowerment also.

Although women self-selected to participate in the study, the motivation to participate may be the desire to help others and that their experiences may be helpful either people in similar positions or to help educate health professionals (Boeije 2014:52). Therefore, it was important to have resources available to women should they require any additional information or support either throughout or following their interview. This included signposting to support for pregnancy loss or stillbirth, contact details for a birth listening service, current clinical midwifery knowledge about pregnancy, labour, birth and the postnatal period and information about resources available from Crohns and Colitis UK.

Weighing up the risks against the benefits of participation in a study is extremely difficult with qualitative research due to the individual nature of the participants – sharing their experience may prove beneficial to one whilst cause distress to another, and highlights the importance of ensuring that steps are taken to minimise the potential of harm.

3.7 Online Survey

3.7.1 Informed consent

Information relating to the study was displayed on *Qualtrics*© which gave potential participants unbiased information about the study, including the purpose of the study, length of time of participation, how their confidentiality would be maintained, how their data would be stored and used and their right to withdraw from the study (**Figure 7**). This enabled potential participants to make an informed decision about participation in the study. Potential participants were then able to select the 'I consent – begin the survey' option on *Qualtrics* © which started the survey (**Figure 8**). If 'I do not consent- I do not wish to participate' option was selected a message was displayed thanking them for considering

participating and informing them that as the consent to participate was not selected, they were unable to complete the survey.

Figure 7: Screen shot of Participant Information used on Qualtrics

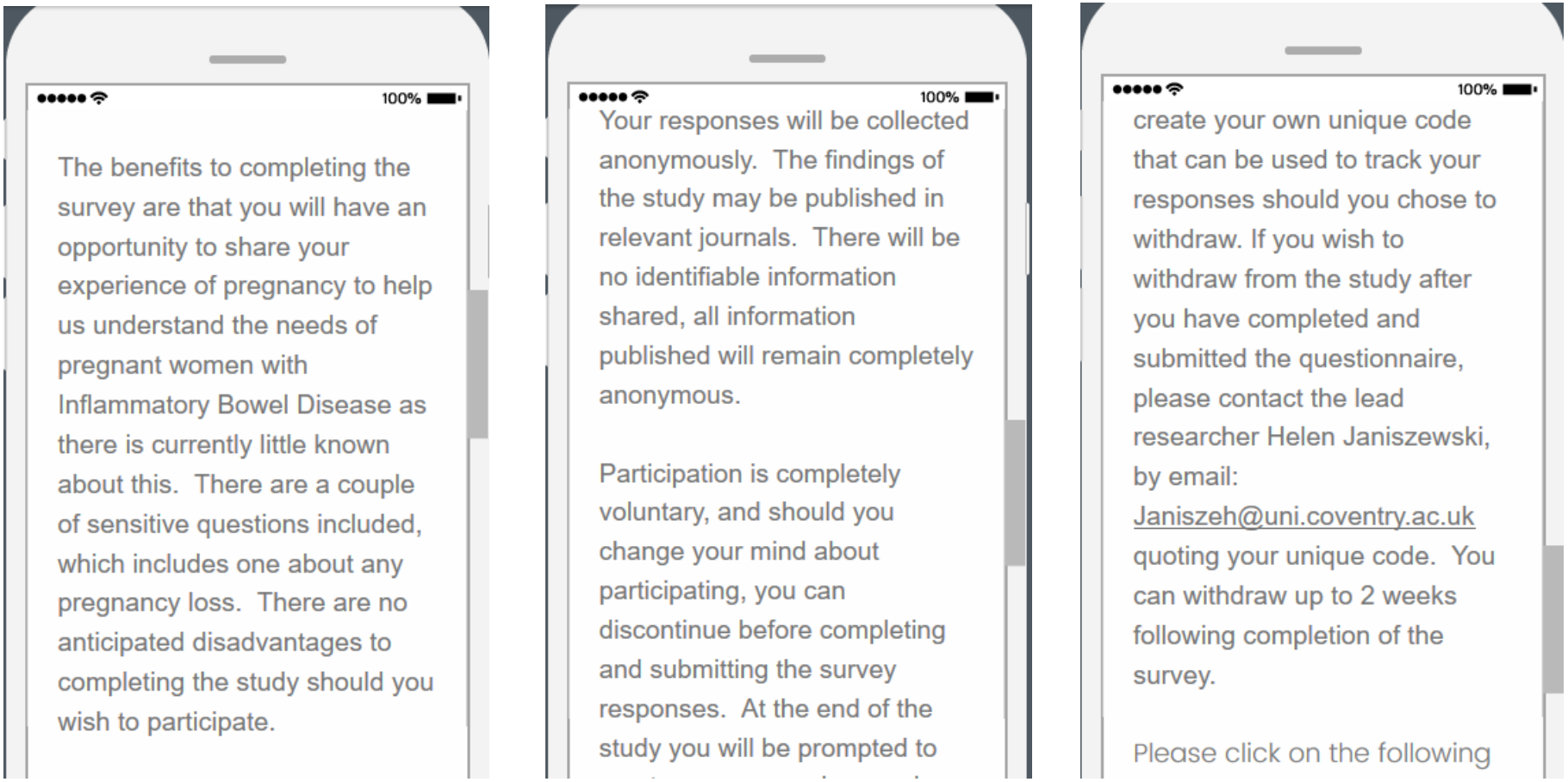
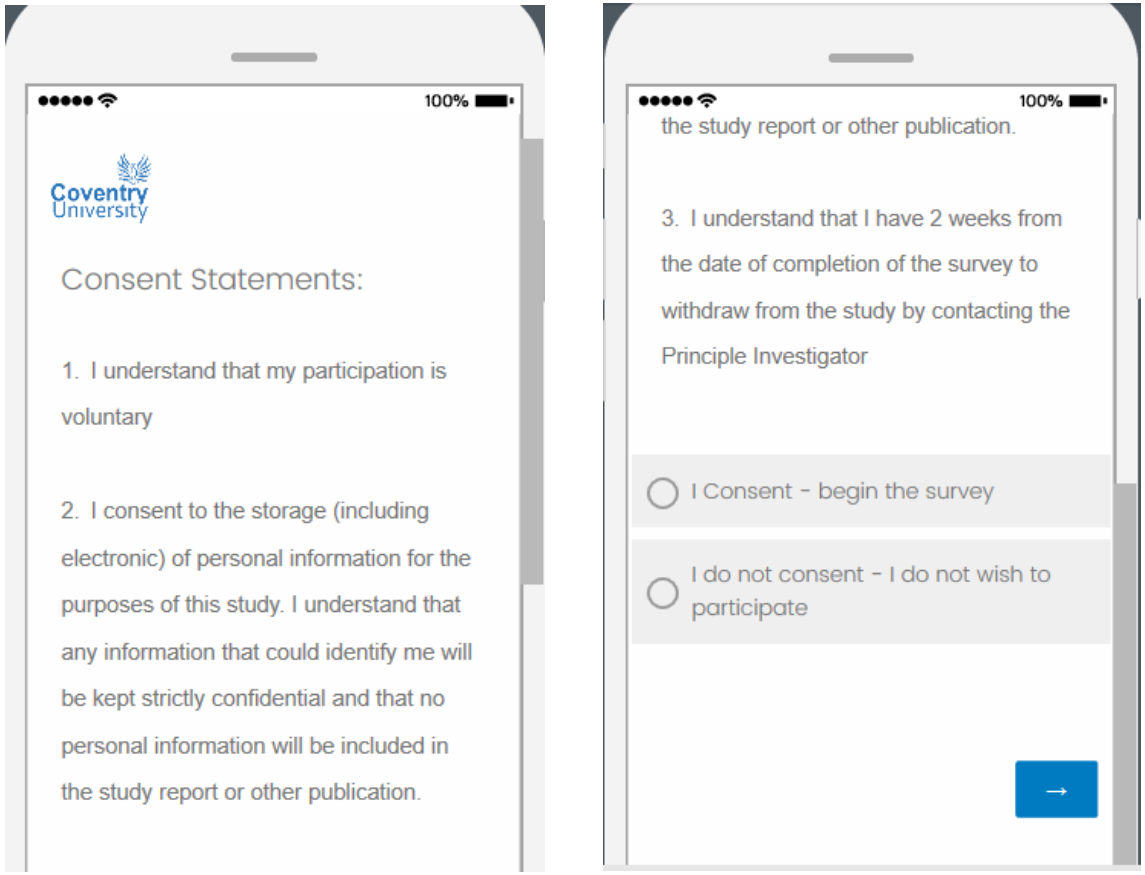


Figure 8: Consent statements used on Qualtrics



3.7.2 Privacy, confidentiality and anonymity

3.7.2.1 Privacy

Participants have a right to have their privacy respected which includes the collection, storage, use and reporting of their data (Health Research Authority 2017:13) and the study design ensured that this was adhered to. It is essential that a participant has all the information needed about the study to make an informed decision about whether to participate and this is a key element in maintaining privacy (Bryman 2016:131).

Data were collected using an anonymous online survey generated through *Qualtrics*© with participants being free to choose whether to divulge particular information through answering certain questions or not which minimised the risk of an invasion of privacy (Bryman 2016:131). Data were stored on a password protected memory stick and saved on the secure University cloud-based server, and only used as outlined in the Participant Information.

3.7.2.2 Confidentiality and anonymity

The study design ensured that participants right to have their privacy respected when participating in research was respected (Health Research Authority 2017:13).

The online survey was anonymous and did not request any identifying information. The withdrawal mechanism required participants to create a unique identifier which comprised of the last three digits of the participants postcode and the last three numbers of their 'phone number. This does not contain any information which makes to the participant identifiable to anyone other than themselves but remains relatively easy to recall if prompted. The IP address of the participant was captured within *Qualtrics*©, and due to the withdrawal period

being two weeks after completion, data remained in *Qualtrics*© during this period and were pseudonymised. Data were then exported from *Qualtrics*© and the IP address removed ensuring the data were saved in a fully anonymised form. Data were stored on a password protected memory stick and within the university secure server in accordance to the Data Protection Act 1998.

3.7.3 Deception, risk of harm and exploitation

3.7.3.1 Deception

There was no deception in the study, with women being fully informed about the nature of the study and how their data would be used as outlined in the participant information used on *Qualtrics*© (**Appendix 5**)

3.7.3.2 Risk of harm

Participants have the right to protected from harm during participation in research, including physical harm, loss of self-esteem and stress (Diener and Crandall 1978:19). The participants were at additional risk due to the sensitive nature of the research topic.

Surveys are considered to have one of the lowest risk of harm attached and are usually considered to be an inconvenience to the participant as opposed to harmful (Rees 2003:105). Participants were free to ignore questions they did not want to answer or to withdraw from the study altogether by closing the internet browser page. The survey was not anticipated to be a burden in terms of completion and was considered to be reasonable (Flick 2015:37) with the completion time being advised at the start of the survey.

3.7.3.2.1 Potential harm with research on sensitive topics

The risk of psychological harm or causing distress when asking women to recall their pregnancy or birth experience required careful consideration with 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 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.

Careful consideration was given to including women in the survey 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. A link to Tommy's Charity which offers support to women and families who have experienced stillbirth was included at the end of the survey.

The risk of psychological harm or distress when asking women about pregnancy loss also required careful consideration. The introduction to the survey contained a statement which

explained the survey contained some sensitive questions, one 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.

3.7.3.3 Exploitation

There was no risk of exploitation as women had to initiate participation through completing the anonymous online survey.

3.7.4 Sampling and recruitment

3.7.4.1 Sampling

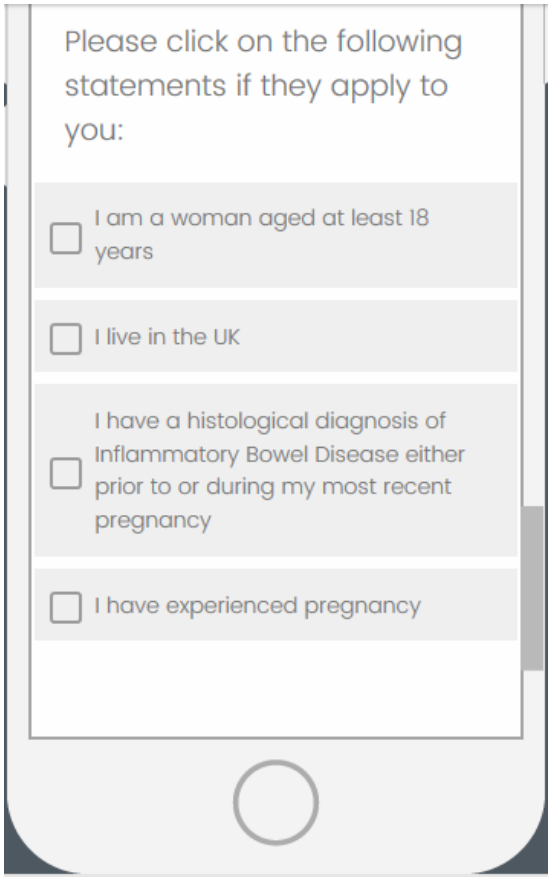
Purposive sampling was used as the survey sought the views of experiences of a particular cohort of the population (Bowling 2014:209). The inclusion criteria included women who had been diagnosed with IBD prior to or during pregnancy, had given birth were aged at least 18 years old and lived in the United Kingdom. A total number of eligible women and sample size was not calculated due to the difficulties in identifying eligible women. The survey was distributed through social media including Facebook groups for women living with IBD and Twitter. Social media was chosen as the distribution platform as it enabled a nation-wide distribution, whilst enabling women to self-select to participate. However, it does rely on

eligible women having access or membership to social media and therefore eligible women may not see the survey due to the chosen distribution method. In 2019, 71% of women used the internet for social networking (Office of National Statisticts 2019). Whilst the lack of visibility of the survey using the selected method was acknowledged, distribution through social media was felt to be the most appropriate method due its associated benefits of being far reaching and enabling anonymous self-selection to participate.

3.7.4.2 Selection

Women were asked to self-identify their eligibility to participate and complete the survey through agreeing to the three statements on *Qualtrics©* as shown in **Figure 9**. If they did not select all of the criteria, a pop-up message appeared thanking them for their interest but as they did not fulfil the inclusion criteria they could not proceed with the survey.

Figure 9: Eligibility criteria used on Qualtrics



Self-selection was the only feasible method of selection due to the recruitment strategy used. the limitations of this approach were carefully considered, including the risk of self-selection bias (Khazaal et al. 2014) and the risk of non-eligible people completing the survey. However due to the inclusion criteria including all women who have a diagnosis of IBD, live in the UK, are aged 18 years or older and have given birth, identification of all eligible women would not have been possible.

3.7.5 Data collection and analysis

Data were collected through the anonymous online survey. The survey was distributed through social media platforms including Facebook and Twitter and was live for four months (21/01/2019-26/05/2019) with a total of 50 participants completing the survey.

The findings and results are presented in **Chapter 4.**

3.7.5.1 Quantitative data collection

Quantitative data were collected using an anonymous online web survey (**Appendix 3**) generated through *Qualtrics*©. An online anonymous survey was chosen as the data collection method due to the wider geographical coverage, faster response time and a suggestion that there is a better response to open ended questions when using an online survey (Bryman 2016:235). It is acknowledged that this distribution method meant that the survey was restricted to those with internet access. However, in 2019, the Office for National Statistics (Office of National Statisticts 2019) published that 93% of UK households has internet access at home and that 79% 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 and the time scale of the study.

The survey contained dichotomous and multiple choice closed ended questions. Agreement scales were also used, as the study is exploring women's experiences, and this increases the sensitivity of closed ended questions (Burns and Grove 2001). Statements expressed both positively and negatively were used to reduce the possibility of participants ticking the same box for each statement. Questions were included that had been used in a smaller exploratory study of the same topic (Janiszewski et al. 2019) and the results of this study were used to shape additional questions. Whilst concern and worry were asked about in the

survey, validated anxiety questions were not asked, as the survey did not aim to specifically explore or even diagnose anxiety but instead to identify if women had concerns or worries.

3.7.5.2 Quantitative data analysis

Nominal, ordinal and dichotomous variables provided the data and due to the amount of data collected, quantitative data was analysed using univariate and bivariate analysis. Data were presented using descriptive statistics. It was not appropriate to undertake any further statistical analysis due to the amount of data collected.

3.7.5.3 Qualitative data collection

Qualitative data were collected using open ended questions as the study is exploratory and it would have been inappropriate to pre-empt responses in order to create multiple choice closed ended questions. Women were asked the following questions to gain further information from the closed ended question which preceded:

a. **If you have been diagnosed with IBD during or following a pregnancy, have you noticed any differences in care for further pregnancies?**
b. **Was medication used for your IBD discussed during your pregnancy, such as changing certain medications or stopping certain medications?**
c. **Do you think your IBD influenced your choices around infant feeding?**

At there the end of the survey there were two open ended questions, each with a maximum word count limit (100 words) for responses. The questions were: 'What would have improved your experience of pregnancy?' and 'Any other comments?'

3.7.5.4 Qualitative data analysis

Qualitative data obtained from the online survey was analysed using Thematic Analysis. Thematic analysis was selected as the data analysis method as themes are sub themes are allowed to emerge from the data using quotes to support the themes (Bryman 2016:585). Software such as *NVivo* may be used to support the Framework approach of thematic analysis, however due to the amount of data collected this was not deemed necessary.

3.8 One to One Interviews

3.8.1 Informed consent

Women who expressed an interest in an interview were sent a Participant Information Sheet (PIS) (**Appendix 7**) either with the invitation letter, or after they had made contact expressing an interest in response to a poster or social media post. To ensure they had adequate time to read the information and decide if they wished to participate, the researcher arranged to contact them for a further discussion after a minimum of 24 hours after sending the information. This also provided an opportunity for any questions to be answered. A further date and time were arranged for the interview if the woman was willing to proceed.

A consent form was taken to the interview along with a copy of the PIS with the participant asked to initial and date each statement if they agreed as this provided both the researcher and the participant with a copy of the form and also enables the participant to be fully informed about the nature of the study and any implications (Bryman 2016:133). A copy was given to the participant, a copy was filed in the NHS patient file and a copy was kept in a locked cupboard in the Biomedical Research Centre (BRC). Women were also informed

that they were free to stop the interview at any point or withdraw from without reason or reprisal (Health Research Authority 2017:12).

The study was adopted by the National Institute for Health Research (NIHR) Nottingham Biomedical Research Centre within Nottingham University Hospitals NHS Trust.

3.8.2 Privacy, confidentiality and anonymity

3.8.2.1 Privacy

As discussed in **Section 3.7.2.1,** participants have a right to have their privacy respected which includes the collection, storage, use and reporting of their data (Health Research Authority 2017:13) and the study design ensured that this was adhered to.

Data were collected using one to one interviews which were audio recorded. Women were free to decline to answer certain questions or choose not to divulge certain information if they feel this is an invasion of their privacy (Bryman 2016:131). Data were transcribed, deleted from the electronic recording device and saved onto a password protected memory stick and the secure university server.

3.8.2.2 Confidentiality and anonymity

The study design ensured that participants right to have their privacy respected when participating in research was respected (Health Research Authority 2017:13). Informed consent is again a key element in ensuring confidentiality and anonymity, with participants having explicit understanding of what will happen not only during data collection (the interview) but also the outcomes such as publications (Smith et al. 2012:53). Prior to starting the interview, it was checked that the participant had a Participant Information Sheet (**Appendix 7**) (all participants had one sent at the time the interview was arranged) and the

consent form was completed by the participant. The informed consent form (A**ppendix 8**) included a statement about consent to direct quotes being used anonymously and also about withdrawal mechanism which is an important element of protecting and ensuring confidentiality and anonymity (Smith et al. 2012:53). Participants were allocated a participant ID which they could use for withdrawal from the study, and this was put on the informed consent form and attached to the audio-recording and transcription. To ensure confidentiality and anonymity the consent form and audio-recording/transcription were not kept in the same location, with the informed consent form being kept in the study file in the BRC and in the NHS patient record and data being kept as outlined above.

3.8.3 Deception, risk of harm and exploitation

3.8.3.1 Deception

There was no deception in the study, with women being fully informed about the nature of the study and how their data would be used as outlined in the Participant Information Sheet used in the interview study (**Appendix 7**).

3.8.3.2 Risk of harm

Participants have the right to protected from harm during participation in research, including physical harm, loss of self-esteem and stress (Diener and Crandall 1978:19). The participants were at additional risk due to the sensitive nature of the research topic and these considerations are discussed in **Section 3.8.3.2.1**.

Interviews may be considered to be more of a burden on participants in terms of time compared to other data collection methods, and can be considered to be intrusive depending on the questions asked (Bryman 2016:494). Participants were free to stop the recording,

not answer questions or terminate the interview at any point. Participants were told about the nature of the interview both on the PIS and further discussion, and when the consent form was signed.

3.8.3.2.1 Potential harm with research on sensitive topics

Asking women to recall their pregnancy and birth experience needs careful additional ethical consideration about the potential risk of harm as it is considered to be a sensitive and emotive topic and the risk of psychological harm or emotional distress through the inclusion of women who's pregnancy may not have resulted in a live baby required careful consideration. However, it was felt that additional distress may be caused if these women wanted to participate but were unable to. To participate in an interview, women needed to have given birth within the last five years, however, it was not specified that that this needed to be a live birth. Only women who had given birth to a live baby received an invitation to study letter, however the study was advertised through social media platforms and posters and if women wanted to share their experience of a pregnancy which did not result in a live birth they would be able to.

The risk of harm of psychological distress to the researcher when researching sensitive topics was also given careful consideration, as the interviews were only semi structured and therefore the women could discuss whatever was important to them. 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.

3.8.3.3 Exploitation

There was no risk of exploitation as women had to initiate participation through contacting the researcher to arrange an interview. Participants received a text message on the morning of the arranged interview to ensure they still were happy to participate.

3.8.4 Sampling and recruitment

3.8.4.1 Sampling

Purposive sampling was also used for the interviews, as the views and experiences of a unique cohort of the population was being sought (Bowling 2014:209). Snowball sampling was used, with eligible women being told about the study by members of their specialist IBD care team (Bowling 2014:210). Due to the data analysis method used – Interpretative Phenomenological Analysis, a sample size of six was decided, as this would provide sufficient cases for meaningful points of similarity and difference between participants to be developed, whilst not being overwhelmed by the amount of data obtained and generated. This sample size is therefore in keeping with the principles of sample size for IPA as recommended by Smith et al. (2012:51).

The inclusion criteria comprised: women aged at least 18 years, who had been diagnosed with IBD prior to or during pregnancy, who had given birth in the last five years and had received either gastroenterology or maternity care at Nottingham University Hospitals. Nottingham University Hospitals NHS Trust was chosen as this would negate the need for a research passport and would enable to the study to be adopted by the NIHR Nottingham Biomedical Research Centre, which also assisted with participant identification. As participants had to only receive either maternity or gastroenterology care at NUH, they would not all necessarily have received the same model of care as women may have given birth

outside of NUH but received their gastroenterology care at NUH since giving birth. As the study is exploring individual experiences, the possible homogeneous sample in terms of place of care does have a significant impact as the study will not aim to provide any generalisations transferable to the larger population of women living with IBD during pregnancy.

Additional recruiting sites were considered but due to the number of participants required were not considered to be necessary. However, should recruitment have proved challenging, this was considered to be an appropriate expansion of the study.

3.8.4.2 Selection

The participants were recruited from the IBD clinics at Nottingham University Hospital NHS Trust. NUH is a is a tertiary-level care academic institution covering a population of approximately 1 million people for secondary-level care and 4.5 million people for tertiary-level care. Collectively it manages approximately 5000 IBD patients' long term. Recruitment was done by the clinical care team, through sending an invitation letter and Participant Information Sheet to eligible women. There are six IBD nurses who are existing members of the clinical team that are key in identifying possible study recruits through the British Society of Gastroenterology IBD Registry – an IBD database of all existing Nottingham IBD patients.

Participants were also recruited though the NIHR Nottingham Biomedical Research Centre at University of Nottingham, where there is a database of patients who are happy to be contacted about upcoming studies and we will search that for eligible patients. Prospective participants were sent an invitation letter along with the participant information sheet.

Using the study flyer with relevant contact details, the study was advertised in Nottingham University Hospitals NHS Trust, in departmental Facebook© and Twitter© posts and in any

departmental mailing/ emailing lists to people who have agreed to be contacted with such information.

Women were offered either a face to face interview held at Nottingham University Hospitals NHS Trust, a home visit or a telephone or skype interview. Location of the woman and personal preference or circumstances of the woman were recognised as possible influences over the type of interview, however all women chose to have a face to face interview at their home. NUH covers a large geographical area, however it was felt that the benefits face to face interviews would have, especially as IPA was being used, would far outweigh the convenience of a skype or telephone interview from a researcher perspective, although had this have been the preference of the participant then this would have been arranged.

3.8.5 Data collection and analysis

Qualitative data were collected through one off, semi-structured, one to one interviews. The results are presented in **Chapter 5**.

3.8.5.1 Recruitment

Participants were recruited through study invitation letters (**Appendix 11**) sent by the BRC and the specialist IBD nurses to eligible women, posters in relevant departments (**Appendix 9**), including maternity and gastroenterology, information posted on social media (**Appendix 9**) and word of mouth. **Table 13** shows how the participants were recruited.

Table 13: Recruitment

Information source about study	Number sent	Number of recruits
Invitation letters sent by the BRU	9	2
Invitation letters sent by the IBD specialist nurses	21	1
Posters in gastroenterology	N/A	0
Posters in maternity units	N/A	1
Social media posts	N/A	2
Word of mouth	N/A	1

3.8.5.2 Data collection

Qualitative data were collected using semi-structured interviews as this would initiate a conversation between myself as the researcher and the participant (Flick 2015:140). A flexible interview tool was prepared (**Appendix 4**). A flexible interview tool was prepared, aiming to facilitate a comfortable interaction between the interviewer and participant which would enable them to give a detailed account of their experiences (Smith et al. 2012:59). The questions were open and expansive, with the first question being "starting from the beginning, tell me about your pregnancy" which enabled the participant to recount their experience descriptively. It also enables the participant to become comfortable talking (Smith et al. 2012:60). The other questions and prompts were open and did not make assumptions or lead them towards certain answers.

The interview questions, prompts and probes were reviewed by the supervisory team and the PPI representative, and the interview questions, prompts and probes were trialled with a woman who had a new baby. Following this trial, it became apparent that one question specifically did not elicit a response relevant to experiences of pregnancy and IBD. This was a question about what was important to women during their pregnancy. It was anticipated that this would elicit responses around pregnancy care, social networks, medication and knowledge, and instead prompted a response about the accessibility and availability of fashionable maternity wear. Whilst this was acknowledged as being important to this particular individual, it raised the awareness that this question may not be useful in exploring women's experiences of pregnancy and IBD specifically as too broad. The question was removed and was replaced with prompts and probes around pregnancy care, social networks, medication and knowledge.

All interviews were audio-recorded with seven women and took place face to face and in the woman's home, as per their preference. Interviews ranged in length from just under 15 minutes and just over 60 minutes. Although there is a considerable difference in times the interviews lasted, the quality and depth of the information gathered in each interview was deemed equitable.

The opening questions were:

Starting from the beginning, tell me about your experience of pregnancy

When needed, prompts and probes were used as illustrated in **Appendix 4** to help encourage elaboration or further discussion on areas of particular interest or to help aid the flow of the interview if needed.

The audio-recordings were manually transcribed verbatim within 24 hours after the interview and this was saved as word document, with informant checking was not being undertaken

due to the interpretation element of the data analysis which meant that findings were developed beyond the participants initial description. The process used for interpreting the data is described in **Chapter 3**.

3.8.5.3 Data analysis

A total of seven one-off, one to one, face to face interviews were undertaken and audio-recorded with seven participants, meaning each participant was interviewed once. The names of the women have been changed to pseudonyms to preserve anonymity. The audio recordings were transcribed verbatim and then the data from the interviews were analysed using the six steps of Interpretative Phenomenological Analysis (Smith et al. 2012:82-100) as shown in **Table 14**. Whilst some qualitative methods encourage the analysed transcribed interview to be returned to the participant for sense checking, as IPA is underpinned by researcher interpretation this is therefore not appropriate.

Table 14: The six steps of Interpretative Phenomenological Analysis

	Step	Description (Smith, Flowers, and Larkin 2012)
Step 1	Reading and re-reading	Immersing in the data - reading and re-reading the written transcript, whilst listening to the audio recording at least once. Recording observations and recollections of the interview
Step 2	Initial noting	Examines semantic content on an exploratory level – usually a commentary on the transcript, which leads to familiarity of the transcript and identify specific ways in which the participant talks about, understands and thinks about issues. A descriptive core of comments will develop with a phenomenological focus and stay close to the participant's explicit meanings.
a	Descriptive comments	Key words, events phrases and explanations are recorded from the

		transcript at face value whilst highlighting the objects which structure the thoughts and experiences of the participant.
b	Linguistic comments	Concerned with the use of language and how meaning and content of the interview are presented.
c	Conceptual comments	Requires a shift towards the participants understanding of the topics they are discussing, which involves personal reflection of the analyst
d	Deconstruction	Involves occasionally de-contextualising the interview to ensure that the participants words and meanings remain in focus, which helps see the interrelationships between experiences
Step 3	Developing emerging themes	The data will have substantially grown after the exploratory commenting and will decrease during this stage whilst maintain the level of complexity. Themes are usually attached to a piece of transcript, however the hermeneutic circle ensures that “the part is interpreted in relation to the whole; the whole is interpreted in relation to the part”(Smith et al. 2012:92).
Step 4	Searching for connections across emergent themes	By step four there will be a set of themes which are ordered chronologically within the transcript, which are mapped and organised in this step
a	Abstraction	Abstraction involves looking for patterns between emergent themes, and renaming the cluster of themes (super-ordinate themes)
b	Subsumption	Subsumption involves giving an emergent theme a super-ordinate status to enable related themes to be brought together
c	Polarization	Polarization focusses on differences rather than similarities
d	Contextualization	Contextualization involves looking at the connections between emergent

		themes through identifying contextual and narrative elements
e	Numeration	Numeration involves looking at the frequency with which an emergent theme occurs throughout the interview. It is only one indication of importance and should not be over-emphasised in terms of importance.
f	Function	Emergent themes are examined within the transcript for their specific function, and enables the way in which the participant presents themselves to be interpreted beyond what the participants present as their meaning
Step 5	Moving to the next case	Each case must be treated individually with the emergent themes from previous cases being bracketed. Whilst the process with subsequent cases will be influenced from findings from previous cases, the skill and systematic approach with IPA allows new themes to emerge independently.
Step 6	Looking for patterns across cases	This step involves looking across all cases for patterns and connections. This may lead to relabelling themes
a	Taking it deeper: levels of interpretation	IPA enables different levels of interpretation; however, caution is needed to avoid being too descriptive – a common flaw of inexperienced researchers
b	Working with larger samples	A sample size of up to six is sufficient for a good IPA study for a student project, with three being advocated as an optimum number, however IPA studies can be used with larger sample sizes. Recurrence is important in larger samples, with emergent themes needing to be present in some or all of the cases which is decided by the researcher.

Adapted from Smith et al. (2012:82-100)

Data were analysed using the six steps of IPA with each interview were analysed in turn, with the transcript being read and re-read to enable becoming immersed in the original data, whilst also listening to the recording during reading. This ensures that the participants become the focus of analysis. This detailed process outlined enables the voices of each participant to be heard whilst analysing the data in a systematic way. Data analysis took in the region of five months and this is in line with what is outlined by Smith, Flowers, and Larkin (2012:55) who suggest anticipating at least two months full time for analysing three cases. This recognised time needed for data analysis indicates the depth of analysis which is undertaken with IPA.

3.8.6 Trustworthiness and authenticity

Rigour is usually associated with quantitative research methods and is concerned with reliability and validity. However, how appropriate these are for qualitative research methods is debatable (Bryman 2016:385) and Lincoln and Guba (1986) proposed new criterion which established alternative ways of establishing and assessing the quality of qualitative research using two criterion: trustworthiness and authenticity. Steps were taken to ensure trustworthiness and authenticity during the analysis process which supports confidence in the findings.

Table 15 shows each criterion for trustworthiness, what this is the equivalent to in terms of quantitative research and how this was applied to the study.

Table 15: Trustworthiness and authenticity

Trustworthy criterion (Lincoln, Y . Guba 1986)	**Quantitative research equivalent criteria**	**Summary of criteria**	**Application to study**
Credibility	Internal validity	As there are more than one version of events, the researcher must therefore determine which version is credible and acceptable to others. Credibility of findings requires ensuring research is undertaken in accordance with the principles of good practice and submitting findings to the members of the social world who were studied to ensure the researcher has correctly understood that social world	Research Protocol adhered to, with HRA ethical approval gained Involvement of Patient Public Involvement representative, who is a woman living with Inflammatory Bowel Disease and moderates a peer support group for others living with the disease, during all stages of the study, including reviewing the findings
Transferability	External validity	Typically entails intensive study of a small cohort, or individuals sharing certain characteristics, findings are particular to a specific aspect of a social world being studied. Therefore, findings may or may not have some transferability to other social worlds as aspects of this, however this is to be judged by the reader based upon the details provided around the culture of those studied.	Detailed 'thick' description of the cohort of women being studied and how the findings emerged. Supervisory team reviewed findings, and the research process
Dependability	Reliability	Researchers should adopt an 'auditing' approach which requires them to keep complete records of all of the research process : participant selection, notes, transcripts, decision making, which can be reviewed by	Reflective journal kept during the study which detailed decision making and was shared with the Progress Review Panel each year as part of the formal assessment, which included an

		peers who can 'audit' these records to establish whether proper procedures have been followed	expert in IPA. It was also shared with the Director of Studies. The stages of extensive analysis IPA were carefully followed, with each stage being saved as formal records (**excerpts are shown in appendix 16)** and demonstrating the transparency of the study process
Confirmability	Objectivity	Recognition that complete objectivity is impossible, therefore the researcher shows that they have acted in good faith and not overtly let personal values or theoretical inclinations influence the conduct of the research	Reflexivity is discussed in **Section 7.4** and acknowledges the personal attributes which may have had some influence over the study and identifies the impact of any potential influence
Authenticity	Fairness Ontological authenticity Educative authenticity Catalytic authenticity Tactical authenticity	Are different viewpoints fairly represented? Does the research help individuals to understand their social environment? Does the research help individuals appreciate the perspectives of those within their social environment better? Has the research encouraged individuals to engage in action change within their circumstances? Has the research empowered individuals to become actively engaged in action?	Authenticity criterion were used throughout the study to generate thought-provoking discussions and decisions.

The appropriateness of trying to demonstrate reliability and validity within a qualitative study is questionable, however the importance of being able to demonstrate that the research has been undertaken with a rigorous, systematic process is essential and Lincoln and Guba (1986) provide criterion for this, which were used within the study.

3.8.7 Data integration within methodological triangulation

This thesis presents two independent studies which address the specific aims of the study, the embedded mixed methods approach (outlined in **Section 3.5**) has determined the process for undertaking the study, however the principles of methodological triangulation are required to ensure that the combination of data does not adversely impact on the validity. The primary data were collected through one to one interviews which were analysed using IPA, with the supplementary data being collected through an anonymous online survey. Different data collection methods were needed to ensure that the objectives of the study were met which ensured the research question could be fully answered.

Mayoh and Onwuegbuzie (2015:92) provide some guidance about how to specifically integrate data obtained from different methods when one is phenomenological. The quantitative data may inform the phenomenological focus of the study, as in the case of this study, where the findings of the survey were used to identify any themes to be explored through prompts in the interviews.

The data collected from the interviews and analysed using IPA were the primary data, and steps were taken to ensure that the study remained faithful to the principles of IPA. The supplementary data from the online survey was analysed prior to undertaking the one to one to interviews as this ensured that the process of data analysis would not influence the analysis of interviews as it may if done concurrently.

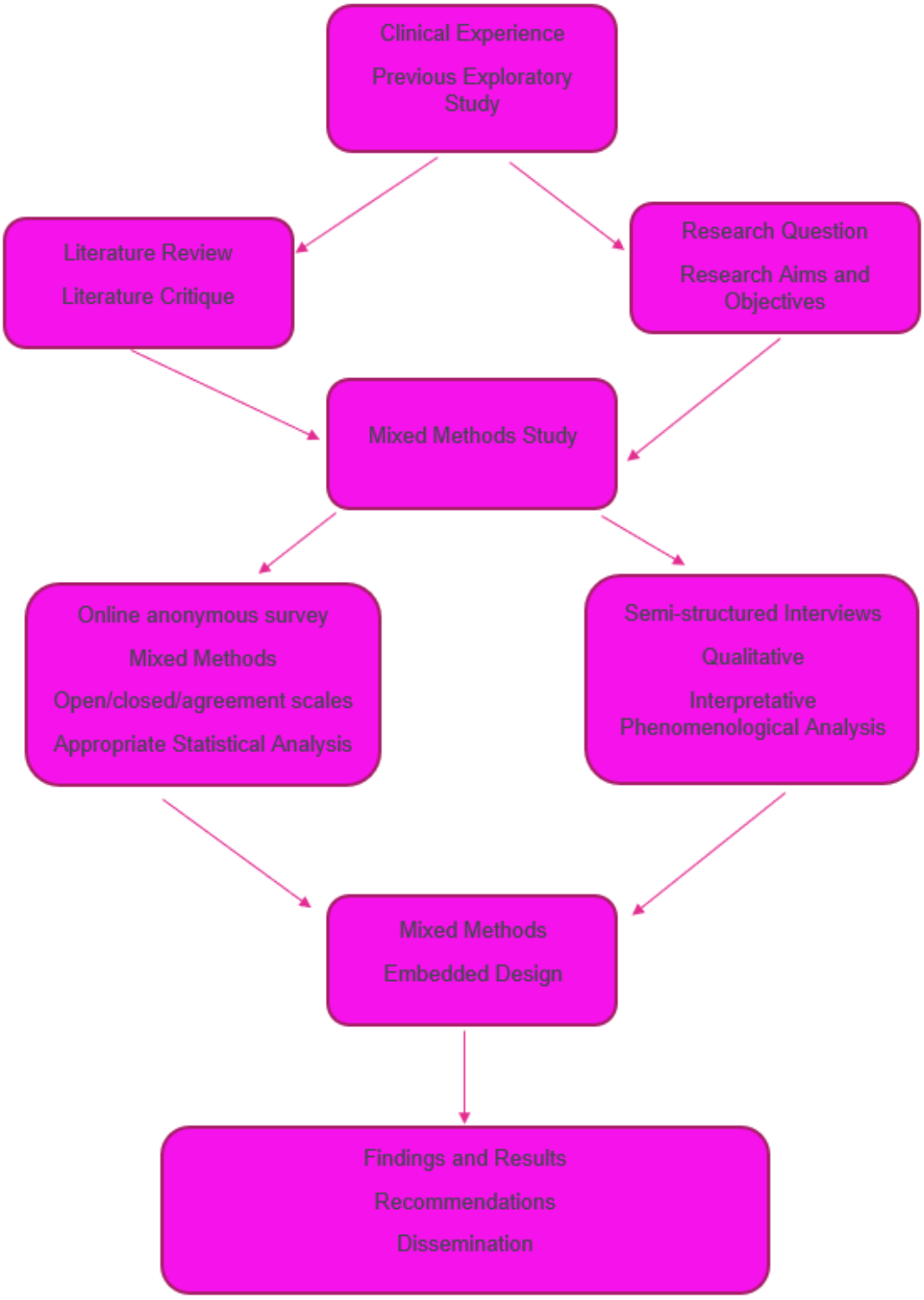
3.9 Chapter Summary

This chapter has discussed the theoretical foundations of the study and design and methods required to address the research question aims and objectives of the study.

The epistemological and ontological positions have been discussed, and differing positions for each objective within the study have been justified as highlighted in **Figure 5**. As the research question requires multiple objectives to ensure it is fully answered, a mixed methods approach is needed with the embedded design being the most appropriate design. The two independent studies, the online survey and the one to one interviews have their own specific ethical considerations, and these have been considered and discussed, with the relevant ethical approvals sought. Careful consideration of most appropriate data collection methods and analysis have been discussed and justified, including how the principles of methodological triangulation will be used within the study. **Figure 10** outlines the study design and process.

Chapter 4 will present the results and findings of the online survey, and **Chapter 5** will present the findings of the one to one interviews.

Figure 10: Study design and process



Chapter 4: Survey results and findings

4.1 Introduction

This chapter will present the findings and results of the online survey. Data was collected using an anonymous online survey, containing closed and open-ended questions, and agreement scales, as outlined in **Chapter 3**. Quantitative data was analysed using univariate and bivariate analysis, whilst qualitative data was analysed using thematic analysis.

The survey provided primarily quantitative data, with qualitative data being obtained from the free text responses.

4.2 Participants, recruitment and characteristics

The anonymous online survey was live for a total of 17 weeks, with the link being distributed through social media platforms, primarily Facebook and Twitter.

A total of 50 women completed the survey and the characteristics being presented in **Table 16**. The women were aged between 29-63 at the time of completion, with the age range at the time of diagnosis being between six and 39 years. Standard deviation was undertaken for the ages at diagnosis and the ages at completion.

Table 16: participant characteristics

Characteristic	
Number of women who completed the survey	50
Type of IBD: ulcerative colitis	28
Type of IBD: Crohns disease	22
Age range at time of completion of the survey	29-63 years
Mean age at time of completion	40 years SD 6.813
Median age at time of completion	39 years
Mode age at time of completion	35 years
Age range at time of diagnosis of IBD	6-39 years
Mean age at time of diagnosis of IBD	23 years SD 6.6.17
Median age at time of diagnosis	24 years
Mode age at time of diagnosis	25 years
Time since last pregnancy in years	0-34 years

As shown in **Table 16**, 28/50 women (56%) had a diagnosis of Crohns disease and 22/50 women (44%) has a diagnosis of ulcerative colitis. Nearly all women were diagnosed with IBD prior to pregnancy, with two women being diagnosed during pregnancy.

4.3 Quantitative results

4.3.1 Pregnancy history

Women were asked about their previous pregnancy history using closed and open-ended questions.

4.3.1.1 Previous pregnancies

For women to be eligible to complete the survey, they needed to have been diagnosed either prior to or during pregnancy. As shown in **Table 16**, nearly all of the 50 women who completed the survey, received a diagnosis of IBD prior to pregnancy with two women being diagnosed with IBD during pregnancy. However, nine women had experienced pregnancy prior to their diagnosis and had subsequent pregnancies since diagnosis making them eligible for the study, with six women having had one baby and the remaining women having had three or more babies prior to diagnosis. Of these nine women, one woman was pregnant for the first time at the time of completion since diagnosis. Of the two women who were diagnosed during pregnancy, one had given birth prior to diagnosis whilst the other was pregnant for the first time when she was diagnosed.

Not all women had given birth at the time of completion of the survey, with a small number of women still being pregnant having had no other children and one woman being pregnant for the first time since diagnosis of IBD. However, most women had given birth since their diagnosis.

Figure 11 shows the number of babies born to women pre and post diagnosis of IBD, with most women having given birth to one or two babies after diagnosis. Women were also

asked how long ago their most recent pregnancy was, as this was the pregnancy that the survey questions related to, and this is shown in **Figure 12**.

Figure 11: Number of babies born to women prior to diagnosis of IBD (pink) and post diagnosis of IBD (blue) (n=50)

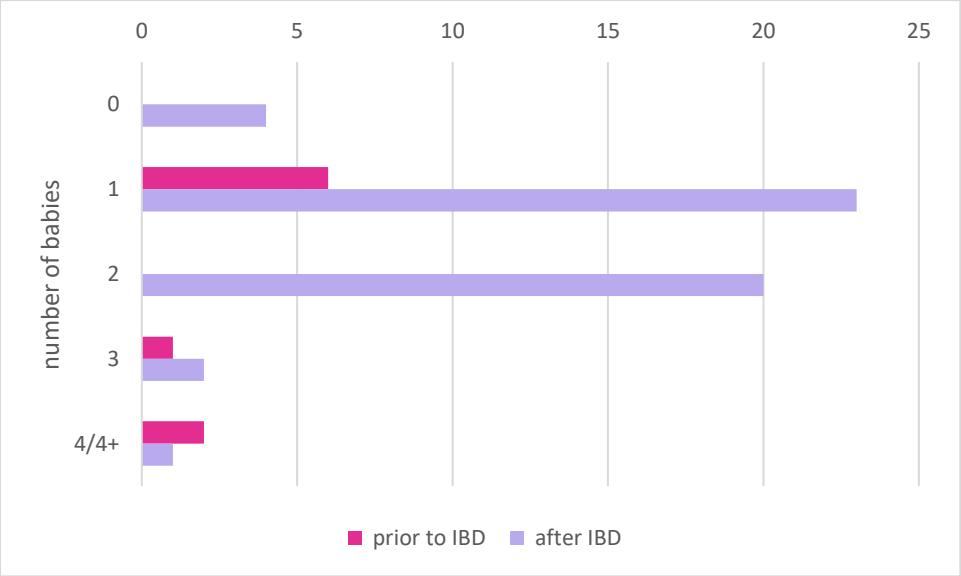
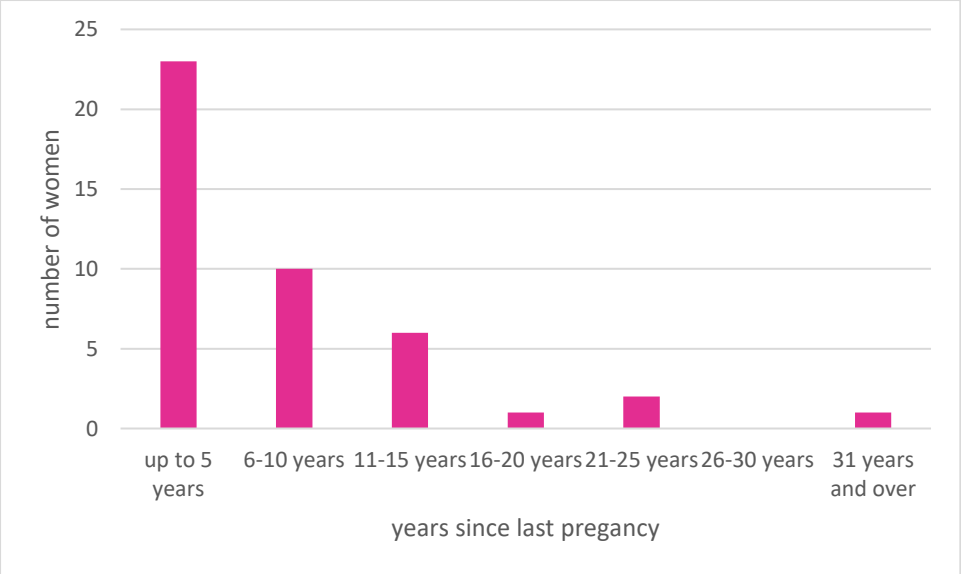


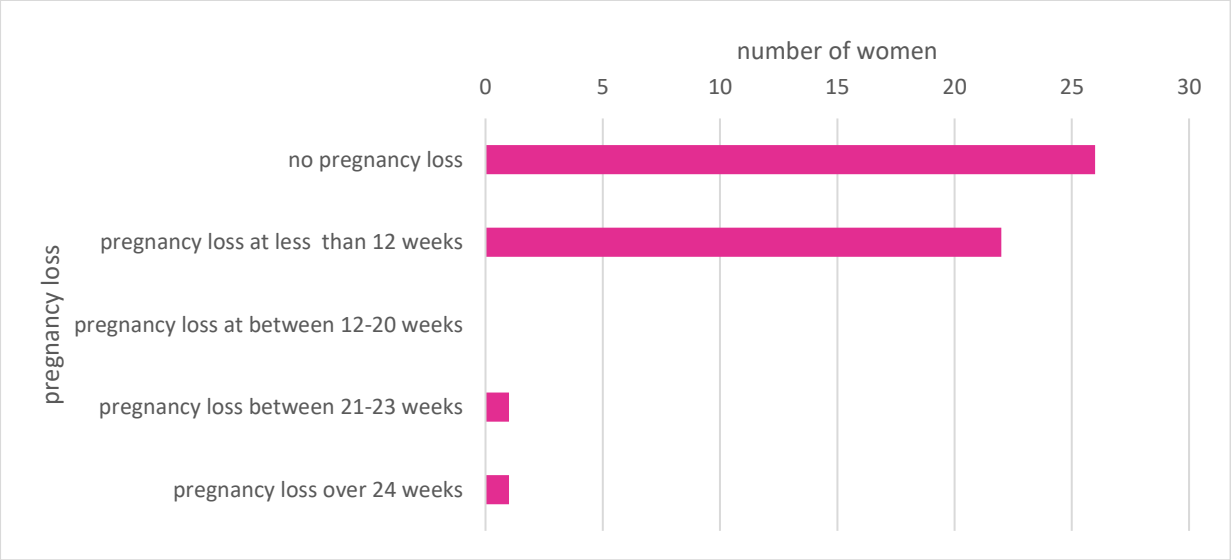
Figure 12 shows the distribution of years, with most women having given birth within the last 12 years.

Figure 12: Frequency of time since most recent pregnancy (n=43)



Women were also asked about pregnancy loss, with nearly half identifying as having experienced a pregnancy loss (pregnancy loss encompasses the death of an embryo or fetus). The number of women experiencing a pregnancy loss and gestation at which this occurred is shown in **Figure 13**, with the majority of pregnancy losses occurred before 12 weeks gestation.

Figure 13: Incidence of pregnancy loss (n=50)



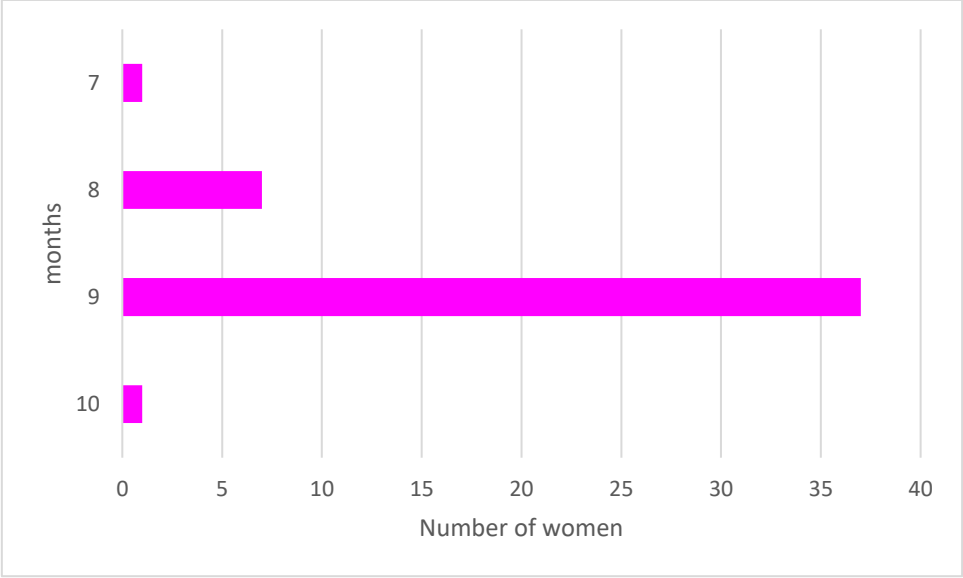
4.3.1.2 Length of pregnancy

Women were asked about their longest duration of pregnancy in months (months is the most commonly used timeframe of pregnancy by women) and these are shown in **Figure 14.** Most women experienced pregnancy duration of at least nine months and this is considered to be full term, however nearly a fifth of women had pregnancy duration of less than nine months and this is considered to be a preterm birth. Preterm birth is when a baby is born before 37 weeks of pregnancy (less than 9 months).

Women were also asked about preterm birth, and a fifth of women stating they had a preterm birth after their diagnosis of IBD and one woman had a preterm baby prior to her

diagnosis. A small number of women identified as having had a longest pregnancy duration of eight months but did not identify as having had a preterm birth. However, it is recognised that this is not a significant finding due to the small numbers. One woman answered 'no' when asked, and one omitted this question. Both women had not given birth prior to their diagnosis of IBD therefore had experienced a preterm birth following diagnosis of IBD. The adjusted number of women who had a preterm birth following diagnosis of IBD is therefore 11/46 due to four women still being pregnant at the time of completion.

Figure 14: Longest duration of pregnancy (n=46)



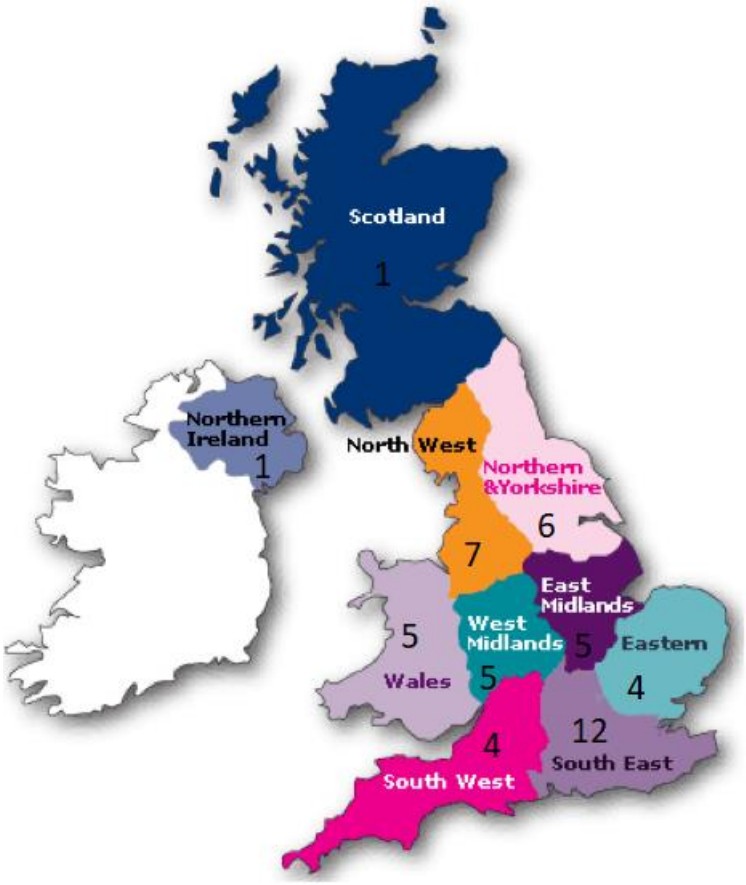
4.3.1.3 Recent pregnancy

The questions in the survey mainly related to the most recent pregnancy, and women were asked if this pregnancy was planned and also how long ago the most recent pregnancy was. Pregnancy was planned for most women , whilst the length of time from the last pregnancy varied from 11 weeks to 34 years.

Women responded from all over the UK, including Scotland, Northern Ireland and Wales,

and were asked which region they lived in during their most recent pregnancy, and **Figure 15** shows the locations and frequencies.

Figure 15: Region of care



4.3.2 Pregnancy care

Women were asked about their pregnancy care through closed ended questions, open ended questions and agreement scales.

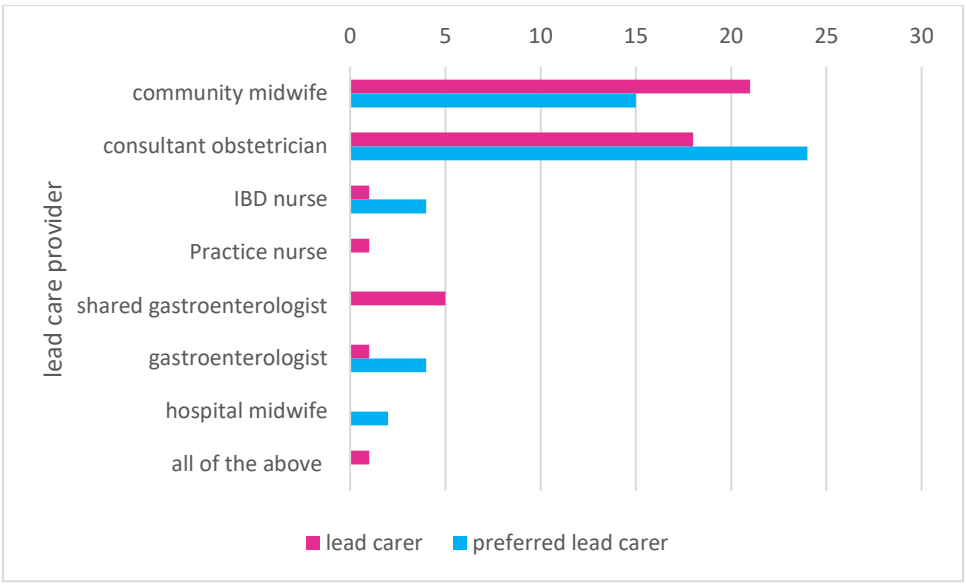
4.3.2.1 Health care provider during pregnancy

Women were asked through multiple choice questions who the lead care provider during their pregnancy was and were then asked who they would have preferred to have led their care during their pregnancy.

A community midwife was the most common lead care provider for most women, with the majority of the remaining women seeing a consultant obstetrician. Other lead core providers were also identified as outlined in **Figure 16**. Women's preferences for who would be the lead carer provider, with most women saying they would have preferred a consultant obstetrician to have led their pregnancy care, with the majority of the remaining women preferring to have a community midwife lead their care. A number of women stated they would have preferred their care to have been led by an IBD nurse or a gastroenterologist and two women would have preferred a hospital midwife.

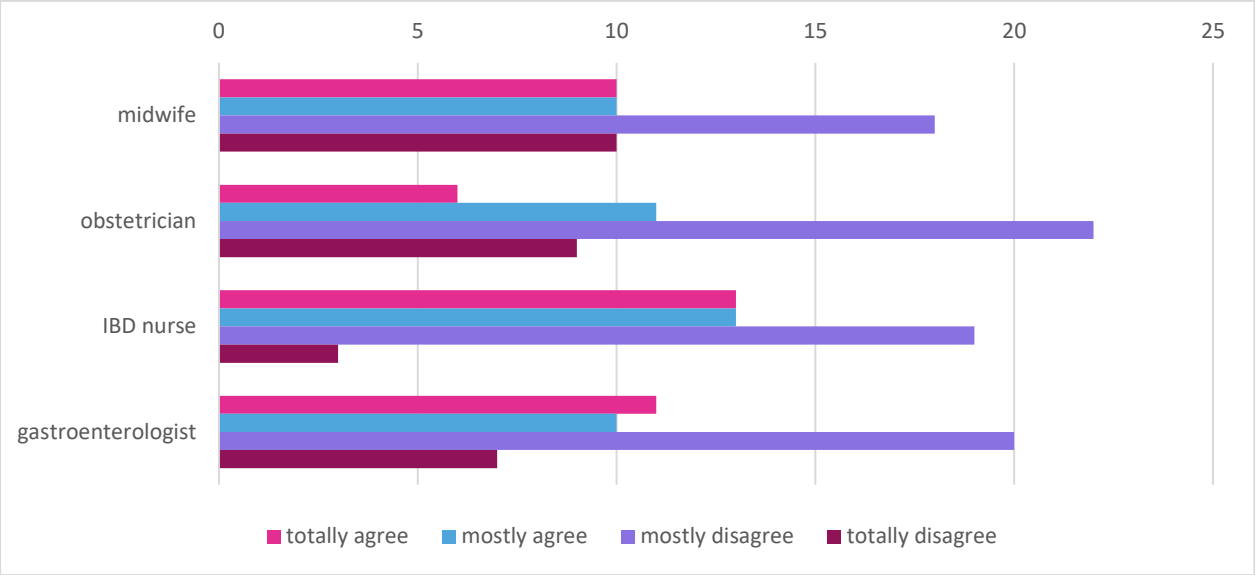
The comparison of lead care provider and preferred lead care provider is demonstrated in **Figure 16.**

Figure 16: Lead care provider and preferred lead care provider during pregnancy (n=49)



Women were given a series of statements to agree or disagree with about their care provider during pregnancy, including the frequency of interactions with relevant health professionals and the results are shown in **Figure 17.** Details about the number of interactions was not asked.

Figure 17: Satisfaction with frequency of interactions in response to 'I would have liked more interactions with this health professional' (n=48)



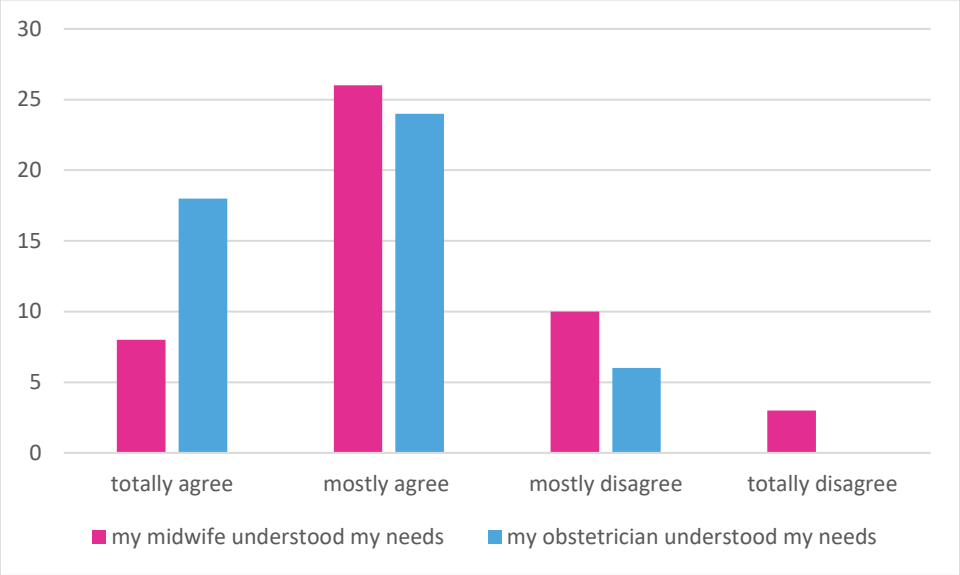
Women were generally happy with the number of interactions they had with their healthcare providers, however expressed they would have liked to have seen their IBD nurse more often.

Women were asked about their confidence in their lead care providers and **Figure 18** shows whether women had confidence in their care provider, with most women having confidence in their lead care provider, with the exception of the one woman whose gastroenterologist led her care, where she reported that she did not have confidence in her lead care provider.

Figure 18: Confidence in lead care provider (n=47)

When asked if their midwife or obstetrician understood their needs, the majority of women felt that their midwife and obstetrician understood their needs, however more felt more strongly that their obstetrician understood their needs than their midwife. A small number of women felt that their obstetrician did not understand their needs, compared with women higher number of women who felt their midwives did not understand, with some women feeling strongly about this lack of understanding. **Figure 19** highlights these results.

Figure 19: Understanding needs (n=47)



4.3.2.2 Information giving

Women were asked specific questions about information they received, which included using an agreement scale about if they received tailored information to their needs, with nearly a quarter of women disagreeing that they received tailored information and the remaining women stating they received tailored information.

Women were also asked about whether mode of birth was discussed during pregnancy, with most women responding that mode of birth was discussed.

As highlighted in **Section 4.3.1.1**, nearly a fifth of women had experienced pregnancy both pre-and post IBD diagnosis and women were asked to identify if there were any differences in care. Data needed to be corrected for this response, as six women selected 'no' despite having only experienced pregnancy post diagnosis. Following data correction, a third of women identified having no difference in pregnancy pre and post IBD diagnosis, and two

thirds of women answered that they had experienced a difference in care. When asked to specify, the comments in **Table 17** were made.

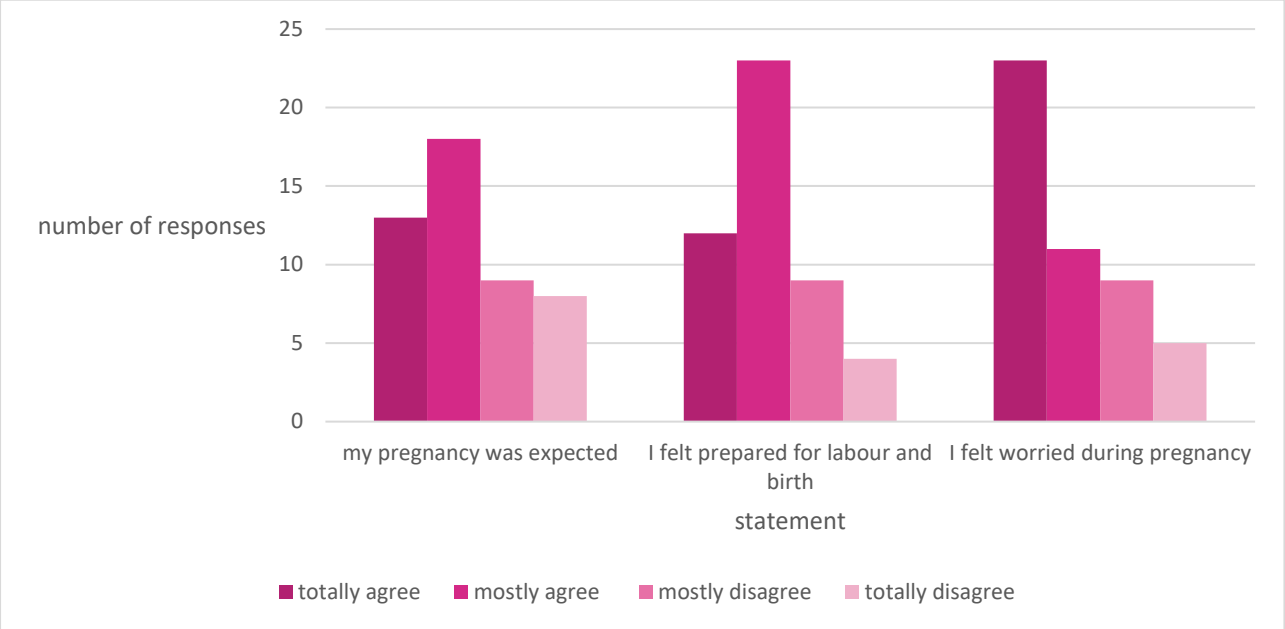
Table 17: Differences in care

Lack of experience of IBD and meds by midwifes. For example, being prescribed aspirin and iron tablets without considering the affects on my UC p45
More hospital appointment p41
Yes but that was only due to my being in a flare and my daughter having a disorder p37
Given steroids from 6-14 weeks to prevent miscarriage due to ulcerative colitis p26
Serial growth scans in view of medication p12
My second pregnancy was consultant led and I had much less input into how he would be born and where p7

4.3.3 Preparation for pregnancy and birth

Women were asked about their feelings about pregnancy and birth using agreement scales, as shown in **Figure 20**. When asked if they felt worried during pregnancy, most women totally or mostly agreed with the statement, with most of these women stating they totally agreed with the statement. Most women also either totally or mostly agreeing that they felt prepared for labour and birth. Pregnancy was as expected for most women, however of the just over a third of women who disagreed with this statement, with half totally totally disagreeing.

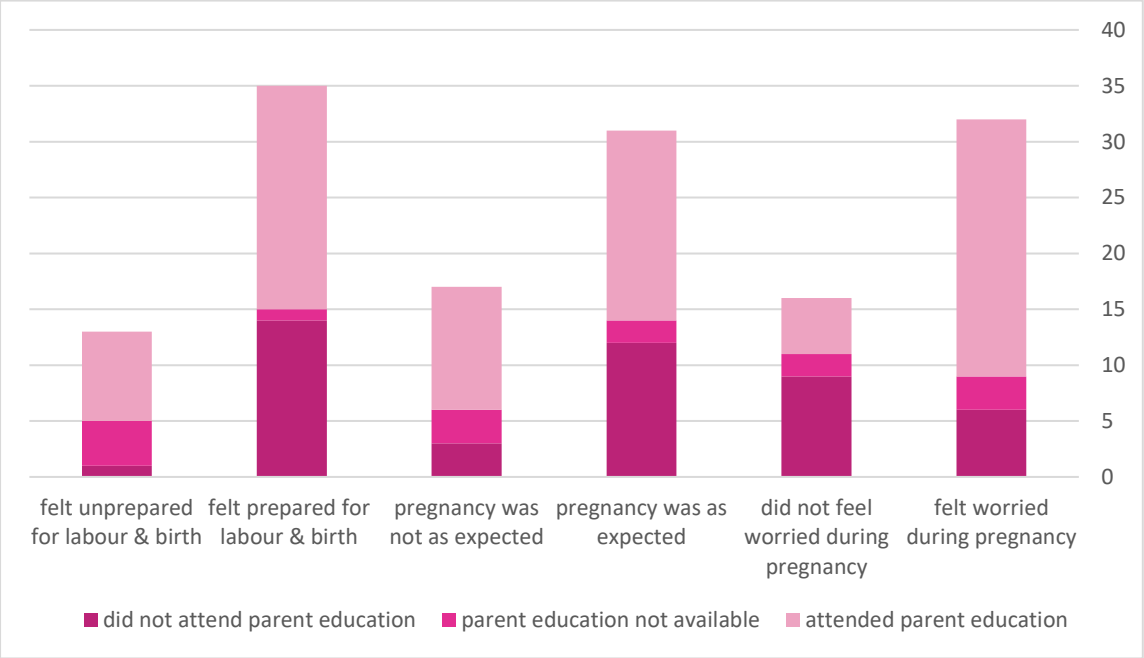
Figure 20: Feelings of preparation for pregnancy (n=48)



Women were asked about parent education classes, which can be either provided through the NHS maternity care provider or accessed privately. Of the 49 women who responded, over half (29/49) attended parent education classes, just under a third did not attend (15/49) and none were available for five women.

The impact of parent education on feelings of preparation for pregnancy and birth is shown in **Figure 21**. Of the women who did not attend parent education, just under half identified as feeling worried during pregnancy, compared to the majority of women who did attend parent education and women for who parent education was not available. Pregnancy was as expected for most women who did not attend parent education, for just over half of women who did attend parent education and for most of women when parent education was not available. Nearly all women who did not attend parent education felt prepared, with women who attended parent education also feeling prepared for labour and birth. However, only one fifth of women for who parent education was not available felt prepared, with majority feeling unprepared.

Figure 21: impact of parent education on expectations, preparation and worry (n=49)



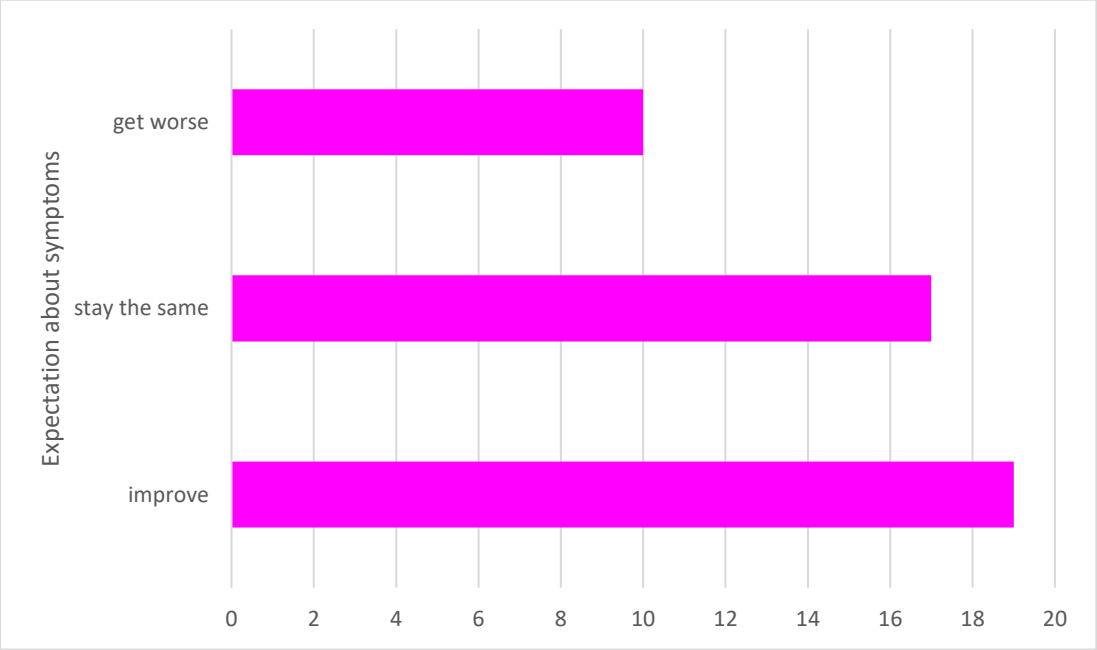
4.3.4 IBD symptoms

Women were asked about symptoms of their IBD prior to, during and after pregnancy including any advice they were given about symptoms.

4.3.4.1 Expected symptoms and advice

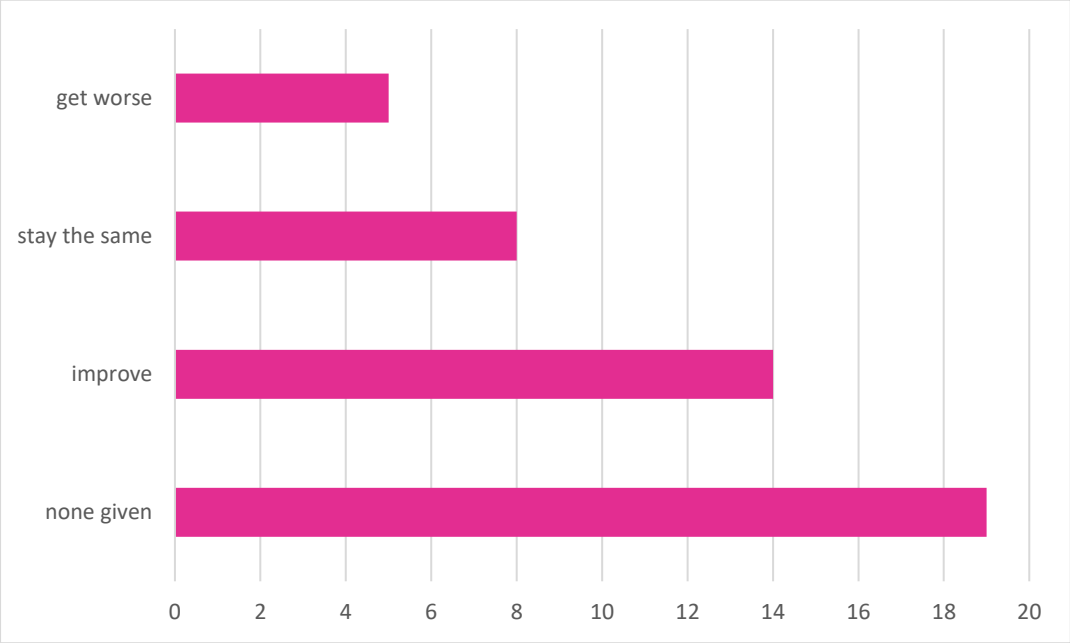
Most women expected their symptoms to get better or stay the same with only a fifth of women expecting their symptoms to get worse. This is shown in **Figure 22**.

Figure 22: Expectations about symptoms during pregnancy (n=46)



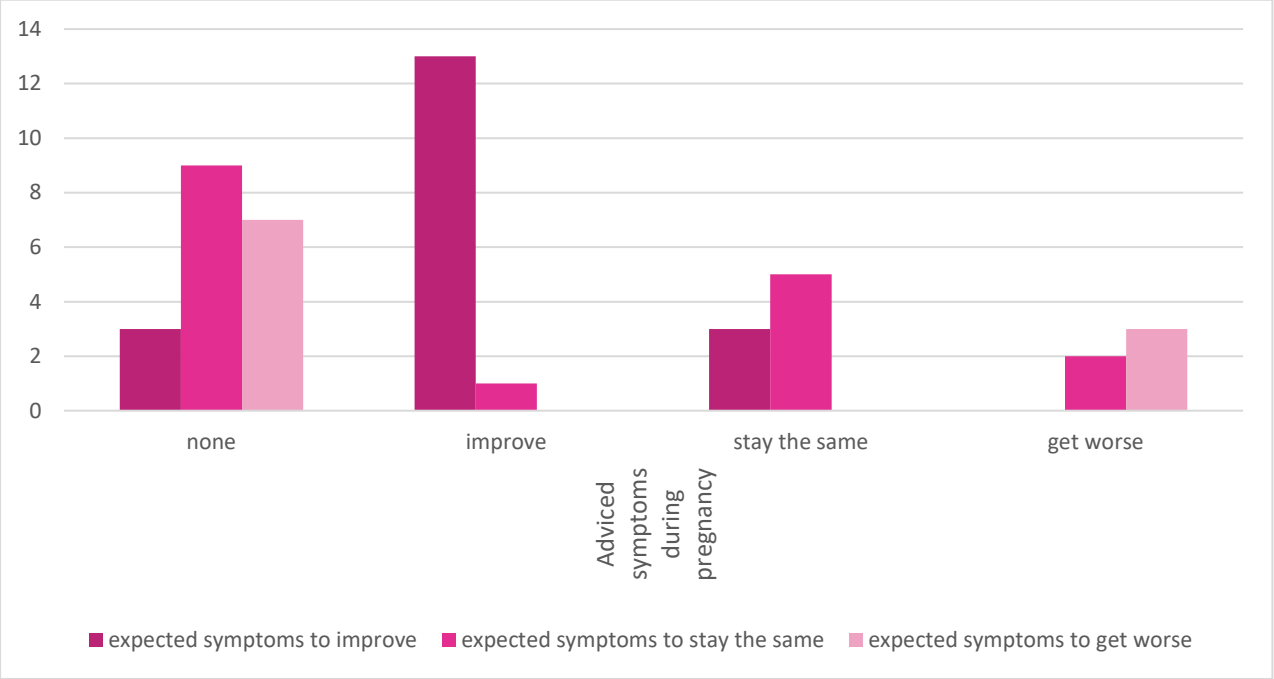
Of the women who were given advice about symptoms during pregnancy, nearly half were told they would experience an improvement in symptoms, a third were told to expect them to stay the same and a fifth of women were told to expect them to get worse. This is shown in **Figure 23**.

Figure 23: Advice given to women about symptoms during pregnancy (n=46)



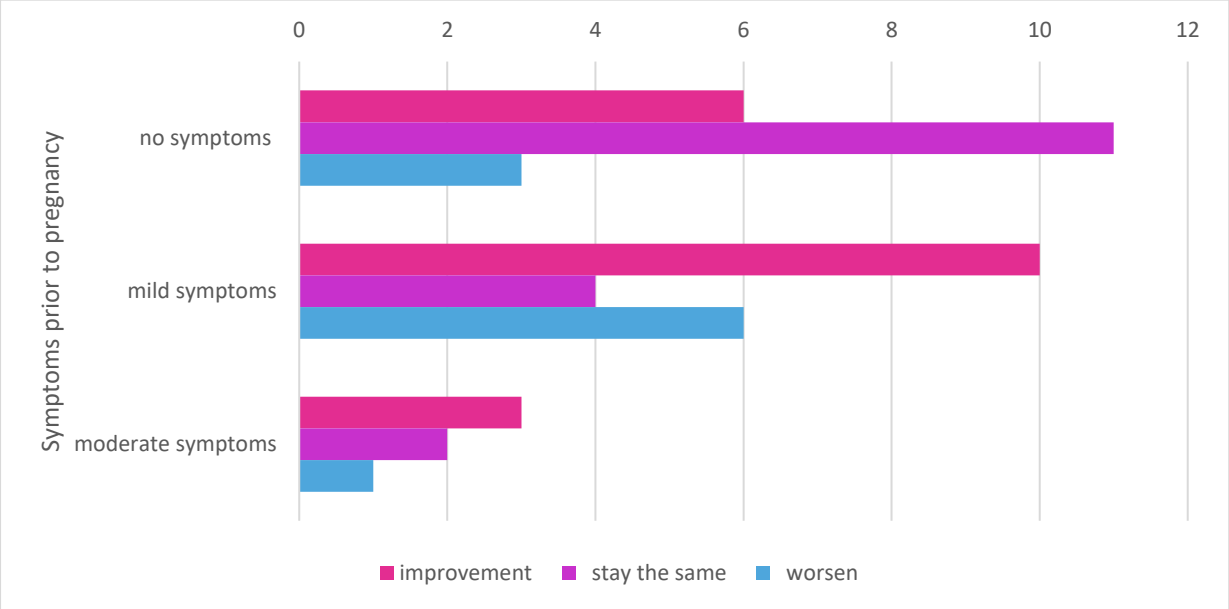
Women expectations were mostly consistent with the advice they were given as shown in **Figure 24**, with nearly all women expecting their symptoms to improve if this is what had been advised, and most women expecting their symptoms to be as they had been advised. For the women who did not receive any advice about their symptoms during pregnancy, 3/19 a small number thought they would improve, nearly half expected them to stay the same and the remainder thought they would get worse. Experiences of symptoms are discussed in **Section 4.3.4.2**.

Figure 24: Symptom expectations compared with the advice given (n=46)



The relationship between symptoms prior to pregnancy and what women expected of their symptoms during pregnancy was also explored, as shown in **Figure 25**.

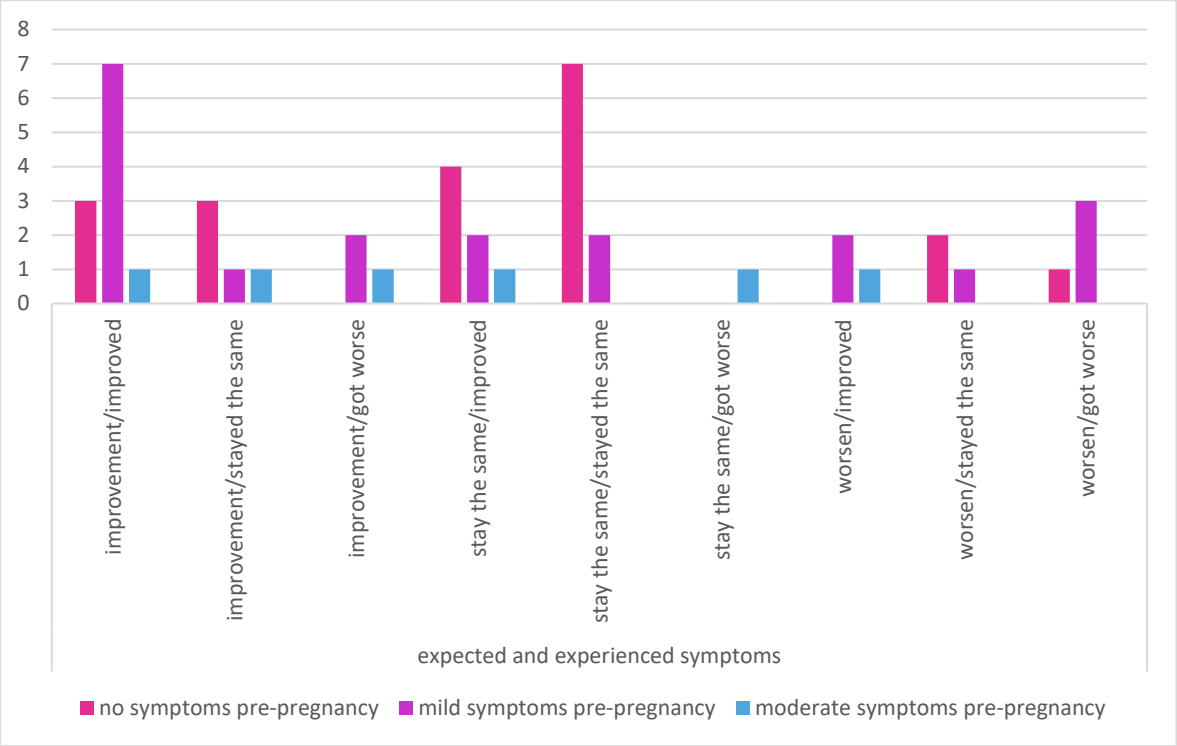
Figure 25: Expected symptoms with symptoms prior to pregnancy (n=46)



Of the 20 women who were not experiencing any symptoms in the three months prior to pregnancy, most expected either an improvement or that they would continue through pregnancy with no symptoms. The remaining women expected their symptoms to get worse. Mild symptoms prior to pregnancy were reported by 20 women, with most expecting their symptoms to improve or remain mild for the duration of their pregnancy. The remaining women expected their symptoms to get worse. For the women who were experiencing moderate symptoms prior to pregnancy, half expected their symptoms to improve during pregnancy, whilst the other half expected their symptoms to either remain moderate or get worse.

Of the women who had no symptoms prior to pregnancy, expectations were matched to their experience, with the majority of the remaining women experiencing an unexpected improvement in symptoms. For the women with mild symptoms pre-pregnancy over half also experienced what they expected, with majority of the remaining women also experiencing an unexpected improvement in symptoms. For the women who had moderate symptoms, only one woman experienced what she expected, with the remaining women experiencing an unexpected improvement in symptoms or experiencing an unexpected worsening of symptoms. This is shown in **Figure 26**.

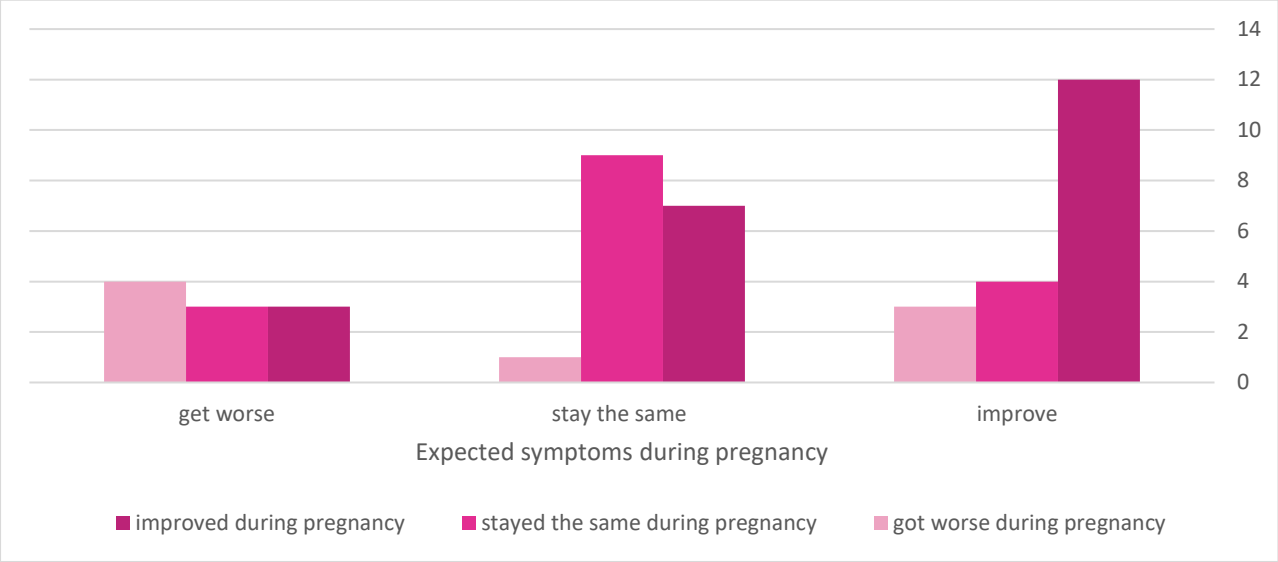
Figure 26: Pre-pregnancy symptoms and expected and experienced symptoms (n=46)



4.3.4.2 Experienced symptoms

Women's expectations about their symptoms of IBD in pregnancy have been presented in **Section 4.3.4.2** along with advice given to them about symptoms changes. However, women were also asked about their experience of symptom changes during pregnancy and three months post birth. **Figure 27** shows comparison between what women expected to happen to their symptoms and what they actually experienced

Figure 27: Expected symptoms compared to experienced symptoms (n=46)

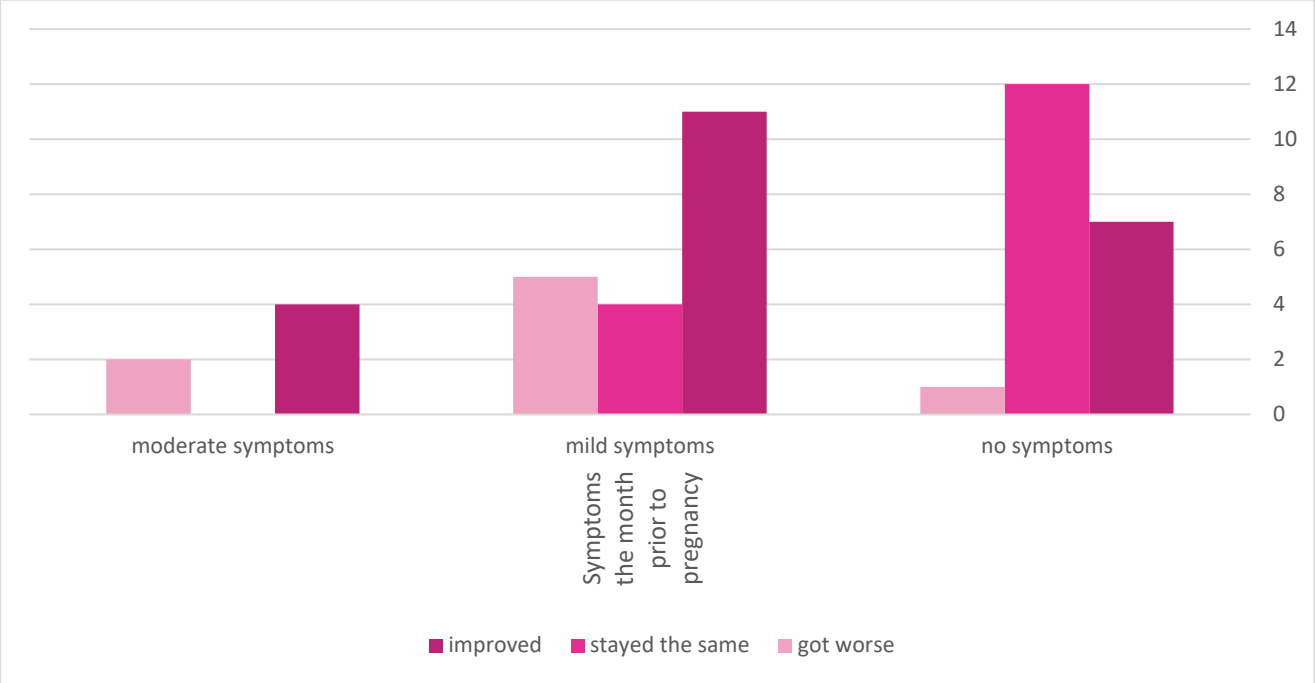


Of the women who expected their symptoms to improve during pregnancy, over half did experience an improvement, symptoms stayed the same for a fifth of women with the remaining women experienced a worsening in symptoms during pregnancy. An expectation that their symptoms would stay the same throughout pregnancy was selected by just over a third of women, and for over half this was their experience, with the remaining women predominantly experiencing an improvement and a few experiencing a worsening of symptoms.

Of the women who expected their symptoms to get worse during pregnancy, four did experience a worsening of symptoms, with the remaining women experiencing an improvement in symptoms or that their symptoms stayed the same.

Women were also asked about the changes to their symptoms from the month prior to pregnancy and during pregnancy. **Figure 28** shows these results.

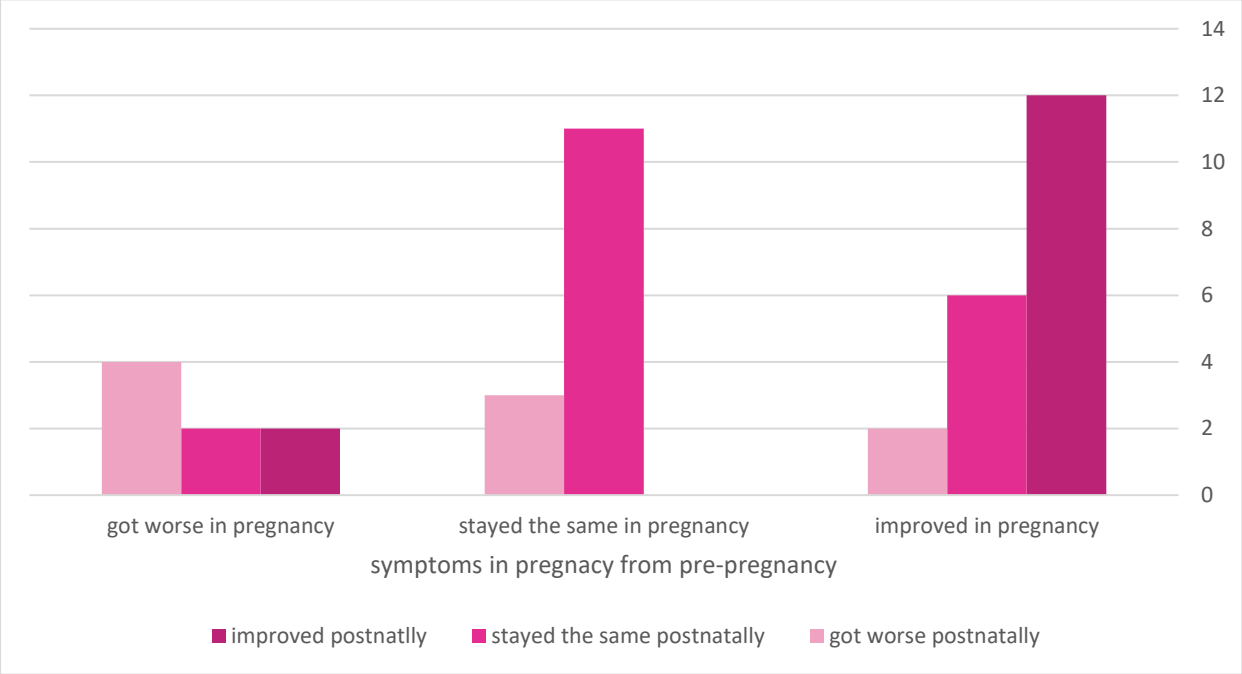
Figure 28: Symptoms changes from the month prior to pregnancy and during pregnancy (n=46)



Of the women who had no symptoms in the month prior to pregnancy, just over a third experienced an improvement, whilst symptoms stayed the same for most women and just one woman experienced worsening of symptoms. Mild symptoms were reported by just under half of women, and for just over half of these women they experienced an improvement in symptoms improving during pregnancy, with the remaining women experiencing either a worsening in symptoms or that their symptoms remained the same. Of the women who had moderate symptoms prior to pregnancy, most experienced an improvement whilst the remaining women's symptoms worsened.

Changes to symptoms between pregnancy and three months post birth were also explored (**Figure 29**).

Figure 29: Changes in symptoms, from pre-pregnancy, pregnancy and three months post birth, (n=46 in pregnancy. The number of women for the 'after pregnancy' is adjusted as four women were still pregnant for the first time since IBD diagnosis n=42)



For the women who experienced an improvement between pre-pregnancy and pregnancy, over half of these also noticed an improvement post birth, with the majority of the remaining women symptoms stayed the same and two women experienced a worsening of symptoms post birth. For the women who identified their symptoms as staying the same pre-pregnancy into pregnancy, the majority stayed the same post birth with the remaining women experiencing a worsening in symptoms, whilst of the women women who experienced a worsening of symptoms between pre-pregnancy and pregnancy, this continued into the postnatal period for half the women, with the remaining women equally experiencing an improvement or that their symptoms staying the same. Changes in symptoms over the course of the pregnancy journey may be attributed to medication use and this will be presented in **Section 4.3.5**.

4.3.5 IBD medications

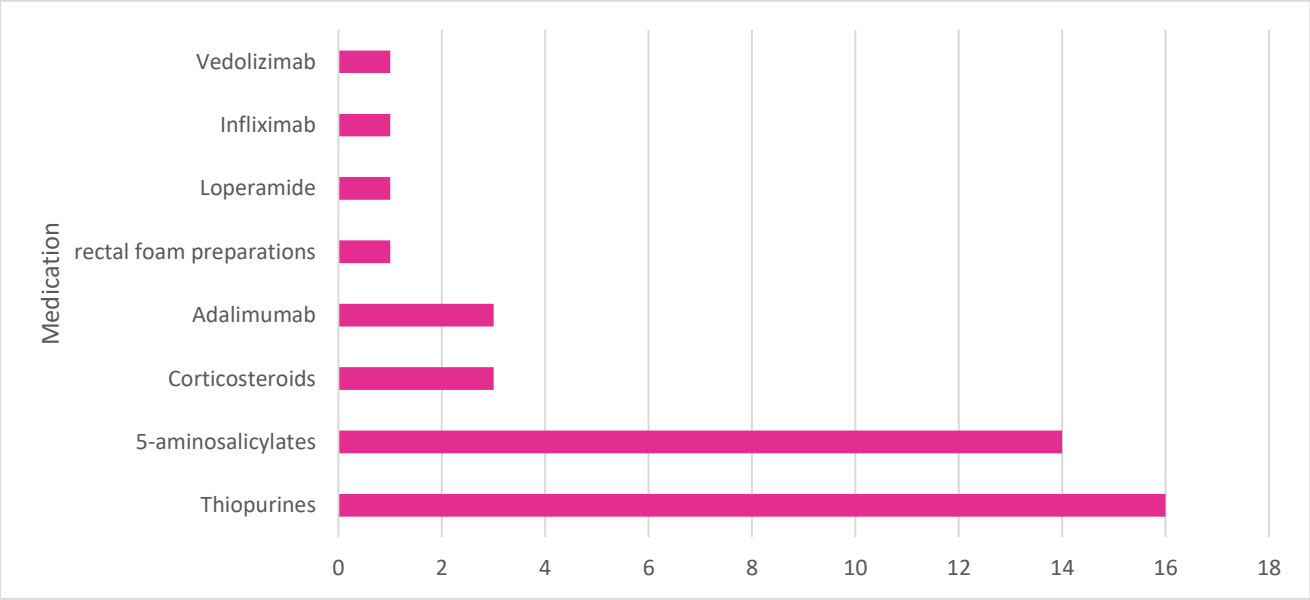
Women were asked about IBD medication use in relation to their pregnancy, including any advice they were given about this.

4.3.5.1 Medication management

Women were asked if they were receiving any treatment in the month prior to finding out they were pregnant for their IBD and were asked to specify what this was. Of the 46 women who responded to this question, 34 were receiving treatment. The majority of women were receiving medicinal treatment with the remaining woman receiving other management.

Of the women who identified as having taken medication in the month prior to pregnancy, women nearly all provided details of this medication. Women most commonly took one medication. Thiopurines were the most common group of medication taken by women with women taking them either alone or in conjunction with other medications, closely followed by 5-aminosalicylates. **Figure 30** shows the different medications taken.

Figure 30: IBD medication taken in the month prior to pregnancy (n=40)



Women were also asked if their medications were changed after pregnancy, with the majority of women (33/46) having no changes to their medications made post birth Only 2 women who were taking medication in pregnancy had it stopped in pregnancy.

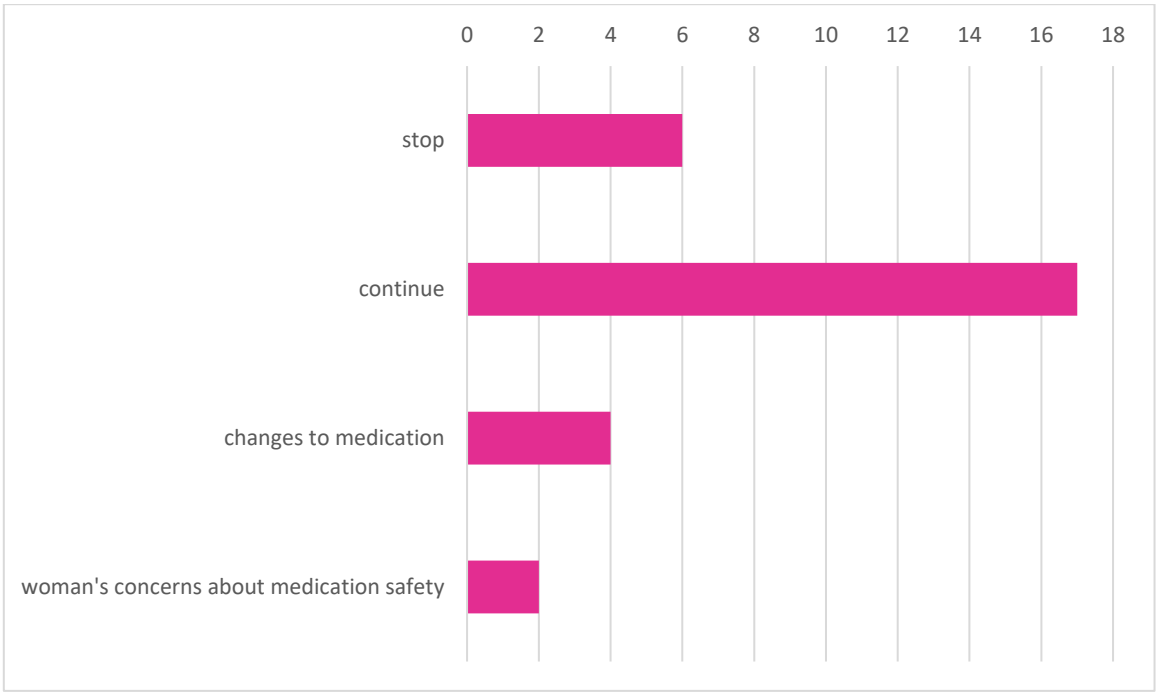
4.3.5.2 Medication advice

Discussions about IBD medication use during pregnancy took place for 29/41 women (71%) who were taking IBD medication, 12/41 women (29%) who were taking IBD medication were not involved any discussions about its use and the remaining 5/46 women (11%) were not taking any IBD medication during pregnancy.

For the 29/41 women (71%) who had a discussion about IBD medication, they were asked to give brief details about what was discussed, and the results are shown in **Figure 31**

Infant feeding will be discussed further in **Section 4.3.6**.

Figure 31: Discussions about IBD medication in pregnancy (n=29)

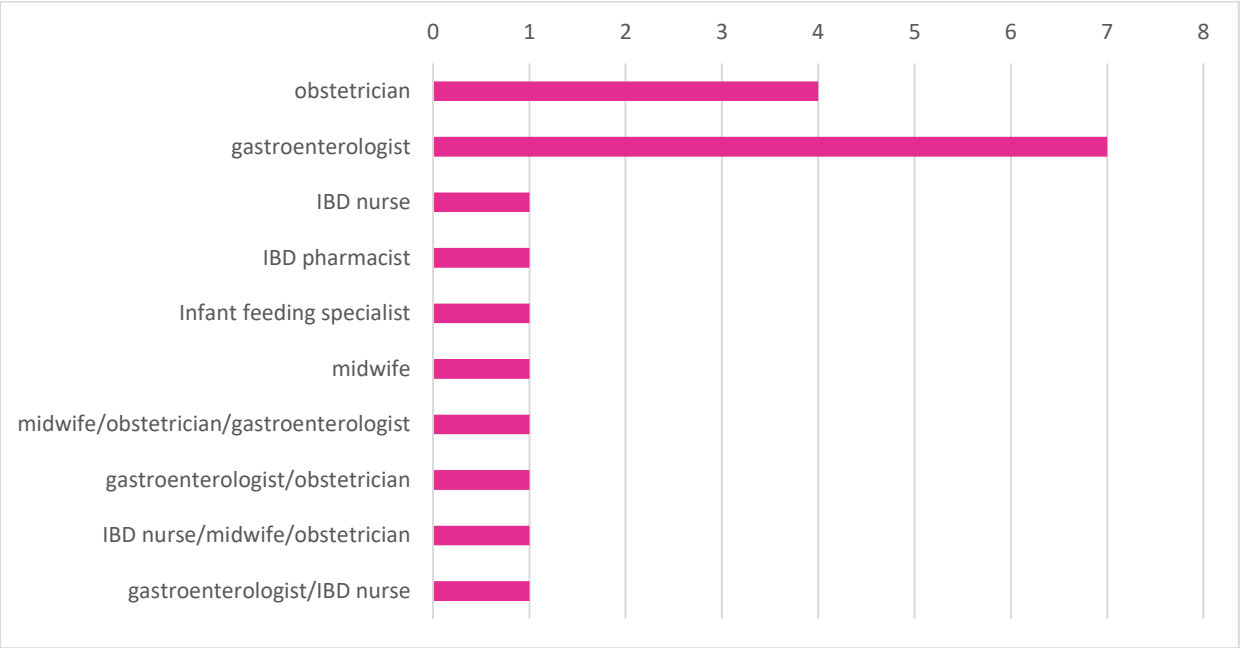


Just over half of women responded that they were told to continue taking their medication, with the remainder having changes made to their medication due to their pregnancy or being told to stop taking their medication. Concerns about the safety of their IBD medication were reported as raised by a small number of women during the discussion, which included a woman seeking assurance her medication was safe to use in pregnancy and a woman who received conflicting advice from her GP and pharmacist about the safety of her medication seeking clarity from her gastroenterology team.

Of the 46 women who responded to the question about discussions about infant feeding during pregnancy and in relation to IBD and IBD medications, just over half reported these discussions had taken place. When asked who had discussed this with the women, not all women provided details of a health care professional, however of those who did respond, gastroenterologists were the most common health professional, followed by an obstetrician. A midwife led the discussion for one women and an IBD nurse for one women. A

multidisciplinary approach was used for fifth of women and an IBD pharmacist and an infant feeding specialist discussed this with one woman each. **Figure 32** highlights the health professionals who discussed infant feeding with women.

Figure 32: Health professional who discussed infant feeding with women (n=19)



4.3.6 Infant feeding

As presented in **Section 4.3.5**, infant feeding was discussed with over half of the women (26/46) (57%) by a health professional, however women were also asked if they IBD influenced their choices in infant feeding.

4.3.6.1 Choices

When asked if IBD influenced choices around infant feeding, with over half of the women saying no. They were asked to provide some detail if answering yes (**Table 18**).

When asked to provide details about how IBD had influenced choices around infant feeding, the most common response related to IBD medication women were taking. The potential

negative effects of breastfeeding on the mother and baby's wellbeing were highlighted by a fifth of women with another fifth stating that the main influence around infant feeding was that breastfeeding reduced the risk of their babies developing IBD. **Figure 33** demonstrates the results.

Figure 33: IBD influence on infant feeding (n=18)

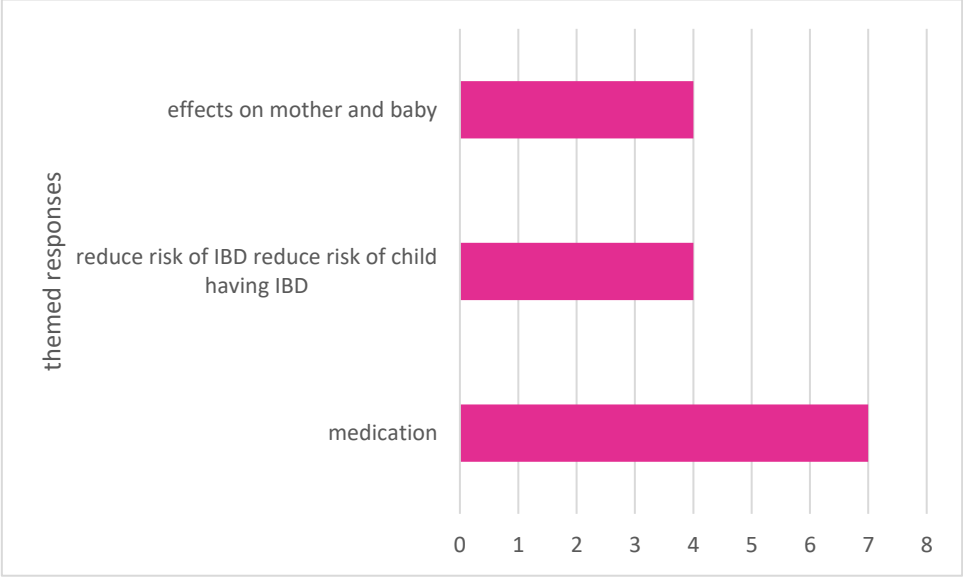


Table 18: IBD influenced infant feeding

I bottle fed due to medication I was taking p3
I was determined to breast feed p5
As above. Was given mixed messages and decided that I didn't want to take the risk p13
I listened to the doctor p14
I was always anxious about the effect of the azathioprine, I chose to breast feed him for 6 weeks after the ibd nurses told me it was mostly p18
Decided not to bf due to meds p19
I decided not to breast feed due to medication p20
I don't want to breast feed as I worry he won't get nutrients p21

I had to bottle feed on paediatrician advice due to effect of azathioprine on baby through breast milk. P22
Advised not to breastfeed due to medication I was taking for IBD p23
I was told under no circumstances was I allowed to breast feed which greatly upset me and also led to a number of incidents with medical professionals and members of the public passing judgement which was incredibly hurtful. P24
I chose to breastfeed as I read it is protective of IBD in my son p30
More due to additional diognosis of ankylosing spondylitis but also needed to recommence medication p31
Too dehyrated to breast feed p35
I had read breastfeeding decreases the chance of my child developing ibd p36
I was Ill after giving birth and struggling with establishing breastfeeding. To ensure I remained healthy and to reduce my fatigue. I eventually gave up with trying to breastfeed and started bottle feeding which also allowed my husband opportunity to help with feeding p41
I was more determined to breast feed as possible links to reducing risk of crohn's p42
Wanted to breastfeed to reduce risk of baby getting ibd p49

Women were not specifically asked about their method of infant feeding in the survey, however for the women who responded that IBD did influence their decisions about infant feeding and provided details about this, most more women stated that they bottle fed (11/17) than breastfed (6/17). The reasons for these choices are related to the reasons shows in **Table 18**.

4.4 Qualitative findings

Women were given the opportunity to provide free-text responses at the end of the survey: “what would have improved your experience of pregnancy?” and “any other comments”. There was a 100 word limit applied to responses as this kept the responses focused.

4.4.1 What would have improved your experience of pregnancy

Over half of the respondents provided a response to the question “what would have improved your experience of pregnancy?”, with five themes emerging from the responses.

4.4.1.1 Health care provider knowledge and information giving

The most common theme was knowledge about IBD and pregnancy by the health care provider during pregnancy, with 12/28 women commenting on this as shown in **Table 19**.

Table 19: The most common theme from the free-text responses to the question about what would have improved your experience of pregnancy

With both pregnancies it was clear there was little understanding of the impact of having an IBD on pregnancy or baby p8
A crohns trained midwife who didn’t just google... I could do that p14
More support, information and advice on breastfeeding and labour p17
More information, more support p18
Less guess work by supposed specialists p24
Better understanding from gastro consultant p26
Midwivery services were OK once we knew what was wrong with me but not very knowledgable. Not sure much could be done to improve my experience other than highlighting to HCP that pregnancy can be a trigger as GPs were not aware at all p27
If my gp was more aware of uc symptoms. He put me on constipation medication which was totally inappropriate. My bowel had actually stopped working. I became anorexic which I feel could have been prevented p34
Some understanding of ibd by midwife and obstetric doctors p43
More awareness overall gastro, midwife and consultant all good but gp and pharmacist made getting medication difficult p49

4.4.1.2 Multidisciplinary team care

The second most common theme was the desire for involvement from multi professionals in their pregnancy was important, as shown in **Table 20**.

Table 20: The second most common theme from the free- question what would have improved your experience of pregnancy

HAVING Gastro involvement led care from the beginning p1
Closer communication between my gastro team and obstetrician p13
I would have thought there would be more joined up working between gastro team and midwife and Obstetrician p17
First few weeks very hard-felt very poorly but IBd team wouldn't help as said too early on, had to practically beg to see a gastro. Once I saw gastro he was excellent but all IBD patients should see doc as soon as they're pregnant p21
Being able to see my gastroenterologist more than once (I had never even been told about IBD nurses at that point) p22
I had a good during both pregnancies. I saw my consultant gastroenterologist when I was 3 months pregnant with my first baby. I didn't need to see him again but do think I would have been able to had there been any issues p23
More knowledge, communication between my obs and gastro teams p45

4.4.1.3 Medication

Medication was the third most common theme within the responses, was about medication as shown in **Table 21**. Women wanted to receive more information about the medications, and for one woman the uncertainty around the risk of harm to her baby from medication detracted from her experience:

Table 21: The most common theme from the free-text responses to the question about what would have improved your experience of pregnancy

More information about medications and impact in pregnancy there seemed to be very little evidence for the clinicians to base their decisions on p7
more discussion about medication effects p30
Having a consultation in relation to the disease and pregnancy and medication p37
More knowledge, communication between my obs and gastro teams and more evidence-based research about Vedo and pregnancy p45
More certainty that the meds I was taking would harm my baby p39

4.4.1.4 Continuity of maternity care provider

When asked about what would have improved their experience of pregnancy, having continuity of maternity care provider was identified in the free-text response as shown in **Table 22**.

Table 22: Continuity of maternity care provider would have improved experiences of pregnancy

Continuity of care p4
Having a community midwife that understood ALL of my needs (IBD is just one of many conditions I have). They would get to know me during pregnancy so they'd learn my family's needs better than 5 different consultants would, because they never communicate with each other in a timely fashion...and pregnancy is time-limited! p9

4.4.2 Any other comments

Women were given the opportunity to provide any additional information they wanted to share, under the heading of "any other comments". This was restricted to a maximum of 100 words also. A total of ten women provided responses.

4.4.2.1 The impact of health care provider knowledge about IBD and pregnancy on care

The most common theme was the impact of health care provider knowledge about IBD and pregnancy on the care women received, with 4/10 (40%) women commenting about this. Women had varying experiences of this with one woman having a good experience as shown in **Table 23**, with one woman having a positive experience and the other three women who commented about health care provider knowledge and its impact on pregnancy did not have such a positive experience.

Table 23: The impact of health care provider knowledge about IBD and pregnancy identified by women

I received great care and information. I was given the number of IBD nurses in case of a flare up but had an MRI/colonoscopy prior to falling pregnant to see how my crohns was. Only when results were in, did I discuss a plan with my gastro about falling pregnant and making sure my crohns remained under control. I then had extra scans to check the babies weight and also advice and appointments with gastro and obstetrician specialists p10
I feel that IBD and pregnancy is not fully understood and i feel my gastro team have just decided to leave me as i am despite having some symptoms of a flare rather then risk changing anything because they dont understand p13
Better knowledge on effect of IBD drugs on baby/placenta/breast feeding would have made my pregnancy much less stressful p22
I felt midwives and consutant obstetician were only interested in monitoring my baby because I was on steroids. Weren't at all interested in what was happening to me, just kept focusing on the fact I'd delivered a healthy, full term NVD baby previously therefore should do the same again. My second pregnancy was as different as it could have been from the first! And noone seemed to be interested in this p27

4.4.2.2 Medication

Medication was commented on by 3/10 (30%) women, with 2/3 women (67%) being concerned about the effects of medication and 1/3 woman (33%) commenting on her level of disease activity necessitating biologic treatment as shown in **Table 24**.

Table 24: Medication described by women in 'any other comments' section

After stopping breast feeding with all 3 babies is when I would flare. Only times in my life and resulting in 2 bowel resections. 7 years on from my last baby I'm still flaring and on vedolizumab p5
I was terrified my first baby would be affected by azathioprine and couldnt enjoy my pregnancy. Medical staff (GP, midwife, obstetrician) could only say it will PROBABLY be ok, as not enough research but the manufacturer's website says NOT to take when pregnant P22
I struggled to produce enough milk to feed my son, I'm not sure if this was a result of medication or not p34

4.4.2.3 Disease activity

Disease activity in relation to pregnancy was commented on by 2/10 women (20%) as shown in **Table 25.**

Table 25: Comments about disease activity in relation to pregnancy when women were asked for 'any other comments'

After stopping breast feeding with all 3 babies is when I would flare. Only times in my life and resulting in 2 bowel resections. 7 years on from my last baby I'm still flaring and on vedolizumab p5
Both elective sections flares throughout p35

4.5 Chapter Summary

This chapter has presented results and findings from the on-line survey, using descriptive, univariate and bivariate statistics. The responses to the survey from 50 women produced a rich dataset providing insight into women living with IBD experiences of pregnancy.

The women had a mixed experience of symptoms and their expectation of symptoms during pregnancy, with advice about symptoms also varying. Pregnancy care varied for the women, in particular the primary health care provider during pregnancy and the women had mixed views on which health professional should lead their maternity care. This also emerged from the free-text responses about pregnancy experience/other comments. Women's feelings of preparation for labour and birth appeared to be influenced by attendance of parent education.

Medication appeared to be of importance to the women both from the responses to the survey questions and with the free-text responses being used to comment about medication and its effect on the experience of pregnancy. Women's experiences of infant feeding, the

information they received varied, with some women using the free-text responses to articulate the difficult decisions they had to make around infant feeding.

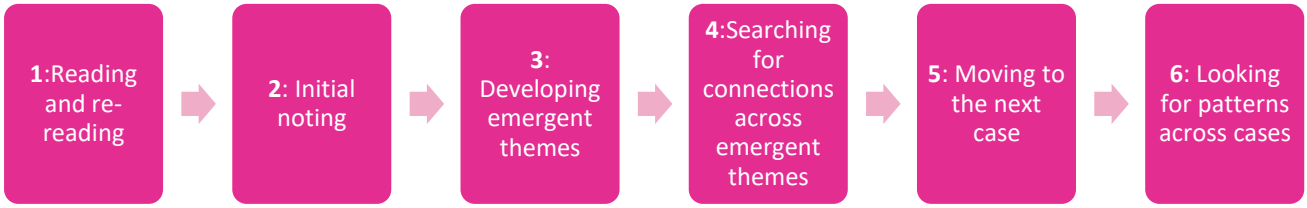
The survey enabled 50 women to share their experiences of pregnancy and the findings of the interviews undertaken exploring pregnancy experiences in greater depth will be presented in **Chapter 5**.

Chapter 5: Findings

5.1 Introduction

This chapter will present the findings of the one to one interviews. Data were analysed using Interpretative Phenomenological Analysis as discussed in **Section 3.8.5.3**. Names of the participants have been changed to preserve anonymity. The six steps analysis using IPA are shown in **Figure 34.**

Figure 34: Six steps of analysis using IPA (Smith et al 2009)



A total of seven women were interviewed, with interview times ranging from just under 15 minutes to just over an hour(14+ minutes to 67 minutes). The majority of women, five out of seven, had been diagnosed with IBD prior to pregnancy, with one woman being diagnosed during her first pregnancy and one woman being diagnosed between her first and second child. The number of children the women had ranged between one and three, with three women having one child, two women having two children and two women having three children. The sample was homogeneous, with all women being diagnosed with IBD prior to or during pregnancy, having given birth to at least one child within the last five years, which is appropriate for IPA.

Table 26 shows the characteristics of the women who participated in the interviews, highlighting timing of diagnosis and number of children. Most women were diagnosed prior to pregnancy.

Table 26: Participant characteristics

Name	Timing of diagnosis	Number of children
Jenny	Prior to pregnancy	1
Ellie	Prior to pregnancy	1
Rosie	Prior to pregnancy	1
Sarah	Between first and second child	2
Emma	Prior to pregnancy	2
Olivia	Prior to pregnancy	3
Laura	Whilst pregnant with first child	3

5.2 Themes

There were three master themes which emerged during analysis, with all three emerging in all seven interviews: 'What did I expect', 'What can I control?' and 'Care for me'. Individual master themes, and superordinate themes are shown in **Figures 35:Jenny, 36:Ellie, 37:Sarah, 38:Olivia, 39:Emma ,40:Rosie, 41:Laura**.

Figure 35: Jenny

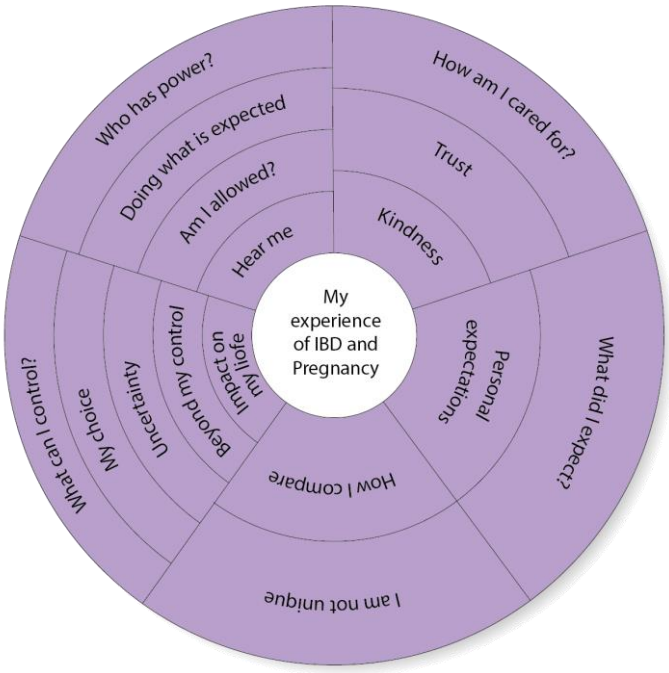


Figure 36: Ellie

Figure 37: Sarah

Figure 38: Olivia

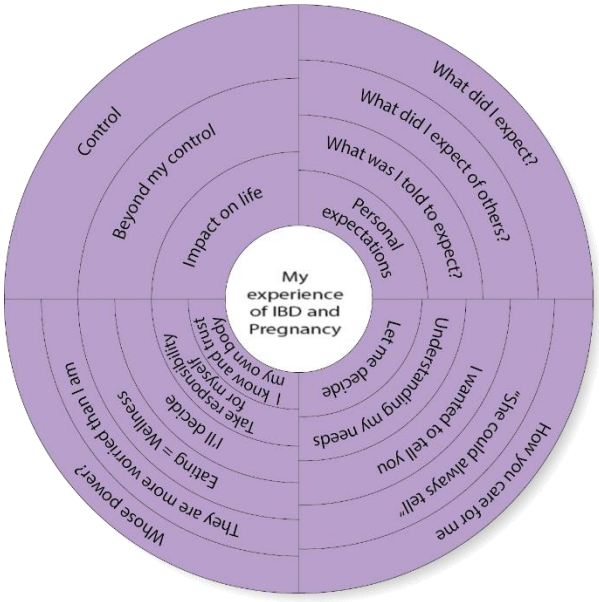


Figure 39: Emma

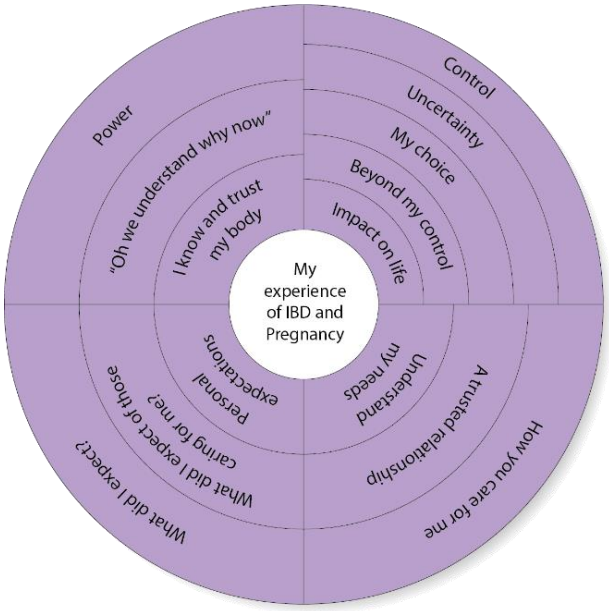


Figure 40: Rosie

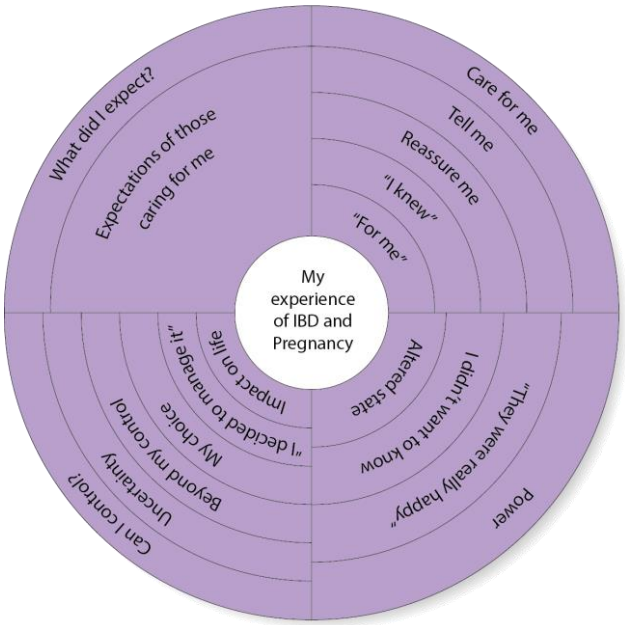
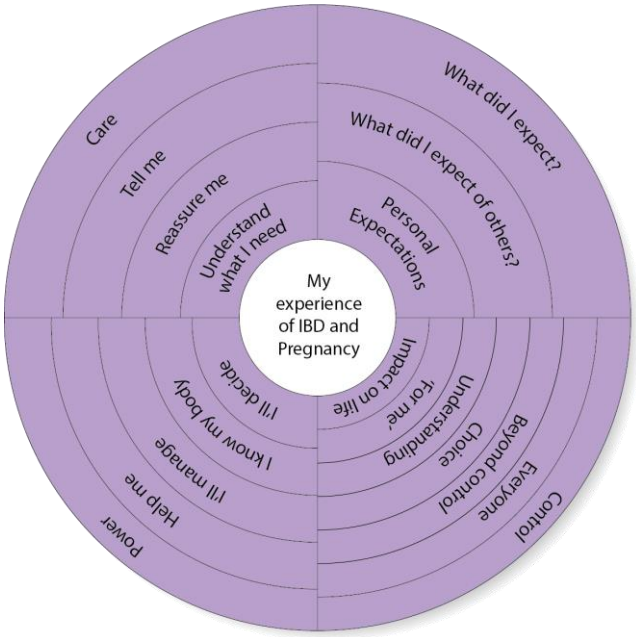


Figure 41: Laura



Within the master themes, there were super-ordinate themes and other themes nested within these.

5.2.1 What did I expect

'What did I expect' emerged as a theme identified as being important by most of the participants and will be explored here in further detail. Expectations were either personal expectations, what participants expected of others or what they were told to expect. Where these expectations originated from were sometimes described.

5.2.1.1 Personal expectations

The participants described what they expected to happen from a personal perspective, about how they thought their pregnancy and labour would be. These expectations were shaped by previous experiences, either of pregnancy or labour, or for one participant, their experience of IBD medication and the similarities they thought there would be for them in pregnancy

5.2.1.1.2 How would my pregnancy and labour be?

Olivia described how her previous experience of pregnancy shaped her expectations of what would happen during this pregnancy. As a mother of three, she was used to what happens to her during pregnancy and expected and accepted that not being able to eat or drink during pregnancy was a part of her pregnancy experience. Similarly, Emma shared this sense of expectation being driven by her previous experience, with her expectations being low during her second pregnancy as she had a negative experience during the first pregnancy. She described a relief and sense of joy that it was different. Whilst Ellie hadn't experienced a previous pregnancy, her expectations were also shaped by experiences of when she had taken medication which made her feel unwell, and she associated the sickness she felt with that she may experience in pregnancy:

"at seven weeks I was already taken into hospital er with severe dehydration and er the the pregnancy pretty much what happens is I don't eat or drink"

Olivia

"I said to my husband I'm so glad like compared to the last time when I had to have an emergency caesarean it was a bit like urgh"

Emma

"but I didn't even have any normal pregnancy symptoms which was quite strange so yeah I think I sort of expected it to be a lot more like sickness because I previously had quite well a lot of when I was on the last medication"

Ellie

5.2.1.2 What was I told to expect

Jenny, Sarah, Olivia and Ellie described how they all similarly recalled having been told what to expect about how their IBD would behave during pregnancy by other people. Jenny, Sarah, Olivia and Ellie all described unprompted being told by other people that their symptoms should improve during pregnancy, however no one was able to recall who told them this information.

"I was actually better than I was before I was pregnant which I knew I thought someone had told me that was a possibility"

Jenny

"I don't know if this is true or just a myth but I hear that you don't tend to have flare up's of IBD whilst you're pregnant" *Sarah*

"I remember her saying how well she'd been and apparently she'd heard and this is the sort of story they were telling you that when you were pregnant you become well and it was almost a broad brush of that's what happens"

Olivia

"someone said that often you can be quite a lot better during pregnancy and then have suddenly have a flare up again afterwards"

Ellie

These positive messages about how their IBD would be during pregnancy appear to have importance to Jenny, Sarah, Olivia and Ellie, as although they couldn't remember who had told them these, they remembered the information, sometimes over a period of many years.

This showed the importance they placed on what they were told regardless of the source and this may have affected their experience of pregnancy as they had preconceptions of what to expect.

5.2.1.3 Expectations of others

Expectations of others were predominantly shaped by what the participants expected from those providing healthcare for them during their pregnancy.

5.2.1.3.1 How did I expect you to care for me

Olivia described not expecting her midwife, or indeed any midwife, to know about IBD, as she expected midwives to only know *"about babies"*. As Olivia had given birth to three babies, this expectation was driven by her experience of the midwifery care she had received, and she considers this to be the usual standard of midwifery care.

"the thing is if you're a midwife you know about babies"

Olivia

Similarly, this expectation was shared by Laura, who described not expecting her midwife to know much about IBD,

"I think it's difficult isn't it I suppose because you wouldn't expect them to know a great deal about it" *Laura*

However, she did feel that there should be more midwifery awareness about IBD and that if her midwife had had more awareness this would have positively impacted on her midwifery care, as the lack of awareness was her *"only criticism"*.

"that was the only criticism I would have I didn't feel like there was any sort of awareness you know" *Laura*

Ellie, pregnant for the first time, similarly described an expectation that her midwife should have known more about IBD and that this would have positively contributed to her care.

"erm maybe my community midwife knowing a bit more about erm IBD would have been helpful" *Ellie*

Rosie, also pregnant for the first time, described the lack of knowledge about treatment for her IBD and how she felt this fell short of her expectations, and seemed to be disjointed care, as she had been *"almost prescribed"* a particular diet by healthcare professionals to help manage her IBD yet those caring for her in pregnancy knew nothing about this diet.

"however considering I'm almost prescribed the FODMAP diet* uh huh *they didn't really know what it was"* *Rosie*

Olivia described her surprise at having been cared for by the same midwife for all three pregnancies, and this surpassed her expectation of midwifery care. This did not just seem to surpass her expectations, but Olivia also expected that it would also surpass the researcher's expectations of midwifery care, as demonstrated by her comment *"you wouldn't believe it"* before describing her experience. This positively influenced the care Olivia received which is described in **Section 5.2.3.1:A trusted relationship** and this impact this on her experience of pregnancy.

"you wouldn't believe it this is unheard of these days she saw me through all three pregnancies" *Olivia*

Laura however described her upset about her care not being as she expected, and that she felt that healthcare providers were being obstructive to her getting the care she needed for

her symptoms which emerged to be IBD, and this was not in line with her expectation. Laura changes the word *"couldn't"* to *"wouldn't"* when describing the challenges, she had in accessing care suggesting she felt that it was in their capacity to provide the care she expected but chose not to

"I for some reason couldn't erm they wouldn't fast track me so I was out on a waiting list to get an appointment" *Laura*

*** FODMAP diet is a three step diet used typically to manage the symptoms of IBS and may reduce IBD symptoms and avoids Fermentable Oligosaccharides, Disaccharides, Monosaccharides And Polyols**

Sarah described how her low expectations driven by previous personal experience of those providing care for her proved to be right, described in terms of professionals reading her notes

"because no matter what notes are written they're too busy to be read them all" *Sarah*

However, this didn't appear to affect her care, and Sarah accepted this is how care is, almost making allowances for the fact her notes will not be read by those caring for her as they are *"too busy"*

Ellie experiencing her first pregnancy, had higher expectations and did expect news of her pregnancy to be shared amongst those caring for her, and found that her expectation had not been met when she had to tell those caring for her individually as they had not had any information passed on.

"and I was like yeah I'm pregnant but they obviously hadn't got any information from the obstetrician" *Ellie*

Ellie's frustration at this is captured in her quote, which includes *"and I was like yeah I'm pregnant"* suggesting she expected them to know and she was frustrated she was having to tell them.

Different elements of expectations have been explored in this section, with in-depth descriptions of what participants expected personally about their labour and birth, their expectations of others and what they were told to expect. Personal previous experiences have been described to shape expectations of labour and birth. Acquired knowledge has been described as considered important in how expectations are shaped regardless of where the information or knowledge originated from. Expectations about their healthcare providers have been described, with participants having differing expectations, especially about midwives knowledge of IBD.

Expectations around care have been explored in this section, as they emerged from expectations the participants described, however 'Care' is discussed as a separate theme in **Section 5.2.3**.

5.2.2 What can I control

Control emerged as being important to the participants, in relation to what they felt was within and beyond their control and ownership (or lack of) of the disease and its effects.

5.2.2.1 Beyond my control

All participants described experiencing events which they felt were beyond their control, which were decisions made for them by those caring for them, feeling *"lucky"* when things went well or their disease was well controlled and an acceptance of things needing to be done for their benefit.

5.2.2.1.1. They decided

Emma and Ellie described similar experiences of their medication being controlled by their healthcare professionals without discussion or seeking any kind of agreement, therefore beyond their control yet they appeared to be accepting of these decisions being made

"for Infliximab© infusions at the time as well and they seems to work wonders at the time but then they stopped them in my third trimester"

Emma

"I think I'd been on erm…Pentasa© for a while and that I think it has started to erm like cause problems with my kidney and I was getting quite bad erm kidney infections and things like that and getting quite ill so then they decided to change me from that onto Azathioprine©"

Ellie

Olivia described a similar experience, however the healthcare professional appeared to involve her more in the decision making, stating they would *"like"* her to start taking medication as opposed to Emma and Ellie's experience of medication being *"stopped"* or changed. Therefore, Olivia was given some degree of control over whether she would actually start taking medication or not, although for her to decide she wouldn't would require her to go against the suggestion of her healthcare provider who would *"like"* her to start taking it. Therefore, whether she actually had any control over this would depend on her ability or confidence to say no if she did not want to

"so I started seeing a consultant at City and erm we started looking into it and yeah..sure as eggs is eggs you have ulcerative colitis [int: right*] crohns and we would like you to start taking medication, now I bob on and off medication"*

Olivia

Laura, who was diagnosed with IBD during her first pregnancy, described shock at being diagnosed with IBD but also the shock at being told she would need to take medication for the rest of her life, a decision she was not involved in and also something she was unprepared for.

*"I remember saying to the consultant er who is still my consultant now what erm when can I stop taking this medication and literally having the shock of my life when she said probably never (*yeah*) you'll have to take it forever and you know* (yeah) *being like sort of diagnosed I dunno like that word disease was probably something I never thought would happen to me* (uh uh) *yeah and you know it was quite a like a not a shock yeah it was a shock really just the idea of having to take medication every day forever"*

Laura

5.2.2.1.2 "quite lucky"

Feeling "lucky" was identified by Ellie, Emma and Laura, who described similar experiences of feelings of inability to control what happened but feeling fortunate or *"lucky"* when things went well. This demonstrated their perceived lack of ownership over their IBD and that when things went well it was due to luck rather than good self-management or care, and was therefore beyond their control

*"when I was on the last medication I had about nine months of where I just felt sick constantly and I couldn't eat anything and I just was constantly nauseous so I thought if I felt like that before but I probably must feel like that when I was pregnant but it was all fine really (laughs) (*yeah) *quite lucky"* *Ellie*

"obviously as soon as I was pregnant my symptoms seem to have be relieved completely with both pregnancies erm which I found myself quite lucky I was like wow" *Emma*

"but yeah I suppose for me I was fairly fairly lucky that it sort of was controlled and settled" *Laura*

5.2.2.2 Whose power

Power emerged as a key theme for participants. The more nuanced elements of who had power and how power was determined had different meanings for the participants and experiences differed. How participants gained power, and the struggles for power between participants and their healthcare providers were described with direct links with feelings of control or loss of control.

5.2.2.2.1 Hear me/Tell me

A struggle to be heard or receive the information they wanted and needed emerged as being important to the participants, which was beyond their control and affected where the power sat.

Laura described how she experienced a struggle to be heard by her healthcare provider, which led to a loss of power for her, as she had to *"plead"* for help.

"and it was only like I said because I pleaded with my gynaecologist and said I'm really upset what can I do" *Laura*

Jenny similarly described her experience of the struggle she had to be heard, and also experienced a struggle in getting information from those caring for her which was beyond her control and which led to tension and a loss of power for her.

"as erm he didn't really seem to be listening to me" *Jenny*

"so we had a few sort of erm not arguments but obviously I was trying to get actually facts out of her and she wouldn't really give me any" *Jenny*

Sarah described her experience of how she was unaware of what was happening to her as she was never told, which led to a loss of power for her and an increase in power of those caring for her, as they were aware yet chose not to tell her

"after (child's name) was born as well sorry I had a big bleed after she was born and ended up in surgery and all sorts oh bless *in theatre although I don't know what they did as they don't tell you they just drag you off"*

Sarah

Ellie described how she had almost become accepting that her questions would not be answered, despite being well informed about certain aspects of her pregnancy. She described how she spend the valuable appointment time explaining her IBD to whoever she saw which meant she couldn't discuss what she needed to

"sometimes I feel that you spend the entire appointment explaining your previous medical history and never (laughs) actually getting onto the things that you sort of went to ask for"

Ellie

The laugh during her comment about this highlights that she may not have become fully accepting of this and that it may still frustrating that she was not able to discuss what she wanted to with her healthcare provider, and that this was beyond her control.

Whilst gaining information and understanding was important to some participants, Rosie described her experience of how she felt able to govern what information she was told or what was discussed. She used this to avoid discussing her IBD which she felt was important as she didn't want to know about it as part of a coping strategy for managing her pregnancy.

> *"so I never picked up the phone to the GP I never asked to go and see the consultant and I didn't speak to the midwives about it especially but that was in part because when the midwives were here they were very much to do what they were doing they did check on me of course they did they were brilliant but it was quite easy to avoid talking to them about Ulcerative Colitis"*
>
> *Rosie*

Through avoiding such discussions and governing what information she allowed herself to be told or to find out she was holding on to the power and retaining control during this time

> *"I wasn't actually told that by any medical profession whether (laughs) it's true or not I never bothered to look up"*
>
> *Rosie*

Olivia described receiving information about her IBD during her pregnancy from her healthcare provider, and that she felt that they were more concerned about it than she was.

"I was always asked you know about how my crohns how is you know mainly that they bobbed back to that whereas it would never be on my agenda"

Olivia

She described her experience of always being asked by healthcare professional about her IBD and how this was not something she felt was necessary or something that she would instigate. Whilst Olivia was happy to discuss this, she had the ability to decide what she shared and how she shared it, ensuring she retained her power. Had she not felt she had the ability to decide what she shared or how she shared this information this may have led to a loss of power, or a power struggle between herself and the health professional. Her ability is demonstrated by the word *"bobbed"* which suggests they kept returning to the topic but that she did not felt obliged to discuss more than she was comfortable with.

5.2.2.2.2 I'll decide

Participants described their experiences of their interactions with their care providers around elements of their pregnancy or IBD care, and how whilst this was sometimes beyond their control, how they responded affected their feelings of power between them and their healthcare provider.

Jenny described her experience of expecting her consultant to give permission for her homebirth and this was something which was important to Jenny as she sought this *"every time"* she discussed her birth choices. Jenny described how a failure to obtain this led to a struggle for power between her and her consultant and a loss of control, with her consultant *"still"* trying to encourage her to change her mind, but without explaining her reasons.

"I thought she every time she'd be like ok have a homebirth don't worry about it but she was still trying to not talk me out of it but heavily trying to sort of sway me away from it sort of thing so yeah" *Jenny*

Jenny described how this experience then led to her comply with some other elements of her care she didn't really want to but almost as to not rock the boat and cause her any further loss of power, as she chose to do them as opposed to feeling they were enforced, which enabled her to retain her power

"so them I wasn't that thrilled when she gave me another appointment with him but I thought I'd just go" *Jenny*

Olivia and Jenny similarly described how they made their own decisions about medication and whether they took it or not. Olivia described taking medication as and when she felt it necessary whereas Jenny described how she decided she no longer would take her prescribed medication, as this was within their control.

"now I bob on and off and on and off medication I believe I am I'm relatively well…historically I wasn't…very well at all but as I've gone into adulthood I believe I am although consultants have said to me 'if you were my sister I would expect I would enforce you inspect you to make sure you took medication' although I still haven't returned religiously to taking that sort of thing"

Olivia

"I stopped taking it maybe six months before I got pregnant not really for any reason not because I was going to try and get pregnant but I just sort of felt it wasn't actually really

doing anything so I thought I would just go off it and see what happens"

Jenny

As Jenny has already described her experience of trying to get permission about making personal choices, it may be that this influenced her decision to simply stop taking the medication instead of having the power struggle she had previously with her healthcare provider.

Olivia previously described how healthcare professionals appeared to be more concerned that she was about her IBD, and therefore it may be that she decided that she didn't need to take medication consistently as she did not share the concerns and had the control to decide this

"I was always asked you know about how my crohns how is you know mainly that they bobbed back to that whereas it would never be on my agenda"

Olivia

Laura described a different experience, where she openly vocalised that she would not take certain medications, and she highlighted the power struggle that this caused, as she opposed and refused their attempts to get her to take steroids.

"I'm a little bit stubborn in the respect that I wouldn't and I have never and they have tried to get me to take steroids and I really really really don't want to take steroids"

Laura

Decision making was not confined to medication, with Olivia and Laura both describing their experience of wanting another baby and being *"consumed"* or *"adamant"* that this is what would happen regardless of concerns from healthcare professionals or anyone else

"but my head was absolutely consumed with having another child as some people are" *Olivia*

"….and try and get it to settle down but I was adamant that I was going to have another baby so I ignored her" *Laura*

Although Laura was *"adamant"* that she was going to have another baby, regardless of the advice she received from her healthcare provider, she recognised that this was beyond her control and she needed help to achieve this, and therefore relinquished some power to those caring for her to enable her to achieve her goal of getting pregnant, appreciating that this wasn't something she could accomplish alone and without help

"I'd been diagnosed with endometriosis that's why I was under a gynaecologist (yeah) so he was sort of managing me trying to get pregnant if you like"

Laura

Olivia and Rosie similarly described their experiences of how they decided to self-manage symptoms of their IBD and this was within their control to do this. Olivia described feeling that this was the only option for her as she tried to *"escape the pain"* associated with her IBD. This suggests that she did not choose to try and manage her pain but instead was forced to look for ways to manage it in order to cope. Rosie however decided to manage her IBD symptoms as more of a personal choice, not because she felt that it was her only option.

"so that severe pain that you almost end up hypnotising yourself out of so I spent a lot of time as 15/16 year old lying in the bath trying to escape the pain"

Olivia

"so yeah and that's just how I decided to manage it if it had got much worse I would have gone in"

Rosie

Laura described a different experience, where she expected to have her IBD symptoms managed by healthcare professionals but that she managed her emotional needs on her own.

"obviously things like symptoms can be managed but anxieties and worries and concerns they tend to be things that you deal with on your own"

Laura

Whether this was due to her wanting to manage these needs on her own or whether she felt this is what was expected of her was not defined, however her quote suggests that it is an expectation that symptoms are managed by others and that emotional wellbeing is managed independently.

The experiences of the struggle for power and how power can be achieved, retained or lost have been described in this section. Individual experiences have highlighted similarities and differences in what influences and affects power and whether this is within their control or not.

5.2.2.3 Choice

The ability to make choices emerged as a sub theme within control, with participants describing what impacted on their ability to make choices and also whether these choices were respected by those caring for them.

5.2.2.3.1 My birth my choice?

Laura, Sarah and Ellie all described how they made choices about how they wanted their births to be, with Laura making firm decisions about how her babies would be born, whilst Sarah and Emma described what they had wanted. This demonstrates the control they felt over planning their birth experience, and for Sarah this was shaped by her previous experience

"but I probably think that I was less inclined to want to have a natural birth given my uh *huh health problems yep erm…..so I was happy to have a caesarean and then further on I chose I opted to have a caesarean section for my second and third child"*

Laura

"my birth plan was extensive in fact my consultant said it was a keeper (laughs) because I knew what had happened the first time and what I wanted to put across because that is not the time to be reciting your medical history when you're having contractions"

Sarah

"erm both I wanted a vaginal birth with (child's name) I ended up having an emergency caesarean but with him we had erm a natural birth"

Emma

Jenny also described her experience of knowing what she wanted for her birth:

"and even though I was sure I wanted a home birth I knew that for a first time one I know there like a teeny tiny bit more risk like a teeny amount so that obviously weighed on me a bit erm but I was quite sure from the beginning that was what I wanted to do so I just stuck with that erm and I'm glad we did in the end"

Jenny

By acknowledging the *"teeny bit more risk"* she associated with her choice of a home birth which caused her some concern, which she described *"weighed on"* her but felt confident that her choice was right for her and later described being pleased that she had stuck with her initial choice.

Ellie however described how she had made choices around her birth experience but was told that she would be unable to have these by her healthcare professional, which resulted in a loss of control over her birth

"she thought that I might have erm had a problem with my placenta so she sent us straight into hospital erm and then that I when they said I wouldn't have been able to have a waterbirth cause they needed to keep monitoring me" *Ellie*

5.2.2.3.2 My treatment my choice

The experiences of choice around treatment emerged, with Rosie describing her experience of knowing that her choices would be respected by her healthcare professional, that her consent was needed for any treatment and therefore this was within her control, yet she was fearful of seeking advice as she did not know what would happen

"I avoided going into hospital or really seeking any medical advice because I didn't know what they were going to do and of course they wouldn't do anything without my consent but again friends of mine had been hospitalised and put on drips and this that and the other with a new baby having not to breastfeed"

Rosie

Jenny described a similar experience, of attending an appointment but knowing that treatment would not be started as this would be against her wishes. Both Rosie and Jenny knew that their choices would be respected and that their choice would determine their treatment plans, therefore remaining within their control

"he erm didn't seem to be listening to me and asked me if I was married and erm was acting kind of odd so then I wasn't that thrilled when she gave me another appointment with him but I thought I'd just go and because I knew I wasn't going to start any medication or start treatment I thought I'd do it just to tick the box and waste an appointment"

Jenny

As described in **Section 5.2.2.1.1**, Olivia described her experience where her healthcare provider wanted to involve her in the decision making about her treatment, and offered her a choice, by suggesting they would *"like"* her to start taking medication as opposed to stating that they wanted her to or prescribing it without discussion. This gave Olivia the control over whether to start taking medication or not

"so I started seeing a consultant at City and erm we started looking into it and yeah..sure as eggs is eggs you have ulcerative colitis [int: right*] crohns and we would like you to start taking medication"*

Olivia

Sarah described a similar experience where her healthcare provider gave her medication in case she felt she needed them, again providing her with the choice and control as to if and when she took them.

"she's given me erm some oral granules to take in case I get another flare up"

Sarah

Ellie however was not given a choice about her care pathway and was referred by her healthcare provider for consultant led care, however this may have been in response to concerns Ellie raised with her GP. Whilst the care pathway Ellie was placed on was beyond her control, this was not necessarily perceived to be a negative thing by Ellie

"so we were a bit worried about like whether it would be a an easy pregnancy or not erm so went to the GP and yeah everything sort of went pretty well erm we he referred us erm we were consultant led care through the hospital"

Ellie

Whilst Rosie, Jenny, Olivia and Sarah all described experiences of having their choices respected or their healthcare providers giving them the choice and control about their treatment, Emma described how she made her choice about treatment without discussion with her healthcare provider and told them of her choice and subsequent action to stop taking the medication

"so then I just stopped taking it because I said to my consultant look I feel really well I don't want to take something unnecessarily"

Emma

5.2.2.4 Uncertainty

Feelings of uncertainty, signalling a loss of control emerged as a theme. Laura described how she had no idea what the symptoms she was experiencing were and thought she may

have bowel cancer, following investigations during her first pregnancy these symptoms were due to IBD which was then diagnosed

"you know I've thought you know have I got bowel cancer are these symptoms mimicking what what could potentially be that or you know I had no idea"

Laura

Jenny described the uncertainty she has around her IBD and what her actual diagnosis is, but seemed accepting to have her diagnosis as being within the *"IBD bracket"* and that she did not need a more specific diagnosis

"so I have like Crohns query colitis not sure one or the other the IBD bracket"

Jenny

Uncertainty around IBD medication use, the effects it may have and what was the best thing to do were described by Sarah, Ellie, Rosie and Laura.

Sarah described the conflict she experienced about whether to take the prescribed IBD medication which would keep her well and worry about the possible effects it may have on her baby or to not take the medication and accept that she would become unwell. She was able to control whether she took the medication but was not able to control the effects this may have or the effects of not taking it

"because then I was panicking about what was best for me to do take the medication and worry about the baby or not take it and be ill"

Sarah

The uncertainty was around the possible effects the IBD medication may have on the baby, whereas becoming ill through not taking the IBD medication was a certainty.

Ellie described being solely concerned about the possible effects taking her prescribed IBD medication may have on her baby and that these may not be evident immediately

"then in five years find out that actually she's got some sort of side effect from having Azathioprine© and stuff like that"

Ellie

Rosie described her uncertainty about whether she should be taking her prescribed medication after the birth of her baby or not due to her own wellbeing, although she knew the reasons for why the medication had been prescribed. The medication prescribed was due to her blood loss, but Rosie wasn't sure if she should take it not because of her IBD

"so I was taking iron tablets because of the blood I lost during labour but whether I should or not I wasn't entirely sure"

Rosie

She did take the medication but remained uncertain about whether she *"should or not"*. Laura described how her uncertainty about losing her baby, procedures relating to her IBD and diagnosis, and taking IBD medication made her feel frightened.

"I'd had a miscarriage previously as well so you worry about everything just in terrible anxiety about losing the baby and even these procedures and taking medication whilst I was pregnant you know frightened me"

Laura

She described worrying about *"everything"* and being in *"terrible anxiety"* suggesting this was beyond her control and was a state rather than being fleeting feelings

Ellie's uncertainties also caused her to worry, with her concerns being about whether she would be healthy throughout her pregnancy due to her IBD

"I think just generally I worried quite a lot about whether I would be healthy through the pregnancy"

Ellie

Whilst Emma didn't describe feeling uncertain, her experience of wanting to *"try"* for a vaginal birth after her previous caesarean section suggests she had some uncertainty about whether this would achieved or not,

"everyone was really supportive that I wanted to try for a VBAC" (vaginal birth after caesarean section)

Emma

Rosie had been left with lingering uncertainty from her birth experience about what had actually happened, what may have happened and whether this would have impacted on her IBD and used the interview to try and seek answers to remedy her uncertainty

"I think that for example I still don't know to this day if cutting my perineum would have been a problem and would it?" *Rosie*

The uncertainty described by the participants, particularly around IBD medication use, highlighted the complexities of the control and loss of control experienced, with participants being able to control whether they took the medication or not, but not being able to control any effects this may have on them or their babies, and also the lack of control they had over how their symptoms would be if they decided not to take the medication.

5.2.2.5 Impact on life

Impact on life emerged as being important to the participants, as although they were unable to control how the IBD impacted on their lives, it had both positive and negative effects.

5.2.2.5.1 Additional physical pain and suffering

Laura, Olivia and Rosie all described how they felt that due to their IBD they had endured additional physical and/or psychological pain, which could be termed as suffering as it was prolonged. For Laura, this was due to her not wanting to take pain relief if she had a headache as she felt she was already taking medication for her IBD which caused her anxiety as discussed in **Section 5.2.2.5**.

"yeah like I said if I had a headache or anything like that I wouldn't want to take any paracetamol or anything cause I felt like I was already taking medication"

Laura

Therefore, Laura wanted to reduce the possible negative effects of medication by taking as little as possible. However, this meant that she had to endure additional suffering as she felt unable to take any additional medication to relieve a headache.

Olivia described her experience of being heavily pregnant and having to get up out of bed to use the toilet multiple times during the night due to her IBD.

"I'm heavily pregnant as well and I'm getting up to go to the toilet four to five times a night and can you imagine if you're not eating and drinking"

Olivia

In describing how she wasn't eating or drinking at this time, together with disruption to her sleep and increased bowel movements was causing her additional suffering than if she had not had IBD.

Rosie described a similar experience of how having to use the toilet in a more unplanned way, and urgent way, than would be in the absence of IBD caused her additional suffering as she had to interrupt breastfeeding her baby

"also just you know half way through breastfeeding you have to go to the toilet"

Rosie

5.2.2.5.2 Additional worry and anxiety

Ellie described how she felt like she was a burden whilst at work due to the additional time she needed off work during her pregnancy due to additional appointments she needed due to her IBD.

"you sort of still feel like a bit more of a burden because you're having to leave it til last minute and where I work as well we were quite short staffed at the time.."

Ellie

The feeling of being a burden was compounded by the fact her team was *"quite short staffed at the time"* which was also beyond Ellie's control.

Laura described how she felt that being pregnant with her first baby was complicated by her diagnosis of IBD

"having a first baby is just can you know be an anxiety inducing time of your life erm so yeah and then add something like that you know can impact how you feel"

Laura

Laura described how pregnancy can be an *"anxiety inducing time of your life"* suggesting that most women feel this way, and then the additional of IBD increases this anxiety and worry due to the unpredictability of IBD and also the uncertainties around IBD medication use and wellbeing increased this anxiety.

5.2.2.5.3 Respite from symptoms

Overwhelmingly pregnancy was described as providing respite from the symptoms of IBD. Ellie described the immediate relief from symptoms that IBD provided for both of her pregnancies, and Rosie experienced such relief that she no longer needed to follow the prescriptive diet she usually followed.

"I was really quite healthy I was actually healthier in sort of the nine months of being pregnant that had been for the last like four years before"

Ellie

*"I was mostly on mesalazine erm but I also managed it with the FODMAP diet (*ahhh ok) *and I actually found that almost works better at times well that completely keeps it at a level and when it's bad I need to add the medication on top of that and actually when I got pregnant I didn't even need to follow the diet"*

Rosie

Emma described her experience of having her IBD symptoms being completely relieved whilst pregnant on both occasions, with the word *"obviously"* suggesting that this was not unexpected. This may have been expected due to it happening with the first pregnancy or that it is assumed that this is a common for women to experience a respite of IBD symptoms whilst pregnant. Laura and Jenny similarly describe how pregnancy provided them with respite from their IBD symptoms. However, Laura did not seem to expect this, unlike Emma, and this is shown by the word *"actually"* suggesting that she felt a sense of surprise about this.

"obviously as soon as I was pregnant my symptoms seem to have been relieved completely with both pregnancies"

Emma

"I think it probably I think was probably more settled actually during being pregnant"

Laura

"so before I was pregnant I had sort of IBS type symptoms rather than IBD so I have the odd issue rather than a constant issue every day and then that probably improved as I really didn't have that during pregnancy I was kind of fine erm and I could eat whatever I wanted"

Jenny

However, this was not the case for Olivia, with instead birth providing the much-needed respite from her IBD symptoms. Olivia seemed to realise that this is quite uncommon as

demonstrated with how she uses the words *"actually as it happens"* suggesting that this is outside of the norm, or not would be usually expected to happen

"but actually as it happens giving birth to me is the best bit of the pregnancy because pregnancy I rubbish"

Olivia

5.2.3 Care for me

How the participants were cared for emerged as an important theme, with two main sub themes being the relationship between the participant and their healthcare provider and the importance of the healthcare practitioner understanding the individual needs of the participant.

5.2.3.1 A trusted relationship

Emma described how her relationship with her healthcare provider had mutual trust in it, that she trusted him and that he also trusted her, demonstrating this by supporting her wishes and plans.

"so then I just stopped taking it because I said to my consultant look I feel really well I don't want to take something unnecessarily erm so he said yeah that's fine if you're happy with that then go for it"

Emma

Sarah described a similar experience, where she had been told that she could not give birth in the pool, however her healthcare provider said she was able to labour in the pool but reiterated she needed to get out for birth.

"and she said most women won't get you again and you've got to get out you know that don't you and suggested and I think (laughs) she knew full well that I probably wouldn't but she'd managed to risk assess that it would be ok because otherwise they would never have let me in which is what I assumed but what the midwife said had happened actually is that I just delivered her quite quickly before they could get me out "

Sarah

The healthcare provider trusted Sarah to do this, however Sarah thought that there was an unspoken agreement that she was actually supportive of Sarah giving birth in the pool otherwise she would not have let her get in for labour. Sarah achieved the birth she wanted, giving birth in the pool, however it transpired that this was not with agreement of her healthcare provider and was instead due to the speed in which her baby was born

Olivia described how her relationship with her midwife meant that she was able to tell if Olivia was feeling unwell, and she always got this right. As described in **Section 5.2.1.3.1**, the same midwife cared for Olivia for three of her pregnancies

"and she was quite experienced in the fact that she would also be able to look at you and go I don't think you're very well today are you? she could always tell"

Olivia

Olivia put this down to the experience of the midwife, however in a previous **Section 5.2.1.3.1**, Olivia described how she did not expect her midwife to know anything about IBD, therefore her perception of Olivia being unwell when she was is more likely based on the relationship they had and how well her midwife knew and understood Olivia.

Both Laura and Jenny described how they felt that their relationship with their healthcare providers meant that they advocated for them, with Laura's consultant agreeing for her to have a caesarean section for the birth of her baby and with Jenny's feeling that it was her private midwife who enabled her to stay at home, whereas a midwife who she did not know may have wanted her to go to hospital

"and right at the last minute she decided er she said it was the second person that she'd ever agreed to having an elective caesarean section based on the baby's size and the size of the mother" *Laura*

"so the other reason I was glad I'd had a private midwife just because I think they might have wanted me to come in because it was a bit early"

Jenny

The importance of having good relationships with their healthcare providers, in particular ones which had mutual trust emerged as being important to the participants. The trust the participants had in their healthcare provider to care for them, advocate for them and support them with their individual wishes.

5.2.3.2 Understand my needs

Understanding their individual needs emerged as a theme, with all participants describing their experiences of what their unique needs were and whether these were understood or not by those caring for them.

***hyperemesis is a pregnancy condition in which women experience severe nausea and vomiting, which often requires medical treatment. It is more common in the first 12 weeks of pregnancy**

Emma described how important information which would impact on her care such as her intolerances to particular pain relief was noted, and this meant that she didn't have to explain this to those caring for her whilst she was in labour

"and like when I went into hospital to have him erm like my intolerance to certain pain relief and stuff was noted" *Emma*

In contrast to this positive experience of when needs were met, Olivia described her experience of when she had hyperemesis***** yet her doctor signed her off work with stress, despite her insistence it was not stress.

"I was signed off work with stress in inverted commas I had hyperemesis didn't have stress I had stress they said so they signed me off work so then I gave up work early because you know you can"

Olivia

Olivia's frustration at this lack of understanding or lack of willing to understand by her GP was highlighted by her decision to then give up work earlier than she planned as this ensured she would not need to pursue this again with her GP.

Rosie and Ellie described their contrasting experiences, with Rosie feeling that she would have liked more information in advance from her healthcare provider in particular about the mode of birth which Rosie had. Ellie described how helpful her healthcare provider was in helping them understand what the evidence was around particular areas of concern to Ellie was

"so I think that there could have been more information in advance even just a conversation particularly around the instrumental birthing"

Rosie

"she was really helpful in helping us to kind of understand what evidence there is erm yeah so I think that did sort of help" *Ellie*

Whilst Ellie described how helpful her healthcare provider was in understanding and responding to her individual needs, she also described a contrasting experience of how she struggled to relate to things she was told at the antenatal classes she attended as she did not feel they apply to her as she felt that her IBD made her different to other women. Therefore her individuals needs were not met through this forum

"whenever you go to classes and things like that there's not really anyone else who has the same like medical history as you" *Ellie*

Sarah described how her healthcare provider would give her useful information but that she was unable to remember it all once she had left the consultation unless she wrote it down immediately. She therefore valued this information as it was important to her that she was able to remember it all and developed a mechanism to support this, although

she didn't feel that this was an ideal solution but as she *"can't expect them to write everything down all the time"* although it *"would be helpful if they would"* it was the only solution she could do herself

"unless I've written it all down as soon as I've come out the room I can't quite remember so that would be helpful if they would….I don't….I can't expect them to write everything down all time…but…" *Sarah*

Jenny described the importance of knowing the midwife who would care for her in labour well and to be *"comfortable*" with her. Jenny described how having this relationship with her midwife helped her labour to be *"really quick and easy"*.

"they were lovely erm but that's the other reason I wanted a private midwife as by the time he was born I knew her so well that I was really comfortable and I think that helped the whole labour be really quick and easy" *Jenny*

Laura described how her needs were met, and that the care she received was *"at times probably more than I needed"*

"I think that the care I received personally was very collaborative and very you know erm at times probably more that I needed" *Laura*

All participants described their unique needs and what contributed to them being understood or not by their healthcare provider. How receptive their healthcare professional was and how well they supported the participants shaped their individual experiences of pregnancy.

5.2.3.3 Communication

Communication emerged as an important component of care for the participants. The importance of healthcare professionals talking to each other, information being shared and the opportunity for participants to discuss their wellbeing with their healthcare provider were identified as being important.

Olivia described her experience of her Crohns disease not being discussed by those caring for her, with Laura describing a similar experience of not being given information she considered to be important by her healthcare provider, and having to seek out this information from *"different places"*.

"……..but I don't remember having many many discussions about Crohns"

Olivia

"nobody sat down with me and said….this is what might happen IBD in pregnancy you can get pregnant your medication won't you know nobody really that information sort of came from different places"

Laura

Rosie's experience was also similar, having not being told the information she needed, however she never found out the answers to some questions she had

"but there were lots of questions that I never really got answered"

Rosie

Emma, Ellie and Sarah described similar experiences of their different healthcare providers not talking to each other, with Emma having to tell her obstetrician that she had seen her gastroenterologist, and Ellie having to make her own appointment to see the IBD team when she became pregnant.

"I don't think they were really aware when I was going to see my erm Crohns consultant I don't think they knew about that I think I had to tell them that I'd been to see them" *Emma*

"there really wasn't like a link between the sort of pregnancy side of things and the IBD team so I had to contact the IBD team and ask for an appointment with them"

Ellie

Sarah was less specific and felt that the communication between all of those caring for her was lacking

"but there wasn't it didn't feel like a lot of communication between any of them"

Sarah

The participants described their experiences of the health professionals caring for them not sharing information relating to them between the other professionals involved in their care, which meant that the participants had to bridge this gap and explain what was happening, resulting in disjointed care between the IBD professionals and the maternity care providers. Participants also described how they struggled to get the information they felt they needed which left them with unanswered questions, highlighting the importance of communication not only between the professional groups but also the participant.

5.2.3.4 Reassure me

'Reassure me' emerged as a theme, with participants describing what they found gave them reassurance during their pregnancy.

"we were consultant led care through the hospital and that was quite reassuring as it meant that we had quite regular check ups and things" *Ellie*

"you know during that times the scans are very reassuring you know having regular scans knowing that you are being looked after" *Laura*

Ellie and Laura described their similar experiences of finding that being assigned to consultant led care during pregnancy and the additional interventions as being reassuring. The additional check ups and scans were identified as being particularly reassuring, as they were associated with being well looked after. Sarah described how she felt she was able to discuss her concerns or worries as they arose, as she was already having regular

appointments with her healthcare provider, rather than having to arrange an appointment to discuss these which she felt would have been the case if she wasn't assigned to consultant led care.

"we could discuss any issues I was having or anything I was worried as it cropped up as opposed to ringing and waiting ages for an appointment so that was really good"

Sarah

Jenny and Ellie described finding the interactions with their healthcare providers as being reassuring as opposed to any interventions, with Jenny more actively seeking reassurance by voicing concerns.

"they were lovely and really reassuring most of my appointments were me just worrying about things and them saying not worry and it's normal"

Jenny

"she was really really helpful erm and I think just really reassuring about it and erm yeah I think that did make us feel a lot better" *Ellie*

The reassurance appeared to have a positive effect on both Jenny and Sarah, with Jenny describing her healthcare providers as *"lovely"* and Ellie saying that it made them feel *"a lot better"*.

For Rosie, she described the reassurance she was given as being more specifically about the impact her medication may have. It may have been that Rosie sought reassurance specifically about her medication, or that her healthcare provider was receptive to what her needs were

“he was very clear like the medication won’t have an impact you’re absolutely fine”

Rosie

Despite the participants not always choosing the care pathways they were assigned to during their pregnancy, the reassurance they gained from the additional care within these pathways were described as being important. Whilst some participants sought reassurance about specific elements of their pregnancy or care, others were reassured by the additional surveillance of their pregnancy, such as scans, or the ability to access health professionals regularly.

5.3 Findings summary

The analysis of the data obtained through the one to one interviews using IPA has been presented. It has given an in-depth insight into the unique, personal experiences of seven women living with IBD and pregnancy. The similarities and differences in experiences and the different responses to the experience and effects this had on individual participants have been highlighted. The differing expectations and what shaped these highlighted the importance the participants placed on what they were told to expect during their pregnancy regardless of the origins of this information. Care emerged as being important to the participants with it featuring in all three of the main themes; how they were cared for, what their expectations of their healthcare professionals were, the power struggles sometimes experienced between the participants and their health professional and how the relationship with their health professional affected their experience. The theme about control emerged to be multifactorial, with control being lost, gained and retained in varying ways, including the usually positive influence pregnancy had on the symptoms of IBD.

Whilst there were three main themes, the superordinate themes within these varied, demonstrating each participant's unique experience. This will be discussed in depth in **Chapter 6: Discussion**.

Chapter 6: Synthesis of results and findings

6.1 Introduction

The results and findings of the survey and interviews have been presented independently in **Chapters 4 and 5,** with the systematic review of the relevant literature being presented in **Chapter 2**. This section will now present a synthesis the findings and results of the three data sources.

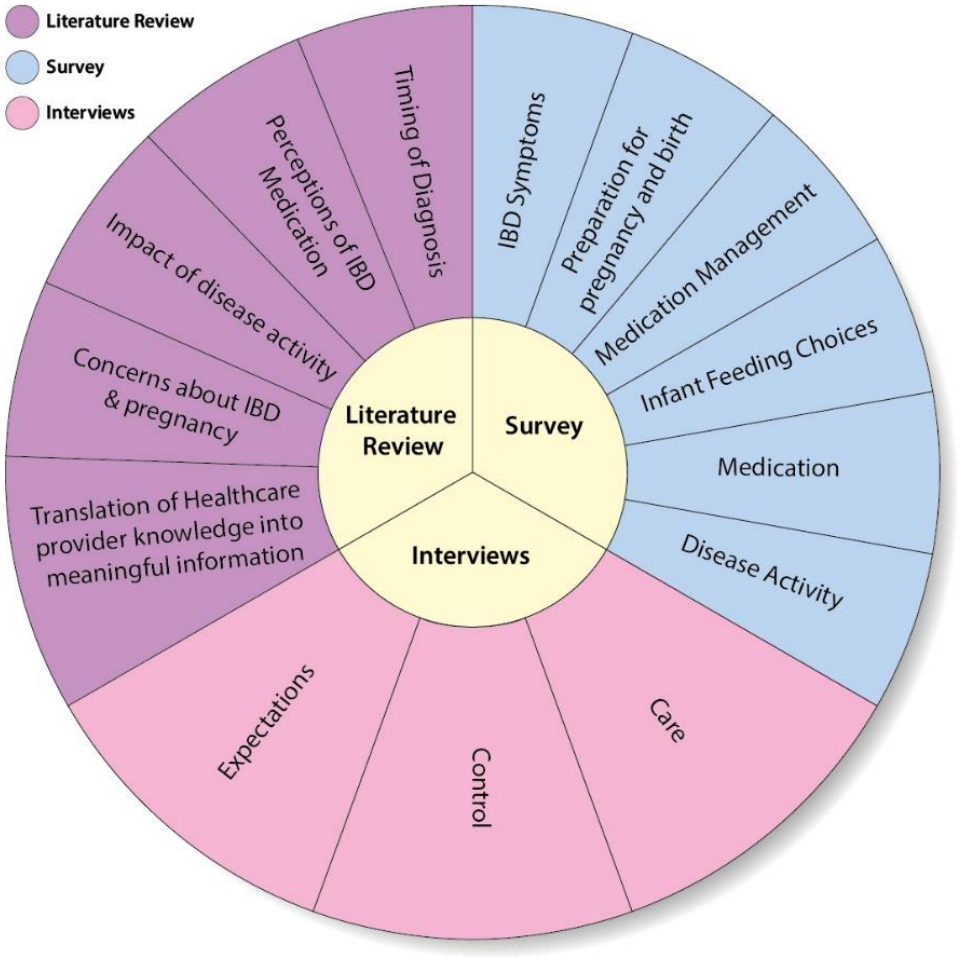
As discussed in **Section 3.5,** an embedded approach was used to combine the qualitative and quantitative data obtained from the online survey and the one-to-one interviews. The data obtained from the interviews was the primary data with the data collected from the online survey being supplementary.

Interviews, analysed using IPA were the primary data, as this links to the first aim of the study of exploring in-depth women's experiences of pregnancy when living with IBD and the survey provided the supplementary data as this builds context around the experiences of women living with IBD who have experienced pregnancy. The survey results and findings were used to develop interview prompts and probes particularly around care pathways and health professional involvement as whilst the survey provided valuable data about this, a deeper exploration was needed in order to achieve aim two of the study.

Data integration using principles of methodological triangulation were used to ensure that the integrity of data was not compromised by its integration as described in **Section 3.5.1**.

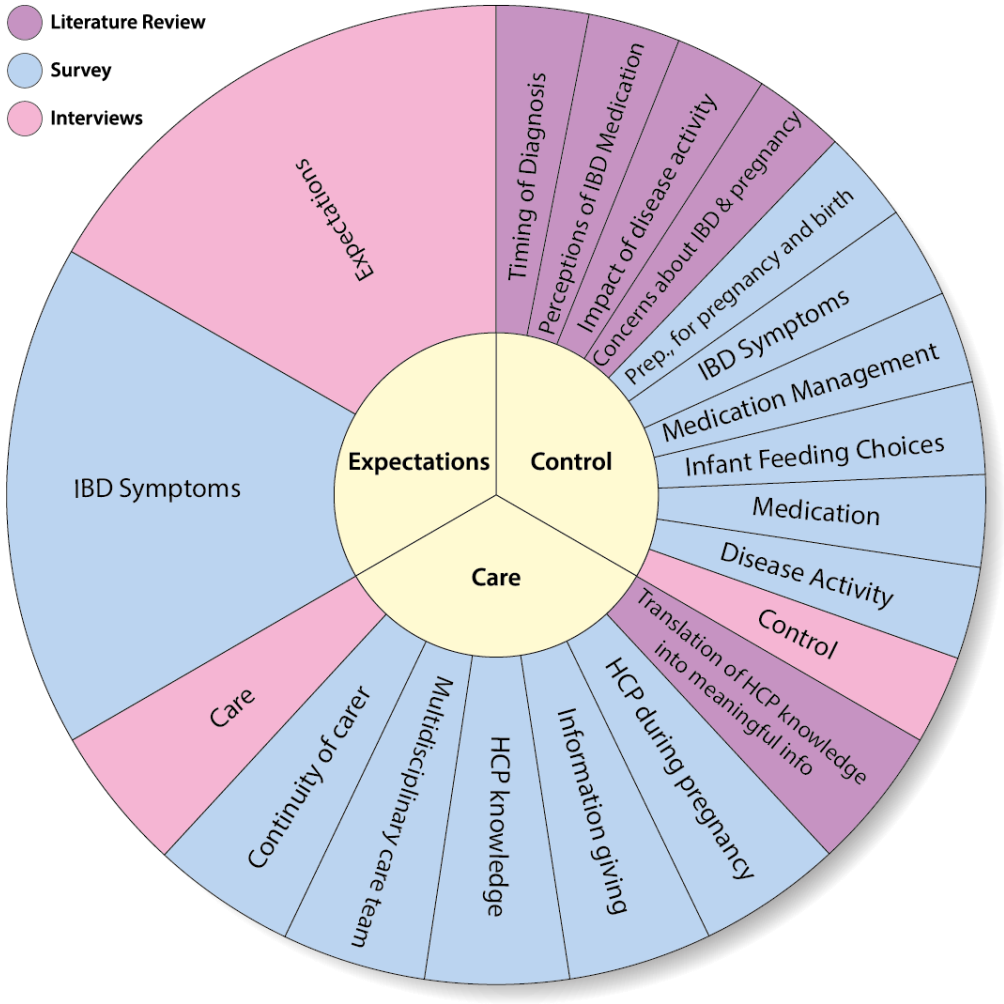
The themes which emerged from the literature review, the survey and the interviews are shown in **Figure 42**, which shows the similarities and differences in themes between the three sources.

Figure 42: study themes



As the interviews provided the primary data, the emergent themes from these became the key themes with the themes from the literature review and survey supplementing these findings. This process of synthesis involved mapping the themes from all of the different data sources out and then grouping them into themes of either expectations, control or care. The synthesised themes from the literature review, survey and interview are shown in **Figure 43.** Each synthesised theme will be discussed in this section: expectations, control and care.

Figure 43: combined themes



6.2 Expectations

Experiences around expectations about IBD symptoms and pregnancy and what women were told to expect emerged from the interviews and the survey, yet did not feature in the systematic review, suggesting that this is a novel finding which has not been explored before. Expectations for women were either personal expectations, expectations about others or what they were told to expect.

Expectations about midwifery knowledge about IBD emerged from the interviews, with different women having different expectations. For some women, they expressed that midwives did not need to know about IBD as this was beyond their remit of care, whilst others felt midwives should have at least some basic knowledge about how this may affect a pregnancy. A lack of knowledge was generally felt to detract from their experience and this was reflected in both the women who were interviewed and those who responded to the survey.

The results from the survey demonstrated that women's experiences around symptoms during pregnancy were well matched to their expectations with the majority of women experiencing what they expected. However, this was more apparent for women who expected an improvement in their symptoms with 63% experiencing this improvement as anticipated. For the women who expected their symptoms to stay the same during pregnancy, 53% reported symptoms stayed the same, with 41% of women experiencing an improvement. Therefore, although this wasn't expected it was positive to experience alleviation of the debilitating effects of disease activity of pregnancy and the respite pregnancy provided as discussed in **Sections 4.3.4 and 5.2.2.5.3**. For the women who expected a worsening in symptoms, this was experienced by 40% of them, with the remainder equally (30%/30%) experiencing either an improvement or symptoms staying the same. Again, for the 30% of women who experienced an improvement after expecting a worsening, this is likely to have had a positive effect on their experience of pregnancy.

Women's expectations were also influenced by the advice they were given about how their symptoms may be during pregnancy, with the majority of women expecting what they had been advised. However, if women were not given any advice, the majority expected their symptoms to stay the same.

Women who participated in an interview placed importance on what they were told to expect about how their symptoms would be during pregnancy, as although none could remember who had given them advice, they all recalled being given advice that symptoms usually get better during pregnancy. Although this was the experience for some of the participants, not all who were given such advice experienced improvement in symptoms during pregnancy. Nevertheless, this advice remained with them and they were able to recall what they were told, suggesting they placed importance on this advice and that it helped to shape their expectations.

Symptoms prior to pregnancy also appeared to shape women's expectations, with women who were experiencing no or mild symptoms predominantly expecting their symptoms to either improve or remain mild or absent during their pregnancy. However, half of the women who were experiencing moderate symptoms expected their symptoms to either get worse or remain moderate. Women's experience mostly matched their expectation or they experienced an unexpected improvement in symptoms, however this was not as common for the women with moderate symptoms pre-pregnancy.

The participants described how their expectations were formed and the importance they put on what they were told, regardless of the where this came from. Previous experience, both of pregnancy and IBD symptoms shaped their expectations of what would happen during pregnancy, and most women experiencing what they expected with their IBD symptoms.

6.3 Control

Control emerged as a theme for the women who were interviewed and women who completed the survey, with three sub-themes: beyond my control, impact on life and choice. Participants who were interviewed described their experiences of how their healthcare

provider would make decisions about their medication or treatment, which is a contrast to the experiences described by some participants who felt they had a choice in their care, which will be discussed later.

Whilst the participants described not being involved in decisions about which care pathway they were placed on, they did express how they found the additional surveillance of their pregnancy associated with the consultant led care pathway as being reassuring such as additional scans and appointments with her healthcare providers.

Therefore, this suggests that for some participants they are accepting of the loss of control arising from having some decisions made for them by their healthcare professional, and this may be especially true if there are perceived benefits associated with the decision, in this case additional surveillance of the pregnancy which proved to be reassuring. However, this was not the case for one participant who was interviewed, who wanted a homebirth yet was not supported by her healthcare professional in this decision. A conflict in decision making arose, and the participant was unaccepting of the decision her healthcare provider had made which led to a loss of choice and subsequently a loss of control for her.

A feeling of being 'lucky' was also described by some of the participants who were interviewed. This sense of being 'lucky' was when if they remained well during their pregnancy or if their IBD was well controlled. This suggests they felt they had no ownership of the disease or indeed any control over how it would behave. Feeling well and their IBD being well controlled was attributed to good luck rather than good self-management or care or treatment they may have been receiving.

Being beyond their control did not always contribute to a negative experience for women, especially if the decisions which were made for them about them by their healthcare provider had perceived benefits to them such as additional surveillance of their pregnancy.

Remaining well was something which was also felt to be beyond their control and again the women were accepting of this, and their feelings of being ‘lucky’ demonstrated this. However, it is important to recognise the negative impact the loss of control had on the experience of one participant who was not accepting of the care pathway she was placed on and its associated additional care and therefore not assume that all women perceive additional care as being beneficial if diagnosed with a high risk pregnancy.

The women who were interviewed overwhelmingly described their experiences of the respite pregnancy gave them from their IBD symptoms, which included the freedom to eat foods they usually restricted and having their symptoms not just improve but completely diminish. The results of the survey supported this notion of pregnancy providing respite from IBD symptoms, with the majority of women experiencing an improvement in their symptoms regardless of how their symptoms were prior to pregnancy. For women who reported having no symptoms in the month prior to pregnancy nearly all either reported an improvement or that their symptoms remained the same. If there were no symptoms initially, it could be assumed that there wasn’t necessarily an improvement but more of a continuation of the absence of any symptoms but it may be that the participants felt that their overall wellness improved hence the response given. Over half of the women who reported mild symptoms prior to pregnancy reported an improvement, as well as women who reported moderate symptoms. Although the majority of women did get some respite, pregnancy did not provide a respite for a small number of women, with symptoms either staying the same or in some cases worsening during pregnancy. Whilst the numbers of these studies were small, they may offer some contradiction to the findings of the meta-analysis undertaken by Abhyankar, Ham, and Moss (2013:5) which concluded that disease activity at conception is a good indicator of how the disease activity and associated symptoms will be during pregnancy. The women who participated in the study by Ghorayeb et al. (2018) had more extreme

variations of experiences in terms of how their symptoms were during pregnancy, with one woman considering a termination of pregnancy due to the debilitating effects of IBD symptoms and another woman having two pregnancies in quick succession due to the relief pregnancy provided.

Whilst the majority of women did experience some respite of their IBD symptoms, this may be multifactorial. However, it does offer some new insight into the much used prediction of a third of women will experience an improvement in symptoms during pregnancy, a third will experience a worsening of symptoms and a third will stay the same.

Additional suffering during pregnancy attributed to their IBD, was highlighted by the participants within the study. This was both additional psychological suffering which included anxiety and worry, and also physical suffering either caused directly by the IBD, or the confusion which may occur due to IBD symptoms mimicking complaints of pregnancy or visa-versa, women not receiving the appropriate treatment therefore prolonging their suffering. Women living with IBD are also more likely to experience complications of pregnancy which may increase their suffering also. Women in the study did describe experiencing complications of pregnancy, including pre-term birth, caesarean section, hyperemesis and pregnancy loss, however with the exception of pregnancy loss this did not appear to be disproportionate to that of the general population.

Increased anxiety and worry emerged as a theme for the women who were interviewed, which was predominantly attributed to the uncertainty about the perceived risk of harm from IBD medications and the internal conflict felt about whether to take the medications. The conflicts described were whether to risk the potential harm the medication may cause either to the baby or themselves or not take the medication and risk the possible harm disease

activity may cause. These concerns were echoed by a small proportion of women in the survey, with women using free-text responses to report that they raised concerns about their medication in pregnancy to their healthcare provider, and that they sought reassurance about the risk of harm of such medications. However, whilst the majority of women who responded to the survey were taking medication in the month prior to becoming pregnant, the majority of these women also had a discussion about medication use in pregnancy with their healthcare provider and it may be that this offered some reassurance about the safety of the medication to them and their baby. The study by Mountifield et al. (2010:179) also highlighted the high proportion of women who identified concerns about the risk of harm IBD medications may pose to their unborn baby, and this was echoed in the studies by Ellul et al. (2016) and Hoekstra et al. (2018). Ellul et al. (2016:888) however also identified that women were concerned about aspects of IBD other than medication which included their IBD harming their unborn baby, their pregnancy being complicated by IBD or that they may not be able to care for their baby once born due to the debilitating effects of IBD.

Concerns voiced by women were not limited to those about medication, with the majority of women who responded to the survey agreed with the statement relating to feeling worried during pregnancy. Whilst there was not an opportunity for them to divulge what their concerns were, this showed that they were experiencing worry. Interestingly, of the women who attended parent education classes, the majority identified as feeling worried during pregnancy, as did women who parent education classes were not available. Information giving by healthcare professionals will be discussed in **Section 6.4**.

In addition to the additional anxiety and concerns women felt they suffered, additional physical pain and suffering emerged as a theme from the interviews. The debilitating symptoms of IBD

negatively affected sleep through numerous trips to the toilet whilst heavily pregnant and caused disruption to breastfeeding, again for numerous toilet visits which without the IBD would not have been necessary. One participant described her aversion to taking medication for anything other than IBD whilst pregnant as she felt this was already causing concern about the risk of harm to her baby and wanted to avoid any further medication. This resulted in her feeling that she endured additional suffering when she had a headache for example as she did not feel able to take pain relief for this. Therefore through having IBD meant she suffered more pain than she would have done had she not had IBD. Ghorayeb et al. (2018:7) discussed symptom confusion, where either pregnant women or those caring for them frequently attributed symptoms they suffered such as abdominal pain, pelvic pain, musculoskeletal pain, sickness and fatigue as being complaints of pregnancy. These may also be symptoms of disease activity and if not correctly recognised and ignored may lead to an increase in disease activity as it is not being appropriately managed if it is not recognised for what it is. This risks associated with increased disease activity as well evidence, including preterm birth (<37 weeks) both spontaneous and iatrogenic, preterm prelabour caesarean section or induction of labour, low birth weight (< 2.5kg) and caesarean section (Getahun et al. 2014), (Boyd et al. 2015) (Shand et al. 2016) (Bortoli et al. 2011). Equally there may also be symptom confusion where complications of pregnancy may be incorrectly attributed to IBD, including labour pains being attributed to IBD relapse and rectal bleeding being attributed to IBD as opposed to haemorrhoids (Ghorayeb et al. 2018:7).

Whilst this was not the case for the woman interviewed who was diagnosed with IBD during her pregnancy, she struggled to get the medical care needed for a diagnosis and thought her symptoms were bowel cancer. This was a similar experience to that described by Cooper et

al. (2011). The consequences of misdiagnosis of symptoms presented in pregnancy by both those with a diagnosis of IBD or those who present with symptoms but are not yet diagnosed may have significant implications to the physical wellbeing of the woman and her baby, with increasing risks being associated with increasing disease activity. It is essential that symptoms are not attributed to either pregnancy or IBD without thorough investigation whilst have detailed discussions with the woman.

Women with IBD are also more likely to have complications of pregnancy, including the development of maternal gestational diabetes through the use of corticosteroids used to manage IBD and caesarean section (Getahun et al. 2014), (Boyd et al. 2015) (Shand et al. 2016) (Bortoli et al. 2011). Therefore, women living with IBD are at increased risk of complications of pregnancy or birth which may lead to additional physical suffering.

The additional physical suffering women may experience during pregnancy directly due to their IBD symptoms can have a negative impact on their sleep, their ability to breastfeed and on their everyday life. However, they may also suffer additionally due to the reluctance to take medication as discussed previously and therefore their reluctance to take an additional medication for pain relief. Symptoms confusion for both women and their healthcare providers must be acknowledged, and it is important that presenting symptoms are not directly attributed to either pregnancy or IBD without thorough investigation.

Choice emerged as a sub theme within the theme of *Control* for the women who were interviewed, and this was predominantly focussed on their choices about birth and their treatment. Women felt strongly about the type of birth they wanted and appeared to be a way for them to remain in control of what happened to them. Not all women wanted the same type of birth, and previous experiences shaped the choices made for women with

more than one child. Their choices were not always supported by their healthcare professional either, with one participant really having to fight for her choice of a homebirth despite her IBD being well controlled and unmedicated for some time prior to pregnancy. She was unable to ascertain exactly what the concerns were about a homebirth, other than she was assigned to a consultant led care pathway due to her IBD. Conversely another participant described her experience of wanting to have a caesarean section not predominantly due to her IBD but due to personal circumstances and her healthcare provider was supportive of this choice.

Choices about how to feed their babies emerged as important for the women who responded to the survey, with just under half stating that their IBD influenced their choice around infant feeding. Whilst women were not asked specifically about how they chose to feed their babies, two thirds of the women who positively responded that IBD had influenced their decisions about infant feeding chose to bottle feed their babies with one third choosing to breastfeed. However, there were influencing factors identified behind these choices, and the choice was not always easy to make. The three main influencing factors in decision making around infant feeding were perceptions around medication use and it is possible effects on the baby (as discussed previously), the negative effects breastfeeding may have on the mother's physical wellbeing or baby through not receiving enough nutrients and the protective effect breastfeeding has upon the development of IBD for babies born to women with the disease. Medication was the predominant reason women gave, and the additional anxiety and worry this causes women has been discussed previously so it is unsurprising that this had the most influence over women's choice about infant feeding. However, not all of the perceptions women have about medication use in pregnancy are correct and the role

of the healthcare provider in ascertaining any misconceptions as well as giving information to women living with IBD either preconceptually or in pregnancy will be discussed in depth in **Section 7.2.2.2**. However, the impact of misconceptions and not receiving correct information is clearly demonstrated, with women choosing not to breastfeed their baby due to concerns about medication they take, which in some cases are completely unfounded.

Choice around treatment emerged as a sub theme from *Control* for the women who participated in an interview, and this was about medication use as a treatment. Concerns about medication and the anxiety and worry taking medication can have has been discussed in detail and therefore it is unsurprising that medication use elicited responses. Women who were interviewed portrayed a strong sense of being in control with what treatment they would or would not accept, and whilst they had different ways of retaining this control, they were aware of their rights to refuse treatment, hence their choice. Avoidance was used by one participant, who felt that by avoiding contact with healthcare providers when she became unwell, she could avoid any treatment for her IBD which she was concerned may result in her being separated from her baby through hospitalisation and needing to stop breastfeeding. Although she managed to retain control over her treatment, she was not able to retain control over her disease and symptoms, however this appeared to be more acceptable and she was pleased with her choice. Other participants described their experiences of complying with appointments but acknowledging that they were in control of whether they would start any treatment and that this could not be done without their consent. Healthcare providers were described as respecting the choices the women made, and in some situations actually gave the women the choice as to when to start medication should they feel they needed it. One participant chose to stop taking her medication without

discussing it with her healthcare provider and told them at a subsequent appointment. However, for one participant, she did not feel she had a choice over her treatment and was put on a care pathway without discussion or agreement as discussed. Most of the women who were interviewed described how they felt they were able to retain control and make choices over their treatment which were respected by their healthcare provider if they were made aware of their choices. It may be that how confident the women felt in rejecting treatments influenced the tactic they used, with those who complied with appointments feeling confident to attend and refuse treatment if suggested, opposed to the women who either avoiding all contact with their healthcare practitioner or stopped taking their medication of their own accord who maybe didn't feel confident to have such discussions. 'Choice' emerged as a sub-theme of 'Control' as whether women felt they had a choice or not was determined by whether they felt they were in control. They described choices they made in order to stay in control and how sometimes choices were made for them and this led to a loss of control.

Control had a significant influence on the experiences of the women who participated in the study, with a loss of control predominantly detracting from their experience. Participants felt they had to endure additional physical and psychological suffering during their pregnancy due to their IBD which was beyond their control, or that they sometimes had to make decisions which they felt were beyond their control or resulted in them losing control.

However, a loss of control or something being beyond their control was did not always detract from their experience and in some cases had a positive effect, such as the respite from symptoms experienced during pregnancy. The lack of control women felt over their

IBD emerged but in a positive way, as an almost acceptance, in that they felt lucky when things worked out well.

6.4 Care

Care during pregnancy emerged as being important to women who were interviewed and the women who completed the survey. Women who completed the survey were specifically asked about elements of their maternity care, which included who was their lead care provider, their confidence in this professional, who their preference would be for their lead care provider, and their satisfaction with the number of interactions they had. Women used the free text responses to provide details of their experience relating to their maternity care.

Women who responded to the survey were also asked about their satisfaction with the amount of interactions they had with their lead carer, who their lead care professional was, who they would have preferred to lead their care and their confidence in their lead carer.

'Who cares for me' emerged as being important to the women who were interviewed, with the positive effects of having a midwife who knew them well, having cared for them throughout their pregnancy and in one case during all of her pregnancies, were described. These included the midwife being able to recognise when the participant was unwell with her IBD despite her not raising this with the midwife, and one participant attributed her labour being quick and easy to the fact she knew her midwife so well and she felt so comfortable with her. A small number of women used the free text section in the survey to express how having the same midwife care for them throughout their pregnancy would have improved

their experience. Therefore, having the same midwife throughout pregnancy appears to have both experienced and anticipated benefits for the women in study.

Women who completed the survey were asked specifically about this, with most women responding that a community midwife was their lead care provider, with the majority of the remaining women being cared for by a consultant obstetrician. A small number of women were cared for by an IBD nurse, a gastroenterologist, a practice nurse, shared care between a gastroenterologist and one woman stated she was cared for by all of these health professionals. Whilst for the majority of women a community midwife was their lead care provider, most women responded that they would have preferred this to have been a consultant obstetrician, with the remainder preferring a community midwife. Interestingly no women responded that they would have preferred collaborative care shared between their obstetrician and gastroenterologist. As previously discussed, women with IBD fulfil the criteria for a 'high risk' pregnancy as they have a medical condition which may affect the outcome of their pregnancy (Lee, Ayers, and Holden 2015:43), and this requires collaborative care of the relevant specialties, in this case an obstetrician and a gastroenterologist (Kapoor, Teahon, and Wallace 2016). It has been suggested that the gastroenterologist is key in providing evidence based information about IBD and pregnancy early in the pregnancy and therefore their involvement is essential (Mountifield, R. et al. 2010:181).

For the women who were interviewed, a lack of communication between their obstetrician and gastroenterologist emerged as a theme, with experiences being described of pregnancy care being given almost in isolation to the care of their IBD. A lack of communication was described, even down to each health professional not being aware that the woman had seen

the other and asking the woman to tell them what had been discussed. There was an expectation described that once pregnancy was confirmed the women expected the gastroenterologist would be informed by the obstetrician, yet this did not happen. Women described their care as being disjointed between their obstetrician and their gastroenterologist and described needing to be proactive in their own care, arranging their own appointments and telling relevant health professionals of their pregnancy.

Better multidisciplinary team working was identified as a factor which would have improved their experience of pregnancy for nearly a third of women who responded to the survey question 'what would have improved your experience of pregnancy?'. Women reported that more joined up working between their obstetrician and gastroenterologist, and better communication between the two health professionals would have improved their experience, suggesting that the lack of communication and non-collaborative working actually detracting from their experience. Whilst there is a lack of guidance about multidisciplinary care for women living with IBD during pregnancy, there is clear guidance about the importance of sharing information and good communication. The experiences of the women in this study have demonstrated the negative impact on the experience of pregnancy if this does not happen, with this being identified as something which has specifically detracted from their experience and the steps women have taken to ensure that all of those caring for them are aware of their ongoing pregnancy and gastroenterology needs.

Women who responded to the survey were asked about their satisfaction with the number of interactions they had with health professionals involved in their pregnancy care. Women responded that they were generally happy with the number of interactions with a community

midwife, consultant obstetrician and gastroenterologist, yet over half of the women would have liked to have seen their IBD nurse more often. Unfortunately, there was no opportunity to explore the reasons behind this, however the women who were interviewed described their experiences of having trusted relationships with those who cared for them, and therefore it may be that the women who wanted to see their IBD nurse more throughout their pregnancy had an established relationship with already. Which professional led their care did not appear to be of significance, but the positive impact this trusted relationship on their experience was described in detail. Women described feeling that their lead healthcare provider advocated for them, supported their wishes and that there was mutual trust in the relationship in that they felt their healthcare professional trusted their decisions and that they trusted their decisions. They also overwhelmingly described the importance of their needs being understood, and the effects it had if these were or were not understood or responded to. A healthcare professional who understands individual needs were described as making the experience of pregnancy better for the women who were interviewed, and in one case even safer, as healthcare professionals noted her medication intolerances without having to be retold which appeared to be a relatively unique experience.

Women who responded to the survey were asked if they felt their lead healthcare professional understood their needs, with the majority of women cared for by a midwife or obstetrician responding that positively, however more women felt that their midwife did not understand their needs compared to obstetricians. Whilst there was no opportunity within the survey for women to expand on their experiences about this, it may be that this difference in the understanding of needs is due to obstetricians being more experienced in providing care to women with long term conditions, even if not specifically IBD, and therefore

were able to meet the needs of women who wanted or needed the additional care associated with their IBD. As discussed in previously the additional care associated with a high risk pregnancy and consultant led care was described to be reassuring for many women who were interviewed and therefore it may be that the care routinely given by consultant obstetricians met the needs of women without them having to explicitly outline their individual needs. However, it is important to remember that not all women living with IBD will have the same needs during her pregnancy, and this was highlighted by the experiences described by the women who were interviewed. Whilst many found the additional care they received as reassuring, one participant described how she felt she actually received more care than she felt she really needed, with another describing how the availability of help or support was enough and that she had not needed to utilise it.

Another participant described the contrast in how her needs were met by her healthcare professional, yet her needs remained completely unmet when she attended a parent education course. She described how she felt she was unique due to her medical history and therefore the information she was given did not relate to her and therefore did not meet her needs. Parent education was also explored in the survey, as discussed previously and highlighted how attending parent education led to an increase in feelings of worry during pregnancy. The experience described about unmet needs from parent education appear to echo those of the women who responded to the survey, and therefore suggests that giving impersonalised, generic pregnancy education to women living with IBD, or indeed other long term conditions is not helpful, and may in fact evoke additional worry.

The importance of multidisciplinary working as already been discussed earlier in this section, with the benefits experienced by the participants described and the impact that the lack of

multidisciplinary team working had, however this demonstrates how personalised care needs to encompass all elements of maternity or pregnancy care, including parent education.

Power emerged as theme from the interviews, with women describing the struggles they had to retain power and the struggles for power between themselves and their healthcare provider. The more nuanced elements of how power is retained and who has power had different meanings for the participants, however power emerged as being an important element within their pregnancy care and experience of pregnancy.

Participants described the struggles that they had in being heard by their healthcare professionals, with experiences of healthcare professionals appearing unengaged and not listening to them during appointments, to having to repeat their medical history at each consultation which took up the entire appointment and left no time to ask any specific questions, which led to a loss of power for them. Participants also described experiences of the struggles they had to get information from their healthcare professional about their care which also resulted in an imbalance of power.

Some participants developed strategies to help them retain power, with avoidance of certain interactions with healthcare professionals being described, due to concerns that this may lead to decisions being made about care which the participant did not want to happen. This suggests they did not feel she had the power to decline and that there was an imbalance of power, which she could only rectify by avoiding such situations. Other strategies included regulating what information was told to the healthcare professional so that only some information was shared which the participant was happy to share and that she felt safe to share as it wouldn't lead to interventions or power imbalance. One participant described how

she almost bargained with her healthcare provider, who was unsupportive of her plans for a homebirth, so she complied with other elements of the care so as not to rock the boat and retain her power over decisions. Having the power to make their own decision was described by the participants, and these decisions were sometimes against medical advice, such as having another baby. Whilst retaining power was important for some participants when making decisions, one participant described how she was almost forced to make a decision to self-manage her pain as she was unable to get help and therefore became powerless. Another participant described how she readily relinquished her power as she was desperate for help from her healthcare professional and consequently she felt her loss of power was inevitable and unavoidable if she was going to get the help she needed.

Whilst power was a theme which only emerged in the interviews, it has provided valuable insight into how relationships are formed or affected when there is a power struggle or how women may develop or choose strategies to retain their power in situations they feel it may be threatened.

Whilst originally emerging as a sub theme within 'power', information giving was highlighted as being important by women who were interviewed and women who completed the survey, with women describing their experiences of struggling to get information from their healthcare provider or not being told about elements of their care leaving them with unanswered questions years after the birth. The struggle to get information for one participant was around risks associated with a homebirth due to IBD and was therefore important in helping with decision making. However, the participant described a reluctance, or even the withholding of information which led to some tension within the relationship and

seeking involvement from another healthcare professional who would advocate for her and her preferences about birth.

The positive effects on improving outcomes of giving pre-conceptual information to women living with IBD are well evidenced (Pinder, Lummis, and Selinger 2016:326) with Hoekstra et al. (2018:704) and Selinger et al. (2012:62) recommending that all women living with IBD are given information about IBD and pregnancy routinely.

The literature overwhelmingly suggests that the gastroenterologist is best placed to provide such information (Ellul et al. 2016, Mountifield, R. E. et al. 2010, Hoekstra et al. 2018) and that they should provide evidence based information about pregnancy to enable women to make fully informed decisions and understand the importance of good disease control at conception and during pregnancy (Ellul et al. 2016:890) (Mountifield et al. 2010:181).

Before a healthcare professional can give information about pregnancy and IBD, they must have a good understanding themselves of the evidence base and current practices. A lack of healthcare knowledge about IBD and pregnancy emerged from the women who responded to the survey, with nearly half of all comments about what would have improved their experience of pregnancy being about this. Women used this opportunity to express their experiences of lack of awareness, understanding and knowledge they felt their healthcare provider had, with midwives and general practitioners being predominantly cited. The lack of knowledge, information and understanding not only detracted from their experience of pregnancy, but also had a negative impact on the physical and emotional wellbeing of the women and also they felt this negatively affected the care they received. Women used the ‘other comments’ box to describe their experiences. The lack of information about medication and how it may affect their baby increased how stressful pregnancy was for one respondent, and women described being left with symptoms as their

healthcare provider would not change management due to a perceived lack of understanding about IBD and also their current pregnancy. However, one woman did use this opportunity to share how collaborative her care had been between her gastroenterologist and obstetrician and that she had been able to plan her pregnancy with advice and information from her gastroenterologist. The negative impact a lack of knowledge their healthcare provider has on the care women receive was also evidenced in the literature review, with a delay in recognition and subsequent diagnosis being attributed to the lack of healthcare provider knowledge about IBD and pregnancy (Cooper et al. 2011:32) and how misconceptions and how this can lead to suboptimal decisions can be attributed to knowledge and information not being adequately shared with women. Midwives and GP's were identified as having particularly poor knowledge, and this was echoed by the experiences of the women who responded to the survey.

6.5 Synthesis Summary

The results and findings from the survey and interviews, along with the results from the systematic review have been synthesised. As previously discussed, the data from the interviews is the primary data, with the data from the surveys being supplementary. Principles of methodological triangulation were used when integrating the data, using the embedded mixed methods design, to ensure that the validity was not compromised.

The three main emergent themes expectations, control and care highlighted the individual ways in which experiences are shaped and what contributes to this.

The voices and experiences of the seven women who were interviewed have been heard and this chapter has presented the results of those interviews which were analysed using IPA. The emergent master themes and subordinate themes have highlighted both

similarities and differences in experiences and have captured valuable insight into what women considered to be important to them during their pregnancy. The findings and results of the interviews, surveys and systematic review have been synthesised and presented and will now be discussed within the wider context of IBD and pregnancy care, including national guidance and policy in **Chapter 7**.

Chapter 7: Discussion

7.1 Introduction

The data collected from the survey and interviews were analysed separately as per the embedded mixed methods study design, and then synthesised to integrate the results and findings. As previously discussed in **Section 3.5: Mixed Methods**, the data from the interviews were primary as this was the first-hand accounts of the women experiences and therefore the womens' voices were the priority, with the survey data being supplementary. Triangulation was used to ensure that whilst the data was integrated, the validity of each methodological approach was not compromised. Furthermore, the data synthesis has been outlined and discussed in **Chapter 6: Synthesis.** This chapter will now pull all the thesis together and critically discuss the overall study findings and results in relation to the relevant literature, guidance and policies. The strengths and limitations of the data presented in this thesis will be discussed, along with the recruitment strategies used, and how the characteristics of the participants may have shaped the findings.

In order to demonstrate how the aims of the study have been met, the discussion will be structured by revisiting the aims of the study and by addressing the way in which each was met in turn.

Recommendations for clinical practice, education and further research will be made at the end of this chapter.

7.2 Revisiting the aims of the study

The study had two aims:

- to gain an in-depth understanding of the experiences of pregnancy in women living with Inflammatory Bowel Disease
- to explore recommendations about a care pathway model for women living with Inflammatory Bowel Disease during pregnancy from women living with IBD who have experienced pregnancy.

To fully answer the research question: **what are the experiences of pregnancy for women living with Inflammatory Bowel Disease?** two individual studies were undertaken, with each having a different focus driven by the aims of the study. Aim one of the study was fulfilled with the findings from the interviews, whilst aim two was fulfilled using the survey results and findings and the interview findings. The integration of the two studies enabled both aims to be fulfilled and the overall research question to be answered.

The first aim of the study was focussed on gaining an in-depth understanding of pregnancy for women living with IBD. It was through this integration and synthesis of data that the key themes emerged. Whist it was the interviews that provided primary data, supplementary data collected from the survey enabled a wider exploration of experiences from a larger cohort of women. The interviews provided an in-depth understanding of the experiences of pregnancy of seven women, however the additional 50 experiences gathered from the survey enabled further 'voices' to be heard and captured a broader range of the experiences due to the more expansive eligibility criteria. It was through the integration and synthesis of these 57 experiences that an in-depth understanding of the experiences of pregnancy for women was gained in order for Aim one of the study to be met.

Through the synthesis and integration of the data, key themes emerged that were considered by the women to shape their experience of pregnancy. There were two main themes: expectations and control, with sub-themes within control.

7.2.1 Aim one: to gain an in-depth understanding of the experiences of pregnancy in women living with Inflammatory Bowel Disease

Expectations emerged as a theme from the interviews and this included women's personal expectations, their expectations of others and what they were told to expect. These themes were supported by the findings and results of the survey which explored expectations about changes to disease activity during pregnancy and what women were told in relation to their disease activity, which led to an overall theme of *Expectations*. *Control* emerged as a theme from the interviews but had sub-themes as *Control* emerged to be multifaceted. The survey findings and results supported these sub-themes as provided additional insight into the impact IBD had on everyday day during pregnancy, the additional suffering women felt they experienced due to their IBD and their ability to make choices. *Choice* emerged as sub-theme of *Control* with women's abilities to make choices being determined by the control they had. The integration and synthesis of the data gathered from the interviews and survey enabled an in-depth understanding of the experiences of pregnancy for women living with IBD and provides a novel insight. Expectations appeared to be key in shaping experiences and will therefore be critically discussed first.

7.2.1.1 Expectations

Women described their expectations around what they expected to happen during pregnancy and what they actually experienced, what they expected to be told and what they expected their healthcare provider to know about – in particular midwives.

Data from this study highlighted that women's expectations varied but were directly impacted on their personal experiences and relationships. Whilst it is acknowledged findings are not generalisable, this was an important and novel aspect of the results and findings. Furthermore, the relationship between expectations and experiences had a potential to influence experiences with health professionals.

Currently the advice given to women is that during pregnancy, a third of women will experience an improvement in symptoms, a third will stay the same, and a third will experience a worsening of symptoms as discussed in **Section 1.1.5**, yet where this figure originated from is unclear. It does not appear to be based on current evidence yet is repeatedly used within the literature and with discussion with women and healthcare professionals about IBD behaviour in pregnancy. It is therefore difficult to understand what is shaping expectations and therefore experiences. It is possible that the way information is shared, and care is experienced, could positively influence self-efficacy and optimism which could then translate into the perception of experienced symptoms. This has possible positive implications for maternity care when caring for women living with IBD. It may be that through shaping an expectation well, an improved experience of symptoms and a reduction in physical discomfort and anxiety may be achieved, and this a novel finding that requires further exploration before conclusions can be drawn. The findings of this small study mirror the conclusions drawn from the meta-analysis undertaken by Abhyankar, Ham, and Moss (2013), that disease activity at conception provides some additional, evidence-based

prediction about disease behaviour, with the women who had mild or non-existent symptoms in the month prior to pregnancy experiencing an improvement or plateau in symptoms compared to those who had moderate symptoms pre-pregnancy. As the numbers in this study are small, and the meta-analysis by Abhyankar, Ham, and Moss (2013) was undertaken some time ago, further research is needed about disease activity behaviour predictions, which will be discussed in **Section 7.6**.

With regards to expectations about their symptoms, overall women were either more optimistic and this has driven how they perceive their experience, or just realistic and understood how symptoms could be affected by pregnancy. However, rather than being less optimistic, it may be that women with active disease pre-pregnancy (which gives them moderate symptoms) are actually just realistic in their expectations that their symptoms will either stay the same or worsen during pregnancy, as opposed to improve. Conversely, women with absent or mild symptoms prior to pregnancy were optimistic about how their symptoms would be and this proved to be the reality for most women, and this offers some insight into what information should be given to women pre-pregnancy.

Whilst this study has highlighted the need for further research into the relationship between disease activity at conception and disease activity during pregnancy, the advice women were given about how their IBD would be during pregnancy appeared to have a positive correlation to how their IBD was actually experienced. This finding led to the consideration of what may have influenced this and the impact of positive expectations of self-efficacy were considered. By being told that their IBD would improve in pregnancy, may have positively influenced their self-efficacy, as although verbal persuasion is considered to be weaker than other influences, it is still considered to be useful as outlined by Bandura (1977:198) who first described the concept.

Optimism bias may also play a part in the expectation's women had about their symptoms. Optimism bias is when there is a belief that things will be get better regardless of the advice given and expectations that positive things will happen are overestimated as opposed to an underestimation of expected negative events and can reduce the effects of a poor outcome prediction (Barlow et al. 2016:8). Not all women who were told their symptoms would get worse during pregnancy by their healthcare practitioner expected this to happen, and despite the advice they were given, had an overestimation of the positive situation of an improvement in symptoms. A systematic review undertaken by (Giangiordano et al. 2020) looked at the relationship between obstetrical outcomes, which they defined as preterm birth (<37 weeks), Pre-eclampsia and Small for Gestational age baby (<10th centile) and the dispositional optimism of women, which they determined using a recognised assessment tool. A total of 3570 pregnancies were included for the two studies which fulfilled their inclusion criteria. They found that women with higher levels of dispositional optimism were less likely to have a preterm baby, however there was no difference in the other two outcomes. They did also find there were other influences over the levels of dispositional optimism, and this included maternal age, married or married like status, public assistance, smoking status, ethnicity and educational level. Women ages ≤ 30 years, who were married or had married like status, did not need public assistance, were non-smokers, were white and had higher educational levels had higher levels of dispositional optimism. Therefore, it may be possible to increase the levels of dispositional optimism for women with modifiable traits, and further prospective research into this was recommended. This offers some insight into what influenced the optimism the women in the study experienced, and that the belief that things may not be a bad as they were told was driven by their personal social factors. All women who participated in the interviews were married or had married like status and were white and this may have therefore increased their level of dispositional optimism.

As discussed in **Section 4.3.4.1** this improvement in symptoms was not always the reality and therefore optimism bias was observed in the study.

Improved levels of self-efficacy were not limited to just being advised to expect an improvement in symptoms; women who experienced more than one pregnancy following their diagnosis of IBD and were well during pregnancy may also have increased self-efficacy due to their previous positive outcome however if they were not well during pregnancy this may lead to a decrease in their self-efficacy (Bandura 1977:195). Women who have peers with IBD may also be exposed to vicarious experiences of IBD and pregnancy and this can also positively impact on self-efficacy if the peers are well throughout pregnancy (Bandura 1977:197). Seeing others with IBD experience pregnancy without adverse effects on their health, which could also include exposure through social media and support groups, gives a positive message and this may positively influence self-efficacy. However, it is important to remember that whilst observing or being exposed to positive experiences may increase self-efficacy, the effects of exposure to negative experiences may result in a reduction. Whilst the positive effects of exposure to positive experiences of IBD and pregnancy were reported by one participant in the study, the powerful effect exposure to both positive and negative experiences may have on levels of self-efficacy should be recognised. The women overwhelmingly described how their expectations about how their IBD would behave during pregnancy was key in shaping their experience, and this was a novel finding. This has real importance for shaping and improving maternity care for women living with IBD and has been realised through the in-depth exploration of the experiences of pregnancy for these women.

As previously discussed, women's experiences were not confined to their personal expectations, they also described their expectations of others, namely the midwives caring

for them during pregnancy. They described their expectations of what they their midwives should know about IBD and pregnancy and this highlighted the different expectations the women had about what they felt their midwife should know, with some feeling that knowledge about IBD was beyond their remit of care of a midwife, whilst others voiced that they felt they should have some knowledge and awareness. Overwhelmingly the lack of knowledge and awareness of those providing care was considered to detract from the pregnancy experiences for women, and this included midwives, GPs and gastroenterologists. Whilst women generally did not expect midwives to be experts, they did expect them to have some awareness of IBD and pregnancy. Within the current midwifery training curriculum there is no standard for training about IBD, so knowledge and awareness are gained experientially. This is in part where the research topic for this PhD originated from. Until midwives' care for women with IBD and become involved in the relevant care pathways, gaining knowledge from both other health professionals involved and also the women themselves, there is no formal resource for midwives to pre-educate themselves or gain awareness about IBD. Therefore, although the detrimental effects on the experience of pregnancy were voiced, the women who expected midwives to have no or little knowledge were more realistic in their expectations given the lack of training and resources available to midwives. However the expectation that midwives should have awareness and knowledge should be used to shape future care as there are safety issues which may arise from a lack of knowledge and care, including failure to recognise IBD as a condition which may adversely impact pregnancy, if it is confused with IBS or if it not understood. The role of specialist midwives for conditions which may adversely affect the mother or baby, including long term conditions and those arising in pregnancy are considered to be an essential part of ensuring safe maternity care by the National Institute for Health and Care Excellence

((NICE) 2015:68) who outline the need for care from a specialist midwife when indicated in their guidance about safe midwifery staffing in maternity settings.

Whilst specialist midwifery roles in diabetes, multiple births and perinatal mental health have evolved, the evidence about what impact this has on care appears to be limited. A narrative review of specialist nursing and midwifery roles undertaken by Casey et al. (2017) found there was limited evidence and information about the contributions to care these specialist roles and called for further research to capture the impact.

Whilst the women in the study described differing expectations of what their midwife should know about IBD, overwhelmingly they felt that a lack of knowledge about IBD did detract from their experience. Drawing on the findings of the narrative review by Casey et al. (2017), a specialist IBD midwife may not necessarily improve the care given to pregnant women. Therefore, it could be argued that resource would be better used in educating all midwives about IBD to enable them to recognise and signpost appropriately. This study did not seek the views of midwives or midwifery lecturers about the provision of education or training on IBD and pregnancy, but this is something which requires exploration

This study has provided valuable and novel insight into what expectations women may have, what influences and drives these, the importance women place on receiving advice about IBD during pregnancy and how all of these may impact on the experience of pregnancy for women and for healthcare providers caring for women both pre and during pregnancy to be aware of these.

7.2.1.2 Control

The theme of control also emerged in this study both positively and negatively in terms of the control the women felt that they had over the choices they made, what they felt they could and could not control within their experiences, and the steps they sometimes took to help retain control. Respondents to the survey echoed many experiences which included a respite from symptoms of IBD during pregnancy and the positive effect this had, the additional worry and anxiety women felt during pregnancy due to their IBD and the sometimes difficult choices women had to make which were not always within their control. This provided novel insights into how control impacted on the experiences of pregnancy and a contributed to the overall in-depth understanding required for aim one of the study.

7.2.1.2.1 Beyond my control

Being 'beyond their control' was something commonly described by the women in the study, in the context of not being involved in decision making, this included being assigned to care pathways without consultation or discussion

Women describing being 'lucky' when their IBD was well controlled and how fortunate they felt when their symptoms were manageable is a positive example of how being outside of individual control is not always negative, and due to the unpredictable nature of IBD, symptoms are usually seen as being beyond control. . This may offer an insight into how the women perceive the management and care of their IBD, that they feel it is not guaranteed to work and that they have no control over this and they are therefore grateful or feel 'lucky' when it does.

However, it is important to recognise that whilst symptoms do fall into categories of absent, mild, moderate or severe, how women perceive these may be subjective, and what is manageable for one woman may be considered to be more debilitating to another and therefore assumptions about the impact symptoms have should not be made.

Although care pathways are determined by factors relating to the woman or her pregnancy, women should have a Personalised Care Plan as outlined in Better Births (National Maternity Review 2016), created in partnership between the woman, her midwife and any health care professionals involved in her maternity care. This personalised care plan should be bespoke to the woman's individual needs, and should not only include the pregnancy, but also any wider health needs she may have (National Maternity Review 2016:8). This however did not happen for many women in the study, who were instead assigned care pathways without discussion or consultation, and had care plans created for them, not created as a partnership. It may be that Trusts had not yet implemented Personalised Care Plans, that their use was not fully embedded, or that how Personalised Care Plans actually work for women with co-morbidities is not defined. Maternity care providers are able to design their Personalised Care Plans and therefore there is no standardisation in the quality of these, just standardisation of the principles underpinning it. As previously discussed in this chapter, women living with IBD fall into the category of "high risk" for pregnancy, and this require pregnancy care by the multidisciplinary team which involves an obstetrician and gastroenterologist (Kapoor, Teahon, and Wallace 2016:205). As also discussed in **Section 1.1.5**, there is little national guidance about how to care for women with IBD during pregnancy, and therefore referring women for obstetric led care is appropriate. However, despite this limited guidance, it is inappropriate for healthcare providers to not include women in the decision making, which was the experience described by some women in the study. As discussed previously, personal care plans should be created in partnership with

the woman, the lead maternity care provider and any other professionals involved in her care and this is regardless of the severity of their symptoms or disease activity, clinical presentation or absence of available guidance or evidence.

Whilst this would indicate the need for multidisciplinary obstetric led care, women should be involved in such decisions about both her pregnancy and with regards to her IBD, and this is not limited to maternity care or indeed women with IBD, with the NHS outlining expectations of how people living with long term conditions should be empowered to manage their own health and make decisions about their treatment and have control over their care and treatment in its Five Year Forward View document (NHS England 2014:12). The experiences described by the women in this study were that shared decision making not did always happen, especially around assignment to care pathways, and that their pregnancy care and IBD care were disjointed which is discussed in **Section 6.4**. This again may be due to lack of guidance around maternity care for women with IBD, as other long-term conditions including diabetes have extensive guidance about how multidisciplinary care should be delivered. However, it is important to recognise that having guidance does not automatically result in better care, guidance needs to be implemented effectively for this to be achieved. This study therefore offers an insight into the impact of the absence of national guidance on the multidisciplinary pregnancy care for women living with IBD, which left women feeling that their care was beyond their control, they were not involved in decision making and that their IBD and pregnancy were cared for in isolation. This further demonstrates the inequity in maternity care of women living with IBD compared to those living other long-term conditions, as women should be empowered to make decisions and have control over their IBD care and pregnancy care with support and evidence based, impartial advice from their healthcare providers.

Although the care the women in this study received was often 'beyond their control', women expressed they found reassurance in the additional surveillance of pregnancy which being assigned to a high-risk care pathway provided, such as additional scans and appointments. Therefore, although this was something the women felt they were not able to control, they did not perceive this to be a negative aspect of their care if they received perceived benefits which provided them with reassurance, which will be discussed further in **Section 7.2.2.1**.

It is also important to understand that shared decision making may be affected by a variety of internal and external influences which include the woman's beliefs, personal experiences, advice women may have been given, and the media (Agoritsas et al. 2015:2) and these must be explored thoroughly by those providing care. The women in the study described the importance they put on what they were told about what to expect with regards to their IBD and how this shaped their expectations and therefore may also affect shared decision making. However shared decision making for the women in the study is also likely to have been affected by the lack of knowledge held by their healthcare provider about IBD and pregnancy, as the free sharing of knowledge between healthcare provider and woman is essential in shared decision making (Begley et al. 2019:118) and this is discussed in further detail in **Section 7.2.2.1**.

7.2.1.2.2 Impact on life

The women in the study described how pregnancy whilst living with IBD had an impact on their lives in varying ways, both negatively and positively, with most women experiencing a respite from their symptoms of IBD during pregnancy, but also experiencing additional

physical or psychological pain, which can be termed as suffering, due to their IBD. The positive impact pregnancy had IBD activity often meant women were able to enjoy activities during their pregnancy, such as the freedom to expand their food choices, which they would not usually be able to do due to their IBD. Therefore, this respite, although experienced in pregnancy, had wider reaching positives to their life in general. The additional stresses and anxiety, predominantly caused by decision making around medication use, were also described to feature outside of pregnancy, but pregnancy compounded and exacerbated these concerns as women were now concerned about their unborn baby as well as themselves.

7.2.1.2.2.1 Respite from symptoms

The women in the study overwhelmingly described how pregnancy provided them with some respite from their IBD symptoms, which had previously been extremely debilitating for some women. The interviews provided a first-hand account of the debilitating effects IBD symptoms had on everyday life, whilst although the interviews did not ask for this level of detail, women were able to identify how their symptoms were in terms of 'none', 'mild' and 'moderate'. These are terms commonly used by gastroenterologists and those caring for women with IBD and therefore there is some shared knowledge about what each term means. Whether this respite was anticipated or not has been discussed in **Section 7.2.1.1** with most women experiencing what they expected with their symptoms. Their freedom to eat what they wanted and not have their diet dictated by their IBD was seen a real symbol of their wellness during pregnancy and respite from their IBD for the women who were interviewed. This also highlighted how the women's food choices were not controlled by their IBD. However, pregnancy did not provide a respite for all women, with some women

experiencing a worsening in symptoms and regardless of whether this was expected or not will undoubtedly have affected experiences of pregnancy. It could be argued that the women who participated in the study generally experienced an improvement in their symptoms as the majority embarked on pregnancy with mild or absent symptoms, and therefore are much less likely to experience a worsening of symptoms than those who became pregnant with moderate symptoms, however this study has still provided a valuable insight into how the respite in symptoms positively affected women's experience of pregnancy and what respite actually meant for them. As discussed in **Section 7.2.1.1** the healthcare provider has a role to play in informing women about how their symptoms may change during pregnancy, either for the better or the worse and support them physically and emotionally through any worsening of symptoms.

7.2.1.2.2.2 Additional Suffering

Women in the study identified that they experienced both additional physical and psychological pain, over a prolonged period of time, which could be considered as suffering, caused by the IBD. Whilst the term 'suffering' was not used by the participants, it reflects the additional physical and/or psychological pain described over the duration of their pregnancy. Ménage et al. (2017:565) describe suffering as something which is considered to be a motivation for compassion, and therefore healthcare professionals caring for women need to be able to recognise this suffering if they are to provide compassionate care and alleviate the suffering. However, the women in the study did not describe wanting their suffering alleviating, more that they were accepting of the additional physical and psychological pain and discomfort they experienced throughout pregnancy, with the participants who were interviewed sharing their experiences of what physical and/or psychological discomfort or pain they experienced prior to pregnancy in **Section 5.2.2.5.1**. This highlights how they were

accustomed to pain and discomfort prior to pregnancy due to their IBD and that pregnancy brought additional pain or discomfort. Additional physical suffering was described as being multifactorial, with the physical impact of IBD symptoms causing physical pain, disruption to sleep and fatigue. However, reluctance to take analgesia for simple ailments such as a headache was also described by a small number of women, with the reluctance stemming from the concerns about taking additional medication during pregnancy when they are already taking medication in pregnancy for their IBD. Therefore, had they not needed medication for their IBD they may have taken analgesia more readily, and this supports the findings of a study undertaken by Mulder et al. (2018:5) which surveyed all women attending an obstetric care facility asking about their concerns and perceptions of risk and benefits associated with various medication use during pregnancy. They found most women reported taking medication whilst pregnant (82.2%) with paracetamol being the most commonly taken medication. Whilst women in this study did have concerns about medications, these were mainly around antidepressants, sedatives and NSAIDs with concerns including congenital birth defects, miscarriage and child allergic disease. However, paracetamol was considered by the women to be low risk and of high benefit, hence the high proportion of women who took it during pregnancy. Therefore, this contributes the novel observation of the impact IBD had on women's attitudes to medication, and the reluctance to take an analgesia, which is considered to be low risk for women not taking additional medication necessitated by a medical condition. Careful discussions are needed with women who may 'refuse' to take pain relief to understand their reasoning and support must be given to ensure that they do not suffer unnecessarily, whilst respecting their views.

Women seemed accepting of the additional suffering this would cause them, which may be due to the pain/discomfort they have become accustomed to experiencing due to their IBD. This may become a barrier to providing care to women, if they are accepting of additional

suffering and therefore decline interventions/medications they consider to be unnecessary or unacceptable. Whilst the women did not describe wanting their suffering alleviating, healthcare professionals should remain mindful of the positive impact compassionate care can have on suffering, although it is hoped that care is always compassionate.

The internal conflict women experienced around medication use in pregnancy were described numerous times, with this having a real impact on the experience of pregnancy and also on the emotional wellbeing of the women. Women described the internal conflict they had about whether to take medication they feared would harm their baby in a quest to stay well or whether to not take it and risk becoming unwell. These findings echoed those of the studies by Ellul et al. (2016) and Mountifield, R. et al. (2010) which both found women living with IBD were concerned that IBD medication may harm their babies. This was considered as a definite additional element of suffering compared to women who did not need to take regular medication during their pregnancy, and whilst some participants acknowledged pregnancy was a generally anxiety inducing time, the decision making over medication use caused additional worry and anxiety.

The women in this study were pregnant women living with IBD, and it could be argued were at an increased risk of psychological difficulties which are predominantly anxiety and/or depression. Not only do these women have the increased risk of having a co-morbid mental health illness, predominantly anxiety or depression, as they have a long term condition (NHS England 2020a) with two out of three people living with a long term condition also having a co-morbid mental health illness, but their pregnancy also further increases their risk of mental illness with one in five women developing diagnosed with a mental health during or after pregnancy (Royal College of Psychiatrists 2020) . A study by Zadeh et al. (2012:110)

undertook a study which compared self-reported depression scores in the postnatal period (using an approved scoring tool) between women with a high risk pregnancy due to medical conditions affecting either the mother or the baby and women with a normal term pregnancy and concluded women diagnosed with a high risk pregnancy, which does encompass IBD, were more likely to develop anxiety and/or postnatal depression. One explanation for this was that women who have medication conditions are more likely to have babies affected by a medical condition and this generates additional anxiety, worry or depression. This finding echoes the experiences of the women who described the worry and anxieties they had due to their IBD and the possible effects the medication they took for their IBD may have on their baby. Therefore, as pregnant women living with IBD have numerous factors which all increase their risk of developing a mental illness, predominantly anxiety or depression, either during or after pregnancy, it is not surprising that anxiety or worry emerged from both the interviews and the survey. Although being diagnosed with a high risk pregnancy may increase the risk of developing anxiety or postnatal depression (Zadeh et al. 2012:110), women who participated in the interviews described how they found the additional scans and appointments with their healthcare provider during pregnancy reassuring. Therefore, for the women in the study, the associated additional surveillance or appointments with the high-risk care pathways provided reassurance and may have helped reduced anxieties or concerns. This offers valuable insight into the experiences of women assigned to a high-risk pregnancy care pathway, and the positive impact reassurance has may have on experiences. However, the reassurance gained through a scan or appointment may only be short-lived, with the anxiety quickly returning as the scan has not alleviated the overarching concerns about their baby. Anxiety may also be increased if a scan or appointment is not available, for which the woman feels she needs to be reassured. Therefore, although the women in the study reported the additional surveillance or appointments as being reassuring,

healthcare professionals should be aware of the implications this may have longer term or if the scan or appointment is cancelled or deemed clinically unnecessary.

Women within the study described the additional suffering they felt they suffered due to their IBD, and how they found reassurance and it may be that women sought out additional activities which they thought may provide reassurance, including parent education. The survey specifically asked about parent education and looked at the impact this had on feelings of worry. Interestingly, the women who attended parent education, or those who wanted to attend but were unable to, reported feeling more worried about pregnancy than those who choose not to attend. Parent education is considered to be a positive health promotion activity, with NICE (2019b) outlining the need for antenatal classes to be used to support important information given to women throughout their pregnancy. However, this may show the impact that not receiving tailored information has, as parent education classes provide generic information and women with IBD may have specific concerns which are not being addressed. It may also be that the women who chose not attend parent education did not have any concerns or worries and this continued throughout their pregnancy, and those who did attend were hoping to alleviate worry or anxiety they felt. As this observation emerged from the survey, with no opportunity for women to expand on their response, it is not possible to understand women's reasons for attending parent education and how their needs and expectations could have been better met. However, the findings of this study echo those of Serçekuş and Mete (2010:400) who found that antenatal classes did increase worry for some women and that it was important to understand the individual expectations of the antenatal education programme to ensure that needs can be met.

Relatively unique experiences of diagnosis of IBD in pregnancy were captured both in the survey and in detail from the interviews. The participant who was diagnosed in pregnancy

provided a detailed account of the struggle she had to receive the necessary medical care for a diagnosis to be made and how she become convinced she had bowel cancer due to the similarity in symptom, which undoubtedly led to additional physical and emotional suffering for her. Cooper et al. (2011) reported a similar experience, however where symptoms were incorrectly attributed to pregnancy due to them being similar to common pregnancy ailments. Whilst diagnosis of IBD in pregnancy is relatively unusual, such experiences provide valuable insight into the impact it has and creates awareness for healthcare professionals about the importance of not attributing symptoms without thorough investigation. Attributing disease symptoms to pregnancy ailments is not unique to IBD, with certain cancers, predominantly breast cancer sometimes being diagnosed at a later stage if diagnosed in pregnancy due to symptoms being attributed to breast changes common in pregnancy or the changes in breast tissue in pregnancy masking the symptoms of cancer (Cancer.net 2018). The experience described within the study of the development of IBD symptoms during pregnancy, which she feared to be bowel cancer, and the struggle for the medical attention which resulted in diagnosis, illustrates how pregnancy may cloud clinical judgements when women present with certain symptoms.

Women living with IBD may experience further anxiety and worry in addition to that experienced by women living without IBD as described by the women in the study. This was due to the impact of their health condition and 'high risk pregnancy' both in terms of the affect this may have on psychological wellbeing but also the difficult decisions they made about medication use and the perceived harm this may cause whilst balancing the risk of them becoming unwell. This finding has significant implications for the healthcare provider caring for pregnant women who are living with IBD, as they must ensure their psychological

wellbeing is monitored as well as their physical wellbeing, and that their increased risk of mental illness is recognised and responded to accordingly.

7.2.1.2.3 My choice

Choice emerged as a sub-theme within *Control* for the women in the study, with them describing what influenced the choices they made, how supported they were in their choices, whether they really had a choice or an acceptance of a lack of choice. As the sub- theme emerged it become apparent that choice was very closely linked with whether the women felt they had a voice to make themselves heard by those caring for them and this centres around control. Without control, women were not able to make choices and women sometimes described making choices to help them retain control.

Place of birth merged as being important to the women who were interviewed, with many describing the choices they made about birth, whether this choice was supported by their healthcare provider and therefore whether this was something they could control or not. The struggles one woman had to be heard about her choice of place of birth led to her employing strategies to retain control and how the lack of support without adequate explanation of reasons led to a power struggle and tensions within the relationship as discussed in **Section 5.2.2.1.1.** Women whose choice was supported by their healthcare provider, but did not come to fruition due to clinical reasons, understood and were accepting of this. Healthcare provider knowledge about IBD and pregnancy was found to be varied by the women in the study, and it may be that the lack of available guidance means healthcare providers are not able to make evidence based decisions which may translate into a reluctance to support birth choices they do not feel confident with or knowledgeable about. A small study by Daemers et al. (2017) offers insight into the clinical decision making of midwives and found

that decisions are not only influenced by knowledge but also personal and/or professional attitudes. Therefore, whilst deficient knowledge may be a contributing factor to the lack of support women encounter about birth choices, it may also be due to attitudes the healthcare professional has.

In terms of choice, reassuringly most women were asked about mode of birth. As discussed previously IBD does not usually influence mode of birth from medical perspective, unless there is perianal disease or active disease involving the rectum in which case a caesarean section would be indicated (van der Woude et al. 2015:109). However it is important to remember than women may request a caesarean section as a vaginal birth is not acceptable to them and this should be respected and undertaken after discussion and an offer of support (National Institute for Health and Care Excellence (NICE) 2011:96). This experience was described by a participant during interview, with her request for caesarean section being supported by her healthcare professional and therefore her choice being respected and fulfilled.

Lack of knowledge by those caring for women living with IBD during pregnancy about birth choices may negatively influence the care they give, in terms of the advice they give or how they support choice. This therefore needs to be addressed, as women's experiences and pregnancy care cannot be compromised due to a lack of knowledge from those caring for them. Women living with IBD will often be very knowledgeable about their condition with NHS England (2014:12) considering people living with long term conditions to be 'experts by experience'. Therefore, most women will be well-informed about their IBD, however may not be as knowledgeable about pregnancy, especially if their first, and this may be reflected in the need for information from those caring about them about integrated IBD and pregnancy.

Whilst this knowledge about IBD is not only empowering to the individual in terms of enabling them to drive decisions about their care, there is also some suggestion by Barker et al. (2018:994) that this reduces the utilisation of healthcare provision, as patients feel confident to manage their own condition and care and this was described by some women in the study who felt confident managing their IBD particularly around medication use, knowing when they needed or did not need medication to control their IBD symptoms. However, this was not described by the women in relation to their pregnancy, with most women looking to their healthcare provider for management and accepting the loss of control that came with this.

Snow, Humphrey, and Sandall (2013:7) discuss how the benefits of women being an expert of their own condition should also not be overlooked by those caring for them, as healthcare professionals cannot be experts in every condition and therefore through collaboratively working together, the knowledge of the woman becomes extremely valuable. However, despite such benefits, this did not always happen for the women in the study, with some women describing the struggles they had to have their voices heard and the associated loss of control, whilst others described contrasting experiences of being heard and their choices respected and remained in control.

Women in the study described the difficult choices they made about infant feeding, including the impact of IBD on breastfeeding. Women had mixed views about this, with some being concerned about the detrimental effect breastfeeding may have on their own wellbeing and whilst others felt reassured by the protective effect of breastfeeding and these influencing factors over infant feeding choices were equal in frequency. For women to choose to breastfeed their babies due to its protective factor highlights the concerns women have

about their babies inheriting the disease and this is echoed in the study by Ellul et al. (2016:888) who found over two thirds of women identified they had concerns about this inherited risk. Breastfeeding, along with numerous other positive health benefits for women and their babies, does also offer a protective factor against the development of IBD in babies, which is especially important as babies born to either mothers or fathers who have IBD have a three to twenty fold increase in risk of developing IBD (Kevans et al. 2016:210). As discussed in **Section 1.1.5** women with IBD have significant changes in their microbiome composition during pregnancy, which is also present in their unborn babies (Torres et al. 2020:48), however in exclusively breastfed babies, there is an increased presence of bifodobacterium which is the first infant gut coloniser and promotes health benefits. Therefore, it appears that exclusively breastfeeding counteracts the disruption to the microbiome in babies born to women living with IBD, due to the strong influence of breastmilk on the intestinal microbiome in the baby and reduces the inherited risk of the baby developing IBD either in infancy or adult onset (Xu et al. 2017:781). This information should be shared with women, to enable them to make informed decision about infant feeding.

However, did the women who made the decision not to breastfeed their babies due to concerns about the detrimental effects this may have on their health really 'choose', or were they making decisions which they felt were for the best given the situation they found themselves in and beyond their control? 'Choice' suggests that women have been free to make decisions without immense influences but the concern that you may harm yourself through your choice will mean that your 'choice' has been heavily influenced and is not really a choice anymore but rather a decision to minimise the risk of perceived harm. What the women described was the loss of control they experienced and how the loss of control meant they were not able to make choices but instead made decisions influenced by their

views and information they received. The experience of one participant is described in **Table 17,** when responding to a question if IBD had influenced choices about infant feeding, where she described being told she was not allowed to breastfeed and then encountered negative judgement from healthcare professionals and members of the public about her not breastfeeding. This demonstrates that although this was considered to be a choice, it was not a free from external influences and was a decision made by someone else which she complied with, which was therefore something beyond her control. No woman should encounter judgement from any healthcare professional, or the indeed anyone, about how she feeds her baby, and it is appalling that this was the experience described by a woman in the study.

Similarly, women in the study described the choices they made about medication and treatment, with some refusing to take certain medications due to their perceived concerns about the risk of harm to their baby and the lack of reassurance they received due to the lack of knowledge of their care provider. For the women who were interviewed, they described their experiences of generally being supported by their healthcare provider about the choices they made regarding treatment, which usually was to stop the medication and they therefore were able to remain in control. However, women who made such choices needed a voice and was it really a 'choice' given the reasons for their decision.

The choices women make can be influenced by numerous factors and may be more subtle than choice around mode of birth or how to feed their baby and is underpinned by control – either their ability to retain control or a loss of control. It is important that the healthcare provider seeks to discuss and understand the reason behind women's choices and ensure that they feel able to make informed decisions from the current evidence they have been given. A decision to not breastfeed, or not take certain medication may be influenced by

misconceptions or unfounded concerns, or concerns which would benefit from further discussion. Healthcare providers caring for women living with IBD during pregnancy need to be aware of how retaining control, losing control and the acceptance of loss of control can impact on women's experiences and how it may affect the way in which they access information or care during their pregnancy.

Aim one of the study sought to provide an in-depth understanding of the experiences of pregnancy for women living with IBD, and this was achieved through the integration of the data gathered from the interviews and the online survey. The women described what contributed to and shaped their experiences and this has implications for way in which maternity care should be provided. Novel findings of the study included what shaped women's expectations about their IBD during pregnancy and the impact this had on experiences, including how women's expectations can be positively influenced. The additional suffering women described due to their IBD and how this may also be influenced by shaping expectations and improving self-efficacy also provides a novel insight and has implications for maternity care. These novel findings and insights were facilitated by the in-depth methods used within the studies, and enabled aim one of the study to be achieved. Aim two of the study focussed on exploring pregnancy care pathway recommendations from women living with IBD who had experienced pregnancy and will be discussed in the next section.

7.2.2 Aim Two: to explore recommendations about a care pathway model for women living with Inflammatory Bowel Disease during pregnancy from women living with IBD who have experienced pregnancy

Aim two was focussed on what women considered to be important with regards to the care they received during their pregnancy, and how this could be incorporated into a pathway of pregnancy care for women living with IBD . The survey included specific questions about care and asked about who provided maternity care, who would be the preferred maternity care provider, levels of confidence in the care provider, whilst the interview used prompts where needed to draw out discussions about the maternity care the participants received. There were two emergent themes from the interviews and surveys; care for me and information giving with sub themes within the theme of care for me. The women discussed what was important to them with regards to their maternity care, what they felt was lacking and if this influenced their experience and made suggestions and recommendations about how maternity care should look and what should be included in a care pathway.

7.2.2.1 Care for me

Who cares for me emerged as an important theme for the women in the study, with the positive effects of being cared for by a midwife known to the woman and had developed a relationship with, being described. This included both health benefits, such as recognising when a woman was unwell and also being considered to have a positive effect on the labour and birth experience. Maternity care, and how to improve outcomes of maternity services in England was outlined in 2016 by the National Maternity Review – Better Births (National Maternity Review 2016) as discussed in **Section 1.1.7** and this included recommendations and national ambitions about who should provide maternity care and how this care should be

provided. Continuity of carer, defined as having a small team of midwives caring for a woman during pregnancy, labour and postnatally with one named midwife providing the majority of the care (The Royal College of Midwives 2018:2), is one element of Better Births (National Maternity Review 2016) with the benefits of continuity of carer on pregnancy outcomes including a reduction in preterm birth and a reduction in assisted vaginal births (Sandall et al. 2016:17). The limitations of the study where this data originates from has been discussed in **Section 1.1.7** however it still has important implications for maternity care. As previously discussed in **Section 1.1.5** women living with IBD are at higher risk of having a low birth weight baby and/or giving birth to a preterm baby (before 37 weeks gestation) and this increases with increased disease activity (Getahun et al. 2014) (Boyd et al. 2015) (Shand et al. 2016) (Bortoli et al. 2011). Therefore, any opportunity to reduce the inherent risk of preterm birth for women living with IBD has particular relevance, and continuity of carer demonstrates these benefits (Sandall et al. 2016:17). However, despite the benefits associated with continuity of carer, it is important to understand who are caring for women living with IBD during pregnancy and who they actually want to care for them during their pregnancy. Whilst the midwife was the lead maternity care provider for most women in the study, they would have preferred this to haven been their obstetrician, and when questioned further, the women in the survey responded that they felt their obstetrician understood their needs better than their midwife did. This may offer some explanation as to why the obstetrician is their favoured lead professional. Having their needs understood by those caring for them emerged as being extremely important.

Exactly how multidisciplinary or interprofessional integration works in practice is often not defined (Mayer, Bick, and Taylor 2020:8) as although Better Births outlines the need for personalised care, the practicalities of how this multidisciplinary team working is not defined. The guidance around the involvement of health professionals in pregnancy care for women

with IBD is also limited, with ECCO recommending that if a woman has a flare in the third trimester she should receive care from a specialist multidisciplinary team with expertise in treating active IBD in pregnancy (van der Woude et al. 2015:117), whereas the National Institute for Health and Care Excellence (NICE 2019) (NICE) 2019b) recommend effective communication and information sharing between the multidisciplinary team. Interestingly, this is exactly what the women who responded to the survey stated they wanted. However, as discussed in **Section 1.1.5**, ECCO offers extensive guidance about the care of women living with IBD during pregnancy, labour and in the postnatal period, yet this has not been utilised within the NICE guidance. It could be argued that the evidence and guidance is available but is not being used to contribute to guidance for women under the care of the NHS. Despite contributing the ECCO guidance, the USA only recently developed a care pathway for women living with IBD and pregnancy (Mahadevan et al. 2019). Australia have only recently started to develop care of IBD and pregnancy consensus statements, with this being due for completion at the end of 2020. Therefore, it would appear that lack of guidance for the care of women living with IBD is not unique to the UK. However, it is important to recognise that any UK guidance would need to take into consideration the structure of maternity care in the UK, the Continuity of Carer model and access to multidisciplinary team working.

The benefits of a trusted relationship between women and those caring for them emerged, which included women feeling more supported in their decisions, advocated for by their healthcare provider and that there was mutual trust between them, so they trusted their healthcare provider to do the right thing and they felt their healthcare provider trusted them in their decisions and choices.

A lack of communication between the health professionals involved in their pregnancy care was highlighted as being a detractor from the experience for many women, who felt that their pregnancy care was managed in isolation to their IBD and that they sometimes had to compensate for this by telling each health professional what the other had said. This clearly is not ideal and is not in line with the national guidance about pregnancy care for those needing multidisciplinary care. Better Births (National Maternity Review 2016) outlines the need for personalised care for all women, which should include a care plan which collaborates care with their midwife and any other professionals needing to be involved in their care which reflects wider health needs.

Women in the study described how they were not always involved in decisions made about their care, and that they were often assigned care pathways by their healthcare professional. This occurred without their healthcare provider giving them information about why this was the recommended course of action and therefore was not a shared decision. Shared decision making can be defined as enquiry by the healthcare provider and woman which aims to decide upon a course of care, or not, and relies on the healthcare provider making their complete knowledge available to the woman (Begley et al. 2019:1119). The key issue here may be the lack of knowledge held by the healthcare provider assigning the care pathway, as without comprehensive knowledge, such discussions cannot take part and therefore shared decision making cannot take place. The women in the study described the lack of knowledge about IBD and pregnancy they felt their maternity care providers had, and therefore this is likely to have affected their ability to make their knowledge available to the woman and therefore hinders shared decision making. The maternity healthcare providers do not have the access to the necessary guidance about IBD and pregnancy care as discussed in **Section 1.1.1.5** and therefore this will also impact on their ability to share information and facilitate shared decision making.

The importance of a trusted relationship, having their needs understood, and good communication between those involved in their care also emerged as being important, and whilst these are national standards, this study suggests this may not be happening in practice.

7.2.2.1.2 Power

Women in the study described how power had influenced their experiences with some women experiencing a loss of power or a power struggle with those caring for them, or how they developed strategies which they felt enabled them to retain power in situations they felt it may be compromised. Power struggles between themselves and those caring for them were described by women who felt their healthcare provider was not supportive of their decisions, in particular birth plans and medication use. Whilst the women were able to remain confident in their decisions, tension did emerge, and the women developed strategies to over come these. Women have the right to make choices about their maternity care even if it means crossing traditional boundaries (National Maternity Review 2016:43) and should be involved in all decisions about their care (National Maternity Review 2016:44). Women with long term conditions should be supported to manage their own health and have control over their care and treatment (NHS England 2014:11) and the struggles women described were not limited to their maternity care provider, but instead encompassed the multidisciplinary team involved. As discussed in **Section 5.2.2.5.2** pregnancy increases the already increased risk of mental health difficulties for women living with a long term conditions and therefore efforts should be made to ensure that those providing their maternity care are compassionate and avoid unnecessary stress and anguish which may be caused through power struggles. Women did also discuss the strategies they employed to

retain power, and these including avoiding discussing things they felt may result in decisions being made which they did not want to happen, such as hospitalisation when symptoms got severe, or choosing what information they were will to share with those caring for them. Whilst this may have helped the women retain power, it demonstrates the lack of trust they felt in those caring for them and that they felt they would not have their decisions respected and therefore they had to avoid being in that situation. Avoiding interactions or discussions about health may be detrimental to health, with the potential for women to get unwell if they are not discussing their symptoms with their healthcare provider for fear of what they feel will be imposed upon them. However, this was not the experience for all women, with some women describing how they made decisions about their care, which were sometimes against medical advice, and they informed their care giver of their decisions.

Regardless of the power struggles sometimes encountered, all women remained determined in the decisions they had made and sought to achieve these, with or without the support of their healthcare provider, including place of birth, subsequent pregnancy and medication use. As nearly all of the women had lived with a long term condition for some time, it may be that they are used to having such interactions and power struggles and therefore have become more accustomed to navigating through these challenges, hence their tenacity. Snow, Humphrey, and Sandall (2013:6) highlighted how expert patient knowledge was not always considered to be positive by those caring for them and how they sometimes felt uncomfortable when the patient knew more than they did.

Whilst this theme was specific to the women who participated in the interviews, it has provided a valuable insight into the struggles women sometimes encounter and the decisions women may make about their care to retain power, either through disengaging completely or modifying what information they share with those caring for them. This

highlights the importance that a trusted relationship can have on care and also experiences and the need to healthcare professionals and women to make collaborative care plans, where the women's views are truly respected and listened to.

7.2.2.2 Information giving

Information giving originated as a sub-theme from power but was felt to warrant its own theme due to the importance women in the study placed on it. Women described their experiences of either struggling to get the information they needed or wanted, either through a perceived lack of knowledge of the health professional or that information was intentionally withheld, although this was only the experience for one woman. The lack of knowledge, awareness and understanding about IBD was prevalently that of midwives and GPs and this echoed the insights gained by Cooper et al. (2011) and Ghorayeb et al. (2018). As discussed in **Section 7.2.1.1** the midwifery training about IBD is lacking and therefore this perceived lack of knowledge is accurate and understandable and as discussed previously women appear to have differing expectations of what midwives should have knowledge about, and therefore this highlights how useful national guidance would be about what care, including information giving, women with IBD should receive during pregnancy and by whom. However, this was not the experience for all women in the study, and there were examples described of good collaborative working between the multidisciplinary team involved in pregnancy care and the planning of pregnancy. This demonstrates the inequality in experiences women have received across the UK, however due to the timeframes of the study, it may be that women are reflecting changes in practice such as recommendations and guidance from Better Births about multidisciplinary care.

As discussed in **Section 7.2.2.1** women expressed their preference for their gastroenterologist to be the lead carer in their pregnancy care although the reasons for this were not explored, it may be that they had already built up an established relationship with their gastroenterologist throughout the course of their IBD or that they were able to obtain useful information from them as opposed to their midwife or GP who was not able to provide this information due to their lack of knowledge. The gastroenterologist is best placed to give women information about pregnancy and their IBD (Ellul et al. 2016)(Mountifield, R. et al. 2010)(Hoekstra et al. 2018) and the gastroenterologist should support women to make evidence based decisions, which will require information to be given, about their pregnancy care (Ellul et al. 2016:890) (Mountifield et al. 2010:181). As discussed previously the national guidance around pregnancy care for women living with IBD is sparse, however the Second European Evidenced-Based Consensus on Reproduction and Pregnancy in Inflammatory Bowel Disease (van der Woude et al. 2015:117) recommend that all women living with IBD should have pre-conceptual counselling available to them to advise and optimise management of pregnancy before it occurs.

However as previously discussed in **Section 1.1.7** not all pregnancies are planned, with a third being unplanned or ambivalent (Health Education England 2018) and therefore the timing of such consultations or counselling can be challenging. It could be argued that it is not appropriate to assume all women of childbearing age wish to have children and to therefore given all women information about pregnancy is not providing them with personalised information. The The Second European Evidenced-Based Consensus on Reproduction and Pregnancy in Inflammatory Bowel Disease (van der Woude et al. 2015) argue that if education about IBD and pregnancy is not given, there is an increase in the number of women who feel psychologically unable to have children due to the concerns they have about the disease. Hoekstra et al. (2018) concluded that the age at diagnosis of IBD

affected the information given about pregnancy, with women aged below 35 years at diagnosis being more likely to have discussions initiated with her by her gastroenterologist about pregnancy than women aged over 35 years. This assumes women aged over 35 years will not be pursuing pregnancy, however with the average age for a first time mother being 30.6 years (Office for National Statistics 2019) and women having on average 1.9 babies (Office for National Statistics 2019), women who are diagnosed after the birth of their first baby may miss out on this valuable information if they have another pregnancy with an interval of more than 4 years. It is not only the timing of the information which may be challenging but also who should provide the information. It could be suggested that during the postnatal period may be an opportunity to discuss subsequent pregnancies, as IBD is an unpredictable, long-term condition and may impact subsequent pregnancies. It may be a key opportunity to discuss the importance of conceiving whilst disease activity is mild or ideally absent and personalised information about medication use. Therefore, there are multiple reasons why women are not receiving important information about pregnancy and their IBD. However this study has highlighted the impact that a lack of information can have on the emotional and physical wellbeing of women as well as detracting from their experiences of pregnancy, with women describing experiences including additional worry due to the lack of information given to them about medication and a reluctance to change medications due to a lack of knowledge about them.

Information giving has been highlighted by the women in the study as being important, with women identifying this as being a gap in their care, predominantly through a lack of knowledge in those caring for them. The lack of national guidance about caring for pregnant women living with IBD compounds the difficulties a lack of knowledge has for healthcare

providers caring for these women and therefore further exploration is needed into the educational needs of healthcare providers caring for pregnant women with IBD to help improve knowledge and therefore improve pregnancy and experiences and pregnancy care.

Whilst the survey specifically asked about maternity care, women also used the free-text boxes to make comments about their experiences of maternity care and make recommendations about improvements. Similarly, the women who were interviewed also described their experiences of their care during pregnancy, highlighting both positive and negative examples and suggesting ways in which improvements could be made. Care during pregnancy emerged as being important to the women in the study, with particular importance being put on who they wanted to provide their care, how information was, or was not, given and the value of a trusted relationship between woman and her caregiver. However as discussed in **Section 1.1.7** there are challenges with Continuity of Carer for women living with conditions which mean they require multidisciplinary care and therefore the opportunity to build up trusted relationships may be more difficult than for women who have purely midwifery led care with their named midwife/midwives in line with Continuity of Carer. Continuity of Carer is currently delivered as a team of midwives and does not include other members of the multidisciplinary team, which would be needed to care for women with medical conditions. However, a more tailored care package, which includes continuity of a multidisciplinary team could be used to ensure women requiring multidisciplinary care are also able to build up important trusted relationships.

Aim two looked to explore recommendations about pregnancy care from women living with IBD who had experienced pregnancy, and through the integration of data obtained from the survey and interviews, women identified who they wanted to care for them, how often they wanted to see the healthcare professionals involved in their care, and what they needed

from them. A trusted relationship emerged from the women who were interviewed as being extremely important to the women and the positive effects this had on pregnancy experiences was described. It also emerged that not all women wanted the same things, especially around preferred lead care provider and therefore whilst recommendations about a care pathway model were made by the women, ensuring it is personalised to meet the individual needs of the woman is essential.

Through exploration of the care women received and hearing first hand recommendations about how women would have liked their care to have been, novel insights and findings were made, which could inform a proposed, personalised care pathway model for pregnant women living with IBD.

However, it is acknowledged that the study was small, the exploration of experiences of pregnancy for women living with IBD has not been undertaken before. The strengths and limitations of the study will be discussed in the next section.

7.3 Strengths and limitations of the study

This mixed methods study sought and gained the experiences of women living with IBD who had experienced pregnancy. The survey captured the experiences of women who had a diagnosis of IBD and had given birth whilst the interviews sought the more detailed experiences of women living with IBD who had given birth in the last five years. It enabled the voices of 57 women who were living with IBD and had experienced pregnancy to be heard. This study has provided a unique insight into the experiences of pregnancy as few studies around decision making about pregnancy, management of pregnancy and adjustment to motherhood have been undertaken, but with the exception of the previous small exploratory study undertaken as part of a Masters in Research (Janiszewski et al.

2019). Although the sample size was small, it was of appropriate size for IPA method and valuable insights into pregnancy care women received and how this compared with what they want or need. A strength of the study was the transcription being undertaken as this facilitated a deep familiarisation of the interviews and the accounts the women told. Although it is not always considered necessary for the researcher to complete all transcription, as this was the first-time undertaking IPA, it was felt to really contribute to the deeper understanding needed as the participants made sense of their experiences.

The recruitment strategies used for the study had both strengths and limitations which will be critically reflected upon in detail.

7.3.1 Recruitment strategy

7.3.1.1 Strengths and limitations of the recruitment strategy for the online survey

The recruitment strategy for the online survey involved using a link generated through *Qualtrics* © and was open to all women who had a diagnosis of IBD prior or during pregnancy, had experienced pregnancy, were at least 18 years old and lived in the UK.

Following ethical review, changes to the wording of the inclusion criteria which involved removal of the word 'birth' and replaced with 'experience of pregnancy' meant that women who were still pregnant were eligible to complete the survey. The survey was intended for women who had given birth and therefore experienced a pregnancy in its entirety. However, the word 'birth' may have connotations of being a live birth and therefore the ethics reviewer did not want to exclude women who may have had a stillbirth. The outcome of birth was not asked for as it was not deemed to be important in terms of capturing the experience and it

was not the intention to exclude women who had not had a live birth, however the terminology was changed in accordance to ethical review. However, this resulted in the survey collecting responses from women who had not experienced all of pregnancy and therefore were either unable to answer some questions pertaining to the postnatal period or aspects of pregnancy they had not yet experienced or answering them inaccurately for the same reasons.

7.3.1.2 Strengths and limitations of the recruitment strategy for the one to one interviews

The recruitment strategy for the interviews was determined by the adoption of the study by the NIHR Nottingham Biomedical Research Unit. Women were recruited through invitation letters sent to eligible women by the BRU or IBD specialist nurses, posters displayed in the maternity wards and through social media posts, namely *Facebook* ©. One woman was recruited through word of mouth. The sample size was determined by the guidance around IPA, which suggests between four and ten interviews are appropriate for a PhD study, particularly when the PhD involves more than one self-contained but relevant studies as in the case of this PhD (Smith, Flowers, and Larkin 2012:52), and that a sample size of six is considered to be sufficient for 'good' IPA study. A total of seven women participated in an interview. The interviews were all one off and took place in the women's homes as per their preference. IPA was chosen as it facilitated the in-depth understanding of the unique experiences, and whilst a broader qualitative study involving more women could have been undertaken, this would not have enabled the nuanced elements of the themes and sub-themes to emerge. Seven women were interviewed, and this was an acceptable sample size for IPA, data saturation had occurred by the seventh interview and recruitment was

closed. Further interviews could have been undertaken but this would have been challenging given the time constraints of the PhD, and also given that data saturation had occurred it could be argued were not necessary. The balance between the time allocated for interviewing, transcribing and data analysis and getting the depth of experiences was carefully managed and closing recruitment at seven interviews ensured this balance was maintained.

7.3.2 Participant bias

A total of 50 women responded to the survey, with a mean age of 23.4 years (SD 6.617) at the time of IBD diagnosis and 40 years (SD 6.813) the time of survey completion. Most women were diagnosed with IBD in adulthood (>18 years old), however a fifth of women were under 18 years. Being diagnosed with IBD in childhood may have an impact on maintaining independence during pregnancy and birth, with those diagnosed in childhood being more reliant on others which may be due to the parent/child relationship when the symptoms of IBD first arose and the subsequent diagnosis (Ghorayeb et al. 2018:7). Age at diagnosis may shape the experience of pregnancy and this may be useful information to capture by the healthcare professional at the onset of pregnancy.

A total of seven women participated in a one-off interview. Age was not asked, however throughout the interviews it emerged that all women were diagnosed with IBD during adulthood.

As described previously in **Sections 3.7.5.1** and **3.7.5.3**, the survey took both a quantitative and qualitative approach to data collection and sought responses about pregnancy experiences from women living in the UK who had experienced pregnancy, and either been diagnosed with IBD prior to or during pregnancy and included multiple choice questions,

open ended questions and agreement scales. Due to the feedback received from the survey distributed for a previous study (Janiszewski et al. 2019), the inclusion criteria included all women who had experienced pregnancy and had a diagnosis of IBD prior to or during pregnancy. This was in response to feedback when women expressed their disappointment at not being able to share their experience as the inclusion criteria excluded women who had given birth over 12 months ago. Therefore, there was no upper limit on the length of time from the last pregnancy for the survey, with any woman who had been diagnosed prior to or during pregnancy being able to respond. This expansion of the inclusion criteria was supported by the study undertaken by Simkin (1991:209) who found that women were to accurately recall their birth experience for up to 15 to 20 years after. All except four women who completed the survey had given birth within the last 15-20 years, whilst the rest had given birth more recently with over half having given birth within the last 5 years. This will be discussed in further detail in **Section 7.3.2.1**.

The one to one interviews, analysed using IPA and sought the detailed experiences of women who had given birth within the last five years, as this would mean their experiences were of current maternity and IBD care (discussed further in **Section 7.3.2.1** and had been diagnosed with IBD prior to or during pregnancy and followed an flexible interview tool (Appendix 4) with an opening question of **"starting from the beginning tell me about your experience of pregnancy"** with the use of probes and prompts also. Together, they formed an embedded mixed methods study, with the data from each study being integrated and then synthesised. Four main themes emerged: expectations, control, care for me and information giving, with sub-themes also emerging within these larger overall themes.

7.3.2.1 Previous pregnancies

Women who responded to the survey were specifically asked about previous pregnancies, with questions including diagnosis, number of babies pre and post diagnosis, length of duration of pregnancy, preterm birth, pregnancy loss, if the pregnancy was planned and how long ago the most recent pregnancy was (as this is the pregnancy the survey relates to). Not all women who completed the survey had experienced pregnancy in its entirety as three women were still pregnant, and one woman was pregnant for the first-time following diagnosis. Therefore, at times, the numbers of respondents are adjusted to allow for this.

Nearly all women (48/50) who responded to the survey were diagnosed with IBD prior to pregnancy, with two women (2/50) being diagnosed during pregnancy. For one woman this was during her first pregnancy and for the other it was during her second pregnancy. Most of the women who participated in the interviews were also diagnosed prior to pregnancy, with one participant being diagnosed between her first and second baby and another being diagnosed during her first pregnancy and then having another two pregnancies. Both the survey and the interviews managed to capture the experiences of women who had the more unusual scenario of being diagnosed with IBD during pregnancy. The women who responded to the survey (excluding those who were still pregnant for the first time since diagnosis) had given birth to between one and four babies, with one or two being the most common. The women who participated in the interviews had between one and three babies, with a fairly even distribution of one, two and three babies, with the most recent baby being aged under five years as per the inclusion criteria of the study. For the women who responded to the survey, their youngest children were aged between 11 weeks and 34 years, with up to five years being the most common time frame, and the majority of women experiencing pregnancy within the last ten years. This suggests that women with younger

children wanted to share their experiences, yet the wider timeframe reinforces that the decision to include all women who had experienced pregnancy whilst living with IBD was correct as women with older children still wanted to share their experience. It also means that as the majority of women had experienced pregnancy within the last ten years, their experiences were reflective of the current management and treatment of IBD. Whilst there have been changes within pregnancy care and midwifery care over the last ten years, this is not as vast as the changes which have occurred over the last 34 years, and therefore the experiences of most women were reflective of relatively current midwifery care.

Due to the in-depth nature of IPA and the interviews, the maximum time limit of five years was applied as an inclusion criteria to help minimise recall error, although it has been argued that women were able to recall their birth experiences with complete accuracy 15-20 years after (Simkin 1991:209). As discussed previously, there have been significant changes to both IBD management and treatments and pregnancy and midwifery care over the past 34 years and therefore to include all women would have meant that experiences would not have been reflective of current practice and management and therefore limited the ability to meet Aim 2. Choice and personalisation of care has evolved over the past decade, with it being relatively non-existent 34 years ago where all women routinely had prescribed care including interventions which were not evidence based but were thought to be necessary. Therefore, to only include women who had experienced pregnancy within the last five years ensured that their experiences were reflective of current midwifery practice and care and IBD management and treatments.

7.3.2.2 Preterm birth

Women were asked about the length of duration for their longest pregnancy as this would provide insight into how long the women's pregnancies were and if the women had a

preterm baby (before 37 weeks of pregnancy/before 9 months). Women were also asked specifically about preterm birth, and the figures from both of these questions were crossed referenced with other information provided about pregnancy, as some women did not consider themselves to have had a preterm baby despite stating their baby was born before 9 months. There was inconsistency in the format women were asked to respond with the duration being in months and the question about preterm birth using weeks and therefore it is acknowledged that this may have been confusing and may not have elicited accurate responses. For this reason, extensive cross referencing of data was undertaken, extracting all the information women provided about pregnancy in the survey.

A total of 11 women (11/46 – adjusted as four women were still pregnant at the time of completion of the survey) gave birth to a preterm baby, giving a percentage of 19.6%, which is considerably higher than the UK average of 7.3% of livebirths (NICE 2019:27). It may be that women who had a preterm birth were more drawn to sharing their experience and this may help account for the higher figure, or it may be that due to the small number of respondents this higher figure is not representative of the larger population. However, having a preterm birth can have significant impact on the experience of pregnancy and therefore for nearly a fifth of the women who responded to the survey will have had this additional complication which may have shaped their experience.

Of the 11 women who gave birth to a preterm baby, four identified having moderate symptoms in the three months prior to pregnancy, which means four out of the six women who identified as having moderate symptoms in the three months prior to pregnancy had a preterm birth. This may also offer some insight into the high number of women who had a preterm birth in this study compared to the national average. The literature highlights the increased risk of pregnancy complications including preterm birth if there is active disease at

conception (Getahun et al. 2014), (Boyd et al. 2015) (Shand et al. 2016) Preterm birth was not specifically asked about in the interviews, and nor did any of the women divulge that their babies were born preterm. As this was not discussed, it is assumed that the women in the interviews did not experience a preterm birth, although it is acknowledged that this was not specifically asked and this could be considered a limitation, although this was not something the study aimed to explore specifically and if important would have emerged.

Pregnancy loss was specifically asked about in the survey, with women being asked if they had experienced a pregnancy loss and if so at what gestation of pregnancy. Nearly half of the respondents had experienced a pregnancy loss, with the majority being before 12 weeks gestation. The average rate of pregnancy loss for women in the UK is 15%, most of which will be before 12 weeks (Lucas et al. 2020:2) and may reflect the impact IBD has on early pregnancy. However, it may also be due to selection bias, and that women who responded felt they had an experience they wanted to share which may include pregnancy loss. The women who participated in the interviews were not specifically asked about pregnancy loss, although one participant discuss how her experience of a miscarriage contributed to the additional worry and anxiety she experienced in pregnancy, as discussed in **Section 7.2.1.2.2.2.** Although this was only the experience of one woman, it offers a valuable insight into how pregnancy loss may impact psychologically on subsequent pregnancies, especially if women have additional medical needs which may necessitate medication use which can be an contentious issue for women as discussed in **Section 6.2.1.2.2.2**. It cannot be assumed that pregnancy loss was not experienced by other women who were interviewed, as there is still a taboo about talking about early pregnancy loss, and women may not have wanted to discuss this during their interview. Due to the high proportion of women who had experienced pregnancy loss who responded to the survey, it could be argued that these results are weighted towards the experiences of pregnancy for women living with IBD who

have experienced pregnancy loss. The study did not aim to produce generalisable results but did aim to provide insight into the experiences of women and explore what may have shaped these experiences.

7.4 Reflexivity

During the course of the PhD, I have gained further experience of the research process, including Health Research Authority (HRA) approval, Participant Identification Centre (PIC) sites and recruitment sites, and also developed my researcher skills. I have written a protocol for a survey, one to one interviews and systematic review, developed an online survey and flexible interview tool, and analysed data using carefully selected methods. I had not interviewed for research before but felt that my experience as a midwife, and through running a birth listening service had provided a basis for the necessary skills needed, yet I still found this quite daunting. I felt that I was outside of my midwifery comfort and although I knew I had the skills to be able to listen to women recount their experience, I was doing this as a researcher and found this provoked some anxiety. As time went on I gained more confidence with interviewing, but I still felt apprehensive before each one.

Women were not forthcoming with the details around their pregnancy, and whilst they described in detail the impact IBD had on, they almost glossed over the actual pregnancy details and needed probes to encourage those details to be shared. This was surprising as from my experience as a midwife, when you ask women about their pregnancy and birth, women usually tell you their experience in great detail. I reflected on this after this happened also during the second interview and changed my interview technique slightly for the next one, yet it proved to be a recurring theme. This led me to think about the effects living with a long-term condition, such as IBD may have on how women view their pregnancy. Does it

become an addition to their already often complex needs, and it's a great relief when things go well, or is it viewed as something completely independent and as long as it is straightforward does not feel to warrant detailed explanation when describing it? Certainly, the way in which women described their experiences to me were not of the detail I am used to hearing as a midwife.

Women knew that I was a midwife, and there was an assumption from the women, that as I was a midwife we had a shared understanding of their experiences within midwifery care, pregnancy, birth and the postnatal period. This may also account for the lack of detail women offered about their pregnancy experiences, as they felt I already was familiar with the processes and that if it was 'straightforward' I understood what that meant. However, I was keen to understand how their experience was for them, without this shared understanding, so again used probes to gently encourage them to discuss the finer details.

I chose not to divulge to women that I was also had a diagnosis of IBD, as I felt that this may influence the interview and sometimes when there is a shared condition, this generates discussion about the condition and this was not how I wanted the interviews to be focussed. I did however decide that if a woman asked directly, I would be honest and share my diagnosis. This may then also explain why women gave much more details about their IBD than they did about their pregnancy, as there was not an assumed shared understanding. One woman did ask me about what led to my interest in IBD, and I did share my diagnosis with her, and as anticipated, this did lead to responses to questions which drew upon her assumption that we shared knowledge about IBD.

It was important that within my PhD supervisory team, I had a Patient and Public Involvement representative, and this was someone who had IBD and moderated a social media peer support group for people living with IBD. Claire was instrumental in the

development of the survey, flexible interview tool and all the public facing documents. She brought a unique contribution to the study, as she was able to be more objective towards the study and provided the voice of a woman living with IBD throughout the study processes.

Having completed the study, I feel excited about the exploring and implementing the recommendations for practice, education and research alongside women with IBD (**Section 7.6**), and using the findings of this novel study to influence future care for women living with IBD during pregnancy.

7.5 Discussion summary

This chapter has discussed the results and findings of the study and how they pertain to relevant literature, guidance and policies.

Whilst the numbers of the study were small, the voices of 57 women living with IBD have been heard with their in-depth experiences of pregnancy and what was important to them being shared. This has not been explored before and therefore contributes novel insights and findings. There were three main themes which emerged from the study: expectations, control, and care, with women describing similarities and marked differences in their experiences. However, these three themes were all considered to be important to the women. Whilst a discrepancy emerged in what midwives were expected to know about IBD and pregnancy, a clear message that poor knowledge of those caring for women during pregnancy detracted from their experience and that advice given to them about how their symptoms would be during pregnancy helped shape their expectations and were considered to be important. Expectations were primarily around symptoms with expected and experienced symptoms being closely matched. Optimism bias may have contributed to this, with women hoping for an improvement in their symptoms, and the advice they were given

increasing their efficacy. This study has given a unique insight into the expectations of women about their symptoms during pregnancy and what influences these expectations, which has implications for pre-pregnancy care.

Women described the ways in which they lost control, or struggled to retain it, or how they were accepting of this if they perceived benefits to be attached to it, such as additional surveillance of their pregnancy which was found to be reassuring. This novel study heard the additional suffering women experienced during pregnancy due to their IBD, both physical and psychological and the negative effects this had on the women, whilst other women described how pregnancy provided them with a respite from the usual debilitating effects of their IBD and how although this was beyond their control, it was very welcomed. It may be that women living with IBD become used to and accepting of living with some level of suffering, which may present barriers to care especially around medication use, therefore needing careful discussions about decisions and choices they make. Women described the choices they made, and what influenced these choices, leading to questioning of whether these were in fact active choices made or whether this relied on the ability to voice preferences and decline or accept proposed interventions or actions. Similarly, women described the power struggles they sometimes encountered with their healthcare professional and how they were able to retain power using bespoke strategies or whether they were willing to accept the loss of power if it meant they could achieve their overall aim. This previously un-explored phenomena has provided novel insights into the experiences of pregnancy for women living with IBD, what shapes their expectations and how control is retained or relinquished or sometimes lost.

It is also important to acknowledge what may consciously or unconsciously drive power struggles from a healthcare professional perspective, predominantly around a disparity in knowledge between the healthcare professional and the patient and how this makes the healthcare professional feel.. The lack of knowledge of healthcare professionals about IBD and pregnancy, in particular midwives and GPs, described in this study mirrored that described by Ellul et al. (2016) and Cooper et al. (2011) and how detracted from the experience of pregnancy. However, this thesis has sought to highlight all healthcare professionals are not and cannot be experts in all areas, and that the evidence for the impact on specialist roles is lacking. Therefore, a solution to this must be explored to not only improve experiences for women but to also ensure that care is safe, and evidence based and will be discussed in **Section 7.6.1.**

Aim two of the study focussed on pregnancy care for women living with IBD and sought recommendations from women about a care pathway for pregnancy. Whilst there were discrepancies in the care women received, the importance of a trusted relationship with their healthcare professional and the necessity for the multidisciplinary team to work collaboratively and talk to each other emerged. The benefits of a trusted relationship cannot be underestimated, which include facilitating shared decision making through giving honest and tailored information, as described by women in the study. The highlighted discrepancies in care and the effect this had on the women's experiences reinforces the need for national, evidence based guidance for the care of women during pregnancy with IBD which will be discussed further in **Section 7.6.1.**

The exploration of experiences of pregnancy for the women living with IBD has provided valuable insight into what shapes an experience, where expectations originate from and

what women consider to be important to them during pregnancy, which is essential if healthcare providers are to provide evidence based, personalised care. Whilst it is acknowledged that these experiences are not representative of all women living with IBD, how women want to be cared for during pregnancy is not something that has been explored before and provides a unique and novel insight which brings new understanding and can be used as a basis to develop a co-designed care pathway.

7.6 Recommendations

Leading on from the data presented the following recommendations are suggested.

Figure 44 shows how the relationship between the recommendations, and the order in which they need to be undertaken, as Recommendation One fundamentally underpins the other recommendations and Recommendation Two provides a platform for the recommended research to be undertaken.

7.6.1 Recommendations for education and practice

Recommendations for education and practice will be discussed together as they go hand in hand, with improvements in education being needed in order to improve practice.

Raising awareness and about IBD and pregnancy for healthcare professionals providing maternity care is essential and this will be achieved through dissemination of the study findings and results through midwifery, obstetric and gastroenterology journals and conferences.

It is recognised that the absence of national guidance about IBD and pregnancy care is detracting from the experiences of women and leading to inequity in care provided by the NHS, both in comparison to women living with other long term conditions and also those

receiving pregnancy care whilst living in different regions within the UK. Recommendation One is that **a national guideline is created, which uses the current evidence to ensure women receive high quality, evidence based, standardised care.**

Women in the study described the inconsistency both in terms of accessibility information given, but also the variation in the information given. Women described the lack of knowledge their healthcare practitioners had about IBD and pregnancy, and the struggle they had to get evidence-based information about IBD medications which led to increased anxiety and suffering. The lack of national guidance may be a contributing factor to the discrepancy and struggles women described around the information they received, however, there is a wealth of clinical guidance already available in the The Second European Evidenced-Based Consensus on Reproduction and Pregnancy in Inflammatory Bowel Disease (van der Woude et al. 2015) which could be used to inform national guidance within the UK. This would help to standardise information given to women and also ensure that all healthcare practitioners had access to evidence based information, which should inform their discussions and support decision making. Consideration was also given to whether a midwifery specialist in IBD should be recommended, however it is appreciated that this is not practical, particualrly in small, non tertiary hospitals, and is also not in line with the emerging continuity of carer model, as it would disjoint care for women living with IBD and disrupt the trusted relationship between them and their healthcare provider. Being able to receive accessible, evidence based information was considered to be of great importance to women and shaped their expectations, which were instrumental in shaping their experiences.

Recommendation Two of this study is, therefore, **a national resource for women and health professionals caring for women living with IBD is created**. It would ideally include:

- **co-designed website/app**
- **a specialist IBD and pregnancy research centre**
- **IBD medication and pregnancy and infant feeding resource**
- **Specialist midwifery care planning**

This could be aligned within existing services initially, with an ambition to become an independent resource once established and income generating. It is appreciated that funding would be needed for this resource and options are currently being explored.

The struggle women had for information about IBD and pregnancy, and the increase in worry described by women who did attend generic parent education suggests that women need information tailored to their needs. Whilst the reasons for accessing parent education was not explored, attendance did not appear to have a positive effect on experiences and lack of information was considered to detract from experiences. Recommendation Three is that **a specific parent education programme for women living with IBD is developed, which would include a built-in evaluation of its impact.**

The lack of midwifery training about IBD and pregnancy became evident throughout the study, with women describing their interactions with midwives and how the lack of knowledge impacted on their experience and care. This was compounded by the researchers own experience of the lack midwifery training and post-registration education about IBD. Recommendation Four is the development of a **training programme for midwives about IBD and pregnancy, using the Royal College of Midwives i-learn platform.** This has been agreed by the RCM, with the RCM having 50,000 members, including midwives, midwifery support workers and student midwives, which entitles them to access to i-learn modules. Over 30,000 members of the RCM have accessed i-learn. Whilst it is acknowledged that midwives do not need to be experts in IBD, they need to be able to

recognise the significance IBD has for pregnancy and be aware of the importance of multidisciplinary care planning, which involves the woman. Adaptions to this training programme could be made to ensure suitability for undergraduate midwifery education and included in the midwifery training curriculum.

The study has given insight into the current gaps in practice and education which are impacting on the experiences of pregnancy and has offered insight into the positive effects that collaborative evidenced based care has. However, it has also highlighted novel findings, some of which require further research, and these are discussed in the next section.

7.6.2 Recommendations for Research

It is acknowledged that although the study provided some novel findings which will have implications to clinical practice and midwifery education, the findings are not, and were not intended to be, generalisable and therefore caution must be used with these findings. However, they do provide valuable insight into a previously un-researched area and give direction about where further research could be undertaken.

Overwhelmingly the women in the study described how if they had absent or mild symptoms at conception, they experienced an improvement in symptoms during pregnancy. Therefore, Recommendation Five is **that the following hypothesis is tested; 'women with absent or mild symptoms at conception can expect an improvement in their IBD symptoms during pregnancy'.**

Women also described the additional suffering they felt they endured during pregnancy due to their IBD, which included additional worry, stress and anxiety. With women living with a 'high risk' pregnancy already being at increased risk of developing anxiety and depression

and living with a long-term condition further increasing this risk, Recommendation Six is **a study exploring the additional psychological support needs of women living with IBD during pregnancy**. It is proposed that this is a collaboration with a midwife researcher who specialises in perinatal mental health.

Whilst published literature does indicate that an increased incidence of preterm birth is associated with IBD activity during pregnancy, this study observed that IBD activity at conception also may have influenced the incidence of preterm birth. Nearly 20% of women who completed the survey had experienced a preterm birth, which is much higher than the national average, and whilst it is appreciated that the numbers within the study are low, and that there may be the influence of participant bias, this warrants further investigation. **Therefore,** Recommendation Seven is that **a larger study that seeks to determine the incidence of preterm birth among women with mild, moderate or severe IBD at the start of pregnancy is undertaken.**

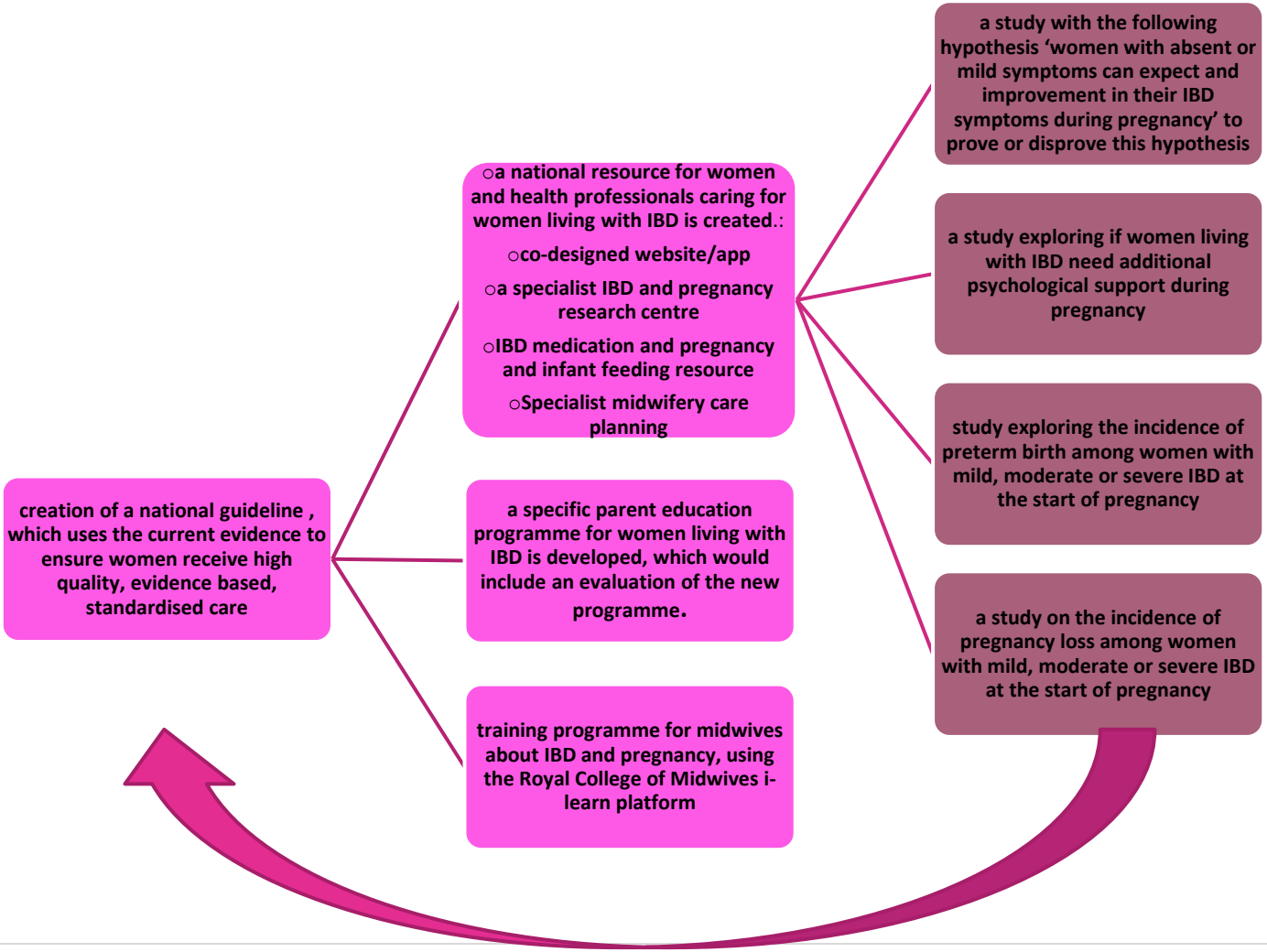
A higher than average incidence of pregnancy loss was also reported by women in the study, and again whilst the small numbers within the study and the influence of participant bias are acknowledged, it felt that this also warrants further investigation. Recommendation Eight is that **a study focussing on the incidence of pregnancy loss among women with mild, moderate or severe IBD at the start of pregnancy is undertaken,** and this study could be undertaken in conjunction with the suggested study into incidence of preterm birth as preterm birth is a contributing factor for pregnancy loss.

The suggested studies outlined in recommendation six, seven and eight could be undertaken in a large, multicentre observational.

7.6.3 Summary of Recommendations

Whilst the limitations of the study are acknowledged, the novel insights and findings have enabled recommendations for clinical practice and midwifery education to be made and provided direction for further research. Funding opportunities are being explored, along with post-doctoral opportunities and building a network of IBD specialist professionals which will support these activities. The paucity is research in IBD and pregnancy experiences, along with the lack of healthcare provider knowledge, patient facing information and national guidance has detracted from experiences of pregnancy and experiences and has highlighted the inequity in care given. Therefore, improvements to clinical practice and midwifery education are essential, along with further research to inform and shape clinical practice which will in turn improve the experiences of pregnancy for women living with IBD.

Figure 44: Recommendations



7.7 Conclusions

This purpose of this study was to explore the experiences of women living with IBD and pregnancy. The two aims of the study had different focuses, with aim one focussing on gaining and in-depth understanding of the experiences of pregnancy, whilst aim two sought recommendations from women who had experienced pregnancy, about care pathways.

Appropriately applied methods were used, taking a mixed methods approach, with an embedded design facilitating the integration of quantitative and qualitative data collected from the online survey and the interviews. Data collected from the interviews was analysed using IPA to allow for in-depth exploration. Whilst the interviews collected what were considered to be primary data, with the survey providing supplementary data, integration and triangulation of the data led to an in-depth understanding of the experiences of pregnancy and recommendations about care pathways.

What influenced experiences was found to be multi-dimensional, with expectations being key. How expectations were shaped emerged, particularly around expectations about IBD symptoms in pregnancy. Whilst the study was small, it provides novel findings in this previously unexplored subject, including novel insights into the way that self-efficacy can be improved and how women's expectations around IBD symptoms in pregnancy generally matched with the reality they experienced. Further research in this area is recommended as this will help shape care and improve experiences.

The findings have highlighted additional suffering during pregnancy, both physically and mentally, and this undoubtedly impacted on experience but also provides insight into how care should be shaped, especially as most focus is currently on the physical wellbeing of the woman. This warrants further research, particularly in view of the increased risk of emotional burden and mental illness pregnant women already have.

The struggle for information described by women detracted from their experience and it predominantly appeared that it was the lack of knowledge held by the healthcare provider and lack of available guidance that led to these struggles. This also impacted on the care women received and the choices they were able to make, with women generally being assigned care pathways and not being involved decisions about their care. The lack of available guidance means that there is no national standard of care for women with IBD during pregnancy and as the study demonstrated this leads to women receiving inequitable care across the UK, but also worldwide with guidance not always being used to inform care. This is further compounded by the lack of knowledge women perceived to be held by their maternity healthcare professionals about IBD, and this lack of knowledge was also evident in other studies. Therefore, the recommendation of national guideline for the care of pregnant women living with IBD will ensure all healthcare professionals are able to provide evidence base care. It is also important to ensure that whilst standardisation of care is important, care must also be personalised and women must be involved with decisions about their care as outlined in Better Births (National Maternity Review 2016). Therefore, the recommendation of a national resource for healthcare professionals and women about IBD and pregnancy will enable care to be personalised, whilst drawing on the most up to date evidence, and provide support to midwives caring for pregnant women with IBD so that Continuity of Carer can be delivered in line with the Maternity Transformation Programme. The national resource would also enable a platform for innovation and research, which could develop much needed specialist services for pregnant women living with IBD. A national level resource could facilitate the research recommended from this thesis through the centralisation of data collection and, allow the exploration of novel topics and questions around IBD and pregnancy, including incidence of pregnancy loss.

This study enabled 57 women living with IBD to share their experience of pregnancy. Detailed analysis and context of the findings within what is known in consideration of

national maternity policy has led to the recommendations about care pathways for pregnancy shaped by the experiences of care participants had received. This study was appropriately sized for the methods and approach of IPA and enabled an in-depth understanding of pregnancy experiences to be gained. It provided novel findings and insights from the right and enlightening data that generated meaningful theme. The findings are not generalisable (and were not intended to be) but provide a starting point from which clinical practice, education and further research into this much needed yet under-researched area can be shaped.

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ehost-live>[12 November 2017]

Appendix 1a: Study Protocol Systematic Review

Review Title	An Exploration of the Experiences of Women Living With Inflammatory Bowel Disease and Pregnancy
Anticipated Start Date	01 May 2019
Anticipated completion date	19 September 2020
Lead author	Helen Janiszewski
Named Contact Email	janiszeh@uni.coventry.ac.uk
Named contact address	2 Mill Lane Kirkby Woodhouse Notts NG17 9EW
Named contact phone number	07870559881
Organisational affiliation of the review.	The University of Coventry Nottingham University Hospitals, Midwifery Nottingham Digestive Diseases Biomedical Research Centre (NDDBRC), The Medical School, Queens Medical Centre Campus, University of Nottingham University Hospitals. The University of Nottingham, School of Medicine.
Review team members and their organisational affiliations.	Helen Janiszewski- Midwife researcher and PhD student- 1,2 Shellie Radford – Senior Research Nurse and MSc by Research Student – 3,4
Funding sources/sponsors.	Coventry University - Sponsors
Conflicts of interest	None
Collaborators	None
Review question	What are the experiences of pregnancy for women living with Inflammatory Bowel Disease?
Searches	A preliminary literature search will be undertaken prior to commencing the literature review, and this involves identifying key words relating to the research topic from the preliminary search results (Bryman 2016:110).

	Relevant key words will be identified and will be individually entered into the following electronic databases; Academic Search Complete, AMED, CINAHL COMPLETE, PsycARTICLES, MEDLINE, PsycINFO. This ensures the key words are appropriate and that relevant articles are retrieved from database searches.
Conditions or domain being studied	Inflammatory Bowel Disease Pregnancy
Participants/population	Women who have a diagnosis of Inflammatory Bowel Disease and have experienced pregnancy
Intervention(s), exposure(s).	Experiences of pregnancy
Types of study to be included.	Studies of any kind (qualitative, quantitative or mixed methods) published in English will be considered for the review
Context.	Inflammatory Bowel Disease is an umbrella term for a chronic disease encompassing two main conditions: Crohn's disease and Ulcerative Colitis, with symptoms including diarrhoea, rectal bleeding abdominal pain, loss of appetite, anaemia, general fatigue, tiredness and diarrhoea (Crohns and Colitis 2017). Symptoms have a remission and relapse cycle, with a worsening of symptoms during relapse and less or no symptoms during periods of remission. The peak incidence of IBD is between 15-30 years of age, however the aetiology of IBD is still unknown, and the reason for this peak age of onset also remains unclear. 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, however to what degree is not stated (Kwan and Mahadevan 2010:651) or chronic disease activity compounded with a malnourished state. The literature reports that approximately a quarter of women will become pregnant following their diagnosis of IBD (Ferguson et al. 2008:1). Approximately 50% of people are diagnosed with IBD before they are 35 years old (Ferguson et al. 2008:1) and the average age of women at the birth of their first baby is 28.6 years (Office for National Statisticts 2016). Disease activity at conception may be a good predictor of disease activity 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. This meta-analysis drew on data from studies

	from 1966-2013 and so the findings may or may not still apply to a current childbearing population. IBD increases risk of pregnancy complications including maternal gestational diabetes (due to the use of corticosteroids in the treatment and management of IBD) , 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 (Getahun et al. (2014), Boyd et al. (2015), Shand et al. (2016) and Bortoli et al. (2011) and severe disease activity during pregnancy further increases the risk of these pregnancy complications. 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.
Main outcome(s).	To gain insight into the experiences of pregnancy for women living with Inflammatory Bowel Disease
Additional outcome(s).	To gain insight into what aspects of pregnancy care positively or negatively contributed to the experience of pregnancy for women living with IBD
Data extraction (selection and coding).	Titles and abstracts of studies will be retrieved using the search strategy and will be screened to identify studies that potentially meet the inclusion criteria outlined above. The full text of potentially eligible studies will be retrieved and independently assessed for eligibility by two review team members. Any disagreement will be resolved through discussion or if necessary, with a third reviewer. Data extraction will be done using a data extraction form. Critical Appraisal Tools specific to study design will be used to extract data for assessment of study quality and evidence synthesis from the included studies.
Risk of bias (quality) assessment.	Two review authors will independently assess the risk of bias in included studies by considering the following factors: Completeness of outcome data: were participant exclusions, attrition and incomplete data adequately addressed in the published report? Selective outcome reporting: is there evidence of selective outcome reporting and might this have affected the study results? Other sources of bias: was the trial/study apparently free of any other problems that could produce a high rick of bias?

	Any disagreements about the risk of bias in particular studies will be resolved by discussion, with involvement of a third reviewer if necessary
Strategy for data synthesis.	Narrative synthesis will be carried put using a framework consisting of: What women living with IBD said about their experiences of pregnancy Developing primary synthesis of findings of included studies. Exploring relationships within and between studies and their findings. The robustness of the synthesis will be continually assessed
Analysis of subgroups or subsets.	It is not possible to predefine the subgroups or subsets as these may evolve whilst the reviewing of the literature.
Language.	English
Country.	United Kingdom
Other registration details.	The title for this review and review protocol are not registered with any other professional or academic body at the time of this registration.
Dissemination plans.	The systematic review will form part of the Thesis submitted for a PhD being undertaken by Helen Janiszewski at Coventry University. It is anticipated the systematic review will be published in midwifery and gastroenterology journals. It may also be presented at local, national and worldwide conferences.
Keywords.	Ulcerative Colitis Crohn's Disease Inflammatory Bowel Disease IBD Antenatal Care Pregnancy Experience Perception Perspective

Details of any existing review of the same topic by the same authors.	None
Any additional information.	
Details of final report/publication(s).	

Appendix 1b: Study Protocol Online Survey

Study Protocol

FULL/LONG TITLE OF THE STUDY

An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and Pregnancy

SHORT STUDY TITLE / ACRONYM

Experiences of pregnancy and IBD

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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	**An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and 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 experienced pregnancy
Planned Size of Sample (if applicable)	
Follow up duration (if applicable)	None
Planned Study Period	Completion 18 September 2020
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 a PhD study at Coventry University.

PROTOCOL CONTRIBUTORS

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

Director of Studies: Dr Elizabeth Bailey – Research Fellow

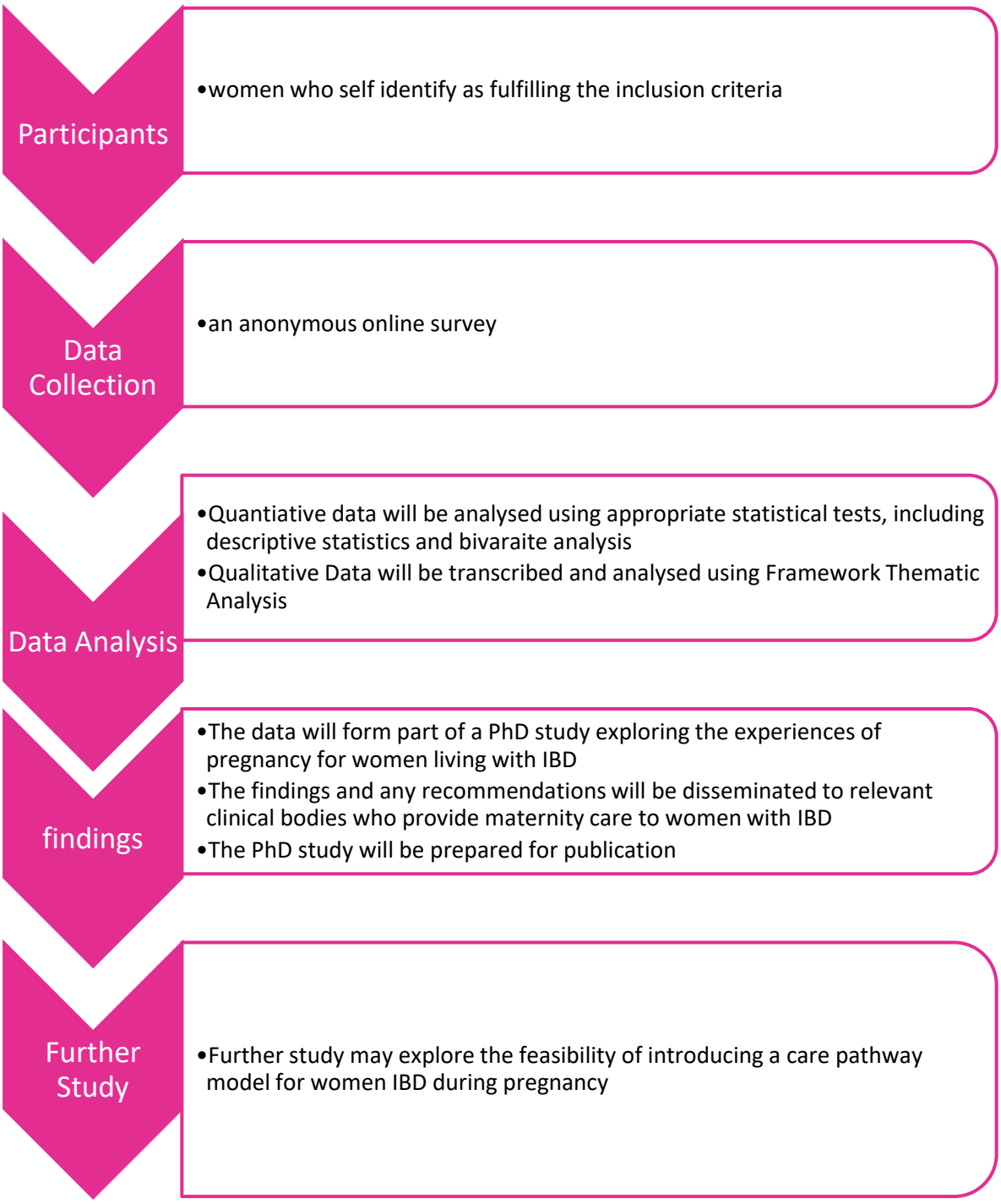
2nd Supervisor: Dr Gordon Moran – Clinical Associate Professor and Honorary Consultant Gastroenterologist

3rd Supervisor: Dr Joanne Cooper – Assistant Director of Nursing (Research, Innovation and Professional Regulation)

4th Supervisor: Professor Jane Coad – Associate Dean in Research

KEY WORDS:	**Childbirth**
	Crohn's Disease
	Inflammatory Bowel 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 data will form part of a PhD study exploring the experiences of pregnancy for women living with IBD
•The findings and any recommendations will be disseminated to relevant clinical bodies who provide maternity care to women with IBD
•The PhD study will be prepared for publication
Further Study
•Further study may explore the feasibility of introducing a care pathway model for women IBD during pregnancy

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 experienced pregnancy, 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.

A previous exploratory study undertaken for the HEE/NIHR Masters in Clinical Research used a shorter survey and included women who had a diagnosis of IBD during or prior to pregnancy, were aged 18 years and older, and had given birth within the last 12 months. This inclusion criteria proved to be restrictive, with women who were not eligible to participate (usually due to age of their child)

contacting the researcher to register their interest should the eligibility criteria change or to express interest in the study and regret they could not participate. Therefore, the more inclusive criteria will enable any woman living with IBD who has experienced pregnancy to participate. The timescale of the study also proved restrictive, with the survey only being live for six weeks, and this was due to the timescale of the Masters in Clinical Research, however this survey will be live for considerably longer.

3 THEORETICAL FRAMEWORK

A preliminary literature review has revealed a paucity of published work into women's experience of pregnancy with IBD. A previous small scale exploratory study for the HEE/NIHR Masters in Clinical Research completed in 2018 explored experiences of pregnancy using an anonymous online survey, and the findings of this study demonstrate a need for further study in this area. 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 it is expected that a sense of their lived experiences will be gained. The findings of the online survey will form part of a PhD study being undertaken exploring the experiences of pregnancy for women living with IBD.

(Cooke, Smith, and Booth 2012)

Sample	Women 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 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

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 shared through social media, which will collect data such as number of pregnancies, 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 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 experienced pregnancy

7.1.2 Exclusion criteria

Women under the age of 18 years, women not self-identifying as having a diagnosis of IBD, women who have not experienced pregnancy

7.2 Sampling

7.2.1 Size of sample

The sample size is unknown, as all women aged 18 years or above with a diagnosis of IBD who have experienced pregnancy are eligible.

7.2.2 Sampling technique

- Purposive criterion sampling will be used

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.

A section at then end of the survey signposts women to Tommys Charity and Crohns and Colitis UK website if they have been affected, upset or distressed by anything in the survey which reads 'If you have been affected, upset or distressed by anything in this survey, please follow the link to Tommy's charity who provide support to women following pregnancy loss, stillbirth or preterm birth or Crohns and Colitis UK who provide support to people living with Inflammatory Bowel Disease https://www.tommys.org https://www.crohnsandcolitis.org.uk''

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

There is a PPI representative attached to the PhD study and all documentation is reviewed and discussed.

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

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

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11. APPENDICIES

11.1 Appendix 1- Required documentation

11.1.1 Participant Information

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 PhD study at Coventry University and is exploring the experiences of women living with Inflammatory Bowel Disease of Pregnancy.

You will need to be at least 18 years old, live in the UK, have experienced pregnancy 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 as there is currently little known about this.

There are a couple of sensitive questions included, which includes one about any pregnancy loss.

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 lead researcher 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.

11.1.2 Eligibility and Consent Information

The following will be built into Qualtrics

Inclusion Criteria:

(This will be on line and potential participant to tick the statements, if all ticked it will proceed to link for the survey, if not all ticked, 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 live in the UK

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

I have experienced pregnancy

Consent – statements below:

(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)

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 lead researcher

Potential participants can then tick either:

I Consent – begin the survey

I do not consent – I do not wish to participate

11.1.3 Survey questions which will be used on 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 PhD study at Coventry University and is exploring the experiences of women living with Inflammatory Bowel Disease of Pregnancy. You will need to be at least 18 years old, live in the UK, have experienced pregnancy 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 as there is currently little known about this. There are a couple of sensitive questions included, which includes one about any pregnancy loss. 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 lead researcher 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 at least 18 years

I live in the UK

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

I have experienced pregnancy

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

2. **How old are you in years?**

3. **What type of IBD do you have?**
    a. Crohn's Disease
    b. Ulcerative Colitis
    c. Other – please specify:

4. **How old were you when diagnosed with IBD in years?**

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

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

7. **How many babies have you given birth to prior to your diagnosis of IBD?**
    a. 0
    b. 1
    c. 2

d. 3

e. 4 or more

8. **How many babies have you given birth to after to your diagnosis of IBD (including diagnosis during pregnancy)?**

    a. 0

    b. 1

    c. 2

    d. 3

    e. 4 or more

9. **What is the longest pregnancy you have experienced in months?** ☐

10. **Have any of your babies been born before 37 weeks?**

    a. Yes -after I was diagnosed with IBD – please specify how many weeks early ☐

    b. Yes –I was diagnosed with IBD during this pregnancy - please specify how many weeks early ☐

    c. Yes - prior to my diagnosis of IBD - please specify how many weeks early ☐

    d. No

11. **Did you plan your most recent pregnancy?**

    a. Yes

    b. No

12. **How long ago was your most recent pregnancy? This is the one that the following questions relate to** ☐

13. **Which region of the UK were you from when you experienced your last pregnancy:**

    a. Northern Ireland

    b. Scotland

    c. North East

d. North West
e. Yorkshire & the Humber
f. East Midlands
g. West Midlands
h. Wales
i. East of England
j. South East
k. South West

14. Who did you see mostly during your pregnancy (please select only one)?

a. Community midwife
b. Consultant Obstetrician
c. Gastroenterologist
d. IBD nurses
e. Practice Nurse
f. Both gastroenterologist and obstetrician in a specialist clinic
g. Other – please specify: ☐

15. Who would you have liked to have taken the lead role in your care whilst you were pregnant (please select only one)?

a. Community midwife
b. Hospital midwife
c. Consultant Obstetrician
d. Gastroenterologist
e. IBD nurses
f. Practice Nurse
g. Other – please specify: ☐

16. I attended Parent Education Classes during pregnancy:

a. Yes
b. No
c. None were available

17. Was mode of birth discussed during your pregnancy?

a. Yes

b. No

18. If you have been diagnosed with IBD during or following a pregnancy, have you noticed any differences in care for further pregnancies?

a. Not applicable

b. No

c. Yes please give brief details

19. 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				

20. Were you receiving any treatment for your IBD in the month before you found out you were pregnant?

a. Yes - please specify

b. No

21. How were your IBD symptoms in the month before you found out you were pregnant?

a. No symptoms
b. Mild symptoms
c. Moderate symptoms
d. Severe symptoms

22. Please identify any of the following advice that you were given about how your symptoms may vary during pregnancy:

a. Get worse
b. Improve
c. Stay the same
d. No advice was given to me

23. What were your expectations about what would happen to your symptoms of IBD during pregnancy?

a. Get worse
b. Improve
c. Stay the same

24. How would you describe your symptoms of IBD during pregnancy:

a. They got worse
b. They Improved
c. They stayed the same

25. Did your symptoms of your IBD during the first 3 months post pregnancy?

a. Get worse
b. Improve
c. Stay the same

26. Was medication used for your IBD discussed during your pregnancy, such as changing certain medications or stopping certain medications?

a. Yes – please give brief details
b. No
c. I wasn't taking any medication

27. If you were taking medication for your IBD prior to pregnancy, was it changed during pregnancy?

a. Yes

b. No

c. I wasn't taking any medication

28. If you were taking medication for your IBD during pregnancy, was it changed after pregnancy?

a. Yes

b. No

c. I wasn't taking any medication

29. Was infant feeding discussed with you during pregnancy in relation to your IBD and any medication you were taking?

a. No

b. Yes – please specify who discussed this with you

30. Do you think your IBD influenced your choices around infant feeding?

a. No

b. Yes – if Yes please explain why

31. What would have improved your experience of pregnancy?

a. Free text answer (max 100 words)

32. Do you have any other comments?

a. Free text answer (max 100 words)

33. 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 have been upset or distressed by anything in this survey, please follow the link to Tommy's charity who provide support to women following pregnancy loss, stillbirth or preterm birth or Crohns and Colitis UK who provide support to people living with Inflammatory Bowel Disease

https://www.tommys.org

https://www.crohnsandcolitis.org.uk

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

11.2 Appendix 2 - Gantt Chart

	10/18	11/18	12/18	1/19	2/19	3/19	4/19	5/19	6/19	7/19	8/19	9/19	10/19	11/19	12/19	1/20	2/20	3/20	4/20	5/20	6/20	7/20	8/20
Study Protocol																							
CU Ethics																							
Online Survey																							
Analyse Data																							
Write up study																							
Disseminate Findings																							

11.3 Appendix 3 – Amendment History

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

Appendix 1c: Study Protocol IPA Study

Study Protocol

Study

FULL/LONG TITLE OF THE STUDY

An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and Pregnancy using Interpretative Phenomenological Analysis

SHORT STUDY TITLE / ACRONYM

Experiences of pregnancy and IBD using IPA

PROTOCOL VERSION NUMBER AND DATE

All draft versions will be numbered 0.1, 0.2 etc.

The final version for submission will be numbered 1.0

The changes made relative to the previous protocol version will be listed after submission

RESEARCH REFERENCE NUMBERS

IRAS Number: 256277

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KEY STUDY CONTACTS

Chief Investigator (C.I)	Elizabeth Bailey elizabeth.bailey@uhcw.nhs.uk
Lead Researcher	Helen Janiszewski janiszeh@uni.coventry.ac.uk
Study Co-ordinator	Full contact details including phone, email and fax numbers
Sponsor	Coventry University Priory Street Coventry CV1 5FB 024 7688 7688
Joint-sponsor(s)/co-sponsor(s)	

STUDY SUMMARY

Study Title	An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and Pregnancy using Interpretative Phenomenological Analysis
Internal ref. no. (or short title)	Experiences of Pregnancy and IBD using IPA
Study Design	Qualitative study, part of a doctoral study
Study Participants	Women aged 18 years or older with a diagnosis of IBD during or prior to pregnancy, who have given birth in the last 5 years, who are receiving care at Nottingham University Hospitals NHS Trust
Planned Size of Sample (if applicable)	12 – 14
Follow up duration (if applicable)	None
Planned Study Period	Completion September 2020
Research Question/Aim(s)	What are the Experiences of Pregnancy for Women Living with Inflammatory Bowel Disease?

KEY WORDS:

Childbirth

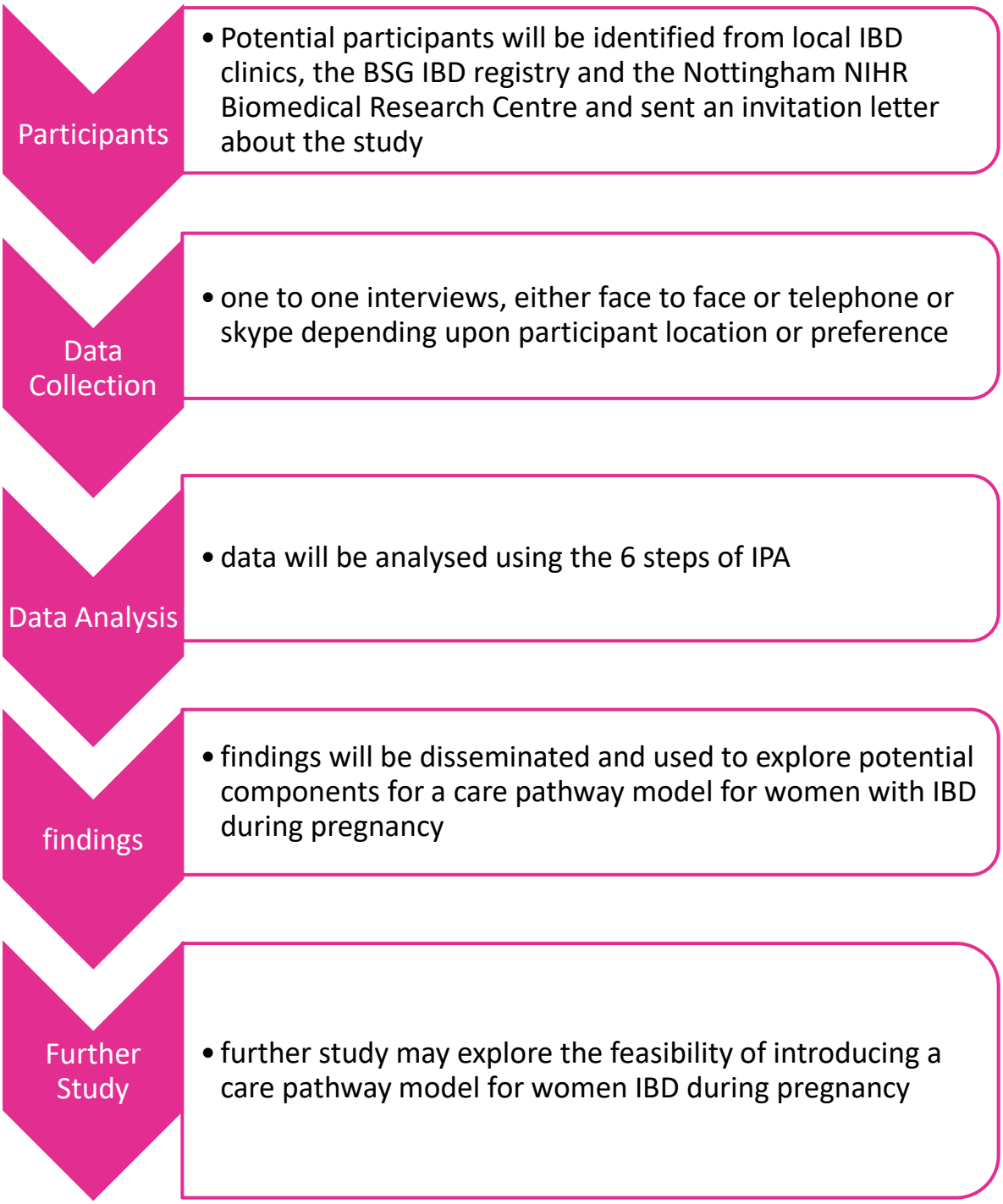
Inflammatory Bowel Disease

IBD

Crohn’s disease

Ulcerative Colitis

STUDY FLOW CHART



STUDY PROTOCOL

An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease of Pregnancy using Interpretative Phenomenological Analysis

1 BACKGROUND

Inflammatory Bowel Disease is an umbrella term for a chronic disease encompassing two main conditions: Crohn's disease and Ulcerative Colitis, with symptoms including diarrhoea, rectal bleeding abdominal pain, loss of appetite, anaemia, general fatigue, tiredness and (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.

There are approximately 146,000 people living with Ulcerative Colitis (National Institute for Health and Care Excellence (NICE) 2013) and 115,00 people living with Crohns disease in the United Kingdom (NICE 2012). The peak incidence of IBD is between 15-30 years of age, however the aetiology of IBD is still unknown, and the reason for this peak age of onset also remains unclear. 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) or chronic disease activity compounded with a malnourished state. Approximately a quarter of women will become pregnant following their diagnosis of IBD (Riis et al. 2006:1539).

Disease activity at conception may be a good predictor of disease activity 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. This meta-analysis drew on data from studies from 1966-2013 and so the findings may or may not still apply to a current childbearing population. IBD increases risk of pregnancy complications including maternal gestational diabetes (due to the use of corticosteroids in

the treatment and management of IBD) , 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 (Getahun et al. (2014), Boyd et al. (2015), Shand et al. (2016) and Bortoli et al. (2011) and severe disease activity during pregnancy further increases the risk of these pregnancy complications. 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, Mahsud-Dornan, and Patterson 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) highlights the importance of effective 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 Crohn's disease also only contains a small subsection about conception and pregnancy, outlining the need to ensure effective communication and sharing of information between specialities including obstetricians and gastroenterologists. Despite these brief mentions of the relative risk of pregnant IBD women no effective guidance is provided by NICE. Moreover, 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. In contrast, 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.

Importantly, 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, but may also be at increased risk of developing a psychological disorder during or after pregnancy. Psychological wellbeing may change throughout the pregnancy, especially if disease activity worsens.

2 RATIONALE

Research exploring the experiences of women living with IBD of pregnancy was recently undertaken as part of the HEE NIHR Masters in Clinical Research. A mixed methods approach was used. Data was collected using an online survey, which was distributed by Crohns and Colitis UK. Qualitative data was collected using open ended questions and quantitative data was collected using closed questions and agreement scales. Prior to undertaking this research, a narrative literature review was undertaken, and a critical appraisal of five articles which fulfilled the inclusion criteria was undertaken. The sample was small, with only 13 participants, however the insight gained into the experiences of pregnancy was invaluable and has highlighted the need for further exploration within this area. Due to the time constraints of the study (8 months), the survey was kept focussed, the inclusion criteria was kept tight, with women who had given birth over 12 months ago being excluded from participating and the survey was only open for six weeks. However, women with IBD demonstrated a willingness to

participate in the study, and some women who did not fulfil the inclusion criteria expressed a desire to participate through emails or posts on social media. The emergent themes were compared and contrasted with the findings of the study, which included mode of birth, disease activity during pregnancy, medication, knowledge, perception of risk and sharing information. The findings of the study highlighted a significant lack of knowledge about IBD and pregnancy in midwives and that the women were not adequately prepared for the unpredictability in disease activity during pregnancy. Some women expected their IBD symptoms would improve in pregnancy, but they actually worsened, and others experienced exacerbation of symptoms and hospitalisation in the post-partum period. Together with a perceived lack of caregiver's knowledge of their condition, concerns over mode of birth and medication as well as unpredictability of symptoms, it is surmised from the exploratory study that women with IBD in pregnancy are at risk of anxiety and poor pregnancy/birth experience as well as adverse pregnancy outcomes.

An in-depth exploration of the experiences of women living with IBD of pregnancy is essential, to hear and explore their current care experiences. Data will supplement the emergent themes and findings of the previous study and will also steer the components of a proposed care pathway model for women with IBD during pregnancy.

3 THEORETICAL FRAMEWORK

As the research takes a qualitative approach, Interpretative Phenomenological Analysis will be used, as this facilitates an in-depth examination of how women living with IBD make sense of their experiences of pregnancy. IPA is extremely well suited to exploring lived experiences which are of great significance or are of great importance, and pregnancy is both of these. The experience of pregnancy can also be influenced by internal and external influences, such as previous experience of pregnancy, previous life events, preconceptions about pregnancy, physical wellbeing and psychological or emotional wellbeing. These experiences will influence the individual experiences women have of pregnancy, and how they make sense of their experiences. IPA uses a small

homogenous sample so is ideal for this study which aims to undertake an immersive exploration of the experiences of pregnancy for women living with IBD.

Women will be recruited through purposive sampling, using local NHS Trusts to identify potential participants. Therefore both CU Ethical Approval and IRAS REC approval will be sought. The sample will be kept relatively small, Smith et al. (2012) suggests that the time required to analyse three cases is approximately two months of full time work. Therefore, careful consideration will be given to the sample size which will balance the depth of the exploration with the time constraints of the study.

Data will be collected through open interviews, with prompts, using the findings of the previous exploratory study to direct the prompts, and the data will then be transcribed and analysed using a systematic qualitative analysis. The six steps of analysis will be used to analyse the data, which are: reading and re-reading the data, initial noting, developing emergent themes, searching for connections across emergent themes, moving to the next case and looking for patterns across cases (Smith, Flowers, and Larkin 2012).

4 RESEARCH QUESTION/AIM(S)

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

Aims:

To gain an in depth understanding of the experiences of women living with Inflammatory Bowel Disease of pregnancy using IPA

To explore recommendations about a care pathway model for women living with IBD during pregnancy and from women living with IBD who have experienced pregnancy

4.1 Objectives

To hear first hand lived experiences regarding pregnancy from women living with IBD

To supplement the findings of my previous exploratory study: A mixed methods exploration of the experiences of women living with inflammatory bowel disease of pregnancy

To explore the potential components of a care pathway model for women living with IBD during pregnancy and from women living with IBD who have experienced pregnancy

4.2 Outcome

An in-depth exploration of the experiences of pregnancy for women living with IBD will meet the stated objectives and provide a better insight into the needs of this cohort of women and these will be shared with maternity care providers nationally. The views sought from the women about potential components for a care pathway model will be shared with obstetricians, gastroenterologists and other key care providers for women with IBD in pregnancy. This will develop during post-doctoral study, when a feasibility trial of a shared care pathway will be undertaken.

Findings, outputs and recommendations from this research have the potential for clinical impact, as previously discussed, the national guidance is inequitable to that for women with other long term conditions and therefore further insight is required to drive national and local guidance regarding the care of pregnant women with IBD.

The findings of the study will be prepared for publication, in maternity, obstetric and gastroenterology journals, and will be shared at national and local conferences and with appropriate Royal Colleges for consideration in their clinical guidance.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Data will be collected through in-depth semi-structured interviews, which will either be face to face or telephone or skype depending upon the geographical location of the participant and their preference. It is acknowledged that location of the interview may impact on the quality of the interview, such as the loss of non verbal communication used in telephone interviews, or possible internet transmission issues when using Skype, however it is appreciated that women with potentially young children may prefer the lack of potential intrusion in their home and opt for a telephone interview and therefore to ensure that recruitment is as inclusive as possible, these options will be offered.

Prompts and probes may be used during the interviews. An Flexible Interview Tool is in Appendix 1.

The interviews will be undertaken by the Lead Researcher only, and will be recorded and then transcribed. Analysis will be according to Interpretative Phenomenological Analysis using the six outlined steps: reading and re-reading the data, initial noting, developing emergent themes, searching for connections across emergent themes, moving to the next case and looking for patterns across cases (Smith, Flowers, and Larkin 2012).

6 STUDY SETTING

The participants will be recruited from The IBD clinics at Nottingham University Hospital and Nottingham Circle treatment Centre. NUH is a is a tertiary-level care academic institution covering a population of approximately 1 million people for secondary-level care and 4.5 million people for tertiary-level care. Collectively we manage approximately 5000 IBD patients.

Recruitment will be done by the clinical care team, through sending an invitation letter and Participant Information Sheet to eligible women.

There are 6 IBD nurses who are existing members of the clinical team that are key in identifying possible study recruits through the British Society of Gastroenterology IBD Registry – an IBD database of all existing Nottingham IBD patients.

Participants will also be recruited though the NIHR Nottingham Biomedical Research Centre at University of Nottingham, where there is a database of patients who are happy to be contacted about upcoming studies and we will search that for eligible patients. Prospective participants will be offered the invitation letter along with the patient information sheet.

Using the study flyer with relevant contact details, the study will be advertised in Nottingham University Hospitals, in departmental Facebook and Twitter posts and in any departmental mailing/ emailing lists to people who have agreed to be contacted with such information

Women will be offered either a face to face interview held at Nottingham University Hospitals, a home visit or a telephone or skype interview. Location of the woman and personal preference or circumstances of the woman will influence the type of interview.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Women who:

are aged at least 18 years old

have a diagnosis of IBD either during or prior to pregnancy,

have given birth within the last five years

are receiving care from an outpatient clinic, the treatment centre or any other care from Nottingham University Hospitals

7.1.2 Exclusion criteria

Women who:

aged under 18 years,

do not have a diagnosis of IBD or who were diagnosed after pregnancy, women who

have given birth over five years ago

do not speak English

are diagnosed with a serious mental illness

are not receiving care from an outpatient clinic, the treatment centre or any other care from Nottingham University Hospitals

7.2 Sampling

7.2.1 Size of sample

The sample will be kept relatively small, as Smith et al.(2012) suggests that the time required to analyse three cases is approximately two months of full time work. Therefore, careful consideration will be given to the sample size which will balance the depth of the exploration with the time constraints of the study. The sample will be approximately twelve to fourteen as this will enable sufficient time to be given to data analysis which will be approximately nine months.

7.2.2 Sampling technique

Purposive sampling will be used.

7.3 Recruitment

7.3.1 Sample identification

Participants will be offered either a face to face interview at NUH NHS Hospitals, with travel being reimbursed (to a maximum of £10), or a skype or telephone interview. The location and availability of the participant may also influence the mode of interview.

7.3.2 Consent

Informed consent will be gained before participation.

Women with IBD will be sent a Participant Information Sheet with an accompanying invitation letter (appendix 6) by the clinical team, with contact details for the potential participant to contact the Lead Researcher should she want to participate or discuss the study further.

If the woman decides she would like to participate, if a face to face interview is preferred, the Consent Form (appendix 4) will be discussed face to face and each consent statement will be discussed and the woman will sign and date each statement to indicate her consent to participate. If a skype or telephone interview is preferred, the Consent Form will be sent to the woman for her to sign and return to the Lead Researcher. Each section will then be discussed at the contact prior to the telephone or skype interview. One copy of the consent form will be retained by the participant, one copy will be kept in the participants medical notes and one copy will be kept in a locked cupboard in the Nottingham NIHR Clinical Research Facility.

Participants will be informed they are free to withdraw from the study at any point leading up to or during the interview, or for up to 4 weeks after the interview, however after this time the data will be transcribed and anonymized and will be included. Women will be asked if they would like their GP informing of their participation in the study, if they do, a letter will be sent to the GP (appendix 5).

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

Person(s) undertaking project:	Helen Janiszewski
Project supervisor:	Dr Elizabeth Bailey

Brief outline of project: *Outline the types of activities that will take place or items fabricated i.e. face to face interviews, public surveys, water sampling, machining vehicle parts, brazing etc.*	Face to face interviews either in the participants home or in an allocated room at Nottingham University Hospitals, telephone interviews and skype interviews about experiences of pregnancy

Dates of study (from – to)	01 October 2018- 30 September 2020
Location(s) of activity: *Country and specific area.*	UK, Nottinghamshire

Will the project involve laboratory work? *If yes, you will be required to complete separate risk assessment(s) prior to carrying out any laboratory work.*	No
Will the project involve workshop work?	No

If yes, you will be required to complete an induction and may carry out a separate risk assessment(s) prior to carrying out any workshop work.	

Will the project involve travel? *(If yes, complete this section as fully as possible. The form may require review prior to travel to add missing details)*		No
Contact details at destination(s): Contact details of next of kin in case of emergency:		
Approximate dates of travel: *Your supervisor must have details of travel plans once confirmed.*		
Arrangements to maintain contact with the University:		
Emergency contact information:	School/Faculty contact (Daytime): 02476 24hr University contact (Protection Service): 02476 888 555 Local healthcare/emergency services:	
Has suitable travel insurance has been obtained? (*Please attach a copy of certificate*)		Yes / No
If EU travel, has EH1C card been obtained?		Yes / No

Has advice/vaccinations from GP been sought (*where appropriate*)?	Yes / No
Are medical kits required (*i.e. in countries with poor healthcare facilities*)?	Yes / No
Are there any warnings issued by the FCO* against travel to the area?	Yes / No
Have you registered with the FCO* service LOCATE? *(British nationals only)*	Yes / No

*FCO = http://www.fco.gov.uk/en/travel-and-living-abroad/travel-advice-by-country/

Hazard	Precautions to be used
Work factors: interviewing on sensitive issues lone working	Participants aware of nature of interview as will have received Participant Information Leaflet prior to interview, participant can terminate interview at any point, researcher is a midwife so is confident at discussing pregnancy and birth, and has provided a birth counselling service previously and is therefore aware of how and where to refer women who need additional information or support about their birth experience. Women will be able to manage the recording of the interview by controlling the digital recorder, enabling them to stop recording at any point should they wish to. Researcher works clinically under Community Midwifery at Nottingham University Hospital and will follow the NHS trust lone working policy which is in line with Coventry University's lone working policy. Researcher will call designated midwife, or one

	of the supervisory team, prior to and after interview if at participants home.

Site specific factors (in the field):	None

Environmental factors (in the field):	None
Equipment:	Digital recorders will be used and once the recording has been transcribed this will be deleted. Data will be transcribed as soon after the interview as possible to reduce the risk of loss of data. Electronic data will be stored on the university SharePoint. The digital recorder will be kept in a locked filing cabinet.

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

Before the start of the study, a favourable opinion will be sought from a REC.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

All correspondence with the REC will be retained.

It is the Chief Investigator's responsibility to produce the annual reports as required.

The Chief Investigator will notify the REC of the end of the study.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before any site can enrol women into the study, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place.

For any amendment to the study, the Chief Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

Any amendments to the study will be submitted to Coventry University Ethics Committee and IRAS REC and approval will be gained before any amendments to the study are made.

8.3 Peer review

Peer review forms part of the Coventry University Ethics approval.

8.4 Patient & Public Involvement

A Patient and Public Representative is part of the study team and will give feedback about the design of the study and public facing documents.

Protocol compliance

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

8.6 Data protection and patient confidentiality

All data will be stored in line with the Data Protection Act 1998. Participants will be given a unique participant ID number which they will quote should they wish to withdraw their data. This is the only identifier for transcribed interview and will be entered on the consent form and onto the transcribed data. The recorded interview will be destroyed once the interview has been transcribed by the Lead Researcher. Transcribed data will be stored electronically on the university SharePoint. All data will be pseudo-anonymised after transcribing. The consent forms and the transcribed data will be kept in

separate locations, with the consent forms being kept in a locked cupboard in the Nottingham NIHR Clinical Research Facility and the transcribed data being kept electronically on the university SharePoint. Data and consent forms will be destroyed once the study is completed.

8.7 Indemnity

Coventry University are the sponsors of the study and will provide indemnity insurance.

8.8 Access to the final study dataset

The Lead Researcher and full supervisory team identified within this protocol will have access to the final anonymised study dataset.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

The study will be written up into a thesis for examination as it is a PhD.

Findings from the study will be published in midwifery and gastroenterology journals, which usually requires peer review

prior to publishing. The findings will also be presented at midwifery and/or research conferences.

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11. APPENDICIES

Appendix 1: Flexible Interview Tool

Flexible Interview Tool for Semi-Structured Interviews

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

Question 1: Starting from the beginning, tell me about your pregnancy

Prompts: What influenced your decision to become pregnant?

Did you have any worries or concerns prior to or during your pregnancy?

What were your symptoms like prior to, during and after pregnancy?

probes: *knowledge pre-pregnancy*

mode of birth,

perception of risk,

medication

expectations of symptoms, where expectations came from, medications, medication changed?

social support networks,

Question 2: **What do you remember about your care?**

Prompts: Can you think of any examples of good practice?

Probes: *model of care provision; perceived gaps;*

medications, medication changed

Appendix 2: Poster

Appendix 2b: Flyer

V1.0 17/12/2018 IRAS ID:256277

Inflammatory Bowel Disease and Pregnancy

Have you given birth within the last 5 years?

Have you been diagnosed with IBD prior to or during pregnancy?

Are you aged 18 years or over?

Researchers at Coventry University would like to speak to women living with IBD who are willing to discuss their experience of Pregnancy to help shape pregnancy care

If you would like to find out more please contact the researcher Helen Janiszewski by text: 07594 859110

or email: janiszeh@uni.coventry.ac.uk

Appendix 2c: Social Media Post

V1.0 17/12/2018 IRAS ID:256277

Inflammatory Bowel Disease and Pregnancy

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or email: janiszeh@uni.coventry.ac.uk

An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and Pregnancy

PARTICIPANT INFORMATION SHEET

You are being invited to take part in research on the experiences of pregnancy for women living with Inflammatory Bowel Disease. Helen Janiszewski, midwifery researcher and PhD student at Coventry University is leading this research. Before you decide to take part it is important you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?

The purpose of the study is to gain an understanding of the experiences of pregnancy for women living with Inflammatory Bowel Disease, and to gain recommendations about a future care plan or pathway for women living with Inflammatory Bowel Disease during pregnancy.

Why have I been chosen to take part?

You are invited to take part in this study because you are aged 18 years or older, have been diagnosed with Inflammatory Bowel Disease either before or during pregnancy and have given birth within the last five years.

What are the benefits of taking part?

By sharing your experiences with us, you will be helping Helen Janiszewski, Coventry University and Nottingham University Hospitals NHS Trust to better understand the experiences of pregnancy for women living with Inflammatory Bowel Disease and to explore how care for women living with Inflammatory Bowel Disease during pregnancy should be planned in future.

Are there any risks associated with taking part?

This study has been reviewed and approved through Coventry University's formal research ethics procedure and has been approved by the Health Research Authority. There are no significant risks associated with participation.

Do I have to take part?

No – it is entirely up to you. If you do decide to take part, please keep this Information Sheet and complete the Informed Consent Form to show that you understand your rights in relation to the

research, and that you are happy to take part. Please note down your individual number (which is on the Consent Form) so that if you change your mind about taking part, the research team can find your data and remove it. You will be able to do this up until 4 weeks after the interview after which time the interview will be written up and anonymised. To withdraw your data, please contact the lead researcher (contact details are provided below). You do not need to give a reason. A decision to withdraw, or not to take part, will not affect you in any way.

What will happen if I decide to take part?

You will be asked a few questions about your experience of pregnancy by the researcher – Helen Janiszewski, who is also a midwife. The interview will take place at a time that is convenient to you and could be at your home or a room at Nottingham University Hospitals, depending upon where you live and your preference. The interview could also take place over the telephone or using Skype, again depending upon your personal preference. We would like to audio record your responses (and will require your consent for this), so the location should be in a fairly quiet area. The interview may take around one to two hours to complete but this is determined by you. You will be reimbursed any travel costs up to a maximum of £10. If you would like your GP to be informed that you are participating in this study, a letter can be sent to them at your request.

Data Protection and Confidentiality

Coventry University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Coventry University will keep identifiable information about you until the study has ended.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you

withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information
https://understandingpatientdata.org.uk/what-you-need-know

Nottingham University Hospitals NHS Trusts and Nottingham CIRCLE Treatment Centre will collect information from you for this research study in accordance with our instructions.

Nottingham University Hospitals NHS Trusts and Nottingham CIRCLE Treatment Centre will keep your name, NHS number and contact details confidential and will not pass this information to Coventry University. Nottingham University Hospitals NHS Trusts and Nottingham CIRCLE Treatment Centre will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Coventry University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Coventry University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Nottingham University Hospitals NHS Trusts and Nottingham CIRCLE Treatment Centre will keep identifiable information about you from this study until the study has finished.

All information collected about you will be kept strictly confidential. Unless they are fully anonymised in our records, your data will be referred to by a unique participant number rather than by name. If you consent to being audio recorded, all recordings will be destroyed once they have been transcribed (typed up). Your data will only be viewed by the researcher/research team. All electronic data will be stored on a password-protected computer file in the researcher's office. All paper records will be stored in a locked filing cabinet in the researcher's office. Your consent information will be kept separately from your responses in order to minimise risk in the event of a data breach. The lead researcher will take responsibility for data destruction and all collected data will be destroyed on or before 01 January 2021.

Data Protection Rights

Coventry University is a Data Controller for the information you provide. You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation and the Data Protection Act 2018. You also have other rights including rights of correction, erasure, objection, and data portability. For more details, including the right to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk. Questions, comments and requests about your personal data can also be sent to the University Data Protection Officer - enquiry.ipu@coventry.ac.uk

What will happen with the results of this study?

The results of this study may be summarised in published articles, reports and presentations. Quotes or key findings will always be made anonymous in any formal outputs.

Making a Complaint

If you are unhappy with any aspect of this research, please first contact the lead researcher:

Helen Janiszewski janiszeh@uni.coventry.ac.uk

If you still have concerns and wish to make a formal complaint, please write to:

Professor Oliver Sparagaro

Chair of the University Applied Research Committee

Coventry University

Coventry CV1 5FB

Email: ab8677@coventry.ac.uk

In your letter please provide information about the research project, specify the name of the researcher and detail the nature of your complaint.

Appendix 4: Consent Form

Participant No:

INFORMED CONSENT FORM:

An Exploration of the Experiences of Women Living With Inflammatory Bowel Disease and Pregnancy

You are invited to take part in this research study for the purpose of collecting data on your experience of pregnancy as a woman living with Inflammatory Bowel Disease.

Before you decide to take part, you must **read the accompanying Participant Information Sheet (version number 1.1 dated 19/02/2019)**

Please do not hesitate to ask questions if anything is unclear or if you would like more information about any aspect of this research. It is important that you feel able to take the necessary time to decide whether or not you wish to take part.

If you are happy to take part, please confirm your consent by writing your initials against each of the below statements and then signing and dating the form as 'Participant'.

1	**I confirm that I have read and understood the Participant Information Sheet for the above study and have had the opportunity to ask questions**	
2	**I understand my participation is voluntary and that I am free to withdraw my data, without giving a reason, by contacting the lead researcher and the Research Support Office at any time until the date specified in the Participant Information Sheet**	
3	**I have noted down my participant number (top left of this Consent Form) which may be required by the lead researcher if I wish to withdraw from the study**	

4	***I understand that all the information I provide will be held securely and treated confidentially***	
5	***I am happy for the information I provide to be used (anonymously) in academic papers and other formal research outputs***	
6	***I am happy for direct quotes from my interview to be published (anonymously) in academic papers and other formal research outputs***	
7	***I am happy for the interview to be audio recorded***	
8	***I would like my GP to be informed that I am participating in this study (optional)***	
9	***I agree to take part in the above study***	

Thank you for your participation in this study.

Your help is very much appreciated.

Participant's Name	***Date***	***Signature***
Researcher	***Date***	***Signature***

Appendix 5: GP letter

Dear Dr……

The following lady has agreed to participate in a study being undertaken by researchers at Coventry University and (insert name of local NHS Trust when approved by IRAS and R &I) and has asked that you are informed of her participation:

Name:

Address:

Date of Birth:

The study is **an Exploration of the Experiences of Women Living with Inflammatory Bowel Disease of Pregnancy and involves an interview discussing her experience and pregnancy.**

I have enclosed the Participant Information Sheet, please do not hesitate to contact me if you would like any further details about the study

Kind regards

Helen Janiszewski

Appendix 6: Invitation Letter

Dear….

Title of Study: An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and Pregnancy

We are presently conducting a research study to explore the experiences of pregnancy for women living with Inflammatory Bowel Disease.

We are contacting you because you have a diagnosis of Inflammatory Bowel Disease and have given birth within the last five years.

We are inviting participants to take part in a one-to-one interview to understand their experiences of pregnancy.

We want to understand the experiences of pregnancy for women living with IBD and explore ways to improve pregnancy care for women living with IBD.

Enclosed is a copy of the Participant Information Sheet for you to read which explains the study and what it involves in greater detail.

If after reading the information sheet you would like to take part, please contact me on 07594 859110.

I look forward to hearing from you.

Yours sincerely

Helen Janiszewski

Midwife at Nottingham University Hospitals

PhD Student at Coventry University

janiszeh@uni.coventry.ac.uk

Appendix 7 – Amendment History

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

	Year 1	10/18	11/18	12/18	1/19	2/19	3/19	4/19	5/19	6/19	7/19	8/19	9/19
	Progress Review Panel												
A	Research Degree Development Agreement			21/12									
C	Study Protocol												
T	Ethics Application Approval CU												
I	Ethics Application Approval IRAS												
V	Recruitment												
I	Data Collection Interviews												
T	Transcribe Data												
Y	Data Analyse Interviews												
	Abstract												
	Background to study												
T	Literature Review												
H	Concept Analysis – Continuity of Care												
E	Theoretical Foundations												
S	Research Design and Methods												
I	Findings												
S	Discussion												
	Conclusion												
	Recommendations												
R	Supervisory Meetings DOS (fortnightly)												
D	Full Supervisory Team Meetings (termly)												
D	Researcher Development Activity												
A	Research Log Book												

	Year 2	10/19	11/19	12/19	01/20	02/20	03/20	04/20	05/20	06/20	07/20	08/20	09/20
A	Progress Review Panel												S
C	Research Degree Development Agreement			21/12									U
T	Transcribe Data Interviews												B
	Data Analysis Interviews												M
T	Abstract												S
H	Findings												S
E	Discussion												I
S	Conclusion												O
	Recommendations												N
R	Supervisory Meetings DOS (fortnightly)												18
D	Full Supervisory Team Meetings (termly)												S
D	Researcher Development Activity												E
A	Research Log Book												P
													T

Appendix 2a: CU Ethics Certificate Systematic Review

Certificate of Ethical Approval

Applicant:

Helen Janiszewski

Project Title:

An Exploration of the Experiences of Women Living With Inflammatory Bowel Disease and 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 Low Risk

Date of approval:

29 April 2019

Project Reference Number:

P90195

Appendix 2b: CU Ethics Certificate Online Survey

Certificate of Ethical Approval

Applicant:

Helen Janiszewski

Project Title:

An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and 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

Date of approval:

17 January 2019

Project Reference Number:

P80386

Appendix 2c: CU Ethics Certificate IPA Study

Coventry University

Certificate of Ethical Approval

Applicant:

Helen Janiszewski

Project Title:

An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease of Pregnancy using Interpretative Phenomenological Analysis

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 High Risk

Date of approval:

30 January 2019

Project Reference Number:

P76258

Appendix 3: Questionnaire

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 PhD study at Coventry University and is exploring the experiences of women living with Inflammatory Bowel Disease of Pregnancy. You will need to be at least 18 years old, live in the UK, have experienced pregnancy 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 as there is currently little known about this. There are a couple of sensitive questions included, which includes one about any pregnancy loss. 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 lead researcher 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 at least 18 years

I live in the UK

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

I have experienced pregnancy

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

34. How old are you in years?

35. What type of IBD do you have?

a. Crohn's Disease

b. Ulcerative Colitis

c. Other – please specify:

36. How old were you when diagnosed with IBD in years?

37. Have you had any pregnancy losses?

a. No

b. Yes at less than 12 weeks

c. Yes between 12 – 20 weeks

d. Yes between 21-23 weeks

e. Yes over 24 weeks

38. Were you diagnosed with IBD prior to your most recent pregnancy?

a. Yes diagnosed prior to pregnancy

b. No diagnosed during pregnancy

39. How many babies have you given birth to prior to your diagnosis of IBD?

a. 0

b. 1

c. 2

d. 3

e. 4 or more

40. How many babies have you given birth to after to your diagnosis of IBD (including diagnosis during pregnancy)?

a. 0

b. 1

c. 2

d. 3

e. 4 or more

41. What is the longest pregnancy you have experienced in months?

42. Have any of your babies been born before 37 weeks?

a. Yes -after I was diagnosed with IBD – please specify how many weeks early

b. Yes –I was diagnosed with IBD during this pregnancy - please specify how many weeks early

c. Yes - prior to my diagnosis of IBD - please specify how many weeks early

d. No

43. Did you plan your most recent pregnancy?

a. Yes

b. No

44. How long ago was your most recent pregnancy? This is the one that the following questions relate to

45. Which region of the UK were you from when you experienced your last pregnancy:

a. Northern Ireland

b. Scotland

c. North East

d. North West

e. Yorkshire & the Humber

f. East Midlands

g. West Midlands

h. Wales

i. East of England

j. South East

k. South West

46. Who did you see mostly during your pregnancy (please select only one)?

a. Community midwife

b. Consultant Obstetrician

c. Gastroenterologist

d. IBD nurses

e. Practice Nurse

f. Both gastroenterologist and obstetrician in a specialist clinic

g. Other – please specify: [ ]

47. Who would you have liked to have taken the lead role in your care whilst you were pregnant (please select only one)?

a. Community midwife

b. Hospital midwife

c. Consultant Obstetrician

d. Gastroenterologist

e. IBD nurses

f. Practice Nurse

g. Other – please specify: [ ]

48. I attended Parent Education Classes during pregnancy:

a. Yes

b. No

c. None were available

49. Was mode of birth discussed during your pregnancy?

a. Yes

b. No

50. If you have been diagnosed with IBD during or following a pregnancy, have you noticed any differences in care for further pregnancies?

a. Not applicable

b. No

c. Yes please give brief details

51. 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				

52. Were you receiving any treatment for your IBD in the month before you found out you were pregnant?

a. Yes - please specify

b. No

53. How were your IBD symptoms in the month before you found out you were pregnant?

a. No symptoms

b. Mild symptoms

c. Moderate symptoms

d. Severe symptoms

54. **Please identify any of the following advice that you were given about how your symptoms may vary during pregnancy:**

    a. Get worse

    b. Improve

    c. Stay the same

    d. No advice was given to me

55. **What were your expectations about what would happen to your symptoms of IBD during pregnancy?**

    a. Get worse

    b. Improve

    c. Stay the same

56. **How would you describe your symptoms of IBD during pregnancy:**

    a. They got worse

    b. They Improved

    c. They stayed the same

57. **Did your symptoms of your IBD during the first 3 months post pregnancy?**

    a. Get worse

    b. Improve

    c. Stay the same

58. **Was medication used for your IBD discussed during your pregnancy, such as changing certain medications or stopping certain medications?**

    a. Yes – please give brief details

    b. No

    c. I wasn't taking any medication

59. **If you were taking medication for your IBD prior to pregnancy, was it changed during pregnancy?**

    a. Yes

    b. No

    c. I wasn't taking any medication

60. **If you were taking medication for your IBD during pregnancy, was it changed after pregnancy?**
    a. Yes
    b. No
    c. I wasn't taking any medication

61. **Was infant feeding discussed with you during pregnancy in relation to your IBD and any medication you were taking?**
    a. No
    b. Yes – please specify who discussed this with you

62. **Do you think your IBD influenced your choices around infant feeding?**
    a. No
    b. Yes – if Yes please explain why

63. **What would have improved your experience of pregnancy?**
    a. Free text answer (max 100 words)

64. **Do you have any other comments?**
    a. Free text answer (max 100 words)

65. **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 have been affected, upset or distressed by anything in this survey, please follow the link to Tommy's charity who provide support to women following pregnancy loss, stillbirth or preterm birth or Crohns and Colitis UK who provide support to people living with Inflammatory Bowel Disease

https://www.tommys.org

https://www.crohnsandcolitis.org.uk

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 4: Flexible Interview Tool

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

Question 1: Starting from the beginning, tell me about your pregnancy

Prompts: What influenced your decision to become pregnant?

Did you have any worries or concerns prior to or during your pregnancy?

What were your symptoms like prior to, during and after pregnanc

probes: *knowledge pre-pregnancy*

mode of birth,

perception of risk,

medication

expectations of symptoms, where expectations came from, medications, medication changed?

social support networks,

Question 2: **What do you remember about your care?**

Prompts: Can you think of any examples of good practice?

Probes: *model of care provision; perceived gaps;*

medications, medication changed

Appendix 5: Participant Information

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 PhD study at Coventry University and is exploring the experiences of women living with Inflammatory Bowel Disease of Pregnancy. You will need to be at least 18 years old, live in the UK, have experienced pregnancy 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 as there is currently little known about this. There are a couple of sensitive questions included, which includes one about any pregnancy loss. 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 lead researcher 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 6: Consent Statements

Inclusion Criteria:

This will be on line and potential participant to tick the statements, if all ticked it will proceed to link for the survey, if not all ticked, 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 live in the UK

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

I have experienced pregnancy

Consent – statements below:

understand that my participation is voluntary

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.

I understand that I have 2 weeks from the date of completion of the survey to withdraw from the study by contacting the lead researcher

Potential participants can then tick either:

I Consent – begin the survey

I do not consent – I do not wish to participate

Appendix 7: Participant Information Sheet

An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and Pregnancy

PARTICIPANT INFORMATION SHEET

You are being invited to take part in research on the experiences of pregnancy for women living with Inflammatory Bowel Disease. Helen Janiszewski, midwifery researcher and PhD student at Coventry University is leading this research. Before you decide to take part it is important you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully.

What is the purpose of the study?
The purpose of the study is to gain an understanding of the experiences of pregnancy for women living with Inflammatory Bowel Disease, and to gain recommendations about a future care plan or pathway for women living with Inflammatory Bowel Disease during pregnancy.

Why have I been chosen to take part?
You are invited to take part in this study because you are aged 18 years or older, have been diagnosed with Inflammatory Bowel Disease either before or during pregnancy and have given birth within the last five years.

What are the benefits of taking part?
By sharing your experiences with us, you will be helping Helen Janiszewski, Coventry University and Nottingham University Hospitals NHS Trust to better understand the experiences of pregnancy for women living with Inflammatory Bowel Disease and to explore how care for women living with Inflammatory Bowel Disease during pregnancy should be planned in future.

Are there any risks associated with taking part?
This study has been reviewed and approved through Coventry University's formal research ethics procedure and has been approved by the Health Research Authority. There are no significant risks associated with participation.

Do I have to take part?
No – it is entirely up to you. If you do decide to take part, please keep this Information Sheet and complete the Informed Consent Form to show that you understand your rights in relation to the research, and that you are happy to take part. Please note down your individual number (which is on the Consent Form) so that if you change your mind about taking part, the research team can find your data and remove it. You will be able to do this up until 4 weeks after the interview after which time the interview will be written up and anonymised. To withdraw your data, please contact the lead researcher (contact details are provided below). You do not need to give a reason. A decision to withdraw, or not to take part, will not affect you in any way.

What will happen if I decide to take part?
You will be asked a few questions about your experience of pregnancy by the researcher – Helen Janiszewski, who is also a midwife. The interview will take place at a time that is convenient to you and could be at your home or a room at Nottingham University Hospitals, depending upon where you live and your preference. The interview could also take place over the telephone or using Skype, again depending upon your personal preference. We would like to audio record your responses (and will require your consent for this), so the location should be in a fairly quiet area. The interview may take around one to two hours to complete but this is determined by you. You will be reimbursed any travel costs up to a maximum of £10. If you would like your GP to be informed that you are participating in this study, a letter can be sent to them at your request.

Data Protection and Confidentiality

Coventry University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Coventry University will keep identifiable information about you until the study has ended.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information
https://understandingpatientdata.org.uk/what-you-need-know

Nottingham University Hospitals NHS Trusts and Nottingham CIRCLE Treatment Centre will collect information from you for this research study in accordance with our instructions.

Nottingham University Hospitals NHS Trusts and Nottingham CIRCLE Treatment Centre will keep your name, NHS number and contact details confidential and will not pass this information to Coventry University. Nottingham University Hospitals NHS Trusts and Nottingham CIRCLE Treatment Centre will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Coventry University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Coventry University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Nottingham University Hospitals NHS Trusts and Nottingham CIRCLE Treatment Centre will keep identifiable information about you from this study until the study has finished.

All information collected about you will be kept strictly confidential. Unless they are fully anonymised in our records, your data will be referred to by a unique participant number rather than by name. If you consent to being audio recorded, all recordings will be destroyed once they have been transcribed (typed up). Your data will only be viewed by the researcher/research team. All electronic data will be stored on a password-protected computer file in the researcher's office. All paper records will be stored in a locked filing cabinet in the researcher's office. Your consent information will be kept separately from your responses in order to minimise risk in the event of a data breach. The lead researcher will take responsibility for data destruction and all collected data will be destroyed on or before 01 January 2021.

Data Protection Rights

Coventry University is a Data Controller for the information you provide. You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation and the Data Protection Act 2018. You also have other rights including rights of correction, erasure, objection, and data portability. For more details, including the right to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk. Questions, comments and requests about your personal data can also be sent to the University Data Protection Officer - enquiry.ipu@coventry.ac.uk

What will happen with the results of this study?

The results of this study may be summarised in published articles, reports and presentations. Quotes or key findings will always be made anonymous in any formal outputs.

Making a Complaint
If you are unhappy with any aspect of this research, please first contact the lead researcher:

Helen Janiszewski janiszeh@uni.coventry.ac.uk

If you still have concerns and wish to make a formal complaint, please write to:

Professor Oliver Sparagaro

Chair of the University Applied Research Committee

Coventry University

Coventry CV1 5FB

Email: ab8677@coventry.ac.uk

In your letter please provide information about the research project, specify the name of the researcher and detail the nature of your complaint.

Appendix 8: Consent Form

Participant No:

INFORMED CONSENT FORM:

An Exploration of the Experiences of Women Living With Inflammatory Bowel Disease and Pregnancy

You are invited to take part in this research study for the purpose of collecting data on your experience of pregnancy as a woman living with Inflammatory Bowel Disease.

Before you decide to take part, you must **read the accompanying Participant Information Sheet (version number 1.1 dated 19/02/2019)**

Please do not hesitate to ask questions if anything is unclear or if you would like more information about any aspect of this research. It is important that you feel able to take the necessary time to decide whether or not you wish to take part.

If you are happy to take part, please confirm your consent by writing your initials against each of the below statements and then signing and dating the form as 'Participant'.

1	**I confirm that I have read and understood the Participant Information Sheet for the above study and have had the opportunity to ask questions**	
2	**I understand my participation is voluntary and that I am free to withdraw my data, without giving a reason, by contacting the lead researcher and the Research Support Office at any time until the date specified in the Participant Information Sheet**	
3	**I have noted down my participant number (top left of this Consent Form) which may be required by the lead researcher if I wish to withdraw from the study**	
4	***I understand that all the information I provide will be held securely and treated confidentially***	

5	***I am happy for the information I provide to be used (anonymously) in academic papers and other formal research outputs***	
6	***I am happy for direct quotes from my interview to be published (anonymously) in academic papers and other formal research outputs***	
7	***I am happy for the interview to be <u>audio recorded</u>***	
8	***I would like my GP to be informed that I am participating in this study (optional)***	
9	***I agree to take part in the above study***	

Thank you for your participation in this study.

Your help is very much appreciated.

Participant's Name	***Date***	***Signature***
Researcher	***Date***	***Signature***

Appendix 9: Study Advertising Material

Nottingham University Hospitals NHS Trust

Coventry University

Inflammatory Bowel Disease and Pregnancy

Have you given birth within the last 5 years?

Have you been diagnosed with IBD prior to or during pregnancy?

Are you aged 18 years or over?

Researchers at Coventry University would like to speak to women living with IBD who are willing to discuss their experience of pregnancy to help shape pregnancy care

If you would like to find out more please contact the researcher Helen Janiszewski by text: 07594 859110 or email: janiszeh@uni.coventry.ac.uk

janiszeh@uni.coventry.ac.uk Phone number 07594859110
janiszeh@uni.coventry.ac.uk Phone number 07594859110
janiszeh@uni.coventry.ac.uk Phone number 07594859110
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janiszeh@uni.coventry.ac.uk Phone number 07594859110
janiszeh@uni.coventry.ac.uk Phone number 07594859110

Appendix 10: Letter to GP

Dear Dr……

The following lady has agreed to participate in a study being undertaken by researchers at Coventry University and Nottingham University Hospitals NHS Trust and has asked that you are informed of her participation:

Name:

Address:

Date of Birth:

The study is **an Exploration of the Experiences of Women Living with Inflammatory Bowel Disease of Pregnancy and involves an interview discussing her experience and pregnancy.**

I have enclosed the Participant Information Sheet, please do not hesitate to contact me if you would like any further details about the study

Kind regards

Helen Janiszewski

Midwife and PhD Student at Coventry University

janiszeh@uni.coventry.ac.u

Appendix 11: Invitation to Study Letter

Dear

Title of Study: An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease and Pregnancy

We are presently conducting a research study to explore the experiences of pregnancy for women living with Inflammatory Bowel Disease.

We are contacting you because you have a diagnosis of Inflammatory Bowel Disease and have given birth within the last five years.

We are inviting participants to take part in a one-to-one interview to understand their experiences of pregnancy.

We want to understand the experiences of pregnancy for women living with IBD and explore ways to improve pregnancy care for women living with IBD.

Enclosed is a copy of the Participant Information Sheet for you to read which explains the study and what it involves in greater detail.

If after reading the information sheet you would like to take part, please contact me on 07594 859110.

I look forward to hearing from you.

Yours sincerely

Helen Janiszewski

Midwife at Nottingham University Hospitals

PhD Student at Coventry University

janiszeh@uni.coventry.ac.u

Appendix 12: HRA Statement of Activities

HRA and HCRW Statement of Activities for participating NHS organisations in England or Wales

(Template version 4.4)

For non-commercial studies, one Statement of Activities should be completed as a template for each site-type in the study. Each Statement of Activities should be accompanied by a completed Health Research Authority (HRA) and Health and Care Research Wales (HCRW) Schedule of Events, as part of the submission via IRAS for HRA and HCRW Approval.

Blue shaded fields (also marked with an asterisk*) should be completed by the sponsor/applicant prior to submission to HRA and HCRW.
Where appropriate, for the purpose of confirming capacity and capability, green shaded fields (also marked with a caret^) should be completed by the participating organisation before returning the document to the sponsor.
Other questions may be completed either by the sponsor/applicant or participating organisation (or collaboratively between both parties), as appropriate.

For participating organisations in Northern Ireland or Scotland, the sponsor should transfer a site specific information form to each local research team for completion and submission to their research management support function.

To provide an answer in the form, click in a box with the blue text and over-write this text, or select the relevant option if presented withdrop-down text.

A separate guidance document is provided and should be consulted prior to completion of this template. Please also read the question specific guidance where present.

IRAS ID*	256277
Short study title*	Experiences of pregnancy and IBD using IPA
Full study title*	An exploration of the experiences of the women living with Inflammatory Bowel Disease of pregnancy using Interpretative Phenomenology Analysis
Contact details of sponsor, or sponsor's delegated point of contact (e.g. Study Manager), for questions relating to study set-up*	Professor Oliver Sparagaro ab8677@coventry.ac.uk
Site Type*	Recruiting Site Select one option. If 'Other', give details. If 'Other', insert details here

Name of Participating Organisation	Where this statement is to be used as the agreement between sponsor and participating organisation, please enter the name of the participating organisation here prior to agreement. If this Statement is being agreed to cover multiple separate entities (e.g. in England, multiple GP practices within a single LCRN region) please make this clear here. Nottingham University Hospitals NHS Trust
Location/s within Participating Organisation	Where it is planned to undertake the research only at specified hospitals or other locations within the participating organisation (as may be the case in an NHS Trust / Health Board comprised of more than one hospital) please name those hospitals/locations here. IBD Clinics

Date HRA and HCRW office use only	Date template assessed by HRA and HCRW 21/02/2019
Version Number HRA office use only	Applicant version assessed by HRA and HCRW 1.0

1. **Does the sponsor intend that this document forms the agreement between itself and the participating organisation/s in England and/or Wales?***

For non-commercial studies other than clinical trials and clinical investigations, HRA and HCRW encourage use of the Statement of Activities as the only form of agreement between sponsor and an English or Welsh participating organisation, in place of bespoke agreements created by sponsors. For research in primary care settings in England, the Statement may be used for a geographical area, e.g. at the LCRN level, although agreement should be between the sponsor and independent legal entity (e.g. GP practice). For clinical trials and clinical investigations the HRA and HCRW expect that sponsors will use the model agreement for non-commercial research (mNCA).

Yes

2. **Date this Statement of Activities confirmed by participating organisation, if applicable.^**

3. **Confirmation on behalf of participating organisation provided by (insert name and job title), if applicable.^**

It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the sponsor and participating organisation. Instead, sponsors are expected to accept confirmation by email from an individual empowered by the participating organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).

4. **If this Statement is <u>NOT</u> intended to form the agreement with the participating organisation/s in England and / or Wales, will the sponsor be using an unmodified model non-commercial agreement (mNCA)?***

Select 'yes' or 'no'

5. **If no, please provide details of the modifications made to the model agreement and the reasons for them. If the sponsor intends to use an agreement not based on the model agreement, please provide detailed justification for this (templates of all 'site agreements' to be used, including for sites in each UK nation (where applicable) should be provided as part of the submission for HRA and HCRW Approval).***

Provide details of modification made to model agreement and the reasons for them.

6. Predicted Participant Recruitment, if applicable.

This is recruitment or identification at participating organisation, not overall for the study. Please clarify if this refers to participants, samples or data. Please clearly state if this is per month, per year, overall etc. Please state if not applicable to this site type.

12 - 14 participants overall

7. Proposed start date of research/participant identification activity at participating organisation.

Applicants may choose to leave the date field blank, for negotiation with individual sites, where there is significant uncertainty as to exact dates at the time of application for HRA and HCRW Approval.

01/05/2019

Where it might otherwise be open to interpretation, please specify whether this date refers to the commencement of screening, the recruitment of the first participant, etc.

commenced of participant identification

8. Predicted end date of research/participant identification activity at participating organisation.

Applicants may choose to leave the date field blank, for negotiation with individual sites, where there is significant uncertainty as to exact dates at the time of application for HRA and HCRW Approval.

01/12/2019

Where it might otherwise be open to interpretation, please specify whether this date refers to the recruitment of the final participant, the final visit of the final participant, database lock, etc.

recruitment of final participant

9. Person responsible for research activities at site.*

Local Principal Investigator

- The HRA and HCRW expect principal investigators to be in place at participating organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single site studies where the Chief Investigator will also be the Principal Investigator.
- Where this is not the case, the HRA and HCRW expect local collaborators to be in place where central study staff will be present at site to undertake research procedures (the role of the Local Collaborator is to support practical arrangements for the presence of research staff under Letters of Access, Honorary Research Contracts or similar arrangements).
- Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at site, the HRA and HCRW do not expect that a Principal Investigator or local collaborator is appointed and you should select Chief Investigator.

10. Are you requesting support to identify a Principal Investigator or Local Collaborator?*

Please indicate whether support from the participating organisation is being requested to identify a Principal Investigator/Local Collaborator and provide further information on expectations below. Where a Principal Investigator or Local Collaborator has already been identified, their details appear on Part C of the IRAS Form.

No

11. Further Information (where applicable).*

Please provide further information on sponsor expectations for a Principal Investigator/Local Collaborator, to help participating organisations identify an appropriate individual if required (e.g. Profession, specialty, seniority etc.)

Provide information on the support required

12. The following capabilities and capacity are needed locally in order to deliver the study, e.g. specific equipment, patient/participant groups, service support nursing time, excess treatment costs, etc.*

Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule.

Provide information on sponsor's expectations for local capacity and capability

13. Projected NHS treatment cost savings at this site type, if applicable.*

Although many studies incur excess treatment costs (see AcoRD for information on cost attribution) many studies also give rise to treatment cost savings during the study (e.g. a two armed study comparing standard care to a less intensive, and less expensive, alternative treatment). Please describe below any projected treatment cost savings, so your participating organisations may include this information when considering the overall treatment costs/cost savings of their portfolio of research. Any funding or support from the sponsor/funder to the participating organisation is set out in the finance schedule. Excess treatment costs will be indicated above (question 12) and in the HRA and HCRW Schedule of Events.

N/A

14. The following training for local staff will be provided by the sponsor. Where only specific team members (e.g. the Principal Investigator) will receive this training, this is described below.*

N/A

15. In addition to the above training, to be provided by the sponsor, the sponsor also expects that the following local research team members will undertake or have already undertaken the following training.*

It would not be usual for the sponsor to expect study specific training additional to that which it will provide, this section does however allow sponsors to state that they will accept, for example, NIHR CRN training in Good Clinical Practice where the study is a Clinical Trial of an Investigational Medicinal Product.

N/A

(Template version 4.4)

Please select one of the following*	
There are no funds/resources/equipment, etc. being provided to this/these organisation/s by the sponsor. This schedule should be left blank.*	☒
The following funding/resources/equipment, etc. is to be provided to this/these local participating organisation/s. However, the finance schedule to cover such transfer is detailed in a separate agreement. Please complete the information below but leave the schedule blank and submit your separate agreement to the HRA and HCRW.*	☐
Enter information on funding, resource and/or equipment etc. to be provided to the site by the sponsor but do not complete the schedule below	
The following funding/resource/equipment, etc. is to be provided to this local participating organisation. This Statement of Activities is intended by the sponsor to form the agreement between them and the participating organisation. The finance schedule below details the funds to be provided to the site by the sponsor. Please complete the information and the schedule below.*[1]	☐
Enter information on funding, resource and/or equipment etc. to be provided to the site by the sponsor and also complete the schedule below	

1 Payment Schedule (i.e. frequency or trigger for payments)* £0
2 Area of Cost (e.g. set-up, procedure, overall cost, etc.)* £0

Payment details

[1] The Statement of Activities is not intended for use with participating organisations in Northern Ireland or Scotland

If VAT is payable, then the sponsor shall pay the VAT in addition to the payment on presentation of a VAT invoice. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

3 Invoices to be submitted to (insert job title, name of body and address)*
Enter address details

4 Payment to be made by cheque to^
Enter cheque payable details
4.1 AND remitted to (insert job title/position and address)
Enter job title/position and address
OR
5 Arrange BACS transfer to: Bank Name
Enter bank name
5.1 Sort Code

Enter sort code
5.2 Account Number

Enter account number
5.3 And send the relevant paper work to the following address

Enter address details

Invoices should be presented promptly. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding from an external funding body has been irrecoverably reclaimed by such external funding body as a result of such delay or inadequacy.

Schedule 2 – Material Transfer Provisions

(Template version 4.4)

These provisions do not remove the responsibility for a sponsor to clearly lay out in their protocol (and to potential participants in the patient information sheet/s) at a minimum the following information for all human biological material taken: 1) The nature of the materials, 2) The reason that the material is being taken, 3) where the material is to be sent, 4) what will happen to any remaining material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction).

Detailed guidance on what information should be included in a protocol may be found on the HRA website.

Please select one of the following*	
This study does not involve the transfer of human biological material (Material) from this participating organisation to the sponsor or its agents. This schedule does not form part of this agreement.*	☒
The sponsor has separately provided to the HRA and HCRW and participating organisation an agreement for the transfer of human biological material. This schedule does not form part of this agreement.*	☐
These provisions form part of the agreement between the sponsor and this participating organisation. Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.*[2]	☐

1. Where the protocol requires the participating organisation to supply Material to the sponsor or to a third party nominated by the sponsor, and where indicated above, this Schedule 2 shall apply.

[2] The HRA Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales.

2. In accordance with the protocol, the participating organisation shall send Material to the sponsor or, in accordance with provision 8 below, to a third party nominated by the sponsor.
3. The participating organisation warrants that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)) and as required by the protocol.
4. Subject to provision 3 above, the Materials are supplied without any warranty, expressed or implied, including as to their properties, merchantable quality, fitness for any particular purpose, or that the Materials are free of extraneous or biologically active contaminants which may be present in the Materials.
5. The sponsor shall ensure, or procure through an agreement with the sponsor's nominee as stated in provision 2 above that:

    5.1 the Material is used in accordance with the protocol, the consent of the participant, and the ethics approval for the study;

    5.2 the Material is handled and stored in accordance with applicable law;

    5.3 the Material shall not be redistributed or released to any person other than in accordance with the protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the participant's consent; and

    5.4 no alteration shall be made to the title, coding or acronym of the Material.

6. The parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.
7. The participating organisation and the sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this Schedule 2.
8. To the extent permitted by law the participating organisation and its staff shall not be liable for any consequences of the supply to or the use by the sponsor of the Material or of the supply to or the use by any third party to whom the sponsor subsequently provides the Material or the sponsor's nominee as stated in provision 2 above, save to the extent that any liability which arises is a result of the negligence of the participating organisation.
9. The sponsor undertakes that, in the event that Material is provided to a third party in accordance with provision 2 above, it shall require that such third party shall undertake to handle any Material related to the study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this Schedule 2.
10. Any surplus Material that is not returned to the participating organisation or retained for future research (in line with participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

(Template version 4.4)

Please select one of the following*	
This study does not involve any processing of personal data by this participating organisation on behalf of the sponsor. This schedule does not form part of this agreement.*	☐
The sponsor has separately provided to the HRA and HCRW (and will provide to the participating site/s) another GDPR Article 28 compliant agreement (e.g. mNCA) for the processing of personal data by the participating organisation. This schedule does not form part of this agreement.*	☐
These provisions form part of the agreement between the sponsor and this participating organisation. Select this option if the site will be processing data on behalf of the sponsor, no other agreement is provided, and the terms below therefore constitute the data processing agreement for this study (for the avoidance of doubt, when used, these provisions are intended to form a legally binding contractual obligation for the purposes of compliance with the GDPR, specifically GDPR Article 28 (3))*[3]	☒

1. The parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including, where applicable, medical confidentiality) in relation to participants.
2. For the purposes of the General Data Protection Regulation (GDPR) and Data Protection Act 2018 (the Data Protection Legislation), the sponsor is the controller and the participating organisation is the sponsor's processor in relation to all processing of personal data (as defined in the Data Protection Legislation) that is processed by the participating organisation for the purpose of this study and for any future research use under the controllership of the sponsor, that would not have taken place but for this agreement regardless where that processing takes place.

[3] The HRA and HCRW Statement of Activities is not intended for use with participating organisations in Northern Ireland or Scotland.

3. The parties acknowledge that whereas the sponsor is the controller in accordance with clause 2, the participating organisation is the controller of the personal data collected for the purpose of providing clinical care to the participants (or other purposes, as applicable). This personal data may be the same personal data, collected transparently and processed for research and for care (or other) purposes under the separate controllerships of the sponsor and participating organisation.
4. Where the participating organisation is the sponsor's processor and thus where the processing is undertaken by the participating organisation for the purposes of the study, clauses 6.7 to 6.16 below will apply. For the avoidance of doubt, such clauses do not apply where the participating organisation is processing the participant personal data as a controller.
5. The participating organisation agrees only to process personal data for and on behalf of the sponsor in accordance with the instructions of the sponsor and for the purpose of the study and thereby to ensure the sponsor's compliance with the Data Protection Legislation;
6. The participating organisation agrees to comply with the obligations applicable to processors described by Article 28 of the GDPR including, but not limited to, the following:

    6.7. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the controller by Article 28(1);

    6.8. to not engage another processor without the prior written authorisation of the sponsor (Article 28(2));

    6.9. to process the personal data only on documented instructions from the sponsor unless required to do otherwise by legislation, in which case the participating organisation shall notify the sponsor before processing, or as soon as possible after processing if legislation requires that the processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a));

    6.10. to ensure that personnel authorised to process personal data are under confidentiality obligations (Article 28(3b));

    6.11. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));

    6.12. to respect the conditions described in Article 28(2) and (4) for engaging another processor (Article 28(3d));

    6.13. to, taking into account the nature of the processing, assist the sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising data subjects' rights (Article 28(3e));

    6.14. to assist the controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the processing and the information available to the participating organisation (Article 28(3f));

6.15. to, at the choice of the sponsor, destroy or return all personal data to the sponsor at the end of the study at the participating organisation, unless storage is legally required (Article 28(3g)) or where that personal data is held by the participating organisation as controller for the purpose of clinical care or other legal purposes; and

6.16. to maintain a record of processing activities as required by Article 30(2) GDPR.

7. The participating organisation shall ensure that:

7.7. its agents do not process personal data except in accordance with this agreement (and the protocol);

7.8. it takes all reasonable steps to ensure the reliability and integrity of any of its agents who have access to the personal data and ensure they:

7.8.1. are aware and comply with the participating organisation's duties under this agreement;

7.8.2. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and

7.8.3. are informed of the confidential nature of the personal data and understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.

8. The participating organisation agrees to:

8.7. allow the sponsor(s) or another auditor appointed by the sponsor(s) to audit the participating organisation’s compliance with the obligations described by this agreement, Data Protection Legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the sponsor complying with all relevant health and safety and security policies of the participating organisation and/or to provide the sponsor with evidence of its compliance with the obligations set out in this agreement; and

8.8. obtain prior agreement of the sponsor to store or otherwise process personal data outside the European Economic Area.

9. Where the participating organisation stores or otherwise processes personal data outside of the European Economic Area as the sponsor’s processor, it warrants that it does so in compliance with the Data Protection Legislation.

(Template version 4.4)

Please select one of the following*	
This study does not involve the transfer of personal data from this participating organisation to the sponsor or its agents, nor is there transfer of confidential information between the parties. This schedule does not form part of this agreement.*	☒
The Sponsor has separately provided to the HRA and HCRW and participating organisation another agreement for the transfer of data (e.g. mNCA). This schedule does not form part of this agreement.*	☐
These provisions form part of the agreement between the sponsor and this participating organisation. Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.*[4]	☐

Data sharing

1. Personal data shall not be disclosed to the sponsor by the participating organisation, save where this is required directly or indirectly to satisfy the requirements of the protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a participant in connection with the study.
2. The sponsor agrees to use personal data solely in connection with the operation of this research study, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,
    2.1. Not to disclose personal data to any person except in accordance with applicable legal requirements and codes of practice.
3. The sponsor agrees to comply with the obligations placed on a controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to processing of personal data (Article 5 GDPR)
4. The sponsor agrees to ensure persons processing personal data under this Agreement are equipped to do so respectfully and safely. In particular:
    4.1. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the participating organisation) processing personal data understand the responsibilities for information governance, including their obligation to

[4] The HRA and HCRW Statement of Activities is not intended for use with participating organisations in Northern Ireland or Scotland.

process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.

4.2. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the participating organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.

5. The sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular,
    5.1. To ensure that personal data are only accessible to persons who need it for the purposes of the study and to remove access as soon as reasonably possible once it is no longer needed.
    5.2. To ensure all access to personal data on IT systems processed for study purposes can be attributed to individuals.
    5.3. To review processes to identify and improve processes which have caused breaches or near misses, or which force persons processing personal data to use workarounds which compromise data security.
    5.4. To adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
    5.5. To take action immediately following a data breach or near miss.

6. The sponsor agrees to ensure data are processed using secure and up to date technology. In particular,
    6.1. To ensure no unsupported operating systems, software or internet browsers are used to support the processing of personal data for the purposes of the study.
    6.2. To put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as cyber essentials.
    6.3. To ensure IT suppliers are held accountable via contracts for protecting personal data they process and for meetings all relevant information governance requirements.

Freedom of information

7. Parties to this Agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another party shall notify and consult that party in accordance with clause 13, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.
8. The parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the Party responding to the request.
9. Where the party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other party in writing, giving at least four (4) working days' notice of its intended disclosure.

Confidentiality

10. The participating organisation agrees to treat the Results, excluding any clinical data of the study, as confidential information of the sponsor and the sponsor agrees to treat personal data and confidential patient information as Confidential Information.
11. The receiving party agrees:
    - 11.1. To take all reasonable steps to protect the confidentiality of the confidential information and to prevent it from being disclosed otherwise than in accordance with this Agreement
    - 11.2. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the study are made aware of, and abide by, the requirement of this clause 11.
    - 11.3. To use confidential information solely in connection with the operation of the Agreement and not otherwise, except in the case where the confidential information is personal data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
    - 11.4. Not to disclose confidential information in whole or in part to any person without the disclosing party's prior written consent or, where the confidential information is personal data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the Data Protection Legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.
12. The provision of clause 11 shall not apply to the whole or any part of the confidential information that is:
    - 12.1. lawfully obtained by the receiving party free of any duty of confidentiality;
    - 12.2. already in the possession of the receiving party and which the receiving party can show from written records was already in its possession (other than as a result of a breach of clause 11.1 or 11.2);
    - 12.3. in the public domain (other than as a result of a breach of clause 11.1 or 11.2);
    - 12.4. independently discovered by employees of the receiving party without access to or use of confidential information;
    - 12.5. necessarily disclosed by the receiving party pursuant to a statutory obligation;
    - 12.6. disclosed with prior written consent of the disclosing party;
    - 12.7. necessarily disclosed by the receiving party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A;

13. The restrictions contained in this schedule 4 shall remain in force without limit in time in respect of personal data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly agreed between the parties, these clauses shall remain in force for a period of 10 years after the end of the study at the participating organisation.

(Template version 4.4)

This Appendix is for use at the discretion of the sponsor and participating organisation, to record the roles and responsibilities of the local research team (where applicable) and the authorisation of the Principal Investigator (PI) for this.

Please select one of the following*	
The sponsor intends to use this template as the delegation log for this participating organisation	☐
The sponsor intends to use a delegation log based on another template for this participating organisation	☐
The sponsor is not proposing that a delegation log is completed for this participating organisation	☒

IRAS ID	**Name of participating organisation**
256277	Nottingham University Hospitals NHS Trust

Name of Principal Investigator	**PI's Signature**[1]	**PI's Initials**	**Start** **(dd/mmm/yy)**	**End** **(dd/mmm/yy)**

[1]*My signature confirms/acknowledges that the information contained in this delegation log is accurate and that:*

- ***a.*** *I will conduct the study in accordance with the protocol and remain responsible for the overall study conduct at the participating organisation and for the reported data.*
- ***b.*** *I will ensure study oversight.*
- ***c.*** *I will authorise the delegation of study-related tasks to each individual as listed.*
- ***d.*** *The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.*
- ***e.*** *I will ensure that all personnel assisting in the conduct of the study are informed about their obligations and will not have performed any delegated study-related tasks prior to appropriate delegation and completion of study training appropriate to the role.*
- ***f.*** *I will ensure that participating organisation staff receive, in a timely manner, the appropriate information and training.*
- ***g.*** *I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.*
- h. Neither I, nor any dependents, have entered into and will not enter into arrangements, financial or otherwise, with any third party providing support, products and/or services to the study that would present a conflict of interests
- i. I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner.
- j. I consent to the sponsor, and to any relevant third party providing support, products and/or services to the Study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

Study Task Key

The sponsor may detail in the below key the main study activities that the PI can delegate to staff at the participating organisation. The task list and delegation log are intended to be maintained as an up to date document throughout the duration of the study at the participating organisation

1. Screens/recruits study subjects	6. Enter other task here	11. Enter other task here	16. Enter other task here
2. Obtains Informed Consent	7. Enter other task here	12. Enter other task here	17. Enter other task here
3. Confirms eligibility (Inclusion/Exclusion)	8. Enter other task here	13. Enter other task here	18. Enter other task here
4. Sends Invitation to study letter to eligible patients	9. Enter other task here	14. Enter other task here	19. Enter other task here
5. Enter other task here	10. Enter other task here	15. Enter other task here	20. Enter other task here

Name	*Signature*[2]	*Initials*	*Study Role*	*Study Task(s) (Select from key)*	*Start of task(s)* (dd/mmm/yy)	*PI Initials*	*End of task(s)* (dd/mmm/yy)	*PI Initials*

[2]*My signature confirms/acknowledges that I accept the assigned study task/s and that:*

1. ***I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority, and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.***
2. I consent to the sponsor, and to any relevant third party providing support, products and/or services to the study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

I confirm that the information contained in this delegation log is accurate and complete. (To be completed by the PI at the end of the study).

PI name: Signature: Date:

Appendix 13: HRA Schedule of Events

Area of Activity (Select this first. You can insert free text if the drop-down options are not suitable)	Specific Activity (drop down only present when Area of Activity selected first - or use free text if the drop-down options are not suitable)	Duration (Minutes)	Undertaken by (drop down or free text)	Day -x to -y Screen
Consent Processes	Eligibility check (exclusions)	5 mins	Local Clinical Nurse Specialist	Service Support Cost
Consent Processes	Mail-out - invitation to study letter	5 mins	Local Clinical Nurse Specialist	Service Support Cost
Participant Consent Procedures	Take informed consent	20 mins	External Staff (Central Research Team)	Service Support Cost
Interventions non clinical	Interview of Participant	60 mins	External Staff (Central Research Team)	

Area of Activity (Select this first. You can insert free text if the drop-down options are not suitable)	Specific Activity (drop down only present when Area of Activity selected first - or use free text if the drop-down options are not suitable)	Duration (Minutes)	Undertaken by (drop down or free text)	Day -x to -y Screen
Study Set Up	Site Initiation Visit	20 mins	Principal Investigator	Service Support Cost
			External Staff (Central Research Team)	
			Local Clinical Nurse Specialist	
Study Set Up	Attendance at training	15 mins	Principal Investigator	Service Support Cost
			Local Clinical Nurse Specialist	
			External Staff (Central Research Team)	
Consent Processes	Database search	10 mins	Local Clinical Nurse Specialist	Service Support Cost
Study Close Down	Archiving	60 mins	Lead Researcher	Service Support Cost
			Principal Investigator	

Appendix 14: Indemnity Insurance

Colmore Gate
2-6 Colmore Row
Birmingham
B3 2QD
t +44 (0)121 253 3000 **f** +44 (0)121 253 3083

Geoffrey Patton

Coventry University

Priory Street

Coventry

CV1 5FB

15th August 2018

Dear Sirs,

Client Information Letter – Coventry University and Subsidiary Companies

We, Aon Limited, are insurance brokers acting on your behalf only in accordance with our terms of business agreement. We have agreed to provide this letter to confirm that the contract(s) of insurance described below (the '**Insurances**') are in force at the date of this letter.

Public and Products Liability

Period of Insurance : 1 August 2018 to 31 July 2019 both days inclusive

Limit of Indemnity	: £25,000,000 any one occurrence but limited to £25,000,000 in the aggregate in respect of Products/Pollution Liability.		
Deductible	: Each and Every Third Party Property Damage Claim – £1,000		
Insurer(s)	: a) Primary	Allianz Insurance plc	£15,000,000
	b) Excess Layer	AIG Europe Ltd	£10,000,000
Policy Number(s)	: a) SZ21707594		
	b) 24632767		
Principal Extension	: Students Liability		

Disclaimer

All of the Insurances are subject to their specific policy terms, conditions and exceptions, not all of which may be summarised in this letter. Please refer to the actual policies for the full terms and conditions.

In the event that you disclose this letter to any third party, such third party shall not be entitled to rely on its contents, and you should inform them of the same. Under **no circumstances** shall any person or entity to whom/which this letter is disclosed by you become insured, nor does such disclosure modify the Insurances in any way.

This letter is provided for information only and is not to be understood as providing advice to you or anyone else on any decision that is under consideration. The reader of this letter is responsible for any assumptions they make as to the coverage afforded by the Insurances, which may be subject to important conditions and/or exclusions.

All of the Insurances are subject to their specific policy terms, conditions and exceptions, not all of which may be summarised above. Please refer to the actual policies if full terms and conditions are required. Subject to the terms and conditions of the policy full cover is in force during the times scales set by Insurers in respect of Risk Requirements, once the deadline has been reached and in the situation that requirements have not been completed Insurers may then impose conditions and restrictions on the policy.

Yours sincerely,

Lisa Walters

Client Service Manager

For and on behalf of Aon UK Ltd

Aon UK Limited

Appendix 15: Sponsor Letter

TO WHOM IT MAY CONCERN QRS/Ethics/Sponsorlet

Wednesday, 30 January 2019

Dear Sir/Madam

Researcher's name: Helen Janiszewski Project Reference: P76258 Project Title: An Exploration of the Experiences of Women Living with Inflammatory Bowel Disease of Pregnancy using Interpretative Phenomenological Analysis

The above named researcher has successfully completed the Coventry University Ethical Approval process and received authorisation for their project to proceed.

I should like to confirm that Coventry University is happy to act as the sole sponsor for this researcher and attach details of our Public Liability Insurance.

Yours faithfully

Olivier Sparagano

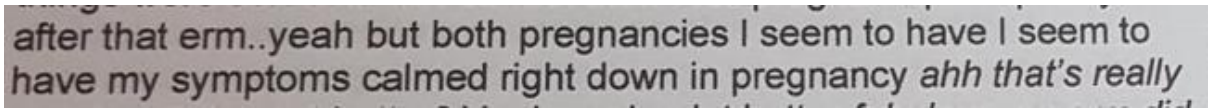
Associate Pro-Vice-Chancellor – Research

Enc

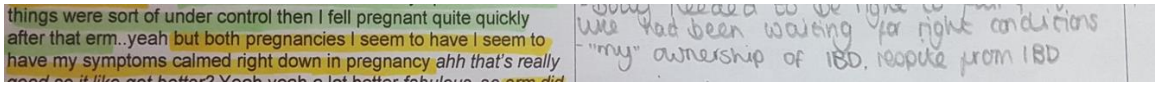
Appendix 16: Stages of IPA

Initial step: Transcribing of the interview verbatim

STEP 1: Reading and re-reading

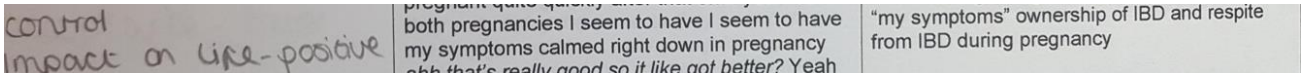

after that erm..yeah but both pregnancies I seem to have I seem to have my symptoms calmed right down in pregnancy *ahh that's really*

STEP 2: Initial noting (a -e)


things were sort of under control then I fell pregnant quite quickly after that erm..yeah but both pregnancies I seem to have I seem to have my symptoms calmed right down in pregnancy *ahh that's really*

we had been waiting for right conditions
"my" ownership of IBD, respite from IBD

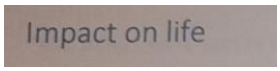
STEP 3: Developing emerging themes

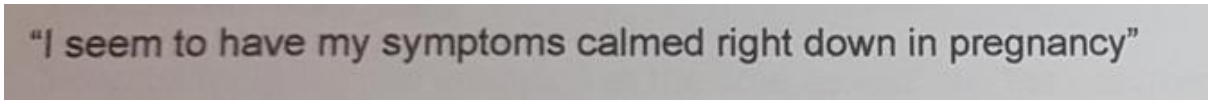

control
impact on life-positive

both pregnancies I seem to have I seem to have my symptoms calmed right down in pregnancy *ahh that's really good so it like got better?* Yeah

"my symptoms" ownership of IBD and respite from IBD during pregnancy

STEP 4: Searching for connections across emergent themes

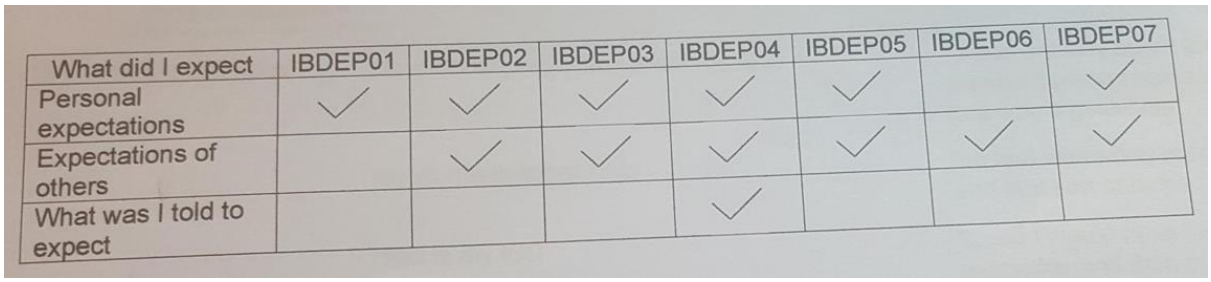

Impact on life


"I seem to have my symptoms calmed right down in pregnancy"

STEP 5: Moving to the next case

(all steps 1 – 4 repeated)

STEP 6: Looking for patterns across cases



What did I expect	IBDEP01	IBDEP02	IBDEP03	IBDEP04	IBDEP05	IBDEP06	IBDEP07
Personal expectations	✓	✓	✓	✓	✓		✓
Expectations of others		✓	✓	✓	✓	✓	✓
What was I told to expect				✓			

Emergent themes and patterns highlighted and cross referenced across all seven cases and development of themes continued to emerge – resulting in the final three master themes and superordinate themes presented in **Chapter 5**