

The Yorkshire and The Humber Maternal Medicine Network



Gastroenterology Principles

Purpose and Scope

This document may use the term women, understanding that practitioners will modify their language in accordance with the preferences of individuals within their care.

The Yorkshire and Humber (Y&H) region have come together to develop the Y&H Maternal Medicine Network (MMN). The aim of the MMN is to align care across the region and to reduce inequalities in care to women with complex medical conditions. The purpose of this document is to outline the key principles that should be adopted when caring for women with gastroenterology problems focusing primarily on inflammatory bowel disease. The document also details advice regarding pre pregnancy counselling content and an overview of medications in pregnancy and breast feeding. It is widely accepted that women who conceive with active IBD have a higher rate of active disease during pregnancy than those who conceive whilst in remission (Narayan and Nelson Piercy 2017). This document should be used in conjunction with the 'Conditions for Consideration of Referral to the Maternal Medicine Centre' document, which can be found at [Yorkshire and Humber Maternal Medicine Network - Criteria for Referral](#). These principles have been approved by governance at both LTHT and STH. They can either be used as a standalone document following ratification by adopting Trusts or can be used as a reference to incorporate into Trust guidance.

Introduction

Inflammatory bowel disease (IBD) affects many women of childbearing age. Women with IBD are at increased risk of adverse pregnancy outcomes including, preterm birth, small for gestational age birth weight, gestational diabetes, stillbirth and are more likely to require a caesarean section (Selinger et al 2020). The management of IBD during pregnancy requires complex decision making, incorporating consideration of maternal and fetal health (Selinger et al 2020).

Findings from national reports, such as MBRRACE, have shown that those who are from a Black, Asian or Mixed Ethnic Background or those who have a severe mental illness or live in the most deprived neighbourhoods, are at higher risk of poorer physical health and care outcomes in addition to their medical condition/s. Therefore, it is important to consider the person's individual needs, circumstances and wider determinants of health and offer reasonable adjustments to address these to ensure improved equity of access, support, and care for individuals. The perinatal period adds further complexity, therefore please ensure you consider mental health needs of the patient and refer to your local perinatal mental health service appropriately. Additional information can be found at www.everymumatters.com

General Principles of Care

Gastroenterology - Pre-Pregnancy Counselling

- Ideally 6 months remission recommended preconception
- Encourage smoking and alcohol cessation.
- Recommend folic acid 400 microgram for 3 months preconception. Consider whether iron and high-dose folate Supplementation required (high dose folic acid recommended if on sulfasalazine or in small bowel Crohn's disease).
- Review medication: Methotrexate should be stopped at least 1-month preconception, JAK inhibitors like Tofacitinib at least 2 weeks preconception. Most other medication including biologics can be continued (see medication table tab).

Gastroenterology - Antenatal Care

- High Dose (5mg) folic acid in those on low residue diets, ileal involvement or on sulfasalazine
- Consider aspirin 150mg od for pre-eclampsia prophylaxis if disease is active.
- Growth scans for those with active disease
- Active IBD scores 3 on VTE risk assessment

Gastroenterology - Intrapartum Care

- Vaginal delivery recommended for most women with IBD.
- Caesarean section recommended in active perianal disease, previous rectovaginal fistulae or previous perineal surgery or pouch.
- Consider risk/benefit of planned Caesarean delivery in women with IPAA or extensive previous abdominal surgery.

Gastroenterology - Postnatal Care

- If stopped biologics, should have a clear plan to recommence as soon as possible after delivery.
- NSAIDs can be used for short defined courses but risk flaring of IBD.
- Risk of disease flare in the puerperium with UC.
- Live attenuated vaccines ie BCG, VZV, Rotavirus, should be withheld within the first 12 months in newborns exposed inutero to biologics.
- Contraceptive plans should be discussed prior to discharge.

Acute Disease in Pregnancy

Medical Management	Surgical Management	Investigations
Acute severe disease should be managed as per the non-pregnant population.	Emergency surgery should not be delayed for pregnant women when indicated.	Ultrasound of the small bowel is safe.
Corticosteroids and Infliximab are considered low risk in pregnancy.	In procedures for UC a temporary ileostomy is generally preferred	It is safe to undertake colonoscopy, flexible sigmoidoscopy, and gastroscopy if the results will affect the antenatal management.
LMWH is advised for VTE prophylaxis for active disease.	Abdominal surgery is safest in the second trimester but risk relatively low in all trimesters.	MRI is safe in the second and third trimesters; theoretical concerns regarding foetal risk in the first trimester have not been reflected in human studies. Gadolinium-based contrast agents should however be avoided at all gestations
Inpatients should be reviewed regularly by the obstetric team during admission.	Consideration should be given to 2 doses of intramuscular antenatal steroids (oral are not sufficient) for fetal lung maturation in viable gestations prior to emergency surgery and concurrent caesarean section in term or near-term pregnancies. Fetal monitoring appropriate to the gestation should be performed post-surgery.	Faecal calprotectin can be useful in monitoring disease activity.

Drugs		
Medication	Pregnancy	Breastfeeding
Low dose aspirin (up to 150mgs)		
	No association found with severe disease complications of IBD. No association with increased disease activity at <325mg/day	N/a
Aminosalicylates (5-ASA)		
Mesalazine (Asacol, Ipocol, Mesren, Octasa, Pentasa, Salofalk) Olsalazine (Dipentum) Balsalazide (Colazide) Sulfasalazine (Salazopyrin)	LOW RISK Sulfasalazine: High Dose folic acid recommended ‘Theoretical risk of neonatal haemolysis in third trimester; adequate folate supplements should be given to mother (BNF) No associated increased risk of congenital malformations Limited data regarding miscarriage. One study available did not identify increased risk’. ‘No robust evidence of increased risks of stillbirth, low birth weight, or preterm delivery’ ‘Actively inhibits folic acid absorption and metabolism – High dose folic acid advised preconceptionally and in the first trimester. There are theoretical concerns regarding an increased risk of neonatal hyperbilirubinemia following in utero sulfasalazine exposure, although there is no good evidence confirming this association’. (UKTIS) Mesalazine: Negligible quantities cross placenta. (BNF) (thought to be preferable to sulfasalazine in pregnancy) Olsalazine: Manufacturer advises avoid unless potential benefit outweighs risk (BNF) Balsalazide: Manufacturer advises avoid (BNF)	LOW RISK Sulfasalazine and Mesalazine poorly excreted in breastmilk. Risk of haemolysis in infants with G6PD deficiency. Can occasionally cause diarrhoea in infants. (LactMed) Sulfasalazine has been linked to a report of episodes of bloody diarrhoea in an exclusively breastfed infant, which resolved within 72 hours of discontinuing therapy. Mesalazine has been linked to case reports of diarrhoea in breastfed infants. (Lexicomp) Sulfapyridine (within sulfasalazine) has the potential to cause kernicterus - infant should be monitored closely for jaundice
Corticosteroids (steroids)		
Prednisolone Budesonide (Entocort)	LOWER RISK Consider growth scans with high dose long term use. Consider need for Hydrocortisone cover in labour	LOWER RISK ‘Amounts of prednisolone in breastmilk are very low. No adverse effect have been reported in breastfed infants

	Testing for GDM required Monitor for hypertension 'Increased rates of cleft lip and palate in animal studies, conflicting limited data in human studied. No robust association with IUGR but data limited. Possible association with preterm birth Limited data on miscarriage, intrauterine death and neurodevelopmental outcome'. (UKTIS) Maternal - increased risk of gestational diabetes - Long courses >4 weeks of >5mg prior to delivery, require hydrocortisone cover in labour.	with maternal use of any corticosteroid during breastfeeding. With high maternal doses, avoiding breastfeeding for 4 hours after a dose should markedly decrease the dose received by the infant. However, this manoeuvre is not necessary with short-term use. High doses might occasionally cause temporary loss of milk supply'. (LactMed)
Mycophenolate Mofetil	CONTRAINDICATED	CONTRAINDICATED
	'MMF/MPA are contraindicated during pregnancy unless there is no possible alternative to prevent rejection of a transplanted organ. This is due to an increased risk of first trimester pregnancy loss and confirmed human teratogenic effects, including craniofacial anomalies (cleft lip and/or palate, microtia, external auditory canal atresia, micrognathia); microphthalmia, coloboma of iris and retina, and hypertelorism; complex congenital cardiac anomalies, including septal defects, conotruncal and outflow tract anomalies; oesophageal atresia, diaphragmatic hernia, and various vertebral and skeletal anomalies. The two largest cohort studies carried out to date report malformation rates of 11.6% and 26% among offspring exposed to MMF in the first trimester.' (UKTIS)	'Information from one patient indicates that relatively large amounts of mycophenolate are excreted into breastmilk, with peak milk levels at about 2 hours after a dose of the delayed-release formulation (Myfortic). A few infants have reportedly been breastfed during mycophenolate therapy, with no adverse effects reported. Because little information is available on the use of mycophenolate during breastfeeding, an alternate drug may be preferred, especially while nursing a newborn or preterm infant.' (lactMed)
Methotrexate	CONTRAINDICATED	CONTRAINDICATED
	'Spontaneous miscarriage risk. High dose methotrexate exposure appears to cause a distinct embryopathy that includes craniofacial defects, malformations of the digits, and defects of the spine and ribs. There are also reports of ear, kidney and lung defects, and	Most authors consider breastfeeding contraindicated with methotrexate use. 'Maternal doses of methotrexate up to 92 mg (1.12 mg/kg) produce low levels in milk, leading some authors

	hypospadias. Low dose doubles miscarriage risk. Cases have been reported of methotrexate embryopathy at low doses.’ (UKTIS)	to state that low single or weekly doses, such as those used for ectopic pregnancy or rheumatoid arthritis, are of low risk to the breastfed infant, although some expert opinion warns against this use. Withholding breastfeeding for 24 hours after a weekly low dose of methotrexate may decrease the infant's dose by 40%. If breastfeeding during long-term, low-dose methotrexate use is undertaken, monitoring of the infant's complete blood count and differential could be considered’ (LactMed)
Thiopurines		
Azathioprine Mercaptopurine	LOW RISK ‘Available data demonstrates no association with congenital malformations/preterm birth or fetal growth Case reports of neonatal leukopenia and thrombocytopaenia. Caution with live vaccines with infants within utero exposure.’ (UKTIS)	LOW RISK ‘Studies in women with inflammatory bowel disease, systemic lupus erythematosus or transplantation taking doses of azathioprine up to 200 mg daily for immunosuppression have found either low or unmeasurable levels of the active metabolites in milk and infant serum. Cases of mild asymptomatic neutropenia in infants have been reported. Avoiding breastfeeding for 4 hours after a dose should markedly decrease the dose received by the infant in breastmilk.’ (LactMed)
Calcineurin Inhibitors		
Tacrolimus Ciclosporin	LOWER RISK – LIMITED DATA Growth Scans Recommended Possible association with growth restriction. Tacrolimus: ‘Although it is not possible to state that there is no increased risk to the fetus following maternal systemic tacrolimus use during pregnancy, the available data do not currently provide evidence that tacrolimus is a major human teratogen. Women being treated with tacrolimus who are planning a pregnancy or who become pregnant should be offered a medication review by their specialist’. (UKTIS) Ciclosporin: ‘There is currently little evidence that use of	LOW RISK – LIMITED DATA ‘Limited data indicate that amounts of systemically administered tacrolimus are low in breastmilk and probably do not adversely affect the breastfed infant.’ Ciclosporin limited and inconsistent data however ‘With typical maternal cyclosporine blood levels, a completely breastfed infant would usually receive no more than about 2% of the mother's weight-adjusted dosage or pediatric transplantation maintenance dosage, and often less than 1%. In most breastfed infants, cyclosporine is not detectable in blood; however, occasionally infants

	ciclosporin during pregnancy increases the risk of congenital malformation. Increased rates of preterm delivery and intrauterine growth restriction have been identified among women receiving systemic treatment. Regular clinical review and monitoring of maternal whole blood ciclosporin concentration is recommended both during and after pregnancy due to the risk of subtherapeutic or toxic blood concentrations as a consequence of the pharmacokinetic changes which may be associated with pregnancy.’ (UKTIS)	have had detectable blood levels, even when milk levels and infant dosage were apparently low.’
Anti TNF		
Infliximab Adalimumab	LOW RISK Considered low risk and can be used throughout pregnancy Withhold live vaccines in infants for 12 months For women with active disease just before or during pregnancy, or with disease that is difficult to control, continuation of anti-TNF throughout pregnancy is recommended. The last dose of anti-TNF in the third trimester should be timed in accordance with the presumed due date to reduce fetal exposure. For women in remission, discontinuing anti-TNF prior to the third trimester is not recommended, as it may increase the risk of relapse and lead to unfavourable pregnancy outcomes. However, if a pregnant patient in long-term remission wishes to discontinue anti-TNF prior to the third trimester, resumption of anti-TNF shortly after delivery is recommended.	LOW RISK ‘Infliximab is usually either not detectable in breastmilk or detectable at very low levels. Absorption of the drug from milk by the infant is minimal. Follow-up of infants exposed in utero and breastfed during maternal infliximab therapy have found no adverse effects and normal development’. (lactmed) ‘Limited information indicates that maternal adalimumab injections produce low levels in breastmilk and do not adversely affect the nursing infant’.(lactmed) ‘While low levels of infliximab, adalimumab, certolizumab, natalizumab and Ustekinumab can be detected in breast milk from mothers receiving these biologics, breastfed infants of mothers receiving biologics, immunosuppressants or combination therapy have similar risks of infection and similar milestone achievement at 12 months to non-breastfed infants or infants unexposed to these drugs’.
Vedolizumab, Ustekinumab		
	LIMITED DATA ‘Case series and registry data did not demonstrate any concerns Advised to counsel patients regarding limited safety data and follow principles of anti TNF if continued’	LIMITED DATA – PROBABLY LOW RISK ‘Some information indicates that maternal vedolizumab injections appear to produce low levels in breastmilk and to not adversely affect the nursing infant. Because

		vedolizumab is a large protein molecule with a molecular weight of about 147,000 Da, it is likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal. Most experts feel that the drug is probably acceptable during nursing. Until more data become available, vedolizumab should be used with caution during breastfeeding, especially while nursing a newborn or preterm infant'. (lactmed) 'Ustekinumab is usually either not detectable in breastmilk or detectable at very low levels in breastmilk. It is also likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal'. (LactMed)
JAK inhibitors e.g. Tofactinib		
	AVOID Teratogenic and fetocidal in high doses in animal studies	NO DATA - AVOID 'No information is available on the clinical use of tofacitinib during breastfeeding. Until more data become available, an alternate drug may be preferred, especially while nursing a newborn or preterm infant' (LactMed)
Metronidazole		
	LOW RISK Manufacturer advises avoid single high doses. 'Metronidazole was shown to be mutagenic and carcinogenic in some animal studies. However, available data, which are almost exclusively based on oral exposure, do not indicate an increased risk of congenital malformation, low birth weight, intrauterine death, or neonatal complications with metronidazole use in human pregnancy'. (UKTIS) Large cohort study demonstrated no adverse pregnancy outcomes	LOW RISK 'With maternal intravenous and oral therapy, breastfed infants receive metronidazole in doses that are less than those used to treat infections in infants, although the active metabolite adds to the total infant exposure' (LactMed) Avoid large single doses

Ciprofloxacin		
	AVOID ‘Neonatal exposure to quinolones have been shown to cause arthropathy in animal studies. Due to the theoretical risk of similar effects on the developing human fetus, the use of quinolones in pregnancy is not generally recommended, except for the treatment of serious or life-threatening conditions unresponsive to other antibiotic therapies considered suitable for use in pregnancy’. (UKTIS)	LOW RISK ‘Amounts of ciprofloxacin in breastmilk are low. Fluoroquinolones such as ciprofloxacin have traditionally not been used in infants because of concern about adverse effects on the infants' developing joints. However, studies indicate little risk.. Use of ciprofloxacin is acceptable in nursing mothers with monitoring of the infant for possible effects on the gastrointestinal flora, such as diarrhea or candidiasis (thrush, diaper rash). Avoiding breastfeeding for 3 to 4 hours after a dose should decrease the exposure of the infant to ciprofloxacin in breastmilk’. (LatMed)
Antispasmodics		
Hyoscine butylbromide (Buscopan)	CAUTION ‘There are limited data on the use of hyoscine during pregnancy, with the available data predominantly relating to use at the time of delivery. Maternal administration of hyoscine derivatives during labour has been inconsistently associated with fetal tachycardia, and anticholinergic symptoms may occur in the neonate. The use of hyoscine during pregnancy may be justified if there is a clear clinical indication’. (UKTIS)	LOW RISK Amount in milk too small to be harmful (BNF)

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