

Faculty of Sexual & Reproductive Healthcare Clinical Guidance



Sexual and Reproductive Health for Individuals with Inflammatory Bowel Disease

> Clinical Effectiveness Unit June 2009

ABBREVIATIONS USED

5-ASA	5-aminosalicylic acid
aTNF-α	anti-tumour necrosis factor alpha
BMD	bone mineral density
CD	Crohn's disease
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception
CI	confidence interval
COC	combined oral contraception
CU-IUD	copper-bearing intrauterine device
DMPA	depot medroxyprogesterone acetate
FSRH	Faculty of Sexual and Reproductive Healthcare
GI	gastrointestinal
IBD	inflammatory bowel disease
IPAA	ileal pouch-anal anastomosis
IUD	intrauterine device
IUS	intrauterine system
LARC	long-acting reversible contraception
LNG-IUS	levonorgestrel-releasing intrauterine system
MHRA	Medicines and Healthcare products Regulatory Agency
NICE	National Institute for Health and Clinical Excellence
OR	odds ratio
POP	progestogen-only pill
PSC	primary sclerosing cholangitis
SPC	Summary of Product Characteristics
UC	ulcerative colitis
UKMEC	<i>UK Medical Eligibility for Contraceptive Use</i>
UC	ulcerative colitis
UKMEC	UK Medical Eligibility for Contraceptive Use
UKSPR	UK Selected Practice Recommendations for Contraceptive Use
VTE	venous thromboembolism
WHO	World Health Organization

GRADING OF RECOMMENDATIONS

- A Evidence based on randomised controlled trials
- **B** Evidence based on other robust experimental or observational studies
- **C** Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities
- Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

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SUMMARY OF KEY RECOMMENDATIONS

As inflammatory bowel disease (IBD) usually presents during the reproductive years, health professionals should consider sexual and reproductive health issues in their management of affected individuals.

Managed clinical care pathways should be developed locally to promote integrated working between different service providers to ensure that the sexual and reproductive health needs of individuals with IBD are met.

IBD and Fertility

- C Health professionals should be aware of the possible effects of some IBD medication on sperm quality and quantity, and the potential impact on male fertility.
- The risk of subfertility following reconstructive surgery should be discussed with women with IBD and their partners.

IBD and **Pregnancy**

- B Women with IBD should be advised to plan to conceive when the disease is well controlled.
- Appropriate referral for pre-pregnancy counselling should be available for men and women in order to optimise their IBD management prior to conception.
- C There is controversy regarding the most appropriate mode of delivery (Caesarean section or vaginal) following ileal pouch-anal anastomosis surgery. Women should be guided in their decision by the advice of the obstetric and gastrointestinal specialists in charge of their care.
- **C** If either partner is taking methotrexate, pregnancy should be prevented by use of effective contraception during and for at least 3 months after treatment.
- **C** Effective contraception must be used by women treated with infliximab or adalimumab and for at least 6 or 5 months, respectively, after treatment.
- Health professionals should check the Summary of Product Characteristics for each medication for specific advice on use while trying to conceive, and while pregnant or breastfeeding. The decision to stop any treatment requires expert clinical judgement, balancing the risks of stopping the drug against the risks associated with continuing.
- Health professionals should consider ectopic pregnancy in their differential diagnosis of abdominal pain and gastrointestinal symptoms in sexually active women with IBD.

IBD and Contraceptive Choice

- B Women can be informed that a causal association between combined oral contraception (COC) use and onset or exacerbation of IBD is unsubstantiated.
- Women should be advised that the efficacy of oral contraception is unlikely to be reduced by large bowel disease but may be reduced in women with Crohn's disease who have small bowel disease and malabsorption.
- C Health professionals should consider the impact of IBD-associated conditions such as venous thromboembolism, primary sclerosing cholangitis and osteoporosis, and other medical conditions when prescribing contraception to women with IBD.
- C Women using combined hormonal contraception should use additional contraception while taking antibiotic courses of less than 3 weeks, and for 7 days after the antibiotic has been discontinued.
- Health professionals should check whether any prescribed medications for rectal or genital administration contain products that may reduce the efficacy of condoms.
- Women with IBD should stop COC at least 4 weeks before major elective surgery and alternative contraception should be provided. Advice regarding recommencing COC should be given individually.
- B Laparoscopic sterilisation is an inappropriate method of contraception for women with IBD who have had previous pelvic or abdominal surgery.
- Women with IBD considering sterilisation, and their partners, should be counselled about alternative methods of contraception including long-acting reversible contraception (LARC) and vasectomy.

IBD, Sexual Function and Psychosexual Health

Health professionals should provide an opportunity for individuals with IBD and their partners to discuss issues relating to sexuality, body image and mental well-being, and know where to refer locally when appropriate.



Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit

A unit funded by the FSRH and supported by NHS Greater Glasgow & Clyde to provide guidance on evidence-based practice

FSRH Guidance (June 2009) Sexual and Reproductive Health for Individuals with Inflammatory Bowel Disease

(Update due by June 2014)

1 Purpose and Scope

This guidance provides information on sexual and reproductive health for individuals with inflammatory bowel disease (IBD). It is intended for use by health professionals working in sexual and reproductive health, general practice, and obstetric and gynaecology settings. Recommendations are based on available evidence and consensus opinion of experts. They should be used to guide clinical practice but are not intended to serve alone as a standard of care or to replace the application of clinical judgement in individual cases. For comprehensive advice on the management of patients with IBD, readers should refer to the guidelines from the British Society for Gastroentrerology.¹ Irritable bowel syndrome is a separate condition that is outside the scope of this guidance. A key to the Grading of Recommendations, based on levels of evidence, is provided on the inside front cover of this document. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this guidance are outlined in the Appendix.

2 Background

2.1 What is inflammatory bowel disease (IBD)?

IBD is thought to affect approximately 1 in 400 people within the UK.¹ IBD refers predominately to two distinct conditions: Crohn's disease (CD) and ulcerative colitis (UC).

Ulcerative colitis involves the large bowel (colon) only and is characterised by diffuse inflammation of the superficial mucosal layer, which bleeds readily. The whole colon is affected (pancolitis) in up to 20% of patients,¹ whilst in 30% of patients disease is confined to the rectum (proctitis).

Crohn's disease can affect the entire gastrointestinal (GI) tract, and clinical symptoms generally reflect the site or pattern of the disease (inflammatory, fistulating or stricturing).¹ It is characterised by patchy, transmural inflammation that can lead to fibrosis and bowel obstruction, or to sinus tract and fistula formation involving adjacent organs.

The exact aetiology of IBD is unknown, although it is thought to be caused by both genetic and environmental factors.¹ Diagnosis can occur at any age, but most commonly between the ages of 10 and 40 years. Because IBD usually presents in the reproductive years, health professionals should be aware of issues relating to sexual and reproductive health in affected individuals and should discuss these issues where appropriate.

C As IBD usually presents during the reproductive years, health professionals should consider sexual and reproductive health issues in their management of affected individuals.

2.2 Extra-intestinal manifestations and associated conditions

IBD may also be associated with extra-intestinal manifestations such as hepatobiliary disease, and with venous thromboembolism (VTE) and osteoporosis/osteopenia.

2.2.1 Hepatobiliary disease

Primary sclerosing cholangitis (PSC) is a chronic cholestatic liver disease characterised by fibro-obliterative inflammation of the hepatic bile ducts leading to progressive cirrhosis and hepatic failure.²

2.2.2 Venous thromboembolism (VTE)³⁻⁷

It is generally accepted that there is an association between IBD and VTE, although the exact prevalence is unclear due to differences in methodologies. The mechanisms underlying the apparent thrombotic tendency in IBD are not fully understood. Several theories have been postulated but no clear consensus has emerged as to whether the risk is related to the disease itself or to related factors such as immobilisation or surgery. There is no evidence of an association with genetic thrombophilias.

2.2.3 Osteoporosis and osteopenia

Osteopenia and osteoporosis are more common in patients with IBD than in the general population, particularly amongst those with CD. The aetiology remains unclear but factors such as age, gender, duration of disease, corticosteroid use, reduced physical activity, smoking, bowel resection and disease activity may influence the degree of risk.^{8,9} Hormone replacement therapy is no longer recommended to be used solely for osteoporosis in women because of cardiovascular and breast cancer risks.^{8,9} Detailed guidance on IBD and osteoporosis is available from the British Society of Gastroenterology.⁸

2.3 Treatment of IBD

Medical management of IBD is tailored to the site, severity and activity of disease. Treatments aim to reduce or prevent recurrence of inflammation using 5-aminosalicylic acid (5-ASA) drugs (mesalazine, olsalazine, balsalazide and sulfasalazine), corticosteroids, immunosuppressant agents (azathioprine, mercaptopurine, methotrexate and ciclosporin) and anti-tumour necrosis factor alpha (aTNF- α) agents (infliximab and adalimumab). Antibiotics may be required to treat infections and complications following surgery, and thalidomide and its associated drugs are very occasionally used in difficult cases.

Surgery for IBD may be performed as an emergency procedure for toxic megacolon, perforation, haemorrhage or acute failure of medical treatment. Elective surgery may also be necessary for chronic failure of medical treatment, complications such as fistulae and stricture, or colorectal cancer. UC can be cured by removal of the large intestine; however for CD, surgery can only improve symptoms. The traditional operation for UC is panproctocolectomy, where all of the colon and rectum is removed, leaving the patient with a permanent ileostomy. In the last 30 years restorative proctocolectomy [colectomy and ileal pouch-anal anastomosis (IPAA)] has been developed, where all of the colon and rectum is removed and the small bowel is fashioned into a reservoir, which is anastomosed to the anal canal. For individuals with CD, the nature of surgery will depend on the distribution of the disease and the type of complications that arise: any part of the small bowel, colon or rectum may require excision. Patients with either UC or CD may require temporary or permanent stoma formation.

In addition to medication and surgery, nurse specialists, information and support groups, and counselling have been shown to complement physician led treatment.^{10–15}

Managed clinical care pathways should be developed locally to promote integrated working between different service providers to ensure that the sexual and reproductive health needs of individuals with IBD are met.

1

3 IBD and Fertility

3.1 Does IBD affect fertility?

Fertility appears to be relatively unchanged among women with IBD, particularly those with UC. A retrospective study which followed women for up to 20 years after diagnosis found that women with IBD had normal fertility compared to women without disease from the same general population.¹⁶ However, other studies have identified fertility problems more commonly in women with CD.^{17–23} Little evidence is available on the impact of IBD on male fertility.

3.2 What is the effect of IBD treatment on fertility?

3.2.1 Medication

Little evidence was found to suggest that medications used in the treatment of IBD have a longterm effect on female fertility. With regard to the effect of IBD treatment on men, there is some evidence from a small prospective study that infliximab may decrease sperm motility but there is no evidence as to whether this translates into impaired fertility.²⁴ The Summary of Product Characteristics (SPC) for methotrexate states that it affects spermatogenesis and oogenesis.²⁵ The oligospermia associated with methotrexate (and also the less commonly used drug, sulfasalazine) appears to resolve on stopping treatment.^{26,27}

C Health professionals should be aware of the possible effects of some IBD medication on sperm quality and quantity, and the potential impact on male fertility.

3.2.2 Surgery

There is evidence to suggest that women may experience subfertility following IBD reconstructive surgery.^{16,28–30} Because IPAA is a relatively recent development, this operation has been extensively studied, whereas few data are available for most other operations. A meta-analysis found that IPAA increased the risk of infertility three-fold compared with medical management, although it was unable to identify any patient or procedural factors that consistently affected risk.²⁹ A systematic review concluded that women's fertility was reduced after restorative proctocolectomy and postulated that this may be partly due to obstruction of the Fallopian tubes and ovaries from pelvic adhesions.²⁸

The effects of surgery on male fertility are less well studied. Potential complications of reconstructive surgery, such as retrograde ejaculation or erectile dysfunction, could theoretically make conception more problematic.

The risk of subfertility following reconstructive surgery should be discussed with women with IBD and their partners.

4 IBD and Pregnancy

The National Association for Colitis and Crohn's Disease fact sheet on pregnancy in IBD states that the children of individuals with IBD have a slightly increased risk of developing IBD, although factors other than a genetic predisposition are required to trigger IBD. The risk is estimated at about 5% if one parent has IBD and up to 35% if both do.³¹

Ideally women should be encouraged to plan to conceive when the disease is controlled and they are well nourished. They should be encouraged to continue with their maintenance medication and to take folic acid supplementation.¹ The standard preconception dose of 400 μ g folic acid daily is usually adequate but a higher dose may be required, for example in women taking sulphasalazine (which may affect folate absorption) or women who have malabsorption following small bowel resection.

B Women with IBD should be advised to plan to conceive when the disease is well controlled.

Appropriate referral for pre-pregnancy counselling should be available for men and women in order to optimise their IBD management prior to conception.

4.1 What is the effect of pregnancy on IBD?

The limited evidence available suggests that most women with inactive or mild disease have no worsening of the disease during pregnancy and no disease relapse.^{16,32} There is evidence to suggest that pregnancy may positively affect bowel resection rates in women with CD.⁹

4.2 What is the effect of IBD on pregnancy outcomes?

The evidence in relation to pregnancy outcomes for women with IBD is often conflicting and is limited mainly to observational studies, which are vulnerable to bias and confounding factors.

4.2.1 Spontaneous abortions

Whilst a retrospective case-control study found no increase in early pregnancy loss amongst women with IBD,³³ other studies have shown that there may be a slight increased risk of spontaneous abortion amongst women with IBD, particularly CD. One retrospective study suggested that women with CD are more likely to miscarry than women with UC or women without disease.²³ A recent retrospective case-control study found that in post-diagnosis pregnancies spontaneous abortions were significantly higher than in pre-diagnosis pregnancies.³⁴

4.2.2 Premature birth and low birth weight

A higher incidence of premature birth has been cited in several studies,^{23,33,35} including one which indicated an increased risk of preterm delivery amongst individuals hospitalised with disease relapse.³⁶ There may be an increased risk of preterm delivery particularly among CD patients. One retrospective study showed that even before diagnosis women with CD were at increased risk of preterm delivery compared to healthy controls and individuals with UC [odds ratio (OR) 4.62, 95% confidence interval (CI) 2.77–7.73, p<0.001 vs control and OR 3.52, 95% CI 1.75–7.07, p<0.001 vs UC].³⁵ Low birth weight has been noted particularly amongst infants born to mothers with CD,^{34,35} although it is not clear whether this is related to premature delivery.

4.2.3 Congenital abnormalities

Some studies have shown that incidences of congenital abnormalities may potentially be increased in IBD pregnancies.^{34,35} Whilst one case-control study found an increased risk of some specific congenital abnormalities, the overall risk of congenital abnormalities was not significantly increased.³⁷

4.2.4 Caesarean section

A variety of studies have shown increased rates of Caesarean section in women with IBD.^{28,30,38} This may be the best mode of delivery for individuals who have an ileoanal pouch or perianal CD, as a way of minimising the risk of damage to the anal sphincter. However, there does not appear to be agreement as to whether an elective Caesarean section should be recommended in such cases, and there is some evidence to suggest that women who have undergone reconstructive surgery can successfully undergo vaginal delivery with few complications.^{28,30,38}

C There is controversy regarding the most appropriate mode of delivery (Caesarean section or vaginal) following IPAA surgery. Women should be guided in their decision by the advice of the obstetric and GI specialists in charge of their care.

4.3 What is the effect of IBD treatment on pregnancy outcomes?

4.3.1 Medication

5-ASA drugs have limited placental transfer. A meta-analysis of pregnancy outcomes in women exposed to 5-ASA drugs found no statistically significant increase in adverse outcomes. The ORs were 1.16 for congenital abnormalities (95% CI 0.76–1.77, p = 0.57), 2.38 for stillbirth (95% CI 0.65–8.72, p = 0.32), 1.14 for spontaneous abortion (95% CI 0.65–2.01, p = 0.74), 1.35 for preterm delivery (95% CI 0.85–2.13, p = 0.26) and 0.93 for low birth weight (95% CI 0.46–1.85, p = 0.96).³⁹

A retrospective cohort study similarly found no significant differences in pregnancy outcomes when investigating the effect of the 5-ASA drugs, metronidazole, ciprofloxacin, corticosteroids, 6-mercaptopurine, azathioprine and ciclosporin.⁴⁰ There are limited data on the use of infliximab in pregnancy and current evidence is insufficient to exclude adverse

effects.^{41–43} Table 1 outlines guidance from the *British National Formulary* (BNF) and manufacturers on the use of certain IBD drugs prior to conception, during pregnancy and when breastfeeding.^{26,44}

The decision to stop any treatment for conception, during pregnancy and whilst breastfeeding requires expert clinical judgement based on the balance of risk between stopping the drug versus the risks associated with continuing. Guidelines for the management of IBD in adults suggest that azathioprine can be continued in pregnancy although the risk of low birth weight should be discussed.¹ Similarly, the risks to pregnancy from disease activity are greater than from continued corticosteroid use, and thus corticosteroids can be used for active disease.¹ Because drugs such as methotrexate can have a teratogenic effect even if it is the male partner who is taking them, men receiving medication for IBD should also be advised about the effects of certain drugs on pregnancy outcomes.

Type of medication	Drug	BNF and manufacturer guidance in relation to pregnancy (2008)	BNF and manufacturer guidance in relation to breastfeeding (2008)
5-Aminosalicylic acid drugs	Mesalazine	Negligible placental transfer. Use with caution.	Mesalazine concentration in breast milk is low whereas the metabolite, acetyl- mesalazine, appears in similar or increased concentrations. Hypersensitivity reactions such as diarrhoea cannot be excluded. Caution with use in nursing mothers.
	Olsalazine	Experience in pregnant women limited therefore advice is to avoid use unless potential benefits outweigh risks.	Manufacturer advises avoidance.
	Balsalazide	Human experience limited therefore manufacturer advises avoidance.	Manufacturer advises avoidance.
	Sulphasalazine	Studies have failed to reveal any teratogenic or icteric hazards. There is a theoretical but unproven risk of neonatal haemolysis. Expectant mothers should be given adequate folate supplements.	Small amount in milk. The amount of drug in breast milk should not present a risk to a healthy infant. Theoretical risk of neonatal haemolysis especially in glucose-6- phosphate dehydrogenase (G6PD)-deficient infants.
Immunosuppressive agents	Azathioprine Ciclosporin	Little evidence that azathioprine or ciclosporin are teratogenic but some reports of premature birth and low birth weight (particularly in combination with corticosteroids), and some reports of spontaneous abortion following maternal or paternal exposure. Should be used in pregnancy only if benefits outweigh risks.	For azathioprine no evidence of harm in small studies despite teratogenic metabolite identified in milk in low concentrations. Use can be considered if potential benefits outweigh risk. Ciclosporin is passed in breast milk therefore women taking ciclosporin should not breastfeed.
	Methotrexate Mercaptopurine	Teratogenic, therefore contraindicated in pregnancy. Manufacturer advises use of effective contraception during treatment and for at least 3 months after treatment if taken by either partner.	Breastfeeding should be avoided whilst taking drug.
Anti-tumour necrosis factor alpha agents	Infliximab Adalimumab	There is currently limited experience of use of these drugs during pregnancy; therefore it is advised that they are avoided. Manufacturer advises adequate contraception during treatment and at least 5 months after last dose of adalimumab and 6 months after last dose of infliximab.	Breastfeeding should be avoided for at least 6 months after last dose of infliximab and at least 5 months after last dose of adalimumab.
Corticosteroids		Benefit of treatment outweighs risk. Betamethasone and dexamethasone cross placenta readily, whereas 88% of prednisolone is inactivated as it crosses placenta. Prolonged administration may cause intrauterine growth restriction but no evidence with short-term use.	Systemic effects in infant unlikely with maternal dose of prednisolone up to 40 mg daily. Monitor infant's adrenal function with higher doses. Amount in breast milk too small to be harmful. Benefits of breastfeeding likely to outweigh risks.

Table 1 Summary of information from pharmaceutical companies and the British National Formulary (BNF)^{26,44}

- C If either partner is taking methotrexate, pregnancy should be prevented by use of effective contraception during and for at least 3 months after treatment.
- C Effective contraception must be used by women treated with infliximab or adalimumab and for at least 6 or 5 months, respectively, after treatment.
- Health professionals should check the SPC for each medication for specific advice on use while trying to conceive, and while pregnant or breastfeeding. The decision to stop any treatment requires expert clinical judgment, balancing the risks of stopping the drug against the risks associated with continuing.
- 4.3.2 Surgery

Much of the literature on pregnancy and IBD surgery has focused on restorative proctocolectomy. There is a limited body of evidence in relation to surgery for CD and pregnancy. Pregnancy following restorative proctocolectomy has been found not to be associated with an increase in complications.²⁸ A prospective cohort study looking at pregnancy and delivery before and after IPAA in the same females found no difference in birth weight, duration of labour, delivery complications, vaginal delivery rates and unplanned Caesarean section.³⁸ Pregnancy and delivery in patients with a stoma is generally considered safe; however, stoma size may increase during pregnancy.

4.4 Other considerations relating to pregnancy and IBD

Ectopic pregnancy may present with GI symptoms, as highlighted in the UK enquiries into maternal deaths.^{45,46} Clinicians should consider ectopic pregnancy in the differential diagnosis of abdominal pain and GI symptoms in sexually active women with IBD.

Health professionals should consider ectopic pregnancy in their differential diagnosis of abdominal pain and GI symptoms in sexually active women with IBD.

5 IBD and Contraceptive Choice

5.1 Does contraception influence IBD?

There is no clear consensus on the relationship between contraception and IBD. A metaanalysis found evidence of an association between the use of oral contraception and the development of IBD, in particular CD.⁴⁷ Postmarketing surveillance has recently identified colitis as an adverse event in Evra[®] combined patch users.⁴⁸ Despite these apparent associations, a causal relationship has not been confirmed. There are limited data on COC use and disease severity. A study of women with CD found that COC use did not alter the course of the disease.⁴⁹

B Women can be informed that a causal association between COC use and onset or exacerbation of IBD is unsubstantiated.

5.2 Does IBD affect contraceptive choice?

5.2.1 Medical eligibility

For any individual, the suitability of a contraceptive method may depend on factors such as age, smoking, family history, medical conditions and drug treatment. For individuals with IBD, mobility, malabsorption, surgical treatment, extra-intestinal manifestations of IBD, and associated conditions such as osteoporosis may further influence contraceptive choice.

The UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) have been developed to provide guidance for health professionals on the suitability of contraceptive methods in specific clinical conditions.⁵⁰ Recommendations are based on available evidence and expert opinion, and classify conditions into one of four categories (Table 2). UKMEC includes guidance on IBD and some of its associated medical conditions (Table 3).

Women with IBD who fulfil medical eligibility criteria can use intrauterine devices (IUDs). Although pelvic infection may occur and should be considered in the differential diagnosis of abdominal pain, the risk of pelvic infection is only increased in the 21 days following IUD insertion.⁵¹ Thereafter the risk of pelvic infection is not increased unless there is exposure to sexually transmitted infections. Studies on pelvic infection and IUDs, however, are not specific to women with IBD.

Table 2 Definition of UK Medica	Eligibility Criteria for	Contraceptive Use	(UKMEC) Categories ⁵⁰
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UKMEC Category	Definition
1	A condition for which there is no restriction on the use of the contraceptive method.
2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method.
4	A condition that represents an unacceptable health risk if the contraceptive method is used.

Table 3 UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) in inflammatory bowel disease and associated conditions⁵⁰

Condition	СНС	PO pill	PO injectable	PO implant	Cu-IUD	LNG-IUS	Barrier methods
Inflammatory bowel disease	2	2	1	1	1	1	1
Major surgery with immobilisation	4	2	2	2	1	2	1
Personal history of VTE ^a	4	2	2	2	1	2	1
Primary sclerosing cholangitis ^b	4	3	3	3	1	3	1

^aVenous thromboembolism (pulmonary embolus or deep vein thrombosis).

^bCausing severe cirrhosis.

CHC, combined hormonal contraception; Cu-IUD, copper-bearing intrauterine device; LNG-IUS, levonorgestrel-releasing intrauterine system; PO, progestogen-only; VTE, venous thromboembolism.

5.2.2 Absorption of oral contraception

Oral contraception may be less reliable in women with IBD who have malabsorption due to severe small bowel disease or resection, or who have vomiting or severe diarrhoea for more than 24 hours. No evidence was identified to suggest any reduction in the efficacy of the combined patch, progestogen-only injectables, progestogen-only implants or intrauterine methods in women with IBD.

Women should be advised that the efficacy of oral contraception is unlikely to be reduced by large bowel disease but may be reduced in women with CD who have small bowel disease and malabsorption.

5.2.3 Osteoporosis

Concerns have been raised about the use of the progestogen-only injectable method, depot medroxyprogesterone acetate (DMPA), and its potential effects on bone mineral density (BMD). Several studies, including a systematic review performed for the National Institute for Health and Clinical Excellence (NICE) on long-acting reversible contraception (LARC)⁵² have concluded that there is conflicting evidence of a link and that any effect may be reversible upon cessation of the method.⁵³ The Department of Health Medicines and Healthcare products Regulatory Agency (MHRA)⁵⁴ and the Faculty of Sexual and Reproductive Healthcare (FSRH)⁵³ recommend that:

- In women aged under 18 years, DMPA may be used after all other options have been discussed and considered unsuitable or unacceptable.
- A re-revaluation of the risks and benefits of treatment for all women should be carried out every 2 years in those who wish to continue use.
- For women with significant lifestyle and/or medical risk factors for osteoporosis other methods of contraception should be considered.

As osteoporosis and osteopenia are more common amongst individuals with IBD, women should be assessed for other risk factors and counselled about the effect of their disease on BMD. The possible effects of DMPA on BMD should be weighed against the possible benefits (i.e. low risk of thrombosis and the fact that contraceptive efficacy is unaffected by malabsorption or drug interactions). For those women who choose to use DMPA, re-evaluation should occur at least every 2 years as outlined above. A systematic review⁵⁵ exploring combined hormonal contraception (CHC) and bone health concluded that the relationship between COC and BMD is unclear. There are no studies of COC use and BMD or fracture risk in women with IBD. There is no evidence of a clinically significant effect on BMD with the use of the progestogen-only implant.^{56,57}

C Health professionals should consider the impact of IBD-associated conditions such as venous thromboembolism, primary sclerosing cholangitis and osteoporosis, and other medical conditions when prescribing contraception to women with IBD.

5.3 How might IBD treatment affect contraceptive use?

5.3.1 Medication

No specific interactions are listed between estrogen or progestogen and the majority of antiinflammatory and biological medications used to treat IBD,²⁶ although plasma levels of ciclosporin may be increased by sex steroid hormones.²⁶ The SPC for ciclosporin⁵⁸ indicates that measuring blood levels of ciclosporin is questionable in non-transplant patients because the relationship between blood levels and clinical effect is less well established. Therefore, if drugs are being used concomitantly that are known to increase ciclosporin concentration, frequent assessment of renal function and careful monitoring of ciclosporin side effects may be more appropriate.⁵⁸

Short courses of broad-spectrum antibiotic may reduce the efficacy of CHC. Additional contraception such as condoms should be advised during non-liver enzyme-inducing antibiotic courses of less than 3 weeks, and for 7 days after the antibiotic has been discontinued. Further information on drug interactions with hormonal contraception can be found in separate CEU guidance.⁵⁹

Women with IBD may wish to use barrier methods of contraception (i.e. condoms, cervical caps and diaphragms). However, the typical failure rates make these methods inappropriate for women who are using teratogenic drugs.

There is a theoretical risk that some IBD medications for rectal administration may reduce the efficacy of latex condoms if the product spreads to the genital skin. Whilst no direct evidence of an interaction was found, it is known that the strength of condoms can be reduced by contact with oil- or witepsol-based products. Information on product constituents can be obtained from the package insert or pharmaceutical company.

C Women using CHC should use additional contraception while taking antibiotic courses of less than 3 weeks, and for 7 days after the antibiotic has been discontinued.

Health professionals should check whether any prescribed medications for rectal or genital administration contain products that may reduce the efficacy of condoms.

5.3.2 Surgery

Major surgery, hospitalisation and immobilisation are all considered risk factors for VTE. The risk of postoperative VTE is higher amongst COC users.^{60–62} For individuals undergoing major surgery with prolonged immobilisation the UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) classify CHC use as a Category 4 (the method should not be used).⁵⁰ In women with IBD, COC should be stopped at least 4 weeks before elective major surgery. Counselling and provision of alternative methods is important and advice can be found in the UK Selected Practice Recommendations for Contraceptive Use⁶³ as to how and when best to do this. Advice regarding recommencing the COC should be given individually.

Women using progestogen-only methods do not appear to be at increased risk of VTE⁶⁴ and need not discontinue them prior to surgery. All progestogen-only methods are UKMEC Category 2 for individuals undergoing major surgery with prolonged immobilisation;⁵⁰ the copper-bearing IUD and barrier methods are UKMEC Category 1 (Table 3).⁵⁰

Sterilisation can be offered if other options are unsuitable. Laparoscopic sterilisation is an inappropriate method of contraception for women who have had previous abdominal or pelvic surgery because of the risk of complications. The Collaborative Review of Sterilisation concluded from a large, prospective, multicentre, cohort study that women who had previous abdominal or pelvic surgery were twice as likely to develop complications following

laparoscopic sterilisation than women who had no previous surgery (OR 2.0, 95% CI 1.4–2.9).⁶⁵ The UKMEC Category for surgical sterilisation in women with IBD is Category S (Special), meaning that the procedure should be undertaken in a setting with an experienced surgeon and other backup support.⁵⁰ Alternative methods such as vasectomy and LARC methods may be as effective, if not more so, than sterilisation.⁶⁶ Hysteroscopic sterilisation techniques may become a suitable alternative in the future.⁶⁷ If abdominal surgery is indicated for a woman with IBD who wishes sterilisation, both procedures may be performed at the same time providing the woman has been counselled preoperatively and has given specific consent.

- Women with IBD should stop COC at least 4 weeks before major elective surgery and alternative contraception should be provided. Advice regarding recommencing COC should be given individually.
- B Laparoscopic sterilisation is an inappropriate method of contraception for women with IBD who have had previous pelvic or abdominal surgery.
- Women with IBD considering sterilisation, and their partners, should be counselled about alternative methods of contraception including LARC methods and vasectomy.

6. IBD, Sexual Function and Psychosexual Health

Several studies have explored the impact of IBD surgery on sexual function.^{68–71} The results vary and methodological problems include small samples and lack of a preoperative baseline.

Complications that have been noted following IBD surgery include dyspareunia in women, and loss of ejaculation and retrograde ejaculation in men.^{28,68,69,71} These problems are associated with pelvic surgery rather than abdominal surgery. However, one systematic review²⁸ found that although dyspareunia increased after proctocolectomy surgery in women, it did not appear to have a negative impact on overall sexual satisfaction. A prospective study of individuals with UC found that despite around a third reporting dissatisfaction with their sex life before surgery, the majority were happy afterwards.⁶⁸ The effect of successful surgery on general well-being after a long period of systemic illness presumably contributes to changes in attitude about sexual health.

Some individuals with an ileostomy report that a stoma negatively affects their sex life.⁶⁸ Concerns noted include feeling sexually undesirable and anxious about detachment of their stoma.⁶⁸ Depression, which is more prevalent amongst those with IBD in comparison to the general population,⁷² has been identified as a determinant of low sexual function.⁷³

Health professionals should provide an opportunity for individuals with IBD and their partners to discuss issues relating to sexuality, body image and mental well-being, and know where to refer locally when appropriate.

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APPENDIX: DEVELOPMENT OF CEU GUIDANCE

GUIDELINE DEVELOPMENT GROUP

Dr Louise Melvin – Director, Clinical Effectiveness Unit Mrs Julie Craik – Researcher, Clinical Effectiveness Unit

Dr Nabil Nathan Acladious – FSRH Council member, Consultant in Sexual and Reproductive Health, Royal Bolton Hospital, Bolton

Dr Elspeth Alstead – Consultant Gastroenterologist, Whipps Cross and the Royal London Hospital, London Ms Susan Downs – Patient representative

Dr Christina Fey – FSRH Clinical Effectiveness Committee member, Consultant Community Gynaecologist, Derby Contraception and Sexual Health Service

Mr Roy Foot – Lead Pharmacist, Formulary and Prescribing Interface, Greater Glasgow and Clyde Health Board, Glasgow

Dr Louise Massey – FSRH Clinical Standards Committee member, Consultant in Public Health, Wolverhampton Primary Care Trust

Dr Sara McCartney - Consultant Gastroenterologist, University College London Hospital, London

Dr Ruth McKee – Consultant Colorectal Surgeon, Glasgow Royal Infirmary, Glasgow

Dr Hilary Natusch – FSRH Education Committee member, Consultant in Contraception and Sexual Health, The Hathersage Centre, Manchester

Dr Poornima Prabhu – Associate Specialist and Lead Clinician, Contraception and Sexual Health, Worcester Primary Care Trust

Ms Angela Star – Nurse representative, National Association for Nurses Working in Contraception and Sexual Health

Dr Steven Twaddle - General Practitioner, Abronhill Health Centre, Cumbernauld

INDEPENDENT PEER REVIEWER

Professor Subrata Ghosh – Consultant Gastroenterologist, Imperial College, London

No competing interests were noted by members of the multidisciplinary group. Administrative support to the CEU team was provided by **Ms Janice Paterson**.

CEU guidance is developed in collaboration with the Clinical Effectiveness Committee of the FSRH. The CEU guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialities, and user representation. In addition, the aim is to include a representative from the FSRH Clinical Effectiveness Committee, the FSRH Education Committee and FSRH Council in the multidisciplinary group.

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2008); EMBASE (1996–2008); PubMed (1996–2008); The Cochrane Library (to 2008) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for relevant systematic reviews, meta-analyses and controlled trials. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Clinical Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded as in the table on the inside front cover of this document using a scheme similar to that adopted by the RCOG and other guideline development organisations. The clinical recommendations within this guidance are based on evidence whenever possible. Summary evidence tables are available on request from the CEU. An outline of the guideline development process is given in the table on the inside back cover of this guidance document.

Discussion Points for Sexual and Reproductive Health for Individuals with Inflammatory Bowel Disease (IBD)

The following discussion points have been developed by the FSRH Education Committee.

Discussion Points

- 1 What are the contraceptive choices available to a 30-year-old woman newly diagnosed with Crohn's disease?
- 2 Discuss differential diagnosis of abdominal pain in sexually active women with inflammatory bowel disease (IBD).
- 3 Which sexual and reproductive health issues should be discussed with individuals presenting with IBD?
- 4 Discuss how managed clinical pathways could be developed locally to ensure that the reproductive and sexual heath care needs of individuals with IBD are met.

Questions for Sexual and Reproductive Health for Individuals with Inflammatory Bowel Disease (IBD)

The following questions and answers have been developed by the FSRH Education Committee.

Indicate your answer by ticking the appropriate box for each question				
1	Generally fertility appears to be unchanged among women with inflammatory bowel disease (IBD), particularly those with ulcerative colitis.			
2	Oligospermia is a recognised side effect of sulfasalazine use in men.			
3	Among patients with Crohn's disease there may be an increased risk of preterm delivery.			
4	Effective contraception is advised during treatment with methotrexate and for at least 1 month after treatment.			
5	Women should be advised that the efficacy of oral contraception might potentially be reduced if they have large bowel disease.			
6	It would be appropriate to recommend a barrier method of contraception for women taking teratogenic drugs.			
7	The use of progestogen-only methods in women with extra-intestinal manifestations of IBD such as primary sclerosing cholangitis are UKMEC Category 2.			
8	Suppository-based medications prescribed to individuals with IBD may contain products that reduce the efficacy of condoms.			
9	Women with IBD should stop taking the combined oral contraceptive pill at least 4 weeks before major elective surgery.			
10	Laparoscopic sterilisation is an appropriate method of contraception for women with IBD who have had previous abdominal or pelvic surgery.			

9 Tr∪e

4 False

e False

] Tr∪e

∑ Ealse

2 Tr∪e

8 True

3 Tr∪e

Answers

JO False

5 False

STEPS INVOLVED IN THE DEVELOPMENT OF CEU GUIDANCE

STEP	TIME TAKEN		
Formulation of key clinical questions by the Clinical Effectiveness Unit (CEU).	This process must be completed in a maximum of 8 weeks.		
Systematic literature review involving searching electronic, bibliographic databases by CEU researchers.			
Obtaining and reviewing copies of the full papers of all relevant publications identified through the searches.			
Formal, critical appraisal of key papers and development of short evidence tables.	The CEU has overall responsibility for writing the Guidance document. The Multidisciplinary Group		
Draft One Guidance document is written, providing recommendations and good practice points based on the literature review.	and other peer reviewers should highlight inconsistencies and errors or where the text is incomprehensible.		
Peer review by Multidisciplinary Group comprising stakeholders and including service user representation; representation from the Faculty of Sexual and Reproductive Healthcare (FSRH) Education Committee; and where possible representation from the FSRH Clinical Effectiveness Committee (CEC) and FSRH Council.	At this stage the CEU usually holds a one-day meeting of the Multidisciplinary Group. When existing Guidance is being updated (as is the case for this Guidance document) feedback from peer reviewers is provided in writing.		
Preparation of Draft Two Guidance document based on discussion at the Multidisciplinary Group (or on written comments from peer reviewers).			
Peer Review of Draft Two Guidance document by the Multidisciplinary Group.			
Preparation of Draft Three Guidance document by the Multidisciplinary Group, the FSRH CEC and two independent peer reviewers.	Minor comments can be accepted at this stage.		
All written feedback and comments on Draft Three Guidance document are tabulated and the CEU response to these comments outlined.			
Draft Four Guidance document is prepared and sent to the Multidisciplinary Group, FSRH CEC and independent peer reviewers.	Proofreading stage.		
The Final Guidance document is published by the FSRH.	A pdf version of the Guidance is available on the FSRH website.		

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published Guidance can be sent directly to the Clinical Effectiveness Unit (CEU) at **ceu.members@ggc.scot.nhs.uk**.

You will receive an automated acknowledgment on receipt of your comments. If you do not receive this automated response please contact the CEU by telephone [+44 (0)141 232 8459/8460] or e-mail (ceu.members@ggc.scot.nhs.uk).

The CEU is unable to respond individually to all feedback. However, the CEU will review all comments and provide an anonymised summary of comments and responses which, after review by the Clinical Effectiveness Committee, will be posted on the Faculty website (**www.fsrh.org**) at regular intervals.