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Standards for the provision of antenatal care for patients with Inflammatory Bowel Disease:

Guidance endorsed by the British Society of Gastroenterology position statement and the British Maternal and Fetal Medicine Society

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Abstract

Background:

Pregnant women with Inflammatory Bowel Disease (IBD) are at increased risk of adverse pregnancy outcomes. Comprehensive guidelines on medical management have been published yet there is limited guidance on service set-up and minimum standards of care for pregnant women with IBD.

Aim:

To develop a position statement on service set-up and minimum standards of care in the United Kingdom.

Methods:

A working group consisting of 16 gastroenterologists, obstetricians, obstetric physician, IBD specialist nurses and midwives was assembled. Initial draft statements were produced and a modified Delphi process with 2 rounds of voting applied. Statements were modified according to voters' feedback after each round. Statements with ≥80% agreement were accepted.

Results:

All 15 statements met criteria for inclusion. To facilitate optimal care regular and effective communication between IBD and obstetric teams is required. There should be nominated link clinicians for IBD in obstetric units and for pregnancy in IBD units. Preconception counselling should be available for all women with IBD. All pregnant women should be advised on the safety of IBD medication during pregnancy and breast feeding, the optimal mode of delivery, the management of biologics (where applicable) and safety of childhood vaccinations. Regular audit of pregnancy outcomes and documentation of advice given is recommended.

Conclusion:

Position statements have been developed that advise on the importance of joined-up multidisciplinary care, proactive decision making with clear documentation and communication to the woman and other health care practitioners.

Summary Box

What is already known about this subject?

IBD affects pregnancy outcomes and requires complex decision making
Excellent international guidelines provide advice on medical management

What are the new findings?

This position statement provides IBD and obstetric services with guidance on service set up and delivery
Minimum standards of care have been developed to guide clinicians

How might it impact on clinical practice in the foreseeable future?

IBD and obstetric services should review current practice to ensure that standards of care are being met
Regular audits using the proposed standards can be performed to guide quality improvement

Conflict of interest statement:

CPS has received unrestricted research grants from Warner Chilcott, Janssen and AbbVie, has provided consultancy to Warner Chilcott, Dr Falk, AbbVie, Takeda, Fresenius Kabi and Janssen, and had speaker arrangements with Warner Chilcott, Dr Falk, AbbVie, MSD, Pfizer and Takeda.

CNP had speaker arrangements with Dr Falk, UCB, Sanofi, Alliance and Alexion.

KBK has provided consultancy to Amgen and PredictImmune, and had speaker arrangements with Janssen and Takeda.

AK has provided consultancy to Abbvie, and had speaker arrangements with Pfizer, Janssen and Takeda.

JKL has received research grants from Takeda, consultancy and speaker fees from Abbvie, Janssen, MSD, Pfizer and Takeda.

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Contributor statement:

CPS, NC, SC, CNP, AF, HV, KH, JL, LS, MS, MG, AM, KM, AK, KBK and TG developed the guidance statements by contributing to face to face discussion on the guidance statement, formulating the statements and voting on the statements. The draft article was written by CPS. NC, SC, CNP, AF, HV, KH, JL, LS, MS, MG, AM, KM, AK, KBK and TG critically reviewed the article.

Background

Inflammatory Bowel Disease (IBD) affects many women of child bearing age, who often have poor knowledge of pregnancy related issues in IBD,[1] views adverse to medical guidelines,[2] and higher levels of voluntary childlessness.[3 4] Women with IBD are at increased risk of adverse pregnancy outcomes including pre-term birth, small for gestational age birth weight, gestational diabetes, stillbirth and are more likely to have a caesarean section. [5] Over the past two decades the management of women with IBD during the reproductive period has evolved and comprehensive guidelines have been published by the European Crohns and Colitis Organisation, [6 7] the Canadian Society of Gastroenterology (Toronto consensus), [8] and the American Gastroenterology Association. [9] These guidelines address most aspects of care including advice on medication, vaccinations, investigations, and mode of delivery.

There is however limited guidance for clinicians on how to set up services to deliver safe and effective care for pregnant women with IBD. Women with IBD may encounter a multitude of health care professionals from different professional backgrounds including general practitioners, midwives, obstetricians, IBD specialist nurses and gastroenterologists during their pregnancy. Knowledge of IBD related pregnancy care varies between different medical specialties increasing the risk of divergent advice being offered by practioners.[10] Furthermore obstetric and IBD care occurs not infrequently across different health care organisations increasing the difficulties in providing coordinated care. Uncoordinated care could increase women's anxiety about the correct management and risk inappropriate cessation of IBD therapy. Poor communication between health care professionals could lead to delays in treating flares, delays in closely monitoring fetal health during flares, decisions on mode of delivery not taking IBD into account, reduced uptake of breast feeding and risk of inappropriate live vaccinations in infants exposed to biologics in utero.

Effective guidance on service set up, clear standards on communication and responsibilities in providing advice could help improve the safe provision of antenatal care for women with IBD. This position statement aims to provide guidance for clinicians involved in the care of pregnant patients with Inflammatory Bowel Disease (IBD). The focus of the position statement is on service set up and minimum standards of care as well as audit recommendations.

Methods

British Society of Gastroenterology (BSG) endorsed guidance statements are significant and influential brief statements addressing novel, topical or controversial subjects where it is felt that the Society needs to clarify its position and give clear advice where possible to the membership.[11] BSG endorsed guidance statements are often limited to an expert opinion based on the latest best available evidence. [11] This endorsed guidance statement was produced to address questions on service set-up, responsibilities of clinicians, minimum standards of care and suggestions for audit standards. While many aspects may be applicable to the wider IBD community the endorsed guidance statement was developed to specifically address care in the National Health Service for women living in Great Britain and Northern Ireland.

A modified Delphi process with a consensus meeting followed by two rounds of online voting and subsequent statement modification was applied. A working group was formed under the auspices of the BSG and expert clinicians in the field were identified and invited by two of the authors (CPS and TG). The final working group consisted of 6 IBD expert gastroenterologists, 5 obstetricians, 1 obstetric physician, 3 IBD specialist nurses and 1 midwife. While the majority worked in academic teaching hospitals 3 working group members came from District General Hospitals providing views of services outside of large academic centres. Themes of care provision were identified by the working group members through a narrative literature review and a face to face meeting in London in October 2018. The endorsed guidance statement was drafted in accordance with the guidance of the British Society of Gastroenterology (BSG) on endorsed guidance statements, which in contrast to full guidelines advocates a less stringent approach without full systematic literature review and without grading of statements.[11] Working group members rated their agreement on 5 point Likert scales from 1) totally disagree, 2) mostly disagree, 3) neutral, 4) mostly agree to 5) totally agree. Statements were included when ≥80% voted agree or totally agree. The final endorsed guidance statement was first reviewed and approved by the BSG clinical services and standards committee and then reviewed and endorsed by the council of the British Maternal and Fetal Medicine Society.

Results

The face to face meeting was attended by 14 working group members and voting rounds were closed after the minimum of 10 votes was reached for each round. All 15 statements reached the ≥80% agreement threshold and were included in the endorsed guidance statement.

Domain 1: Set up of services

Traditionally pregnant patients with IBD were likely to have received separate care from IBD and obstetric services with great variation in care and service set up. Due to the complexity of caring for pregnant IBD patients the care needs to be coordinated between services and provision by staff with relevant experience and expertise of IBD and pregnancy is highly desirable. Specific IBD antenatal services can facilitate coordinated high-quality care with subsequent good maternal and fetal outcomes [12] Joint consultations may not be feasible for all services but can provide the best model of care for communication between teams, providing unified patient advice and can reduce the number of total appointments required during a pregnancy. This may be out of the scope of some units where the number of pregnant women with IBD are insufficient to make the provision of joint clinics feasible.

Statement 1:

To facilitate optimal care and joint decision-making, regular and effective communication between IBD and obstetric teams is required. As a minimum there should be a nominated link clinician for IBD in every obstetric unit and a nominated link clinician for pregnancy in every IBD unit. [0% mostly, 90% totally agree]

Statement 2:

Specially set-up IBD pregnancy clinics can provide optimal specialised care. This is best facilitated by a joint clinic with an obstetric clinician and an IBD clinician present during the consultation. [30% mostly, 70% totally agree]

Domain 2: Minimum standards of care

Many patients have poor knowledge of IBD related issues in pregnancy[1] and hold attitudes contrary to medical guidelines.[2 13] These may in turn lead to poor adherence [14]and an increased risk of flaring disease during pregnancy. As active disease is associated with adverse pregnancy outcomes patients should be medically optimized prior to pregnancy, advised on the importance of maintaining remission from IBD and be given general advice on pre-conception health (smoking; alcohol, folic acid, etc). Patients who received IBD-specific pre-pregnancy counselling experienced better disease control during pregnancy and better pregnancy outcomes. [12]

Statement 3:

Pre-conception counselling should be available to all women with IBD to optimize preconception health. Poor patient knowledge on reproductive issues is associated with voluntary childlessness and adverse pregnancy related outcomes. Pro-active approaches to pre-conception counseling are considered the gold-standard. [0% mostly, 100% totally agree]

Medical management of IBD during pregnancy requires weighing of potential risks of medication versus the usually higher risk of active disease. The IBD team is best placed to measure disease activity and take disease and treatment history into account. Advice on medication issues should be provided by the team with the best experience and knowledge. Gastroenterologists and IBD nurses have excellent IBD related pregnancy knowledge. [1 15] For most women with IBD the IBD service can provide pre-pregnancy counseling but for women with other health issues or significant problems during previous pregnancies further advice from a maternal medicine obstetrician or an obstetric physician should be sought. Up to 40% of pregnancies are not planned and ideally all women with IBD of child bearing age should receive at least basic information about IBD, contraception and pregnancy.

Statement 4:

The IBD team must advise all patients with IBD who are pregnant or considering pregnancy on drug safety during conception, pregnancy and the importance of maintaining remission. [0% mostly, 100% totally agree]

Women with IBD are at increased risk of adverse pregnancy outcomes and therefore have in general above average risk pregnancies. [5] A consultant led clinic should review the patient and assess for IBD and non-IBD risk factors to facilitate the most appropriate care and follow-up during pregnancy. The initial antenatal assessment should be delivered in a consultant led antenatal clinic. The visit should be used to stratify disease and pregnancy risk and provide a detailed plan for the antenatal care including as a minimum the timing, setting and modality for maternal and fetal surveillance. Routine antenatal care should be provided by midwives and obstretricians in line with current national obstetric guidelines.

Statement 5:

Pregnant women with IBD should be offered consultant led obstetric care. Following initial clinic assessment care in different clinical settings may be appropriate. [40% mostly, 60% totally agree]

Statement 6:

All pregnant women with IBD should be offered IBD specialist care by a consultant or IBD nurse with experience in IBD pregnancy care. [0% mostly, 100% totally agree]

Statement 7:

The frequency of IBD, obstetric and or joint clinic follow-up should be determined by IBD disease activity in the absence of other obstetric concerns. Patients with mild disease can be monitored remotely (via "telephone" or "virtual" clinics) but moderate to severe disease requires follow-up by IBD, obstetric and/or joint clinics. [20% mostly agree, 80% totally agree]

Management of biologics during pregnancy requires complex decision making to ensure optimal patient outcomes. European and North American guidance differ on the question of continuation during the 3rd trimester.[7-9] Discontinuation of anti-TNF at the end of the 2nd trimester leads to lower drug levels in cord blood,[16] which was thought to reduce the risk of serious infections in the infant.[16] A large French study has however shown that women who discontinued anti-TNF experienced more flares while no differences in infant infection rates were seen between those exposed to 3rd trimester anti-TNF and those not exposed. [17] Women with IBD need to be advised on risks and benefits of continuing biologics during the 3rd trimester on an individual basis taking into account their disease and treatment history.

Statement 8:

All pregnant women receiving biological therapy for IBD need to receive individual advice on whether to continue or stop therapy during the 3rd trimester and when to restart therapy postpartum.

This discussion and the decision need to be clearly documented.
All women on biologics need to be counselled on safety aspects for the infant including vaccinations and advice on infection-related complications. [0% mostly, 100% totally agree]

While the majority of women with IBD can have a vaginal delivery, choosing caesarean sections is crucial for the subset of women with active perianal disease.[7] Women with ileo-anal pouches have borderline continence and may therefore benefit from caesarean sections to reduce the risk of sphincter injury.[7] Women with IBD have caesarean sections

significantly more often than then general population.[5] Obstetricians should be advised by IBD teams whether an IBD indication for caesarean section is present or whether obstetric concerns alone in conjunction with patient wishes should guide the mode of delivery decision. Discussion with the surgical team may influence both timing and mode of delivery with early elective delivery (38 weeks) being preferable to emergency surgical delivery in some women with previous complex surgery. If early delivery is required, antenatal corticosteroids may need to be considered, to improve fetal lung maturity.

Statement 9:

All pregnant women with IBD should be advised on whether their IBD influences the mode of delivery

A clear recommendation on optimum mode of delivery should be made well in advance of the expected delivery date. Considerations need to be made in regard to absolute contra-indications for a vaginal delivery. G***old standard is a joint IBD-obstetric decision.***
For patients with IPAA or perianal disease a joint approach that may include surgical input is required. [0% mostly, 100% totally agree]

Breast feeding conveys many benefits to the infant including optimal nutrition, beneficial effects on the immune system and a potential reduction in the risk of developing IBD.[7 18] The amount of biologic agent found in breast milk is likely to be small and unlikely to be significantly systemically absorbed by the infant. Therefore breast feeding should normally be encouraged.[8] Patients require individual advice on the risks and benefits to make informed decisions on the choice of infant nutrition.

Statement 10:

All pregnant women with IBD should be counselled on the benefits of breast feeding with specific advice on the suitability of their medical treatment on breast feeding well in advance of the expected delivery date and the decision should be documented. [0% mostly, 100% totally agree]

Child hood vaccinations are important for the infant's health and the appropriate use of vaccinations needs to be based on medical advice. Only biologic agents require an

adjustment from the routine vaccination schedule as live vaccinations carry potential risks and should therefore be delayed.

Statement 11:

All pregnant women with IBD should be counselled on the safety of vaccinations for the newborn. Women on relevant biological drugs should be advised that the infant should avoid the rota virus vaccination and that the BCG vaccination should be delayed. This should be documented. [0% mostly, 100% totally agree]

Pregnant women with IBD have an increased risk of preterm labour and small for gestation birth weight.[5] This risk is largely from active inflammation and seems to be much lower in women having achieved remission from IBD.[5 19] Fetal growth scanning can help obstetricians identify and/or monitor high risk patients. Growth scans at 28 and 34 weeks gestation may be useful in women with active disease but the benefit of routine scanning in the third trimester in women with mild disease or in clinical remission from IBD is unclear.

Statement 12:

Additional growth scans in the 3rd trimester should be considered for patients with active IBD and/or other comorbidities as determined by the supervising obstetrician. [10% mostly, 90% totally agree]

Patients with IBD are at increased risk of venous thromboembolism (VTE) during flares and this risk is further increased during pregnancy.[20] For women with active IBD thromboprophylaxis with low molecular weight heparin should be considered. The Royal College of Obstetrics and Gynaecology (RCOG) guidelines provide helpful advice that includes all known risk factors for VTE.[21]

Statement 13:

In patients with active IBD prophylaxis against venous thromboembolism should be considered taking into account other risk factors using the RCOG VTE guidelines. [0% mostly, 100% totally agree

Continuity of care post-delivery is important for all women with IBD. This particularly busy period for new mothers can be challenging. Clear advice on when and how to contact the IBD service is vitally important to allow for swift follow-up where needed without burdening new mothers with routine appointments when in remission. Some women with UC experience a higher risk of post-partum flares[8] and should be advised on how to manage this. Furthermore women who discontinued biologics need to be advised when to restart these.

Statement 14:

Prior to delivery women should be advised on the plan for follow-up post partum and given contact details for the IBD service. [0% mostly, 100% totally agree]

Domain 3: Audit of services

Routine capture of pregnancy outcome is advised to help services review their results and allow for quality improvement programs. We have proposed four audit standards on decision making and documentation that are vital to ensure safe high quality care. We suggest that services audit their IBD antenatal care to ensuring minimum standards of care are met.

Statement 15:

Pregnancy related outcome data should be captured regularly where possible and should include: delivery date, mode of delivery, complications and breast feeding status.

Services should aim to achieve a 90% target for:

Documented decision on biological therapy during pregnancy
Documented advice on delivery method
Documented advice on vaccination for the newborn
Documented advice on breast feeding [20% mostly agree, 80% totally agree]

Discussion

The management of IBD during pregnancy requires complex decision making incorporating consideration of maternal and fetal health. For the vast majority of patients the risk of active IBD poses a risk that far outweighs any medication risk (except for Methotrexate or Tofacitinib) and continuation of maintenance therapy is vital to ensure well controlled IBD which in turn is associated with better pregnancy outcomes. [5 7 12 22] Patients however often harbor concerns

and fears over IBD medications during pregnancy, which increases the risk of non-adherence. [13] [23]

Clinician knowledge varies according to specialty, and advice by clinicians not versed in the management of pregnant IBD patients may lead to inappropriate (usually over-cautious) medical advice. [10] Furthermore uncoordinated care between obstetric and IBD units may increase the risk of the patient perceiving medical advice from the respective units to be conflicting. Opportunities to optimize care and instigate tighter monitoring of the pregnancy may be missed, which in turn could lead to adverse pregnancy outcomes. In light of this the IBD antenatal working group was formed to provide this endorsed guidance statement on service standards for the care of pregnant women with IBD. The standards are often based on expert opinion as evidence for high quality care was sometimes lacking. This endorsed guidance statement does not aim to replicate the excellent medical guidance offered by European and North American detailed guidelines, [7-9] but aims to provide practical advice for clinicians in the United Kingdom on how to organize services and what should be seen as minimum standards of care.

Collaborative working between obstetric and IBD units is, in the view of the working group, key to providing high quality care. A dedicated IBD pregnancy clinic in the Netherlands has shown that coordinated care and pre-pregnancy counselling are associated with better maternal and fetal outcomes.[12] While such specially set up clinics are models for high quality care they are resource intensive and may not be justified in smaller IBD units where the patient numbers do not justify this set-up. Coordinated working can also occur via nominated link clinicians and routine communication after every clinical encounter. This is especially important in Trusts where different electronic systems for health records are used in maternity and gastroenterology.

To avoid confusion for patients and general practitioners advice on safety of medications during pregnancy, breast feeding and child hood vaccinations should be provided to all pregnant women with IBD and clearly documented and communicated. Decisions on mode of delivery should be informed by advice from the IBD unit whether there is an IBD indication for a mode of delivery.

In summary, this endorsed guidance statement provides advice on how to organise services for pregnant women with IBD and sets minimum standards of care. Further work including potentially a nationwide audit is required to assess quality of care for pregnant women with IBD. Qualitative research into how women perceive their care would also be important.

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