Obstetric Cholestasis Diagnosis and Management Clinical Guideline

V2.0

June 2019
1. **Aim/Purpose of this Guideline**

1.1 To give guidance to obstetricians and midwives on the management of women with Obstetric Cholestasis (OC).

1.2 This version supersedes any previous versions of this document.

1.3. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We can’t rely on Opt out, it must be Opt in.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the ‘information use framework policy’, or contact the Information Governance Team rch-tr.infogov@nhs.net

2. **The Guidance**

2.1. **Introduction**

Pruritus in pregnancy is common, affecting 23% of pregnancies, of which a small proportion will have Obstetric Cholestasis. Obstetric Cholestasis, sometimes referred to as Intrahepatic Cholestasis of Pregnancy (ICP), is a multifactorial condition of pregnancy characterised by pruritus and abnormal liver function tests (either raised Alanine aminotransferase (ALT) or Bile acids or both) both resolving completely after delivery. Itching that involves the palms and soles of the feet, is particularly suggestive of OC.

The clinical importance of OC lies in the potential fetal risks, which may include spontaneous preterm birth and iatrogenic preterm birth. Although stillbirth is quoted as being increased in OC, recent evidence has shown that the risk of stillbirth associated with OC is only in cases in which the peak Bile Acid levels exceed 100 umol/L at any point. There is no association between increases in ALT and stillbirth in OC regardless of the increase (NEW 2019). There can also be maternal morbidity in association with the intense pruritus and consequent sleep deprivation.

2.2. **Pathway for referral:**

2.2.1 Pregnant women with itching after 24 weeks without a rash will be suspected to have OC and should be assessed by the community midwifery team or GP to confirm or refute the diagnosis.
2.2.2 Women with a rash should be referred to the GP from the community.

2.3. Initial assessment for diagnosis of Obstetric Cholestasis

Initial assessment, blood tests and diagnosis is made in the community unless the woman presents after 37 weeks in which case a referral to Day Assessment Unit (DAU) should be made.

2.3.1 A detailed history should be taken including the following:

- Unexplained pruritus
- Usually no rash (excoriations only)
- Pale stools, dark urine, jaundice
- Family history or personal history of cholestasis (or gallstones)
- Multiple pregnancy & Hepatitis C (earlier onset before 26 weeks)
- Drug history- herbal remedies or recent antibiotics

2.3.2 A full antenatal examination should be performed including:

- Abdominal palpation and symphysis fundal height measurement
- Fetal heart auscultation
- Check for presence of normal fetal movements
- Blood pressure and maternal pulse
- Urinalysis

2.4 Blood Tests

- Full Blood Count (FBC)
- Liver function tests (LFTs). Pregnancy specific reference range which is 20% lower than non-pregnant range should be used.
- Bile acids. (Bile acid levels can peak transiently after a meal therefore blood should not be taken within 2 hours of eating).
- Clotting screen only if already suspected low platelets/ bleeding tendencies or already highly deranged LFTs (ALT> 200)

<table>
<thead>
<tr>
<th>Clinical Chemistry Test</th>
<th>Normal level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bile Acid</td>
<td>0-14 umol/L</td>
</tr>
<tr>
<td>ALT (Alanine transaminase)</td>
<td>0-55 iu/L</td>
</tr>
</tbody>
</table>

2.4.1 If results are normal but unexplained pruritus persists, bloods should be repeated fortnightly until LFT/bile acids become abnormal or symptoms stop. Tablets to take out (TTO) Piriton 4mg TDS and aqueous menthol 1% cream may be given if symptoms severe. This should be undertaken in the community setting, only once blood results are abnormal should referral be made to DAU.

2.4.2 If ALT and/or bile acid levels are raised then a provisional diagnosis of OC should be made and referral should be made to DAU for further investigations and Obstetric Consultant antenatal clinic appointment arranged.
2.5 Further Investigations when ALT or Bile acids are raised

2.5.1 When bile acids or ALT elevated the woman should be referred to DAU for further investigations.

2.5.2 In DAU: Other causes of pruritus and abnormal LFTs should be excluded by:

- Virology Screen (Hepatitis A, B, and C, Epstein Barr and Cytomegalovirus)
- Liver autoimmune screen for chronic active hepatitis and primary biliary cirrhosis (anti-smooth muscle and anti-mitochondrial antibodies)
- Liver ultrasound scan

2.5.3 If ALT rises rapidly a coagulation screen should be performed (new 2017)

2.5.4 When a woman has had OC in a previous pregnancy the necessity for full repeat investigation should be individualised by an experienced obstetrician.

2.5.5 Pre-eclampsia and acute fatty liver of pregnancy are pregnancy-specific causes of abnormal LFTs that may form part of differential diagnosis in atypical or early cases.

2.6. Treatment of Obstetric Cholestasis:

- Aqueous Menthol cream 1% (PRN)
- Chlorpheniramine (Piriton) 4mg TDS for symptomatic relief
- If the prothrombin time is prolonged (new 2017) Vitamin K 10mg should be taken daily (water soluble) from 34 weeks until delivery to reduce risk of maternal and fetal haemorrhage
- Ursodeoxycholic Acid (UCDA) has not been shown to improve the symptoms in OC any greater than placebo and therefore this should not be recommended or prescribed for this purpose (NEW 2019)

2.7. General Advice for Women:

- Have frequent tepid baths
- Try not to get too hot
- Wear loose cotton clothing
- Gently scratch skin with a baby’s soft hairbrush if necessary
- Lower fat intake

2.8. Management:

2.8.1 Patients with confirmed Obstetric Cholestasis should have consultant-led care
2.8.2 Once the raise in Bile acids +/- ALT has been investigated and a diagnosis of OC is confirmed the women can continue to have OC monitoring in the community.

2.8.3 Blood should be taken fortnightly in the community for LFTs and Bile Acids until 36+6 weeks of gestation (New 2019) and then weekly from 37 weeks

2.8.4 Refer to DAU or consultant clinic for review if rapid increases in Bile Acids or ALT or if woman is very symptomatic (NEW 2019)

- If Bile Acids have ever been over 40 umol/L the women should be referred to DAU at 37 weeks of gestation for twice weekly assessments and monitoring of bloods. (New 2019)
- If BA have always been <40 umol/L continue weekly blood monitoring until delivery.
- DAU to arrange review in Obstetric clinic at 36 weeks if OC diagnosed prior to this
- Drugs that can commonly cause cholestasis should be avoided (Erythromycin, Augmentin and Flucloxacillin) unless benefits outweigh the risks
- Ultrasound and Cardiotocograph (CTG) are not reliable methods for preventing fetal death in OC and are not necessary unless other indications for monitoring present
- Women should be given written information on OC (RCOG / British Liver Trust patient information leaflets) to support verbal advice
- In severe cases of sleep deprivation and anxiety signpost to support networks (e.g. British Liver Trust)

2.9. Additional risks associated with pregnancies complicated by OC:

Women should be advised that:
- The incidence of premature birth, especially iatrogenic, is increased
- There is increased likelihood of meconium passage in pregnancies affected by OC
- There have been no reports of any harmful effects to babies from OC pregnancies once they have been delivered

2.10. Induction:

2.10.1 The prevalence of stillbirth is not increased in women in whom the Bile Acids have always been less than 100μmol/L. Women should be reassured about this. (New 2019)

2.10.2 Induction of labour should be offered after 37 weeks of gestation for women in whom the Bile Acids has exceeded 100μmol/L at any point as this has been shown to be associated with an increased risk of stillbirth. (New 2019)

2.10.3 If Bile Acids rise to levels between 40-100μmol/L induction of labour could be considered after 39 weeks of gestation (as although the study did not show any significant increase in stillbirth in this group
the number of women going over 39 weeks in this group were lower than the group in whom Bile Acids were <40μmol/L). (NEW 2019)

2.10.4 Women with OC whose Bile Acids have never risen above the threshold of 40μmol/L can be reassured that early IOL (i.e. <T+12) is not necessary. If however she is affected by OC symptoms and prefers not to go over expected date of delivery (EDD) it is reasonable to offer induction of labour at term. (New 2019)

2.10.5 Induction of Labour (IOL) should not be offered to women with OC if the only increase has been in the ALT as this has not been shown to increase the risk of stillbirth (NEW 2019).

2.11. Delivery:

OC has been linked with an increased incidence of passage of meconium, premature delivery, fetal distress, delivery by caesarean section and postpartum haemorrhage. Women diagnosed with OC should give birth in the consultant unit and continuous fetal monitoring advised.

2.12. Postnatal Management:

2.12.1 Postnatal resolution of symptoms and normalisation of LFTs is crucial in confirming the diagnosis of OC.

2.12.2 All women with provisional diagnosis of OC should have a repeat LFT two weeks after delivery in the community (LFTs increase in the first 10 days of the puerperium). A discussion regarding future pregnancies and contraception should also be undertaken. If LFTs are still abnormal refer to Consultants obstetric clinic.

2.12.3 Women with OC should be advised:

- Advise women that there is a 10% risk of developing pruritus or hepatic impairment or both with oestrogen containing contraception
- The recurrence rate in the following pregnancy is 40-90%
- There are no known developmental problems for the baby and no increased risk of developing neonatal jaundice
3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Number of cases of OC a year and CTG compliance with no CTG monitoring against outcome</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Lead</th>
<th>Day Assessment Unit and Ante Natal Ward Manager</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Tool</th>
<th>Day Assessment Unit audit database to be kept of all women seen with OC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>To record outcome of pregnancy</td>
</tr>
<tr>
<td></td>
<td>Whether CTG monitoring was undertaken in an otherwise normal pregnancy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Annual review of the data</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Reporting arrangements</th>
<th>Reported though the Maternity Patient Safety Forum</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Acting on recommendations and Lead(s)</th>
<th>Day Assessment Unit and Ante Natal Ward Manager</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Change in practice and lessons to be shared</th>
<th>Reported though the Patient Safety Management Forum</th>
</tr>
</thead>
</table>

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion & Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
## Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Obstetric Cholestasis Diagnosis and Management Clinical Guideline V2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>6&lt;sup&gt;th&lt;/sup&gt; June 2019</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>June 2019</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>June 2022</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Magda Kudas Antenatal Ward Manger Obs and Gynae Directorate</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252149</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>To give guidance to obstetricians and midwives on the management of women with Obstetric Cholestasis (OC).</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Obstetric Cholestasis, OC, Cholestasis, itching, Piriton, Bile Acids, LFTs</td>
</tr>
<tr>
<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td></td>
</tr>
<tr>
<td>Date revised:</td>
<td>June 2019</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>OBSTETRIC CHOLESTASIS – CLINICAL GUIDELINE FOR DIAGNOSIS AND MANAGEMENT V1.2</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Maternity Guideline Group Obs &amp; Gynae Directorate</td>
</tr>
<tr>
<td>Care Group General Manager confirming approval processes</td>
<td>Debra Shields, Care Group Manager</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Not Required</td>
</tr>
<tr>
<td>Name and Signature of Care Group/Directorate Governance Lead confirming approval by specialty and care group management meetings</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Name: Caroline Amukusana</td>
<td></td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and)</td>
<td>Internet &amp; Intranet</td>
</tr>
</tbody>
</table>

Obstetric Cholestasis Diagnosis and Management Clinical Guideline V2.0
Page 8 of 13
Related Documents:


- Knight, LJ. Rates of iatrogenic delivery for obstetric cholestasis at less than 37 weeks of gestation including observations of perinatal outcome. January 2012. Royal Cornwall Hospital.


Training Need Identified? None

Version Control Table

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6th February 2014</td>
<td>V1.0</td>
<td>Initial Issue</td>
<td>Karen Stoyles Antenatal Ward Manger</td>
</tr>
<tr>
<td>12.1.2017</td>
<td>V1.1</td>
<td>Reviewed and updates to 2.5 &amp; 2.6</td>
<td>Magda Kudas Antenatal Ward manager</td>
</tr>
<tr>
<td>5th April 2018</td>
<td>V1.2</td>
<td>Section 2.10 updated</td>
<td>Magda Kudas Antenatal Ward manager</td>
</tr>
<tr>
<td>6th June 2019</td>
<td>V2.0</td>
<td>Section 2.8 and 2.10 updated</td>
<td>Magda Kudas Antenatal Ward manager</td>
</tr>
</tbody>
</table>

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

Controlled Document
This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.
# Appendix 2. Initial Equality Impact Assessment Form

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obstetric Cholestasis Diagnosis And Management Clinical Guideline V2.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Directorate and service area:</th>
<th>New or existing document:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midwifery and Obstetrics</td>
<td>Existing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of individual completing assessment:</th>
<th>Telephone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magda Kudas</td>
<td>01872 252149</td>
</tr>
</tbody>
</table>

1. **Policy Aim**
   *Who is the strategy / policy / proposal / service function aimed at?*
   
   To give guidance to obstetricians and midwives on the management of women with Obstetric Cholestasis (OC).

2. **Policy Objectives**
   
   Ensure timely diagnosis and management of Obstetric Cholestasis in pregnant women. Ensure the correct follow up for women, who have been diagnosed with Obstetric Cholestasis, in the postnatal period.

3. **Policy – intended Outcomes**
   
   Treatment of Obstetric Cholestasis in pregnant and newly delivered women.

4. **How will you measure the outcome?**
   
   Data collection and audit with compliance monitoring tool.

5. **Who is intended to benefit from the policy?**
   
   Pregnant and newly delivered women with Obstetric Cholestasis.

6a **Who did you consult with**

   b). Please identify the groups who have been consulted about this procedure.

   - Workforce
   - Patients
   - Local groups
   - External organisations
   - Other

   - x

   - Clinical Guideline Group
   - Obstetrics and Gynaecology Directorate
   - Policy Review group

**What was the outcome of the consultation?**

Guideline agreed
7. The Impact
Please complete the following table. **If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.**

Are there concerns that the policy **could** have differential impact on:

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>x</td>
<td></td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td>x</td>
<td></td>
<td></td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Race / Ethnic communities / groups</td>
<td></td>
<td>x</td>
<td></td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</td>
<td>x</td>
<td></td>
<td></td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
<td></td>
<td>x</td>
<td></td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Marriage and Civil partnership</td>
<td></td>
<td>x</td>
<td></td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td></td>
<td>x</td>
<td></td>
<td>All pregnant women</td>
</tr>
<tr>
<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
<td>x</td>
<td></td>
<td></td>
<td>All pregnant women</td>
</tr>
</tbody>
</table>

**You will need to continue to a full Equality Impact Assessment if the following have been highlighted:**
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation - this **excludes** any **policies** which have been identified as not requiring consultation. **or**
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended.  
   | Yes | No | x 
---|-----|----|---
9. If you are **not** recommending a Full Impact assessment please explain why.

Not indicated
This EIA will not be uploaded to the Trust website without the approval of the Policy Review Group.

A summary of the results will be published on the Trust’s web site.