

OBSTETRIC CHOLESTASIS – CLINICAL GUIDELINE FOR DIAGNOSIS AND MANAGEMENT

1. Aim/Purpose of this Guideline

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

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 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, iatrogenic preterm birth and fetal death. There can also be maternal morbidity in association with the intense pruritus and consequent sleep deprivation.

2.2. Pathway for referral

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.

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 DAU should be made.

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

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

- 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 raise significantly after a meal therefore blood should be taken before a meal, fast for approximately 4 hours).
- Clotting screen **only** if already suspected low platelets/ bleeding tendencies or already highly deranged LFTs (ALT > 200)

Clinical Chemistry Test	Normal level
Bile Acid	<14 umol/L
ALT (Alanine transaminase)	<32 iu/L

If results are normal but unexplained pruritus persists, bloods should be **repeated fortnightly** until LFT/bile acids become abnormal or symptoms stop. 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.

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.

2.5. Further Investigations when LFTs are raised

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

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

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

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

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) improves pruritus and liver function in women with OC. 500mg BD (divided doses recommended) may be prescribed initially, the dose can be increased to TDS dose to 1.5g daily. Advise women to take with a meal or immediately after.

Women should be informed that UCDA has been used for many years and although there have been no reports of adverse effects for the unborn baby when the mother takes UCDA, there is a lack of robust data.

2.7. General Advice for Women

- Lower fat intake
- 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

2.8. Management

- Patients with confirmed Obstetric Cholestasis should have consultant-led care
- Blood should be taken weekly in the community for LFTs and Bile Acids
- Planned weekly telephone consultation with DAU midwife with blood results
- DAU midwife to refer to DAU on call SpR/ Consultant if clinical concerns or after 37 weeks gestation at presentation
- DAU to arrange review in Obstetric clinic at 36 weeks to discuss Induction of Labour (IOL)
- Drugs that can commonly cause cholestasis should be avoided (Erythromycin, Augmentin and Flucloxacillin) unless benefits outweigh the risks
- Ultrasound and 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

Stillbirths in OC have been reported at all gestations. The risk of premature delivery must be balanced against the uncertain fetal risk of continuing the pregnancy. Women may be offered Induction of labour after 37+0 weeks of pregnancy.

The decision should be made after careful counselling with the women and discussion with the Consultant preferably at Consultant clinic review at 36 weeks gestation. The case for intervention after 37 weeks gestation may be stronger in those with more severe biochemical abnormality, especially Bile Acids >40 mmol/L, but delivery decisions should not be based on results alone.

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

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

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.

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

Element to be monitored	Number of cases of OC a year and CTG compliance with no CTG monitoring against outcome
Lead	Day Assessment Unit and Ante Natal Ward Manager
Tool	Day Assessment Unit audit database to be kept of all women seen with OC To record outcome of pregnancy Whether CTG monitoring was undertaken in an otherwise normal pregnancy
Frequency	Annual review of the data
Reporting arrangements	Reported though the Maternity Risk Management Forum
Acting on recommendations and Lead(s)	Day Assessment Unit and Ante Natal Ward Manager
Change in practice and lessons to be shared	Reported though the Maternity Risk Management Forum

4. Equality and Diversity

4.1 This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement.

4.2 Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	OBSTETRIC CHOLESTASIS – CLINICAL GUIDELINE FOR DIAGNOSIS AND MANAGEMENT			
Date Issued/Approved:	20 th January 2017			
Date Valid From:	20 th January 2017			
Date Valid To:	20 th January 2020			
Directorate / Department responsible (author/owner):	Magda Kudas Antenatal Ward Manger Obs and Gynae Directorate			
Contact details:	01872 252149			
Brief summary of contents	To give guidance to obstetricians and midwives on the management of women with Obstetric Cholestasis (OC).			
Suggested Keywords:	Obstetric Cholestasis, OC, Cholestasis, itching, Piriton, Bile Acids, LFTs			
Target Audience	RCHT	PCH	CFT	KCCG
	✓			
Executive Director responsible for Policy:	Medical Director			
Date revised:	12 th January 2017			
This document replaces (exact title of previous version):	New Document			
Approval route (names of committees)/consultation:	Maternity Guideline Group Obs & Gynae Directorate			
Divisional Manager confirming approval processes	Head of Midwifery			
Name and Post Title of additional signatories	Not Required			
Signature of Executive Director giving approval	{Original Copy Signed}			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only	
Document Library Folder/Sub Folder	Clinical/Midwifery and Obstetrics			

Links to key external standards	None
<ul style="list-style-type: none"> • Related Documents: 	<ul style="list-style-type: none"> • RCOG Green Top Guideline No 43. <i>Obstetric Cholestasis</i>. May 2011. RCOG Press. • 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. • Kenyon AP, Tribe RM, Nelson-Piercy C, Girling JC, Williamson C, Seed PT, et al. Pruritus in pregnancy: a study of anatomical distribution and prevalence in relation to the development of obstetric cholestasis. <i>Obstet Med</i> 2010;3:25–9. • Lee RH, Kwok KM, Ingles S, Wilson ML, Mullin P, Incerpi M, et al. Pregnancy outcomes during an era of aggressive management for intrahepatic cholestasis of pregnancy. <i>Am J Perinatol</i> 2008;25:341–5. • Rioseco AJ, Ivankovic MB, Manzur A, Hamed F, Kato SR, Parer JT, et al. Intrahepatic cholestasis of pregnancy: a retrospective case–control study of perinatal outcome. <i>Am J Obstet Gynecol</i> 1994;170:890–5. • British Medical Association, Pharmaceutical Society of Great Britain. Vitamin K. <i>British National Formulary</i>. London: British Medical Association, Pharmaceutical Society of • British Liver Trust. <i>Fighting Liver Disease: Obstetric Cholestasis</i>. 2011 www.britishlivertrust.org.uk/home/the-liver/liverdisease/obstetric-cholestasis.aspx

Training Need Identified?	None
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Version Control Table

Date	Version No	Summary of Changes	Changes Made by (Name and Job Title)
6 th February 2014	V1.0	Initial Issue	Karen Stoyles Antenatal Ward Manger
12.1.2017	V1.1	Reviewed and updates to 2.5 & 2.6	Magda Kudas Antenatal Ward manager

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 on Document Production. 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

Name of Name of the strategy / policy /proposal / service function to be assessed (hereafter referred to as <i>policy</i>) (Provide brief description): OBSTETRIC CHOLESTASIS – CLINICAL GUIDELINE FOR DIAGNOSIS AND MANAGEMENT	
Directorate and service area: Obs and Gynae Directorate	Is this a new or existing Policy? New
Name of individual completing assessment: Magda Kudas	Telephone: 01872 252149
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) Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?	No
b) If yes, have these *groups been consulted?	N/A
C). Please list any groups who have been consulted about this procedure.	N/A

7. The Impact

Please complete the following table.

Are there concerns that the policy could have differential impact on:			
Equality Strands:	Yes	No	Rationale for Assessment / Existing Evidence
Age		X	All pregnant women
Sex (male, female, trans-gender / gender reassignment)		X	All pregnant women
Race / Ethnic communities /groups		X	All pregnant women
Disability - learning disability, physical disability, sensory impairment and mental health problems		X	All pregnant women
Religion / other beliefs		X	All pregnant women
Marriage and civil partnership		X	All pregnant women
Pregnancy and maternity		X	All pregnant women
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		X	All pregnant women
<p>You will need to continue to a full Equality Impact Assessment if the following have been highlighted:</p> <ul style="list-style-type: none"> • You have ticked “Yes” in any column above and • No consultation or evidence of there being consultation- this <u>excludes</u> any <i>policies</i> which have been identified as not requiring consultation. or • Major 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.			
N/A			
Signature of policy developer / lead manager / director Magda Kudas Antenatal Ward Manger		Date of completion and submission 12 th January 2017	
Names and signatures of members carrying out the Screening Assessment	1. Magda Kudas 2.		

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead,
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department,
Knowledge Spa, Truro, Cornwall, TR1 3HD

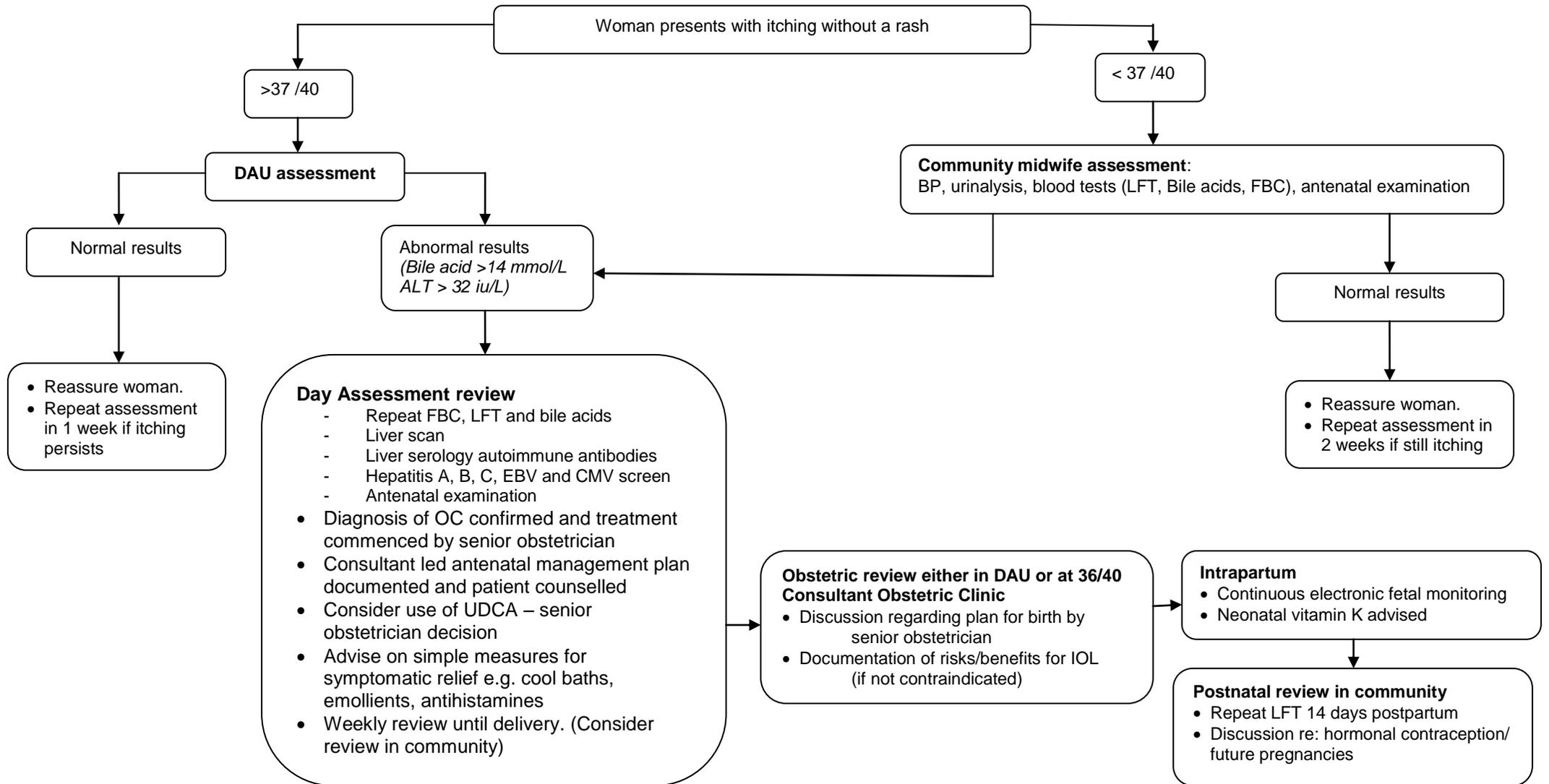
A summary of the results will be published on the Trust's web site.

Signed: Sarah-Jane Pedler

Date: 20th January 2017

Appendix 3.

Obstetric Cholestasis – Antenatal, Intrapartum and Postnatal Management Care



Appendix 4: DAU Obstetric Cholestasis Assessment Proforma

Patient identity label

Parity:..... EDD/...../201.....
 Consultant:
 Patient telephone No:.....
 Date of diagnosis:/...../ 201.....

Gestation: Hb: g/l WCC: Platelets: ALT: Bile Acid:
Initial DAU Attendance: Date:/...../201... Referred to DAU by:.....

Patient information

Cholestasis discussed with patient: Patient information leaflet given:

Tests

Liver scan: Requested: Performed Date:/...../201...
 Result: ALT: Bile Acid:
 Cytomeglovirus: POS/NEG Epstein Barr virus; POS/NEG Hepatitis A, B & C: POS/NEG
 Autoimmune liver antibodies POS/NEG
 BP:..... Pulse:..... Temp:..... SFH:.....cms

Symptoms

Itching: Mild Moderate Severe **Skin:** Rash Broken Skin
Sleep: Normal Disturbed Lack of sleep affecting daily activities
 Fetal Movements: Normal Reduced Fetal heart rate:.....

Management Plan

Review by: Con/ SpR

Medication

Piriton Ursodeoxycholic Acid Dose: Vitamin K Aqueous / Menthol 1% cream

DAU Midwife: Name: Signature:.....

Follow up Telephone Consultations

1. Date: Time:
Blood results: Hb: g/l WCC: Platelets: ALT: Bile Acid:
 Symptoms:
 Itching: Mild Moderate Severe Skin: Rash Broken Skin
 Sleep: Normal Disturbed Lack of sleep affecting daily activities
 Fetal Movements: Normal Reduced **Management Plan:**
 Midwife signature: Midwife Name:

2. Date: Time:
Blood results: Hb: g/l WCC: Platelets: ALT: Bile Acid:
 Symptoms:
 Itching: Mild Moderate Severe Skin: Rash Broken Skin
 Sleep: Normal Disturbed Lack of sleep affecting daily activities
 Fetal Movements: Normal Reduced **Management Plan:**
 Midwife signature: Midwife Name:

3. Date: Time:
Blood results: Hb: g/l WCC: Platelets: ALT: Bile Acid:
 Symptoms:
 Itching: Mild Moderate Severe Skin: Rash Broken Skin
 Sleep: Normal Disturbed Lack of sleep affecting daily activities
 Fetal Movements: Normal Reduced **Management Plan:**
 Midwife signature: Midwife Name: