Standard Operational Procedure for the Management of Obstetric Cholestasis

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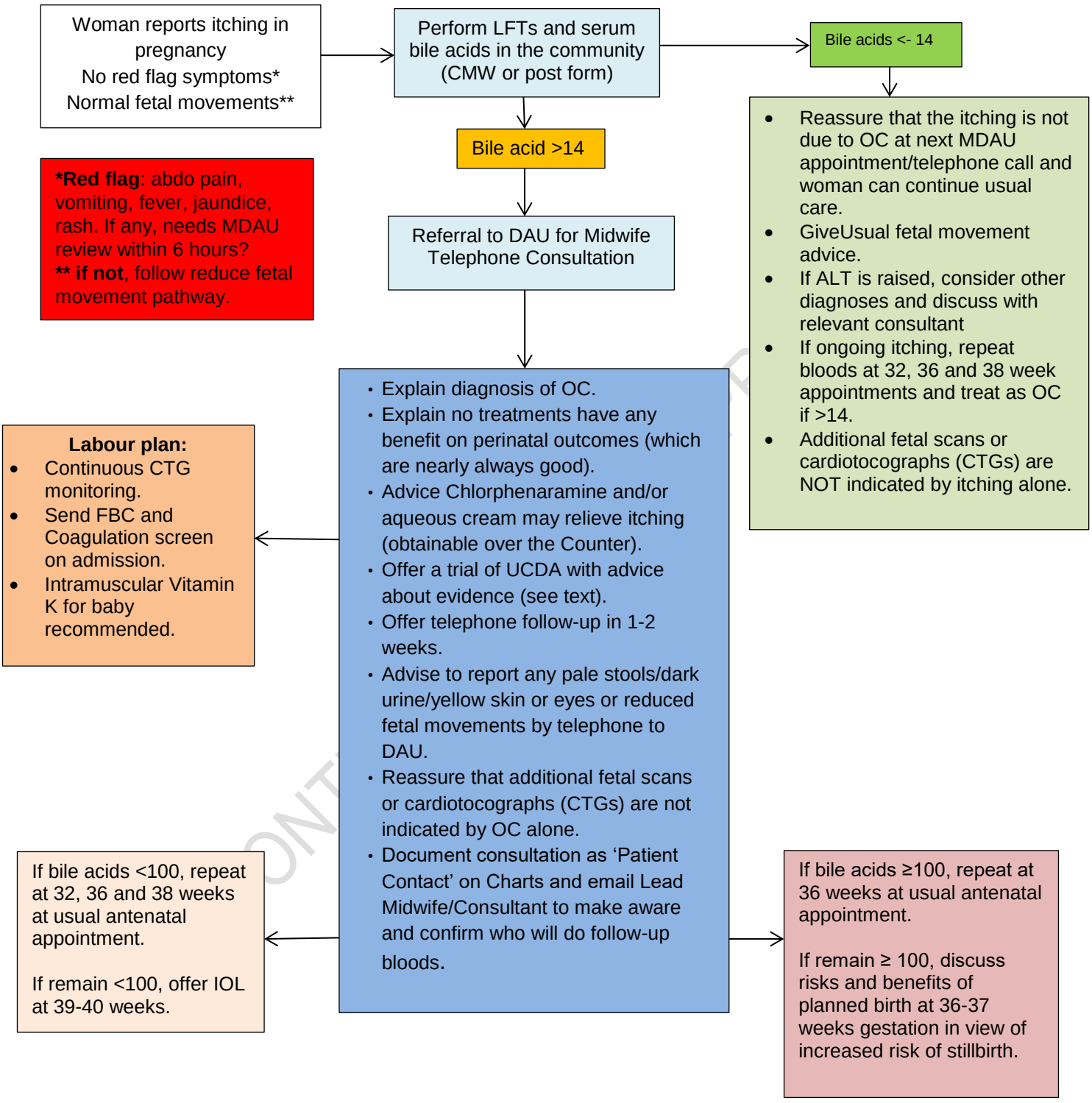
Management of women with itching in pregnancy (>24/40)



1. Background and Purpose

Obstetric Cholestasis (OC) is a condition of pregnancy typically expressed by pruritus and absent skin rash in the presence of abnormal liver function tests (LFTs) and or bile acids (BA) that resolves completely after delivery.

This document provides recommendations and guidance relating to the diagnosis and management of women with OC. It aims to reduce adverse perinatal outcomes by improving the care of this population of pregnant women.

2. Scope:

This document is for use by all Obstetricians and Midwives and it applies to all women cared for by the Maternity Services at St Mary's Hospital.

3. Responsibilities

It is the responsibility of all Midwifery Nursing and medical staff to:

- Access read understand and apply this guidance
- Attend any mandatory training pertaining to the guidance

It is the responsibility of the department to:

- Ensure the guideline is reviewed as required in line with trust and national recommendation
- Ensure the guideline is accessible to all relevant staff

4. Procedure:

Pregnant women with itching after 24 weeks should be referred to the maternity Day Assessment Unit (DAU) for assessment to confirm or refute the diagnosis.

4.1 Antenatal Management

History of itching in palms and soles not associated with rash along with pale stools and dark urine is suggestive of OC (Obstetric Cholestasis).

If history is suggestive of OC, take bloods for both Liver function tests (LFTs) and bile acid (BA). If itching is nonspecific do LFTs first and if that is elevated

then check BA level. Pregnancy reference range should be used to interpret the blood results for all. The LFTs and BA are 20% below the upper limit of normal reference range (see Appendix 1).

- If both LFTs and BA are normal and itching persists repeat test 2 weekly until itching resolves.
- If only LFTs are raised and BA remains normal send bloods for Hepatitis A,B,C, Epstein Barr virus, cytomegalovirus serology, anti-mitochondrial and anti-smooth muscle antibody) and arrange liver ultrasound scan.
- If both LFTs and BA are raised with no rash most likely diagnosis is OC, patient should be seen by a senior clinician (Middle grade and above). From the time of diagnosis repeat bloods weekly for LFTs +/- BA until delivery by CMW/GP and follow up in community. if there are concerns about rising biochemical markers, &/or worsening symptoms ANC appointment should be arranged by DAU staff.
- In proven cases of OC the women should be prescribed urso-deoxycholic acid 250 mg bd/tds following consultation with a senior clinician (middle grade and above) as this helps in reducing itching and meconium staining of liquor.
- If clotting results are abnormal water soluble Vitamin K (menandiol 10mg daily) should be prescribed.
- There is no evidence that fetal monitoring by either ultrasound or CTG for this condition is of any value

4.2 Induction

- Aim to deliver between 37 and 38 weeks if bile acids in excess of 100mmol/l.
- If Bile acids are between 40 and 99mmol/l then deliver at 39 weeks.
- If bile acid is less than 40mmol/l then there is no need for early induction.

Decision for delivery should be individualised for each patient and earlier induction may be necessary if other causes of maternal or fetal compromise present.

4.3 Intrapartum Management

- During labour these women should be offered continuous fetal monitoring if BA are above 40 mmol/l.
- Consider intermittent auscultation only for women with BA less than 40 mmol/l if there are no other features raising concerns over fetal hypoxia.
- In view of risk of PPH intravenous (IV) access must be established FBC, Group and save sent. If clotting abnormality cross match 2 units of blood.
- Be vigilant for meconium staining and request a paediatrician at delivery

4.4 Postnatal management

- Ensure adequate communication to GP at discharge.
- GP to repeat OC bloods 6 weeks post-delivery.
- Advise women to avoid estrogen containing contraceptives.

5 Implementation/training/awareness

- This is a review of a current document and it formalises current practice.
- Once ratified it will be available in all clinical areas within the Maternity Unit and on the intranet.
- All new, reviewed and ratified documents are notified to staff via the monthly maternity newsletter

6. Auditable Standards

What aspects of compliance with the document will be monitored	What will be reviewed to evidence this	How and how often will this be done	Detail sample size (if applicable)	Who will coordinate findings	Which group or report will receive findings
Appropriate dose of UDCA prescribed	Maternal Notes	Yearly	10 sets of notes	Audit Midwife	LW Forum
Delivery has taken place at the correct Gestation	Maternal Notes	Yearly	10 sets of notes	Audit Midwife	LW Forum

7. Related Documents

Guidelines /SOP's:

- SOP- Antenatal Care
- SOP normal care in Labour
- SOP- CTG
- SOP-Dawes Redman
- SOP- DAU

8. References

- Green-top Guideline No 43 Obstetric Cholestasis – April 2011
- Chappell L.C., Chambers J., Thornton J.G., Williamson C. Does ursodeoxycholic acid improve perinatal outcomes in women with intrahepatic cholestasis of pregnancy? BMJ. 2018;360:k104
- Ovadia C., Seed P.T., Sklavounos A., Geenes V., Di Illio C., Chambers J. Association of adverse perinatal outcomes of intrahepatic cholestasis of pregnancy with biochemical markers: results of aggregate and individual patient data meta-analyses. Lancet. 2019;393:899–909

9. DISCLAIMER

It is the responsibility of staff to check the Trust intranet to ensure that the most recent version/issue of this document is being referenced.

DOCUMENT HISTORY

Date of Issue	Version No.	Next Review Date	Date Approved	Director Responsible for Change	Nature of Change
20/04/14	0.1				New document
29/04/14	1.0	29th April 2017	29th April 2014		Ratified by Maternity CSG
April 2017	2.0	Nov 2019	April 2017	Amanda Pearson	Reviewed – no changes
August 2019	1.0	August 2022	August 2019	MCEG	Changes made in line with regional care pathways
Aug 2020	2.0	August 2023	26th Aug 2020	MCSG	Changes made in line with national guidance

Appendix 1- Normal Blood Values

Table 1

Normal reference ranges and their interpretation during pregnancy *

Analytes	Normal (non-pregnant)	Pregnancy	Abnormalities and possible interpretations
Haemoglobin (g/dL)	11.5–16.5	11.0–15.0	Abnormal results need to be considered in conjunction with the patient's clinical state
White cell count (x 10^6 per mL)	4.0–11.0	Unchanged	
Platelets (x 10^6 per mL)	150–450	Unchanged	
Sodium (mmol/L)	135–145	132–140	Abnormal results need to be considered in conjunction with the patient's clinical state
Potassium (mmol/L)	3.5–5.5	3.2–4.6	
Urea (mmol/L)	2.5–6.8	1.0–3.8	↑ in: dehydration hyperemesis gravidarum late stages of pre-eclampsia renal impairment
Creatinine (mmol/L)	0.06–0.1	0.04–0.08	↑ in: renal impairment late stages of pre-eclampsia
Fasting glucose (mmol/L)	3.0–5.4	3.0–5.0	↑ in: gestational diabetes mellitus (refer to reference 3 for diagnostic criteria)
Total calcium (mmol/L)	2.2–2.60	2.0–2.40	↑ in: primary hyperparathyroidism
Ionized calcium (mmol/L)	1.16–1.30	1.16–1.30	
Magnesium (mmol/L)	0.6–1.0	0.6–0.8	↓ in: vomiting hyperemesis gravidarum
Albumin (g/L)	33–41	24–31	↓ in: malnutrition recurrent vomiting hyperemesis gravidarum
Bilirubin (micromol/L)	3–22	3–14	↑ in: intrahepatic cholestasis of pregnancy HELLP late stages of pre-eclampsia acute fatty liver viral hepatitides
Alanine aminotransferase (U/L)	1–40	1–30	↑ in: intrahepatic cholestasis of pregnancy HELLP late stages of pre-eclampsia acute fatty liver viral hepatitides
Aspartate aminotransferase (U/L)	1–30	1–21	↑ in: intrahepatic cholestasis of pregnancy HELLP late stages of pre-eclampsia acute fatty liver viral hepatitides
Alkaline phosphatase (U/L)	25–100	125–250	↑ in: metabolic bone disorders but placental serum alkaline phosphatase needs to be excluded

Adapted from reference 7

↑ increased concentration

↓ decreased concentration

HELLP Haemolysis-Elevated Liver enzymes-Low Platelets

* Each laboratory, where practicable, should develop its own reference ranges for pregnant women. Care should be exercised in comparing results from different laboratories due to differences in assay methodologies.