Mid Essex Hospital Services NHS Trust

OBSTETRIC CHOLESTASIS	**CLINICAL GUIDELINES** **Register No: 07073** **Status: Public**

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5.0	Anita Dutta, Lead Consultant for Obstetrics & Gynaecology	20th December 2017

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1.0 Purpose

1.1 This guideline identifies the fetal risks associated with obstetric cholestasis and provides guidance on the different management choices and the options available for its treatment.

2.0 Equality and Diversity

2.1 Mid Essex Hospital Services NHS Trust is committed to the provision of a service that is fair, accessible and meets the needs of all individuals.

3.0 Background

3.1 In England, obstetric cholestasis (also referred to as intrahepatic cholestasis of pregnancy) affects 0.7% of pregnancies in multi-ethnic populations1 and 1.2–1.5% of women of Indian–Asian or Pakistani–Asian origin.

3.2 Prevalence is influenced by genetic and environmental factors and varies between populations worldwide. For example, in Chile, 2.4% of all pregnancies are affected, with a 5% prevalence in women of Araucanian–Indian origin.

3.3 Obstetric cholestasis is a multifactorial condition of pregnancy characterised by pruritus in the absence of a skin rash with abnormal liver function tests (LFTs), neither of which has an alternative cause and both of which resolve after birth. Most authorities accept elevations of any of a wide range of LFTs beyond pregnancy-specific limits.

3.4 Investigations to exclude other causes of pruritus and of abnormal LFTs should be performed. The clinical importance of obstetric cholestasis 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.

4.0 Risk Factors

4.1 Obstetric cholestasis occurs when there is a reduced flow of bile down the bile ducts from the liver. Some of the bile then ‘leaks’ out into the blood stream, in particular, the bile salts. These then circulate in the bloodstream and can cause symptoms, such as pruritus (itching).

4.2 There is evidence that obstetric cholestasis runs in families. There is also a risk of obstetric cholestasis recurring in a subsequent pregnancy.

4.3 Some doctors believe that pregnancy related hormones affect the way that the liver works and can cause obstetric cholestasis.

4.4 In a hospital setting, the current additional risk of stillbirth in obstetric cholestasis above that of the general population has not been determined but is likely to be small

4.5 Women with obstetric cholestasis should be booked in under consultant-led, team based care and give birth in a hospital unit.

5.0 Signs and Symptoms of Obstetric Cholestasis

5.1 The following list highlights details of the signs and symptoms of cholestasis:

- Itching that generally begins or is most intense on the arms, legs, palms of hands and soles of feet
- The itching is usually worse at night
- Some patients scratch so intensely that their skin breaks and bleeds
- There is difficulty sleeping
- Tiredness
- Poor appetite
- Nausea
- Feeling unwell
- Dark urine and pale stools
- Jaundice of eyes and skin (uncommon)

5.2 Obstetric cholestasis is diagnosed when otherwise unexplained pruritus occurs in pregnancy and abnormal liver function tests (LFTs) and/or raised bile acids occur in the pregnant woman and both resolve after delivery. Pruritus that involves the palms and soles of the feet is particularly suggestive.

6.0 Referral Guidance

6.1 Patients with the above symptoms should be referred to DAU (Day Assessment Unit) or ANC (Antenatal Clinic), for assessment and blood to be taken. Abnormal liver function tests (LFT`s) and bile acids can aid diagnosis.

7.0 Initial Assessment

7.1 Ascertain any relevant family history.

7.2 Inspection of the skin, will confirm whether the itching is related to other skin conditions, such as eczema.

7.3 Investigations to be undertaken as follows:

- Bloods to be taken for FBC; U&E's and LFT's
  (Refer to the guideline for 'Receiving and acting on test results in maternity by both hospital and community'; register number 06031)

7.3.1 If the LFT blood results are abnormal; taking into consideration the 'cut-off' levels in pregnancy; the following should be initiated:

- For transaminases, gamma-glutamyl transferase and bilirubin,
  the upper limit of normal throughout pregnancy is 20% lower than the non-pregnant range
- It is important to check for other causes of abnormal liver function tests
- A viral screen for hepatitis A, B, C, Epstein Barr and cytomegalovirus should be performed
- Liver auto-immune screen – anti-smooth muscle antibody chronic active hepatitis. Anti-mitochrondrial antibody to exclude primary biliary cirrhosis
- Ultrasound examination of liver and gall bladder to exclude gallstones.

7.4 Pre-eclampsia and acute fatty liver of pregnancy are pregnancy specific causes of abnormal LFT's and bile acids.

7.5 Take and record blood pressure (temperature and pulse, if on DAU) and complete urinalysis. Undertake an abdominal palpation, measure fundal height, ascertain fetal position and auscultation of fetal heart.

7.6 Obstetric cholestasis rarely occurs prior to 28 weeks gestation; thus if the assessment is on DAU and the pregnancy is more than 28 weeks gestation, perform a CTG for at least 20-30 minutes, longer if necessary making sure that the patient uses the fetal movement indicator. Assess the quality of the trace using the NICE (National Institute for Clinical Excellence) classification for CTG (cardiotocograph) interpretation. In cases of obstetric cholestasis prior to this gestation, an assessment should be made on an individual basis. (Refer to the guideline entitled 'Fetal heart rate monitoring in pregnancy and labour; register number 04265)

7.7 Care plan depends on place of initial assessment:

- All patient can have blood results reviewed on DAU the following day, if suitable for discharge
- Patients can remain in DAU (or transfer from ANC) to await blood results and review by the obstetric registrar. Care plans should be documented in patient's healthcare records
- All patients who are considered to have obstetric cholestasis, or awaiting confirmation of diagnosis, require an ANC appointment and plan of care by the consultant.

7.8 Pregnancy-specific reference ranges for LFTs should be used. Other causes of itching and of liver dysfunction should be excluded.

7.9 Once other causes of hepatic impairment have been excluded; then a diagnosis of obstetric cholestasis can be made.

8.0 Management of Obstetric Cholestasis

(Refer to Appendix A)

8.1 General measures to relieve symptoms:

- Have frequent cool baths
- Wear loose cotton clothing
- Do not get too hot
- Keep your body uncovered at night

8.2 Possible treatment – there is no evidence that any specific treatment improves maternal symptoms or neonatal outcomes.

8.3 Topical emollients. This includes Diprobase, calamine lotion and aqueous cream with menthol. These are all safe to use in pregnancy and clinical experience suggests that some patients may obtain slight temporary relief from pruritus, although there is no trial data to support or refute this.

8.4 Antihistamines, such as Chlorpheniramine, may provide some sedation at night, but do not significantly impact on pruritus.

8.5 Urosodexycholic Acid – this is the most commonly used agent prescribed in the UK for relief of pruritus in obstetric cholestasis. Urosodexycholic acid (UDCA) was thought to enhance bile acid clearance across the placenta from the fetus. As the pathophysiology of obstetric cholestasis and the mechanism of fetal demise are uncertain, the possible role of UDCA is unclear. UCDA dosage is as follows: 500mg twice daily.

8.6 Menadiol (drug name for Vitamin K, refer to the British National Formulary for specific notes) -: Patients should be offered a supplement of water-soluble vitamin K, usually 10mg daily, by mouth. Data supporting the use of menadiol is sparse, but if there is frank steatorrhoea or prolongation of the prothrombin time, the clinical case for menadiol is stronger. The use of menadiol is aimed at improving both fetal and maternal levels, therefore reducing postpartum haemorrhage and fetal or neonatal bleeding.

8.7 The following blood tests are required on a weekly basis:

- Coagulation screen – only if the LFT's are abnormal or platelets are low

- Liver Function Tests – abnormalities in transaminases i.e. serum glutamic-pyruvic transaminase (ALT) and serum glutamic –oxalocetic transaminase (AST), gamma glutamyl transferase (Gamma GT), bilirubin and / or bile salts are considered sufficient enough to diagnose obstetric cholestasis. Bilirubin is infrequently raised, with most patients having increased levels of one or more of the remaining LFT`s. Bile salt

  assessment is not easily available and whilst isolated elevation of bile salts may occur; this is uncommon and normal levels of bile salts do not exclude the diagnosis

- It should be noted that the level of AST/ALT is not related to the severity of ICP (intra-hepatic cholestasis of pregnancy)

- The investigations need the addition of anti-smooth muscle antibody analysis. If present the results will indicate chronic hepatitis

- Women with persistent pruritus and normal biochemistry should have LFTs repeated every 1–2 weeks

8.8 Fetal Wellbeing

- Stillbirth is considered to be a major concern in the management of obstetric cholestasis. The current stillbirth rate for obstetric cholestasis is comparable with the general population; the risk of 'untreated' obstetric cholestasis is unclear

- Research shows that there is an increased incidence of premature birth, but evidence of an increased risk of meconium stained liquor, caesarean section or postpartum haemorrhage is inconclusive

- Ultrasound scans for fetal growth will be indicated only on clinical grounds; ultrasound is not reliable methods for preventing fetal death in obstetric cholestasis

- Poor outcome cannot currently be predicted by biochemical results and delivery decisions should not be based on results alone

8.9 Plan of Care

- All patients with suspected obstetric cholestasis should be reviewed by their consultant, who will confirm diagnosis and form a plan of care
- Once obstetric cholestasis is diagnosed, it is reasonable to measure LFTs weekly until delivery
- Care will be shared between the obstetric consultant and, if suitable, outpatient care in DAU (Day Assessment Unit). Regular attendance in antenatal clinic will allow for reviews by the obstetric consultant
- Visits to DAU, 1 -2 times weekly (dependant on severity of woman's condition) will enable the client to receive continuous care and support. During each visit observations of temperature, pulse, blood pressure and urinalysis will be checked and recorded. An abdominal palpation will be performed alongside a cardiotocograph (CTG). The midwife should give the patient the obstetric cholestasis patient leaflet and various internet sites and discuss the importance of monitoring fetal movements and the possible increased risk of stillbirth
- Blood will be taken for FBC, U's &E's, LFT'S, bile salts and coagulation screen. All care to be recorded in the patient's handheld maternity records
- The obstetric registrar on call for labour ward will be able to review the client and alter the care plan if the investigations show a change in the severity of the signs and symptoms
- Menadiol (Vitamin K) 10mg orally to be administered daily from 34 weeks of gestation. Ensure Menadiol is named to ensure that the water soluble version is dispensed and issued by Pharmacy
- Intramuscular steroid injections for gestations < 37 weeks to increase surfactant levels to aid fetal lung maturity may be required for a premature delivery.

8.10 Delivery – there is insufficient evidence to support or refute the practice of induction of labour around 37 weeks gestation, aimed at reducing late stillbirth. The timing of a delivery involving cholestasis should be decided by the consultant on an individual basis.

8.11 Women should be informed of the increased risk of perinatal morbidity from early intervention (after 37+0 weeks of gestation).

8.12 Women should be informed that the case for intervention (after 37+0 weeks of gestation) may be stronger in those with more severe biochemical abnormality

(transaminases and bile acids).

8.13 Women should be informed of the increased risk of maternal morbidity from intervention at 37+0 weeks of gestation.

8.14 Women should be informed of the inability to predict stillbirth if the pregnancy continues.

8.15 Consider delivery if bile acids are more than 40mmols or above at gestational age of

37 weeks or above

8.16 Continuous CTG monitoring should be undertaken when in labour.

8.17 Women should be offered follow-up with a healthcare professional with the necessary

skills and expertise to provide appropriate counselling and to ensure that LFTs have returned to normal. The blood test should be deferred for at least 10 days, as LFT's can increase in the first 10 days after a pregnancy where obstetric cholestasis has occurred.

8.18 If the blood tests remain abnormal after the 10th day they need to be repeated 6 weeks post delivery. If the blood tests continue to be abnormal then refer to the gastroenterologist.

9.0 Staff Training

9.1 All staff should ensure that their knowledge and skills are up-to-date in order to complete their portfolio for appraisal.

9.2 All qualified midwifery staff are fully trained to take specified blood samples for investigations into cholestasis. Some Maternity Care Assistants (MCAs) are also trained to perform maternal venepuncture. Regular updates for venepuncture are available from the Practice Development Midwife. Midwifery students may undertake venepucture once they have the theoretical knowledge and while under the supervision of a midwife or Obstetrician.

10.0 Professional Midwifery Advocates

10.1 Professional Midwifery Advocates provide a mechanism of support and guidance to women and midwives. Professional Midwifery Advocates are experienced practising midwives who have undertaken further education in order to supervise midwifery services and to advise and support midwives and women in their care choices.

11.0 Infection Prevention

11.1 All staff should follow Trust guidelines on infection prevention by ensuring that they wash their hands before and after each procedure and when taking samples of blood for investigation to use the Aseptic Non-Touch Technique (ANTT).

12.0 Audit and Monitoring

12.1 Audit of compliance with this guideline will be considered on an annual audit basis in accordance with the Clinical Audit Strategy and Policy (register number 08076), the Corporate Clinical Audit and Quality Improvement Project Plan and the Maternity annual audit work plan; to encompass national and local audit and clinical governance identifying key harm themes. The Women's and Children's Clinical Audit Group will identify a lead for the audit.

12.2 The findings of the audit will be reported to and approved by the Multi-disciplinary Risk Management Group (MRMG) and an action plan with named leads and timescales will be developed to address any identified deficiencies. Performance against the action plan will be monitored by this group at subsequent meetings.

12.3 The audit report will be reported to the monthly Directorate Governance Meeting (DGM) and significant concerns relating to compliance will be entered on the local Risk Assurance Framework.

12.4 Key findings and learning points from the audit will be submitted to the Patient Safety Group within the integrated learning report.

12.5 Key findings and learning points will be disseminated to relevant staff.

13.0 Guideline Management

13.1 As an integral part of the knowledge, skills framework, staff are appraised annually to ensure competency in computer skills and the ability to access the current approved guidelines via the Trust's intranet site.

13.2 Quarterly memos are sent to line managers to disseminate to their staff the most currently approved guidelines available via the intranet and clinical guideline folders, located in each designated clinical area.

13.3 Guideline monitors have been nominated to each clinical area to ensure a system whereby obsolete guidelines are archived and newly approved guidelines are now downloaded from the intranet and filed appropriately in the guideline folders. 'Spot checks' are performed on all clinical guidelines quarterly.

13.4 Quarterly Clinical Practices group meetings are held to discuss 'guidelines'. During this meeting the practice development midwife can highlight any areas for future training needs will be met using methods such as 'workshops' or to be included in future 'skills and drills' mandatory training sessions.

14.0 Communication

14.1 A quarterly 'maternity newsletter' is issued to all staff to highlight key changes in clinical practice to include a list of newly approved guidelines for staff to acknowledge and familiarise themselves with and practice accordingly. Midwives that are on maternity leave or 'bank' staff have letters sent to their home address to update them on current clinical changes.

14.2 Approved guidelines are published monthly in the Trust's Staff Focus that is sent via email to all staff.

14.3 Approved guidelines will be disseminated to appropriate staff quarterly via email.

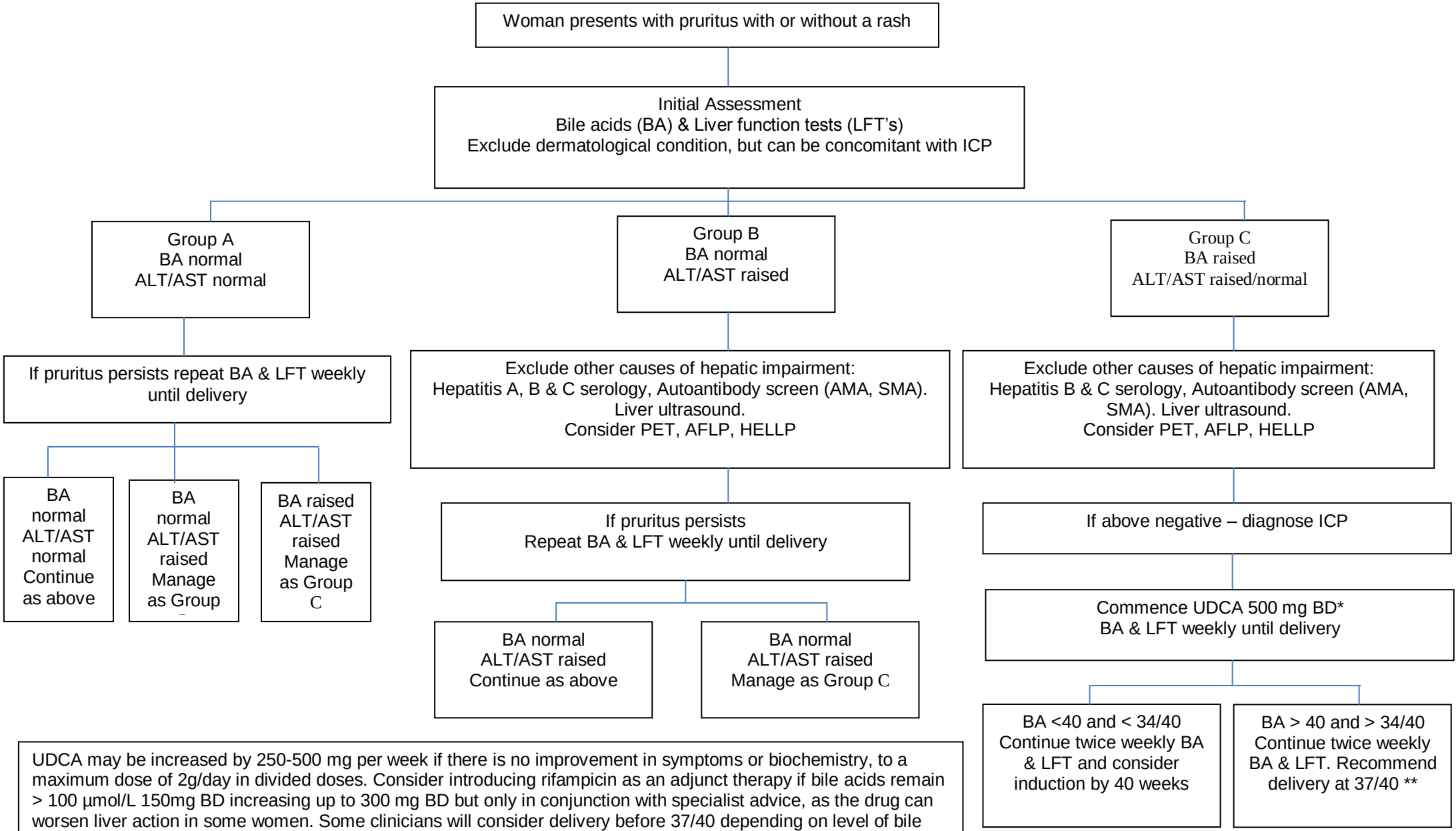
14.4 Regular memos are posted on the guideline and audit notice boards in each clinical area to notify staff of the latest revised guidelines and how to access guidelines via the intranet or clinical guideline folders.

15.0 References

Royal College of Obstetricians and Gynaecologists (2011) Obstetric Cholestasis. Green top Guidelines Guideline No. 43, April. RCOG: London

Appendix A

Flow Chart for the Diagnosis, treatment and Management of Obstetric Cholestasis



UDCA may be increased by 250-500 mg per week if there is no improvement in symptoms or biochemistry, to a maximum dose of 2g/day in divided doses. Consider introducing rifampicin as an adjunct therapy if bile acids remain > 100 µmol/L 150mg BD increasing up to 300 mg BD but only in conjunction with specialist advice, as the drug can worsen liver action in some women. Some clinicians will consider delivery before 37/40 depending on level of bile acids