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Royal Cornwall Hospitals NHS Trust

OBSTETRIC CHOLESTASIS – CLINICAL GUIDELINE FOR DIAGNOSIS AND MANAGEMENT V1.2

1. Aim/Purpose of this Guideline

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.
There is insufficient data to support or refute the practice of early (37- 38 weeks) induction of labour, aimed at reducing stillbirth (RCOG, 2011) **(New 2018).** Individual discussion should take place with the woman regarding induction of labour preferably at Consultant clinic review at 36 weeks gestation.

Offering delivery at 37 weeks of gestation is not evidence based (there is no clear causal association between OC and stillbirth) and the iatrogenic consequences of elective delivery must be considered. Early term infants (37-39 weeks gestation) and pre-term infants (34-37 weeks) are at increased risk for short-term respiratory morbidity, admission to neonatal intensive care units, as well as increased risk for lower cognitive ability **(New 2018).**

The case for early *induction of labour at* 37 weeks gestation may be stronger in those with more severe biochemical abnormality, especially Bile Acids >40 mmol/L, also consider severe maternal symptoms. Delivery decisions should not be based on biochemical 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 Patient Safety 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 Patient Safety 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 V1.2			
Date Issued/Approved:	5th April 2018			
Date Valid From:	5th April 2018			
Date Valid To:	5th April 2021			
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:	5th April 2018			
This document replaces (exact title of previous version):	OBSTETRIC CHOLESTASIS – CLINICAL GUIDELINE FOR DIAGNOSIS AND MANAGEMENT V1.1			
Approval route (names of committees)/consultation:	Maternity Guideline Group Obs & Gynae Directorate			
Divisional Manager confirming approval processes	David Smith			
Name and Post Title of additional signatories	Not Required			
Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings	{Original Copy Signed}			
	Name: Caroline Amukusana			
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			
Related Documents:	• RCOG Green Top Guideline No 43. *Obstetric Cholestasis.* 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. Obstet Med 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. Am J Perinatol 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. Am J Obstet Gynecol 1994;170:890–5. • British Medical Association, Pharmaceutical Society of Great Britain. Vitamin K. British National Formulary. London: British Medical Association, Pharmaceutical Society of • British Liver Trust. Fighting Liver Disease: Obstetric Cholestasis. 2011			

	www.britishlivertrust.org.uk/home/the-liver/liverdisease/obstetric-cholestasis.aspx
Training Need Identified?	None

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
6th 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
5th April 2018	V1.2	Section 2.10 updated	Magda Kudas Antenatal Ward manager

Appendix 2. Initial Equality Impact Assessment Form

This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.

<table>
<tr><td colspan="6">Name of Name of the strategy / policy /proposal / service function to be assessed

OBSTETRIC CHOLESTASIS – CLINICAL GUIDELINE FOR DIAGNOSIS AND MANAGEMENT V1.2</td></tr>
<tr><td colspan="3">Directorate and service area:
Obs and Gynae Directorate</td><td colspan="3">Is this a new or existing Policy?
Existing</td></tr>
<tr><td colspan="3">Name of individual completing assessment:
Magda Kudas</td><td colspan="3">Telephone:
01872 252149</td></tr>
<tr><td>1. Policy Aim*

Who is the strategy / policy / proposal / service function aimed at?</td><td colspan="5">To give guidance to obstetricians and midwives on the management of women with Obstetric Cholestasis (OC).</td></tr>
<tr><td>2. Policy Objectives*</td><td colspan="5">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.</td></tr>
<tr><td>3. Policy – intended Outcomes*</td><td colspan="5">Treatment of Obstetric Cholestasis in pregnant and newly delivered women.</td></tr>
<tr><td>4. *How will you measure the outcome?</td><td colspan="5">Data collection and audit with compliance monitoring tool.</td></tr>
<tr><td>5. Who is intended to benefit from the policy?</td><td colspan="5">Pregnant and newly delivered women with Obstetric Cholestasis.</td></tr>
<tr><td rowspan="3">6a Who did you consult with

b). Please identify the groups who have been consulted about this procedure.</td><td>Workforce</td><td>Patients</td><td>Local groups</td><td>External organisations</td><td>Other</td></tr>
<tr><td>X</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">Please record specific names of groups
Clinical Guideline Group
Obstetric and Gynaecology Directorate
Policy Review group</td></tr>
<tr><td>What was the outcome of the consultation?</td><td colspan="5">Guideline agreed</td></tr>
<tr><td colspan="6">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.</td></tr>
</table>

Are there concerns that the policy **could** have differential impact on:				
Equality Strands:	Yes	No	Unsure	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 impairment, sensory impairment, mental health conditions and some long term health conditions.		**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**

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.

No areas indicated

Signature of policy developer / lead manager / director Magda Kudas Antenatal Ward Manger	Date of completion and submission 5th April 2018

Names and signatures of members carrying out the Screening Assessment	1. Magda Kudas 2. Human Rights, Equality & Inclusion Lead	

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

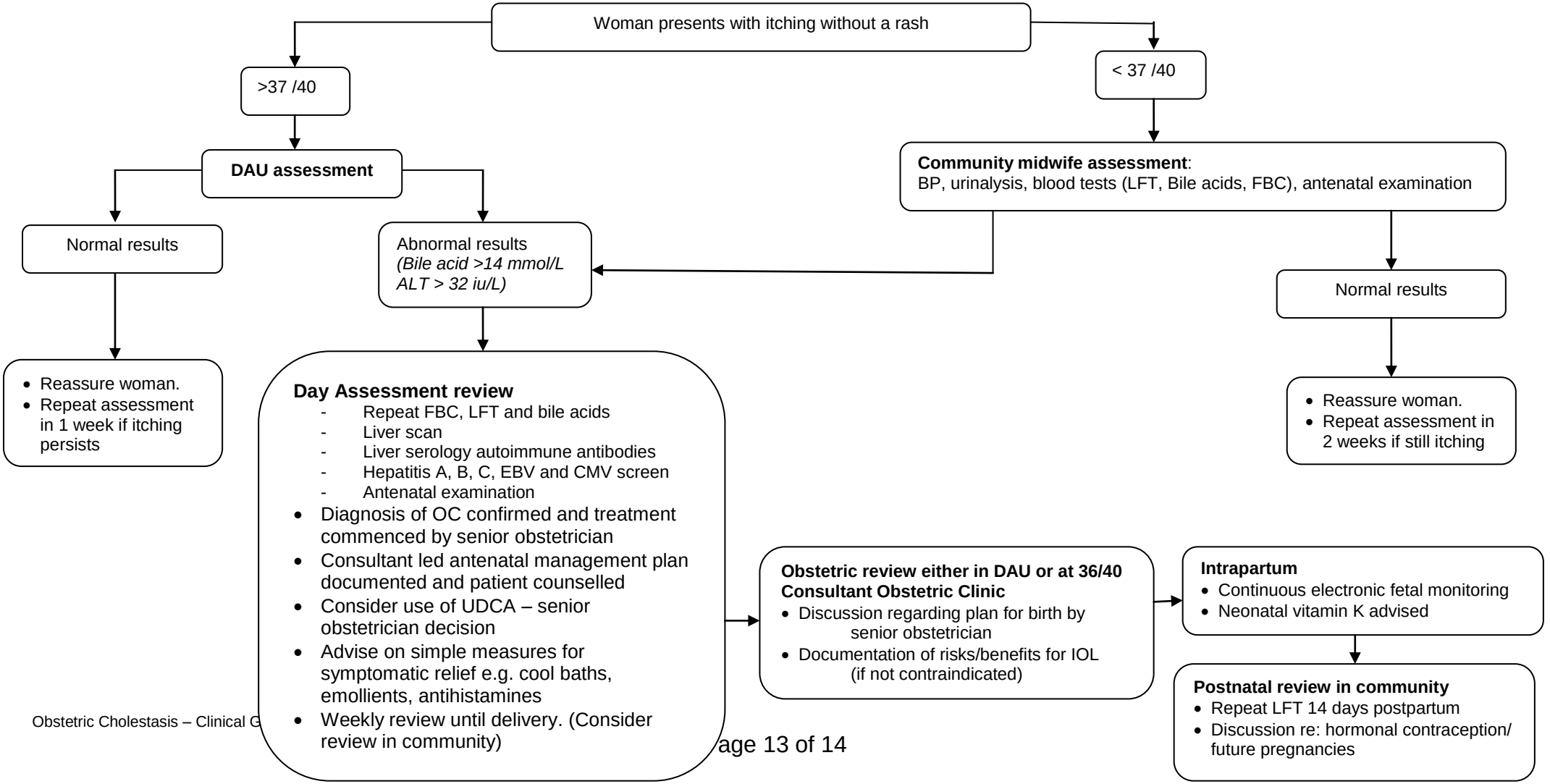
This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.

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

Signed: Sarah-Jane Pedler

Date: 5th April 2018

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: