

Intrahepatic Cholestasis of Pregnancy (ICP)

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Pruritus in pregnancy is common, affecting 23% of pregnancies, of which a small proportion will have Intrahepatic Cholestasis of Pregnancy (ICP), formerly known as Obstetric Cholestasis (OC). ICP is a multifactorial condition of pregnancy characterised by intense pruritus in the absence of a skin rash, particularly on the palms of the hands and soles especially at night. It is diagnosed with rising bile acids and / or abnormal liver function tests (LFTs), where no alternative cause is found. Symptoms and biochemical changes in ICP should both resolve after birth (RCOG 2011).

The Prevalence of ICP Is influenced by genetic and environmental aspects and varies between populations. In the UK, ICP affects 0.7% of pregnancies in multi-ethnic populations, and 1.2%–1.5% of women of Indian-Asian or Pakistani-Asian origin.^{(RCOG} 2022)

The onset of symptoms is most common in the third trimester, but can be earlier in pregnancy.⁴ Alternative diagnoses (such as pre-eclampsia) should always be considered before a diagnosis of ICP is made;(RCOG2022)

The clinical importance of this condition lies in the potential fetal risks, which may include spontaneous/ iatrogenic preterm birth, meconium stained liquor during labour and abrupt fetal death in the absence of fetal growth restriction. There can also be maternal morbidity in association with the intense pruritus and consequent sleep deprivation. (RCOG, 2011, pp.2-3) Women with ICP are more likely to have pregnancies complicated by gestational diabetes mellitus and/or preeclampsia. ICP occurs more commonly in multi-fetal pregnancy, with assisted conception, and in women of South Asian or Aracunian Indian ethnicities. In the majority of cases the hepatic impairment resolves after delivery, and where it does not, alternative pathologies should be considered. ¹

Executive Summary

- Persistent itching in pregnancy can be managed in the community setting until blood tests become abnormal.
- ICP is diagnosed with raised bile acids > 19mmol/l and /or abnormal LFT's (specifically AST and ALT)
- Additional laboratory and/or imaging investigations are not recommended unless itch is associated with atypical clinical symptoms, the presence of relevant comorbidities, or in early onset severe ICP. Consider additional postnatal investigations in women in whom resolution of abnormal liver function tests is delayed or does not occur. (RCOG 2022)
- ICP is a high-risk pregnancy and must be Consultant Led
- ICP is associated with increased fetal morbidity and mortality and maternal morbidity
- Consider discussing the care of women with severe, very early or atypical presentation of what appears to be ICP with a hepatologist.
- Confirm the diagnosis of ICP in the postnatal period at least 4 weeks after birth, with resolution of itching and liver function tests returning to normal (including bile acids). [RCOG 2022)
- Women should be informed of the 50-90% recurrent rate in subsequent pregnancies and informed to avoid oestrogen – containing contraceptives (i.e COCP) as this can precipitate similar symptoms.

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• Advise women with isolated ICP and a singleton pregnancy that the risk of stillbirth only increases above population rate once their serum bile acid concentration is 100 micromol/L or more.

• In women with peak bile acids 19–39 micromol/L (mild ICP) and no other risk factors, advise them that the risk of stillbirth is similar to the background risk. Consider options of planned birth by 40 weeks' gestation or ongoing antenatal care according

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1.0 Roles and Responsibilities:

- Midwives decision making, examination, antenatal care
- Junior Doctors decision making, examination, diagnosis, planning.
- Senior Doctor Management plan, ensure the primary investigations are done Consultant Management plan, regarding induction of labour andoverall responsibility.

2.0 Implementation and dissemination of document

This Guideline is available on the Intranet and has followed the Guideline review process prior to publication.

3.0 **Processes and procedures**

Women presenting with pruritus in pregnancy in the late second trimester or third trimester should be monitored for intrahepatic cholestasis as symptoms may present weeks before the bile acids and LFTs become abnormal.

3.1 Initial Assessment

Unexplained pruritus - The pruritus of intrahepatic cholestasis is typically worse at night on the palms of the hands and/or the soles of the feet, however can be widespread.

- Full history is needed of timing of pruritis, evidence of rash or skin changes
- Pale stools, dark urine, jaundice (symptom of significant cholestasis rare in ICP)
- Family history (genetic link with the condition)
- Personal history of liver dysfunction ie cholestasis /gallstones/Hep B/C (at increased risk)
- Liver dysfunction/itch induced by oral contraceptives
- Multiple pregnancy (increased risk)
- Drug history herbal remedies or recent antibiotics / allergic reactions (precipitate LFT rise)



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A full antenatal examination should be carried out including -

- BP, Urine analysis, SFH and FH auscultation
- Inspect skin to look for trauma due to intense itching,
- Presence of skin rashes other causes need to be ruled out.
- Assessment of fetal wellbeing, CTG need only be performed if there are concern in reduction of fetal movements

3.3 Initial Biochemical Investigations

ox 1. Liver function test reference ranges								
Biochemistry marker	Nonpregnant Pregnant		1 st trimester	2 nd trimester	3 rd trimester			
ALT (iU/L)	0 – 40	6 – 32						
AST (iU/L)	7 – 40		10 – 28	11 – 29	11 – 30			
Bilirubin (µmol/L)	0 – 17		4 – 16	3 – 13	3 – 14			
GGT (iU/L)	11 – 50		5 – 37	5 – 43	3 – 41			
ALP (iU/L)	30 – 130		32 – 100	43 – 135	133 – 418			
Bile acids (µmol/L)	0 – 10	0 – 19						

Box 1. Liver function test reference ranges

- If LFTs and bile acids are in the NORMAL range (Group 1), these blood tests should be measured two weekly until 33⁺⁶/40 and weekly from 34/40 until delivery if symptoms persist.
- If LFT's are ELEVATED but bile acids are NORMAL (<19µmol/L) (Group 2), a viral screen for hepatitis A, B, C, Epstein Barr and cytomegalovirus should be perfomed *if clinical signs and symptoms support those conditions* e.g jaundice, fever or lymphadenopathy. Liver autoimmune screening for chronic active hepatitis and primary biliary cholangitis (anti-smooth muscle and antimitochondrial antibodies), and liver ultrasound should be performed, and a clotting screen considered, for those with persistently elevated liver enzymes. Pre-eclampsia, acute fatty liver of pregnancy (AFLP), HELLP syndrome and adverse drug reactions are pregnancy specific causes of abnormal LFTs and should be remembered in the differential diagnosis. They may occur in conjunction with ICP.
- If bile acids are ELEVATED (>19 µmol/L) (Group 3), the diagnosis of ICP is most likely. Consider other liver investigations as for Group 2 where history-indicates likely alternate pathology. In all cases hepatitis C should be tested as it occurs more commonly in women with ICP.



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3.4 Consider differential diagnosis

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- Dermatological causes eg Polymorphic eruption of pregnancy or Atopic eruption of pregnancy or pemphigoid gestationalis
- Viral hepatitis, (CMV, EBV, Hep B/C), autoimmune hepatitis (primary biliary cirrhosis, primary sclerosing cholangitis) or recent common self-limiting viral infections
- Drugs Recent antibiotics / herbal remedies/ allergic reactions may cause transient rise in LFTs
- Pre-eclampsia and acute fatty liver of pregnancy

4.0 Management/ Treatment

- Consultant led care.
- Women should be given RCOG patient information leaflets
- Information regarding support groups Intrahepatic Cholestasis of Pregnancy support <u>https://www.icpsupport.org/</u>, British Liver Trust (www.britishlivertrust.org.uk)
- Inform woman regarding the association of perinatal morbidity (meconium stained liquor) / mortality (if bile acids > 100mmol/l)

General advice – lower fat intake, frequent tepid baths, to use baby soft hairbrush for itching, loose fitting cotton dress. Liberal use of menthol emollient cream and anti-histamines if these help.

The frequency and content of monitoring for women and pregnant people with ICP should be determined in conjunction with the woman or pregnant person and based on the amount of discomfort or distress they experience, bile acid concentrations, gestational age and the presence of other morbidities.(RCOG-2022)

4.1 Antenatal Care

4.1.1 Pruritus with normal LFT's and bile acids

Manage in the Community until abnormal blood results or other risk factors indicate referral to ADAU.

- Refer to ANC for next available appointment for persistent itching.
- Fortnightly Community Midwife appointment to include full antenatal check to include fetal movements / growth assessment / auscultation.
- 2 weekly bloods if <34 weeks; weekly if >34 weeks: LFT's, and Bile Acids, <u>It is the</u> responsibility of the Community Midwife taking the bloods to ensure the results are chased within 24 hours.
- Offer Topical Aqueous cream with menthol 1%, Chlorpheniramine (Piriton) 4mg up to TDS for symptomatic relief.
 Advise woman to observe fetal movements and report any concerns without delay.

4.1.2 Confirmed Cholestasis

(Pruritus with deranged LFTs and / or raised bile acids)

Refer directly to ADAU for same day Obstetric review, Maternal and Fetal wellbeing assessment and additional biochemical investigations:

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- Obstetric review and documented plan
- Bloods to rule out differential diagnosis to include:
 - Virology screening (Hepatitis A, B, C and Epstein Barr Virus (EBV) and Cytomegalovirus (CMV)

 \circ Liver autoimmune screen for chronic active hepatitis and primary cirrhosis (anti smooth muscle and anti-mitochondrial antibodies) \circ Arrange Liver ultrasound scan

- Arrange Antenatal Clinic Appointment for Consultant Led Care
- Weekly appointments in ADAU from 34 weeks for a full antenatal check, and bloods to include LFT and Bile Acids +/- FBC and +/- clotting screen
- For women <34 weeks, ADAU appointments can be 1-2 weekly depending on Bile Acids and LFTs.
- CTG only if concerns with fetal movements.

The subsequent frequency at which women and pregnant people have biochemical assessment will be determined on an individual basis and according to the impact that the result might have on further care :

• If the woman has mild ICP with peak bile acids 19–39 micromol/L, they could have weekly testing as they approach 38 weeks' gestation in order to inform timing of birth.

• If the woman has moderate ICP with peak bile acid 40–99 micromol/L, especially if they are approaching 35 weeks' gestation, weekly testing should be considered, as timing of birth may be influenced if levels rise to 100 micromol/L or more.

• If the woman has severe ICP with peak bile acid 100 micromol/L or more, further routine testing of bile acids might not impact on decision making and therefore may not be routinely required. *(RCOG-2022)*

In ICP, there is evidence that cardiotocography (CTG) monitoring or biophysical profile do not predict stillbirth.

ICP is not associated with fetal growth restriction, with no difference in birthweight centiles compared with babies born to women without ICP,^I and therefore strategies for antenatal monitoring for placental insufficiency are unlikely to be beneficial in women with isolated ICP. *[Evidence level 3]*

All pregnant women and pregnant people should be advised to monitor the quality and quantity of their fetal movements, and report any reduction or change to their local maternity unit immediately, as recommended in national guidance. ¹ Maternal detection of movements is simple and not time consuming for women or staff, but its specific role in monitoring pregnancies complicated by ICP has not been assessed.

4.1.3 Treatment

The role of drug treatment in ICP is to try to reduce maternal itching (which may be of variable intensity and is unrelated to bile acid concentrations). There is no evidence that routine medical treatment improves maternal raised bile acid concentrations or perinatal .(RCOG-2022)

• Offer Topical Aqueous cream with menthol 1%, Chlorpheniramine (Piriton) 4mg up to TDS for symptomatic relief.

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- Ursodeoxycholic acid (UDCA), 250mg BD up to 500mg Max dose 2g/day can be considered after careful discussion with the woman. The medication is unlicensed in pregnancy and long term outcomes on the fetus are not yet known. (Rationale – It is a water-soluble bile acid given for easy elimination of bile acids from the body as it replaces endogenous fat-soluble bile acid.) For some women, it can be offered for symptomatic relief of itching, however the PITCHES trial (ursodeoxycholic acid v placebo) demonstrated that most women did not benefit from UDCA; and there is no proven protective effect for the fetus.
- Please discuss with Maternal Medicine consultant if concerned.
- If prescribed: starting dose is 250 mg BD with 250–500 mg increments if no improvement in symptoms or biochemistry, to a maximum dose of 2 g/day in divided doses.
- Vitamin K 10mg once a day may be considered with very high transaminitis, and abnormal clotting screen.
- Women with persistently high bile acids (>100 mmol/l) should be urgently referred to Maternal medicine clinic for consideration of commencing Rifampicin in combination with ursodeoxycholic acid.

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- UDCA is not licensed for use in pregnancy and women should be informed of the lack of robust data concerning treatment for itching and protection against stillbirth and safety to the fetus or neonate (RCOG), however there are no reports of adverse maternal or fetal effects. (RCOG, 2011, p.8)

Women should be informed that Peak total bile acid concentrations were associated with stillbirth risk, whether or not women were taking ursodeoxycholic acid. *Ovadia, C., et al.* (2019) Association of adverse perinatal outcomes of intrahepatic cholestasis of pregnancy with biochemical markers: results of aggregate and individual patient data meta-analyses. The Lancet [Online] 393(10174), pp.899-909

4.2 Decision for birth

- Consultant led care in antenatal clinic
- Discuss indications and timing of induction of labour (IOL) for women with ICP.
- Where Bile acids > 100mmol/l at ANY POINT during pregnancy, sudden intra-uterine death can
 present from 35-36 weeks (Ovadia et al); discussion and offer of induction from 34-36 weeks on
 a case by case basis in a Maternal Medicine Clinic. These women may also need twice weekly
 bloods to monitor the bile acids.
- Consider options of planned birth by 40 weeks' gestation or ongoing antenatal care according to national guidance in women with mild ICP (peak bile acids 19– 39 micromol/L) and no other risk factors; advise women that the risk of stillbirth is similar to the background risK
- Consider planned birth at 38–39 weeks' gestation in women with moderate ICP with peak bile acids 40–99 micromol/L and no other risk factors; advise them that the overall risk of stillbirth is similar to the background risk until 38–39 weeks' gestation.
- Consider planned birth at 35–36 weeks' gestation in women with severe ICP with peak bile acids 100 micromol/L or more; advise them that the risk of stillbirth is higher than the background risk.



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- Advise women that the presence of co-morbidities (such as gestational diabetes, preeclampsia, multifetal pregnancy) appear to increase the risk of stillbirth and may influence decision-making around timing of planned birth
- Women with bile acids <100 mmol/l, can be reassured that the risk of stillbirth is similar to background risk in the pregnant population, provided repeat bile acid testing is done until delivery. Offer induction of labour from 38-39 weeks.

See appendix flow chart 2 ICP Support (2020) *Guideline for managing ICP* [Online]. Available from: <u>https://www.icpsupport.org/protocol.shtml</u>

4.3 Intrapartum Care

- Obtain IV access, FBC, group and save (ensure up to date LFT and bile acids, consider clotting profile)
- Continuous fetal monitoring should be offered
- Active management for 3rd stage prophylactically as increased risk of Postpartum Haemorrhage (risks range from 2-22%)
- Offer continuous electronic fetal monitoring (CEFM) to women with peak bile acids 100 micromol/L or more.
- There is insufficient evidence for or against CEFM in women with peak bile acids below 100 micromol/L. A shared decision can be made based on co-morbidities and preferences.(RCOG2022)
- Advise women that the presence of risk factors (such as gestational diabetes, preeclampsia, multifetal pregnancy) appear to increase the risk of adverse perinatal outcomes and that these conditions themselves may necessitate monitoring during birth or in conjunction with ICP may influence decision-making around monitoring in labour.(RCOG 2022)
- Advise women that meconium-stained liquor is more common in moderate and severe ICP, and that this will influence decision-making around CEFM.(RCOG2022)

4.4 Post Natal Care

- Vitamin K should be given to neonate (as per guideline Vitamin K prophylaxis in newborn babies) Explain the risks in future pregnancies (45-90%) (RCOG, 2011, p.10)
- Avoid using oestrogen containing oral contraceptives.
- LFTs and bile acids to be repeated at 10 days by CMW and 6 weeks postnatal by GP to ensure LFT's are returning to normal levels.

Perform a baseline liver function test and bile acid concentration with booking blood investigations



5.0 Statement of evidence/references

British Liver Trust. Intrahepatic Cholestasis of Pregnancy (ICP). *British Liver Trust*. [Online] <u>https://britishlivertrust.org.uk/information-and-support/living-with-a-liver-condition/liver-conditions/obstetric-cholestasis/</u> [Accessed 25 February 2020]

Chappell, L.C., et al. (2019) Ursodeoxycholic acid versus placebo in women with intrahepatic cholestasis of pregnancy (PITCHES): a randomised controlled trial. *The Lancet* [Online] 394(10201), pp.849-60. Available from: <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)31270-X/fulltext</u> [Accessed 25 February 2020]

Geenes, V., et al. (2015) Rifampicin in the treatment of severe intrahepatic cholestasis of pregnancy. *European Journal of Obstetrics & Gynecology and Reproductive Biology* [Online] 189, pp.59-63. Available from: https://www.clinicalkey.com/?auth_type=SHIBBOLETH#!/content/journal/1-s2.0-S0301211515001001 [Accessed 25 February 2020]

Gurung, V., et al. (2013) Interventions for treating cholestasis in pregnancy. *Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No.: CD000493. DOI: 10.1002/14651858.CD000493.pub2. Available from: <u>https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000493.pub2/full</u> [Accessed 25 February 2020]

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National Institute for Health and Care Excellence (2015) *Itch in pregnancy*. Clinical Knowledge Summary. [Online]. Available from: <u>https://cks.nice.org.uk/itch-in-pregnancy</u> [Accessed 25 February 2020]

Ovadia, C., et al. (2019) Association of adverse perinatal outcomes of intrahepatic cholestasis of pregnancy with biochemical markers: results of aggregate and individual patient data metaanalyses. *The Lancet* [Online] 393(10174), pp.899-909. Available from: <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31877-4/fulltext</u> [Accessed 25 February 2020]

Royal College of Obstetricians & Gynaecologists (2011) *Obstetric cholestasis*. Green-top Guideline No.43. 3rd ed. [Online]. Available from: <u>https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg43/</u> [Accessed 01 Dec 2022]

Royal College of Obstetricians & Gynaecologists (2012) *Obstetric cholestasis*. Patient information leaflet. [Online]. Available from: <u>https://www.rcog.org.uk/en/patients/patient-leaflets/obstetric-cholestasis/</u> [Accessed 25 February 2020]



6.0 Governance

Version number: 1

Section

6.1 Record of changes to document

Amendment

t Date: 27.4.17 Deletion Addition Reason				
		Deletion	Addition	Reason
		Date: 27	.4.17	
	t			

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Number	Amenument	Deletion	Addition	Reason
Appendix 1	Flowchart added			Simplify process
1.3	Change of Bile Acid parameters from 12µmol to 14µmol in line with British Liver Trust Guidance			Evidence based parameters
2	Faryal Nizami/Joyce Elliott/Anja Johansen-Bibby			Complete review
Version 3	Anja Johansen-Bibby		 Induction of Labour changes Monitoring changes Frequency of bile acid blood sample changes 	Complete review of document
3.1	Updated in line with RCOG guidance update		who gets full liver screen and timing of birth	12/2022

6.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
Julie cooper	Head of midwifery				
Manish Nathwani	Pharmacy	01/2021	12/2020	Yes	Yes
Consultants					
Registrars/SHO					
Maternity Guideline Review Group		25/08/2021	25/08/2021	Flowchart required	Yes
Women's Health CIG		01/09/2021	01/09/2021	Approved	N/A



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6.3 Audit and monitoring

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This Guideline outlines the process for document development will be monitored on an ongoing basis. The centralisation of the process for development of documents will enable the Trust to audit more effectively. The centralisation in recording documents onto a Quality Management database will ensure the process is robust.

Audit/Monitoring Criteria	ΤοοΙ	Audit Lead	Frequency of Audit	Responsible Committee/Board
Number of women with a case of diagnosed intra- hepatic cholestasis.		ADAU	Annually	
Perinatal outcome of cases of ntra-hepatic cholestasis.				
Gestational age at delivery. Percentage of women receiving documentation of appropriate counselling.				
Percentage of women with postnatal follow-up completed. Percentage of women offered hospital follow-up.				
Percentage of women with iatrogenic delivery for ntra- hepatic cholestasis at less than 37 weeks of gestation.				
Percentage of women receiving documentation of risks and benefits of UDCA.				
Percentage of women with appropriate investigations performed before confirmation of diagnosis.				
Documentation of appropriate counselling.				

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5.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

	E	quali	ty Impact As	sessmen	t		
Division	Women and children				Department	Maternity	
Person completing the Eql	qIA Erica Puri				Contact No.		
Others involved:	yes				Date of assessment:	02/2021	
Existing policy/service	yes				New policy/service	No	
Will patients, carers, the public be affected by the policy/set		aff Yes					
If staff, how many/which gro affected?	oups will	be	All staff				
Protected characteristic		Any ii	mpact?	Comme	nts		
Age			NO		impact as the policy aims		
Disability		NO		-	recognise diversity, promote inclusion fair treatment for patients and staff		
Gender reassignment		NO			inent for patients and s	blall	
Marriage and civil partner	ship	NO NO NO NO NO NO					
Pregnancy and maternity							
Race							
Religion or belief							
Sex							
Sexual orientation		NO					
What consultation method(s) have y	/ou ca	rried out?				
meetings							
How are the changes/amer	dments	to the	policies/serv	ices comn	nunicated?		
Email and meetings							
What future actions need to be taken to overcome any barriers or discrimination?							
What? Wh	hat? Who will lead this? Dat				Resources nee	eded	
Review date of EqIA							



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Appendix 1: Flowchart



normal

Appendix 2 - ICP Support (2020) Guideline for managing ICP





Woman presents with pruritus, with or without a rash, or if ICP suspected Initial assessment Non-fasting BA & liver blood test (also known as liver function test)



Consider other causes of hepatic impairment: Maternal diseases that may present with ICP include HCV, AIH and extrahepatic biliary obstruction (requires liver USS) Consider PET, AFLP, HELLP, CMV If pruritus persists, repeat BA & liver blood test every two weeks < 34/40 and then weekly until birth

> BA normal ALT/AST raised Continue as above

BA raised ALT/AST raised Manage as Group C









