HYWEL DDA UNIVERSITY HEALTH BOARD

Management of Intrahepatic Cholestasis of Pregnancy (ICP) Guideline

Guideline information

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07/10/2028

Summary of document:
Clinical guideline to provide evidence-based management of women with Intrahepatic Cholestasis of Pregnancy.

Scope:
This guideline is for the use of healthcare professionals when providing care for women with Intrahepatic Cholestasis of Pregnancy (ICP).

The guidance uses the term “woman” (pronouns she or her) or Mother to describe individuals whose sex assigned at birth was female, whether they identify as female, male or non-binary. It is important to acknowledge it is not only people who identify as women for whom it is necessary to access women’s

health and reproductive services. Therefore, this should include people who do not identify themselves as women but who are pregnant or have recently given birth. Obstetric and midwifery services and delivery of care must therefore be appropriate, inclusive and sensitive to the needs of those individuals whose gender identity does not align with the sex that they were assigned at birth.

To be read in conjunction with:
667 Induction of Labour Guideline - opens in a new tab
813 Continuous Intrapartum Fetal Monitoring Guideline - opens in a new tab
621 Hypertensive Disorders in Pregnancy guideline - opens in a new tab
632 Care of women with Diabetes in pregnancy guideline - opens in a new tab

Patient information:
https://www.rcog.org.uk/media/xzwha1lm/intrahepatic-cholestasis-ofhttps://www.rcog.org.uk/media/xzwha1lm/intrahepatic-cholestasis-of-pregnancy-patient-information-leaflet.pdfpregnancy-patient-information-leaflet.pdf

Owning group: Maternity Guideline, Audit and research Group

Executive Director job title: Andrew Carruthers, Chief Operating Officer.

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1 – New guideline – 22.8.2022
5 – Updated – 07.10.2025

Keywords: ICP, Intrahepatic, Cholestasis, Pregnancy

Glossary of terms

ALT	Alanine Aminotransferase
AST	Aspartate Transaminase
BA	Bile Acids
CTG	Cardiotocograph
CEFM	Continuous Electronic Fetal Monitoring
ICP	Intrahepatic Cholestasis of Pregnancy (previously known as : Obstetric Cholestasis
LFT	Liver Functions Test
RCT	Randomised Controlled Trial
Steatorrhea	Excessive amounts of fat in faeces. Stools tend to be looser, smellier and paler in colour, like clay. They might float.
UDCA	Ursodeoxycholic Acid
UK-MEC	UK- Medical Eligibility Criteria for contraception use

Contents

Scope
This guideline is for the use of healthcare professionals when providing care for women with Intrahepatic Cholestasis of Pregnancy (ICP).

Aim
To give guidance to obstetricians and midwives on the diagnosis and management of women with intrahepatic cholestasis of pregnancy, and the maternal and fetal risks of intrahepatic cholestasis of pregnancy (ICP), previously called obstetric cholestasis.

Objectives
The aim of this document will be achieved by the following objectives:

- Provide a clear pathway for the management of women who are diagnosed with ICP based on the latest available evidence

Introduction
Pruritus is common in pregnancy with around 25% of pregnant women develop itching of which a small proportion will have Intrahepatic cholestasis of pregnancy.

The prevalence of ICP varies by population and is influenced by genetic and environmental factors. In the UK ICP affects7:1000 pregnancies (0.7%) and is more common in Indian – Asian Indians and Pakistani women where it affects 12-15:1000 (1.24% and 1.46%) respectively.

ICP is characterised by the presence of an unexplained itching (pruritus), typically worse on the palms and soles during the night , varies in intensity, usually no rash (excoriations only) and raised bile acid (BA) concentration of 19 micromol/L or more.

The onset of symptoms is most common in the third trimester but can onset earlier in pregnancy. The diagnosis of ICP requires elevated maternal BA concentrations, and women with itching and isolated raised transaminases alone (with normal BA concentrations) should not be given a diagnosis of ICP. The intensity of a woman's itching is not associated with the level of BA concentrations.

Potential fetal risks may include spontaneous preterm birth and iatrogenic preterm birth, meconium-stained liquor, fetal distress, delivery by caesarean section and stillbirth. Women with ICP have a higher chance of developing pre-eclampsia or gestational diabetes.

The risk of stillbirth associated with ICP is only in cases in which the peak Bile Acid levels exceed 100 micromol/L at any point in pregnancy.

There is no association between increases in ALT / AST and stillbirth in ICP regardless of the increase.

Pathway for Referral
Pregnant women with itching in the second and third trimesters of pregnancy without a rash will be suspected to have ICP and should be assessed in triage/ Day assessment.

If a woman phones the maternity unit reporting itching in pregnancy, she should be invited in for assessment and consideration of blood tests. This should be at a convenient time but will usually be within 2-3 days.

A structured history and examination should be taken to consider other potential diagnosis i.e. pre-eclampsia, drug reactions, allergic reactions and urticarial.

History to include:
• Pattern of itching.
• Change in stools/urine/skin colour.
• Family history or personal history of cholestasis (or gallstones).
• Multiple pregnancy and Hepatitis C (earlier onset before 26 weeks).
• Drug history- herbal remedies or recent antibiotics.

Alternative diagnosis (such as pre-eclampsia) should always be considered before a diagnosis of ICP is made, it is possible for other conditions to co-exist.

Women less than 20 weeks' gestation with itching and no rash, the community midwife should arrange taking of Bile acids and liver function tests and refer into ANC if results are abnormal

Terminology to describe the condition

Peak bile acid concentrations refer to the highest BA concentration recorded during a woman's pregnancy which means that a woman's diagnosis may progress in severity during pregnancy.

The upper limit of normal bile acid concentrations in pregnancy is 18 micromol/l

Diagnosis	Clinical Features
Gestational Pruritus	Itching and peak bile acid concentrations ≤18 micromol/L
Mild ICP	Itching and raised peak bile acid concentrations 19–39 micromol/L
Moderate ICP	Itching and raised peak bile acid Concentrations 40–99 micromol/L
Severe ICP	Itching and raised peak bile acid Concentrations ≥100 micromol/L

Diagnosis of ICP

- Raised Bile acid concentration of **19 micromol /L or more**, and itching in skin of normal appearance supports a diagnosis of ICP

- In women with persistent itch, normal skin and normal blood results an initial diagnosis of gestational pruritus should be considered.

- Women with itching, raised transaminases and **normal** bile acids (BA less than 19micromol) should not be given a diagnosis of ICP.

Women with itch, no rash and normal Results

ICP can develop in these women up to 15 weeks after a diagnosis of gestational pruritus. As pruritus often precedes biochemical changes if itching continues in women with normal bile acids, repeat blood tests they should be offered review and repeated LFTs and bile acids every two weeks. They may need to be more frequent later in the 3rd trimester when an ICP diagnosis may alter care i.e. plan for birth.

Resolution of Itching and blood results normalisation.

During pregnancy if resolution of itching is associated with **normalisation** of BA and LFTs, the diagnosis of ICP is unlikely to be correct. In clinical practice, diagnoses should be reconsidered if the clinical presentation changes, other causes included drug reactions (e.g. to antibiotics or non-specific viral illnesses).

Note. When considering of returning women to low-risk care pathways caution must be used if peak Bile levels was equal to or above100 micromol/l at any time.

Additional Investigations

Additional laboratory and/or imaging investigations are not recommended in every woman but could be considered on an individual basis.

Consider antenatal testing e.g. liver ultrasound, virology, autoimmune bloods **if** there are atypical clinical symptoms.

These may include:

1) Women with markedly elevated transaminases.
2) Early onset of ICP in the first or second trimester.
3) A rapidly progressive biochemical picture.
4) Any features of liver failure.
5) Evidence of acute infection.
6) If resolution does not occur after birth.

Consider discussing the care of women with severe, very early or atypical presentation of what appears to be ICP with a hepatologist.

Antenatal Monitoring and Management

- Women with ICP should be reviewed within a consultant-led maternity unit.

- Non fasting bile- acid has been shown to improve the diagnostic accuracy of ICP diagnosis. (Mitchell 2021) Recommend woman eat 30 mins -120 mins before test.

- All women with itch and an initial raised bile acid level, should have a second bile acid measurement repeated around 1week later before any diagnostic or care decisions are

determined, as it is common for women with bile acid levels over 100micromol/L and 40–100micromol/L to have subsequent bile acid concentrations that are much lower.

- At every monitoring appointment for ICP, monitoring for signs of pre-eclampsia should also be performed (BP, urinalysis, routine assessment of fetal wellbeing).

- Additional testing for gestational diabetes is **not** currently recommended; risk assessment and testing for gestational diabetes should follow Hywel Dda guidelines.

- The intensity of a woman's itching is not associated with the level of BA concentrations.

- In the absence of other risk factors or clinical indications do not offer CTG nor USS to predict or prevent stillbirth in ICP.

- Advise all women with ICP to monitor fetal movements and present for immediate assessment if they have any concerns

- For women with ICP, subsequent timing of bloods are performed whilst considering whether timing of birth will be influenced if levels increase

Bile Acid Level (micromol/L)	Classification	Monitoring Frequency
19-39	Mild	Weekly BA levels from 35-40 weeks in order to inform timing of birth
40-99	Moderate	Weekly BA levels from 32-38 weeks- timing of birth will be influenced if levels rise to 100micromol/l or more
100 or more	Severe	Further routine testing of bile acids might not impact on decision making and therefore may not be routinely required

Maternal and Perinatal Risks

- Advise women with isolated ICP and a singleton pregnancy that the risk of stillbirth only increases above population rate once their Bile acid concentrations are 100 micromol/L or more.

- In women with **mild ICP** and no other risk factors, advise them that the risk of stillbirth is similar to the background risk.

- In women with **moderate ICP** and no other risk factors, advise them that the risk of stillbirth is similar to the background risk until 38–39 weeks' gestation.

- In women with **severe ICP**, advise them that the risk of stillbirth is higher than the background risk

Table 1 below, confers risk of stillbirth correlating to bile acid levels up to a gestation of 39 weeks. No evidence is available for risk of stillbirth beyond 39 weeks.

Table 1

	Peak bile acid concentrations	Prevalence of stillbirth	Absolute numbers of stillbirths
National UK stillbirth rate from 28 weeks (2015)		**0.29%**	
Mild ICP	19–39 micromol/L	**0.13%** (0.02 0.38%	3/2310
Moderate ICP	40–99 micromol/L	**0.28%** (0.08 0.72%)	4/1412
Severe ICP	≥100 micromol/L	**3.44%** (2.05 5.37%)	18/524

The presence of risk factors or co-morbidities and ICP such as gestational diabetes and/or pre-eclampsia and/ or multiple pregnancy, appear to increase the risk of stillbirth and may influence decision-making around timing of planned birth.

Treatment options for Management:

There are no treatments that improve pregnancy outcome (or raised BA concentrations). Any treatments offered are to improve maternal discomfort i.e. itching and are of limited benefit.

Drug	Action	Recommended
Topical emollients - aqueous cream (with or without menthol added) e.g. Dermacool 1% cream, twice per day	May relieve some discomfort caused by itch	Yes
Antihistamine – Chlorphenamine 4 mg PO every 4-6 hrs, max 24 mg/day or Loratadine (non-sedative) 10mg PO OD	Sedating antihistamine – particularly at night relief may be more from sedating effect	Yes
Ursodeoxycholic Acid (UDCA)	In some women with BA >40micromol/L, who are 34-36 weeks, UDCA may offer some	**Do not** routinely offer UDCA (Ursodeoxycholic Acid) for the purpose of reducing adverse

	benefit in reducing late preterm birth. Does not reduce adverse perinatal outcomes. Only very small reduction in itching (less than 5%).	perinatal outcomes in women with ICP.
Vitamin K Menadiol sodium phosphate PO 10mg day		**Only consider** in women with steatorrhea and /or have had a coagulation assessment with abnormal prothrombin time.

Timing and Mode of birth

Advise women that ICP in itself does not impact their choice around mode of birth and that these decisions should be based on usual obstetric practice for that woman.

Timing of Birth

NOTE: The Timing of birth is determined by the Peak (i.e. highest) Bile acid Concentration recorded in pregnancy.

Severity	Timing of birth	Risk of stillbirth
Mild ICP Peak Bile Acid 19-39 micromol/l with **no** other risk factors	Consider planned birth by 40^{+0} weeks' gestation or ongoing antenatal care according to national guidance	No increase in SB risk secondary to ICP i.e. similar to the background risk (0.29%)
Moderate ICP Peak Bile Acid 40-99 micromol/l with **no** other risk factors	Consider planned birth at $38–39^{+0}$ weeks' gestation	similar to the background risk until 38–39 weeks' gestation
Severe ICP Bile acid >100 micromol/L with **no** other risk factors	Consider planned birth at $35–36^{+0}$ weeks' gestation	Higher than the background risk (3.44%)
ICP BA ≥40 **with risk factors/ comorbidities** e.g. multiple pregnancy, GDM or Pre-eclampsia.	Individualised plan from consultant determining time of birth	Higher than the background risk

Intrapartum Care

- Offer continuous electronic fetal monitoring (CEFM) to women with peak Bile acids of 100micromol/L or more (severe ICP)

- Mild and Moderate ICP does not require CTG, therefore, birth in low-risk setting is not contraindicated.

- The presence of may influence the use of continuous CTG in women with peak Bile Acids below 100 – but in isolation bile acids below 100 is not an indication for a continuous CTG.

- Advise women that the presence of risk factors/co-morbidities (such as gestational diabetes, pre-eclampsia, 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.

- Meconium-stained liquor is more common in moderate and severe ICP, and that this will influence decision-making around CEFM

- Offer women with uncomplicated ICP standard analgesia and anaesthesia options for birth.

- There is no increased risk of postpartum haemorrhage associated with uncomplicated ICP

Postpartum Care

- Postnatally in ICP, resolution of itching and the returning to normal range of bile acid concentrations and other liver function results should occur within 4 weeks after birth. Persistently elevated levels may point to other diagnosis.

- On discharge document include GP request for follow up at least 4-6 weeks after birth to confirm resolution of ICP (resolution of itching and normalisation of LFT and BA)
  Ensure that woman is given a blood form requesting Bile acids and LFT dated for after 4 weeks after birth follow-up.

- Advise women with a history of ICP that they have an increased chance of recurrence of ICP in subsequent pregnancies (precise magnitude of this is unclear).

- Perform a baseline LFTs and BA concentration with booking blood investigations **in the next pregnancy**

Postnatal Contraception

- Women with ICP (UKMEC 2) can use combined hormonal contraception provided they do not also have a history of contraception related cholestasis. Resolution of itching and LFTs and BA concentrations returning to normal levels should be confirmed before commencing this method.

- If itching or biochemical abnormalities persist beyond 6 weeks postpartum, consideration of other diagnoses would be required depending upon the history and examination findings e.g. non-alcoholic fatty liver. Referral to a hepatologist may be required.

- For women with an atypical presentation of ICP, atypical postnatal clinical course, where other diagnoses are suspected, or where itching and LFTs have not resolved, a personalised approach to contraceptive choice would need to be undertaken, with provision of information about avoidance of pregnancy with active liver disease

- While using combined hormonal contraception if recurrence of itch occurs then advise women to attend for review with their GP. This could indicate a diagnosis of contraceptive-related cholestasis (UKMEC 3) and alternative contraception options would need to be discussed..

Links and Support Groups

Information for healthcare professionals
Maternal use of medication in pregnancy (UK Teratology Information Service)
http://www.uktis.org/html/maternalexposure.html

Information for women and families
For women regarding medication in pregnancy *BUMPS* website:
Bumps - Best use of medicines in pregnancy -opens in a new tab.

RCOG *Intrahepatic Cholestasis of Pregnancy*. Information for you
Intrahepatic cholestasis of pregnancy | RCOG -opens in a new tab.

Research based charity and support group ICP Support
http://www.icpsupport.org

Information for women and their families on use of medicines in pregnancy
http://www.medicinesinpregnancy.org

Auditable Standards

- Proportion of women with raised bile acid concentrations offered timing of birth in line with RCOG Green-top Guideline. (>90%)
- Proportion of women with uncomplicated raised bile acid concentrations having additional investigations routinely performed. (<10%)
- Proportion of women with raised bile acid concentrations offered ursodeoxycholic acid in line with RCOG Green-top Guideline. (<5%)
- Proportion of women with severe ICP (peak bile acids ≥100 micromol/L) offered continuous electronic fetal monitoring during labour. (>90%)

These targets have been set in recognition of the need for individualised care particularly in women with comorbidities and atypical ICP.

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- UK Medical Eligibility Criteria Category 2 (UKMEC2)

https://www.fsrh.org/Common/Uploaded%20files/Standards-and-Guidance/fsrh-ukmec-full-book-2019.pdf