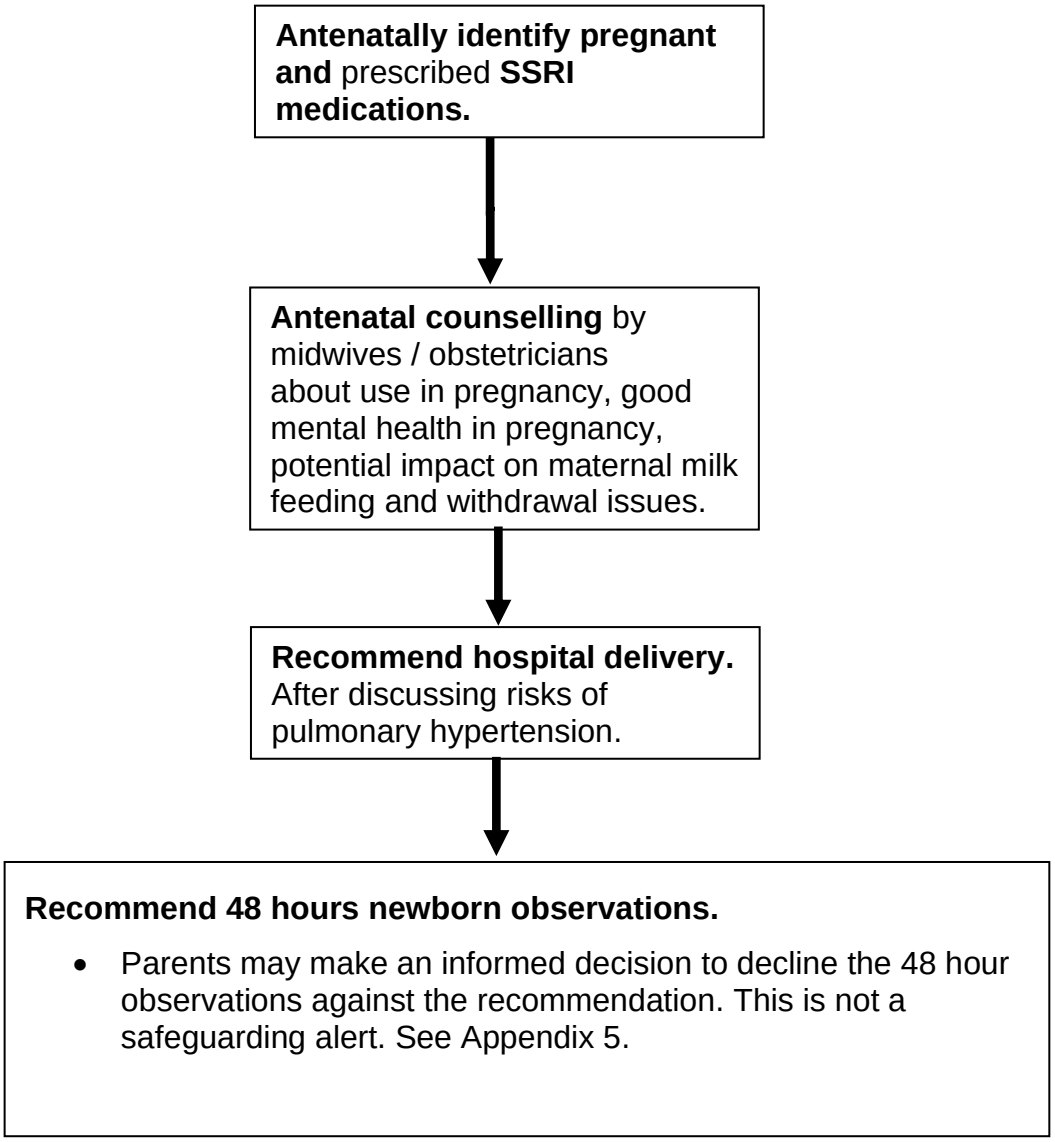
Royal Cornwall Hospitals
NHS Trust

Maternal Use of SSRIs Neonatal Clinical Guideline

V4.1

July 2024

Summary


Antenatally identify pregnant and prescribed **SSRI medications.**
Antenatal counselling by midwives / obstetricians about use in pregnancy, good mental health in pregnancy, potential impact on maternal milk feeding and withdrawal issues.
Recommend hospital delivery. After discussing risks of pulmonary hypertension.
Recommend 48 hours newborn observations.
• Parents may make an informed decision to decline the 48 hour observations against the recommendation. This is not a safeguarding alert. See Appendix 5.

1. Aim/ Purpose of this Guideline

1.1. To provide guidance on management of neonates exposed antenatally to maternal selective serotonin reuptake inhibitors (SSRIs) e.g., fluoxetine, and related drugs - selective noradrenaline reuptake inhibitors (SNRIs), e.g., venlafaxine and specific serotonergic antidepressants (NaSSA's) e.g., mirtazapine. All drugs will now be described under SSRIs.

1.2. Medications not listed in this guideline or the Neonatal Abstinence Syndrome guideline, do not routinely require monitoring observations.

1.3. Aimed at midwifery and neonatal staff.

1.4. This version supersedes any previous versions of this document.

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

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2. The Guidance

Background:

Depression occurs in 7-15% of all pregnancies and is an important perinatal factor affecting neonatal outcome[1]. SSRIs are the commonest prescribed pharmacological treatment for depression and anxiety in pregnancy[1]. Neonatal abstinence syndrome has been shown to occur in up to 30% of infants exposed to SSRIs in the third trimester of pregnancy[2].

2.1. Adequate treatment of perinatal depression has important consequences for both mother and infant. Undertreated maternal depression is associated with perinatal complications including prematurity and low birth weight. It is therefore vital that the mother has appropriate support and treatment.

2.2. SSRIs and related drugs in pregnancy show no clear association with congenital abnormalities with a debatable small increased risk of congenital heart defects[1]. Neonatal withdrawal (or poor neonatal adaptation syndrome (PNAS)) commonly includes tremors, jitteriness, irritability, muscle tone abnormalities, excess crying, sleep disturbance, tachypnoea and feeding problems[1]. Less commonly lethargy, weak cry, hypoglycaemia and convulsions[1].

2.3. Symptoms generally occur within 2 days after birth (occasionally not until days 5-7) and may persist for 2-4 weeks[1].

2.4. There is an association of late perinatal exposure to SSRIs and persistent pulmonary hypertension of the newborn (PPHN) [1, 3]. A recent large study suggests that there is an increased risk, but that the absolute risk is small[6]. This is a serious condition but if recognized and treated early can have a good outcome.

2.5. **Effects during lactation.**

SSRIs are excreted into breast milk, with great variability depending upon individual drugs, maternal dose and the infant's metabolism. **Breast feeding is not discouraged** however, the majority of manufacturers have not conducted clinical trials on the use in lactation and in the "Summary of Product" characteristics recommend that they are not used by breastfeeding mothers.

Of the SSRI's, fluoxetine is present in breast milk in the highest amounts compared to the other drugs in this group and is best avoided. Citalopram also appears in breast milk in relatively high levels and, together with limited data on adverse effects, is best avoided. However, if these agents have been taken during the pregnancy it is commonly acceptable to breastfeed. The breastfed infant should be monitored for behavioural side effects such as colic, agitation, irritability, poor feeding, and poor weight gain, although be aware that similar symptoms may also be displayed by the infant as result of withdrawal in the immediate post-partum period.

2.6. **Practical guidance- antenatal.**

Management of maternal depression or anxiety disorder is best evaluated and adjusted before conception to ensure proper treatment during pregnancy. If possible, non-pharmacological treatment is preferred. If pharmacological treatment is indicated, several factors are of influence in the choice of antidepressants: prior response to pharmacological treatment, gestation, intention to breast feed and the safety profile based on the available experience. In general, treatment should be unchanged in patients whose symptoms are well controlled. Place of delivery and duration of inpatient observations should, whenever possible, be agreed before delivery. Infant feeding method and information concerning SSRIs and lactation should be provided, and whenever possible the intended feeding method (breast or formula) should be agreed and documented antenatally. There should be very few situations in which the decision on whether or not to initiate and continue breast feeding cannot be made before the baby's birth.

2.7. **Practical Guidance- neonatal management after SSRI exposure during 3rd trimester.**

A hospital delivery to allow early assessment of the baby is advised. A subsequent period of observation for 48 hours is also advised in line with common practice across the UK.

- Parents may make an informed decision to decline or reduce the 48-hour period of observations against this recommendation, accepting that there is a risk to their baby.
- If period of observation is declined, ensure parents are aware of risks of Pulmonary hypertension and Poor Neonatal Adaptation Syndrome and give appended patient leaflet.
- Ensure parental decision is documented in notes.
- Once parents have made an informed decision to decline observation as above, this does not need escalating to the neonatal team, nor is this a safeguarding issue. A discharge against medical advice form does not need to be complete.
- Ensure Oxygen Saturation screening is normal prior to discharge.
- If home on day of birth, for midwifery home visit to assess baby on day 1.
- If concerns regarding baby on day 1, contact neonatal tier 1 staff member and consider readmission.

An inpatient scoring system for withdrawal is recommended- **see Appendix 3**.

A parent information leaflet is copied in **Appendix 4**.

3. Monitoring compliance and effectiveness

Information Category	**Detail of process and methodology for monitoring compliance**
Element to be monitored	Key changes in practice recommended by guidance.
Lead	Charlotte Lea; Neonatal Consultant.
Tool	Audit using a WORD or Excel template. To be included in the Neonatal Clinical Audit Programme. Findings reported to the Child Health Directorate Audit meeting / Governance Meeting.
Frequency	As dictated by audit findings.
Reporting arrangements	Child Health Directorate Audit and neonatal Clinical Guidelines meetings.

Information Category	Detail of process and methodology for monitoring compliance
Acting on recommendations and Lead(s)	Chris Bell; Neonatal Consultant. Neonatal Clinical Guidelines Group.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 3 months of audit. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Maternal Use of SSRIs Neonatal Clinical Guideline V4.1
This document replaces (exact title of previous version):	Maternal Use of SSRIs Neonatal Clinical Guideline V4.0
Date Issued/Approved:	July 2024
Date Valid From:	July 2024
Date Valid To:	May 2027
Directorate / Department responsible (author/owner):	Charlotte Lea; Neonatal Consultant
Contact details:	01872 252667
Brief summary of contents:	This guideline is designed to provide guidance on the management of infants exposed to SSRI and related drugs in pregnancy.
Suggested Keywords:	Neonatal. Jaundice. Prolonged. Neonate.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical officer
Approval route for consultation and ratification:	Neonatal Audit and Guidelines meeting
Manager confirming approval processes:	Caroline Chappell
Name of Governance Lead confirming consultation and ratification:	Tamara Thirlby
Links to key external standards:	None required
Related Documents:	1. Sie SD, Wennick JMB, Maternal use of SSRIs, SNRIs and NaSSAs: Practical

Information Category	Detailed Information
	recommendation during pregnancy and lactation. Arch Dis Child Fetal Neonatal Ed 2012;97:472-476. 2. Levinson-Castiel R, Merlob P. Neonatal abstinence syndrome after in utero exposure to selective serotonin reuptake inhibitors in term infants. Arch Pediatr Adolesc Med 2006;160:173-176. 3. Grigoriadis S, et al. Prenatal exposure to antidepressants and persistent pulmonary hypertension of the newborn: systematic review and meta-analysis. BMJ. 2013;348:f16932. 4. Hendrick V, Stowe ZN, Altshuler LL et al. Fluoxetine and norfluoxetine in pregnancy and lactation. Biol Psychiatry 2001;50;775-782. 5. Berle JO, Spigset O. Antidepressant use during breast feeding. Current Womens Health Rev 2011 Feb; 7(1):28-34. 6. Antidepressant Use Late in Pregnancy and Risk of Persistent Pulmonary Hypertension of the Newborn. Krista F. Huybrechts, MS, PhD1,2; Brian T. Bateman, MD, MSc1,2,3; Kristin Palmsten, ScD4; Rishi J. Desai, PhD1; Elisabetta Patorno, MD, DrPH1,2; Chandrasekar Gopalakrishnan, MD, MPH1; Raisa Levin, MS1; Helen Mogun, MS1; Sonia Hernandez-Diaz, MD, DrPH5. Neonatal Abstinence Syndrome Clinical Guideline RCHT.
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical/ Newborn Care

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
February 2015	V1.0	Initial Issue and formatting.	Dr Paul Munyard; Neonatal. Formatted by Paul Munyard.
August 2018	V2.0	Added appendix 3 with scoring chart and symptom list. Added flow chart.	Dr Paul Munyard; Neonatal Consultant
November 2021	V3.0	Breast feeding and PPHN information updated along with clarification on neonatal review process.	Chris Bell; Neonatal Consultant
February 2024	V4.0	Updated flow chart and appendix 5	Dr. Chris Warren; Paediatric Consultant
July 2024	V4.1	Update to guidance regarding fluoxetine. Section 2.5 updated.	Dr. Charlotte Lea; Paediatric Consultant

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Maternal Use of SSRIs Neonatal Clinical Guideline V4.1
Directorate and service area:	Neonatal
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Neonatal Audit and Guidelines Group
Contact details:	01872 252667

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide guidance on management of neonates exposed antenatally to maternal selective serotonin reuptake inhibitors (SSRIs) e.g., fluoxetine, and related drugs - selective noradrenaline reuptake inhibitors (SNRIs), e.g., venlafaxine and specific serotonergic antidepressants (NaSSAs) e.g., mirtazapine. Aimed at midwifery and neonatal staff.
2. Policy Objectives	As above.
3. Policy Intended Outcomes	As above.
4. How will you measure each outcome?	Audit.
5. Who is intended to benefit from the policy?	Neonates and their parents.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Neonatal Audit and Guidelines Group.
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	Any information provided should be in an accessible format for the parent/ carer/ patient's needs- i.e., available in different languages if required/access to an interpreter if required.

Protected Characteristic	(Yes or No)	Rationale
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	Those parent/ carer/ patients with any identified additional needs will be referred for additional support as appropriate- i.e., to the Liaison team or for specialised equipment. Written information will be provided in a format to meet the family's needs e.g., easy read, audio etc.
Religion or belief	No	All staff should be aware of any beliefs that may impact on the decision to treat and should respond accordingly.
Marriage and civil partnership	No	All staff should be aware of any marital arrangements that may have an impact on care (for example: separated parents, domestic abuse).
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Neonatal Audit and Guidelines Group.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Neonatal Abstinence Syndrome Symptom Assessment Chart

Can be found at http://doclibrary-rcht-intranet.cornwall.nhs.uk/DocumentsLibrary/RoyalCornwallHospitalsTrust/Forms/FormsToPrint/Specialty/Neonatal/CHA4593NeonatalAbstinenceSyndromeSymptomAssessmentChart.pdf or on the forms to print section of the intranet, under Neonatal.

Appendix 4. Antidepressants (SSRI and Similar Drugs) in Pregnancy and Breastfeeding Patient Information Leaflet RCHT 1552

Can be found at Antidepressants (SSRI and similar drugs) in pregnancy and breastfeeding (cornwall.nhs.uk).

Appendix 5. Pathway when Recommended Management is Declined