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Guidance for Newborn Assessment Exposed to Psychotropic Medication In-Utero

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Executive Summary

This document is to provide guidance for health care professionals involved in the care of babies born to women who have taken medication for mental disorders (psychotropic medication) during pregnancy. Its aim is to optimise and standardise the care of exposed babies and to provide guidance to health professionals (in particular neonatologists, paediatricians, healthcare workers, health visitors and midwives) on the appropriate assessment and management of the risks and needs of the newborn baby.

Any psychotropic medication that has been taken by the mother during her pregnancy and / or delivery should be documented in the baby's notes. Babies who have been exposed to such medication should undergo a relevant assessment as set out in this document. This assessment will take place in the hospital, birthing unit or home (if home birth). Information on this process should be given to mothers during their pregnancy and at the time of the post-birth assessment, so they can feel confident about their baby's wellbeing.

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1. Introduction

This document sets out to standardise and optimise the care given to newborn term babies when their mothers have taken psychotropic medication during pregnancy.

Ideally, a woman's history of taking psychotropic medication should be asked about in pregnancy and during delivery and documented in her records. When knowledge of the fetus/baby being exposed is identified, a tailored assessment of the newborn baby should be planned for and instigated following delivery. The mother should be provided with information during pregnancy about the assessment process for her newborn baby to both inform her of what to expect and reassure her about her baby's wellbeing.

This guidance is to ensure that both the relevant professionals are aware of the needs and risks of the exposed baby and that the baby's physical and emotional welfare is monitored and maintained.

2. General Principles

The general principles outlined below are to be considered for all babies who have been exposed to psychotropic medication in utero. They highlight the importance of history taking, communication and ensuring that the needs of the baby across all appropriate parameters are thought about and met.

1. Separation of a baby from his/her mother should only occur if there is an immediate risk of death or long-term impairment to the baby.
2. A prolonged stay in hospital may cause agitation and distress to the mother, so this must be avoided whenever possible.
3. The mother's hand held records, medical notes and electronic records should always be read by the individual clinician carrying out the examination of the newborn. The medication summary sheets will be on green paper. The clinician must be mindful of any type of alert placed on the mother's records. Most neonatal units/labour wards will also hold local information/alerts for 'high risk' pregnancies in a separate folder available as a hard copy.
4. It should never be assumed that a baby is irritable or lethargic solely because of his/her mother's medication. If a newborn baby has any signs or symptoms they must be appropriately investigated for underlying medical causes.
5. A medication history must be taken from the baby's mother (including herbal and OTC medication). Consideration must also be given to secondary exposure from family members who smoke (tobacco and cannabis).
6. The clinician responsible for the assessment of the newborn should not advise the mother about her medication. This is the responsibility of the mother's treating clinician i.e. the GP and/or psychiatrist. The mother's medication must only be altered by the mother's clinician or a psychiatrist following clinical discussion and consultation with the mother's notes and care-plans. Stopping her medication can

potentially cause a relapse with life threatening consequences for mother and for baby.

7. The mother must not be advised by the clinician assessing the baby to stop or alter medication in order to enable breastfeeding.
8. The midwives and obstetricians must be informed if on assessing the infant, the mother is believed to be unwell. The baby must not be discharged until the mother has been assessed by PRAMS (if known to service) or liaison psychiatry (if unknown to PRAMS or out of hours).
9. If there are concerns about a mother's mental health or her psychotropic medication there should be a low threshold for calling the psychiatric liaison team or the on-call psychiatric team for advice.
10. The mother's capacity to make decisions must always be assessed.
11. The clinician must ensure that there are no safeguarding issues and must not discharge the baby if he/she is concerned about safeguarding the baby or the mother.
12. Advice must be sought from a more senior clinician if the examining clinician has concerns.
13. Consideration should be given to including both parents in decision making.
14. Keep detailed and accurate records and be open with parents about what is documented.
15. The content of the notes/records and discharge summary must be clear and comprehensive.
16. There should be full communication with other professionals about the discharge plan.
17. If there are safeguarding concerns (new or in place) it is mandatory that these are shared with all relevant professionals and that they are documented in the baby's notes and records. It is always advisable to inform the parents and work in partnership with them if possible, however the baby's safety and wellbeing are the clinician's prime concerns.

3. Intervention

Below is a table summarises the point of contacts where interventions should be offered to the mother and newborn through the antenatal and postnatal period.

Point of contact	Recommended action	Responsibility
Booking in appointment	<ul style="list-style-type: none"> Review medication history. Provide BUMPS leaflets for any psychotropic medication. (www.medicinesinpregnancy.org) Provide general leaflet on psychotropic medication. (see Appendix 1) Refer to PRAMS if threshold met (see Appendix 2) If threshold for PRAMS not met request GP to review medication and to discuss breastfeeding. 	Midwife GP
28/40 to 32/40	<ul style="list-style-type: none"> If under PRAMS and considered to have complex or severe mental illness a perinatal psychiatry care plan will be developed with copy of plan shared with midwife, health visitor with copy in mother's notes. 	PRAMS
Birth	<ul style="list-style-type: none"> Midwife to review notes and double check what medication mother is taking. Put green summary sheet for any group of psychotropics the mother is taking e.g. antidepressants, in mother and newborn's notes (Appendix 3). Check if there is a care plan from PRAMS in the notes, if present read and follow recommendations. 	Midwife
Within 24 hour post birth	<ul style="list-style-type: none"> Practitioner completing the initial baby check to conduct additional checks on any psychotropic summary sheet included in the newborn's notes. If no concerns at this stage and mother in hospital or birth centre, mother and newborn can be discharged home. Ensure the discharge letter is completed and passed to relevant parties (Appendix 4) 	Practitioner completing newborn infant physical examination
Day 2 post delivery	<ul style="list-style-type: none"> A further check on the newborn is required, as indicated on the summary sheet. This can be done in the community if discharged after the 24 hour check. This review must also be documented on the 	Midwife nursery nurse Doctor/ANNP

	medication summary sheet in the baby's hospital notes.	
Up to 12 months postnatal	<ul style="list-style-type: none"> Consider a referral to PRAMS if any concerns about mother's mental health. 	Health visitor GP

Interventions that need to be considered include physical assessment and monitoring of the baby, communication with the baby's parents and healthcare practitioners, information sharing and consideration of any safeguarding concerns.

1. Pre-birth perinatal mental health care-plans are usually completed by 32 weeks gestation following a multi-disciplinary and multi-agency meeting which includes mother and partner/family. The meeting sets out current status and management plans relating to the physical aspects of the pregnancy and fetal development; the mental health problem and its treatment; the benefits and risks of treatment to fetus and mother; intra-partum care; breastfeeding and mental health assessment post-delivery/pre-discharge. These plans are held in the mother's hand-held notes and distributed to the appropriate professionals and agencies as appropriate (e.g. midwifery, obstetrician, HV, GP, Perinatal Mental Health or community psychiatric team and children's social care). Neonatology needs to be included in this distribution list. The clinician carrying out the assessment of the baby must read the care-plan before carrying out the assessment. These care-plans are used for women with the more severe mental disorders and will not be in place for a woman with for example mild to moderate depression/OCD on an SSRI (who make up the bulk of women with exposed fetuses). There may however be letters from the mental health clinician who sees the mother, which sets out details of diagnosis and the management plan.
2. A summary sheet has been developed for each group of psychotropic medications which we would recommend to follow when assessing the newborn on any occasion postnatally, particularly within the first 48 hours.
3. Be aware that lack of sleep is a common precipitating factor for a relapse of severe psychiatric illness.
4. The mother will be supported to feed her baby however she chooses to feed.
5. Clear and timely information should be sent to the GP, health visitor and community midwife.
6. Relevant information should be written in the Parent's Child Health Record (*the red book*) in paper or electronic format.

7. It must be ensured that there is careful documentation of the address the mother and baby are being discharged to and who they will be living with. This may be different from the booking address and there may be multiple addresses.

4. Components of the Newborn Assessment

The following areas need to be considered for all babies who have been exposed to psychotropic medication in utero.

1. The Newborn Infant Physical Examination (NIPE) should be carried out within the first 24 hours after birth. Particular attention is to be paid to examination of the palate and cardiovascular system, and results of antenatal scans must be reviewed.
2. The care plan for babies who have been exposed to maternal antidepressant medication in utero and who go home after 24hrs or have been born at home should include reassessment for Poor Neonatal Adaptation Syndrome (PNAS)* on day two (see antidepressant summary sheet in Appendix 3).
3. If the baby has symptoms, such as poor feeding, lethargy or irritability he/she should be assessed and treated for possible sepsis and hypoglycaemia, polycythaemia etc. It must not be assumed that the baby's symptoms are solely due to withdrawing from or other effects of maternal medication (clinician prescribed or self-prescribed) or from psychoactive substances. Withdrawal is a diagnosis of exclusion.
4. Pulmonary hypertension is a rare complication of maternal SSRI use and will present with cyanosis. However, this may not yet be visible at the time of the routine assessment. Pulse oximetry should be part of the cardiovascular assessment.
5. The clinician should be familiar with the antenatal plan for infant feeding before starting the NIPE, and support the family with breastfeeding if this is appropriate and what the mother has planned for.
6. Admission to the neonatal unit or transitional care unit should be based on clinical need, rather than on the maternal psychiatric history.
7. Babies that are born in hospital can be discharged safely after 24 hours in the majority of cases.

*see glossary

5. Communication with Mother/Parents

Clear, compassionate communication with the mother and (if appropriate) the father of the baby is an essential part of the overall assessment.

1. The consultation with the mother should be undertaken in an open, compassionate and mindful manner holding in mind that stigma in relation to mental health problems may be a barrier to provision of good care, communication and help-seeking.
2. Communicate with the mother regarding the assessment of the baby, its outcome and any concerns raised by this or her own worries about the wellbeing of her baby.
3. Information should be given regarding the appropriate monitoring of the baby at home. This will include any warning signs the mother/parents need to be aware of and what action needs to be taken if needed.
4. It is important to appropriately reassure the mother about the wellbeing of her baby as this will enhance attachment with the baby.
5. It is important to inform the mother where and when she can and should seek help and to signpost her to the roles of the GP, health visitor, community midwife and A&E.
6. It should be acknowledged with the mother that it takes time to get to know one's new baby.
7. The mother should be encouraged to seek support from her family and friends.
8. Communication with the father of the baby is important. Mother should be asked if she wishes father to be present for or advised about the assessment and its outcome. There can be complex relationship and communication issues between the parents of the baby, as well as legal and confidentiality issues. The clinician needs to be open with the mother and make a judgement about how to proceed when circumstances are difficult. Advice from a senior colleague should be sought if any uncertainty arises.
9. All mothers of babies who have been exposed to maternal antidepressants or psychotropic medications should receive a discharge letter from the practitioner completing the newborn examination informing them of the important symptoms to

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be aware of and any further action that needs to take place. The letter be found in appendix 3. This letter should be personalised to each patient and shared with the health visitor, community midwife and GP (with mum's consent).

6. Psychotropic Medication: General Principles

The following general principles apply to the understanding and planning of all assessments of the baby who has been exposed to psychotropic medication in utero.

1. Risks to the fetus related to medication include congenital defects, long-term neurobehavioural sequelae, neonatal adaptation syndrome, and withdrawal effects.
2. It is important to understand which congenital defects or other effects are associated with individual drugs and whether any congenital defects have been excluded by antenatal scans
3. There are also risks to the fetus from untreated mental disorder in the mother.
4. There are potential benefits to the fetus from the mother being treated.
5. There are significant risks associated with suddenly stopping medication in the mother. Any risk to the mother is a risk to the infant.
6. Women with mental health conditions are more likely to be smokers. They also have significant exposure to other factors that affect the development of the fetus including obesity, poverty, social adversity, alcohol and substance misuse, childhood adversity and domestic abuse. These need to be assessed with respect to safeguarding.
7. Seek up to date advice regarding medication from pharmacy or PRAMS.
8. Women may be taking more than one psychotropic drug.
9. Sedation in the mother due to medication needs to be taken into account. Many psychotropic medications have sedative properties including anti-psychotic, anti-depressant, mood stabilising, hypnotic and benzodiazepine drugs. It is important to therefore understand what practical and emotional support the mother has in relation to feeding and caring for her baby in this context. The guidance to reduce the risk of cot death should be used to inform advice given to the mother and family.
10. A method for estimating risk to the baby from exposure to maternal psychotropic medication in breast milk is to calculate the Relative Infant Dose (RID). The RID is

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calculated by dividing the baby's dose via milk (mg/kg/day) by the mother's dose in mg/kg/day. If the RID is less than 10% most medications are considered safe to use. The RID of the vast majority of drugs is < 1%. The relative infant dose (RID) of each medication is found on the LactMed website:

<https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm>

11. Some of the evidence for fetal malformations (first trimester of pregnancy) caused by drugs used for maternal mental health issues is conflicting. Interpreting the data in relation to risks to the newborn baby following exposure to maternal psychotropic medication can be difficult and confusing. Much of the information available has been obtained from studies that are retrospective with all of the issues that this method involves. Malformations and other problems in the newborn baby who has been exposed are more likely to be reported than when the outcome is normal and the baby healthy, as there is increased vigilance in women taking medication. This also applies to studies that look at larger populations. Increased screening for malformations among babies exposed in pregnancy to a drug can lead to increased detection. This may mean that minor malformations that are of no clinical significance are reported and the literature may not always differentiate between minor clinically insignificant malformations and more serious ones. Some of the data may come from studies where the medications are prescribed for non-psychiatric indications. More recently, there have been several studies on anti-depressants reporting on >100,000 exposures in pregnancy and even so, it has been difficult to draw firm conclusions about the effects on the developing fetus of the SSRIs.

7. Table of Issues to be considered with Individual Classes of Psychotropic Medication *(please see individual guideline sheets in appendix 3 for ABMU specific guidance)*

ANTIDEPRESSANTS Indications: depressive illness; panic disorder; generalised anxiety disorder; obsessive compulsive disorder; bulimia nervosa; social anxiety disorder; post-traumatic stress disorder; pain				
Class of drug	Examples	Assessment & monitoring	Neonatal risks	Breastfeeding
Selective Serotonin Reuptake Inhibitors (SSRIs)	Citalopram escitalopram fluoxetine paroxetine sertraline	<p>Confirm no congenital cardiac defects.</p> <p>Monitor for Poor Neonatal Adaptation Syndrome** (PNAS) (see appendix 3)</p> <p>Assess and monitor for Persistent Pulmonary Hypertension of the Newborn (PPHN).</p>	<p>Statistical not clinical evidence of increased risk. Risk reduced when depression associated confounders adjusted for.</p> <p>Central nervous system, motor, respiratory and gastrointestinal symptoms. The symptoms develop within 8 – 48 hours postpartum and fade within 72 hours.</p> <p>Risk approx. 30/10,000 babies of mothers taking SSRIs beyond 20 weeks gestation (compared to background rate 20/10,000)</p>	<p>All present in milk but amount probably too low to be harmful.</p> <p>RID* (Relative Infant Dose) (see end of table)</p> <p>Citalopram 2-9%</p> <p>Escitalopram 5-8%</p> <p>Paroxetine <2%</p> <p>Fluoxetine 3-12%</p> <p>Sertraline <0.5%</p> <p>Advice is to breastfeed unless other contraindications present.</p> <p>Baby should be observed for sedation and adequate weight gain.</p>
Mirtazepine		Confirm no congenital cardiac defects.	Lonely one study looking specifically at birth defects, it showed no increased risk.	Doses up to 120mg daily produce low levels in milk and not expected to cause any adverse effects on breastfed infants.

		<p>Monitor for Poor Neonatal Adaptation Syndrome** (PNAS) (see appendix 3)</p> <p>Assess and monitor for Persistent Pulmonary Hypertension of the Newborn (PPHN).</p>	<p>No large studies investigating this with Mirtazepine. Advice still to monitor for PNAS following delivery.</p> <p>There is one single report of PPHN in a baby exposed to Mirtazepine in utero. Since studies have shown an increased risk in antidepressants that work in a similar way, monitoring for PPHN is recommended.</p>	<p>Advice is to breastfeed unless other contraindications present.</p> <p>Baby should be monitored for behavioral side effects and adequate growth.</p>
Serotonin and Noradrenaline Re-uptake Inhibitor (SNRI)	Venlafaxine Duloxetine	Monitor for Poor Neonatal Adaptation Syndrome (PNAS) (See appendix 3)	Central nervous system, motor, respiratory and gastrointestinal symptoms. The symptoms develop within 8 – 48 hours postpartum and fade within 72 hours.	<p>Venlafaxine The RID is 4-15%, this greater than that for the SSRIs but remains <10%.</p> <p>Duloxetine is thought to be excreted in low levels into breastmilk.</p> <p>Advice is to breastfeed unless other contraindications present.</p> <p>Baby should be observed for sedation and adequate weight gain.</p>
Tricyclic Antidepressants (TCAs)	amitriptyline clomipramine dosulepin doxepin	Confirm no congenital cardiac defects. (Poss statistical link with Clomipramine)		Low risk (amount in breast milk too small to be harmful) except doxepin (accumulation of metabolite may cause sedation and respiratory depression).

	imipramine lofepramine nortriptyline trimipramine	Monitor for Poor Neonatal Adaptation Syndrome (PNAS) (See appendix 3)	Central nervous system, respiratory, endocrine and metabolic disturbances. The symptoms after antidepressants develop within 8 – 48 hours postpartum and fade within 72 hours	RID Amitriptyline <2% Clomipramine <3% Doxepin <3% Imipramine <3%
Monoamine Oxidase Inhibitors (MAOIs)	phenelzine isocarboxazid tranlycypromine meclobemide <i>rarely prescribed</i>	Confirm no congenital cardiac defects.	Little data available.	Lack of published data - avoid
ANTIPSYCHOTICS Indications: schizophrenia; psychoses; mania and hypomania				
Class of drug	Examples	Assessment & monitoring	Neonatal risks	Breastfeeding
First generation “typicals”	haloperidol, chlorpromazine promethazine flupentixol trifluoperazine promazine sulpride zuclopenthixol	Assess and monitor for extra-pyramidal symptoms Sedation	No current evidence that first generation anti-psychotics lead to malformations. Possible extra-pyramidal symptoms (EPS – abnormal muscle movements – hypertonia, tremor, dystonia, motor restlessness) and sedation. Assess level of alertness, waking for feeds, poor sucking	Anti-psychotics do enter the breastmilk. Levels are generally low and breastfeeding can be advised. Observe infant for sedation and extrapyramidal symptoms. RID flupentixol <1%

Second generation “atypicals”	Amisulpiride aripiprazole clozapine quetiapine olanzapine risperidone paliperidone	Assess and monitor for extra-pyramidal symptoms Sedation	No current evidence that the atypical anti-psychotics lead to malformations, apart from risperidone. Abnormal muscle movements, hypertonia, tremor, dystonia, motor restlessness Assess level of alertness, waking for feeds, poor sucking	Low RID values for olanzapine and quetiapine. Moderate RID values for risperidone and aripiprazole. High RID values for amisulpride. No serious adverse effects reported. Monitor for drowsiness, irritability, motor abnormalities and poor feeding following exposure to these drugs especially if at high risk (e.g. premature or LBW babies) Do not breastfeed while on clozapine. Drug concentrates in breastmilk. Risk of agranulocytosis and seizures. Aripiprazole may lower prolactin levels, affecting milk supply.
MOOD STABILISERS Indications: treatment and prophylaxis of mania, bipolar disorder and recurrent depression; aggressive or self-harming behaviour, prevention of depressive episodes associated with bipolar disorder				
Class of drug	Examples	Assessment & monitoring	Neonatal risks	Breastfeeding
Lithium	Lithium carbonate Lithium citrate	Confirm no congenital cardiac defects	Possibly associated with first trimester cardiac abnormalities (Ebstein’s anomaly and other cardiac defects)	Generally contraindicated RID 11-42%

		<p>Monitor for 48 hours post delivery</p> <p>Assessment of neonatal withdrawal syndrome</p> <p>Lethargy, flaccid muscle tone, hypotonia</p>	<p>Lithium toxicity</p> <p>Hypothyroidism</p> <p>Hypoglycaemia</p>	
<p>Sodium valproate</p> <p><i>Do not prescribe for mental health problems in women planning a pregnancy, pregnant or breastfeeding.</i></p>	<p>sodium valproate (valproic acid, Depakote)</p>	<p>Assess for congenital malformations</p>	<p>Early pregnancy exposure increases the risk of congenital malformations to approx. 10% and significant associations have been reported for spina bifida (an approximate 13-fold increased risk from approximately 0.09% in the general population to between 1% and 2%), atrial septal defects, cleft palate, hypospadias, polydactyly and craniosynostosis.</p> <p>There is a risk of serious developmental disorders up to 40%.</p>	<p>There are relatively low levels of valproate in breast milk</p> <p>Women often taking in combination with other anticonvulsants which stimulate metabolism making RID highly variable and less meaningful. Some reports suggest 7-9%.</p>
<p>Carbamazepine</p>		<p>Assess for congenital malformations including spina bifida</p>	<p>Early pregnancy exposure to carbamazepine reported to be linked with an approximately two-fold increased rate of major congenital malformation</p>	<p>Carbamazepine has relatively high levels in breastmilk and breastfed babies have serum levels that are measurable.</p>

		<p>Assess for sedation, poor sucking, withdrawal reactions and hepatic dysfunction</p> <p>Possible increased risk of Haemorrhagic Disease of the Newborn (Vitamin K deficiency bleeding, VKDB). Give parenteral neonatal Vitamin K</p>	(from around 2% to approximately (3.5–5%))	<p>Most infants have had no adverse reactions, but sedation, poor sucking, withdrawal reactions and cases of hepatic dysfunction have been reported.</p> <p>If mother chooses to breastfeed then baby needs to be monitored for growth, development and liver function.</p> <p>Calculation of RID is less meaningful as carbamazepine induces metabolism of other drugs and so RID is highly variable.</p>
Lamotrigine		Monitor for apnoea, rash, drowsiness, poor sucking.	Neonatal levels may reach 50% of maternal levels.	<p>Serum levels of infants exposed to lamotrigine via breastmilk tend to be high, averaging 30–35% of maternal serum levels.</p> <p>Newborn babies are particularly at risk for high plasma levels because their ability to metabolize the drug by glucuronidation is limited, plasma protein binding is relatively low, and maternal plasma and milk levels can rise dramatically in the immediate postpartum period if the dosage is not reduced to the pre-pregnancy dosage.</p> <p>However, breastfed infants should be carefully monitored for side effects such as apnoea, rash, drowsiness or poor sucking, including measurement of serum levels to rule out toxicity if there is a concern. Monitoring of the platelet count and liver function may also be</p>

				advisable. If an infant rash occurs, breastfeeding should be discontinued until the cause can be established.
ANXIOLYTICS Indications: short term relief of severe anxiety; panic disorder resistant to antidepressant therapy; insomnia (short term use), acute behavioural disturbance				
Class of drug	Examples	Assessment & monitoring	Neonatal risks	Breastfeeding
Benzodiazepines	<p><i>Longer acting -</i> diazepam nitrazepam flurazepam alprazolam chlordiazepoxide clobazam clonazepam</p> <p><i>Shorter acting –</i> lorazepam loprazolam lormetazepam temazepam oxazepam</p>	<p>Neonatal adverse events are uncommon but should be used cautiously.</p> <p>Prolonged use near term, especially in high doses may increase risk of neonatal withdrawal syndrome</p> <p>May lower Apgar score</p> <p>Respiratory depression and/or “floppy infant syndrome”</p>	<p>Monitor for irritability, tremors</p> <p>Monitor and assess for hypothermia, lethargy, feeding difficulties, poor respiratory effort</p> <p>Observe sleeping habits, temperature stability, weight changes – nutritional support may be needed if sucking poorly.</p>	<p>Limited information on RID. Longer acting are between 2-3% Temazepam – undetectable Oxazepam <1% Lorazepam 8%</p> <p>Avoid longer acting drugs. If a benzodiazepine is required during breast-feeding a short-acting agent eg lorazepam should be prescribed in divided doses. Mothers should be advised not to stop medication suddenly and to contact their doctor if the infant is observed to have sleepiness, low energy or poor suckling. Sedation, poor feeding, weight loss and apnoea may be more likely to occur with longer-acting agents.</p> <p>Lorazepam has a short half-life relative to many other benzodiazepines and does not appear to</p>

				<p>cause adverse effects in breastfed infants with usual maternal dosages.</p> <p>Clonazepam can cause sedation in breastfed infants, especially when given with other central nervous system depressants. Monitor the infant for drowsiness, adequate weight gain, and developmental milestones, especially in younger, exclusively breastfed infants and when using combinations of psychotropic drugs</p>
Beta Blockers	Propranolol	<p>Assess for congenital malformations including cleft lip, palate, cardiac and neural tube.</p> <p>Monitor for bradycardia, hypotension, hypoglycaemia</p>	<p>No conclusive evidence of congenital abnormalities with beta-blockers.</p> <p>Neonatal beta- adrenoceptor blockade</p> <p>Respiratory distress</p>	<p>Because of the low levels of propranolol in breastmilk, amounts ingested by the infant are small and would not be expected to cause any adverse effects in breastfed infants. Studies during breastfeeding have found no adverse reactions in breastfed infants clearly attributable to propranolol. No special precautions are required.</p>
Promethazine		No known increased risk of birth defect	None known	<p>Based on other phenothiazine derivatives, low levels in breastmilk.</p> <p>With repeated dose, observe infants for excess sedation.</p> <p>It may interfere with the establishment of lactation if given during labor.</p>
Busiprone	No data available			

HYPNOTICS				
Class of drug	Examples	Assessment & monitoring	Neonatal risks	Breastfeeding
'Z' drugs	zopiclone, zolpidem or zaleplon		Not associated with an increased risk of congenital malformations	<p>Low levels of zolpidem and zaleplon in breastmilk and regarded as safe in breastfeeding.</p> <p>Observe for sedation.</p> <p>Little data on zopiclone. Use alternative.</p>

Resources

Medications and Mothers' Milk. Thomas Hale. 15th Edition 2017. Hale Pub.

British Association for Psychopharmacology consensus guidance on the use of psychotropic medication preconception, in pregnancy and postpartum 2017. R Hamish McAllister-Williams et al https://www.bap.org.uk/pdfs/BAP_Guidelines-Perinatal.pdf.

LactMed. The database contains information on drugs and other chemicals to which breastfeeding mothers may be exposed.

<https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm>

Best use of medicine in pregnancy (BUMPS). Bumps is provided by the UK Teratology Information Service (UKTIS). UKTIS (previously the National Teratology Information Service, NTIS) has been providing scientific information to health care providers since 1983 on the effects that use of medicines, recreational drugs and chemicals during pregnancy may have on the unborn baby.

<https://www.medicinesinpregnancy.org>

Antenatal and postnatal mental health: clinical management and service guidance
CG192 June 2015

<https://www.nice.org.uk/guidance/cg192/chapter/introduction>

Antipsychotic use in pregnancy and the risk for congenital malformations.

JAMA Psychiatry 73: 938–946 Huybrechts KF, Hernandez-Diaz S, Paterno E, et al. (2016).

Electronic Medicines Compendium

Summary of Product Characteristics for individual drugs

www.medicines.org.uk

Guideline for the Examination of the palate

RCPCH

http://www.rcpch.ac.uk/system/files/protected/page/Cleft%20palate%20best%20practice%20guide%20FINAL_1.pdf

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HEE PMH Programme

Online modules

<http://www.e-lfh.org.uk/programmes/perinatal-mental-health/>

Prenatal anti-depressant exposure and child behavioural outcomes at 7 years of age: A study within the Danish National Birth Cohort

BJOG 123: 1919–1928. Grzeskowiak LE, Morrison JL, Henriksen TB, et al. (2015)

Prenatal exposure to antidepressants and persistent hypertension of the newborn; systematic review and meta-analysis

Gregoriadis, 2014

<http://www.bmj.com/content/348/bmj.f6932>

Selective serotonin reuptake inhibitors and risk for major congenital anomalies

Obstet Gynecol 118: 111–120. Malm H, Artama M, Gissler M, et al. (2011)

SIGN 127: Management of Perinatal Mood Disorders

March 2012

<http://www.sign.ac.uk/pdf/sign127.pdf>

UNICEF UK Baby Friendly Initiative

Breastfeeding assessment tools for mothers, midwives and HV's.

<https://www.unicef.org.uk/babyfriendly/baby-friendly-resources/guidance-for-health-professionals/tools-and-forms-for-health-professionals/breastfeeding-assessment-tools/>

The Breastfeeding Network (BfN)

An independent source of support and information for breastfeeding women and others.

<https://www.breastfeedingnetwork.org.uk/breastfeeding-ad-perinatal-mental-health/>

The effect of prenatal antidepressant exposure on neonatal adaptation: A systematic review and meta-analysis

J Clin Psychiatry 74: e309–e320. Grigoriadis S, VonderPorten EH, Mamisashvili L, et al. (2013)

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The Lancet, Perinatal Mental Health, Series 1

[http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(14\)61276-9.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(14)61276-9.pdf)

The Lancet, Perinatal Mental Health, Series 2

[http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(14\)61278-2.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(14)61278-2.pdf)

The Lancet, Perinatal Mental Health, Series 3

[http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(14\)61277-0.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(14)61277-0.pdf)

The Lullaby Trust

Safer sleeping and SIDs information

<https://www.lullabytrust.org.uk/LThome>

The Maudsley Prescribing Guidelines In Psychiatry 12th Edition

Wiley-Blackwell, David Taylor, Carol Paton, and Shitij Kapur

ISBN: 978-1-118-75460-3

The Protection of Children in England: A Progress Report

12 March 2009, Lord Laming

Glossary

Mental Disorders. Any disorder or disability of the mind, for example: depression, anxiety, psychosis, mania, personality disorder, substance misuse.

Poor Neonatal Adaptation Syndrome (PNAS). This is a condition that sometimes occurs in the newborn after delivery if their mother's took antidepressants during the pregnancy. We think between 25-30% of infants whose mothers took antidepressant medication in the late third trimester are at risk for this syndrome. No treatment is usually required. The baby's symptoms occur between 8 - 48 hours following birth and resolve often by 72 hours. If a baby does not display symptoms shortly after birth they may develop later. Given all this, a practical approach is to reassure women that if PNAS occurs, it is mostly mild. If they are at home and become concerned they should be advised to ask the Community Midwife or GP for advice and in emergencies attend A&E.

Persistent Pulmonary Hypertension of the new born (PPHN). Some studies show that when mothers take antidepressants in pregnancy, particularly in the later stages, there may rarely be an increased risk of persistent pulmonary hypertension in the newborn. PPHN occurs when not enough oxygen is getting to the baby's heart, brain and other organs. A baby with PPHN breathes abnormally fast and needs extra oxygen to stay pink after delivery. These babies may look blue or pale and have difficulty in breathing. Initial treatment of PPHN will consist of simple measures such as keeping the baby warm (but not too hot) and giving oxygen, usually through small prongs (short plastic tubes) in the nostrils, or in an incubator. As a baby is not likely to feed well while they have PPHN, they will receive fluids containing sugar for energy through a drip. If these simple measures do not bring the oxygen levels up easily, the baby is likely to need to be moved to a neonatal intensive care unit .

Extra-Pyramidal Symptoms(EPS). EPS is the name given to a group of abnormal movements that may occur in a newborn whose mother took antipsychotic medication during pregnancy. The symptoms subside within hours or days and do not require specific treatment; other newborns may require longer hospital stays.

Neonatal Abstinence Syndrome (NAS). This syndrome sometimes occurs after delivery when the mother is taking a drug that can cause dependency during pregnancy; e.g. codeine, heroin. The onset of symptoms vary depending on the medication but usually 1 to 3 days after

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delivery but sometimes longer. The symptoms are monitored for using the Finnegan Score. It is mainly used when the mother is taking opioids during pregnancy.

Finnegan Score. This score is used to help diagnose Neonatal Abstinence Syndrome

Psychoactive substances. Substances that, when taken in or administered into one's system, affect mental processes e.g. memory, concentration, perception or mood.

Psychotropic medication. Medication that is used to treat the symptoms of a mental disorder, for example: anxiety, low mood, paranoia, hallucinations, delusions, sleep problems etc.

Relative Infant Dose (RID). RID is method for estimating risk to the baby from exposure to psychotropic medication taken by the mother in breast milk. The RID is calculated by dividing the baby's dose via milk (mg/kg/day) by the mother's dose in mg/kg/day. If the RID is less than 10% most medications are considered safe to use. The RID of the vast majority of drugs is < 1%. The relative infant dose (RID) of each medication is found on the LactMed website <https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm>

Term Baby. A baby born from 37 complete weeks gestation i.e. gestation of 37 weeks + 0 days onwards (source: NICE Guideline NG25 November 2015 Preterm labour and birth).

Appendix 1 - Patient information sheet for women who are taking psychotropic medication during pregnancy

I need to take medication for my mental health during pregnancy – what does this mean when my baby is born?

Women need to take medication for many different physical and mental health problems during pregnancy. You have been given this leaflet as you and your doctor decided that it would be safest for you to take medication for your mental health during pregnancy. This includes **antidepressants**, **antipsychotics** and **anti-anxiety medications**. Some babies can experience symptoms after birth because of these medicines. For this reason, your baby will have a physical health check within 24 hours of birth. You should not worry about this – even if babies do develop symptoms these usually settle down within a few days without the need for any treatment



Do I need to do anything when I am pregnant?

- Make sure you tell the people involved in your care what medication you are taking.
- Don't stop or make any changes to your medication without talking to your doctor first.
- Take medication regularly and make sure you don't run out – if this happens make sure you talk to your GP or psychiatry doctor about what to do.
- Your doctor will tell you about any symptoms your baby might experience.

What about after my baby is born?

- If you give birth in hospital a health professional will check your baby just after birth (usually within the first 24 hours) to make sure that he/she is not experiencing any physical health problems.
- The reviews will include checking your baby's alertness and looking for any signs of irritability or distress, testing his/her movements for any stiffness or floppiness as well as listening to the baby's heart and lungs.
- You will also be asked if you have any worries about your baby's wellbeing, including how he / she is settling, feeding and sleeping.
- The check will not take long and is not harmful or painful for your baby.
- Any concerns found with your baby will be discussed with you and whether these are due to medication or other causes. The health professional will then explain any investigations or treatment needed.
- You will receive a letter telling you any symptoms you should look out for and what to do if your baby develops any of these.
- If you go home from hospital within 24 hours, or have a home birth, your baby will be examined again on the second day of life by a community midwife.
- You will be supported to feed your baby however you choose to feed.



Who should I speak to if I'm worried about my baby's health?

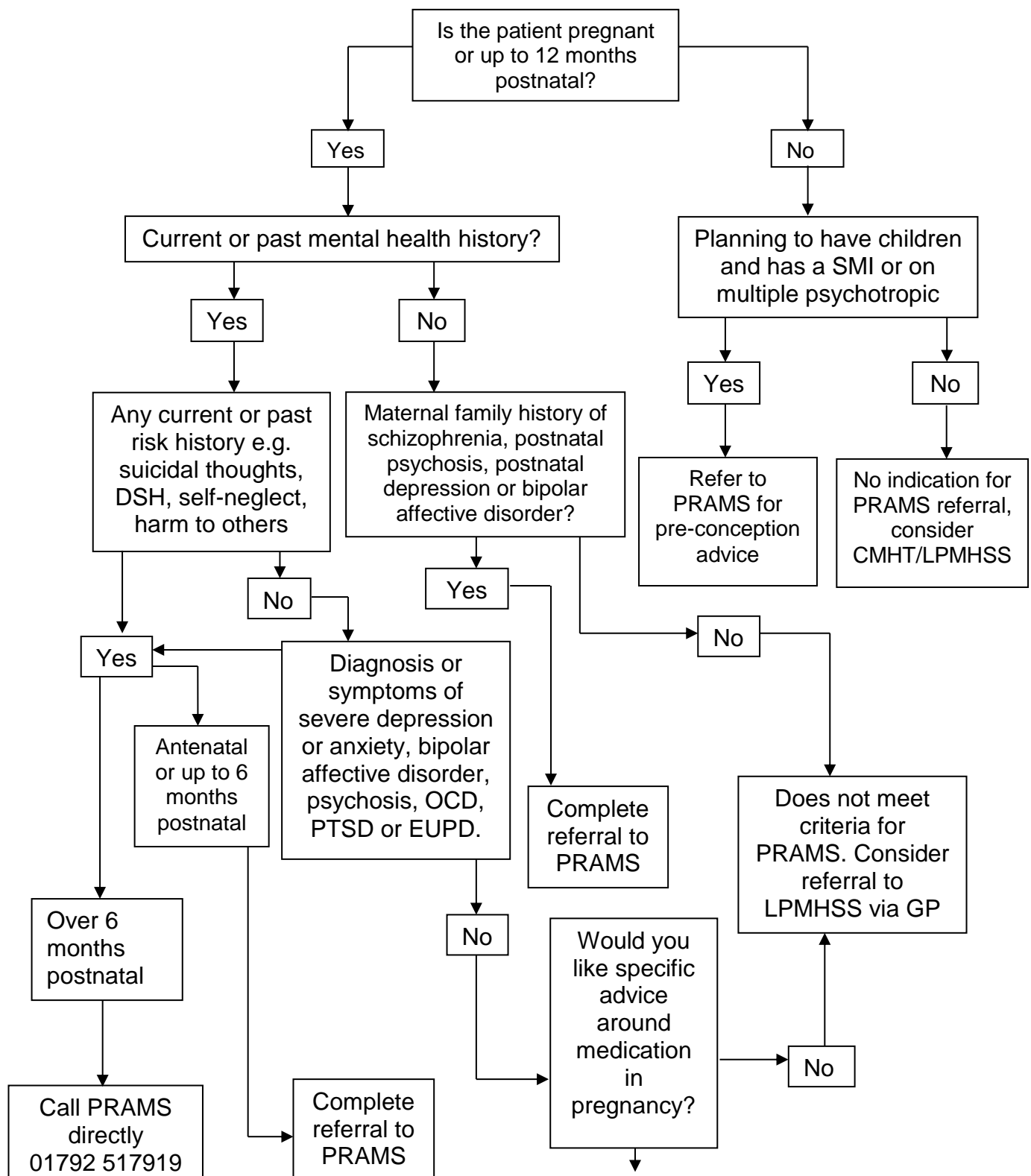
- If you are worried about your baby, speak to your GP, midwife or health visitor.
- If at any time your baby appears unwell, drowsy or has feeding difficulties you should see your GP or take him/her to A&E.

Further information about medications in pregnancy can be found at:

BUMPS (Best Use of Medicines in Pregnancy) www.medicinesinpregnancy.org/

Royal College of Psychiatrists: www.rcpsych.ac.uk/healthadvice/problemsdisorders/mentalhealthinpregnancy.aspx

Appendix 2 - PRAMS Referral Flowchart



Yes



Please email abm.pramswest@wales.nhs.uk
for medication advice

Appendix 3 - Summary Sheets for individual psychotropic medications, including:

- Antidepressants
- Antipsychotics
- Anxiolytics
- Hypnotics
- Mood Stabilisers
 - Carbamazepine
 - Lamotrigine
 - Lithium
 - Sodium Valproate

Antidepressants

SSRIs: Citalopram, escitalopram, fluoxetine, paroxetine, sertraline

SNRIs: Venlafaxine, duloxetine

TCAs: Amitriptyline, clomipramine, dosulepin, doxepin, imipramine, lofepramine, nortriptyline, trimipramine

MAOIs: Phenelzine, isocarboxazid, tranylcypromine (rarely prescribed), Moclobemide

Mirtazepine

Breastfeeding Information:

- All **SSRIs, SNRIs, Mirtazepine and TCAs** are present in breast milk but amount probably too low to be harmful – **Advice is to breastfeed.** With the exception of **Doxepin** which accumulation of metabolite may cause sedation and respiratory depression.
- There is a lack of published data on the safety of **MAOIs** and breastfeeding – **therefore advice is to avoid breastfeeding.**

Assessment and Monitoring:

- **Risks:** PNA (poor neonatal adaptation), congenital cardiac defects, jaundice, hypoglycaemia. **SSRIs, Mirtazepine:** risk of persistent pulmonary hypertension of the newborn (PPHN) → check pre-and postductal saturations.
- **Symptoms and signs of PNA can include:** insomnia, restless sleep, sedation, poor sucking, irritability, vomiting, diarrhoea, agitation, jitteriness, increased tone, fever, hypothermia, temperature instability, hypoglycaemia, respiratory distress, nasal congestion, excessive sweating, convulsions and acrocyanosis.
- Low threshold to measure blood sugar and bilirubin.
- See next page to document review at 24 and 48 hours.

Please confirm review in first 24 hours of life			Place patient sticker here
Date	Time	Name of person checking	
		Midwife/Nursery Nurse/ANNP/Doctor	
Signs/Symptoms found:			
<u>In case of SSRIs:</u> preductal saturations..... postductal saturations.....			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:

Please confirm review on day 2 of life		
Date	Time	Name of person checking
		Midwife/Nursery Nurse/ANNP/Doctor
Signs/Symptoms found:		
Please sign to confirm paediatric team contacted if signs/symptoms found:		
Date & Time:		

Antipsychotic Medication

First generation 'typicals': haloperidol, chlorpromazine, promethazine, flupentixol, trifluoperazine, promazine, sulpride, zuclopenthixol

Second generation 'atypicals': amisulpride, aripiprazole, clozapine, quetiapine, olanzapine, risperidone, paliperidone

Breastfeeding information

- Antipsychotic medications do enter the breastmilk, but levels are generally low and breastfeeding can be advised.
- Breastfeeding is contraindicated in **clozapine** (risk of seizures and agranulocytosis)
- Aripiprazole may lower prolactin levels in mother affecting milk supply

Assessment and Monitoring

- Babies exposed to antipsychotic medications are at risk of extra-pyramidal signs and symptoms. If any of these signs are observed, please discuss with the paediatric team with regards to further assessment:
 - **Abnormal muscle movements (dystonia)**
 - **Tremors**
 - **Increased tone**
 - **Motor restlessness (constantly moving)**
 - **Sedation: drowsiness, poor feeding / suck, not waking for feeds**
 - **Poor sucking**
- **Clozapine:** risk of maternal agranulocytosis (if present, consider testing infant – d/w consultant); can lead to a larger maternal appetite:
↑ risk of diabetes and hence infant hypoglycaemia, low threshold for monitoring infant blood sugar.

- Please see next page to document reviews.

Please confirm review in first 24 hours of life			Place patient sticker here
Date	Time	Name of person checking Midwife/Nursery Nurse/ANNP/Doctor	
Signs/Symptoms found:			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:

Please confirm review on day 2 of life		
Date	Time	Name of person checking Midwife/Nursery Nurse/ANNP/Doctor
Signs/Symptoms found:		
Please sign to confirm paediatric team contacted if signs/symptoms found:		
Date & Time:		

Anxiolytics and hypnotics

Benzodiazepines:

Long acting: diazepam, clobazam, clonazepam, nitrazepam,

Shorter acting: lorazepam, temazepam, oxazepam

Beta Blockers: Propranolol

Promethazine

Breastfeeding Information:

- Breastfeeding is advised.
- With repeated doses, observe baby for excess sedation.

Assessment and Monitoring

- **Beta Blockers:** risk of congenital malformations (neural tube defects, cleft lip and palate, cardiac), bradycardia, hypotension, respiratory distress → check and document **heart rate and blood pressure** in neonate, ECG if found to be bradycardic, monitor for **hypoglycaemia** as per hypoglycaemia guideline.
- **Benzodiazepines** used in third trimester of pregnancy may increase risk of neonatal withdrawal syndrome – refer to NAS guideline

- Please see next page to document reviews.

Please confirm review in first 24 hours of life			Place patient sticker here
Date	Time	Name of person checking	
		Midwife/Nursery Nurse/ANNP/Doctor	
Signs/Symptoms found:			
<u>In case of propranolol:</u> HR..... Bloodpressure.....			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:
Please confirm review on day 2 of life			
Date	Time	Name of person checking	
		Midwife/Nursery Nurse/ANNP/doctor	
Signs/Symptoms found:			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:

Other hypnotics

Drug examples: zopiclone, zolpidem, zaleplon

Breastfeeding information:

- Zolpidem and zaleplon are regarded as safe in breastfeeding. Little data on zopiclone, therefore advise mother to ask her doctor for an alternative if breastfeeding.

Assessment and Monitoring:

- Observe for sedation: drowsiness, poor feeding / suck, not waking for feeds.
- Please document reviews in boxes on next page.

Please confirm review in first 24 hours of life			Place patient sticker here
Date	Time	Name of person checking	
		Midwife/Nursery Nurse/ANNP/Doctor	
Signs/Symptoms found:			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:

Please confirm review on day 2 of life		
Date	Time	Name of person checking
		Midwife/Nursery Nurse/ANNP/Doctor
Signs/Symptoms found:		
Please sign to confirm paediatric team contacted if signs/symptoms found:		
Date & Time:		

Mood Stabilisers: Lamotrigine (requires at least 24 hour inpatient observation)

Breastfeeding information:

- Taking Lamotrigine is not necessarily a reason to discontinue breastfeeding because many infants have breastfed without adverse reactions.
- Infants should be carefully monitored for side effects such as apnea, rash, drowsiness or poor sucking.
- If there are any concerns a serum level should be taken to rule out toxicity.
- If a rash occurs, urgent medical attention should be sought through A&E and breastfeeding discontinued until the cause is found.

Assessment and Monitoring:

- **Risks:** sedation, rash, apnoea, congenital malformations.
- Newborn infant physical examination with special attention for any possible **congenital malformations, rash, lethargy, poor feeding, apnoeas** in the **first 24 hours of life**. In the majority of cases, if well, can then be discharged home **after 24 hours**.
- Please see next page to record reviews on day 1 and 2 of life.

Please confirm review in first 24 hours of life – needs to stay inpatient for at least 24hrs			Place patient sticker here
Date	Time	Name of person checking Midwife/Nursery Nurse/ANNP/Doctor	
Signs/Symptoms found:			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:

Please confirm review on day 2 of life			
Date	Time	Name of person checking Midwife/Nursery Nurse/ANNP/Doctor	
Signs/Symptoms found:			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:

Mood Stabilisers: Lithium (needs 48 hour inpatient observation period)

Breastfeeding information:

- We would **not recommend** for a mother to breastfeed whilst taking Lithium.

Assessment and Monitoring:

- **Risks:** congenital cardiac defects, floppy infant syndrome (occurs shortly after birth, esp if mother taking lithium 24-48 hrs prior to delivery or if she is dehydrated), hypothyroidism (ensure day 5 blood spot done), nephrogenic diabetes
- Monitor for **floppy infant syndrome signs for minimum of 48 hrs:** lethargy, flaccid muscle tone, hypotonia, respiratory distress, cyanosis (use NEWTT chart)
- Measure **lithium levels and electrolytes** in infant shortly after delivery in view of risk of lithium toxicity and hypernatraemia.

**Please confirm a review in the first 24 hours of life
Needs at least 48 hours inpatient observation**

Date

Time

Name of person checking

Midwife/Nursery Nurse/ANNP/Doctor

Signs/Symptoms found:

Please sign to confirm paediatric team contacted if signs/symptoms found:

Date & Time:

Place patient sticker here

Please confirm review on day 2 of life

Date

Time

Name of person checking

Midwife/Nursery Nurse/ANNP/Doctor

Signs/Symptoms found:

Please sign to confirm paediatric team contacted if signs/symptoms found:

Date & Time:

Mood Stabilisers: Valproate

***This medication should not be prescribed for women with mental health problems who are pregnant or of child bearing age* Note MHRA guidance:** <https://www.gov.uk/guidance/valproate-use-by-women-and-girls>

Breastfeeding information:

- There are relatively low levels of Valproate found in breastmilk.

- **Women can breastfeed** whilst taking this medication but monitoring of infant serum valproate levels, platelets and liver enzymes should be considered.
- The mother taking Valproate alongside other mood stabilisers or antipsychotics may cause infant sedation or withdrawal reactions.

Assessment and Monitoring:

- **Risks:** Congenital malformations (10%): spina bifida, cardiovascular malformations (ASD), cleft lip and palate, hypospadias, polydactyly, craniosynostosis. 30-40% will have developmental problems long-term
- Newborn infant physical examination with special attention for any possible **congenital malformations/lethargy/poor feeding**
- Please see next page to record reviews on day 1 and 2 of life.

Please confirm a review in the first 24 hours of life			Place patient sticker here
Date	Time	Name of person checking	
		Midwife/Nursery Nurse/ANNP/Doctor	
Signs/Symptoms found:			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:

Please confirm review on day 2 of life		
Date	Time	Name of person checking
		Midwife/Nursery Nurse/ANNP/Doctor
Signs/Symptoms found:		
Please sign to confirm paediatric team contacted if signs/symptoms found:		
Date & Time:		

Mood Stabilisers: Carbamazepine

Breastfeeding information:

- Taking Carbamazepine is not a reason to discontinue breastfeeding.
- Carbamazepine has relatively high levels in breastmilk and breastfed babies have serum levels that are measurable, but usually below the mood stabilizer therapeutic range.
- Most infants have no adverse reaction, but sedation, poor sucking, withdrawal reactions and cases of hepatic dysfunction have been reported: monitor LFTs if decision to breastfeed.

Assessment and Monitoring:

- Risks: Congenital malformations (neural tube defects, cleft lip and palate, cardiovascular and urinary tract malformations), and sedation / poor feeding.
- Monitor for **sedation**: drowsiness, not waking for feeds, poor feeding.
- Exposure to **carbamazepine** can lead to liver dysfunction as well as an increased risk of Haemorrhagic Disease of the Newborn – **ensure IM Vitamin K given.**

Please confirm review in the first 24 hours of life			Place patient sticker here
Date	Time	Name of person checking Midwife/Nursery Nurse/ANNP/Doctor	
Signs/Symptoms found:			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:

Please confirm review on day 2 of life			
Date	Time	Name of person checking Midwife/Nursery Nurse/ANNP/Doctor	
Signs/Symptoms found:			
Please sign to confirm paediatric team contacted if signs/symptoms found:			Date & Time:

Appendix 4 – Poor Neonatal Adaptation Syndrome (PNAS) Monitoring Chart

Patient sticker



Poor Neonatal Adaptation Syndrome (PNAS) Monitoring Chart

Please use this chart alongside the routine neonatal NEWTT Chart

Discuss with the paediatric team how often observations are required

If any of the following signs/symptoms are observed, please discuss with the paediatric team

Date & Time:							
Insomnia/restless sleep							
Poor sucking							
Significant/persistent vomiting							
Diarrhoea							
Tremors/jitteriness							
Fever							
Hypothermia							
Nasal congestion							
Signs of respiratory distress							
Blue lips							
Blue extremities							

Appendix 5 - Letter to Carer and Community Healthcare Practitioners

Baby details:

Name:

NHS number:

Hosp Number:

DOB:

Discharge address and phone number :

Looked after child: yes/no

Mother's details:

Name:

NHS number:

Hosp Number:

DOB:

Discharge address and phone number

Main carer (*if not mother*):

Name:

DOB:

Discharge address and phone number

Baby's mother was taking the following medication during pregnancy:

- 1.
- 2.
- 3.

Breastfeeding is/ not contraindicated

The following signs may be observed, close body contact such as skin to skin care could help

- 1.
- 2.
- 3.

If at any time the baby appears unwell, drowsy or has feeding difficulties they should be referred to the local paediatric team for rapid assessment.

Professionals involved:

Follow up plans: