Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Prescribing Guidance for Mental Health Prescribers and GP's in Perinatal Mental Health (MG18)

Document author	Assured by	Review cycle
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Contents

1. Prescribing Psychotropic Medication in Pregnancy – General Principles

- Prescribers should discus with all women of childbearing potential prescribed psychotropics, the risks and benefits of medication prescribed for treating their mental health relating to conception and the perinatal period. These discussions must be recorded in their notes.
- Prescribers should be aware that the evidence base for prescribing psychotropics in the perinatal period is generally weak; studies are often retrospective with confounding issues being prominent. There is much uncertainty with regards to the data.
- Pregnancy is not protective against episodes of mental illness
- Poor mental health in pregnancy is a strong predictor of mental illness postnatally
- Treatment of antenatal mental illness is likely to decrease the risk of onset or exacerbation of illness postnatally
- It is a priority to keep the mother mentally well during pregnancy
- **The risk of relapse in the immediate postpartum period for women with a history of bipolar disorder, schizoaffective disorder or postpartum psychosis is particularly high**
- **It is extremely important to review each woman and pregnancy on an individual basis taking into account previous *effective* drug therapy**
- **If there is strong evidence of a good past response to a medication there should be good reason not to recommend it as the medication of choice for the woman. It may be inadvisable to prescribe a medication of unknown efficacy *even if* it has a potentially lower risk in pregnancy.**
- Generally AVOID STOPPING psychotropic medication suddenly in pregnancy. This does not necessarily remove risk of malformations and may pose a risk to the mother's health.
- In general avoid switching psychotropic medication during pregnancy unless the benefits are likely to outweigh the risks, in order to minimise the number of drugs that the foetus is exposed to.
- Sub-therapeutic doses of psychotropic medication in pregnancy should be avoided. Any reduction in dose should always be considered very carefully and may be detrimental to the mother's mental health.
- **Valproate is contra-indicated in pregnancy for the treatment of bipolar disorder and should not be prescribed to women of childbearing potential** unless conditions of the pregnancy prevention programme are met. Further advice is available here
- There are a number of online resources (eg Best Use of Medicines in Pregnancy (BUMPS) www.medicinesinpregnancy.org from UKTIS) that provide evidence-based and updated information to assist women in making informed decisions about treatment
- Medicines are not licensed by the manufacturer for prescribing in pregnancy therefore all medicines are used "off license" in pregnancy.

Summary of Lower Risk Psychotropics in Pregnancy

Important – please note:

It is extremely important to review each patient and pregnancy on an individual basis taking into account previous *effective* drug therapy

If there is strong evidence of a good past response to a medication, there should be a good reason not to recommend it as the medication of choice for the patient. It may be inadvisable to prescribe a medication of unknown efficacy even if it has a potentially lower risk in pregnancy

Antidepressants	**Sertraline** – for previously untreated patients If high risk of relapse patient should be maintained on the same antidepressant during and after pregnancy. (See section1.1 for further information)
Antipsychotics	**Quetiapine-** for previously untreated patients Consider using/continuing antipsychotic the patient has previously responded to rather than switching Clozapine should usually be continued (See section 1.2 for further information)
Mood Stabilisers	Valproate is contra-indicated in pregnancy Consider using a mood stabilising antipsychotic eg **Quetiapine** or **Olanzapine** (see section 1.3 for further information)
Hypnotics/Sedatives/Anxiolytics	Non-drug measures are preferred Benzodiazepines and Z drugs are probably not teratogenic but best avoided in late pregnancy Promethazine is widely used but supporting safety data is scarce (see section 1.4 for further information)

1.1 Antidepressants in Pregnancy

- Patients who are already receiving antidepressants and are at a high risk of relapse are often best maintained on the same antidepressant during and after pregnancy.
- If initiating an antidepressant during pregnancy or for a woman contemplating pregnancy previous responses to specific medications must be taken into account
- For **previously untreated** patients **Sertraline** should be considered as the preferred option
- Babies born to mothers with depression, treated with antidepressants during pregnancy, may have better longer term emotional and behavioural development, compared to babies born to mothers with depression that was untreated.
- The risks of not treating depression include harm to the mother through poor self-care, lack of obstetric care or self-harm, and also harm to the foetus or neonate ranging from neglect to infanticide

Tricyclic Antidepressants (TCA's)

- Foetal exposure to TCA's during pregnancy is high
- TCA's have been widely used historically in pregnancy without apparent adverse effect to the foetus
- TCA's are often fatal in overdose and this should limit their use generally
- A weak association between Clomipramine and cardiovascular defects can not be excluded and therefore Clomipramine is not recommended in pregnancy
- Nortriptyline has less anticholinergic and hypotensive side effects associated with it and therefore may be preferred to Amitriptyline and Imipramine.

Selective Serotonin Reuptake Inhibitors (SSRI's)

- Sertraline appears to result in the least placental exposure. For **previously untreated** patients **Sertraline** should be considered as the preferred option
- There have been concerns about antidepressants (mainly SSRI's and possibly particularly Paroxetine) being associated with cardiac malformations. However, this may not be the case once all confounders are taken into account.
- Some studies have reported an association between exposure to SSRI's in utero and autism spectrum disorders or ADHD in later childhood. However, the data are mixed with other studies suggesting the association may be due to confounding factors.
- Although the risk of persistent pulmonary hypertension of the newborn (PPHN) in babies exposed in utero to SSRI's after 20 weeks is increased, the absolute risk is low (from 2 in 1000 births background rate to 3 in 1000 on SSRIs).
- SSRI's have been associated with an increased rate of spontaneous abortion and decreased birth weight. However it is possible that these effects are associated primarily with maternal depression.
- SSRI's may be associated with an increased risk of postpartum haemorrhage but the magnitude and clinical significance of this risk is uncertain
- There is some evidence of neonatal effects following late pregnancy exposure to SSRI's particularly respiratory distress and neonatal behavioural syndrome (also called Neonatal adaption syndrome – NAS). Babies of mothers on SSRI's will generally require up to 48 hours on the postnatal ward for monitoring of the baby.

Duloxetine

No specific risks were identified in a study that followed 233 women through pregnancy and delivery. (8) However a case of suspected withdrawal syndrome requiring hospitalisation has been reported (9)

Venlafaxine

Venlafaxine has been associated with cardiac defects, anencephaly and cleft palate, neonatal withdrawal and poor neonatal adaptation syndrome. However data are conflicting as newer data suggest that first trimester use appears not to be associated with an increased risk of major congenital malformations.

Mirtazapine

There is little data supporting its safety but data suggests it is not associated with malformations but maybe associated with an increased rate of spontaneous abortion (like SSRIs).

Trazodone

There is little data supporting its safety.

Monoamine oxidase inhibitors (MAOI's)

MAOI's should be avoided in pregnancy because of a suspected increased risk of congenital malformations and also due to the risk of hypertensive crisis.

Electroconvulsive Therapy (ECT)

In resistant depression NICE recommends that ECT is used before/instead of drug combination

1.2 Antipsychotics in Pregnancy

- In chronic schizophrenia the risk of a postnatal relapse is evenly increased throughout the first postnatal year
- Schizophrenia is associated with a range of adverse obstetric and neonatal outcomes. Potential reasons for this include the underlying illness, lifestyle factors eg smoking, alcohol and drug abuse, and poor nutrition, medical morbidities eg diabetes, obesity and hypertension, social issues eg poverty and poor antenatal care
- There are now more published safety data in pregnancy for second generation antipsychotics than first generation antipsychotics
- There is no clear evidence that any antipsychotic is a major teratogen
- **Switching antipsychotics during pregnancy is not usually advised due to the risk of relapse**
- Consider using the antipsychotic that the woman has previously responded to after discussion of benefits and risks
- **Quetiapine** has a relatively low rate of placental passage. **It should therefore be considered for a woman who has not been treated with an antipsychotic previously**.
- The risk of gestational diabetes may be increased by antipsychotics. Enhanced diabetes screening, including an oral glucose tolerance test is advised for all women prescribed an antipsychotic during pregnancy.
- If a woman is prescribed Clozapine, it is recommended that it should usually be continued during pregnancy.
- NICE recommends that long acting antipsychotic injections (depots) should be avoided in pregnancy, unless a depot is needed to keep a woman well during the perinatal period. If the benefits of a depot outweigh the risks particularly if there is a history of non-compliance with oral medication and a high risk of relapse, then the depot should be continued. However, due to the pharmacokinetics of long acting antipsychotic injections, there will be a prolonged need for monitoring of neonatal symptoms.
- Women taking an antipsychotic should give birth in a unit with access to neonatal intensive care facilities. Any baby that has been exposed to an antipsychotic near delivery should be monitored closely. This would involve admitting the mother and baby to a post natal ward for enhanced monitoring for several days following delivery.

1.3 Mood Stabilisers in Pregnancy

- No mood stabiliser is clearly safe in pregnancy. NICE recommends the use of mood stabilising antipsychotics e.g. Quetiapine, Olanzapine in preference to continuation with a mood stabiliser. However women with severe illness or who relapse quickly after discontinuing a mood stabiliser should be advised to continue their medication after discussion of the risks.
- The risk of relapse is very high if medication is discontinued abruptly
- Risk of relapse in the immediate postpartum period for women with a history of bipolar disorder is particularly high with around 1 in 5 women experiencing a psychotic relapse post-partum
- The risk of relapse appears to be higher if the woman is not taking medication prior to or during pregnancy
- In women who have pre-existing bipolar disorder and who are unmedicated during pregnancy, re-starting previously effective medication, or an antipsychotic such as Quetiapine or Olanzapine on Day 1 postnatal may prevent some but not all early recurrences of bipolar disorder
- The risk of not stabilising mood include harm to the mother through poor self-care, lack of obstetric care or self- harm or to the foetus or neonate ranging from neglect to infanticide
- **Valproate is contra-indicated in pregnancy for the treatment of bipolar disorder** and should not be prescribed for women of childbearing potential unless conditions of the pregnancy prevention programme are met. Further advice is available here

Lithium

- Lithium use during pregnancy has a well known association with the cardiac abnormality Ebstein's anomaly. However recent data suggests that this risk if it exists is likely to be small.
- Lithium should be avoided in pregnancy if possible. However if Lithium is the drug most likely to keep the woman well, she should be advised of the possible increased risk but supported to stay on Lithium.
- If discontinuation of Lithium is planned, it should be reduced gradually, over four weeks and preferably before conception. The maximum period of risk to the foetus is 2-6weeks after conception.ie often before a woman is aware that she is pregnant. Consider restarting in the second or third trimester
- If Lithium is continued during pregnancy high resolution ultrasound and echocardiography should be performed in liason with obstetric services
- In the third trimester, an increasing dose of Lithium is needed to maintain the Lithium level during pregnancy as total body water increases. However the Lithium level can sometimes increase again particularly in late pregnancy. The Lithium requirements return abruptly to pre-pregnancy levels immediately after delivery. NICE recommends monitoring Lithium levels every 4 weeks until 36 weeks and weekly thereafter, adjusting the dose to maintain the plasma Lithium level within the woman's usual therapeutic range. Lithium should be stopped during labour and the plasma level checked 12hours after the woman's last dose. If levels are not above the therapeutic range, restart Lithium on Day 1 postnatally at the pre-pregnancy dose and check the level again after one week.
- Delivery must take place within a hospital where fluid balance can be monitored and maintained.

Valproate

- **Valproate is contra-indicated for the treatment of bipolar disorder in pregnancy** and should not be prescribed for women of childbearing potential unless conditions of the pregnancy prevention programme are met. Further advice is available here
- If a woman becomes pregnant whilst taking Valproate then it should be withdrawn and consideration of replacing it with an antipsychotic mood stabiliser
- Valproate is associated with a significant increased risk of a range of major congenital malformations
- Valproate exposure in utero throughout pregnancy is associated with a decreased IQ in school age children and an increased risk of autistic spectrum disorder.

Lamotrigine (bipolar depression only)

- Lamotrigine is probably not associated with significant risks of structural teratogenicity, or associated with neurodevelopmental problems
- There is increased clearance of Lamotrigine during pregnancy, which then reduces postpartum to pre-pregnancy levels. To aid the management of depressive relapses in the perinatal period, serum levels of lamotrigine should be monitored, if possible from preconception to one month postpartum and the dose adjusted accordingly.
- There is some evidence that Folic acid may reduce the effectiveness of Lamotrigine. However see the statement below on Folic Acid supplements during pregnancy.

Carbamazepine

- **Do not initiate Carbamazepine in preconception or pregnancy because of its teratogenic potential and uncertain efficacy in bipolar disorder**
- Carbamazepine can reduce the effectiveness of oral and parental contraceptives
- There is some data to suggest that Carbamazepine increases the risk of major congenital malformations
- There is no evidence that Carbamazepine is associated with neurodevelopmental problems
- Consider the possibility of stopping Carbamazepine in pregnancy or if planning a pregnancy.
- If Carbamazepine is considered essential in pregnancy, prescribe the lowest **effective** dose, as the teratogenic effect is probably dose related. To avoid bleeding disorders in the neonate prophylactic Vitamin K should be administered to the mother in the last few weeks of pregnancy and to the neonate after delivery.

Folic Acid Supplements with Anticonvulsant Drugs

- There is little evidence that folic acid protects against anticonvulsant induced harm to the foetus if given during pregnancy.
- However NICE guidelines (for epilepsy) recommend high dose Folic Acid (5mg once a day) in the 3 months before and after conception for women on anticonvulsants including Lamotrigine, as it may protect if given prior to conception.

1.4 Hypnotics/Sedatives and Anxiolytics in Pregnancy

- Anxiety and stress during pregnancy can be associated with long term behavioural and mental health problems in the offspring
- The preferred treatment for anxiety disorders are CBT and for insomnia sleep-hygiene measures
- However if the disorder is causing severe distress and/or impairment then medication may be required.
- SSRIs are the first line medication for anxiety disorders- see information on SSRIs above in treatment of depression

Benzodiazepines and 'Z Drugs'

- Studies have previously found an association between benzodiazepine exposure and oral clefts in the neonate. However this finding has not been replicated
- There is no convincing evidence in the available data of an increased risk of birth defects associated with benzodiazepines.
- Limited data suggests that benzodiazepine exposure in utero may be associated with delayed psychomotor development
- Third trimester use of benzodiazepines is commonly associated with floppy baby syndrome.
- There is no convincing evidence in the available data of an increased risk of birth defects associated with 'Z drugs' – Zopiclone or Zolpidem
- Zolpidem may increase the risk of pre-term delivery and low birth weight and an increased likelihood of caesarean section. The magnitude of this risk if it exists is uncertain.

Pregabalin and Gabapentin

There is very limited data on the safety of Pregabalin and Gabapentin in pregnancy. A study detected no increase in the rate of congenital malformations among infants exposed to Pregabalin during pregnancy (and no reported malformations in infants exposed to Gabapentin) in a group of women being treated for epilepsy (10). However, an increased risk of major malformations was associated with Pregabalin exposure in a recent study but the small number of exposed pregnancies and potential confounding may account for the findings. (11)

Promethazine

- Promethazine has been used in hyperemesis gravidarum and appears not to be teratogenic although data is limited
- Promethazine is widely used in pregnancy but supporting safety data is scarce.
- The Summary of Product Characteristics (SPC) for Promethazine recommends that it is not used in the 2 weeks prior to delivery in view of the risk of irritability and excitement in the neonate. However the clinical risk to the patient of not treating severe insomnia should be considered and balanced with the possible risk.

2. Prescribing Psychotropic Medication in Breast Feeding

- **Wherever possible the safest treatment available should be used so that breast feeding can still take place. However the choice of psychotropic should be balanced with effective treatment of the woman's mental health. Each woman should be individually assessed, taking into account previous effective drug therapy and should be considered whilst pregnant. If the woman is being treated successfully with a psychotropic, do not change it for breast feeding.**
- NICE advises that breast feeding should not be discouraged. However where the pressure of breast feeding is likely to have a detrimental effect on the mother's mental health, support the mother in alternative methods of feeding, or consider mixed feeding.
- All psychotropics are excreted in breast milk to some degree.
- **Breast feeding is not recommended in women prescribed Clozapine or Lithium**
- **The Relative Infant Dose (RID) indicates how much of the maternal dose the infant is receiving.** It is calculated by dividing the infant's dose via breast milk (mg/kg/day) by the maternal dose in mg/kg/day.The lower the RID, then the lower the dose of medication that the infant will be exposed to. Usually it is considered that an RID less than 10% poses less risk in breast feeding.
- **It should be noted that for many drugs there is very little data on levels in breast milk and safety in breast feeding. Therefore recommendations are often based on just a small number of case reports. The range in RID can vary according to source. Absence of information does not imply safety.**
- Drugs with a short half life (t½) are preferred. Drugs with a long t1/2 can accumulate in the breast milk and infant serum. The preferred situation in breast feeding is to prescribe a drug that has both a low RID and preferably a short t½.
- There is little clear evidence to support the discarding of breast milk or timing of breast feeding in relation to time of maternal drug administration. Such recommendations could potentially add to the difficulties and challenges of establishing breastfeeding.
- Medicines are not licensed by the manufacturer for prescribing in breast feeding therefore all medicines are used "off license" in breast feeding.
- The online resource https://www.breastfeedingnetwork.org.uk/resources/ provides evidence-based and updated information to assist women in making informed decisions about drug treatment and breast feeding.
- **All infants should be monitored carefully and regularly for side effects of the medication concerned as well as for sedation, feeding patterns, growth and development.**
- Take care with any sedating medication postnatally excessive sedation can hinder baby care and breastfeeding. **Strongly advise women against co-sleeping with their baby**
- The advice in this document applies to term, healthy infants. **Seek specialist advice for babies whose weight at birth is low or who have medical comorbidities.**

Summary of Lower Risk Psychotropics in Breast Feeding

It is usually advisable to continue a drug that has been used successfully in pregnancy if breast feeding

Antidepressants	**Sertraline** Other drugs may be used (see section and table 2.1)
Antipsychotics	**Quetiapine** **Olanzapine** Women taking Clozapine should not breast feed. Clozapine should be continued. Other drugs may be used(see section and table 2.2)
Mood Stabilisers	**Quetiapine** **Olanzapine** Women taking Lithium should not breast feed. Lithium should be continued. Other drugs may be used (see section and table 2.3)
Hypnotics/Sedatives/Anxiolytics	**Lorazepam** may be considered as an anxiolytic **Zolpidem** may be considered for night sedation (see section and table 2.4 for details on other medication)

2.1 Antidepressants in Breast Feeding

- If **initiating** an antidepressant postnatally in a woman who wishes to breast feed then Sertraline is the preferred antidepressant.
- However the risks of other antidepressants may be outweighed by their clinical advantages for the patient for continuation of treatment if effective
- Monitor infants for sedation, irritability, feeding problems and weight gain

Table 2.1

Drug	RID(%)
Agomelatine (non-formulary)	No information
Amitriptyline	1.9-2.8
Citalopram	3-10.9
Clomipramine	2.8
Duloxetine	<1
Escitalopram	3-8.3
Fluoxetine *	1.6-14.6
Imipramine	0.1-4.4
Mirtazapine	0.5-4.4
Moclobemide	3.4
Paroxetine	0.5-2.8
Reboxetine	1-3
Sertraline	0.5-3
Trazodone	2.8
Venlafaxine	6-9
Vortioxetine	No information

Relative Infant Dose (RID) obtained from an amalgamation of sources
*Fluoxetine- can be used cautiously in breast feeding but caution as has a long half-life (up to 140hours) - further discussion with patient recommended

2.2 Antipsychotics in Breast Feeding

- Encourage women who are taking an antipsychotic to breast feed unless they are taking Clozapine.
- Women taking clozapine should avoid breast feeding due to the risk of neutropenia and seizures in the baby. Clozapine should be continued
- Avoid stopping or switching antipsychotics in the postnatal period. Risk of relapse is higher than in pregnancy
- If **initiating** an antipsychotic whilst breast feeding the preferred antipsychotic is **Quetiapine or Olanzapine.**

- Monitor infants for sedation, feeding problems, weight gain, motor abnormalities and neurodevelopment.

Table 2.2

Drug	RID (%)
Amisulpride	10.7
Aripiprazole	0.7-6.4
Chlorpromazine	0.3
Flupentixol	0.7-1.75
Haloperidol	0.2-12
Lurasidone (non-formulary)	No data available
Olanzapine	0.28-2.24
Quetiapine	0.02-0.1
Risperidone	2.8-9.1
Sulpiride	2.7-20.7
Zuclopenthixol	0.4-0.9

Relative Infant Dose (RID) obtained from an amalgamation of sources

2.3 Mood Stabilisers in Breast feeding

- It is preferable to prescribe an antipsychotic that is effective in bipolar disorder to women who wish to breast feed rather than a mood stabiliser. Quetiapine or Olanzapine are the antipsychotics of choice
- **Women taking Lithium should not breast feed. Lithium therapy should be continued.**
- Carbamazepine may be considered with caution
- Valproate **must not** be prescribed for women of childbearing potential unless conditions of the pregnancy prevention programme are met. Further advice is available here Women taking Valproate should avoid breast feeding.
- Lamotrigine can very cautiously be prescribed during breast feeding. Discontinue lamotrigine/breast feeding if the infant develops a rash and monitor carefully.

Table 2.3

Drug	(RID) %
Lamotrigine	9.2-18.27
Carbamazepine	3.8-7.3
Olanzapine	0.28-2.24
Quetiapine	0.02-0.1

Relative Infant Dose (RID) obtained from an amalgamation of sources

2.4 Hypnotics/Sedatives and Anxiolytics in Breast Feeding

- It is important to note that insomnia postnatally (inability to sleep even when not being disturbed by the baby) may precipitate severe illness such as postpartum psychosis
- Benzodiazepines with a long half-life such as Diazepam should not be prescribed in breast feeding.
- Lorazepam is the preferred benzodiazepine, prescribed cautiously in low doses if absolutely necessary
- The 'z' hypnotics are preferred, as they have shorter half-lives than the benzodiazepines and appear to pass into breast milk in smaller amounts.
- Several benzodiazepines are described as 'short acting', but have significantly longer half-lives when compared to the 'z' hypnotics.
- Where possible use short-term, intermittent dosing to reduce infant exposure.
- Monitor the infant closely for sedation, feeding problems and adequate weight gain.
- Co-sleeping with the infant is strongly advised against when the mother has taken a hypnotic/sedative

Table 2.4

Drug	RID (%)	Half-life(t1/2) hrs
Diazepam	0.88-7.14	21-50 Active metabolite 48-120
Lorazepam	2.6-2.9	8-25
Gabapentin	6.6	5.2-10.8
Pregabalin	7.18	6.3
Promethazine *	Not available	9-19
Temazepam	Not available	5-11
Zolpidem	0.02-0.18	2-3
Zopiclone	1.5	3.5-6

Relative Infant Dose (RID) obtained from an amalgamation of sources
*Promethazine should be used cautiously. It can lower basal prolactin secretion and may reduce lactation

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