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Thoughtfulness of clinician in prescribing psychotropic medication to **ALL** women of childbearing potential.
Contraception should be used on every conceivable occasion”  Spike Milligan 1972

- Often inconsistent and inadequate use
- Hyperprolactinaemia and amenorrhoea
- Cognitive impairment, disorganisation, ambivalence
- View of self as feminine
- Weight, smoking, age, BP, lipids, physical co-morbidities

- Abstinence techniques
- Withdrawal
- Barrier methods
- OCP
- Depot/ implant
- IUDs
- Tubal Ligation
Prescribing for women:

- **Physical attractiveness:** weight, hirsutism, dermatological side-effects, galactorrhoea
- **Femininity:** fertility, libido, body shape, polycystic ovaries, menstruation
- **Health and well-being:** weight gain, metabolic syndrome, osteopenia, raised prolactin, EPSEs, interaction with pregnancy, effects on fetus/infant, interaction with other prescribed medication/ herbal remedies/ alcohol/ illicit drugs
- **Emotional/ Psychological:** general ‘dulling’, sleepiness/ fatigue, lack of emotional responsivity/ availability
- **Social:** stigma, impairment of occupational function, impact on parental and caring roles and responsibilities
Prescriber’s personal attitude towards risk

Individual risks have different subjective experience to different women

Required to calculate risk profiles for 2 individuals involving multiple predictors and outcomes
### Critical Periods in Human Development

<table>
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<th>Age of Embryo (in weeks)</th>
<th>Fetal Period (in weeks)</th>
<th>Full Term</th>
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#### Not Susceptible to Teratogens

- Heart
- Upper Limbs
- Lower Limbs
- Palate
- External Genitalia
- Ear

#### Prenatal Death

- Major Congenital Anomalies (red)
- Minor Congenital Anomalies (yellow)

#### Central Nervous System

- Heart
- Upper Limbs
- Eyes
- Lower Limbs
- Teeth
- Palate
- External Genitalia
- Ear

*Red indicates highly sensitive periods when teratogens may induce major anomalies.*
Information and advice for women who are planning a pregnancy, pregnant or in the postnatal period

Mental health professionals providing detailed advice about possible risks of mental health problems or the benefits and harms of treatment should include discussion of the following, depending on individual circumstances:

• the *uncertainty* about the benefits, risks and harms of treatments
• the *likely benefits* of each treatment, taking into account severity of the problem
• the woman’s *response* to any previous treatment
Mental health professionals providing detailed advice about possible risks of mental health problems or the benefits and harms of treatment should include discussion of the following, depending on individual circumstances:

- the *background risk of harm* to the woman and the fetus or baby and the risk to mental health and parenting associated with no treatment
- the possibility of *sudden onset* of symptoms, particularly in the first few weeks after childbirth (for example, in bipolar disorder)
- the risks or harms to the woman and the fetus or baby associated with treatment options
- the need for *prompt* treatment
- the risk or harms to the woman and the fetus or baby associated with *stopping or changing* a treatment
Threshold for pharmacological interventions higher arising from the changing risk–benefit ratio for psychotropic medication at this time

• Discuss risks associated with stopping psychotropic medication
• Choose the drug with the lowest risk profile for the woman, fetus and baby, taking into account a woman’s previous response to medication and her preference
• Avoid polypharmacy
• Take into account that dosages may need to be adjusted in pregnancy
Risks of Drugs

- Risk of teratogenicity
- Risk of neonatal toxicity and withdrawal
- Risk of longer term neurobehavioural / cognitive problems
- Physical risks to mother eg gestational diabetes, obesity etc

Risks of illness

- May affect birth weight and gestational age at delivery
- Accessing antenatal care
- Relationships with family, carers and professionals
- Diet, smoking, alcohol, illicit drugs, risk taking behaviours
- Possible detrimental effect of the mental disorder in pregnancy on the fetus
- May impact on mother-infant attachment and capacity to parent
Information and Advice

When discussing likely benefits and risks of treatment with the woman and, if she agrees, her partner, family or carer:

• acknowledge the woman's central role in reaching a decision about her treatment and that the role of the professional is to inform that decision with balanced and up-to-date information and advice

• use absolute values based on a common denominator (that is, numbers out of 100 or 1000)

• acknowledge and describe, if possible, the uncertainty around any estimate of risk, harm or benefit

• use high-quality decision aids in a variety of numerical and pictorial formats that focus on a personalised view of the risks and benefits (in line with the guidance on patient experience in adult NHS services, NICE guideline CG138)

• consider providing records of the consultation, in a variety of visual, verbal or audio formats.

NICE APMH 2014
Discuss breastfeeding with all women who may need to take psychotropic medication in pregnancy or in the postnatal period.

Explain the benefits of breastfeeding, the potential risks associated with taking psychotropic medication when breastfeeding and with stopping some medications in order to breastfeed.

Discuss treatment options that would enable a woman to breastfeed if she wishes and support women who choose not to breastfeed.
Monitoring babies for effects of psychotropic medication taken in pregnancy

If a woman has taken psychotropic medication during pregnancy, carry out a *full neonatal assessment* of the newborn baby, bearing in mind:

- the variation in the *onset* of adverse effects of psychotropic medication the need for further monitoring
- the need to *inform* relevant healthcare professionals and the woman and her partner, family or carer of any further monitoring, particularly if the woman has been discharged early.
What are the dilemmas facing women and clinicians?

- Planning a pregnancy while taking medication for a known disorder
- Unplanned pregnancy while taking medication for a known disorder: confirm pregnancy, scan, discussion of risks
- New illness episode in pregnancy: how to treat, what to initiate if unmedicated, what changes to existing medication, addressing potential non-adherence
- Onset of illness in pregnancy: how to treat, what medication to initiate
- Medication in the intra-partum period: risk of relapse, risks to mother, risks to fetus, drug interaction
- Prophylaxis
- How to re-instate medication post-delivery in woman at high risk of relapse
- Breastfeeding
Issues: the Patient

• What are her worries?
• How to stay well: prophylaxis, lifestyle, psychological support, triggers, relapse indicators, relationship with trusted professional
• Risk of relapse
• Previous history
• Risks: relapse in pregnancy, in labour, post-natally; medication- teratogenesis, neuro-behavioural sequelae, withdrawal and toxicity in neonate, breastfeeding, interaction with other meds, differences in metabolism during pregnancy, specific risks in pregnancy; monitoring – compliance, mental state, blood Li level, side-effects, blood tests, need for change in dose; breastfeeding
• Prompt and effective treatment
• Planning for parenthood: risks of medication (sedation, reduced emotional availability, sleep pattern), sleep loss, breastfeeding
• Who needs to be involved: partner, other family member, GP, MW, HV, SW
Issues: the Clinician

• Who is she?
• What are the risks: of not treating; relapse in pregnancy, in labour, post-natally; medication- teratogenesis, neuro-behavioural sequelae, withdrawal in neonate, toxicity in neonate, metabolism in fetus, breastfeeding, interaction with other meds, differences in metabolism during pregnancy, specific risks in pregnancy (DM, BP, sedation); swopping or stopping; monitoring – compliance, mental state, blood Li level, side-effects, blood tests, need for change in dose, medication free; risks assoc with other patient factors eg smoking, alcohol, domestic abuse, poor living conditions, poor social support, finances, cognitive dysfunction, co-morbidity
• How to explain risk
• Patient consent
• Recording of discussions
• Communication with other professionals
“Generally the unlicensed use of medicines becomes necessary if the clinical need cannot be met by licensed medicines; such use should be supported by appropriate evidence and experience.”
SIGN 127, 2012

“Prescribing medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescribers’ professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.”
SIGN 127, 2012

BUT
No psychotropic medication is licensed for use in pregnancy or in breastfeeding mothers. The BNF and product information advise at least caution in their prescription at this stage or in most cases contraindication. Drug trials exclude pregnant or breastfeeding women and no randomised controlled trials of psychotropic medication have been conducted in pregnancy or lactating women. Despite this, prescribing of psychotropic medication is commonplace in women of reproductive age and up to 27% of women are receiving psychotropic medication at the time when their pregnancies are first diagnosed (Rubin et al, 1986; Williams et al, 1998).
Advice for prescribers says you should:
• be satisfied that an alternative treatment would not meet the patient’s specific needs before prescribing the unlicensed medicine
• be satisfied that there is a sufficient evidence base and/or experience of using the medicine to show its safety and efficacy...following a risk benefit analysis
• take responsibility for prescribing the medicine and for overseeing the patient’s care, including monitoring and follow-up
• record the medicine prescribed and the reasons for prescribing this medicine
• record that you have discussed the issue with the patient
• give the patient sufficient information about the proposed treatment, including known serious or common adverse reactions, to enable her to make an informed decision
• answer questions from patients (or ‘carers’) about medicines fully and honestly.

Medicines and Healthcare products Regulatory Agency 1 April 2009
GMC Good practice in prescribing and managing medicines and devices (2013)
Lack of randomised controlled trials confirming the efficacy, quality and safety of drugs used in pregnant women means that off-label prescribing in this patient population is commonplace. Absence of evidence of harm is not the same as evidence of absence of harm.

If a licensed drug harms a patient, the responsibility lies with the manufacturer. When an off-label/unlicensed drug causes harm, the responsibility lies with the doctor. Theoretically, a doctor could be involved in a claim of negligence for using an off-label drug if harm was caused. It is however, more likely that a failure to provide adequate information on which the patient can give informed consent will result in litigation.

The doctor must ensure that the patient fully understands the relative risks and benefits of the treatment, what is meant by off-label/unlicensed drug use and the reasons why treatment with the drug(s) is advised. Consenting process must be fully documented.

Sensible prescribing is key.
Na Valproate

- Major malformations: 7.7% prevalence rate
- Pre-term delivery, IUGR,
- Foetal valproate syndrome
- Facial dysmorphias (44% moderate-severe)
- Neural tube defects in 5.9% (gen pop rate =0.1%)
- Low verbal IQ (22% <70, 20% 70-79)
- Delayed development
- Dose > 800mgs/day
- Foetal/neonatal distress
- Childhood autism : 2.50% (adjusted hazard ratio: 5.2; 2.7-10.0)
- Autism spectrum disorder: 4.42% (adjusted hazard ratio: 2.9; 1.7-4.9)
- At increased risk of ADHD diagnosis at age 6

J Neurol. Neurosurg. Psychiatry 2004; 75; 1575-1583. Adab, Kini et al
Antipsychotics

Do not offer depot antipsychotics to a woman who is planning a pregnancy, pregnant or considering breastfeeding, unless she is responding well to a depot and has a previous history of non-adherence with oral medication
Summary

• Think Prevention
• Pre-pregnancy counselling

• Understand the individual woman, her life, her physical & sexual health
• Think Family
• Get the diagnosis right
• Don’t forget what is known about illness course & the individual woman’s illness