In December 2014 NICE updated its prescribing guidelines for ‘Antenatal and postnatal mental health’, the content has been significantly updated since the earlier version. Shortly afterwards, early in 2015, the MHRA issued specific guidance around the use of valproate in women of childbearing potential.

What the NICE guidance covers
The main medicines that new NICE guidelines focus on are antidepressants, benzodiazepines, and antipsychotics, followed by anticonvulsants used for mood disorders such as bipolar disorder, and lithium. The mental illnesses focused on are generally those seen in primary care or in non-specialist services. There is a great emphasis on the need during pregnancy and the postnatal period to recognise new mental illness such as depression and anxiety, insomnia, eating disorders, alcohol and drug misuse; and more severe perinatal mental illnesses such as postpartum psychosis.

Medicines in pregnancy
There are a number of general difficulties in providing robust guidance for the use of any medicine in pregnancy. Firstly, there is a lack of evidence about the use of each specific medicine at each stage of pregnancy and postpartum (i.e. the effects on the development of the child) – as it would be unethical to conduct randomised clinical trials of medicines in pregnant mothers (indeed in most clinical trials the subjects are predominantly males). Therefore it is almost impossible to prove unequivocally that a medicine is safe. Hence the manufacturers commonly err on the side of legal caution and recommend that their products are avoided in pregnant women. In general data regarding the neurodevelopmental effects on the baby of medicines used in pregnancy and the effects of medicines taken during breastfeeding are even more lacking.

Secondly, what data there is (often small studies, case reports, case series or from preclinical studies in animals where extrapolation into humans is difficult) is often confounded not only by the primary illness itself but also by other illness, concurrent medication, social factors and lifestyle.

Thirdly, this is all attempting to assess whether there is any increase in the incidence of something that occurs relatively rarely in the general population. There is a background risk of major foetal malformations in all pregnancies of between 2 and 3 in 100 and a risk of spontaneous miscarriage between 10 and 20 in 100 in the general population. Over 75% of these malformations are of unknown aetiology; only 1–2% are thought to be due to medicines. This background risk may be increased by the presence of a mental illness alone, and psychotropic medicines may potentially further increase the risks.

Main recommendations with medicines in pregnancy
Having considered the above restrictions, these new NICE guidelines are extremely helpful as they put a lot of focus on the general issues to consider. The guidelines give lots of general advice and outline the principles that should shape prescribing decisions. There is no easy ‘one-size-fits-all’ answer when it comes to considering the use of psychotropic medicines in pregnancy. These guidelines are far less prescriptive about exactly which medicine to use and when, than the previous version. They put considerable emphasis on prescribers reviewing (in discussion with patients) the overall risks when a patient is planning a pregnancy, on the need to discuss the risks versus benefits of stopping a medicine (and if so, how) before or during a pregnancy compared with the risks of continuing it. Each prescribing decision really does need to be tailored to the specific patient, in line with their preferences (as far as possible) and their preferred choice in light of the risks. This will vary considerably between patients, depending on the severity of illness and risk of relapse, current medicines and their effectiveness. Whichever decision is made there are risks, and usually a decision requiring such a balancing act results in a compromise. Because of the complexity of these scenarios prescribers should actively develop integrated care plans which should be coordinated by a named healthcare professional. These are personalised treatment plans balancing the risks of the medicines for the baby against the risks to mum and therefore the baby if she is untreated.

NICE antenatal and postnatal mental health clinical guidelines
Caroline Parker FFRPS, FRPharmS, FCMHP
As a general rule the care of women with a psychiatric or substance misuse disorder during pregnancy and the postnatal period should be the same as for anyone with a psychiatric or substance misuse disorder.

Main recommendations with medicines in breastfeeding
The World Health Organization stresses the desirability of breastfeeding exclusively for at least four to six months. It is therefore important to consider prescribing options that will allow the mother to safely breastfeed. It is usually inappropriate to withhold psychotropic medicines from the mother simply so that she can breastfeed, particularly in those at a high risk of relapse.

Specific advice includes:
• As far as possible try to avoid medication in the first trimester, or at least avoid starting any new psychotropics, as this period is the point at which medicines could potentially have a teratogenic effect
• Valproate is no longer recommended in women of childbearing potential as far as possible, due to the associated adverse neurodevelopmental effects on the young children born to women who took valproate when pregnant
• Take into account the woman’s previous response to treatment
• Use the least number of psychotropic medicines and the lowest effective dose to maintain remission of maternal symptoms
• Breastfeeding is encouraged in all women except whose taking carbamazepine, lithium or clozapine.

Key messages for patients
• If you are planning a pregnancy and you are prescribed psychotropic medicines, discuss this with your prescriber as soon as possible
• Do not suddenly stop your psychotropic medicines in order to get pregnant, as this may put you at a greater risk of a relapse of your illness, and it is important that you stay well
• There is no ‘one-size-fits-all’ recommendation about psychotropic medicines in pregnancy.

Further information
• UKTIS: 0844 892 0909. UKTIS is able to provide information on individual medication Individual monographs for medicines in pregnancy can be found on their website www.uktis.org
• UKMI Drugs In Lactation Advisory Service provides information on using medicines in lactation www.midlandsmedicines.nhs.uk/content.asp?section=6&subsection=17&pageId=1
• LactMed: This American database contains information on the use of different medicines including psychotropic in breastfeeding. Information is updated monthly: toxnet.nlm.nih.gov/newtoxnet/lactmed.htm
• Bumps: (best use of medicines in pregnancy): This new website developed in 2014 by UK Teratology Information Service (UKTIS) provides information on the use of medication in pregnancy: www.medicinesinpregnancy.org

Resources for patients
• Use of valproate in pregnancy: The MHRA issued a booklet to provide to any woman of childbearing potential who is prescribed valproate following on from their warning on the use of valproate in women in pregnancy https://assets.digital.cabinet-office.gov.uk/media/54bd3a23e5274a15b300009/Valproate_booklet_for_patients_Jan_2015.pdf
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