Chapter 1

Introduction to pharmacology

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Aim

The aim of this chapter is to introduce the reader to pharmacology and to consider specific applications related to pregnancy, labour and the postnatal period.

Learning outcomes

After reading this chapter the reader will:

- Have an understanding of the Code (NMC, 2018) and related documents that support the use of medicines in practice
- Consider the role of the pre-registration standards for midwifery programmes (NMC, 2019a) in relation to medicines management
- Be able to discuss the importance of medicines optimisation in relation to the pregnant woman
- Develop an awareness of the use of medicines during pregnancy, labour and the postnatal period, and the effect that some drugs may have on the developing fetus and/or newborn infant.

Test your existing knowledge

- Consider the role of the NMC in relation to the supply, keeping and administration of medicines.
- What does medicines optimisation mean?
- Define *teratogenic*.
- When is the period of greatest risk to the fetus from the administration of drugs?
- Where can information regarding the use of medication in pregnancy be accessed?

Introduction

Despite pregnancy and childbirth being a low-risk event for the majority of women, it is thought that 50% of women will be prescribed medication on at least one occasion during their pregnancy, with up to 90% of these being in the first trimester (Lassiter and Manns-James, 2017). This covers a

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variety of medications, such as analgesics, antibiotics and antidepressants, but many women also enter pregnancy with an underlying health condition, such as epilepsy or a cardiac condition, requiring regular medication.

In planning for and during pregnancy, labour and breast feeding, when prescribing any drug, consideration also must be given to the fetus and newborn infant. It is known that certain drugs cross the placental barrier and cause harm to the fetus during its development, and some drugs will filter into breast milk, thus affecting the baby. The midwife should have a general understanding of the drugs that are used in this crucial period of a woman's – and fetus's – life and be able to work with both women and medical practitioners to ensure safety for women whilst achieving optimal clinical requirements.

Pharmacology

The word 'pharmacology' stems from *phaemakon*, the Greek word for medicine or poison (Brucker, 2017). Essentially, pharmacology is concerned with how drugs work and how they affect the chemistry of the body (British Pharmacological Society, 2021). It is important to have an understanding of the changes brought about by the use of different drugs in order to ensure that they are safe to use in a range of situations, and that side-effects which may be harmful can be reduced or eliminated. Recently, the importance of this has been seen in discussions regarding the new vaccines developed for COVID-19, in particular the Oxford/AstraZeneca vaccine where there were reports of blood clots in a minority of individuals receiving the vaccine (NHS, 2021). In line with this, the science of pharmacology helps to develop an understanding of why the action and reaction of and to various medications differ from one person to another (British Pharmacological Society, 2021).

Nursing and Midwifery Council (NMC)

As the regulatory body for the nursing and midwifery professions, the NMC sets standards for the training and conduct of nurses and midwives with the main aim of protecting the public. This includes its role in the management, supply and administration of medicines. In order to practise within the United Kingdom, nurses and midwives must be registered with the NMC following a period of training, and then provide evidence that they have maintained and updated their knowledge and skills through the revalidation process every 3 years (NMC, 2019b). They must also uphold the principles set out in the Code (NMC, 2018) related to both their practice and behaviour.

The Code (NMC, 2018) consists of four sections, clearly outlining the standards of professionalism that are required in order to support and protect the general public, putting the patient at the forefront of care and service provision (Figure 1.1).

This includes the role of the professional in the use of medicines, as set out in Clause 18, where nurses and midwives are guided to advise on, prescribe, dispense or administer medicines within the limits of their training and competence, the law, NMC guidance and any other policies, guidance or regulations (NMC, 2018). Only midwives who have completed further training post registration are able to prescribe medications.

Clear expectations of midwives at the point of qualification are also laid out by the NMC in the *Standards of proficiency for midwives* (2019c). The midwife is seen as the lead professional in the care of women throughout their pregnancy and the postnatal period, working in partnership with them to support their views and decisions with regard to their care as well as with the multidisciplinary team as and where appropriate. **Six domains are identified within these standards (NMC, 2019c)**.

1. Being an accountable, autonomous, professional midwife.
2. Safe and effective midwifery care: promoting and providing continuity of care and carer.
3. Universal care for all women and newborn infants.
4. Additional care for women and newborn infants with complications.
5. Promoting excellence: the midwife as colleague, scholar and leader.
6. The midwife as a skilled practitioner.

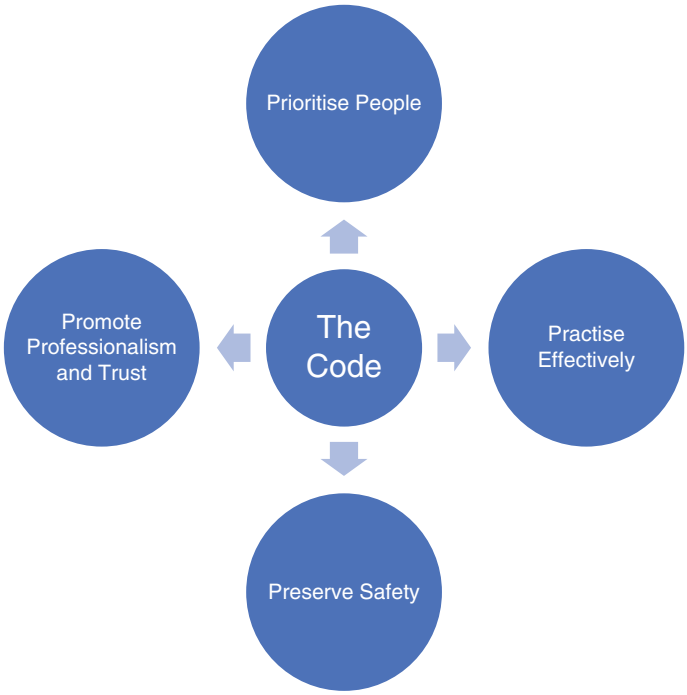

Figure 1.1 The Code.
Source: Based on NMC (2018)

The standards relating to the safe and effective use of medicines can be seen in Box 1.1.

Professional guidance on the safe handling of medicines in practice has been issued by the Royal Pharmaceutical Society (RPS, 2018) replacing the *Standards for Medicine Management* (2007) which were withdrawn by the NMC in 2019. Further guidance on the safe administration of medicines in practice has been produced jointly by the RPS and the Royal College of Nursing (RCN and RPS, 2019). Midwives and student midwives, as well as other health professionals, should be aware of these documents and the information provided within. Midwives also need to relate to the Human Medicines Regulation Act 2012, Section 17, which outlines the prescription-only medicines that can be given under Midwives' Exemptions.

Box 1.1 The *Standards of proficiency for midwives* related to the safe and effective use of medicines.

Domain 3.18 demonstrate knowledge and understanding of pharmacology and the ability to recognise the positive and adverse effects of medicines across the continuum of care; to include allergies, drug sensitivities, side effects, contraindications, incompatibilities, adverse reactions, prescribing errors and the impact of polypharmacy and over the counter medication usage

Domain 3.19 demonstrate knowledge and understanding of the principles of safe and effective administration and optimisation of prescription and non-prescription medicines and midwives exemptions, demonstrating the ability to progress to a prescribing qualification following registration

Domain 6 relates to the skills required for safe evidence-based practice

Domain 6.50 demonstrate the ability to work in partnership with the woman to assess and provide care and support across the continuum that ensures the safe administration of medicines

6.50.1 carry out initial and continued assessments of women and their ability to self-administer their own medications

6.50.2 recognise the various procedural routes under which medicines can be prescribed, supplied, dispensed and administered; and the laws, policies, regulations and guidance that underpin them

6.50.3 use the principles of safe remote prescribing and directions to administer medicines, including safe storage, transportation and disposal of medicinal products

6.50.4 demonstrate the ability to safely supply and administer medicines listed in Schedule 17 of the Human Medicines Regulations (Midwives' Exemptions) and any subsequent legislation and demonstrate the ability to check the list regularly

6.50.5 undertake accurate drug calculations for a range of medications

6.50.6 undertake accurate checks, including transcription and titration, of any direction to supply and administer a medicinal product

6.50.7 exercise professional accountability in ensuring the safe administration of medicines, via a range of routes, to women and newborn infants

6.50.8 administer injections using intramuscular, subcutaneous, intradermal and intravenous routes and manage injection equipment

6.50.9 recognise and respond to adverse or abnormal reactions to medications for the woman and the newborn infant, and the potential impact on the fetus and the breastfed infant

6.50.10 recognise the impact of medicines in breastmilk and support the woman to continue to responsively feed her newborn infant and/or to express breastmilk.

Source: Adapted from NMC (2019c).

Medicines optimisation

The most common intervention in healthcare is the prescription of medications (NICE, 2015), yet it is also recognised that up to half of the drugs prescribed are not taken as they should be (RPS, 2013). This is obviously concerning as not only are patients not benefiting from the treatment they should be having, but there is also a huge financial cost to the NHS. The aim of medicines optimisation is that, by involving patients in decision making regarding their medication, they will be more motivated to follow the treatment plan, thus achieving improved outcomes for them, as well as a reduction in the wasting of medicines and drugs across the board (RPS, 2013).

The principles of medicines optimisation are that there is an ongoing communication with the patient and multidisciplinary team, so that up-to-date evidence is given to the patient, and their views regarding both the drugs and their condition are taken into consideration (NICE, 2015). This could be particularly important for a woman planning a pregnancy where the medication she is taking for an established condition is known to be teratogenic.

Embryology

In order to understand the effects of medicines on the fetus, we first need to consider the development of the fetus from fertilisation to term. There are essentially three outcomes if the developing fetus is affected by medications taken by the mother, as indicated in Box 1.2. The fertilised ovum, the *zygote*, starts to undergo the process of mitosis, cell division. At the point where there are 12 cells, this is known as the *morula*, with the cells beginning to communicate with each other and moving to form the *blastocyst*. The cells of the blastocyst migrate to form an outer layer, the *trophoblast*, which will go on to develop into the placenta and chorion, and the inner cell mass which develops into the fetus. The blastocyst enters the uterus at around 4 days after fertilisation and embeds into the decidua. From implantation until 8 weeks gestation, the conceptus is known as the embryo. Initially, the cells are pluripotential, meaning that they have the potential to develop

Box 1.2 Effects of exposure to certain drugs on the developing fetus

Embryocidal – fetal death
Teratogenic – the development of the fetus is affected, leading to congenital abnormalities
Fetotoxic – the growth and/or development of the fetus is altered during the second and third trimesters

into any of the cells within the body (Mitchell and Sharma, 2005). During this preimplantation stage, if affected by any medication taken by the mother, the cells will either die or they will survive. The development of the cells is not affected if they survive at this stage.

Organogenesis, when the cells begin to differentiate into the various tissues and organs, begins at around 3 weeks post fertilisation and continues until 8 weeks, during which time the major organs will be formed. This period is known as the embryonic period (Webster and de Wreede, 2016) and is the time when the fetus is at maximum risk from teratogenic drugs with the potential for major developmental abnormalities (Lassiter and Manns-James, 2017). Table 1.1 shows fetal development and risks associated with exposure to teratogens.

From 8 weeks onwards, the fetus grows and develops until term, when the newborn is able to survive independently. This is the fetal period and although the chances of major developmental abnormalities are lower, the fetus is still at risk from drugs which can cross the placenta, altering its growth and development (Lassiter and Manns-James, 2017).

Although it is thought to act as a barrier, most drugs can cross the placenta to the fetal blood, although the majority of these are harmless to the fetus (Bailey, 2020). Initially there are several layers lining the chorionic villi through which substances must pass by diffusion: the syncytiotrophoblast membrane and cell, the cytotrophoblast and the endothelial lining of the fetal blood vessels (Lassiter and Manns-James, 2017). However, this barrier thins as pregnancy progresses. Some drugs, such as antibiotics and anaesthetics, diffuse easily across the placenta, whilst those with a high molecular weight, such as heparin, insulin and oxytocin, are not able to cross the barrier (Lassiter and Manns-James, 2017). A discussion on some of these drugs may be found further on in this text.

The use of medicines in pregnancy

Wherever possible, the use of medications in pregnancy should be avoided due to the risks to the developing fetus. However, as stated earlier, it is thought that at least 50% of pregnant women are prescribed drugs during their pregnancy (Lassiter and Manns-James, 2017), and many will take non-prescription medications, often before they even realise that they are pregnant.

There are actually very few drugs that are known to have teratogenic effects on the fetus (BNF, 2021a), with only about 1% of fetal abnormalities being related to the taking of drugs in pregnancy (Rang et al., 2016). The aim of this chapter is not to discuss each one individually. Although extensive trials are carried out on new drugs before they are used in practice, these trials do not generally involve pregnant women, so it is through trial and error that effects of drugs on the fetus may be discovered (Lassiter and Manns-James, 2017).

Two bodies are responsible for the safe and effective use of medicines in the UK; the Medicines and Healthcare products Regulatory Agency (MHRA) regulates the use of both medicines and medical devices to ensure that the benefits of the product outweigh any risks involved, whilst the Commission on Human Medicines (CHM) is the body that advises the government on all medicines and devices (MHRA, 2021).

The first drug to be recognised as causing teratogenic abnormalities was thalidomide in the 1960s. The drug was used for morning sickness in the UK from 1958 to 1961, when the link between the drug and the number of babies born with a variety of disabilities, including shortening of the limbs, was made (Thalidomide Trust, 2017). This led to the establishment of drug regulation agencies in many countries, including the Medicines Act 1968 in the UK (Rang et al., 2016).

Table 1.1 Fetal development and risks associated with exposure to teratogens. Source: Adapted from Webster and de Wreede (2016)

			Fertilisation										
			Embryonic period						Fetal development				
Weeks from fertilisation	1	2	3	4	5	6	7	8	9	10	16	32	40
												Central Nervous system	
							Heart						
							Limbs						
					Cleft lip		Upper lip						
										Ears			
									Eyes				
									Palate				
										External genitalia			
	Not susceptible to teratogens		Major congenital abnormalities							Minor abnormalities and Functional disorders			
	The embryo dies and spontaneous abortion occurs												
			Pale violet - Systems highly sensitive to teratogens Dark violet - Systems less sensitive to teratogens										

The guiding principles for the use of medications in pregnancy are based around avoiding medications in the first trimester if at all possible. Where the use of medication is indicated, this should only be where the benefit to the woman is greater than the potential risk to the developing fetus, and the smallest possible dose of the drug should be prescribed (BNF, 2021a). The advice is also to avoid new drugs and use those that have previously been used during pregnancy, where no adverse effects have previously been noted (BNF, 2021a).

Pre-existing conditions

Those already taking medications for pre-existing conditions will, ideally, have a consultation with their GP and/or specialist consultant prior to conception. This may also involve a referral to an obstetrician. A plan would be made which would either involve staying on their existing treatment if this is not known to cause harm to the fetus or perhaps changing the medication if the one they are taking is known to be teratogenic. The principles of medicines optimisation certainly apply to the decisions made during these discussions. For the women who discover they are pregnant and have not made such plans, the medication should be continued and an urgent referral to a specialist is recommended to discuss the situation and the best options to take.

Where a drug is being taken that is known to have teratogenic potential, the advice is that these risks should be fully discussed with the woman, and that she should then be strongly encouraged to use an effective form of contraception that is suitable for her and her personal circumstances (MHRA, 2019). The medicines prescribed for epilepsy are known to have teratogenic properties, with the use of valproate in particular being highlighted in the British press over recent years (BBC, 2020). A review was published by the MHRA and CHM in January 2021 to establish the safety of antiepileptic drugs in pregnancy. The risks of taking valproate in pregnancy include spina bifida, facial and skull defects as well as deformities in the limbs, heart, kidneys and sexual organs (MHRA, 2021). These is also a risk of autism, and effects on speech, language and memory. Due to this, the recommendations are that if valproate is prescribed to any woman with child-bearing capacity, a pregnancy prevention programme must be in place (MHRA, 2021; BNF, 2021b). In the case of valproate, the effects on the fetus are teratogenic and fetotoxic (see Box 1.2).

Other epilepsy medications are also associated with birth defects, for example carbamazepine and phenobarbital, and data are still be collected on gabapentin, clobazam and zonisamide. In general, lamotrigine and levetiracetam are safer to use in pregnancy, as they do not appear to have teratogenic properties (MHRA, 2021). Chapter 17 of this text discuses medications and the nervous system.

The risk to the fetus of taking drugs in pregnancy varies as the pregnancy progresses and is also dependent on the drug itself. Many drugs are known to have teratogenic properties; that is, they are known to interrupt the fetal development process, leading to birth defects and abnormalities. As the pregnancy progresses, the risk of teratogenesis lessens but the fetus may still be susceptible to other forms of harm, such as growth retardation or underlying mental health issues, some of which are not identified for many years (Rang et al., 2016).

Another drug which a woman may be taking before planning a pregnancy is warfarin, as discussed in the following episode of care.

Episode of care

Susan is a 34-year-old para 1 who had a pulmonary embolism following the birth of her first baby 18 months ago. She has been taking warfarin since then and is now planning a second baby. She attends an appointment with the practice nurse at her local surgery to discuss the best way forward and is referred to the obstetric consultant. The risks of taking warfarin in pregnancy are explained to her as an increased risk of early miscarriage and, if taken in the first trimester, 'fetal warfarin syndrome', a condition resulting in a flat facial profile, defects in the spinal bones, arm and leg bones, and heart and brain defects. If taken throughout pregnancy, there is the potential for fetal bleeding (Best Use of Medicine in Pregnancy (BUMPS), 2021; BNF, 2021g). A plan is made for Susan to change from taking warfarin to using heparin.

As seen with valproate, there are also concerns that some drugs taken during the second and third trimesters can lead to restrictions in fetal growth. This may be due to interference with fetal hormones or a restriction in the supply of nutrients (Rang et al., 2016). Throughout the pregnancy, there is a risk of interference with the development of the brain and neurological system. Although the main development of the brain takes place between weeks 3 and 16, there is continual rapid growth and differentiation which can be affected by certain drugs (Moore et al., 2016), an example being valproate, as discussed earlier.

Occupational exposure

Occupational exposure to drugs and other forms of teratogens may also need to be taken into consideration when planning or discovering a pregnancy. A risk assessment should be carried out to identify any potential situations that may cause harm to the fetus, and reasonable adaptations to working practices put in place and adopted. An example is those working with x-rays and ionising radiation. A report published by the British Institute of Radiation (Temperton, 2009) found that the dose of radiation to those working in these areas was well below the recommended annual dose and that, when wearing a lead apron, the dose to the fetus would be even lower. Those working with MRI scanners are recommended to leave the room during the scan.

Pharmacists may also have to consider alterations to their practice when handling some drugs as some substances may be absorbed through the skin. An example is finasteride, a drug for treating enlarged prostate glands in men. Although no studies exist on humans, trials in animals suggested that there is an increased risk of miscarriage, and birth defects in the male sex organs. The recommendations are that gloves should be worn when handling this drug (MotherToBaby, 2020).

A further example of an occupational hazard is if the pregnant woman is working with chemical substances. Again, a full risk assessment would be needed as early in the pregnancy as possible, with suitable adjustments to working practices being established.

Drugs used in labour

Certain drugs are used on a regular basis in labour for a variety of reasons, with those related to labour itself being discussed in Chapter 10. With regard to induction of labour, there are no concerns that the use of vaginal progesterone or intravenous oxytocin will cause any long-term effect to the fetus (BNF, 2021c, 2021d).

Opioid analgesia may be administered in labour at the request of the woman, with the drug of choice varying in individual healthcare providors between morphine, diamorphine and pethidine. It is known that all opioids cross the placenta, pethidine within 2 minutes and diamorphine within an hour (Davey and Houghton, 2021). Due to the immaturity of the fetal liver, the drugs are metabolised more slowly in the fetus, and are not readily transferred back to the mother through the placenta due to the lower pH of the fetal blood. This can lead to respiratory depression in the fetus at birth and, as the excretion is slower, the newborn infant may also be slower to initiate and establish breast feeding (BNF, 2021e, 2021f).

Should a general anaesthetic be required for a caesarean section, the midwife and neonatologist present at the birth should be prepared for a newborn that is slow to establish respirations, depending on the time taken from initiation of the anaesthetic to the birth. As with opioids, the drugs used for a general anaesthetic will cross the placenta and depress the respirations of the newborn (Ritter et al., 2008).

Episode of care

Naga Mohan, a 40-year-old gravida 5, para 4, had had four previous caesarean sections, the last one 14 months previously. It was known that she already had scar tissue and that this would, in all probability, be a difficult caesarean section to perform, so, after discussion with Naga and her partner, it was decided that a general anaesthetic would be the best option.

Due to the potential difficulties in performing the surgery, plans were made for a senior experienced midwife and a neonatologist to be present at the birth. The resuscitaire was checked and in full working order, and naloxone was drawn up in preparation in case the baby did not respond at birth.

Following the general anaesthetic, it was almost 10 minutes until the baby was born. The male infant was wrapped and taken to the resuscitaire, dried and, as no respiratory effort was made, inflation breaths were given. These were effective and the heart rate remained above 100 beats per minute, but the baby was not breathing, so ventilation breaths were carried out. After 4 minutes, the baby was still not breathing spontaneously, so naloxone 200 µg was given intramuscularly. The baby started breathing very quickly following this and was then observed closely in the SCBU.

Group B streptococcus infection is an example of when antibiotics are given to the mother with the aim of preventing infection in the newborn. For those women identified as group B streptococcus positive in pregnancy, the risk is that the fetus will become infected as it passes through the birth canal, which can lead to sepsis within the first few hours of life. Intravenous antibiotics are given to the mother in labour with the aim that they will cross the placenta to protect the fetus from infection (Lowe et al., 2017).

Breast feeding

There have been few studies into the relative amounts of drugs that enter breast milk (Schaefer, 2015), meaning that there is minimal information available to support the theories that any medications taken by the mother whilst breast feeding will cause harm to the fetus (BNF, 2021h). Due to the fact that there is little information on many drugs, the guidance is that only essential medication should be given to the breast-feeding mother (BNF, 2021h). The majority of drugs taken by the breast-feeding mother transfer to the breast milk through diffusion, due to the balance of the drug in the mother's blood and the milk. As levels in the maternal system rise, the drug is then forced across into the milk (Baker and Hale, 2017).

On the whole, it is thought that there are seldom sufficient levels of a drug within the breast milk to cause harm to the infant, and this is especially relevant if the medication has been given parenterally or is not absorbed well when taken orally (BNF, 2021h). The risks are, however, increased in premature infants and those who are jaundiced. There is also a relatively small possibility that the infant may develop a sensitivity to the drug and have a reaction to this (BNF, 2021h).

The lack of in-depth evidence regarding the effects of many drugs related to breast feeding can lead to some confusion both for the professional and for the women using them. An example is tinzaparin, a low molecular weight heparin frequently administered postnatally as prophylaxis for women at risk of developing deep vein thrombosis or pulmonary embolism in the postnatal period. The BNF (2021i) advises that, as the molecular weight of this drug is relatively high, it is unlikely to pass into the breast milk, but also states that the manufacturers do not support its use during breast feeding. This information is readily available to the public and could lead to women not using the heparin they have been prescribed due to fears for the infant.

There are a number of drugs which will pass into breast milk and may affect the baby's ability to latch and feed effectively. As discussed above, opioids may affect the infant at birth, and the effects may last for a few hours as the drug is excreted from the infant's body. However, if morphine is given in the postnatal period, for example following a caesarean section, the dose given is thought not to be at a sufficient level to further depress the respirations of the infant or affect feeding (BNF, 2021j).

As with other medications, there is little evidence related to breast feeding regarding the use of drugs to treat anxiety and depression. Some of the symptoms reported in infants are thought to be related to the adjustment in the infant from the dosage in pregnancy to that at birth and is rarely seen as a reason not to take the medication (Schaefer, 2015). An exception to this is the benzodiazepine group, which includes diazepam. This is not recommended for use with breast-feeding mothers (BNF, 2021k) as neonatal respiratory depression has been noted, as well as associated

tremors, hypertonicity of muscles, and diarrhoea and vomiting where the drug is used over a period of time (Schaefer, 2015). Associated with this is a reluctance to feed, and seizures have been reported.

For women taking antibiotics in the postnatal period, the amount of antibiotic that reaches the infant is negligible (Schaefer, 2015). However, the normal gut flora may be affected, leading to a more watery stool, but this is temporary and does not normally require any treatment. It has been recognised that metronidazole passes into the breast milk, but no adverse effects had been identified in infants (Schaefer, 2015). Chapter 9 of this text discusses antibiotics and Chapter 20 addresses medications and breast feeding in more depth.

Conclusion

Pharmacology is the study of drugs and the effect they have on the body. The use of any medication during pregnancy and the postnatal period should be treated with caution, with consideration of the suitability of the drug before it is prescribed. The principles of medicines optimisation apply during these times, ensuring that the woman is fully involved in the decision making regarding her treatment, that she is aware of the reasons for the medication, and the potential effects for both her and the fetus/newborn infant.

There is insufficient information on the majority of drugs related to pregnancy and breast feeding, with many manufacturers stating that a particular drug should not be used in these circumstances. However, some have been used with no ill effects, and are prescribed in practice. This may lead to confusion for the woman if she accesses conflicting information regarding the drug.

The guiding principles for both pregnancy and breast feeding should be that the need for medication should outweigh the risks to the fetus/newborn. At all times, the smallest possible dose of any drug should be prescribed. Although only a few drugs have been highlighted in this chapter, the principles of care apply to all medications.

Glossary

Blastocyst The fertilised ovum enters the uterus at day 4

Embryo From implantation of the blastocyst into the decidual lining of the uterus until 8 weeks from fertilisation

Embryonic period The first 8 weeks following fertilisation

Fetal period From 9 weeks until birth. A time of growth and development

Morula Twelve-cell stage

Neurulation The formation of the brain and spinal cord between days 19 and 25 following fertilisation

Organogenetic period From 4 to 8 weeks following fertilisation when the formation of major organs occurs

Teratogen Any substance which leads to a birth defect

Zygote The oocyte and spermatozoa combined

Test yourself

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