An update on contraception
Part 1: oral and emergency

With GPs facing an ever increasing array of drug choices and consumer expectations regarding the risks and benefits of prescribed medications, it is important to review the evidence, the practice and the role of oral contraceptives.

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This article, the first in a series of three on contraception, gives a concise overview of the oral contraceptive methods, including the combined oestrogen and progestogen pill and the progestogen-only pill. It provides information about medical contraindications to the contraceptive pill, as well as some helpful tools on how to start the pill and what to do if problems arise. Information on when to consider taking emergency contraception if pills are missed is also included. The second and third articles, to be published in future issues of *Medicine Today*, will discuss long-acting hormonal contraceptives, barrier methods, natural family planning and contraceptives of the future.

An issue with easily reversible methods such as the oral contraceptive pill is the propensity for failure due to missed pills. A US study indicated that although in research studies the pill was 99.7% effective, the typical user rate of taking the pills was only 92% effective because of failure to take the medication properly.[1]

Situations in which a woman may present for contraception

Managing fertility before having children

The whole issue of how not to get pregnant is a primary issue generally for young women. The average age of first sexual intercourse in Australia is now around 16 years (with some young women starting at the age of 12 or 13 years), and the average age at which women in Australia have their first child is now 29.8 years. This leaves a gap of at least 13 years in which the reversible management of fertility is critically important.

Access to medical care, ensuring that her practitioner understands her needs and obtaining the contraceptive of her choice can all prove to be significant hurdles for young women. To provide clinical care to this younger age group, particularly to adolescents under 16 years of age, there is the need for detailed knowledge of the doctors' legal responsibilities. These requirements, particularly around informed consent and child protection (mandatory reporting) vary

IN SUMMARY

- **Oral contraceptives are reversible, effective and user friendly. More women in Australia use this form of fertility management than any other method.**
- **New and clearer guidelines have been developed and published over the past decade to aid healthcare providers prescribe oral contraception safely and appropriately.**
- **An important factor is the potential for use of the combined oral contraceptive pill to have an unfavourable or dangerous risk for women with existing medical or lifestyle conditions.**
- **A practical problem with the oral contraceptive pill is side effects such as nausea and irregular bleeding, which can often be resolved by changing the type or formulation of the pill.**
- **Hormonal emergency contraception prevents or delays ovulation and may affect implantation. It should be taken within 120 hours of unprotected sex.**

between the different states and territories in Australia.[2,3]

Postpartum and spacing pregnancies

Women who are postpartum or would like spacing between their pregnancies represent a different group from that described above. These women will almost certainly have a different lifestyle, they may be breastfeeding or there may have been medical problems during the last pregnancy such as hypertension or diabetes that need to be taken into account when prescribing contraception.

Medical condition

A common conundrum for practicing GPs is advising a woman about a method of oral contraception when there may be a medical condition present that impacts on its safe use. Listed below are questions that may arise.

- Can I give the pill to a woman with cardiovascular disease or who has had deep vein thrombosis?
- What about prescribing the pill to a woman with epilepsy who is taking antiepileptic drugs? Will there be an interaction that may reduce the effectiveness of either the contraceptive pill or the antiepileptic drugs?
- If a woman has had only a couple of migraines with aura several years ago, will this interfere with her ability to use the oral contraceptive pill now?

The World Health Organization and the UK Faculty of Reproductive and Sexual Healthcare have produced guidelines categorising the risk of the various contraceptive methods used concomitantly in women with specific medical conditions (see the box on page 48). Sexual Health and Family Planning Australia has published a handbook called *'Contraception: an Australian clinical practice handbook'*,[2] which uses the guidelines described above and other evidence-based references to produce a practical Australian reference. This handbook discusses in detail the use of contraceptives such as the pill and compares this with the risk of the existing medical condition and the risk of pregnancy for that woman.

Emergencies

A common presentation is a woman who has had unprotected sex or has had problems with her contraception and fears that she could be pregnant. After the immediate crisis has been discussed, this could be an ideal time for the woman to start contraception or to review her contraceptive method.

After termination of a pregnancy

A woman may present for contraceptive advice at the time of termination of a pregnancy. The pregnancy may have been a planned one that was terminated due to fetal abnormality or maternal health risk, or an unintended pregnancy that was unable to be continued for a number of reasons. The combined oral contraceptive or progestogen-only pill can be started the day following the procedure and will be immediately effective. The woman should be reviewed by her GP two weeks later. This is then a good time to reinforce important information on her chosen method of contraception and to manage any problems that may have occurred since the termination, such as ongoing bleeding or pain. If the woman has chosen to take the oral contraceptive pill, this visit is an excellent time to again cover how to take the pill correctly and what to do if pills are missed.

Types of oral contraceptive pills

Combined pill: oestrogen and progestogen

The combined oral contraceptive pill consists of 20 to 50 μg of ethinyloestradiol and varying doses of a progestogen. In Australia, there are

Medical conditions and contraceptive methods: assessing the risk[2]

The World Health Organization and the UK Faculty for Reproductive and Sexual Healthcare have produced guidelines for healthcare professionals categorising the risk of the various contraceptive methods used concomitantly in women with specific medical conditions. These guidelines are known as: Medical eligibility criteria for contraceptive use (WHO) and the UK medical eligibility criteria for contraceptive use (2005/2006). They are available online at: www.who.int/reproductive-health/publications/mec/ and www.ffprhc.org.uk/.

Conditions affecting a woman's eligibility to use the contraceptive method are defined as representing:

- an individual's personal characteristics (e.g. age, history of pregnancy, BMI)
- an individual's known pre-existing medical/pathological condition (e.g. diabetes, hypertension, past deep vein thrombosis)
- medications that she is taking.

Conditions affecting eligibility for the use of each contraceptive method can be classified under one of the four categories listed below.

- **Category 1:** A condition for which there is no restriction for the use of the contraceptive method.
- **Category 2:** A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
- **Category 3:** A condition where the theoretical or proven risks usually outweigh the advantages of using the contraceptive method.
- **Category 4:** A condition that represents an unacceptable health risk if the contraceptive method is used.

seven progestogens available, and 14 distinct pill formulations and 29 brands of the combined oral contraceptive pill. Formulations are either monophasic or triphasic, with biphasic pills having been withdrawn. Triphasic pills are not often used but may be useful for managing breakthrough bleeding problems. A monophasic combined pill containing ethinyloestradiol 30 µg plus levonorgestrel 150 µg (Levlen ED, Microgynon 30 ED, Monofeme, Nordette) or ethinyloestradiol 35 µg plus norethisterone 500 µg (Brevinor 21 Day, Brevinor 28 Day, Norimin 28 Day) is a good first pill choice. These pills are PBS listed and are among the pills with the lowest increase in risk of deep vein thrombosis.

Most combined contraceptive pills are packaged with 21 active pills followed by seven placebo pills. During the seven-day break there is a varying degree of ovarian activity. The more activity there is, the higher the chance of ovulation, particularly if active pills are missed soon after the placebo interval. In 2008, Yaz (ethinyloestradiol 20 µg plus drospirenone 3 mg) was launched with a formulation of 24 active pills and four placebo pills – the 24/4 regimen. Women who take this pill have less ovarian activity in the placebo interval than women who take other types of contraceptive pills, and there may also be a lower risk of failure if the active pills are missed close to the start of a woman's cycle.

Australia has four types of pill packaging of the combined pill, including different packaging among hormonally identical brands. It is important for women, particularly when initiating or switching brands, to be aware of which pills in the pack are active and which ones are inactive.

Progestogen-only pill

There are two types of progestogen-only pills available in Australia. One contains levonorgestrel 30 µg (Microlut) and the other contains norethisterone 350 µg (Locilan 28 Day, Micronor, Noriday 28).

Unlike with combined pills, all the progestogen-only pills in a pack are active and must be taken. This type of pill is usually chosen by women who have contraindications to oestrogen-containing pills (e.g. during the first six months of breastfeeding) or who do not tolerate oestrogen (e.g. experience nausea).

Mechanism of action

The primary action of the combined oral contraceptive is the same in all women: if taken correctly, it effectively inhibits ovulation. In addition, it causes thickening of the cervical mucus, thereby preventing sperm transit, and alters the endometrium so as to discourage implantation.

In contrast, the progestogen-only pill has several modes of action that vary between women and between cycles. For most women, the progestogen-only pill does not suppress ovulation and its primary action is to thicken the cervical mucus, effectively blocking sperm movement. As this is very much a day-to-day effect, its efficacy is more vulnerable than the combined oral contraceptive pill. Therefore, all the pills in the pack are active and strict adherence to the time of pill-taking is crucial.

Medical conditions and oral contraceptives

Perhaps the most important factor is the potential for combined oral contraceptives to have an unfavourable or dangerous risk for women who have existing medical or lifestyle conditions that may be exacerbated or complicated by use of the contraceptive

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Table 1. Initiation of combined and progestogen-only contraceptive pills

Previous contraceptive method	Timing of initiation	When the method becomes effective	
		Combined pill beginning with an active pill	Progestogen-only pill
No method of contraception (including barriers)	Pill started on day one to five of cycle*	Immediately	Immediately
	Pill started at any other time	Seven days†	48 hours‡
Combined contraceptive pill (changing formulation or brand)	New pill started after placebo interval or immediately the previous pill packet is ceased (if pills have been taken correctly)	Immediately (even if changing from a higher to a lower dose combined oral contraceptive)	Immediately
Vaginal ring	Pill started after the placebo interval or immediately the ring is removed (if ring has been used correctly)	Immediately	Immediately
Progestogen-only pill (changing formulation or brand)	Menstrual cycle is regular and pill started on day one to five of cycle	Immediately	Immediately
	Menstrual cycle is regular and pill started on day six or later in cycle; irregular menstruation or amenorrhoea	Seven days	Immediately
DMPA injection	Pill started any time if within 14 weeks of last injection	Immediately	Immediately
Etonogestrel implant	Pill started any time if within three years of insertion	Seven days	Immediately
Abortion	Pill started within five days of an abortion	Immediately§	Immediately§
Copper IUD or levonorgestrel IUD	Menstrual cycle is regular and pill started on day one to five of cycle*	Immediately	Immediately
	Menstrual cycle is regular and pill started after day five of cycle (use condoms for seven days prior to removal of IUD)	Seven days	48 hours‡
	Irregular cycle or amenorrhoea and pill started at any time	Seven days	48 hours‡
Hormonal emergency contraception	Pill should be started immediately	Seven days‖	48 hours‡‖

ABBREVIATIONS: DMPA = depot medroxyprogesterone acetate; IUD = intrauterine device.

* Day one is the first day of bleeding in a normal menstrual cycle. Day five is four days later.

† Pregnancy can be excluded with a high degree of confidence if a woman has not had sex since the start of last normal period, is in day one to five of a normal menstrual cycle or a urinary pregnancy test is negative and the woman has not had unprotected intercourse for at least three weeks prior to the test. If pregnancy is not excluded before initiating the combined oral pill or progestogen-only pill, a pregnancy test should be performed in four weeks' time.

‡ The pill is effective after three tablets have been taken.

§ It may be difficult to determine whether irregular bleeding is related to the termination of pregnancy or due to initiation of a hormonal method of contraception.

‖ The woman should be advised to return in four weeks' time for a pregnancy test.

Table 2. Initiation of combined and progestogen-only contraceptive pills in postpartum women

Stage	Situation/timing of initiation	When the method becomes effective	
		Combined pill beginning with an active pill	Progestogen-only pill
Breastfeeding or not breastfeeding and less than 21 days' postpartum	–	Not recommended[§]	Immediately
Fully breastfeeding and less than six months' postpartum (pregnancy excluded)[†]	–	Not recommended[‖]	48 hours[‡]
Fully breastfeeding and more than six months' postpartum; or partially breastfeeding and more than six weeks' postpartum[‖ ¶]	Menstrual cycle resumed – no method of contraception or barriers currently being used: pill started on day one to five of cycle[*]	Immediately	Immediately
	Amenorrhoeic: pill started at any time (exclude pregnancy)[†]	Seven days	48 hours[‡]
Not breastfeeding and more than 21 days' postpartum	Menstrual cycle resumed – no method of contraception or barriers currently being used: pill started on day one to five of cycle[*]	Immediately	Immediately
	Amenorrhoeic: pill started at any time (exclude pregnancy)[†]	Seven days	48 hours[‡]

[*] Day one is the first day of bleeding in a normal menstrual cycle. Day five is four days later.
[†] Pregnancy can be excluded with a high degree of confidence if a woman has not had sex since the start of last normal period, is in day one to five of a normal menstrual cycle or a urinary pregnancy test is negative and the woman has not had unprotected intercourse for at least three weeks prior to the test. If pregnancy is not excluded before initiating the combined oral pill or progestogen-only pill, a pregnancy test should be performed in four weeks' time.
[‡] This means the pill is effective after three tablets have been taken.
[§] Use of the combined oral pill is Category 3 in women less than 21 days' postpartum and who are not breastfeeding.
[‖] From six weeks' to six months' postpartum, use of the combined oral contraceptive is Category 3 for fully breastfeeding women and Category 2 for partially breastfeeding women.
[¶] Partially breastfeeding is defined as half or less of the baby's feeds are breastfeeds.

pill (see the box on page 48).

The risk of pregnancy should be assessed against the risk of harm that may be triggered by the use of the contraceptive pill. It is the combined contraceptive method that presents the most significant risk for women. The combined pill is contraindicated in women with a past history of cardiovascular or venous diseases, or who have significant risk factors – for example, women who have migraine with aura, are heavy smokers aged over 35 years, or have a known thrombogenic mutation. It is also contraindicated in women with severe liver disease and/or recent breast cancer.

The most common serious side effect of the combined contraceptive pill is thromboembolism. This risk increases with the dose of oestrogen in the preparation but it is also influenced by the type of progestogen used. There is generally a very low absolute risk for healthy women of a childbearing age. For a woman not taking any form of hormonal contraception, the thromboembolic risk is 5 in 100,000; for those taking an oral contraceptive pill containing levonorgestrel, norethisterone or drospirenone, the risk is 15 in 100,000; whereas for a pregnant woman, the risk is 60 in 100,000.[4]

Correct initiation

Correct initiation of the oral contraceptive pill is an important issue. Information about contraceptive practice such as when to initiate oral contraceptives is generally based on World Health Organization guidelines ('Selected practice recommendations for contraceptive use'; available online at: www.who.int/reproductive-health/publications/spr/spr.pdf). These guidelines recommend initiating oral contraceptives by starting with an active pill on any of days one to five of the menstrual cycle. However, to decrease the risk of a pregnancy occurring while waiting for the next menses and to increase the

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Case study. A 22-year-old woman taking the oral contraceptive pill presents with irregular bleeding

Initial presentation

Jane is a 22-year-old woman who presents to her GP with a recent onset of some irregular bleeding between her periods. She is in a three-year relationship with Brendan and has been using a pill containing ethinyloestradiol 30 µg plus levonorgestrel 150 µg for contraception for five years. Jane has a past history of asthma, but is otherwise well. She had a normal Pap test 12 months ago and had a negative chlamydia screen six months ago.

What actions should be taken?

Firstly, a thorough history of the bleeding is needed, including a check for associated symptoms. It is important to work out whether the bleeding is postcoital and whether there is any suggestion of the symptoms being related to another condition such as a sexually transmissible infection. Secondly, a sexual history is necessary even though you know Jane is in a three-year relationship and has had a negative chlamydia screen recently. Thirdly, a discussion of factors that could interfere with the efficacy of the pill is necessary.

Thorough history

Jane has been experiencing irregular bleeding for the past three months with two to three episodes of light spotting scattered throughout her cycle, usually lasting for one to two days. Use of a pad or tampon is not required. The bleeding is unrelated to sex. She has not noticed any pelvic pain, dyspareunia or changes in discharge. Her periods have always been light and no changes have occurred.

Although Jane is currently in a relationship, five months ago she had a one-off episode of sex with a former boyfriend, during which a condom was used. She has not had sex with anyone else in the past four years. As far as she knows Brendan has not had sex with anyone else while they have been together.

Jane is regular with her pill taking and is rarely more than an hour late. She has not had any episodes of vomiting or diarrhoea and has not taken any medications in the last three months. She does take a multivitamin tablet most days, but has never taken St John's Wort (which, as a liver enzyme-inducing medication, could affect efficacy of the pill).

Examination and investigations

The most important investigation is to exclude pregnancy. At this stage, a screen for sexually transmissible infections is advisable even though Jane does not appear to be at significant risk. Although she is not due for a Pap test, if she has not had one within the previous three months, a diagnostic Pap test should be taken.[5]

Results

The pregnancy test was negative. Jane was found to have a normal cervix and no per vaginal tenderness or masses. PCR testing of an endocervical swab for chlamydia and gonorrhoea was negative. Vaginal swab microscopy and culture were also negative and a Pap test was normal.

Management

No underlying cause was found for the abnormal bleeding. This is quite a common scenario and the reason for the change in bleeding pattern is often unknown. As the bleeding is clearly not postcoital, a trial of another pill or the vaginal ring is the next step. There is limited evidence to help with the choice. The dose of oestrogen could be increased, which may include a triphasic pill, or the progestogen in the combined oral contraceptive could be changed to norethisterone 1 mg, or to desogestrel or gestodene. Alternatively, the vaginal ring has proven superior to the combined pill in cycle control, although it contains a lower dose of oestrogen.

Outcomes

Jane has a healthcare card and preferred a PBS-listed contraceptive. She changed to a triphasic pill and although some improvement was noted, she still experienced occasional light spotting. After three months, Jane changed to norethisterone 1 mg combined oral contraceptive and the irregular bleeding finally settled.

chance of a woman starting and continuing her contraceptive, both the combined pill and the progestogen-only pill can be started anywhere in the cycle. It is not necessary to wait for a period to begin. Immediate start may mean that it is not possible to exclude a very early pregnancy and the woman should be counselled to return for a pregnancy test if she has not experienced a withdrawal bleed at the expected time. If pregnancy has occurred, the combined pill and progestogen-only pill are not considered teratogenic if accidental exposure occurs in early pregnancy.

Table 1 provides detailed information on initiation of the combined oral contraceptive and progestogen-only pill. Table 2 provides additional information on initiation in postpartum women.

Managing problems

A practical problem with the oral contraceptive pill is that of side effects such as nausea, irregular bleeding or other problems arising from one type of pill. These problems may be solved by changing the type or formulation of a pill (see the case study in the box on this page).[5]

There is limited information from randomised control trials on the differences

Table 3. Emergency contraception formulations available in Australia

Generic name	Brand name	How to take	Prescription needed
Levonorgestrel-only method: preferred method, 85% effective, few side effects			
Levonorgestrel 1.5 g	Postinor-1	Take immediately	No
Levonorgestrel 750 µg	NorLevo	Take two tablets immediately	No
Levonorgestrel 30 µg	Microlut‡	Take 25 tablets immediately; repeat in 12 hours	Yes*
Yuzpe method: 74% effective, nausea and vomiting are common†‡			
Levonorgestrel 150 µg, ethinyloestradiol 30 µg	Levlen ED, Microgynon 30 ED, Monofeme, Nordette	Take four tablets immediately; repeat in 12 hours	Yes*
Levonorgestrel 125 µg, ethinyloestradiol 30 µg	Logynon ED, Trifeme, Triphasil, Triquilar	Take four tablets immediately; repeat in 12 hours	Yes*
Levonorgestrel 100 µg, ethinyloestradiol 20 µg	Loette, Microgynon 20 ED, Microlevlen ED	Take five tablets immediately, repeat in 12 hours	Yes

* PBS-listed pills; therefore may be cheaper.
† Should only be used if there is no possibility of a woman using the levonorgestrel-only method (i.e. a woman cannot afford to buy the levonorgestrel-only pill or there is no access to it).
‡ Microlut and all brands of pills mentioned in the Yuzpe method are used off-label for emergency contraception.

between combined oral contraceptives. The information that is available is as follows:

- pills containing gestodene (Femoden ED, Minulet), desogestrel (Marvelon 28) and cyproterone acetate (Brenda-35 ED, Diane-35 ED, Estelle-35 ED, Juliet-35 ED) are associated with a higher risk of venous thromboembolism than other types of pills
- although some contraceptive pills have an indication for acne as well as contraception, all pills are likely to improve acne. A recent Cochrane review concluded that few differences were found between types of combined oral contraceptives in their effectiveness for treating acne[6]
- in clinical trials, women taking a pill containing ethinyloestradiol 30 µg plus drospirenone 3000 µg (Yasmin) experienced a small weight loss[7]
- lowering the dose of the progestogen and oestrogen in the combined pill improves general side effects such as nausea, breast tenderness and headaches, but increases breakthrough bleeding
- breakthrough bleeding may be managed by increasing the dose of oestrogen, which may include changing to a triphasic pill or changing the progestogen in the combined contraceptive to norethisterone 1 mg, or to desogestrel or gestodene
- lowering the dose of the progestogen or trying a drospirenone-containing pill, which has a mild diuretic effect, may help with premenstrual syndrome. The 24/4 regimen drospirenone-containing pill (Yaz) has an indication for the management of premenstrual dysphoric disorder in women requiring contraception.

Missed pills

For progestogen-only pills, any pill that is more than three hours late is considered a missed pill. A woman is then not protected from pregnancy until she has taken three consecutive pills; she will need to take emergency contraception if she has had sex without using a condom during this time.

In contrast, the rules are less stringent but more complicated for the combined oral contraceptive pill. A combined pill is not missed until it is more than 24 hours late. If this occurs, condoms should be used until the woman has taken seven consecutive active pills. However, if one (or more) of the last seven active pills of the pack were missed and she has since had unprotected sex, the placebo interval should be skipped and she should start the new pack beginning with the active pill the next day. If one (or more) of the first seven active pills were missed and she has had unprotected sex up to five days before pills were missed or within seven days after pills were missed, then she will need to consider emergency contraception. If in doubt, there is no harm in using emergency contraception other than the expense and potential for breakthrough bleeding. For a full explanation of what to do if the combined contraceptive pill is missed see the flowchart on page 57.

Severe diarrhoea and vomiting may compromise the oral absorption of the pill, so additional precautions such as a barrier method should be used during the

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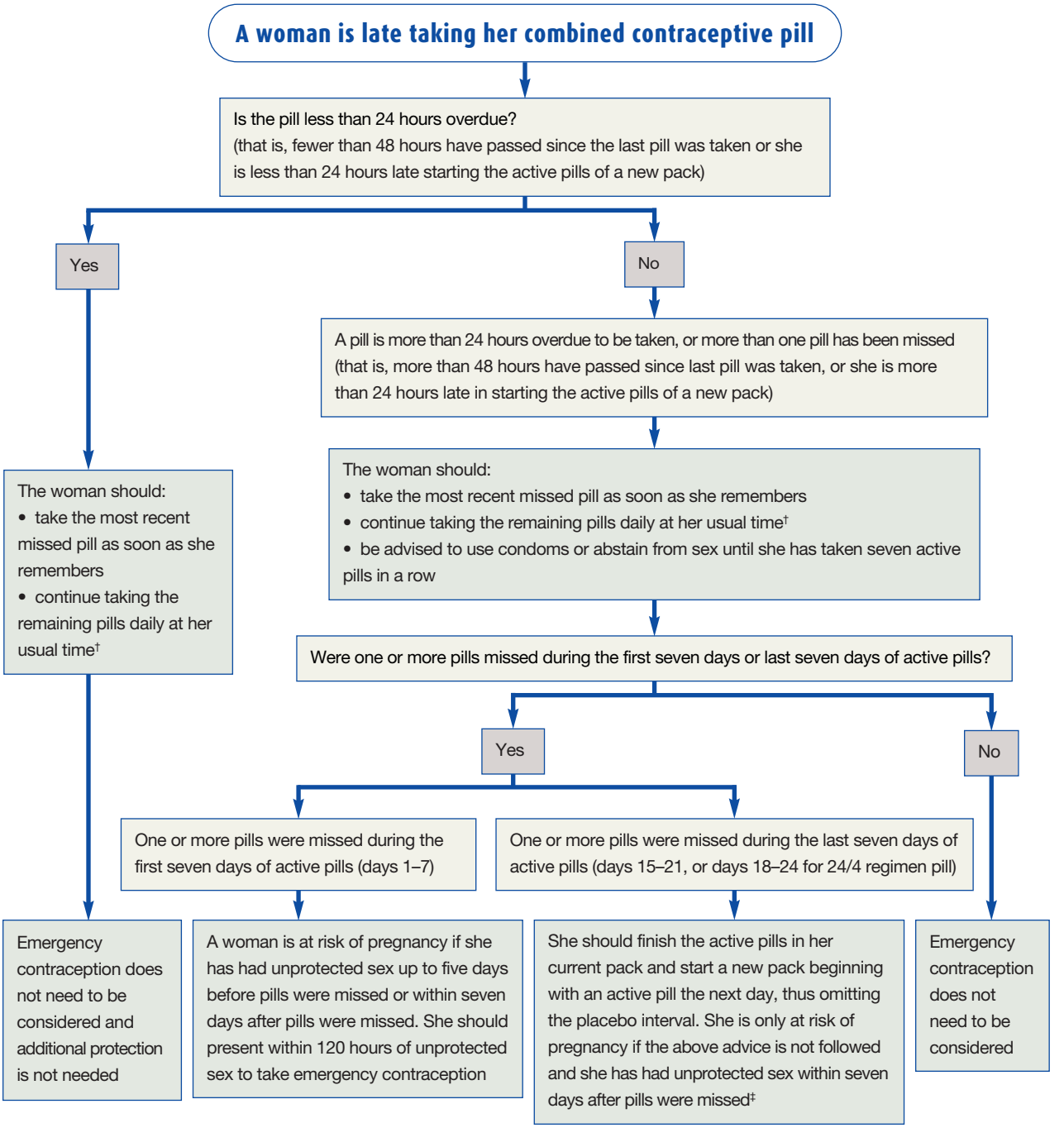
Guidelines: rationalising the number of occasions when emergency contraception needs to be considered in women taking combined oral contraceptives*



* It is assumed that a woman takes her combined pill as instructed in the PI (e.g. for most combined pills this is 21 active pills followed by seven inactive pills).
† Depending on when she remembers her missed pill, she may need to take two pills on the same day, one at the moment she remembers and the other at the regular time, or even two at the same time.
‡ A woman should present within 120 hours of unprotected sex to take emergency contraception.

episode and until seven consecutive active pills have been taken. The use of antibiotics may interfere with bowel flora and also compromise absorption, so women are advised to use barrier methods while taking antibiotics and and until seven consecutive active pills have been taken.

Emergency contraception

Hormonal emergency contraception prevents or delays ovulation and may affect implantation. Ideally, it should be taken within 72 hours of unprotected sex to be most effective, but it can be taken up to 120 hours after unprotected sex. The earlier it is taken the more effective it is likely to be. Table 3 lists the formulations available in Australia.

Conclusion

Oral contraceptives are reversible, effective and user friendly. More women in Australia use this form of fertility management than any other method. New and clearer guidelines have been developed and published over the past decade to aid healthcare providers prescribe oral contraception safely and appropriately.

With GPs facing an ever increasing array of drug choices and consumer expectations regarding the risks and benefits of prescribed medications, it is important to review the evidence, the practice and the role of oral contraceptives. MT

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COMPETING INTERESTS: Dr Read has provided expert opinion for Bayer, Schering Plough and Wyeth as part of her employment with Family Planning NSW. She has received support for conference attendance from Bayer and Schering Plough and is an investigator for a Schering Plough contraceptive study. Dr McNamee has provided expert opinion for Bayer and Schering Plough as part of her employment with Family Planning Victoria. She has received support for conference attendance from Organon (now Schering Plough).