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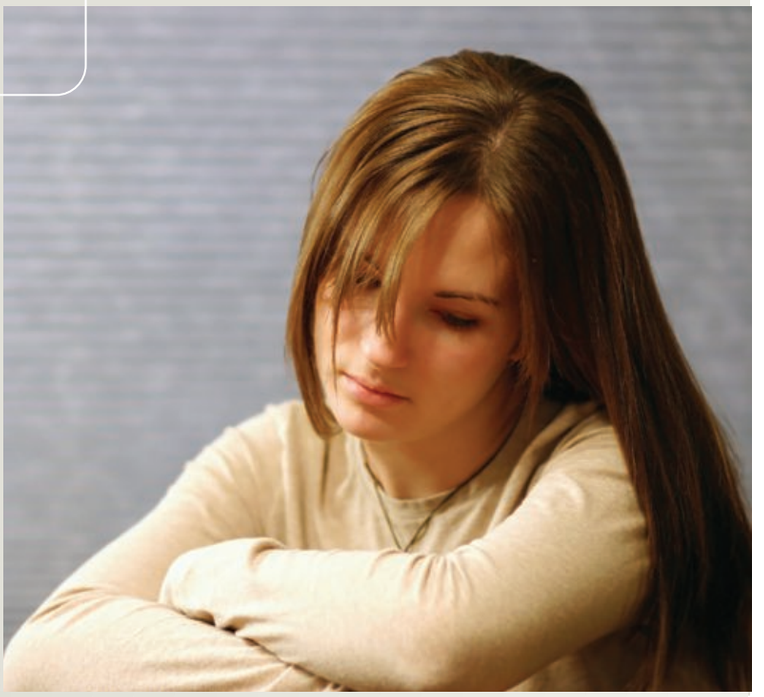
An update on contraception

Reprint Collection

Part 1: oral and emergency

Part 2: rings, implants and injections

Part 3: IUDs, barriers and natural family planning



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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, originally published in *Medicine Today*, June and July 2009, 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

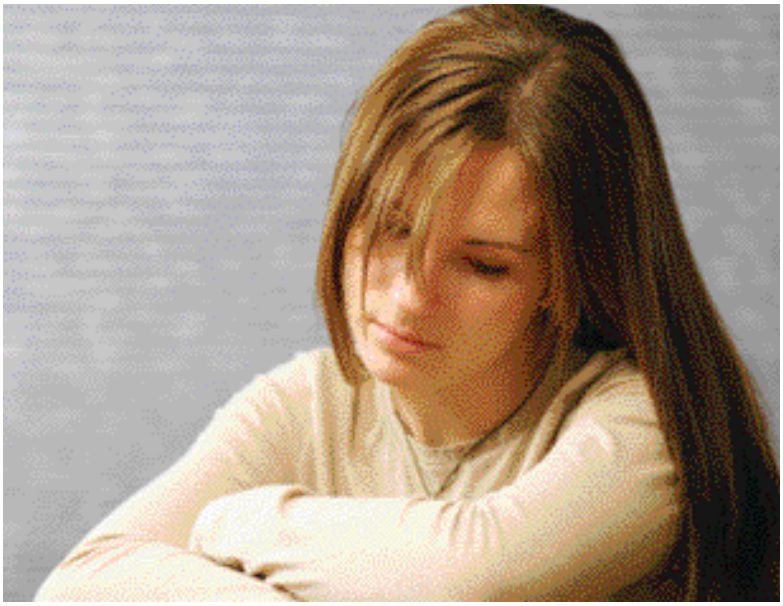
A common conundrum for practicing GPs is advising a woman about a method of oral contraception when there may be a medical condition present that impacts on its safe use. Listed below are questions that may arise.

- 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 4). 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.



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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: http://whqlibdoc.who.int/hq/2008/WHO_RHR_08.19_eng.pdf and www.ffprhc.org.uk/admin/uploads/298_UKMEC_200506.pdf.

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

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.

continued

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 4).

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: http://whqlibdoc.who.int/hq/2008/WHO_RHR_08.17_eng.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

continued

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

continued

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.

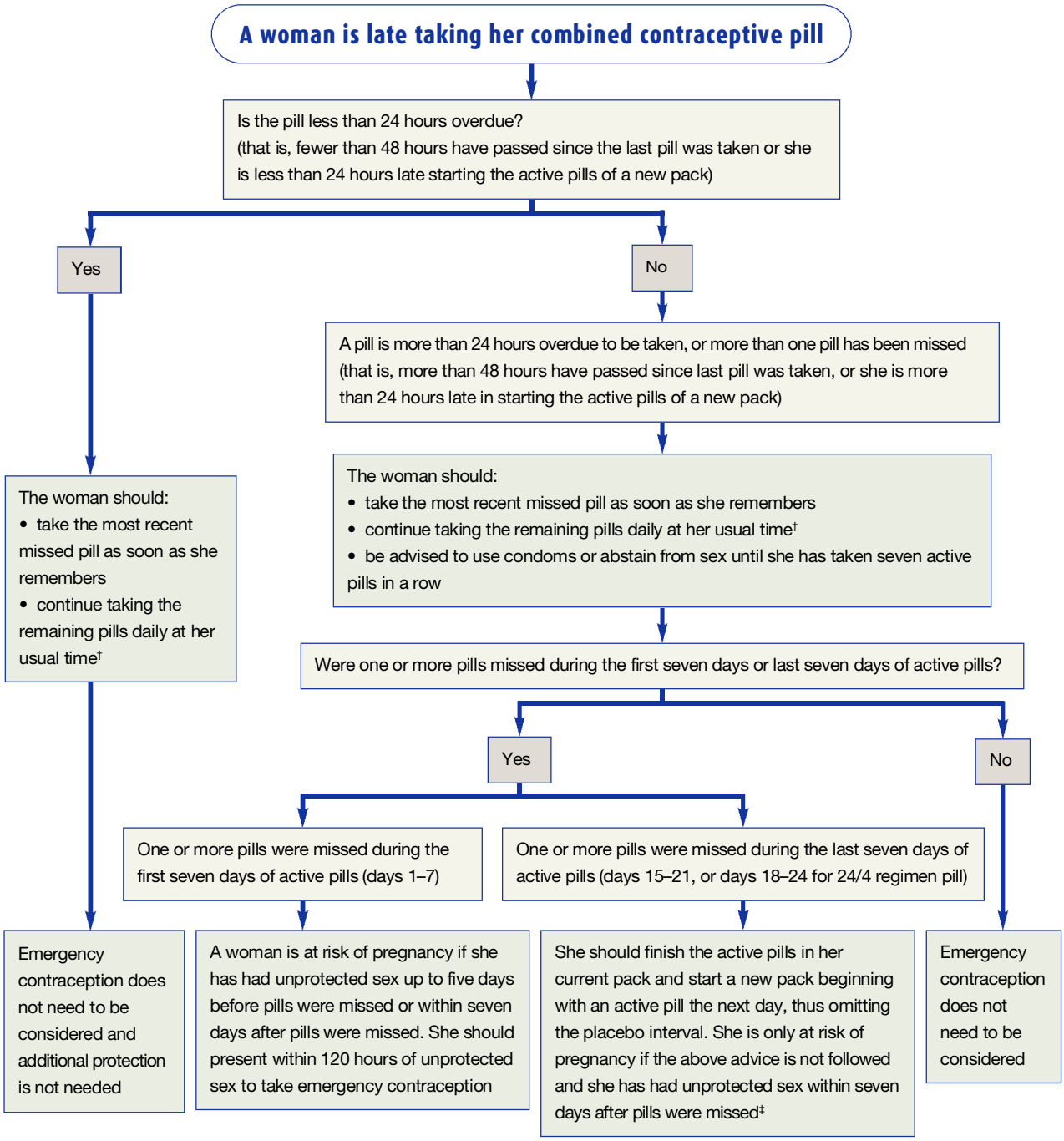
Missed pills

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 11.

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

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).

An update on contraception Part 2: rings, implants and injections

Long-acting reversible hormonal contraceptives are less prone to issues with compliance than the more commonly used combined pill and have great potential to reduce unplanned pregnancies. It is important to include a discussion of their use in routine contraceptive counselling and encourage uptake, particularly in women who are at high risk of unplanned pregnancies.

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This article, the second in a series of three on contraception, considers some of the long-acting reversible contraceptives (LARCs), defined here as a method that requires administering once or less per cycle. The LARCs available in Australia are:

- etonogestrel implants (Implanon Implant)
- combined hormonal vaginal ring containing ethinyloestradiol and etonogestrel (NuvaRing)
- copper intrauterine devices (IUD; Multiload-Cu375, TT380) and levonorgestrel IUDs (Mirena).
- depot medroxyprogesterone acetate (DMPA) injection (Depo-Provera, Depo-Ralovera)

A woman's choice between these methods will be directed by a variety of factors including age, personal preference, cost, availability, fear of injections, tolerance of irregular bleeding, privacy needs, drug interactions and lactation. Although the levonorgestrel IUD is a hormonal method of contraception, this article will only discuss the hormonal LARC methods that act systemically via the hypothalamic–pituitary–ovarian axis to prevent ovulation (copper and levonorgestrel IUDs will

IN SUMMARY

- **A woman's choice between the different contraceptive methods will be directed by a variety of factors including age, personal preference, cost, availability, fear of injections, tolerance of irregular bleeding, privacy needs, drug interactions and lactation.**
- **Long-acting reversible contraceptives (LARCs) are underused in Australia. They are less prone to issues with compliance than the more commonly used combined pill and have great potential to reduce unplanned pregnancies.**
- **LARCs such as the vaginal ring, etonogestrel implant and depot medroxyprogesterone acetate (DMPA) injection can be administered any time in a woman's menstrual cycle as long as pregnancy has been excluded. They are immediately effective if initiated on day one to five of a normal cycle.**
- **The vaginal ring, implant and DMPA injection have the advantage of a low user input once initiated, and all three methods can be used to treat dysmenorrhoea.**
- **It is important to include a discussion of LARCs use in routine contraceptive counselling and encourage uptake, particularly in women who are at high risk of unplanned pregnancies.**

be discussed in the third article in this series). All guidance is based on *Contraception: an Australian Clinical Practice Handbook* produced by Sexual Health & Family Planning Australia (SH&FPA).[1] The handbook can be purchased by visiting your local state or territory Family Planning organisation website or following the link from the SH&FPA website (www.shfpa.org.au).

Limited data available on contraceptive practices of women in Australia show that the combined pill and condoms are the most commonly used reversible contraceptive methods. These methods have a high level of efficacy with perfect use (i.e. no user mistakes); unfortunately the efficacy rate is much lower with typical use, most likely because they require a high degree of day-to-day attention.

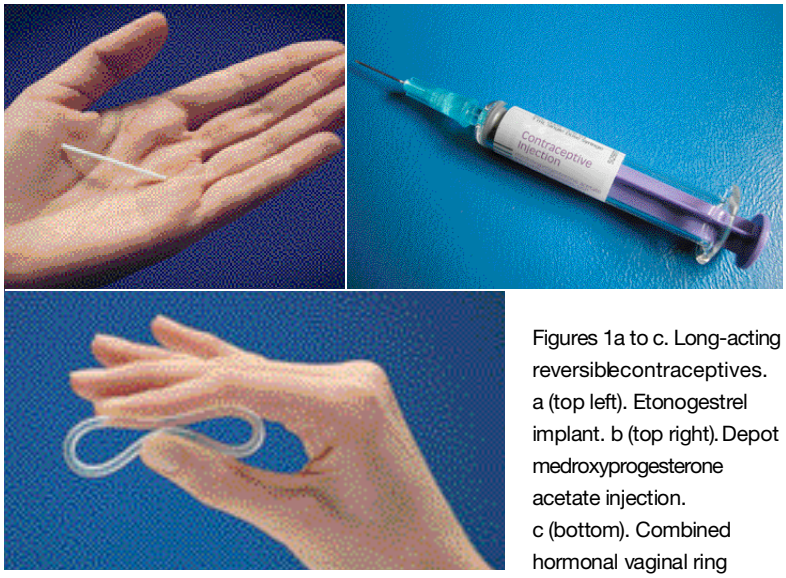
Accordingly, attention has turned to the less frequently used LARCs. These methods require less user input once initiated and generally have the advantage of higher rates of efficacy with typical use. Higher user rates of LARCs are associated with fewer unplanned pregnancies, with international research showing that teenagers who have recently been pregnant and now use a long-acting injectable contraceptive or implant are at a significantly lower risk of a repeat pregnancy within a year than those who take the pill.[2,3] Injections and implants are more cost effective than the pill even if used for less than a year. Discussion of LARCs should therefore be a standard part of any contraceptive consultation.[4]

As in the previous article in this series, Categories 1 to 4 of the UK medical eligibility criteria for contraceptive use 2005/2006 (Table 1) are used to describe levels of contraindication to the use of contraceptive methods.[5]

It is important to discuss the range of contraceptive options and the pros and cons of each method related to the individual's needs. Written information can help a woman decide which method is best for her, and fact sheets on all methods of contraception can be downloaded free of charge from your state or territory's Family Planning Association website.[1]

Administration

The vaginal ring, etonogestrel implant and DMPA injection can be administered at any time in a woman's cycle as long as pregnancy has been excluded (see the box on this page). They are immediately effective if initiated on day one to five of a normal menstrual cycle (day one is the first day of bleeding in a normal menstrual cycle; day five is four days later). All three methods will be effective after a maximum of seven days from administration, depending on the circumstances (Tables 2 and 3).



Figures 1a to c. Long-acting reversible contraceptives. a (top left). Etonogestrel implant. b (top right). Depot medroxyprogesterone acetate injection. c (bottom). Combined hormonal vaginal ring containing ethinyloestradiol and etonogestrel.

The etonogestrel implant is a soft flexible single rod impregnated with 68 mg etonogestrel, which is released slowly over three years once implanted. It is inserted subdermally at the inner side of the nondominant upper arm about 8 to 10 cm above the medial epicondyle of the humerus. It should be replaced before three years of use have passed.

DMPA is given as a deep intramuscular injection of 150 mg/mL of depot medroxyprogesterone acetate suspension. The injection site should not

Excluding pregnancy

Pregnancy can be excluded with a high degree of confidence if:

- a woman has not had sex since the start of last normal period; or
- she is at day one to five of a normal menstrual cycle; or
- her urinary pregnancy test is negative and she has not had unprotected sex for at least three weeks prior to the test.

If pregnancy is not confidently excluded before initiating a method of contraception, a pregnancy test should be performed four weeks later.

continued

Table 1. The UK Medical Eligibility Criteria (UKMEC) Categories* for hormonal LARCs

Circumstances	UKMEC Category*		
	Etonogestrel implant	DMPA	Vaginal ring
Aged under 18 years	1	2	1
Aged 40 to 45 years	1	1	2
Aged over 45 years	1	2	2
Current breast cancer	4	4	4
Past history of breast cancer not active for five years	3	3	3
Past history of arterial disease	2	3	4
Develops arterial disease while using the method	3	3	4
Past history of migraine with aura	2	2	4
Develops migraine with aura while using the method	3	3	4
BMI 30–34 kg/m^2	1	1	2
BMI 35–39 kg/m^2	1	1	3
BMI ⩾40 kg/m^2	1	1	4
Hypertension systolic ⩾160 mmHg or diastolic ⩾95 mmHg	1	2	4
Women aged >35 years and smoking ⩾15 cigarettes per day	1	1	4
Diabetes, no vascular disease and <20 years' duration	2	2	2
Diabetes with micro- or macrovascular disease or >20 years' duration	2	3	3/4
Multiple risk factors for cardiovascular disease (e.g. age, smoking, diabetes and hypertension)	2	3	4
Current VTE (taking warfarin)	3	3	4
Past history of VTE or known thrombogenic mutation	2	2	4
Severe cirrhosis	3	3	4
Mild cirrhosis	2	2	3
Hepatitis B or C carrier with no cirrhosis	1	1	1

*** UKMEC Categories**
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 method.
Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

be rubbed. DMPA injection should be repeated every 12 weeks (± 2 weeks) but can be given up to 16 weeks since the last injection with a low risk of pregnancy.[6]

The vaginal ring is a soft flexible ring impregnated with ethinyloestradiol and the progestogen etonogestrel, which are released into the circulation through the vaginal wall at a rate of 15 µg and 120 µg per day, respectively. The vaginal ring has the lowest oestrogen exposure of the available combined contraceptives. It is inserted into the vagina and left for three weeks, after which it is removed and disposed of. There is a ring-free week during which a woman usually experiences a withdrawal bleed and after which a new ring is inserted.

Cost

Both the etonogestrel implant and DMPA are PBS listed and hence inexpensive for women with Medicare or healthcare cards. However, costs associated with regular visits for intramuscular injections of DMPA and for the etonogestrel implant insertion and removal, as well as the limited availability of a trained practitioner, may create barriers for some potential users. The vaginal ring is not PBS listed and costs vary from around $20 to $30 per ring. Per cycle this is similar to the cost of some of the newer combined contraceptive pills.

Efficacy and continuation rates

All three methods are highly effective with efficacy rates of 99.7%, more than 99.9% and 99.7% for perfect use of DMPA, etonogestrel implant and the vaginal ring, respectively. Efficacy rates of DMPA for less than perfect use due to late or missed injections is 97%, and are more than 99.9% and 92% for typical use of the etonogestrel implant and vaginal ring, respectively.[7]

As there are few community studies of the vaginal ring, this efficacy of typical use is assumed to be the same as that of the combined pill. It is hoped, however, that the true figure for typical use for the vaginal ring will be higher, particularly with the widespread use of mobile phone

Table 2. Initiation of etonogestrel implants, DMPA injections and vaginal rings

Previous contraceptive method	Timing of initiation of new method	When new method becomes effective
No contraception or barriers	Day one to five of a cycle*	Immediately
	Any other time (ensure pregnancy has been excluded)†	Seven days
Combined pill or vaginal ring	Any time if pills/vaginal ring have been taken/used correctly	Immediately
Progestogen-only pills	Any time if pills have been taken correctly; otherwise ensure pregnancy has been excluded	Seven days
DMPA injection	Any time if within 14 weeks of last injection	Immediately
Etonogestrel implant	Any time if within three years of implant insertion	Seven days (however, if a new etonogestrel implant is inserted it will be effective immediately)
Abortion	Within five days of an abortion	Immediately‡
Copper IUD or levonorgestrel IUD	Day one to five of a cycle and regular menstruation*	Immediately
	Any other time and regular menstruation	Seven days (or where possible begin new method seven days before removal). Use condoms for seven days prior to removal of IUD
Levonorgestrel IUD	Any time and irregular cycle or amenorrhoea	Seven days (or where possible begin new method seven days before removal)
Hormonal emergency contraception	Immediately	Seven days§ (etonogestrel implant or DMPA are not recommended until pregnancy has been excluded)

ABBREVIATIONS: DMPA = depot medroxyprogesterone acetate; IUD = intrauterine device.
* Day one is the first day of bleeding in a normal menstrual cycle. Day five is fours days later. † See the box on page 15 for how to exclude pregnancy. If pregnancy is not excluded before initiating a method of contraception a pregnancy test should be performed in four weeks' time. ‡ 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.

reminders and women in Australia having access to a free SMS and/or an email reminder service made available by the manufacturer. Continuation rates for DMPA and the vaginal ring in Australia are unknown. In the USA, around 55% of women who have DMPA injections will have continued the method at one year.[7] Unpublished Australian data suggest that after insertion around 74% and 50% of women continue to use etonogestrel implants at the end of one and two years, respectively.

Advantages and disadvantages

DMPA injections, etonogestrel implants and the vaginal ring have the advantage of a low user input compared with the pill and condoms, and all three methods can be used to treat dysmenorrhoea. As non-oral methods, they may be useful for women with inflammatory bowel disease or other malabsorption conditions. Women who have DMPA injections or an etonogestrel implant may achieve amenorrhoea, and women who use the vaginal ring usually experience light regular predictable withdrawal bleeds. Vaginal ring cycles can be run together, replacing the ring every three to four weeks to manipulate cycles. Both the etonogestrel implant and vaginal ring are rapidly reversible. Both may improve acne, although some women will develop this condition for the first time during their use. DMPA and the vaginal ring are very private methods of contraception (that is, their use is easy to conceal from others).

All three methods of contraception have inflexible dosing regimens. The vaginal ring may be costly, may cause device-related side effects and may accidentally fall out, and vaginal administration is not acceptable for some women. DMPA cannot be withdrawn once given so side effects may persist for some time. It is also associated with loss of bone density and regular injections may be a deterrent to some women. Although both DMPA injections and the vaginal ring are long acting, they require a greater user input than etonogestrel implants. The procedure of insertion of an etonogestrel implant can be associated with bruising and occasionally scarring. Some women will dislike the idea of the procedure or having a foreign body inside them. As previously mentioned there may be access issues related to costs and availability of suitably trained doctors. If the implant is inserted deeply it may require a more invasive procedure for removal.

Contraindications

Summaries of important and common medical eligibility criteria for the three

continued

Table 3. UKMEC Categories* and initiation of etonogestrel implants, DMPA injections or vaginal rings in postpartum women

Situation	Days postpartum	UKMEC Category*			When method becomes effective
		Etonogestrel implant	DMPA	Vaginal ring	
Not breastfeeding	<21 days	1	1	3	Immediately
	⩾21 days	1	1	1	Immediately if menstruation has returned and contraceptive method started on day one to five of cycle† Seven days if contraceptive method is started on day six or later in the cycle or amenorrhoea. Exclude pregnancy first‡
Breastfeeding	<Six weeks	1	2	4	
	>Six months	1	1	1	
Fully breastfeeding	Six weeks to six months	1	1	3	
Partial breastfeeding§	Six weeks to six months	1	1	2	

ABBREVIATION: DMPA = depot medroxyprogesterone acetate. * UKMEC Categories; see below. † Day one is the first day of bleeding in a normal menstrual cycle. Day five is four days later. ‡ See the box on page 15 for how to exclude pregnancy. § Partially breastfeeding is defined as half or less of the baby's feeds are breastfeeds.

*** UKMEC Categories**

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 method.

Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

Table 4. Liver enzyme-inducing drugs

Carmazepine
Rifampicin
Rifabutin
St John's wort
Griseofulvin
Phenytoin
Barbiturates
Primidone
Topiramate
Oxcarbazepine

hormonal LARCs are listed in Tables 1 and 3. The vaginal ring has all the same contraindications as the combined pill (see the first article in this series originally published in *Medicine Today*, May 2009). Additional considerations are chronic constipation and vaginal prolapse, which may be associated with ring expulsion. Both the available progestogen-only LARCs (DMPA injections and the etonogestrel implant) can be used safely in most women who cannot tolerate oestrogen or in whom oestrogen is contraindicated. Because oestrogen is considered cardioprotective in perimenopausal women and circulating levels drop in women who have DMPA injections, risk factors for cardiovascular disease are considered more seriously in women who have DMPA injections compared with those using other progestogen-only methods.

Side effects

Approximately 50% of women who use DMPA will become amenorrhoeic compared with about 22% of women who use etonogestrel implants.[8] In contrast, approximately 35% of women who use DMPA and 23% who use etonogestrel implants experience frequent or prolonged bleeding. Bleeding patterns tend to establish themselves in the first three to six months of use and for both methods unacceptable bleeding is the most common single reason for discontinuation.[9] It is important that women are well counselled on cycle irregularities before initiation of these methods. In contrast, bleeding abnormalities are a very uncommon reason for discontinuation in users of the vaginal ring.

Weight gain attributable to a contraceptive method is difficult to assess. It is a common complaint for users of both progestogen-only methods but more so for users of DMPA than users of etonogestrel implants. There is no evidence of weight gain in users of the vaginal ring. Other common side effects common to all three methods are headaches, acne, breast tenderness and mood changes. Nausea and vaginal symptoms such as discomfort and increased discharge may occur with the vaginal ring. Loss of bone density, which is likely to be reversible, is an established side effect of DMPA injections.

Drug interactions

For users of the vaginal ring, condoms should also be used while antibiotics are being taken and until the woman has had seven consecutive days of ring use after the antibiotics have ceased. This may mean skipping a ring-free interval and reinserting a new ring at the time the expired one is removed. Neither of the progestogen-only methods are affected by use of antibiotics.

Use of either the etonogestrel implant or vaginal ring for contraception in women taking liver enzyme-inducing medications is classed as UKMEC Category 3 (Table 4). Although this means these methods are not absolutely contraindicated, the Australian recommendation

is that they should not be used as the dose cannot be increased to counteract the more rapid metabolism. In contrast, liver enzyme inducers have no effect on the efficacy of DMPA and its use is classed as a Category 1. DMPA injections are, therefore, often a method of choice for women taking liver enzyme inducers in the long term.

Stopping the method

Etonogestrel levels are undetectable within a few days of implant removal. For women who use an implant or the vaginal ring, return to pre-existing ovulatory pattern is usually rapid. This rapid reversal is of great advantage if a woman is experiencing side effects. In contrast, DMPA cannot be reversed and is detectable in the serum many months after the last injection is given. There is also a predictable delay in return to fertility of up to 18 months after the last DMPA injection.

Special circumstances

Young women

Longer-acting methods of contraception can be suitable for young women. Their use should be discussed if difficulties with compliance with the combined contraceptive pill are identified (see case 1 in the box on page 20).

Excluding pregnancy

Although pregnancy should be excluded before a woman starts any nonbarrier method of contraception, this is most important with progestogen-only LARCs. Case 2 in the box on page 20 examines the issues for a woman returning late for a repeat DMPA injection. The principles discussed emphasise exclusion of pregnancy before initiating any method of contraception.

Bleeding problems

The mechanism for irregular and unpredictable endometrial bleeding with progestogen-only methods of contraception is complex and ill understood. It is important to consider other causes for bleeding, particularly if there has been a recent change, and to have a low threshold for testing for chlamydia, particularly in women aged less than 25 years.

The following treatment suggestions, based on a SH&FPA consensus, can be trialled in women with abnormal bleeding provided that there is no contraindication:

- oestrogens; use for three weeks
  - the combined pill (any brand)
  - oestradiol patch 100 µg per week
  - oestradiol 100 µg daily
  - conjugated oestrogens 0.625 mg daily
- other medications; use for five days
  - mefenamic acid (Ponstan) 500 mg twice daily
  - doxycycline 100 mg twice daily
  - tranexamic acid (Cyklokapron) 500 mg twice daily.

The treatments listed above have been shown to have some degree of short-term success in controlling abnormal bleeding, but none has been shown to increase the chances of women continuing with the use of the long-term contraceptive method.[12]

Late for changeover/administration problems with progestogen-only LARC methods

Late changeover or administration problems are a common scenario with the progestogen-only LARCs and advice differs between the different regimens. Recent conception/pregnancy cannot always be excluded by undertaking a sensitive pregnancy test in women who have had unprotected sex since their progestogen-only LARC method expired (see case 2 in the box on page 20).

Problems with the vaginal ring

Late changeover for the new ring

For users of the vaginal ring, the principles of late changeover or administration problems are the same as those for the combined pill as discussed in the first article in this series. The most common mistake with compliance is being late for a new ring insertion. Unfortunately, this is also the time of the cycle when the risk of pregnancy is highest if mistakes are made. It is vitally important that a woman decides on a way to help her remember to insert a new ring, such as the free SMS reminder service made available by the manufacturer. If a woman is more than 24 hours late in inserting the new ring after the ring-free interval, she:

- should insert a new ring immediately
- should use condoms or abstain from sex for the next seven days (if this advice is not followed she is at risk of pregnancy)
- is at risk of pregnancy if she has had unprotected sex during the ring-free interval or within seven days after having been 24 hours late or more in inserting the new ring. Emergency contraception can be considered if she had unprotected sex within the last five days.

Early removal of the ring

It is not recommended that women remove the vaginal ring during its three weeks of use. If the ring is removed for more than three hours its efficacy maybe compromised; the woman should reinsert the ring immediately and use condoms or abstain from sex for the next seven days. If the ring was removed for more than three hours in the first seven days of a cycle of use and the woman has had unprotected sex during this time, she should consider emergency contraception. If the ring was removed for more than three hours and there were fewer than seven days of ring use left in the cycle, the woman should skip the ring-free interval and reinsert a new ring immediately after the old one is removed.

Late removal of the ring

The contraceptive efficacy of the ring is adequate for up to four weeks of use; therefore, if a woman has left the ring in place for more than three weeks but not

Case presentations

Case 1. A 16-year-old girl who has difficulty remembering to take the combined pill

Kristy has just turned 16 years of age and presents requesting a repeat prescription of the pill. She has been taking a pill containing 30 µg ethinyloestradiol plus 150 µg levonorgestrel for the past six months and has had no side effects. On further questioning, however, it becomes apparent that she has trouble establishing a routine with pill taking and has been missing several pills a month. She has little knowledge of other methods of contraception but is anxious about her risk of pregnancy and is interested in considering a change to a longer-acting method of contraception.

Kristy lives at home with her father, stepmother and two stepbrothers. She feels unable to discuss contraception needs with her parents. She is in year 11 at a local high school and is doing well. She is in a relationship with Paul who is aged 17 years. He is her second sexual partner.

Although use of DMPA is classed as UKMEC Category 2 for women aged less than 18 years because of bone density concerns, the vaginal ring, etonogestrel implant and DMPA injection all have their pros and cons and each could be used in this age group. For sexually active young women there is no agreed absolute age below which hormonal contraception cannot be initiated. Medical contraindications are uncommon; issues around contraception provision are more focused usually on assessing the young person's maturity in decision making, capacity to consent to clinical management and child protection considerations. Each case should be considered individually with regard to legislation, which varies in different states and territories in Australia. When discussing contraception options with young women it is always important to respect their needs for confidentiality and emerging autonomy in decision making, as well as encouraging parental involvement, where possible.

Etonogestrel implants are an excellent choice for young women. They have an extremely high efficacy rate and for many women will be associated with infrequent or no bleeding problems. There is no ongoing concern about cost or getting to the doctor or pharmacist on time. The implant is sometimes visible and always palpable and privacy may be an issue.

DMPA has broadly similar advantages and disadvantages, although it more commonly causes amenorrhoea and is a very private method. Its main drawbacks are the potential to cause loss of bone density, the need for more frequent medical attention and the unpredictable bleeding that may occur and persist for months after the last injection. There remains a concern about the bone density loss in young women (at a time when they have not yet attained peak bone density) and for this reason DMPA is generally not regarded as a first choice option for such women.

The vaginal ring has the advantages of having an ultra low dose and being associated with good cycle control. It has a high acceptance in young people.[10] It is also a private method and only needs to be administered once per cycle. Its main disadvantages are cost, the need for repeated visits to the pharmacy and the reluctance of some women to use a vaginal method.

After counselling Kristy on available options she decides to try an etonogestrel implant. It is important to offer chlamydia screening and discuss the benefits of condom use for prevention of sexually transmitted infections in this situation.

Case 2. A 27-year-old woman who presents late for her DMPA repeat injection

Jane, aged 27 years, has been using DMPA for three years. She is amenorrhoeic and very happy with the method. She presents at 16 weeks and four days since her last injection. She has continued to have frequent sex and does not use condoms. She is very keen to maintain cover with DMPA as she feels a long stint of condoms will not work in her relationship. A sensitive urine pregnancy test is negative.

It is most important to be aware that the negative pregnancy test does not exclude pregnancy/recent conception. Traditional advice would be to ask Jane to abstain or use condoms for three weeks, review and repeat the pregnancy test and if it is negative give the DMPA injection and advise her to use condoms for another seven days. However, she has already signaled the difficulty with this.

There are a number of issues to discuss with Jane. Firstly, the risk of pregnancy increases with the interval between injections. You may feel on balance that following the traditional path is best, but it may be that she comes back three weeks later and has used condoms inconsistently and you are still unable to exclude pregnancy. Her risk would then be higher than before.

The following factors should be discussed with Jane:

- her concern for any possible effects of DMPA on a fetus in the event of an existing undiagnosed early pregnancy. There are no known teratogenic effects of DMPA on a fetus,[11] although they cannot be absolutely excluded. It is particularly important that women taking DMPA know this as the injection cannot be reversed. Jane feels clear at this stage that if she were to fall pregnant she would seek a termination.
- the importance of excluding pregnancy.

Although Jane is amenorrhoeic, she may ovulate and conceive with no symptoms to alert her to the possibility of a pregnancy, risking a late diagnosis. Jane agrees to return for a pregnancy test in four weeks time and you place her on a recall list as a back up. As she had unprotected sex three times in the last five days you give her emergency contraception and give the DMPA injection. You stress that it is very important that she uses condoms for the next seven days. Jane feels she can manage this.

You check Jane's record five weeks later. She has not returned. You call her and she tells you she did not think it was necessary as she has had a 'period'. She returns and a repeat pregnancy test is negative.

more than four weeks, she:

- should remove the ring
- should have a shortened ring-free interval and then insert a new ring as had been initially scheduled (28 days after the current ring was inserted)
- does not require any further protection.

If a woman has left the ring in place for more than four weeks, she:

- should remove the ring
- should immediately insert a new ring
- should use condoms or abstain from sex for the next seven days (if this advice is not followed she is at risk of pregnancy); and
- is at risk of pregnancy if she has had unprotected sex after the ring has been left in place for more than four weeks. Emergency contraception can be considered if a woman has had unprotected sex in the last five days.

Conclusion

LARCs are underused in Australia. Each of the three methods discussed in this article have many advantages. They are less prone to issues with compliance than the more commonly used combined pill, and they have a great potential to reduce unplanned pregnancies. It is important to include a discussion of their use in routine contraceptive counselling and encourage uptake, particularly in women who are at high risk of unplanned pregnancies. MT

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COMPETING INTERESTS: 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). Dr Harvey has provided expert opinion for Bayer and Schering Plough as part of her employment with Family Planning Queensland. She has received support for conference attendance from Organon (now Schering Plough).

An update on contraception
Part 3: IUDs, barriers and natural family planning

Intrauterine devices provide highly effective and very long-acting contraception with minimal action required on the part of the user. Their effect is rapidly reversible once they are removed and they are relatively inexpensive because of their long duration of action.

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This article, the last in a series of three on contraception, gives an overview of intrauterine devices (IUDs), barriers and natural family planning methods of contraception, and briefly discusses what might lie ahead in the contraceptive field. All guidance is based on the handbook *Contraception: an Australian Clinical Practice Handbook*, which is produced by Sexual Health & Family Planning Australia (SH&FPA).[1] The handbook can be purchased by visiting your local state or territory Family Planning Association website or following the link from the SH&FPA website (www.shfpa.org.au).

Intrauterine devices

IUDs are small flexible devices made of metal and/or plastic. These devices may be inert or they may release copper or a hormone. After a long period of very low usage in Australia, it now appears that they are becoming more popular, although there are no recently published Australian population data on these changing patterns of contraceptive use.

Myths about IUDs as a cause of pelvic infection, subsequent infertility and the associated risks of their use in nulliparous women have been

IN SUMMARY

- **Both the copper and hormonal intrauterine devices (IUDs) prevent fertilisation by inhibiting sperm migration through the cervix and into the upper genital tract, inhibiting ovum transport and preventing implantation.**
- **IUDs are long-acting methods of contraception with minimal action required on the part of the user. They have an effect that is rapidly reversible once the device is removed and are relatively inexpensive because of their long duration of action.**
- **Barriers are totally patient controlled, can be used by anyone because they do not contain hormones and are not contraindicated in women or men with any medical condition, except perhaps in those with an allergy to latex.**
- **The use of natural family planning methods requires that couples be diligent and committed because these methods generally reduce spontaneity and may require long periods of abstinence. It can take six to 12 menstrual cycles to accurately identify fertile days of a woman's cycle. Women with irregular periods could also have difficulty in predicting their fertile days.**
- **There are constant changes and developments in the contraceptive field. One area of research currently being undertaken is on changing the use of the oral contraceptive pill to have fewer or no pill-free days. There are also smaller IUDs (both copper and hormonal) currently being marketed or trialled.**

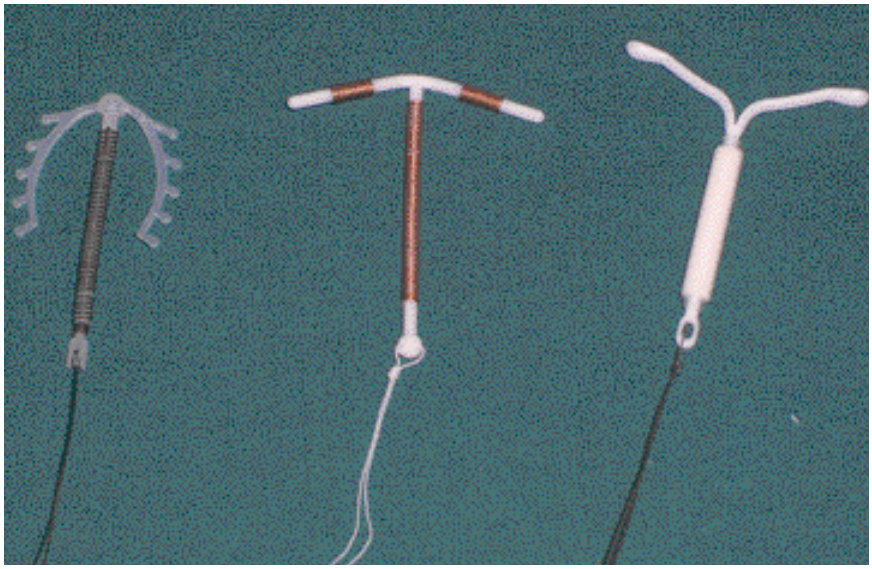

Figure. From left to right, Multiload-Cu375, TT380 and Mirena IUDs.

challenged for at least a decade; however, women and doctors in Australia have remained reluctant to use or prescribe IUDs until recent years. It is now established that although there is a small procedure-related increase in the risk of pelvic infection in the first few weeks after insertion of IUDs, the risk thereafter relates to the risk of acquiring a cervical sexually transmitted infection (STI) with chlamydia or gonorrhoea. There is no evidence that women who have used IUDs have increased rates of infertility, and nulliparous and young women who are at low risk of STIs can safely use these devices.[2,3]

Available IUDs

There are two types of IUDs available in Australia – copper and hormonal. The only two copper IUDs marketed in Australia are the Multiload-Cu375 and the TT380 device, the latter replacing the Copper T380A in 2008. The TT380 is available in a standard and short version; the latter is suitable for women with uterine cavities of less than 6.5 cm in length. There is one hormonal IUD available in Australia, which is a T-shaped, plastic device that releases levonorgestrel (Mirena). All the above IUDs have an efficacy rate greater than 99%.[4] The TT380 Standard is approved for 10 years of use, whereas the Multiload-Cu375, Mirena and the TT380 Short devices are approved for five years of contraceptive use.

Mechanism of action

Both the copper and hormonal IUDs prevent fertilisation by inhibiting sperm migration through the cervix and into the upper genital tract, inhibiting ovum transport and preventing implantation. The levonorgestrel IUD additionally has pro-gestogenic effects on cervical mucus, reducing sperm penetration and contributing to the contraceptive effect. However, in women who use levonorgestrel IUDs, the released progestogen has little effect on the hypothalamic–pituitary axis, serum oestradiol levels are not reduced and more than 75% of them continue to ovulate.[3] This differs from all other available hormonal methods (except progestogen-only pills) for which contraceptive effect relies on distribution of the exogenous hormone to the systemic circulation, with resulting disruption of the hypothalamic–pituitary axis and subsequent anovulation.

Advantages

IUDs provide highly effective and very long-acting contraception with minimal action required on the part of the user. They have an effect that is rapidly reversible once they are removed and are relatively inexpensive because of their long duration of action. They provide a very good alternative to sterilisation. The copper IUD is a good choice for women in whom use of hormonal methods are contraindicated or for women who desire a highly effective but nonhormonal method of contraception. The levonorgestrel IUD is particularly suited for women requiring management of menorrhagia in addition to contraception or for those who would find increased bleeding a problem with the copper IUDs.

Disadvantages

IUDs require a procedure for insertion that should be performed only by specially trained doctors. The insertion has specific risks (these are uncommon but include uterine perforation, pelvic infection and vasovagal reactions) and may prove to be moderately uncomfortable for some women. IUDs require medical intervention to discontinue their use, although removal is a simpler procedure than insertion and is well within the scope of all GPs. Some women dislike the idea of the insertion procedure or having a foreign body inside them, and IUDs provide no protection against STIs.

Contraindications

As in the previous articles in this series, Categories 1 to 4 of the UK Medical Eligibility criteria for contraceptive use, 2005/2006,[2] are used to describe levels of contraindication to use of contraceptive methods. Table 1 summarises important and common medical eligibility criteria for the two types of IUDs. The levonorgestrel IUD is considered as both an IUD and a progestogen-only method of contraception. Contraindications to use of both these types of contraceptive methods need to be

considered, although systemic absorption from the levonorgestrel IUD is low and very unlikely to be associated with increased risks of venous and arterial disease.

Cost

The levonorgestrel IUD is PBS listed and hence inexpensive for women with Medicare cards and particularly for those with healthcare cards. Copper IUDs need to be purchased from pharmacies or are stocked by family planning clinics and some other clinics where IUD insertions are performed regularly. Cost to women is about $80 to $110 for a copper device. As many doctors charge a gap fee that is not covered by Medicare, a woman will usually pay out-of-pocket costs for the insertion procedure for either type of device. The up-front costs may, therefore, be a potential barrier for intrauterine methods, despite the fact that over time they are very inexpensive and cost-effective.

Side effects and complications

Women who use copper IUDs are more likely to have increased menstrual loss and dysmenorrhoea, but they usually have a regular menstrual cycle. Persistent vaginal bleeding and/or spotting is common initially in women who use levonorgestrel IUDs. It is also possible for women to bleed small amounts daily in the first three to five months of use (women should be specifically warned about this possibility). Amenorrhoea or regular light bleeding is then the expected pattern for women who use levonorgestrel IUDs.

Risk of pelvic inflammatory disease among women who use IUDs is most strongly related to the insertion procedure and their background risk of STIs. The overall risk of pelvic inflammatory disease is low, at 1.6 per 1000 woman years.[3] There is a sixfold increase in risk of pelvic infection in the first 20 days after insertion of IUDs but the risk thereafter is similar to that in the population of women who do not use IUDs, and remains low unless there is exposure to STIs.

Table 1. UK Medical Eligibility Criteria (UKMEC) Categories* for IUDs

Circumstances	UKMEC Category*	
	Copper IUD	Levonorgestrel IUD
Menarche to under 20 years of age	2	2
Aged over 20 years	1	1
Nulliparous	1	1
Postpartum (includes breastfeeding or not and post LSCS) more than four weeks after delivery	1	1
Postpartum (includes breastfeeding or not and post LSCS) – from 48 hours to less than four weeks after delivery	3	3
Past ectopic pregnancy	1	1
Unexplained vaginal bleeding	4	4
Distorted uterine cavity – by fibroids or other abnormality	4	4
Heavy or prolonged menses, severe dysmenorrhoea, iron deficiency anaemia, endometriosis	2	1
Current breast cancer	1	4
Past history of breast cancer not active for five years	1	3
Multiple risk factors for cardiovascular disease (e.g. age, smoking, diabetes and hypertension)	1	2
Past history of arterial disease	1	2
Develops arterial disease while using the method	1	3
Hypertension systolic ⩾160 mmHg or diastolic ⩾95 mmHg	1	3
Diabetes	1	2
Past history of migraine with aura	1	2
Develops migraine while using the method	1	3
Current VTE (on warfarin)	3	3
Past history of VTE or known thrombogenic mutation	1	2
Past PID with subsequent pregnancy	1	1
Past PID without subsequent pregnancy	2	2
Very high risk of STI (chlamydia and gonorrhoea) exposure	3	3
Increased but not very high risk of STI (chlamydia and gonorrhoea) exposure	2	2
Puerperal sepsis, current PID, chlamydia or gonorrhoea or purulent cervicitis – on insertion	4	4
Current PID, chlamydia or gonorrhoea or purulent cervicitis – for continuation	2	2
Severe cirrhosis or liver tumours	1	3
Mild cirrhosis	1	2
Hepatitis B or C carrier with no cirrhosis	1	1
Concurrent use of liver enzyme-inducing medications	1	1

ABBREVIATIONS: LSCS = lower segment Caesarean section; PID = pelvic inflammatory disease; STI = sexually transmitted infection; VTE = venous thromboembolism.
* **UKMEC Categories**
Category 1: A condition for which there is no restriction for the use of the contraceptive method.
Category 2: A condition in which the advantages of using the method generally outweigh the theoretical or proven risks.
Category 3: A condition in which the theoretical or proven risks usually outweigh the advantages of using the method.
Category 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

Excluding pregnancy

- Pregnancy can be excluded with a high degree of confidence if:
  - a woman has not had sex since the start of her last normal period; or
  - she is at day one to five of a normal menstrual cycle; or
  - a urinary pregnancy test is negative and she has not had unprotected sex for at least three weeks prior to the test.
- If pregnancy is not confidently excluded before initiating a method of contraception, a pregnancy test should be performed four weeks later.

Uterine perforation occurs in up to 2.3 per 1000 insertions and spontaneous expulsion of the device in about 5% of women who chose this method.[3] The absolute risk of pregnancy (intrauterine and extrauterine) in women who use IUDs is very low. However, pregnancy in women with an IUD *in situ* increases the risks of ectopic pregnancy, second trimester septic miscarriage and premature delivery. The absolute risk of ectopic pregnancies is low in women who use IUDs and is certainly lower than in those using no contraception. However, since IUDs are effective at preventing intrauterine pregnancies, when contraceptive failure does occur a greater proportion of these pregnancies are ectopic than that seen in the general population. A history of ectopic pregnancy is not a contraindication for use of IUDs. It is important to exclude ectopic pregnancy if a pregnancy occurs in a woman with an IUD *in situ*. It is not known if there is a risk of fetal exposure to local intrauterine progestogen in women who use the levonorgestrel-releasing IUD.

Counselling and insertion

Discussion with women considering the use of IUDs needs to include the pros and cons of the method compared with other contraceptive methods and details of the insertion procedure. An appropriate history needs to be taken and an examination performed to assess suitability of a woman for an intrauterine method. It is also important to discuss the acceptability and suitability of both the levonorgestrel IUD and copper IUDs as many women will not have considered copper devices, erroneously seeing them as associated with problems or as no longer being available. Written information can be helpful to women considering the different contraceptive methods and fact sheets on all contraceptive methods can be downloaded free of charge from your state or territory's Family Planning Association website.

Screening for STIs can be carried out by risk assessment, demographic or

Table 2. Initiation of intrauterine devices

Previous contraceptive method	Timing of insertion of IUDs (applies to both copper IUDs and the levonorgestrel IUD unless otherwise stated)	When the levonorgestrel IUD becomes effective (Note: copper IUDs are always immediately effective)
No contraception or barriers	On days one to seven of a cycle for the levonorgestrel IUD* On days one to 12 of a cycle for copper IUDs*	Immediately
	At any other time (exclude pregnancy)†	Seven days
Combined pill or vaginal ring	At any time if pills/vaginal ring have been taken/used correctly	Seven days (or continue combined oral contraceptive pill for seven additional days for immediate protection)
Progestogen-only pill	At any time if pills have been taken correctly; otherwise, exclude pregnancy†	Seven days
DMPA injection	At any time if within 14 weeks of last injection	Immediately
Etonogestrel implant	At any time if within three years of insertion	Seven days (or insert levonorgestrel IUD seven days before implant removal for immediate protection)
Postpartum	Less than 48 hours postdelivery or after four weeks postdelivery if pregnancy is excluded†	Seven days

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.
† See the box on this page for how to exclude pregnancy. If pregnancy is not excluded before initiating a method of contraception, a pregnancy test should be performed four weeks' later.

bacteriological methods. Although there is no Australian consensus on the place of routine screening, SH&FPA[1] and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists[5] recommend that consideration be given to screening for bacterial vaginosis and chlamydia prior to insertion or change of an IUD. Routine antibiotics are not recommended to be taken prior to IUD insertion. There is no clear evidence on the use of oral analgesics or topical anaesthetics before or during IUD insertion, although a randomised controlled trial found that no reduction in pain was experienced by women taking oral ibuprofen before the procedure.[6]

IUDs can be inserted any time after pregnancy has been confidently excluded (see the box on page 26). In women using barriers or no contraception, levonorgestrel IUDs are generally inserted between days one to seven, and copper IUDs between days one to 12, of the menstrual cycle. Copper IUDs are always effective immediately but levonorgestrel IUDs require seven days to become effective if they are inserted at times other than day one to seven of a normal menstrual cycle (Table 2).

Doctors who insert IUDs are responsible for ensuring that they are appropriately trained and maintain their competence in the procedure. This should include the ability to manage vasovagal shock, which is an occasional complication of the procedure. Some medical indemnity providers require additional insurance cover for GPs who perform this procedure but most cover it under their 'non procedural' category.

Removal

Recommended removal time of IUDs is within the first seven days of a woman's cycle, although it can be performed at any time if the woman desires pregnancy, has not had intercourse during that cycle or is already covered by another method of contraception. Removal mid cycle carries a small risk of pregnancy if sperm have recently entered the uterus and the IUD is removed shortly thereafter.

Removal of an IUD is a fairly straightforward procedure: the cervix and IUD strings should be well visualised, the strings are then grasped firmly close to the external os with sponge forceps, and gentle firm traction should be applied in alignment with the uterus until the device is fully removed. It is important to maintain counter traction of the uterus by holding the speculum in place while doing this and to warn the woman that she may experience brief uterine cramping with the procedure. (See the case study on this page and the flowchart on page 28.)

Additional practice tips

Practice tips on IUDs are outlined below.

- After insertion of an IUD, the strings should be cut about 3 cm from the external os (cutting the strings too short can cause partner discomfort).
- Antibiotic cover for subacute bacterial endocarditis prophylaxis is no longer generally necessary for IUD insertion and removal. However discussion with the treating cardiologist is advisable for women with cardiac conditions associated with the highest risk of adverse outcomes from endocarditis (this includes women with a prosthetic valve or those who have had endocarditis or cardiac transplantation or who have some categories of congenital heart disease and rheumatic heart disease).[7]
- Before a change of IUD, seven days' abstinence is recommended in case of failed insertion of the new device.
- A copper IUD provides very effective postcoital emergency contraception for up to five days post intercourse but the levonorgestrel IUD cannot be used for this purpose.
- Any copper IUD inserted in women aged over 40 years, or levonorgestrel IUD inserted in women aged over 45 years, can be left *in situ* as effective contraception until after the menopause.[3] The decision on extended use, however, should always be discussed with the woman.[1]
- If a woman develops pelvic inflammatory disease with an IUD *in situ*, the IUD can be left in place if she responds to treatment, is not at risk of repeat infection and wishes to continue with the method.
- If a woman has an IUD *in situ* and has uncomplicated cervical infection (chlamydia or gonorrhoea), this should be treated with a pelvic inflammatory disease regimen of antibiotics.

Case study. A woman presenting for IUD removal but the strings are not visualised

Layla is a 34-year-old mother of two. She was divorced two years ago and has recently remarried. Her husband does not have children and she has attended the surgery to have her intrauterine device (IUD) removed because she would like to become pregnant again. She is not sure what type of IUD was inserted three years ago, but she thinks it was a hormonal device because her periods have been much lighter than previously.

Layla is keen to become pregnant as soon as possible, so there is no need to remove the device at any particular time of her cycle. You decide to remove the device immediately in the surgery, but on a speculum examination, you cannot see a string emerging from the cervical os. A pregnancy test is negative. An ultrasound is ordered and this shows the presence of an IUD in a good position. You are not confident to use a sound to explore the canal or the uterine cavity so you refer Layla to a gynaecologist for removal of the IUD (see the flowchart on page 28).

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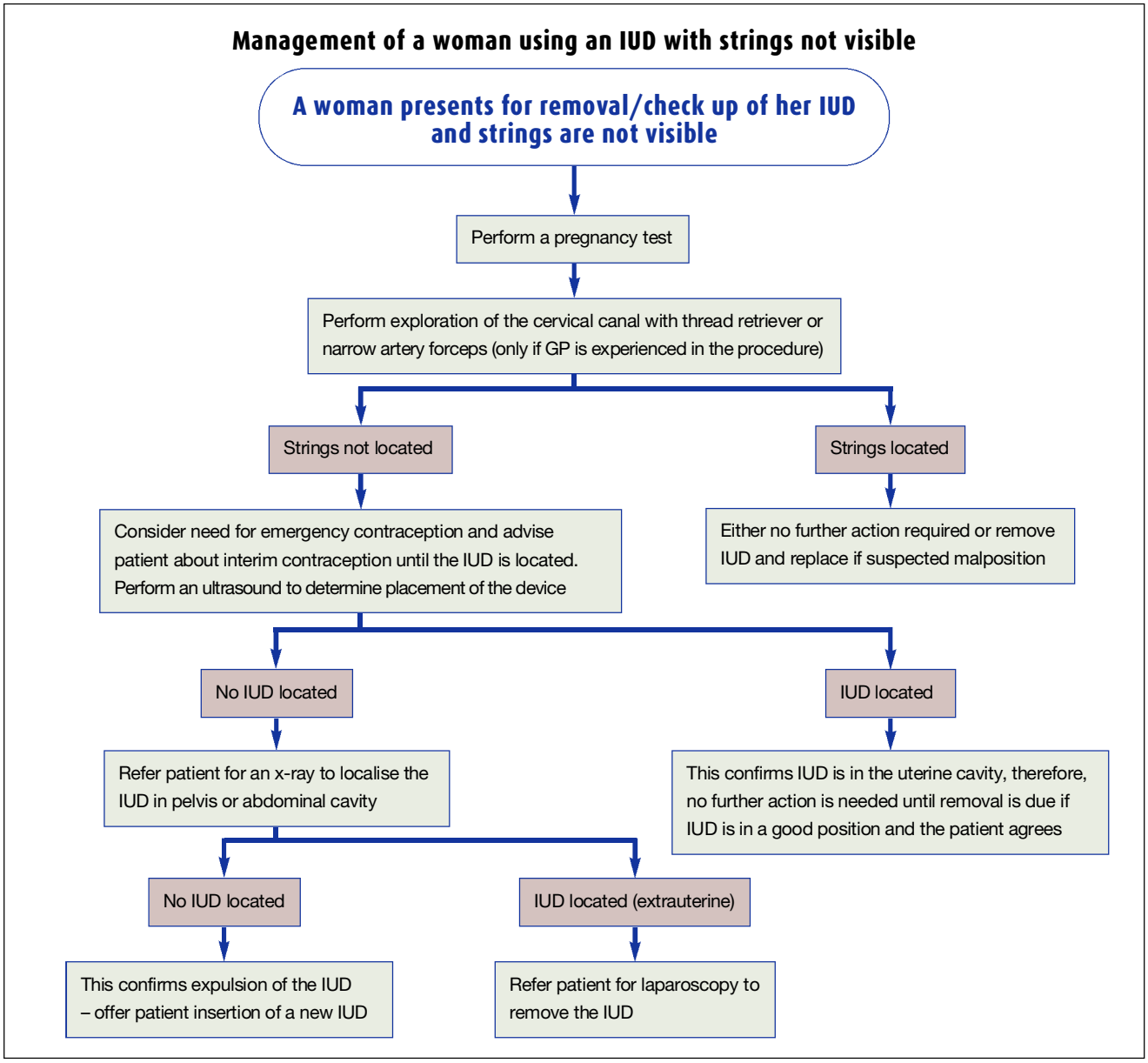

Barrier methods

Barriers are totally patient controlled, can be used by anyone because they do not contain hormones and their use is not contraindicated in women or men with any medical condition, except perhaps in those with an allergy to latex. The main disadvantage is the fact that they do rely on the user (many women who report unplanned pregnancies were using barrier methods for contraception but they or their partners forgot to use them at times). Women who use barriers and natural family planning methods should be specifically educated about the availability of emergency contraception in the event of misuse, nonuse, condom breakage or spillages.

Male condoms

Male condoms are the most common method of contraception used by couples in Australia after the pill.[8] A clear advantage of this method is their ready availability. Use of condoms does not require a visit to a doctor and condoms can be purchased in pharmacies, supermarkets and even service stations. Another particular advantage is their protective capacity because they decrease the risk of transmission of most STIs. They can therefore be promoted for use with other contraceptive methods such as the pill (so called 'double Dutch').

Male condoms are usually made from latex, but there is an alternative polyurethane condom for men (and women) who are allergic to latex. These can be purchased from pharmacies or Family Planning Clinics.

Female condoms

Female condoms are made from polyurethane and are inserted into the vagina. They have not been very popular around the world, but they are an important option as a method that is female controlled. Some of the problems with female condoms are the noise, cost and unappealing look. A new, less expensive and more user-friendly female condom has recently been developed and approved by the Federal Drug Administration in the USA. However, it is not yet available in Australia.

Diaphragms

The diaphragm is a saucer-shaped device made of latex (or silicon) that is inserted into the vagina to cover the cervix. It prevents seminal fluid from reaching the cervix and ascending into the fallopian tubes to fertilise an ovum. The sperm die in the acidic vaginal environment. A diaphragm is sometimes used as an adjunct to natural family planning methods to increase their efficacy. The efficacy of diaphragms alone with typical use is 84%, which is lower than that of most other methods of contraception, making it a less suitable choice for women in whom an unplanned pregnancy would be unacceptable.

Diaphragms are available in a variety of sizes and are fitted by a doctor or nurse to ensure that the size is correct for the individual woman. Women are taught how to insert and remove the device to ensure that it is correctly placed prior to intercourse.

Spermicides may be used in conjunction with the diaphragm; however, there is no clear evidence for increased efficacy and some women find the use of spermicide aesthetically unappealing. Additionally, commercial availability of spermicide is now a problem in Australia. A recent Cochrane review comparing the effectiveness, safety and acceptability of the diaphragm with and without spermicide failed to find any studies suitable for inclusion and stated that further research is needed.[9] The authors of this study concluded that there is no evidence to change the commonly recommended practice of using the diaphragm with spermicide. The WHO makes the following statement: 'limited evidence suggests that the contraceptive effectiveness of the diaphragm and cervical cap may be moderately more effective when used with a spermicide than without'.[10]

Other barriers

Cervical caps are no longer available in Australia but are similar to diaphragms in the way they are used and their effectiveness. Vaginal sponges impregnated with spermicide are less effective than other barriers and are not available or recommended in Australia. Use of spermicide alone has a very high failure rate even with perfect use and is not recommended as a contraceptive method.

Natural family planning methods

The natural family planning (NFP) method uses the concept of fertility awareness to identify the days that a woman is potentially able to conceive. The goal is to avoid having intercourse on the days that conception could occur.

There are a number of NFP methods available and these generally involve either counting and calculating the unsafe days of the month or using physical signs of ovulation to decide when a woman is fertile and then avoiding intercourse on those days. The WHO defines the days of potential fertility for a couple during each woman's menstrual cycle as the time from the first act of intercourse that may lead to pregnancy to the demise of the ovum.

It is difficult to be specific about efficacy with the various NFP methods; however, it is about 94% with perfect use and 84% with typical use.[4] These NFP methods are generally more effective the longer they are practiced and the stronger the motivation is to avoid further pregnancies.

The use of NFP methods requires that a couple be diligent and committed as they generally reduce spontaneity and may require long periods of abstinence. It can take six to 12 cycles to accurately identify fertile days of a woman's cycle. Women with irregular periods could have difficulty in predicting fertile times (see the box on this page).[11]

An example of a natural family planning method: the calendar or rhythm method[11]

The calendar or rhythm method calculates fertile days using the dates of a woman's previous months' cycles. This method, as described below, is best used after charting at least six cycle lengths.

- The first day of a menstrual period is counted as day one of a cycle.
- Cycle length is measured from the start of one period to the day before the start of the next.
- After reviewing six cycle lengths, the woman should select the shortest and longest cycles.
- She should then subtract 21 from the shortest cycle, and 10 from the longest cycle.
- For example, the calculations for a woman whose cycle varies between 26 to 30 days are: 26 – 21 = 5; and 30 – 10 = 20. Therefore, her fertile days are between days 5 and 20, and she should not have unprotected sex on these days if she wishes to avoid pregnancy.
- For women with regular 28-day cycles, their fertile days are days 7 to 18 (i.e. 28 – 21 = 7; and 28 – 10 = 18).

Couples who wish to use fertility awareness methods should be encouraged to seek advice from an expert educator in this field who can not only explain the method but can also coach couples to develop competence and confidence in their interpretation of the important physical signs and symptoms of ovulation. Instructors at NFP organisations teach the method. For more information, contact the NFP Program (phone 1800 807 769 or www.nfpprog.com/contact_us.htm).

There are a number of websites providing access to computerised devices that can be used to predict a woman's fertility. One such fertility monitor claims that by entering data such as temperature and timing of the menstrual cycle into a small personal computer, a prediction can be made about a woman's potential fertility over the next 24 hours. Claims are made that an efficacy rating of 99% can be achieved. There is, however, no good evidence in the current literature of the numbers of pregnancies occurring with the use of these devices.

These NFP methods can also be readily used to determine when a woman can get pregnant because they pinpoint her fertile time each cycle.

Contraception – what's ahead?

There are constant changes and developments in the contraceptive field. One area of research is on changing the use of the oral contraceptive pill to have fewer or no pill-free days (research is being carried out into a new pill that has two pill-free days and contains a natural form of oestrogen). There is an existing 365-day pill already marketed in the USA. There are also smaller IUDs (both copper and hormonal) being marketed or trialled, which may suit some women who have a uterine cavity size too small for conventional IUDs. The progestogen-releasing IUDs are likely to be increasingly used to provide the progestogen component of combined hormone replacement therapy for postmenopausal women.

Research also continues on male hormonal methods. Although trials using combinations of long-acting testosterone and progestogens for men have shown successful suppression of spermatogenesis, contraceptive acceptability and efficacy, it is unlikely that a male hormonal product will be developed and marketed in the foreseeable future. MT

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COMPETING INTERESTS: Dr Harvey has provided expert opinion for Bayer and Schering Plough as part of her employment with Family Planning Queensland. She has received support for conference attendance from Schering Plough.
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.