



CLINICAL PRACTICE GUIDELINE

Contraception

This document should be read in conjunction with this <u>Disclaimer</u>

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Introduction and general principles

Despite availability of several options for contraception, unintended pregnancy in Australia is a public health concern. Unintended pregnancy can be associated with serious social, psychological and physical consequences for women, children and families.

Several studies looking into unplanned pregnancies have highlighted risk factors such as lack of knowledge about contraception, contraceptive misuse or failure¹, lack of awareness regarding superior efficacy and benefits of long acting reversible contraception (LARC), poor accessibility², anxiety about negative side effects of contraception and cultural norms and experiences of sexual coercion affecting the choices of contraception.

Studies also showed that decisions around contraceptive choices were influenced by family; information sources such as friends, internet and school; and interactions with GPs. In a clinical setting, it is important to provide information regarding a wide range of safe contraceptive methods, respect individual privacy and confidentiality and help women make an informed choice. This will increase patient satisfaction and their continued use of contraception.

Choosing a contraceptive method requires consideration of factors such as user characteristics and preferences, medical eligibility for a contraceptive method, the adverse effects, cost and availability of different contraceptive options.

The following information should be provided about each contraceptive method:

- relative effectiveness
- correct usage
- mechanism of action
- common side-effects
- health risks and benefits
- signs and symptoms that would necessitate a return to the clinic
- time to return to fertility after discontinuation
- · sexually transmitted infection (STI) protection

In a multicultural society like Australia, information should be presented using language and formats that can be easily understood by the patient.

Patients seeking contraceptive advice should be reminded of the importance of condom use for preventing the transmission of HIV/STIs and such use should be encouraged.³

Informed choice

For information regarding informed choice, care and consent- see also:

RANZCOG C-Gen 2A: Consent and Provision of Information to Patients in

Australia Regarding Proposed Treatment (2020) (external website, PDF, 216KB)

Department of Health WA Consent to Treatment Policy (2016) (PDF, 1.51MB)

Exclude pregnancy

Before commencing on contraception, it is important to rule out pregnancy.

The provider should be reasonably certain that the woman is not pregnant if she has no symptoms or signs of pregnancy and meets any of the following criteria.

- No intercourse since last normal menses
- Correctly and consistently using a reliable method of contraception
- Within the first 7 days after normal menses
- Within 4 weeks postpartum (for non-lactating women)
- Within the first 7 days post-abortion or miscarriage
- Fully or nearly fully breastfeeding, amenorrhoeic, and less than six months postpartum

Medical eligibility criteria

The Medical Eligibility Criteria (MEC) for Contraceptive Use offers evidence-based recommendations on various contraceptive methods that could be used safely by individuals with certain health conditions or characteristics to prevent an unintended pregnancy. The World Health Organization (WHO) published 5th Edition of MEC in 2015 and the UK Faculty of Sexual and Reproductive Healthcare (FSRH) modified them in 2017 and reviewed in 2019 to suit a developed country.

- The guidance does not indicate a best method for a woman nor do they take into account efficacy of the method.
- The category (UKMEC 1 to 4) for each condition is given for each method of contraception.

UKMEC definitions⁴

UKMEC	Definition	
Category 1	A condition for which there is no restriction for the use of the 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. The provision of a method requires expert clinical judgement and/or referral to a specialist contraceptive provider, since use of the method is not usually recommended unless	

UKMEC	Definition	
	other more appropriate methods are not available or not acceptable	
Category 4	A condition which represents an unacceptable health risk if the method is used	

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- Categories cannot be added together to indicate whether a method is safe or unsafe in a given patient. For an example, if a woman has two conditions that are each UKMEC 2 for use of combined hormonal contraception (CHC), these should not be added to make a UKMEC 4, thereby excluding that option.⁴
- Use of a particular contraception may worsen a preexisting medical condition with increased health risk or a medical condition and it's treatment may reduce the efficacy of contraception.
- When an individual has multiple conditions all scoring UKMEC 3 for a method, use of this method may pose an unacceptable risk; clinical judgement should be used in each individual case⁴.
- For patients with complex medical issues, liaising with relevant specialist and multidisciplinary management needs to be considered.
- Occasionally the initiation and continuation of a contraceptive method can be distinguished and classified differently. Development of a new medical condition while using a particular contraceptive method, will influence the continuation of the method in that patient.⁴
- If a contraception is used for a non-contraceptive indication (e.g. management of heavy menstrual bleeding) the risk/benefit profile and eligibility criteria may differ⁴
- The UKMEC criteria can be found at https://www.fsrh.org/ukmec/ (external website)
 (Note- if link not accessible, refer to local copy of the UKMEC Summary Table (Sept 2019))

Drug interactions with hormonal contraception

Drug interactions can potentially cause adverse effects. When providing hormonal contraception, ask women about their current and previous drug use including prescription, over-the-counter, herbal, recreational drugs, and dietary supplements. Advise women to use the most effective method for them; which may include the additional use of non-hormonal barrier methods when there is concern for potential drug interactions.⁴

For further information on drug interactions, please refer to: <u>FSRH CEU Guidance:</u> <u>Drug Interactions with Hormonal Contraception (2019)</u> (external website)

Conditions that may pose significant health risk during pregnancy⁴

Some conditions that pose a significant health risk with unintended pregnancy include but are not limited to:

- Autoimmune disorders: Rheumatoid arthritis, systemic lupus erythematosus (SLE), systemic sclerosis
- Bariatric surgery within the past 2 years
- Cancer: Breast, endometrial or ovarian cancer; malignant liver tumours (hepatocellular carcinoma)
- Cystic fibrosis
- Diabetes: insulin-dependent, or with nephropathy/retinopathy/neuropathy or other vascular disease
- Epilepsy
- Gestational trophoblastic neoplasia
- HIV-related diseases
- Hypertension (systolic >160 mmHg or diastolic >100 mmHg)
- Ischaemic heart disease, cardiomyopathy, complicated valvular heart disease
- Morbid obesity (BMI ≥40)
- Organ failure/transplant
- Severe (decompensated) cirrhosis
- Sickle cell disease
- Stroke
- · Thrombogenic conditions
- Tuberculosis
- Teratogenic drugs- Women using methotrexate, mycophenolate, some antiepileptic drugs, angiotensin converting enzyme (ACE) inhibitors, angiotensin II antagonists, isotretinoin, lithium, some cancer-fighting medications, some antithyroid medications, thalidomide, warfarin etc.
- Women undergoing endometrial ablation need to use effective contraception.

Women with those conditions should be advised to consider using the most effective LARC methods (hormonal or non-hormonal), which provide a highly reliable and effective method of contraception (failure rate <1 pregnancy per 100 women in a year). Use of barrier methods and methods that are user-dependent (e.g. oral contraception) may not be the most appropriate choice for these women due to their relatively higher failure rates.

Barrier methods

Patients requesting a barrier method should be informed of the efficacy of this method, including the higher failure rate relative to other methods such as LARC. Information should be provided on correct use, factors affecting efficacy, and emergency contraception (EC) in case of slippage or breakage of barrier method.

Types of barrier methods include:

- Male condoms
- · Female condoms
- Diaphragms

For additional information, see also:

- Patient information sheets: Sexual Health Quarters (SHQ): <u>Condoms for Safer Sex</u> (external website); <u>Diaphragms</u> (external website)
- FSRH guideline: <u>Barrier Methods for Contraception and STI prevention</u> (external website)

Male condoms

Efficacy

If used perfectly, condoms are 98% effective in preventing pregnancy^{5, 6}, however, typical use (which includes inconsistent and incorrect use) the efficacy reduces to 82%.⁶

Contraindications

Whilst there are no absolute contraindications, latex allergy is the only relatively strong contraindication for latex male condom use.⁶

Considerations: When making a decision, also consider:

- The requirement for consistent and correct use (as typical use failure rate is high)⁶
- Patients who are unable to obtain a consistent supply of condoms

Education and instructions for use

Instructions and written information regarding the correct use of condoms is available from:

- SHQ: Condoms for Safer Sex (external website)
- Government of Western Australia Department of Health website- Contraception

Instructions and information regarding condom use includes:

- a new condom should be used for each act of sexual intercourse⁶
- checking the expiry date, and that the packet is intact, prior to use⁶
- storage of condoms should be away from heat and sunlight⁶
- the packet should be opened carefully to avoid damage from nails, jewellery, or teeth⁶
- correct application and removal of condoms⁶
- the condom should be applied prior to any genital contact, and the condom removed prior to softening of the penis⁶
- dispose by wrapping in a tissue after checking the condom for visible damage⁶
- if additional lubrication is required a water or silicone-based lubricant should be used⁶
- when using latex condoms the use of oil-based lubricants should be avoided⁶ e.g. petroleum jelly, baby oil, and saliva as they increase the risk for condom breakage⁷
- A non-latex polyurethane condom is thinner and can be used with oil based lubrication, but overall, they have been associated with a higher breakage rate
- Newer condoms containing polyisopren should not be used with oil containing lubrication⁷
- Pregnancy rates are similar with latex and non- latex condoms⁷
- Spermicide-coated condoms increase the risk of *E. coli* urinary tract infections
 due to alterations in the normal vaginal flora. Vaginal irritation and superficial
 abrasions may increase the risk of HIV transmission and therefore
 spermicide-coated condoms are no longer recommended.
- The use of lubricant is recommended for anal sex to reduce the risk of condom breakage⁷
- Adding lubrication inside condom or on penis before using condom is associated with increased risk of slippage⁷
- Inform patients that latex condoms provide protection against many STIs, however
 they are less effective in preventing STIs that are transmitted by skin-to-skin
 contact (e.g. herpes and HPV), than STIs transmitted through bodily fluids, as they
 do not cover all infected skin area. The amount of protection offered from each
 specific STI has not been quantified.⁸

Management of condom method failure

Inform patients of the availability of EC if breakage, spillage or misuse.⁶ Refer to section: Emergency Contraception

Female condoms

The female condom is a loose-fitting polyurethane sheath with a flexible ring at each end. The inner ring is firm and slides behind the pubic bone anchoring it in place, and the soft outer ring spreads over the vulva.⁶

Efficacy

- If used perfectly it has a 95% success rate, whilst typical use produces a 79% success rate.⁶
- Due to high failure rates with typical use, an alternative form of contraception should be considered if a woman has a medical condition requiring a highly effective form of protection against pregnancy.^{4, 6} See also section 'Conditions That May Pose a Significant Health Risk During Pregnancy'.

Contraindications

There are no contraindications⁶, however considerations include:

- avoiding use if the woman is unable to obtain or correctly use female condoms⁶
- avoid recommending this form of contraception in cases of abnormal vaginal anatomy that may interfere with a satisfactory fit or stable placement of female condom e.g. genital prolapse, immediate postpartum period

Side-effects

- May cause skin irritations or allergic reactions⁶
- May cause clicking noise/ slippage during use

Education and instructions for use

Instructions and written information about the female condom, correct usage, and application is available from:

- Government of Western Australia Department of Health website- Contraception
- SHQ (external website)

Instructions regarding use of the female condom:

- Advantages of use hypoallergenic, can be used in latex sensitive patients, polyurethane transfers heat & provides more sensitivity and is less likely to result in breakages compared to the male condom, requires no special storage requirement, can be inserted discreetly several hours before intercourse, protection from STI's.
- A new condom should be used for each sexual act
- Polyurethane is not damaged by lubricating oils. Additional water or oil-based lubricants may be used.⁶

- It does not require an erect penis for insertion. ⁶ Male partners may find it
 more comfortable and less constricting than male condoms.
- The internal and external rings may make sex more enjoyable for the male or both partners by increasing stimulation
- The female condom should not be used simultaneously with the male condom as it may lead to dislodgement of both condoms
- Check the expiry date prior to use⁶
- It is more expensive and less widely available than male condoms. Availability from pharmacies is variable. Contact <u>SHQ</u> (external website) for details.⁶

Management of condom method failure

Inform patients of the availability of EC if breakage or displaced.⁶ Refer to section: Emergency Contraception.

Diaphragms

Diaphragms are available through some pharmacies and through SHQ. This is the 'one-size-fits-most' Caya diaphragm, a thin lilac-coloured silicone dome.

If used perfectly, results in 94% efficacy. Typical use results in 82-86% effective contraception.

Contra-indications⁶

There are no absolute contraindications. History of toxic shock syndrome is the only relatively strong contraindication.

However, diaphragms are not recommended for women:

- who have a medical condition where the health risk associated with pregnancy is high. Consider 'Conditions That May Pose a Significant Health Risk During Pregnancy'.
- with a vaginal or anatomical abnormality that interferes with correct placement or fit e.g. prolapsed uterus, poor vaginal tone, vaginal obstruction, or a shallow retropubic ridge
- who have an inability to correctly fit the diaphragm or feel the cervix
- with a history of recurrent urinary tract infections
- who have birthed within the past six weeks⁶

Education and instructions for use⁶

It is recommended that the health professional instructs the woman on insertion techniques, checking of the correct position, and removal of the diaphragm..⁶

- The use of diaphragms may increase the risk for urinary tract infections (UTI)
- Does not offer protection from STIs.
- If the diaphragm is uncomfortable or if a woman develops signs of a UTI she should return to the medical practitioner for review.
- Diaphragms are a less effective contraceptive than other methods available.
- A diaphragm can be inserted many hours prior to sex, however should be left in place for a minimum of 6 hours after vaginal intercourse.
- The diaphragm should not be left in place longer than 24 hours without being removed for cleaning.
- Avoid the use during menstruation; however if used, the diaphragm should be removed as soon as practical after the 6 hours minimum time after intercourse.
- Rinse the diaphragm clean in warm water with mild unperfumed soap and store away from direct heat.
- The usual lifespan of a diaphragm is up to 2 years, but it should be checked regularly for signs of damage or deterioration.⁶

Instructions and written information regarding the use of and application of diaphragms are available from:

- SHQ (external website)
- Government of Western Australia Department of Health- <u>Contraception</u> <u>Diaphragms</u>
- More information on www.caya.eu/en/

Spermicide

- Spermicide is not available in Australia and is not recommended as a contraceptive⁶
- Most spermicides available online (e.g. Gynol 2) contain nonoxinol-9 (N-9). N-9 is a surfactant that acts to disrupt cell membranes. Repeated and high-dose use of N-9 is linked to increased risk of genital ulcers, which may thereby increase the risk of HIV acquisition.⁷

Management of method failure

 EC is available if diaphragm displacement occurs during intercourse, or the diaphragm is torn.⁶ Refer to section: <u>Emergency Contraception</u>

Long acting reversible contraceptive (LARC)

Background

It is estimated that up to 50% of Australian women experience an unintended pregnancy^{9, 10}. These women may face options like forced parenthood with partner or alone, abortion, or foster parenting and adoption. Unintended childbearing particularly in young mothers is associated with increased risk of maternal depression, anxiety and a decline in psychological well-being¹¹ or psychosocial conditions.^{12, 13}

Long acting reversible contraceptive (LARC) may have the potential to reduce unintended pregnancy and abortion rates.¹⁴ However, despite LARC's proven effectiveness, the use of oral contraception¹³ and permanent contraception in Australia are higher than in other developed countries. LARC is the least used method, with only 5% of women choosing an implant, and 5% using IUDs¹³.

LARC should be recommended as a first line method. RANZCOG recommends health professionals update their knowledge of LARC methods and when discussing contraception, to discuss the risks and benefits of LARCs with women of all ages and parity. A recent study in Victoria showed that using a combination of clinician training on contraceptive effectiveness counselling and women having fast access to clinics where LARC insertion may be performed, resulted in increased LARC uptake, which has the potential to reduce unintended pregnancies. ¹⁵

What is LARC?

Long acting reversible contraception- 'Fit and forget' contraception. LARC is defined as a contraceptive method that requires administration less than once a month.⁶
LARC includes the: hormonal or copper-bearing intrauterine device (IUD), hormonal contraceptive implant and depot medroxyprogesterone (DMPA) injection.⁶

Note- Although DMPA needs 3 monthly injections, and it is included in LARC, it is not a first choice LARC⁶ due to unpredictable return to fertility and concerns about loss of bone density if used over 2 years especially in young women <25 years and postmenopausal women.

Advantages:

LARC uptake results in high continuation rates as well as high levels of effectiveness, with less than one pregnancy occurring in every 100 women. This is compared with up to nine pregnancies for every 100 women using the combined oral contraceptive pill (COCP). ⁶

- The hormonal IUD provides up to five years effective contraception, the copper-bearing IUD up to ten years and the implant up to three years.⁶
- With the exception of the copper-bearing IUD, LARC is subsidised through the Pharmaceutical Benefits Scheme (PBS).

- The implant and both types of IUD can be highly cost-effective⁶, even within the first one to two years of use, compared to other contraceptive methods.
- LARC is not associated with any ongoing costs and does not require frequent visits to a General Practitioner (GP) or family planning clinic following insertion.
- In addition to their contraceptive action, LARC can have additional benefits.
 For example, the hormonal IUD may improve quality of life for many women by reducing heavy menstrual bleeding and menstrual pain.⁶
- LARC is more reliable and effective (failure rate <1 pregnancy per 100 women in a year) than barrier contraception, and has a place in patients with Conditions that may Pose a Significant Health Risk during Pregnancy'. The sole use of barrier methods and user-dependent methods of contraception (e.g. oral contraception) may not be the most appropriate choice for these women given their relatively higher typical-use failure rates.⁴

Australian and international evidence shows that:

- LARC can be offered as a first-line contraceptive option for most women, including young women¹⁶
- IUDs can be inserted without difficulty in a primary care setting, including for young women and those who have not had a pregnancy
- It is safe to insert an implant or an IUD immediately after childbirth, including after a caesarean section and after a miscarriage or abortion, to reduce the risk of rapid repeat pregnancy
- The majority of women have acceptable bleeding patterns when using a contraceptive implant (e.g. Implanon NXT®)

Additional resources relating to LARC

- Department of Health WA <u>Procedure Specific Information Sheets</u> (available to WA Health employees through Healthpoint and EIDO Healthcare Australia).
 See NMHS- KEMH- Procedure information- Gynaecology:
 - 'Inserting a Contraceptive Implant (OG33)'
 - 'Inserting an IUCD (OG27)'
 - 'Inserting an IUS (OG34)'
- SHQ <u>Reducing Unintended Pregnancy for Australian Women Through Increased</u> <u>Access to LARCs- Consensus Statement</u> (external website, PDF, 655 KB)
- SHQ Patient information sheets (external websites):
 - Intrauterine Devices- Hormonal
 - Intrauterine Devices- Copper
 - Contraceptive Implant
 - Contraceptive Injection

- RANZCOG (external websites):
 - Depot Medroxyprogesterone Acetate (C-Gyn 04) (PDF, 270KB)
 - Intrauterine Contraception (C-Gyn 03) (PDF, 415KB) (under review)
 - Long Acting Reversible Contraception (C-Gyn 34) (PDF, 281KB) (under review)
 - > Patient information summary sheet: Contraception
- FSRH guidelines (external websites):
 - > Intrauterine Contraception
 - Progestogen-only Implant
 - Progestogen-only Injectable

Intrauterine devices / systems (IUD/IUS)

Intrauterine devices are LARCs with duration of action ranging from 5 to 10 years. They are most effective contraceptive options with failure rates less than 1 in 100 and are very cost effective with high patient satisfaction and continuation rates with minimal follow up required after insertion.

There are two main types of IUD available-

- Copper bearing (non-hormonal) (Cu-IUD). Several types are available:
 - > TT380 regular- effective for 10 years
 - > TT380 short- effective for 5 years
 - Copper multi load 375 effective for 5 years
 - Monalisa Cu 375 –effective for 5 years
 - Monalisa Cu 375 SL- effective for 5 years
- Hormonal levonorgestrel (LNG) IUD / IUS-
 - Mirena- effective for 5 years
 - Kyleena- effective for 5 years

Notes

- LNG-IUD -Mirena and Kyleena are subsidised through the Pharmaceutical Benefits Scheme (PBS)
- LNG IUD- Mirena is associated with reduced menstrual blood loss, reduced primary dysmenorrhoea and reduced pain associated with endometriosis and adenomyosis
- Use of Cu-IUD may be associated with reduced risk of endometrial and cervical cancer¹⁷
- There is no delay in return to fertility after removal of IUD

- In breastfeeding women, IUD can be inserted 6 weeks after delivery (if no contraindications) with no adverse effects on breastfeeding or infant
- A new hormonal IUD –Kyleena is available in Australia. It has a smaller frame, narrower insertion device, better visibility on ultrasound and a lower dose of LNG. It is an effective contraception for 5 years; however it is not advised for treatment of heavy menstrual bleeding or endometrial protection.
 - For more details of Kyleena and comparison between Mirena and Kyleena, see <u>FSRH New Product Review: Kyleena® 19.5 mg Intrauterine Delivery System</u> (2019) (external website)
- RANZCOG have advised on the management of women requesting IUD as contraception, see <u>Intrauterine Contraception</u> (C-Gyn 3) (external website)

Key points

- Patient suitability should be assessed prior to IUD insertion. The criteria can be found at FSRH: <u>UKMEC UK Medical Eligibility Criteria for Contraceptive</u> <u>Use</u> (external website).
 - These evidence-based guidelines provide guidance to contraception providers on safety of use of contraceptive methods in patients with specific health conditions. It is important to note that these criteria address the safety of initiation and continuation of a contraceptive method, not the most effective or most suitable method in a given patient.
- 2. Prior to insertion of an IUD/system all contraindications should be excluded.

Contraindications

For contraindications- refer to <u>UKMEC Summary Table</u> sheets (external website). (Note- if link not accessible, refer to <u>local copy of the UKMEC Summary Table (Sept 2019)</u>)

Insertion of Cu-IUD⁶

SITUATION	INSERTION OF Cu-IUD	EFFECT
No contraception or barriers	Day 1 (first day of bleeding) to day 12 of a normal menstrual cycle, or any time if pregnancy is excluded	
COCP or vaginal ring	Anytime if pills or ring have been used correctly, otherwise exclude pregnancy	
DMPA	Anytime within 14 weeks of the injection	
ENG implant	Anytime if within 3 years of insertion, if no medication interactions. Otherwise pregnancy should be excluded.	
POP	Anytime if the pills have been correctly taken. Otherwise pregnancy should be excluded	
Cu-IUD or LNG IUD	Consideration to be given to using condoms for 7 days prior to changeover (in case of failed reinsertion)	Immediate
Surgical abortion	Immediately (at time of abortion) ¹⁸ or anytime if pregnancy excluded	
Medical abortion	After complete expulsion of products of conception. If >5 days post abortion, exclude repeat pregnancy.	
Post-partum (includes	< 48 hours post-birth, or after 4 weeks if pregnancy can be excluded	
stillbirths)	Whilst insertion <48 hours is safe, insertion between 10 min and 48 hours after delivery is associated with higher rates of expulsion than insertion 4-6 weeks postpartum. ^{4, 6}	

Insertion of a LNG IUD (e.g. Mirena®, Kyleena) device/ system⁶

SITUATION	INSERTION OF A LNG-IUD	EFFECTIVE
Normal cycle	Day 1 - 7 of normal menstrual cycle.	Immediately
	Any other time if pregnancy is excluded.	7 days
Combined pill or	Anytime if the pills or ring have been used correctly.	Depends on
vaginal ring	Continue pill or vaginal ring after insertion until there	where she is in
DMDA	have been 7 consecutive days of hormone.	the pill pack.
DMPA	Anytime within 14 weeks of injection	Immediately
ENG Implant (ImplanonNXT®)	Anytime within 3 years of insertion, or otherwise exclude pregnancy.	7 days
Progestogen	Anytime if the pills have been correctly taken.	7 days, or
only pill (POP)	Otherwise pregnancy should be excluded.	continue POP
		for 7 more
		days
Abortion 1 st	Immediately (at time of abortion).	Immediate
trimester	Anytime if pregnancy can be excluded	7 days
Abortion 2 nd	Immediately (<48hrs) after abortion.	Immediately.
trimester	Four weeks if pregnancy can be excluded.	7 days
Post-partum	Immediately (< 48 hours post-birth), or after 4 weeks postpartum if pregnancy can be excluded.	7 days
	Whilst insertion <48 hours is safe, insertion between 10	
	min and 48 hours after delivery is associated with higher	
	rates of expulsion than insertion 4-6 weeks postpartum. ^{4,}	
Cu-IUD	Day 1 (first day of bleeding) - 7 of the menstrual cycle.	Immediate
	Other times: Use a condom for 7 days prior to	7 days
	changeover of IUD in case reinsertion fails.	
LNG IUD	Use condoms for 7 days prior to changeover in case reinsertion fails	Immediate

Special circumstances:

- Women who are deemed at increased risk of STI, should be encouraged to use barrier contraception in addition to IUD
- In women >40 years, Cu-IUD of >300mm can be considered to remain in situ as a contraception until 12 months after final menstrual period

- A Mirena® inserted for menorrhagia or contraception after the age of 45
 years, may be retained up to the age of 55 years, or until post-menopausal if
 she is amenorrhoeic
- Use of 2% lignocaine gel or 10% lignocaine spray with long instillation syringe may reduce the pain at the time of insertion.
- In women with history of fainting / vasovagal reaction to cervical instruments, consider sedation in hospital setting.
- Patients on anticoagulants Liaise with haematologist regarding indication of anticoagulation, recent INR and dosage of medication. Consider IUD insertion in hospital setting by an experienced personnel if INR is over 3.5
- Cardiovascular history- Insertion may be arranged in hospital setting with anaesthetists in presence. Discussion with a cardiologist regarding antibiotic prophylaxis is recommended for women with congenital or valvular heart disease.
- Cervical Screening Test (CST) if due. See KEMH Clinical Guidelines,
 Obstetrics & Gynaecology (O&G), <u>Vaginal Procedures</u>: Cervical Screening
- See also: KEMH Clinical Guidelines, O&G, <u>Vaginal Procedures</u>: Swabs: LVS, HVS, ECS & Rectal; and <u>Sexually Transmitted Infections</u>: Screening Tests for Asymptomatic and Symptomatic Females; Vaginal Discharge.

Procedure: Insertion of IUD

All women should have screening for STI prior to IUD insertion.

If there are signs and symptoms suggestive of PID, including fever, lower abdominal pain, presence of smelly mucopurulent discharge from cervix, adnexal tenderness etc., insertion of IUD should be postponed. Swabs should be taken for diagnosis and the patient to be managed as per Australian STI management guidelines/PID guidelines.

See:

- KEMH Clinical Guidelines, O&G:
 - Gynaecology (Non-oncological): Acute PID
 - Sexually Transmitted Infections
- Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM):
 STI Management Guidelines for use in Primary Care (external website)

In asymptomatic patients, IUD insertion is not delayed awaiting STI screening results, however, patient needs to be informed that she will need to complete a course of antibiotics if an infection was detected.

Equipment

- IUD pack containing tenaculum or vulsellum forceps and uterine sound
- Sterile speculum, sterile gloves
- lodine (check for allergies) or Chlorhexidine

- Pair of long scissors for trimming IUD threads
- Sterile packs of gauze or cottonwool x2
- Local anaesthetic gel or spray with separate sterile instillation nozzle as required

	PROCEDURE	ADDITIONAL INFORMATION
1	Pre insertion	
1.1	Provide counselling about:	
	 contraceptive device and action 	
	 possible complications 	
	 insertion procedure 	
	• side effects	
	 duration of contraception 	
	 signs of infection 	
1.2	Obtain written consent on the Generic Consent form prior to insertion.	Consent for IUD insertion is required at KEMH
1.3	Perform and record a blood pressure (BP) and pulse rate measurement.	A blood pressure measurement prior to insertion will provide a baseline reading in case of hypotension associated with a vaso-vagal response during insertion.
2	Insertion	Insertion should only be attempted after specific training has been undertaken and at least the first 5 insertions should be mentored by colleagues skilled in the procedure
2.1	Another staff member should be available to assist, communicate with the woman during the procedure, and for assistance if a vasovagal reaction occurs.	
2.2	Ask the woman to adopt the dorsal position.	
2.3	Confirm the position and size of the uterus by bimanual examination. Take endocervical swabs once cervix is visualised.	After successful sounding of uterine cavity, open IUD package just before insertion.
2.4	Insert the IUD as per training programme and manufacturer's instructions.	A no-touch technique should be used during insertion

	PROCEDURE	ADDITIONAL INFORMATION
2.5	Perform post-procedure pulse and blood	Delayed vasovagal response may occur.
	pressure. Observe the woman in the clinic for 15-20 minutes	Inform her not to drive a vehicle for 1-2 hours.

3 Education

Inform the woman to seek medical assistance in the following circumstances-

- excessive pain, discharge or bleeding
- unexplained fever, dyspareunia
- suspicion of pregnancy
- persistent menstrual abnormalities
- Non-palpable string, change in string length or palpable plastic stem.

4 Documentation

- 4.1 Place the label found on the IUD packaging into the woman's hospital medical records (or transcribe the batch number and expiry date).
- 4.2 Document the insertion information in the woman's hospital medical records. Provide a card to the patient and a letter to her GP with details of type of device, date of insertion and any complications with insertion.

Include – last menstrual period and pregnancy risk assessment, position of the uterus, length of the uterine cavity on sounding, degree of difficulty, type of device, length to which the strings were cut, batch number, and expiry date.

Post procedure management

- 1. Provide the woman with an information pamphlet about the contraceptive device. This is available in pamphlets supplied by the manufacturing company to KEMH, or an information sheet is available from SHQ (external website)
- 2. Discuss the symptoms of pelvic infection especially in first month and inform the woman to arrange GP review if any symptoms present.
- 3. Advise the woman to check the IUD strings after first menstruation or

- 4. Advise the woman to see her GP in three months following IUD insertion to check the strings and discuss effects on menstrual cycles and any other symptoms.
- 5. Inform the woman to use condoms in addition to the IUD if she is at risk for STIs.⁶

Management of menstrual abnormalities for Cu-IUD users

Spotting, heavier or longer menstrual bleeding is common in over 40% users of Cu-IUD

- The following treatment may be offered for the days of menstrual bleeding:
 - > NSAIDs
 - > tranexamic acid (a haemostatic agent) 6
- Aspirin should NOT be used
- Gynaecologic problems should be excluded when clinically warranted. If a gynaecological problem is identified, treat the condition or refer the woman for care
- If the bleeding continues to be very heavy or prolonged, especially if there are clinical signs of anaemia, or if the woman finds the bleeding unacceptable, remove the IUD and help her choose another method.
- To prevent anaemia, provide an iron supplement and/or encourage her to eat foods containing iron.

Management of menstrual abnormalities for LNG-IUD users

Spotting or light bleeding is common with LNG-IUD-Mirena use especially in first 3 -6 months. It is not harmful and usually decreases over time. Amenorrhoea may develop in 17-19% first time users at the end of first year of use, it is reported in 38.4% in prior LNG-IUD users.

- In women with persistent spotting and bleeding, gynaecologic problems should be excluded when clinically warranted. If a gynaecologic problem is identified, treat the condition or refer the woman for care.
- Options include up to 3 months of the COCP once other causes have been excluded, and if not contraindicated.

Additional resources

Information can be found at FSRH:

- <u>Intrauterine Contraception (2019)</u> (external website)
- New Product- Kyleena Intrauterine Delivery System (2019) (external website)

Subdermal contraceptive implant: Etonogestrel Implanon NXT®

Key points

- 1. ImplanonNXT[®] is a progestogen only implant that is a highly effective LARC⁶
- 2. Medical practitioners must attend a training course before inserting ImplanonNXT®6
- 3. Pregnancy should be excluded prior to insertion. Careful history taking and awareness of the limitations of pregnancy testing can reduce the risk of missing an implantation bleed or ectopic pregnancy.⁶
- 4. A single ImplanonNXT® rod provides effective contraception for 3 years.6
- 5. Women with a BMI > 30 kg/m² can use a progestogen-only implant without restriction¹⁹, and while product information suggests heavier women may be at increased risk of failure in the third year of use, evidence does not support this view, and therefore a recommendation for earlier replacement is not required.⁶ No increased pregnancy risk in women <149kg has been shown, however the risk of reduced efficacy cannot be excluded.¹⁹
- 6. Women should be advised an ImplanonNXT[®] implant results in changes of menstrual patterns for all users, ranging from amenorrhoea to frequent and/or prolonged bleeding.⁶ Around 20% of users will experience amenorrhoea, while around half of users will have infrequent, frequent, or prolonged bleeding.⁶ For many women, bleeding patterns in the first 3 months of use are generally predictive of future bleeding.¹⁹
- 7. Women should be informed there is no delay in return of (pre-existing) fertility following removal of the ENG implant.²⁰
- 8. The ENG implant can be safely used in women who are breastfeeding. 6, 20

Background

Implanon NXT[®] is a single-rod progestogen-only implant containing Etonogestrel (ENG) which is placed subdermally 8-10 cm above the medial epicondyle of the non-dominant upper arm to place it over triceps muscle.

It is an effective contraception for up to 3 years and prevents pregnancy by inhibiting ovulation, causing thickening of the cervical mucus to prevent sperm penetration, and altering the endometrium. ImplanonNXT® contains 68 mg of ENG^{6, 20} and is licensed for 3 years of use.

ImplanonNXT[®] provides an alternative form of contraception for women with medical conditions where oestrogen-containing contraception is contra-indicated, or when an oestrogen side-effect such as nausea or breast tenderness becomes problematic.⁶ Women with inflammatory bowel disease or other enteral malabsorption conditions may find this non-oral form of contraception a suitable option.⁶

Irregular vaginal bleeding in the first 3-6 months is observed in up to 16%. As this may be a reason women discontinue, <u>pre-insertion counselling</u> is essential.²¹ Many studies have shown high satisfaction and continuation rates up to 74%.²²

Efficacy

- Perfect & typical use results in >99.9% efficacy⁶
- Note- High efficacy due to user non dependence

Contraindications

For contraindications- refer to <u>UKMEC Summary Table</u> sheets (external website). (Note- if link not accessible, refer to <u>local copy of the UKMEC Summary Table (Sept 2019))</u>

Side-effects⁶

Possible side effects associated with ImplanonNXT® include:

- bleeding irregularities –The menstrual pattern may vary from amenorrhoea to frequent, irregular, unpredictable and/or prolonged bleeding
- local reaction to the insertion site, scarring
- weight gain; emotional lability; breast tenderness; acne
- deep insertion may lead to difficult removal later

Initiation of Implanon NXT® 6

SITUATION	STARTING IMPLANT	EFFECT
No contraception or barriers	Day 1 to 5 of menstrual cycle Any other time if pregnancy is excluded	Immediately 7 days
COCP or vaginal ring	Anytime if pills/ ring correctly used, otherwise exclude pregnancy Continue pill or vaginal ring after	Depends on where she is in pill pack. After 7 consecutive days
	insertion until there have been 7 consecutive days of hormone.	of combined pill or ring use with hormone.
DMPA injection	Any time if within 14 weeks of injection	Immediately
Progestogen only pills	Any time if pills have been taken correctly; otherwise exclude pregnancy	7 days
Cu-IUD	Day 1 to 5 of cycle	Immediately
	Other times – condoms for 7 days prior to IUD removal or leave IUD in place for 7 additional days	7 days
LNG IUD	Anytime before expiry of the device with condoms for 7 days prior to IUD removal	7 days

	Or leave IUD in place for 7 additional days	7 days
Abortion (surgical or medical) or	Up to & including day 5 post abortion	Immediately
miscarriage ≤24 weeks	>Day 5- consider repeat pregnancy	7 days
Post-partum (incl.	< 21 days postpartum – any time	Immediately
breastfeeding, stillbirth &	More than 21 days post-partum and no menses – exclude pregnancy	7 days
termination >24weeks)	Menstrual cycles resumed – as above for no contraception or barriers	See 'No contraception / barriers' above

Medical history and examination prior to insertion Medical history

The medical history should include:

- age- from commencement of menarche (unknown effects prior to menarche)⁶
- breast cancer⁶
- obstetric / sexual / menstrual history
 - last menstrual period (time, heaviness, usual pain/premenstrual symptoms and duration of menses) to exclude implantation bleeds or ectopic pregnancy;
 - history of unprotected sexual intercourse (UPSI) (a negative pregnancy test does not exclude recent conception if UPSI in past 3 weeks).
 - > pregnancy history- suitable immediately after birth, miscarriage, stillbirth⁶
 - ➤ lactation implants are considered safe in lactating women⁶
- cardiovascular risk factors⁶
- thromboembolic disease⁶
- keloid scarring insertion / removal may cause excessive scarring⁶
- liver disease ENG is metabolised in the liver⁶
- medications ENG implants may be less effective with liver enzyme-inducing medications (e.g. rifampicin; some anti-epileptics [phenytoin, carbamazepine, barbituates, primidone, topiramate, oxcarbazepine], some anti-retrovirals and St John's Wort) as they induce the liver to metabolise ENG faster.

Examination

- 1. Perform a blood pressure measurement.6
- 2. Assess the woman's weight and height to calculate the BMI⁶- see key point 5.

3. Assess for sexually transmitted infection (STI) & cervical screening as required.

Counselling prior to insertion ⁶

Prior to insertion, women should be counselled about:

- changes in menstrual patterns (unacceptable bleeding is the most common reason for implant removal)
- complications and side-effects (e.g. acne, local reaction/scarring, and some reports of headaches, loss of libido, mood changes, weight gain, breast tenderness)
- ImplanonNXT[®] information e.g. mechanism of action, duration of use, efficacy, advantages/disadvantages, insertion and removal details, lack of sexually transmitted infection (STI) protection, and return of fertility after removal.
- Provide written information available from <u>SHQ</u> (external website)
 (previously known as Sexual & Reproductive Health WA / Family Planning of Western Australia)

Follow-up

No routine follow-up is required. The woman can self-initiate review, as required, if there are no other indications (e.g. pregnancy test or impalpable implant) for early review.⁶ Advise the woman to return for review if¹⁹:

- she wants to discuss any problems or change contraception
- the implant is not palpable, has migrated or changed shape
- · skin changes or pain around the site
- she becomes pregnant or
- she develops any condition that contraindicates continuing with the implant.

On review:

- palpate the implant
- assess for side-effects
- check for new medical conditions or medications
- assess bleeding patterns
- assess for STI risks and opportunistic CST screening if due

Implanon NXT®- Insertion

This section must be read in conjunction with previous section: **Subdermal** implants- Etonogestrel ImplanonNXT® Implant. Medical and midwifery staff should be familiar with the contents of the previous section.

Key points

- 1. Medical practitioners must attend a training course and achieve competency prior to inserting ImplanonNXT[®]. ^{23 6}
- 2. Following insertion, the medical practitioner and the woman should both palpate the implant to confirm successful insertion.²³
- 3. Written consent must be obtained prior to insertion of ImplanonNXT[®].
- 4. Pregnancy should be excluded prior to insertion of ImplanonNXT[®].6
- 5. An aseptic technique is used for insertion of Implanon NXT[®].²³

Prior to insertion

- 1. Ensure there are no contra-indications to insertion of Implanon NXT^{® 6} as per section Subdermal implants- Etonogestrel ImplanonNXT® Implant.
- 2. The woman should be counselled about the product, side-effects, menstrual pattern changes, complications, insertion/removal procedures, and follow-up.6
- 3. Obtain written consent for the procedure on the generic consent form.
- 4. Perform and document the woman's blood pressure, and her height and weight to calculate the BMI.6
- 5. Exclude pregnancy. 6 This may require a pregnancy test. If there is any doubt, then a pregnancy test should be performed. Note: A negative pregnancy test does not exclude pregnancy if the woman has had unprotected sex in the last 3 weeks.
- 6. Ensure there are no allergies to the antiseptic solution or local anaesthetic.

Equipment

- Dressing pack
- 5 ml syringe & needles
 Pressure bandage
- Iodine / antiseptic
- Sterile gauze
- Local anaesthetic 1% Lignocaine 5mls

- Clear adhesive dressing
- ImplanonNXT[®]

Procedure

PROCEDURE

ADDITIONAL INFORMATION

1 Pre-procedure- Positioning

Position the woman on her back with her non-dominant arm flexed at the elbow and externally rotated so that her hand is positioned behind her head.²³

The practitioner should be seated for the entire procedure.²³ This ensures clear visualisation of the insertion site and needle from the side throughout.²³

Clinicians should have attended a specific training programme and ensure that the first 2-3 insertions and removals are mentored by an experienced colleague.

2 Procedure-Insertion

2.1 Identify the insertion site. The insertion site is over the triceps muscle about 8cm proximal to the medial epicondyle. No more than 3cm from the sulcus.

With a sterile marker, mark the insertion site and mark 5 cm proximal (as an insertion guide).²³

This subdermal position avoids the large blood vessels and nerves that lie deeper in the subcutaneous tissue of the sulcus (groove) between the biceps and triceps muscles.²³

Note: Most impalpable Implanons referred to KEMH for difficult removal have been placed under the muscle sheath and are either reinsertions and/or are in women with a very lean arm, so particular care should be taken with the insertion in these situations.

- 2.2 Clean the site with antiseptic solution.²³
- 2.3 Anaesthetise the insertion area.²³
- 2.4 Insert the ImplanonNXT® subdermally according to the manufacturer's instructions.
- 2.5 Palpate both ends of the implant after insertion to confirm the presence of the 4cm rod.²³
- 2.6 Cover the puncture site with a small clear adhesive dressing.²³ The woman should then be asked to palpate the rod.²³
- 2.7 Apply sterile gauze and a pressure bandage over the area.²³

E.g. Use 1% lignocaine or anaesthetic spray along planned insertion tunnel.²³ Prior to insertion ensure the implant is visible in the cannula.

If the implant is not palpable it may indicate the insertion was placed too deep or the implant was not inserted.²³ .

Instruct the woman how to palpate the ImplanonNXT[®], and ensure confirmation of its presence.²³

Minimises bruising.²³ Advise the woman to keep the bandage clean and dry for 24 hours and then the pressure bandage

PROCEDURE ADDITIONAL INFORMATION may be removed.23 The small bandage is removed after 3-5 days.²³ 3 Post procedure 3.1 Document procedure information in the An adhesive label is supplied by the woman's hospital records.23 manufacturer with the ImplanonNXT® packaging with a check-list. This is placed in the woman's hospital record.²³ 3.2 Provide the woman the supplied card This card is supplied by the manufacturer and document²³: in the packing with the ImplanonNXT® implant.23 • site of ImplanonNXT® insertion date of insertion date for removal by.²³ 3.3 Provide the woman the consumer information leaflet supplied by the manufacturer. 4 Post insertion counselling

Provide instructions about:

- medical practitioner review for any abnormalities of the insertion site. position of the implant, pain, concerns,⁶ becomes pregnant or develops a condition that contraindicates continuing with the implant. 19
- removal of the implant in 3 years (or earlier if the woman desires)²³
- attending the GP for review if the implant is not palpable.6

5 Follow-up

No routine follow-up is required. The woman can self-initiate review with her General Practitioner (GP) as required, if there are no other indications (e.g. pregnancy test or impalpable implant) for early review.6

On review, the GP checks for the implant position, presence of side-effects, change in menstrual pattern, or change in medical conditions or medications.

See also RACGP Implanon NXT: Expert tips for best-practice insertion and removal (external website)

Implanon NXT®- Removal (non-routine)

Background information

A non-palpable Implanon[®] or Implanon NXT[®] implant can result from incorrect insertion, migration, ²³ non-insertion or because the woman has had significant weight gain^{24, 25}. Significant migration of implants does not occur if correctly inserted, but frequently the device can be found approximately 2 cm away from the insertion site²⁶. Other reasons associated with difficult implant removal include the attempted removal by an inexperienced practitioner, scarring from previous unsuccessful attempts at removal, or due to a fibrous capsule around the implant²⁵.

Attempting to remove an implant which is impalpable can cause scarring, nerve and blood vessel damage. The original Implanon was not radio-opaque and could be visualised by ultrasound or magnetic resonance imaging (MRI)²⁴. However the new version (ImplanonNXT®) was released in mid-2011 and contains barium sulphate making the implant visible on X-ray and computerised tomography (CT) scan. ImplanonNXT® is available from the KEMH pharmacy and the old version is no longer available in Australia.

A X-ray of the site can confirm the presence of ImplanonNXT[®].²³ Localisation by ultrasound of the non-palpable ImplanonNXT[®] implant can be done²³ by an experienced sonographer. It is cheaper than CT/MRI examination and can give the location and depth of the implant which allows marking of the site to direct identification. Removal without direct ultrasound guidance should not be attempted if the implant is not palpable.

Key points

- An alternative form of contraception is recommended if ImplanonNXT[®] implant is unable to be found or is non-palpable.²³
- 2. Any queries or concerns regarding ImplanonNXT[®] implants or information on training should be directed to the manufacturer: Merck, Sharp & Dohme, 1800 818 553.
- 3. KEMH is a specialist Implanon removal centre for deep or difficult to remove implants. Impalpable implants should be referred to KEMH where they can be removed under ultrasound assistance.

Management

- A woman referred to KEMH for non-routine removal of an Implanon implant is booked to the <u>Procedural Gynaecology Clinic</u>. The clinic appointment is classified as category 2 priority and if possible an appointment for review is made for the woman to be seen within 6 – 8 weeks.
- 2. A history should be taken to ensure the Implanon implant was in fact inserted and not left in the introducer e.g. did the woman feel the implant in her arm

- after insertion? Note her subsequent bleeding patterns²⁴. A substantial number of impalpable-implants were never actually inserted or fell out of the introducer before attempted insertion. The introducer of the Implanon NXT is designed so that the implant cannot fall out of the needle.
- 3. A non-palpable implant should be located prior to removal.²³ If palpation of the Implanon implant at the clinic appointment is not successful an ultrasound may be arranged for definitive localisation. X-ray, MRI or CT scan provide further tools for implant localisation.²³
- 4. If the implant is found on ultrasound or by an alternative method and is subsequently palpable, removal may be appropriate under local anaesthetic in the clinic. If general anaesthetic is required, the woman is booked to the DSU for the procedure.
- 5. If the Implanon is not palpable it should be removed under direct ultrasound guidance. Relying on skin markings is not sufficient as the position relative to the skin changes with small positional changes of the arm and an attempt to remove it should not be made.
- 6. If Implanon implants not containing barium, cannot be visualised by ultrasound or MRI and there is a reason to believe it is still present in the body, the manufacturer should be contacted for procedure for testing of serum etonogestrel levels.²³
 - For Implanon implants the manufacturer: Merck, Sharp and Dohme, can be contacted on Tel. 1800 818 553.
 - They will provide instructions of how to collect and send serum for processing in Germany. If serum levels indicate the presence of the implant, further ultrasound and MRI examination is to be arranged.

Depot medroxyprogesterone acetate: Depo Provera

Background information

Depot medroxyprogesterone acetate (DMPA) is a progestogen only method of contraception which is given by intramuscular injection. DMPA was the first of the long-acting reversible methods of contraception (LARC methods). It is available in Australia as Depo-Provera® or Depo-Ralovera®. DMPA works by inhibiting ovulation, making cervical mucus thicker to limit sperm penetration and effects on the endometrium which makes it unfavourable for implantation.²⁷

Key points

- 1. DMPA contraception may be a preferable option for women who cannot tolerate oestrogen⁶, or who have a past history of ectopic pregnancy as the anovulant effect prevents pregnancy in any location.
- 2. Women with a history of epilepsy may find that frequency of seizures is reduced when using DMPA.
- 3. In women with sickle cell disease, DMPA causes an improvement of the haematological picture²⁸.
- 4. DPMA can provide a suitable alternative method of contraception for women who are unable to tolerate oral methods e.g. women with inflammatory bowel disease or malabsorption problems.⁶
- 5. DPMA is effective in overweight women although data of DMPA use in women of BMI over 40 is limited.²⁹
- 6. Amenorrhoea occurs in up to 47% of DMPA users after one year of use, which may be beneficial in women particularly with menstrual problems. DMPA has been found to improve dysmenorrhoea especially associated with endometriosis.²⁷
- 7. There has been increasing evidence for protection against endometrial and ovarian cancers and acute episodes of PID.²⁷
- 8. DMPA users experience a mean reduction in bone mineral density as compared to users of other methods. This bone loss is due to anovulatory (hypoestrogenic) effect of DMPA and mostly occurs in the first year of use. It is reversible after discontinuation. Lower BMI, low calcium intake and greater alcohol use were associated with greater BMD loss in adolescents using DMPA. After 2 years of DMPA use, if the woman wishes to continue use, reevaluation of risks and benefits, and alternative methods of contraception need to be discussed. There is limited evidence on fracture risk. 29

For risk factors for osteoporosis- see <u>Osteoporosis Australia: Risk Factors</u> (external website)

- 9. Alternative contraceptive methods should be considered first for women who are over 50 years of age before prescribing DPMA, due to concerns regarding bone loss on DMPA.⁶
- 10. Weight gain can be associated with use of DMPA. Women who gain more than 5% of their baseline body weight in the first six months of DMPA use are likely to continue to experience weight gain.⁶
 - The weight gain effect is more in obese women than thin women and is due to effects of DMPA on insulin and glucose metabolism.²⁷
- 11. Return to ovulation may be delayed for up to 18 months following discontinuation of DPMA.⁶
- 12. Headaches, acne, mood changes, low libido, hair loss and hot flushes have been reported in DMPA users. Although there is no evidence for causative effect, these adverse effects are cited as reasons to discontinue DMPA use.²⁹

Administration and patient selection

- 1. Pregnancy should be excluded prior to administration of DPMA contraception.⁶ See criteria to <u>exclude pregnancy</u>.
- 2. Following childbirth, DMPA injection can be given any time, (provided pregnancy is excluded) however the WHO does not recommend administration less than 6 weeks postpartum due to bleeding irregularities, unless other more appropriate methods are unavailable or unacceptable.³⁰
- 3. DMPA is given by deep intramuscular injection every 12 weeks ± 2 weeks. If more than 14 weeks since the last injection, exclude pregnancy.⁶

Efficacy

Perfect use 99.8 % efficacy, and typical use results in 94% efficacy.⁶

Contraindications

For contraindications- refer to <u>UKMEC Summary Table</u> sheets (external website). (Note- if link not accessible, refer to <u>local copy of the UKMEC Summary Table (Sept 2019)</u>)

Side effects⁶ include:

- irregular bleeding
- headaches
- acne

· weight gain

- breast tenderness
- loss of bone density

- delay in return to fertility
- mood change
- amenorrhoea

• libido loss, hair loss, hot flushes²⁹

Medical history and examination Medical history⁶

- Age, cardiovascular risk factors, breast cancer, liver disease, unexplained vaginal bleeding
- Pregnancy history, current breastfeeding, plans for future pregnancy fertility may be delayed for up to 18 months (mean return to fertility 8 months after DMPA)
- Menstrual history Investigate any abnormal bleeding and ensure the 'last period'
 was not an implantation bleed. Note: a negative pregnancy test does not exclude
 early pregnancy if the woman had unprotected sex in the previous 3 weeks.
- Risk for bone density loss/ osteopenia/ osteoporosis detailed assessment and advice should be completed for new users, and every 2 years for continuing users. Discuss risk of bone mineral density reduction which is associated with DPMA use.
- Cardiovascular history, IHD, stroke assess risk. Note: Multiple risk factors (e.g. smoking, hypertension, diabetes, dyslipidaemia, family history of CVD) increase risk for cardiovascular disease.
- Thromboembolic disease- if on anticoagulants, a haematoma may develop at DMPA injection site

Examination⁶

- 1. Perform a blood pressure, measure weight and calculate the BMI.
- 2. No routine investigations, however if CVD risk factors present, consider liaising with cardiologist

Counselling⁶

Discussion should include:

- time for injection to be effective, mechanism of action, effectiveness
- method and frequency of injections
- risk factors, side-effects, complications, advantages and disadvantages as a contraceptive, expected bleeding patterns and follow-up with the GP or family planning services.
- Return to fertility may be delayed up to 18 months from last DMPA injection
- DMPA does not offer protection against sexually transmitted infections including HIV and at-risk women should be advised on the concurrent use of condoms.

Provide the woman with written information, or where to access information about DPMA, which is available from <u>SHQ</u> (external website). See also 'Useful resources' links at the end of this document.

Dosage and administration

Shake gently²⁰ and administer 150mg medroxyprogesterone acetate in a 1ml aqueous microcrystalline solution by deep intramuscular injection into the gluteal or deltoid muscle every 12 weeks ±14 days.⁶ Do not rub²⁰.

Management if DMPA injection is late (>14 weeks since last dose)⁶

- Pregnancy excluded: A DPMA injection can be safely given if no unprotected sexual intercourse (UPSI) has occurred since 14 weeks after the last injection, but abstinence or condom use is advised for 7 days.
- Pregnancy not excluded: Consider <u>emergency contraception</u> if UPSI occurred in the past 5 days. Intramuscular DMPA is Australian Pregnancy Category A.²⁰ Management options include:
 - ➤ A repeat injection if >14 weeks has elapsed since the last DPMA injection, provided the woman is aware pregnancy cannot be excluded, has a negative pregnancy test, is advised to use condoms/abstinence for 7 days, and returns for a repeat pregnancy test in 4 weeks.
 - ➤ OR to abstain / use condoms for 3 weeks, return after 3 weeks with a negative pregnancy test, and then have the DMPA injection, using condoms/abstaining for a further 7 days.

Initiation of DMPA⁶

SITUATION	GIVEN	EFFECTIVE
No contraception	Day 1 to day 5 of normal menstrual cycle	Immediately
or barriers	At any other time; exclude pregnancy	7 days
COCP or	Anytime if the pills / vaginal ring have been	Depends on where
vaginal ring	taken/used correctly. Otherwise consider	she is in pill pack.
	excluding pregnancy. Continue pill or vaginal	After 7 consecutive
	ring after insertion until there have been 7	days of combined pill
	consecutive days of hormone.	or ring use with
		hormone
Etonogestrel	Anytime if within 3 years of insertion	Immediately
Implant	If >3 years- exclude pregnancy	7 days
POP	Anytime if the pills have been taken correctly	7 days
	otherwise pregnancy should be excluded	
Cu- IUD	Day 1 to day 5	Immediately
	Other times – condoms for 7 days prior to	7 days
	removal of IUD, or leave IUD in another 7 days	
LNG IUD	Anytime if not expired. Condoms for 7 days prior	7 days
	to removal of IUD or leave IUD in another 7	
	days	

Abortion/	Up to and including day 5 post abortion or	Immediately
miscarriage ≤	miscarriage	
24 weeks	If >day 5- consider risk of repeat pregnancy	7 days
Post-partum*	<21 days^ postpartum- Anytime- see note below	Immediately
includes stillbirth	>21 days^ post-partum and no menses-anytime	7 days
in breastfeeding	if pregnancy is excluded- see note below.	
and non-	If the menstrual cycle has resumed – as above	As above
breastfeeding	for no contraception or barriers	
women	*Note: Medroxyprogesterone is considered safe to use during breastfeeding. The timing of initiation of DMPA is controversial. The WHO recommends that injectable DMPA should not be used before 6 weeks postpartum. 30 * Note: Progestogens used before 3 weeks	
	postpartum, may cause heavy irregular bleeding ²⁰	

Management of irregular bleeding on DMPA

Counselling about menstrual alteration before initiation of DMPA use is essential to alleviate concerns and encourage continuation of the method.

For short-term treatment, medications such as Mefenamic acid 500 mg three times daily for 5 days during bleeding or using Oral combined pills for medically suitable patients for 3 months with or without a break is recommended.

Follow-up

Women should be reviewed before each DPMA injection for the presence of side-effects (including injection site reactions), bleeding patterns, changed health status.⁶ Additionally, an annual medical review should include blood pressure, weight (if relevant), new medical conditions, and a bone loss risk assessment every 2 years.⁶ As appropriate, review also for STI risk, pregnancy planning and offer cervical²⁹ / breast screening if due.

Progesterone only pill (POP)

- This is also called minipill as it contains only one hormone- progesterone.
- POP prevents pregnancy by thickening the cervical mucosa rendering it impenetrable to sperm, altering the endometrium to inhibit implantation, and in some users prevents or disrupts ovulation in 60 % of their cycle. An estimated 48 hours of POP use was deemed necessary to achieve the contraceptive effects on cervical mucus.
- The mini pills can be started within 21 days for contraception in postpartum breastfeeding women.
- It can be taken by women in whom combined estrogen and progesterone pills may be contraindicated, e.g. hypertension, migraine headache with aura, and smoking among women age 35 years and older.
- The packet contains 28 pills containing the same dose and one pill is taken daily at the same time without a break. A pill is considered missed if more than 3 hours late in this circumstance the woman should take the pill again as soon as possible, and use an additional method of contraception for 48 hours (EC may be considered if unprotected sex has occurred during this 48 hours).³¹
- Women should be advised that regular pill taking at the same time is required for efficacy. If used correctly and consistently, POPs are 91- 99.7% effective.
- There are two types available in Australia one containing LNG 30mcg (Microlut[®]), and the other norethisterone 350mcg (Locilan 28[®], Micronor[®], and Noriday 28[®])
- POP containing desogestrel are not available in Australia.

Guidance regarding eligibility, starting and missed POPs is available at:

FSRH guideline: Progestogen Only Pills (external website)

Patient information available from SHQ:

Progestogen Only Pill (external website)

Contraindications

For contraindications- refer to <u>UKMEC Summary Table</u> sheets (external website). (Note- if link not accessible, refer to <u>local copy of the UKMEC Summary Table (Sept 2019)</u>)

Initiation of POP⁶

SITUATION	GIVEN	EFFECTIVE
No contraception	Day 1- 5 of menstrual cycle	Immediate ³¹
or barriers	Any other time, exclude pregnancy	48 hours (3 consecutive daily pills)
Amenorrhoeic ³²	Any time (exclude pregnancy)	Effective after 48 hours
CHC (pill or vaginal ring)	Anytime if the pills / vaginal ring have been taken/used correctly. Otherwise exclude pregnancy. Continue pill or vaginal ring after insertion until there have been 7 consecutive days of hormone.	Depends on where she is in pill pack. After 7 consecutive days of combined pill or ring use with hormone.
DMPA injection	Anytime if within 14 weeks of last injection	Immediate
ENG implants	Anytime if within 3 years of insertion	Immediate
Cu- IUD	Day 1- 5 At other times use condoms for 7 days prior to removal of IUD	Immediate 48 hours (3 consecutive daily pills)
LNG- IUD	Condoms for 7 days prior to removal of IUD	48 hours (3 consecutive daily pills)
After abortion or miscarriage ≤24	Up to and including 5 days post abortion/miscarriage	Immediate
weeks	If >day 5 post abortion or miscarriage	48 hours (3 consecutive daily pills)
Post-partum**	<21 days** postpartum	Immediate
>24 weeks	>21 days postpartum and	48 hours (3 consecutive
(includes stillbirth / abortion) in	amenorrhoeic: Anytime (exclude pregnancy)	daily pills)
breastfeeding and non-	Menstrual cycles resumed – as	As above
breastfeeding women	above for no contraception or barriers	

Day 1 refers to the first day of bleeding in a normal menstrual cycle

Counselling and follow-up⁶

Women should be counselled regarding side-effects associated with POP, including

^{**} Contraception is not required within 21 days of birth, however can be commenced earlier depending on the individual woman's circumstances.⁶

irregular bleeding, amenorrhoea, and headaches. Weight or mood changes have been reported by some women.

Prescription of 12 months can be supplied to ensure continuous intake.

If no indication for early review, the woman can initiate review when required. Otherwise review annually for presence of side effects, new medical conditions or medications, bleeding pattern concerns, compliance and understanding of missed pill advice.

Combined hormonal contraceptives

Background

Combined hormonal contraceptives (CHC) are preparations of synthetic oestrogen and progesterone in varying combinations. They are available as a combined oral contraceptive pill (COCP) or vaginal ring form.⁶ Contraceptive patches are not yet available in Australia.

Vaginal rings (e.g. Nuvaring) became available in Australia since 2007 and most of the information applies to both oral pills and vaginal rings unless stated otherwise.

CHC works by inhibition of ovulation, cervical mucus thickening, and may prevent implantation due to effects on endometrium and tubal motility.⁶

COCP can be monophasic (fixed combination) or multiphasic (two or more combination).⁶

Estrogen can be Ethinyl Estradiol (EE) or Estradiol Valerate with one of the progesterone- levonorgestrel (LNG), norethisterone or cyproterone acetate, or newer progestogens such as etonogestrel (ENG), drospirenone, dienogest and nomogestrel acetate.

Newer progestogens were developed to avoid androgenic side effects and to have a minimal negative impact on estrogen induced changes to lipids. Drosperinone has mild diuretic effect. Combined pills with newer progestogens are not available on PBS and may be prescribed for women with a pre-existing condition such as acne, pre-menstrual dysphoric disorder or heavy menstrual bleeding.

CHCs using LNG, norgestimate and norethisterone are at the lower risk for thromboembolism as compared to other newer progestogens and women need to be counselled regarding this.

Nuvaring-The combined vaginal ring is a 54mm ethylene vinyl acetate copolymer ring and releases a combination of 15mcg EE and 120mcg ENG daily. It is available in Australia as NuvaRing[®]. It is placed in the vagina for 3 weeks. It is then removed, disposed of and the woman then has a 7 day hormone free week before a new ring is inserted. It is 91-99.7% effective at preventing pregnancy depending on perfect use.⁶

Key points

- 1. Women taking CHCs may experience a lighter bleed during the hormone-free interval. It is due to withdrawal of hormones rather than a menstrual bleed. Recent evidence suggests that there is no physiological requirement or benefit to schedule a bleed every month and women should be advised regarding tailor-made / back to back/ flexible regimes of CHC. A pill free interval of 4 days provides greater safety, efficacy and reduction of menstrual pain, bleeding days and need for emergency contraception.³³
- 2. The CHCs should not be initiated in the first 21 days post-partum to avoid risk of thromboembolic complications.⁶
- Some medications may decrease efficacy of the CHCs e.g. liver-enzyme inducing medications, some antiepileptic medications, some antibiotics and St. John's Wort.⁶ Advise methods of contraception that are not affected by these medications.⁶
- 4. A blood pressure (BP), BMI and detailed medical history should be conducted prior to prescribing the CHCs.³⁴
- 5. Women prescribed the CHC should be advised of management should they miss/delay taking the CHC, or if they have significant vomiting and diarrhoea.
- 6. All women prescribed the CHC should be advised of side-effects, risk factors, beneficial effects, how to take the medication, tailor made regimes and follow-up with the medical practitioner.

Non-contraceptive beneficial effects of CHC

CHCs are easily accessible, highly effective if used correctly, are easily reversible, and have been associated with an ability to control and reduce bleeding days, improve acne and reduce risk for endometrial, ovarian and bowel cancer⁶. The CHC can be used in management of symptoms of pre-menstrual syndrome, endometriosis, reducing functional ovarian cysts, and for management of polycystic ovarian syndrome and peri-menopausal symptoms and bleeding in eligible perimenopausal women.³⁴

It is assumed that the vaginal ring will offer similar benefits to the COCP but because it is relatively new, extensive supporting evidence is lacking.³⁴

Efficacy

Perfect use results in 99.7% efficacy, while typical use results in 91% efficacy⁶

Contraindications

For contraindications- refer to <u>UKMEC Summary Table</u> sheets (external website). (Note- if link not accessible, refer to <u>local copy of the UKMEC Summary Table (Sept 2019)</u>)

Cautions

- Women trekking to high altitudes over 4500 m for over 1 week are advised to switch to alternative methods of contraception.⁶
- Four weeks before a major surgery or expected period of limited mobility, CHC should be discontinued and alternative contraception should be advised.³⁴

Concomitant use with other drugs³⁴

- Drug treatments affecting liver enzymes will reduce efficacy of CHCs.
 Consider alternative contraception methods
- Patients using Lamotrigine must be warned regarding effect of CHC on serum lamotrigine levels therefore causing reduced seizure control or lamotrigine toxicity
- Patient using teratogenic drugs should be encouraged to use LARC which are not user dependant and are most efficient contraceptive methods
- Before starting CHC, women should be advised to wait for 5 days if they have used ulipristal acetate (UPA) - emergency contraception. They must use barrier contraception or abstain for 5 days

Side-effects⁶

These include:

breakthrough bleeding

headache

· weight gain

breast tenderness

nausea

• chloasma

lowered libido and mood changes

acne

bloating

Risks⁶

The use of COCP has been associated with an increased risk of gall bladder disease, venous thromboembolism, arterial vascular disease, ischaemic stroke, myocardial infarct, and cervical cancer. Individual risks vary and are affected by coexisting morbidity and lifestyle factors.

Management: prior to prescribing Medical history⁶

Complete a medical history and check for contraindications prior to prescribing the CHC:

- Age:
 - Women under 18 years complete a history of sexual activity and risk assessment. This includes confidentiality, legal issues, ability to consent, and child protection issues. Use concept of mature minor. See also RANZCOG C-Gen 2A: Consent and Provision of Information to Patients in Australia Regarding Proposed Treatment (2020) (external website)

- ➤ Women ≥ 40 years have a higher background risk of health conditions and should be carefully assessed for risk factors and gynaecological problems. Assess risk factors for cardiovascular and VTE.
- ➤ The CHC is not recommended for women ≥50 years, and other contraceptive methods should be used if required.
 The woman (≥50) who is amenorrhoeic for 1 year, no longer requires contraception. However other contraceptive methods should be considered if the woman menstruates after ceasing CHC.⁶
- Postpartum- breastfeeding history
- Self or family history for risk of thromboembolic disease
- Contraceptive history (previous types, side-effects, failures, preferences/ ability)
- Menstrual and vaginal bleeding history exclude risk of pregnancy e.g. implantation bleed / ectopic
- Exclude risk factors and negative lifestyle factors e.g. cardiovascular, hypertension, thromboembolic disease, arterial disease, liver disease, cancer, smoking, obesity
- Assess for medications which may decrease the efficacy of the CHC e.g. rifampicin, some anti-epileptic drugs, and St. Johns Wart
- Migraine- women having migraines with an aura are at increased risk for strokes
- Cancer CHC in the woman with breast cancer is contraindicated

Examination

- Perform BP measurement. Perform cervical screening as required.³⁴
- Check for sexually transmissible infections as required³⁴
- Calculate the woman's weight and BMI. A BMI >30 increases the VTE risk.⁶
 See contraindications in <u>UKMEC Summary Table</u> if the BMI ≥35.
 (Note- if link not accessible, refer to <u>local copy of the UKMEC Summary Table</u> (Sept 2019))

Initiation of CHC⁶

SITUATION	ACTIVE PILL COMMENCEMENT	EFFECTIVE *
No contraception	Day 1 to 5 of menstrual cycle	Immediately
or barriers	Any other time if pregnancy is excluded	Effective in 7 days
	See also Quick start method	
COCP or vaginal	Begin new packet on an active hormone pill or	Immediately*
ring	insert vaginal ring no later than the day	
	following the last hormone-free day	

Anytime within 14 weeks of injection	Immediately*
Anytime within 3 years of insertion	Immediately*
	If commenced on the
	same day as Implanon
	NXT [®] is removed,
	allow 7 days to become effective
Anytima if alle base base as weeth taken	
otherwise exclude pregnancy	Effective in 7 days
Day 1-5	Immediately
Other times:	
 Condoms for 7 days prior to removal of IUD, commence CHC on day of removal 	Effective in 7 days
- Commence CHC 7 days before IUD removal	Immediately
Condoms for 7 days prior to removal of the IUD, commence CHC on day of removal.	Effective in 7 days
Commence CHC 7 days before IUD removal	Immediately
Up to and including day 5 post-procedure	Immediately
If taken>5 days exclude repeat pregnancy	7 days
If no menstrual cycle – any time after 3-6	Effective in 7 days
·	As above
as above for no contraception or barriers	As above
No menstrual cycle- anytime >6wks (exclude	7 days
pregnancy). All postpartum women must	
undergo VTE risk assessment prior to starting CHC.	
Menstrual cycle resumed - As above for no contraception or barriers	As above
	Anytime within 3 years of insertion Anytime if pills have been correctly taken otherwise exclude pregnancy Day 1-5 Other times: - Condoms for 7 days prior to removal of IUD, commence CHC on day of removal - Commence CHC 7 days before IUD removal Condoms for 7 days prior to removal of the IUD, commence CHC on day of removal. Commence CHC 7 days before IUD removal Up to and including day 5 post-procedure If taken>5 days exclude repeat pregnancy If no menstrual cycle – any time after 3-6 weeks post-delivery and pregnancy is excluded. All postpartum women must undergo VTE risk assessment prior to starting CHC. If menstrual cycle resumed – follow instructions as above for no contraception or barriers No menstrual cycle- anytime >6wks (exclude pregnancy). All postpartum women must undergo VTE risk assessment prior to starting CHC. Menstrual cycle resumed - As above for no

^{*} If starting CHCs any time other than day 1-5 of the menstrual cycle and if pregnancy excluded, inform women that an additional 7 days are required before there is contraceptive protection.⁶

Counselling

- Provide the woman with written information about the CHC⁶, or refer her to online information available at SHQ (external website)
- Discuss the side-effects, risks and their warning signs, mode of action, administration, difference between hormone and placebo tablets, any temporary additional contraception required, expected bleeding patterns, and drug interactions.⁶
- Management if a hormone pill is late or missed/ forgotten⁶:

Late:

➤ If <24 hours late: Take the late hormone pill as soon as possible, then continue taking the pills as usual (2 pills can be taken on the same day). No additional contraceptive required.</p>

Missed:

- ➢ If >24 and <96 hours late: The most recent pill should be taken and previously missed pills discarded, then continue taking the pills as usual (2 pills can be taken on the same day). Additional contraceptive methods (e.g. condoms) / abstinence are required until 7 consecutive active hormone pills have been taken.</p>
- Missing more than 4 consecutive pills is classified as having 'stopped using the COCP' and the missed pill rules cannot apply. The woman should consider <u>emergency contraception</u> and commence a new packet.
- ➤ Ovulation: Seven consecutive active hormone pills are sufficient to suppress ovulation. The active pills closest to the placebo pills are the riskiest to miss as they prolong the hormone free period.
- ➤ If a pill is missed in the first 7 active pill days after the placebo, emergency contraception should be considered if there has been unprotected sexual intercourse in the past 5 days.
- ➤ If the missed pills are in the last 7 days of active pills before the next placebo, the pill-free interval should be omitted.
- ➤ If the woman is unsure of how to manage when she misses a pill she should contact her prescriber or SHQ.
- Inform the woman if she has significant vomiting within 2 hours or severe diarrhoea then the rule for missed pills should be applied.⁶
- A woman using antibiotics (that do not contain liver-inducing enzymes) does not require additional contraceptive measures.³⁴
- Inform the woman to discuss with her medical practitioner the compatibility of the CHC with any new medications prescribed.

- Women can safely take fewer (or no) hormone-free intervals to avoid monthly bleeds, cramps and other symptoms such as headaches or premenstrual symptoms.
- If a hormone-free interval is taken, shortening it to four days could potentially reduce the risk of pregnancy if pills or rings are missed.
- It is important to inform patients that unscheduled bleeding is common with continuous back to back use of CHCs.³⁵
- At the first consultation, many women can safely be prescribed a one year supply of CHC instead of the current three month supply.

Follow-up

- Women should be reviewed after four months initially³⁵, then annually by a
 medical practitioner to assess eligibility, compliance, satisfaction with CHC,
 drug interactions and to discuss ongoing CHC or alternative contraception. A
 recheck of the woman's medical history (including conditions such as
 migraine and lifestyle factors), BP and weight should be attended at least
 annually.³⁴
- 2. Inform the woman to return for review anytime if any problems (e.g. signs of side-effects, embolus, cardiovascular symptoms, or blood pressure symptoms).

Additional resources

- RANZCOG (2019) <u>C-Gyn-28: Combined Hormonal Contraceptives</u> (PDF, 268KB, external website)
- FSRH guideline: <u>Combined Hormonal Contraception</u> (external website)
- SHQ: Patient information sheets: <u>Combined Oral Contraceptive Pill</u> (external website); <u>Vaginal Contraceptive Ring</u> (external website)

Postpartum contraception

This chapter should be used in conjunction with the method-specific sections of this document, which contain information regarding individual contraception methods.

Background

A short inter-pregnancy interval (time between a previous birth and conception of the next pregnancy) may be associated with increased risks of maternal and fetal

adverse outcomes (e.g. preterm, low birth weight, small for gestational age (SGA)³⁶, and neonatal mortality).³⁷

As maternal age at first full term pregnancy keeps increasing in developed countries, this may be a concern.

Whilst short inter-pregnancy intervals appear to be associated with increased risks for adverse outcomes for women of all ages, in older women (>35 years) there is greater risk of maternal morbidity, whereas in younger women (20-35) fetal and neonatal risks may be greater.³⁷

In Australia, 10-44% of unintended pregnancies will occur within 12 months after a previous birth³⁸ indicating that there is an urgent need to increase the awareness, knowledge and accessibility of available contraceptive methods and encourage women to use safe and effective contraceptive starting in postpartum period.

Immediate or early initiation of postpartum contraception (PPC) after childbirth eliminates the risk of an unintended pregnancy in the event that planned follow up is delayed or sexual intercourse is resumed before 21 days postpartum³⁹. Considering 10-40% of women may not attend their six-week postnatal check⁴⁰ and 41% couples resume sexual activity before 6 weeks, offering PPC prior to patient discharge allows patients to leave hospital secure in the knowledge that their contraceptive needs are met³⁸.

Women who had a caesarean section or in whom future <u>pregnancy poses additional</u> <u>risks</u> due to a pre-existing condition represent distinct groups for which postpartum contraception education and delivery is essential.

Key points

- 1. **Counselling** Discussion of postpartum contraception is an important part of routine maternity care⁴¹, and should start in the antenatal period. This will ensure that the woman has ample time to consider her choices, ask questions and engage in discussion with health providers. The discussion should explore individual needs and preferences of each woman, their future fertility plans and any potential barriers for effective contraceptive use such as cost, language barriers, compliance, healthcare access and cultural /religious beliefs.
 - The woman should not feel hurried or pressured to use a particular method
 - It is the shared responsibility of all clinicians (including doctors, midwives, pharmacists), to provide women with PPC counselling and education³⁶.
 - Clear documentation of discussion regarding postpartum contraception and the woman's preferred method should be made in patient notes.
 - Provide patient centred counselling, including information about the effectiveness of the different contraceptive methods, especially the superior effectiveness of LARC.³⁶
- 2. Offer all postnatal women the opportunity to start their chosen method of PPC prior to discharge from hospital (unless method contraindicated), especially

women at high risk of unintended pregnancy or where shortened inter pregnancy interval poses significant medical or neonatal risk.³⁶ See <u>Unintended Pregnancy</u> and Increased Health Risks.

- Barrier and progesterone-only methods of contraception can be safely initiated immediately after childbirth in both breastfeeding and nonbreastfeeding women³⁶
- Breastfeeding women should be reassured that no adverse effects on lactation, infant growth or development has been demonstrated with early use of progesterone only methods^{36, 40}
- 3. All postnatal women should be advised of where they can access contraception counselling and provision of services once they are discharged from hospital.
 - The referral pathway for IUD and Implanon insertions is via the woman's General Practitioner (GP), <u>SHQ</u> clinics (external website) or the <u>KEMH</u> <u>Procedural Gynaecology Outpatient Clinic</u> (access for WA Health employees via Healthpoint)
- 4. All women should have an assessment of their venous thromboembolic (VTE) risk assessed prior to starting any hormonal contraceptive, particularly as CHC exacerbates VTE risk.³⁶ Post-partum risk factors for VTE include, immobility, transfusion at delivery, body mass index (BMI) ≥30 kg/m2, postpartum haemorrhage, post-caesarean delivery, preeclampsia, smoking,³⁶ thrombophilia. This is same whether the woman is breastfeeding or not.³⁶
- 5. All women must be informed that while contraception is not needed within 21 days of childbirth, resumption of ovulation is both unpredictable and common before first menses occurs.⁶ The importance of additional precautions must therefore be emphasised if a woman chooses to delay PPC (e.g. 6-8 weeks after childbirth) or declines PPC use altogether.
- 6. LARCs including the contraceptive implant (Implanon NXT®) may be inserted any time after birth. Refer to relevant chapters in this guideline.
- 7. Due to higher rates of expulsion and limited evaluation, IUD insertion between 48 hours and 4 weeks postpartum is not currently recommended. Whilst insertion <48 hours is safe, insertion between 10 min and 48 hours after delivery is associated with higher rates of expulsion than insertion 4-6 weeks postpartum.^{4, 6}
- 8. Use of CHC is not advised before 6 weeks postpartum due to the theoretical risks of exogenous oestrogen entering breast milk and increased risk of thromboembolism. See CHC chapter.

Additional resources

 FSRH guideline: 'Contraception After Pregnancy' available through <u>FSRH</u> or <u>RANZCOG</u> (external websites)

Methods of postpartum contraception

Contraceptive method	Breastfeeding suitability	Criteria for suitability (For contraindications- refer to relevant sections in this guideline)	Additional information
Non-hormonal cor	ntraceptives		
Lactational amenorrhoea (LAM)	Yes	For LAM to be considered an appropriate postpartum contraceptive choice, the following criteria must be fulfilled: • women must remain amenorrhoeic postpartum • it is less than 6 months since giving birth • the baby is fully breastfed day and night (no artificial feeds, supplements or solids) • Short intervals are maintained between feeds (e.g. no more than 4 hours during the day and 6 hours at night)	 Women using LAM should be counselled on the risk of pregnancy if: The frequency of breastfeeding decreases (e.g. stopping night feeds, increasing supplementary feeds, expressing milk etc.) The intervals between feeds lengthen Menstruation returns It is over 6 months since childbirth. The woman should consider other more effective method of contraception.
Condoms (male and female)	Yes	Both female and male condoms can be used without restriction any time after childbirth	Offers protection against STIs May be used in conjunction to other contraceptive methods, particularly at time of contraceptive method change If hormonal contraception is started 21 days or more after childbirth, use of barrier contraception should be advised until the hormonal contraceptive takes effect. ³⁶

Contraceptive method	Breastfeeding suitability	Criteria for suitability (For contraindications- refer to relevant sections in this guideline)	Additional information	
<u>Diaphragms</u>	Yes	 Can be used 6 weeks after birth when uterine involution is complete and vaginal tone returns⁶ Consider woman's mobility and confidence in inserting diaphragm independently 	Only one size diaphragm is available. Correct placement should be assessed by medical practitioner initially if using for the first time. See section Diaphragms	
<u>Cu- IUD</u>	Yes	See section on <u>Cu- IUD</u>	 Note- 6 times more risk of uterine perforation in breastfeeding women. Due to higher risks of expulsion and limited data, IUD insertions are not recommended within 48 hours of delivery. 	
Combined hormor	nal contraceptive	s (CHC)		
CHC- Combined Oral Pill (COCP) and Vaginal ring (e.g. NuvaRing)	<6 weeks postpartum=NO ≥6 weeks postpartum=YES	 For non-breastfeeding women: Can use after 21 days postpartum if there are no other VTE risk factors^{6, 36} For women with additional VTE risk factors, CHC should not be started until 6 weeks postpartum³⁶ For breastfeeding women: Can use > 42 days (6 weeks) postpartum⁶ 	Assess risk factors for VTE- Immobility, transfusion at delivery, BMI ≥30 kg/m², postpartum haemorrhage, post-caesarean delivery, preeclampsia or smoking, 36 thrombophilia. This is same whether the woman is breastfeeding or not. 65 Following a Cochrane review comparing CHC, non-hormonal and progesterone-only contraception amongst breastfeeding women, most trials did not show significant differences in breastfeeding duration, milk composition or infant growth.	

Contraceptive method	Breastfeeding suitability	Criteria for suitability (For contraindications- refer to relevant sections in this guideline)	Additional information		
Progesterone-only	Progesterone-only contraceptives				
<u>POP</u>	YES	 Can be initiated immediately after childbirth and before 21 days without the need for additional precautions Consider a woman's individual circumstance and potential barriers to regular compliance including access to obtaining follow-up prescriptions 	If started on or after day 21 postpartum, women must be advised that additional bridging contraception is required for 2 days If menses have returned, commenced 1 to 5 days of menstrual cycle its effective immediately. See also chapter: POP		
DMPA Progesterone-only injection	YES	 Can be initiated any time after childbirth (UKMEC2)^{6, 29} 	See chapter: <u>DMPA</u>		
Subdermal implant (Implanon NXT)	Yes	 Can be initiated any time after childbirth For more information, see <u>Subdermal Implant</u> 	 Effective for 3 years after insertion High continuation rates have been reported at 6 months and 12 months following delivery when inserted immediately after childbirth, particularly in adolescent populations³⁶ Counsel women regarding irregular bleeding patterns that may occur with use. 		
LNG IUD (e.g. Kyleena, Mirena [®])	Yes	 See <u>IUD</u> chapter Refer the woman to her GP, SHQ, or refer to the KEMH <u>Procedural Clinic</u> outpatient services if difficult insertion anticipated or post-birth special 	 Effective for 5 years after insertion Note- 6 times increased risk of perforation in breastfeeding women 		

Contraceptive method	Breastfeeding suitability	Criteria for suitability (For contraindications- refer to relevant sections in this guideline)	Additional information	
		groups (e.g. WANDAS). Note- Post partum adolescent patients at KEMH (who have been part of the adolescent antenatal clinic (ANC)) will be offered a review at 6 weeks in the adolescent ANC and insertion of IUD can occur at that appointment if that is their wish. Any adolescent who is not part of the adolescent ANC care can be referred to Procedure clinic as described.	Due to limited evidence evaluating IUD insertion between 48 hours and 4 weeks postpartum, insertion during this time is not currently recommended. 17, 36	
Permanent contraception				
Permanent Contraception (sterilisation)	Yes	Ideally done after some time has elapsed after childbirth. Contraindications to general anaesthesia. See section on Permanent Contraception Discussion regarding tubal occlusion or removal, alternative contraceptive methods, reversibility, increased regret and failure in postpartum period is essential prior to consent.	Salpingectomy has less failure rate than tubal occlusion by Filshie's clip due to oedematous fallopian tubes in post-partum period	

Notes

- Refer to relevant sections in this document for contraindications and when to commence the different types of contraception post-partum.
- Exclude repeat pregnancy if commencing contraception >21 days postpartum.
- If not breastfeeding, advise to commence contraception by/at 21 days postpartum to avoid pregnancy.⁶ The earliest ovulation date is considered to be 28 days after birth, with sperm survival up to 7 days.⁶ Therefore contraception is not required before 21 days postpartum.⁶ If progestogen only contraceptives are used <3 weeks postpartum, heavy irregular bleeding may occur.²⁰

Emergency contraception

Background

Access to emergency contraception (EC) is important for women to reduce the risk of pregnancy after unprotected sexual intercourse (UPSI), sexual assault, or contraceptive failure.⁶

Cu-IUD being the most effective EC, has remained underused in Australia due to lack of awareness and knowledge of its efficacy in women and lack of access to trained practitioners to provide Cu- IUD insertions within 5 days of UPSI.⁴²

Key points

- Australian women have three options: two forms of EC pills which are available over the counter at most pharmacies without a prescription, and a Cu-IUD which needs to be inserted by a trained professional. The EC pill price varies between pharmacies.
 - The hormonal-IUDs- Mirena and Kyleena are not suitable for use as EC.
- 2. Due to its low failure rate, all eligible women presenting between 0-120 hours of UPSI should be offered Cu-IUD. This includes obese women, who are at higher risk of oral LNG EC failure.⁴³
- 3. Hormonal methods of EC (LNG, UPA) should be taken as soon as possible after UPSI.⁴⁴ Likelihood of ovulation having already occurred in relation to UPSI and intake of EC is a critical factor⁴⁴ and relates to percentage of expected pregnancies prevented.
- 4. The LNG-EC is licensed to be used within 72 hours of UPSI but has efficacy up to 96 hours³¹ (off-label), and uncertain efficacy up to 120 hours³¹. UPA has proven efficacy up to 120 hours⁴⁵.
- 5. Hormonal EC dose may be repeated (with an antiemetic) if vomiting occurs within 2 hours of taking LNG-EC and 3 hours of taking UPA.⁶

Methods of EC

Copper releasing IUDs

- Cu-IUD (Multiload 375 or Copper TT380-standard or short) interferes with sperm movement, preventing fertilisation and implantation of the fertilised ovum.⁶
- It is the most effective EC with failure rates of less than 1%, and can be used for continued contraception for up to 5 or 10 years depending on the copper device inserted. Cu-IUD is the only effective method if there is a possibility that ovulation has occurred.⁴³



 It can be used in women with BMI >26, postpartum (>4 weeks after childbirth), breastfeeding women or women taking hepatic enzyme inducing medications.⁴⁴

Hormonal methods

These methods prevent or delay ovulation, however they do not prevent fertilisation or inhibit implantation if ovulation has already occurred.⁶

- UPA- 30mg⁶- is a selective progesterone receptor modulator⁴³
- LNG- 1.5mg⁶

Cu-IUD or UPA are preferred options over LNG in patients with BMI over 26. 44

Other methods⁴³

- Mirena IUD is not approved for use as EC.
- Mifepristone-RU 486, an anti progestogenic agent in moderate dosages (25-50mg) is an effective and well tolerated EC and works if taken within 120 hrs of UPSI but it is not approved for this indication in Australia.

Efficacy

The efficacy is the percentage of pregnancies prevented that would have occurred if no method was used:

- EC- Copper-IUD: effective over 99%^{6, 43}
- UPA- Evidence suggests that UPA is significantly more effective than LNG in preventing pregnancy when taken within 120 hours of UPSI.⁶ This may be due to the fact that UPA can delay ovulation even after the start of LH surge. This may be useful for selecting UPA as a choice of EC if the woman is likely to be closer to ovulation. It is also important to remind women that ovulation is delayed by use of UPA and therefore they need to use ongoing effective contraception.⁴⁴
- Both hormonal EC are ineffective if ovulation has already occurred.⁴⁴

Contraindications

Cu-IUD

• See section in this document: Intrauterine Devices

Hormonal oral EC

- Established pregnancy (UKMEC4)⁶
- Allergy or hypersensitivity to EC components (UKMEC4) ⁶

Special precautions for hormonal oral EC

- UPA is not suitable in severe uncontrolled asthma on oral glucocorticoids⁴⁴
- Severe liver disease^{31, 44}

- Patients taking liver enzyme CYP3A4 inducing medications⁴⁵:such as rifabutin, rifampicin, phenytoin, phenobarbitone, carbamazepine, St John's Wort
- Providers should be aware that UPA effectiveness is lowered if the patient was taking progesterone 7 days prior or takes progesterone in 5 days after ulipristal.
- Hormonal contraception cannot be started within 5 days of taking UPA EC⁴⁵ but can be commenced immediately after LNG
- Breast-feeding women^{46, 47}- Consider an alternative agent if possible.⁴⁵ Whilst the manufacturer recommends that breastfeeding women should express and discard milk for 1 week post UPA dose⁴⁵, **there is no need to interrupt breastfeeding**; based on high plasma protein binding and low transfer into breastmilk (relative infant dose = 0.8-1%) the risk to the infant is low.⁴⁸ If wishing to avoid the highest infant exposure, breast milk can be expressed and discarded for 24 hours after taking UPA^{48, 49}.

Side-effects

Hormonal EC

- Altered bleeding patterns, nausea & vomiting, and headaches^{6, 45}
- Abdominal / pelvic / back pain, fatigue, dizziness⁶, breast tenderness⁴⁵

Cu-IUD

• See section in this document: Intrauterine Devices

Medical history and investigations Medical history

This includes:

- risk of existing pregnancy, menstrual history- nature & timing of last normal menstrual period (LNMP) in relation to UPSI, previous episodes of UPSI this cycle, ongoing contraceptive needs, STI risk, breastfeeding, allergies, medical conditions.⁶
- history of failed contraception (e.g. missed pills, broken condom, overdue implant or IUD, sexual assault)
- medications:
 - ➤ Women using liver enzyme inducing medications such as rifabutin, rifampicin, phenytoin, phenobarbitone, carbamazepine (including if ceased in past 28 days), should be advised that Cu-IUD EC is the only method to not be affected by the medication. ^{43, 44} If emergency Cu- IUD is not possible or declined, a double dose of LNG (3mg) may be considered, however effectiveness is unknown. ^{43, 44}
- if applicable (<18), assess for being a 'mature minor' See also:
 - > RANZCOG C-Gen 2A: Consent and provision of information to patients in

Australia regarding proposed treatment (external website, PDF, 216KB);

- Department of Health WA Consent to Treatment Policy (PDF, 1.51MB) (2016) (mature minors) [under review]
- Working with Youth- A Legal Resource for Community Based Health Workers (external website, PDF, 1.64MB) (section 4.1.2 Mature minors)

Investigations

- Pregnancy test should be performed if concern the woman is already pregnant. Urine pregnancy tests performed within 21 days of UPSI may show a false negative. Interpret in conjunction with menstrual & sexual history.⁶
- Offer to screen for STIs⁶ and cervical screening test as required. See also Clinical Guidelines <u>Sexually Transmitted Infections</u>: sections on screening tests for STI and for asymptomatic or symptomatic women.

Examination⁶

None necessary unless inserting IUD- see section: Intrauterine Devices

Counselling

An information sheet is available from SHQ: <u>Emergency Contraception (external website)</u>. When providing advice, maintain the woman's confidentiality, privacy and dignity.⁴³ Women using EC should be provided with information regarding:

- · different EC methods available and
 - efficacy, interactions, medical eligibility, need for additional contraception, and that they are not covered for future UPSI (except Cu-IUD)⁶
 - ➤ adverse / side-effects including signs of an ectopic pregnancy⁵⁰
 - ➤ mode of action, administration⁴³
- ongoing contraception needs^{6, 43}
- follow-up
- risk for sexually transmitted infections^{6, 43, 50}
- prevention of pregnancy management, including what to do if the contraception fails and pregnancy occurs⁴³

Dosage and administration

Ulipristal acetate is approved for use up to 120 hours after UPSI. Evidence indicates improved efficacy the earlier it is given in relation to the UPSI.

Dose: 1 tablet of ulipristal acetate 30mg

LNG

LNG-EC is approved for use up to 72 hours after UPSI, although has proven efficacy up to 96 hours (4 days).⁶ Some evidence has indicated efficacy is improved the

earlier the LNG-EC method is given in relation to UPSI.⁶ While it can be given up to the fifth day post UPSI, there is a greater risk (5 times more risk) of pregnancy compared to administration within the first 24 hours or within 3 days.^{44, 50}

Stat dosage⁶

• 1.5 mg stat dose of LNG (first line preferred method)

Cu-IUD

A Cu-IUD can be inserted within 5 days of the earliest expected date of ovulation⁴⁴ (insert up to day 12) or up to 5 days (120 hours) after the first episode of UPSI (whichever is later) if there are multiple episodes of UPSI in the cycle.⁴⁴

- If the woman and clinician are reasonably sure about the timing of ovulation (e.g. regular cycle & pain/mucous changes with ovulation), then insertion can be up to 5 days after the earliest predicted ovulation (e.g. if ovulation (pain/mucous changes) occurred on day 14, then insertion can occur up to 5 days later).
- See also section: Intrauterine Devices

Management in special circumstances

- Vomiting after taking oral EC- women should seek medical advice, where a
 dose of EC can be repeated if vomiting occurs (within 2 hours of LNG-EC and
 3 hours of UPA)⁶
- Young women- there is no legal lower age limit for over the counter supply if
 the young woman is assessed as a 'mature minor', however pharmacy supply
 is regulated by state law.⁶ In Western Australia there is no legal age limit to
 obtain EC pill.⁵⁰ If interpretation of the state laws restricts over the counter
 supply of LNG-EC, a prescription can be supplied in advance.⁶
- Overweight women- A double dose (3mg) of LNG-EC should be considered if a woman has a body mass index >26kg/m² or weight >70kg (if Cu-IUD and UPA-EC are both not suitable)⁴⁴
- Hormonal LNG-EC can be used for each act of UPSI in any cycle i.e. it should be repeated if UPSI occurs anytime more than 12 hours after EC was taken.⁶
 - Offer the same agent (LNG or UPA) i.e. if already taken UPA-EC can be offered UPA-EC again if further UPSI in the same cycle; If already taken LNG-EC can be offered LNG-EC again if further UPSI in same cycle.⁴⁴
 - ➢ Providers must be aware that if the woman has used UPA EC, she should not be offered LNG EC in the next 5 days for UPSI due to reduced efficacy. Similarly, if a woman has taken LNG EC for one or more times in the same cycle, UPA EC will be less effective.⁴⁴
- Advanced supply: If the woman is travelling to an area with restricted access to LNG-EC, or perceives a barrier to obtaining over the counter LNG-EC, a prescription for advanced supply may be considered.⁶

Follow-up

Review in 2-3 weeks for STI testing if STI risk or symptoms develop.

Hormonal EC

Review is not usually necessary after hormonal EC.⁶ However, women who have used a hormonal method of EC should be informed to seek medical review for a pregnancy test in ≥3 weeks if:

- Her period is ≥ 7 days late⁶, she has a positive home pregnancy test, her next menstruation is abnormal (e.g. light, prolonged, painful, spotting before or after the period)
- She has 'quick-started' hormonal contraception immediately after taking EC or 5 days after UPA⁶
- She is high risk for pregnancy or she used hormonal EC more than once this cycle⁶

Cu-IUD EC 6

Women who use Cu-IUD for EC should have a medical review 3-6 weeks after insertion. Follow-up includes a pregnancy test regardless of menstruation.

Additional resources

- SHQ patient information sheet: <u>Emergency Contraception</u> (external website)
- RANZCOG: Emergency Contraception (C-Gyn 11) (PDF, 4.3MB, external website)
- FSRH guideline: Emergency Contraception (external website)

Permanent contraception

(Previously referred to as 'sterilisation')

Background

Female permanent contraception involves a surgery for tubal occlusion, by transection, ligation, diathermy or removal of fallopian tube as a method of permanent contraception. It is performed via laparoscopy, at open abdominal surgery (e.g. caesarean section), or mini-laparotomy⁵¹ to prevent the passage of sperm and fertilised ova down the fallopian tube. With increased availability and acceptance of LARC methods in Australia, permanent female contraception has been decreasing.⁶

The Essure contraceptive device was cancelled from the Australian Register of Therapeutic Goods (ARTG) on 9 February 2018. It is no longer sold in Australia. This was due to reported adverse effects of Essure, which included corrosion or displacement of the device exposing women to nickel, causing bleeding,

hypersensitivity, inflammation and chronic pelvic pain. This significantly increased the risk of needing further surgery due to complications than those using the more traditional laparoscopic procedure.

Key points

- 1. There are very few contraindications for the procedure. However, being a permanent contraception which needs a surgical procedure, careful comprehensive counselling, thorough clinical assessment and informed consent is necessary prior to the surgery.
- 2. Failed tubal occlusion has been a frequent source of legal claims against medical practitioners. The legal claims have been related to timing the procedure, failure to exclude a pregnancy prior to performing the procedure; inadequate information given regarding failure rates and possibility of ectopic pregnancy, or operative complications and inadequate follow up etc.
- 3. Application of Filshie clips is recommended in the early to mid-follicular phase of the cycle unless other contraception is being used. If the procedure is performed on any other day of the cycle, pregnancy must be ruled out, by performing a sensitive pregnancy test just before the surgery, keeping in mind that a negative test does not exclude luteal phase conceptions.
- 4. Laparoscopic procedure with Filshie clips is the most common method of permanent female contraception in Australia. Recent trends regarding permanent contraception are shifting towards bilateral salpingectomy. This is largely due to evidence from meta-analysis of several trials suggesting that epithelial ovarian cancers may originate from the fallopian tube, and removing the fallopian tubes may play a role in preventing ovarian cancer by up to 49%.

Efficacy

Laparoscopic and laparotomy methods:

- >99.5% with laparoscopic and laparotomy methods⁶
- >99.8% with Filshie clips (cumulative pregnancy rate 1.7 /1000 procedures)⁵¹

Contraindications

Surgical permanent contraception has no conditions that permanently restrict eligibility from voluntary use. The risks of permanent contraception are weighed against risk of pregnancy and other available methods⁶.

It is advised by the WHO to exercise caution, delay or special precautions in timing and preoperative preparation of patients with certain medical conditions.

Caution 52

Procedure conducted in routine setting with extra preparation and precaution for the following:

- Young age (particularly <30); obesity (≥30 BMI- increased surgical & anaesthetic risk); severe lack of nutrition; post-partum (at time of caesarean) or concurrent with elective abdominal surgery.
- Hypertension (adequate control); mild elevated blood pressure (BP) (140/90 to 159/99mmHg); history of IHD, stroke (history of cerebrovascular accident, TIA); uncomplicated valvular heart disease & congenital heart disease
- Uncomplicated systemic lupus erythematosus (SLE) with negative antiphospholipid antibodies; epilepsy; diabetes (without vascular disease or damage to arteries, vision or kidneys); hypothyroidism; cirrhosis (mildcompensated without complications); liver tumours (benign & malignant); thalassemia; sickle cell disease; iron deficiency anaemia; kidney disease.
- Current breast cancer
- Previous abdominal or pelvic surgery, past pelvic inflammatory disease since last pregnancy, uterine fibroids
- Diaphragmatic hernia
- Depression

Delay 52

Delay the surgery until condition is evaluated and/or corrected:

- Pregnancy; post-partum or post-abortion (<6 weeks); postpartum after severe preeclampsia or eclampsia; serious postpartum or post-abortion complications (infection, haemorrhage, trauma) except uterine rupture or perforation (see 'Special' below)
- Venous thromboembolism (VTE) (current on anticoagulation)
- Unexplained vaginal bleeding (before evaluation), suspicious for serious condition; PID (current); purulent cervicitis, gonorrhoea, chlamydia; malignant trophoblast disease; pelvic cancers
- IHD (current); heart disease due to blocked or narrowed arteries
- Gall bladder disease with symptoms (current); viral hepatitis (acute or flare)
- Severe anaemia (iron deficiency <7g/dl)
- Lung disease (acute bronchitis or pneumonia)
- Systemic infection or significant gastroenteritis
- Abdominal skin infection
- Undergoing abdominal surgery for emergency or infection, or major surgery with prolonged immobilisation

Special precautions 52

These conditions require a setting with an experienced surgeon and staff, with equipment for general anaesthesia and back up medical support:

- Several conditions together that increase chances of heart disease or stroke, (such as older age, smoking, high blood pressure); BP moderately or severely raised (systolic ≥160); vascular disease (coronary heart disease, peripheral vascular disease, TIA or hypertensive retinopathy); valvular disease, congenital heart disease (complicated)
- endometriosis; fixed uterus due to previous surgery or infection; known pelvic tuberculosis; previous complex abdominal or pelvic surgery, hernia (abdominal wall or umbilical), postpartum or post abortion uterine rupture or perforation⁵²
- Diabetes for more than 20 years or damage to arteries, vision, kidneys, or nervous system caused by diabetes
- SLE (positive or unknown antiphospholipid antibodies with severe thrombocytopenia or on immune-suppressive treatment); hyperthyroidism; coagulation disorders; cirrhosis (severe decompensated); chronic asthma, bronchitis, emphysema or lung infection; pelvic tuberculosis; abdominal wall or umbilical hernia
- HIV with advanced or severe clinical disease and using anti-retrovirals
 These women should be urged to use Condoms in addition to permanent contraception.

Complications

Laparoscopic and mini-laparotomy methods⁶

- Complications with the procedure: Injuries to bowel, bladder, blood vessels⁵¹ or ureter; diaphragmatic or shoulder pain; risks of general anaesthesia; excessive bleeding or infection, unsatisfactory placement of devices.
 Mortality rates are low for tubal ligation (~4 in 100,000 procedures).
- Complications long term: possibility of pregnancy 2-3 in 1000 women at 10 years (of these 40% are ectopic); if ceasing hormonal contraception, menstrual cycles may be irregular or heavier without hormonal control.
- See also RANZCOG patient information pamphlet: "<u>Laparoscopy</u>" (external website)

Regret

Regret is more common if permanent contraception is performed with a caesarean section, with unstable personal relationships, in younger or nulliparous women,⁶ if coercion from health professional or partner, or if psychosexual issues present.⁵¹ More care is required when counselling women under 30 years old, and those without children.⁵¹ If permanent contraception is to occur at caesarean section, counsel at least 2 weeks in advance.⁵¹

Medical history⁶

Include:

- past and present illnesses, medical conditions, allergies and risk factors for surgery (see also cautions/ delay/ special conditions section)
- previous operations, including gynaecological procedures, previous anaesthetic problems, limitations on activity, substance abuse, social situation
- detailed menstrual obstetric history, history of pelvic disease, current contraception & medications
- discussion regarding the decision for permanent contraception (see also counselling below)
- past or present anxiety, depression or mental health conditions that may affect decision making or recovery

Examination

- a blood pressure; weight and height to calculate BMI (obesity increases risks⁵¹)
- if required- auscultation of heart and lungs; abdominal/ bimanual pelvic palpation⁵¹; examination of the skin at the operative site

Investigations

- Exclude the possibility of pregnancy at the time of procedure
- Investigate for STIs and attend Cervical Screening Test if required
- Order additional tests as required prior to Pre-admission Clinic or hospital admission e.g. cardiac assessment, X-rays

Counselling

- Provide women with printed information, such as 'OG09: Laparoscopic Sterilisation' from Department of Health WA <u>Procedure Specific Information</u> <u>Sheets</u> (access and printing for WA Health employees through Healthpoint and EIDO Healthcare Australia); RANZCOG pamphlet <u>Laparoscopy</u> (external website) as needed
- 2. Discussion should include:
 - Decision making: alternative contraceptive methods, including LARC-long acting options and vasectomy as an alternative⁵¹; what & who influenced the permanent contraception choice and any ambivalence or coercion by partner or others; how long considered permanent contraception; what role fertility plays in the woman's and/ or partner's concept of sexuality.⁶
 - Detailed information about the procedure, preparation required, and risk of complications^{6, 51} - visceral or blood vessel injury 2 in 100,

- conversion to laparotomy, risk for some ovarian carcinomas from the fallopian tubes left insitu and consideration of bilateral salpingectomy)
- Any medical issues that can affect the procedure⁶ e.g.- poor access to fallopian tubes due to adhesions etc.
- The use of contraception until permanent contraception occurs; and that permanent contraception provides no protection from STI⁶
- Irreversible nature of permanent contraception and poor reversal success rates. Successful reversal is most likely if clips are used on the mid-isthmus portion of tube. Reversal operation is not funded by Medicare and in vitro fertilisation (IVF) could be an alternative.
- Post-procedure signs of ectopic pregnancy⁵¹, infection and complications
- Failure rates (2 in 1000) and if pregnancy occurs after the procedure, there is increased risk of ectopic pregnancy (4 in 10); inform about post-procedure signs of ectopic pregnancy
- Risk of future regret⁵¹, if situation changes (e.g. death of children/partner, breakup of relationship/marriage)
- The risks and benefits of bilateral salpingectomy should be discussed with patients who desire permanent contraception.⁵³
- High-grade serous tumours of the ovary and peritoneal surface epithelium (the most common histologic sub-type of epithelial ovarian cancer) may originate in the fallopian tubes. There is evidence of benefit in reducing rates of ovarian cancer or tubal pathology if both tubes are removed as a method of permanent contraception.
- Although bilateral salpingectomy increases the operation time, it does not affect ovarian function or increase risk of readmissions, blood transfusions, postoperative complications, infections, or fever compared with tubal ligation.⁵³
- In some centres around Australia, bilateral salpingectomy is being offered as a first option and Filshie clips reserved for patients with difficult access to fallopian tubes.

Timing of the procedure

- In a woman having menstrual cycles or switching from another method the
 procedure can be performed at any time within 7 days after the start of her
 monthly bleeding. No need to use another method before the procedure.
- If it is more than 7 days after the start of her monthly bleeding, or in a woman with irregular cycles, she can have the procedure any time it is reasonably certain she is not pregnant.

- If she is switching from oral contraceptives, she can continue taking pills until she has finished the pill pack to maintain her regular cycle.
- If she is switching from an IUD, she can have the procedure immediately, but IUD needs to be removed after the next menstrual cycle after permanent contraception procedure.
- If using the progestogen only implant, this can be removed at the time of procedure or any time afterwards.⁵¹
- Within 48 hours after uncomplicated abortion or miscarriage, if she has made a voluntary, informed choice in advance.
- After using EC- The permanent contraception procedure can be done within 7
 days after the start of her next monthly bleeding or any other time if it is
 reasonably certain she is not pregnant. Give her a backup method or oral
 contraceptives to start the day after she finishes taking the ECPs, to use until she
 can have the procedure.
- After childbirth- Immediately or within 7 days after giving birth, if she has made a voluntary, informed choice in advance.
- Any time 6 weeks or more after childbirth if it is reasonably certain she is not pregnant. Tubal occlusion should ideally be performed after some time has elapsed following childbirth.
- The decision to perform tubal occlusion at the time of caesarean section should be discussed and consented at least 2 weeks in advance.³⁶
- Women should be informed that intrapartum, postpartum and post-abortion requests by women for permanent contraception have an increased regret rate and possible increased failure rate.⁵¹

Consent

- Obtain written consent for the procedure on the MR295 Generic Consent Form. It
 is good practice to record discussions in the medical file and in a letter to the
 referring doctor.
- The woman's decision for permanent contraception does not require consent from a partner.⁶
- If the woman lacks capacity to consent, the decision can only be made under direction of appropriate state authority. See also:
 - RANZCOG C-Gen 2A: Consent and Provision of Information to Patients in Australia Regarding Proposed Treatment (external website, PDF, 216KB)
 - Department of Health WA Consent to Treatment Policy (PDF, 1.51MB, 2016)
 - ➤ RANZCOG Fertility and Menstrual Management in Women with an Intellectual Disability (C-Gyn 10) (external website, PDF, 255KB)

 The operating health practitioner should ensure they are satisfied that a complete history, information exchange and examination have occurred, and that the woman does not have any concurrent conditions needing extra precautions/consideration.⁵¹

Pre admission clinic

Women should attend a Pre-admission Clinic (PAC) outpatient appointment within one week of the booked date for the procedure to allow anaesthetic and medical review. If attending Day Surgery her medical history will determine if she needs to attend the PAC. The woman will be advised of any preparation required prior to the procedure and timing of surgery at this appointment.

- Ensure the patient uses other forms of contraception/abstains to prevent pregnancy prior to the procedure, and this contraception should continue until the next menses.
- A sensitive urine pregnancy test is performed on admission⁵¹

Post-procedural care

Women should be provided information on their surgery, any complications that occurred, recovery information and any follow-up care required.⁵¹ See also relevant Department of Health WA <u>Procedure Specific Information Sheets</u> (access and printing for WA Health employees through Healthpoint and EIDO Healthcare Australia) or RANZCOG patient information pamphlets.

Additional resources:

- Department of Health WA <u>Procedure Specific Information Sheets</u> (available to WA Health employees through Healthpoint and EIDO Healthcare Australia).
 See NMHS- KEMH- Procedure information- Gynaecology (if relevant):
 - Laparoscopic Sterilisation (OG09)
 - Laparoscopic Oophorectomy (OG25)
- FSRH guideline: Male and Female Sterilisation (external website)
- RANZCOG patient information: Hysterectomy (external website)
- SHQ patient information: <u>Sterilisation</u> (external website)

Special situations

Quick start contraception

See FSRH link: Quick Starting Contraception (external website)

Switching or starting methods of contraception

See FSRH link: <u>Switching or Starting Methods of Contraception</u> (external website)

Contraception for specific populations

For contraception in women: aged over 40 years, cardiac disease, inflammatory bowel disease, overweight / obesity, and young people, see FSRH link:

<u>Contraception for Specific Populations</u> (external website)

Abbreviations

CHC Combined hormonal contraceptive

COCP Combined oral contraceptive pill

CST Cervical screening test

Cu-IUD Copper bearing intrauterine device

DMPA Depot medroxyprogesterone acetate

EC Emergency contraception

FSRH Faculty of Sexual and Reproductive Healthcare

HIV Human immunodeficiency virus

IHD Ischaemic heart disease

IUD / IUS Intrauterine device / system

LARC Long acting reversible contraceptive

LNG Levonorgestrel

LNG-IUD Levonorgestrel intrauterine device

MEC Medical eligibility criteria

NSAIDs Non-steroidal anti-inflammatory drugs

PID Pelvic inflammatory disease

POP Progesterone only pill

PPC Post-partum contraception

RANZCOG The Royal Australian and New Zealand College of Obstetricians and

Gynaecologists

SHQ Sexual Health Quarters

STI Sexually transmitted infection

UTI Urinary tract infection

TIA Transient ischaemic attack

UKMEC United Kingdom medical eligibility criteria

WHO World Health Organization

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Additional resources (from postpartum chapter)

- Cooper M, Boydell N, Heller R, Cameron S. Community sexual health providers' views on immediate postpartum provision of intrauterine contraception. BMJ Sexual & Reproductive Health, 2018, 44 (2) 97-102.
- Crow M, Walker V, Braunholtz-Speight J, Singh M. Improving the provision of postnatal contraception within inpatient wards: A UK pilot study. BMJ Sexual & Reproductive Health, 2020.
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Related policies and legislation

Legislation -

- <u>Guardianship and Administration Act 1990</u> (part 5, division 3: Limitations on permanent contraception (sterilisation) of persons under guardianship or where application for guardianship made);
- Mental Health Act 2014

Policies:

Department of Health WA:

- OD 0657/16: Department of Health WA Consent to Treatment Policy (2016) (PDF, 1.51MB)
- WA Youth Health Policy 2018-2023 Toolkit (Resources for Health Professionals): Working with Youth- A legal resource for community based health workers (PDF 1.64MB) (2013) (assessment as mature minor)
- NMHS Mental Health: <u>Long Acting Reversible Contraceptives</u> (available to WA Health employees through Healthpoint)

Related WNHS policies, procedures and guidelines

- KEMH O&GD Clinical Guidelines: <u>Sexually Transmitted Infections</u>; <u>Vaginal Procedures</u>
- KEMH Pharmacy: <u>Copper IUD</u> (resource available to WA Health employees through Healthpoint)
- Note- A local copy of the <u>UKMEC Summary Table (Sept 2019)</u> has been uploaded to Healthpoint
 to enable access in the event of link access issues. The copy is considered uncontrolled and was
 current as at 11.9.2020. Check for updates if required from <u>FSRH (external website)</u>.

Useful resources

- <u>KEMH Procedural Gynaecology Outpatient Clinic</u> (WA Health employees access via Healthpoint)
- KEMH Pharmacy Patient Information brochure: 'Contraceptive Methods'
- Department of Health WA (patient websites):
 - HealthyWA (external websites): <u>Contraception</u>; <u>Condoms</u>; <u>Contraceptive pill (the pill)</u>; <u>Diaphragms</u>; <u>Injectable hormonal contraceptive</u>; <u>Contraceptive implants</u>; <u>Emergency Contraception</u>; <u>Intra-uterine device</u>; <u>Fertility awareness (natural family planning)</u>; <u>Sterilisation</u>; <u>Bacterial Vaginosis</u>
 - > Get the Facts: Emergency Contraceptive Pill (the morning after pill) (external website)
- Department of Health WA <u>Procedure Specific Information Sheets</u> (access and printing for WA Health employees through Healthpoint and EIDO Healthcare Australia): See Procedure Information: Gynaecology.
 - ➤ Topics include: Insertion of an IUS; Inserting an IUCD; Inserting a Contraceptive Implant; Laparoscopic Sterilisation
- <u>ImplanonNXT® Product Information</u> (2020) (external website)
- RANZCOG (external websites)
 - Consent and Provision of Information to Patients in Australia Regarding Proposed
 Treatment (C-Gen 2A) (2020) (PDF, 216KB)
 - ➤ Depot Medroxyprogesterone Acetate (C-Gyn 04) (2018) (PDF, 270KB)
 - ➤ Fertility and Menstrual Management in Women with an Intellectual Disability (C-Gyn 10) (PDF, 255KB)
- Sexual Health & Family Planning Australia (external site)
- <u>Sexual Health Quarters</u> (SHQ) (external sites)
 - Patient information: <u>Combined Oral Contraceptive Pill</u>; <u>Condoms</u>; <u>Contraception Choices</u>; <u>Contraceptive Implant</u>; <u>Contraceptive Injection</u>; <u>Diaphragm</u>; <u>Emergency Contraception</u>; <u>Fertility Awareness Methods</u>; <u>IUD Copper</u>; <u>IUD- Hormonal</u>; <u>Progestogen Only Pill</u>; <u>Sterilisation</u>; <u>Vaginal Contraceptive Ring</u> (Note: Refer to SHQ website for multicultural contraception/ sexual health resources)
 - Health professionals: <u>Contraception: A Guide for Youth and Community Workers</u>) (PDF, 1.77MB); <u>Contraceptive Card</u> (1.12MB); <u>Guidance for bleeding on progestogen-only contraception</u> (PDF, 155KB)
- WHO (2015) Medical Eligibility Criteria Wheel for Contraceptive Use (external site, PDF, 404KB)

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	control, breastfeeding amenorrhoea, implant, Depo, lactational amenorrhoea,
	post partum contraception, contraception after childbirth, contraception after

	baby, Essure procedure, micro insert, micro-coil, micro-spiral, laparoscopic tubal ligation, Filshie clips, female sterilisation, sterilisation, tubal occlusion, hysteroscopy, permanent contraception, contraception consent, implanon removal, etonogestrel, non-palpable contraception, direct ultrasound guidance, Etonogestrel Implant, Implanon NXT, insertion of Implanon, progesterone, Implanon, hormone implant, long acting reversible contraceptive, LARC, Depot medroxyprogesterone acetate, DPMA, contraception, depo provera, ralovera, depo, progestin only, birth control, progestogen, progesterone, IM injection, COCP, oral contraceptive, the pill, birth control, contraceptive pill, POP, progestogen only pill, oral contraceptive, progestogen, lactating, Intrauterine, contraceptive, hormonal IUD, IUD, Family Planning, fertility, prevent pregnancy, Mirena, Contraception, barrier methods, condoms, diaphragms, diaphragm, female condom, condom failure		
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