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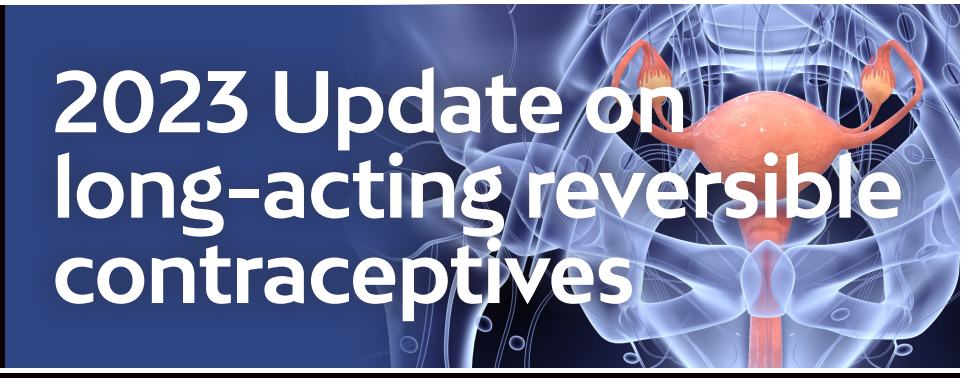
2023 Update on long-acting reversible contraceptives



Making Education Easy 2023

About the expert

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After my medical degree at Trinity College Dublin, I worked at the Rotunda Hospital and then King's College Hospital in London. In 1983, I came to New Zealand and joined Family Planning, becoming the Medical Director and National Medical Spokesperson from 1988-1992. In 1991, I completed the MPH at Yale University in New Haven and on my return took up an academic position in the Department of Obstetrics and Gynaecology, University of Auckland. I was Associate Professor of Women's Health until my retirement. At present, I continue my contraception and menopause clinic at Greenlane Clinical Centre and and have clinics in abortion medicine at Epsom Day Unit.

Abbreviations used in this review
CI = confidence interval
FSRH = Faculty of Sexual and Reproductive Healthcare
GP = general practitioner
IUD(s) = intrauterine devices
IUS(s) = intrauterine system(s)
LARC(s) = long-acting reversible contraceptives
RANZCOG = Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RR = relative risk
STI(s) = sexually transmitted infection(s)
UKMEC = United Kingdom Medical Eligibility Criteria for Contraceptive use

Long-acting reversible contraceptives (LARCs) provide a very effective method of contraception, and they do not require ongoing effort on the part of the women. This update of the recent literature outlines the benefits, as well as any potential management considerations, associated with the use of the LARCs currently available in New Zealand. In addition, the use of LARCs in specific patient populations is briefly reviewed. This publication has been commissioned by Bayer. The production of the content is entirely independent but has been reviewed by Bayer for technical accuracy prior to publication.

Benefits of long-acting contraceptives

LARCs are methods of birth control which provide effective contraception for an extended period without requiring user action and include intrauterine devices (IUDs), intra-uterine systems (IUS), and contraceptive implants.[1-7]

LARCs are a very effective form of contraception.[3] The estimated percentage of women experiencing an unintended pregnancy within the first year of typical use was <1% with LARCs, but 6% with injectable contraceptives, 9% with the oral contraceptive pill, and 18% using a male condom.[8] In addition, the 'typical use' failure rates of LARCs are about the same as 'perfect use' failure rates.[8]

As well as being highly effective, LARCs offer a number of other benefits to users (**Table 1**).[1, 2, 8]

Table 1. Benefits of long-acting reversible contraceptives

- Most effective reversible contraceptive methods available[1, 2, 8]
- Do not require ongoing effort from the woman - "fit and forget" [2, 9]
- Require fewer visits to healthcare professionals[2, 9]
- High rates of user satisfaction as indicated by high continuation rates[10-13]
- Easily reversible with rapid return to fertility[14, 15]
- More cost effective than oral contraceptives or injectable contraceptives[14, 15]
- Associated with fewer contraindications than oral contraceptives[4, 5, 7]
- Suitable for women of all ages and parity, including young nulliparous women[2, 16-20]

Compared with other shorter-acting forms of contraception, which may require regular use on a daily, weekly, monthly, or quarterly basis, LARCs are associated with high rates of continuation and patient satisfaction.[10-13] In the US contraceptive CHOICE Project, involving more than 9000 women of reproductive age, LARC users were more likely than non-LARC users to continue use at 12 months (86% vs 55%) and at 24 months (77% vs 41%).[10, 11] Satisfaction rates in this study were similarly high in LARC users and mirrored continuation rates.[10, 11]

There are very few contraindications to the use of LARCs, with the majority of women being eligible for LARCs (including young, nulliparous women and those postpartum; see below).[2, 4, 5, 7, 16-22] LARCs are also reversible, with women rapidly returning to their normal fertility after removal.[14, 15] In recognition of these benefits, numerous national and international consensus statements/guidelines (including those of the World Health Organization (WHO),[21] and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists [RANZCOG][2]) support LARCs as a first-line option for women of all ages and parity, including young nulliparous women.[2, 16-22]

LARCs in New Zealand

LARCs available in New Zealand (**Table 2**) and funded by PHARMAC now include two levonorgestrel-releasing IUSs (Mirena® and Jaydess®),[4, 5, 23] the copper IUD (Choice Load 375; Choice TT380),[6] and the subcutaneous levonorgestrel implant (Jadelle®).[7]

Although insertion costs still apply in primary care, subsidies may be available depending on the local or regional Health New Zealand or the Māori Health Authority team or primary health organisations.[9] Districts provide low cost consultations ($5) and free LARCs for women on low incomes in some/selected primary care practices. Family Planning, Youth One Stop Shops, and Sexual Health services offer free or low-cost contraception services for many women. Reimbursement for LARC insertion may be available for eligible patients/providers. Health Pathways provides further detail about subsidised insertion options. See: NZ Regional Clinical Pathways | Goodfellow Unit.

Table 2. Contraceptive efficacy for LARC methods available in New Zealand Aotearoa

LARC method	Failure rate
LNG-IUS 52mg (Mirena®)	0.2% at 1 year;[4] 0.7% at 5 years[4]
LNG-IUS13.5mg (Jaydess®)	0.4% at 1 year; 0.9% at 3 years[5]
Cu-IUD (Choice Load 375)	1% at 1 year[3, 6]
Cu-IUD (Choice TT380 short + standard)	0.1-1% at 1 year[3, 6]
LNG implant (Jadelle®)	0.1% for year 1 to 3;[7] 0.0% for year 4;[7] 0.8% at year 5[7]

Cu-IUD = copper intra-uterine device; LNG = levonorgestrel; LNG-IUS = levonorgestrel intra-uterine system.

An online Family Planning survey conducted in May 2020 (6764 respondents) indicated that among respondents who reported they were currently using contraception, the IUS (Mirena®, Jaydess®) was the most commonly used LARC (17%), followed by the Jadelle® implant (10%), and an IUD (9%). Total LARC use among respondents was 36%.[25]

Since PHARMAC started funding IUSs for contraception at the end of November 2019,[23] there has been an increase in the number of women starting an IUS, and also an increase in the IUS starts as a proportion of all LARC starts among Family Planning clients. In particular, from 2018/19 to 2020/21, a 400% increase in use of IUSs was seen among Pasifika clients, a 200% increase among Māori clients, and about a 140% increase in European/other ethnicities.[26]

Patient-centred contraceptive counselling

Evidence-based patient counselling and education on LARC methods must occur so that misperceptions around the use of LARCs are dispelled, and patients are fully informed when making contraceptive decisions.[27] Advice and information provided about LARCs must be patient focused, and women should be provided with the method of contraception that is most acceptable to them, unless it is contraindicated.[27] Women considering LARC methods should receive detailed information – both verbal and written – that will enable them to choose a method and use it effectively. Information should outline the method's contraceptive efficacy, duration of use, risks and possible side effects, non-contraceptive benefits, the procedure for initiation and removal/discontinuation, and when to seek help while using the method.

Training clinicians in evidence-based contraceptive counselling and providing women with this information increases the use of LARCs, as evidenced by outcomes from the CHOICE Project study and the ACCORd study.[10, 11, 28]

The US CHOICE Project provided women with standardised information about, and access to, LARCs free of charge within reproductive health and family planning clinics; the women were then free to choose their contraceptive method.[10, 11] With the barriers of cost, knowledge, and access removed, 75% of the women chose a LARC method (46% selected the Mirena®, 12% selected the copper IUD, and 17% selected a subdermal implant) compared with an estimated 5% using LARCs before the study started.[10] More women were satisfied with the LARC method of contraception than a non-LARC method at 12-months (84% vs 53%).[11]

Similarly, the randomised Australian Contraceptive ChOice pRoject (ACCORd) found that training family physicians in effectiveness-based contraception counselling and providing rapid access to LARC insertion clinics increased LARC use.[28] Significantly more women in an intervention group (who received structured contraceptive counselling from intervention-trained family physicians) than in a control group (who received the usual contraceptive care from their family physician) had a LARC inserted at 4 weeks (19.3% vs 12.9%; p=0.033), at 6 months (44.4% vs 29.3%, p=0.001), and at 12 months (46.6% vs 32.8%; p=0.0015). The levonorgestrel IUS was the most commonly chosen LARC in the intervention group.[28]

In New Zealand, patients can access information about LARCs from:

Family Planning: www.familyplanning.org.nz

Local general practitioner (GP): www.healthpoint.co.nz

Health Navigator: https://www.healthnavigator.org.nz

Healthinfo: https://www.healthinfo.org.nz/patientinfo/Long%20Acting%20Contraceptives.pdf

Intrauterine contraception device

Two basic types of intrauterine contraception device (IUCs) are available in New Zealand; the non-hormonal copper IUD and the levonorgestrel IUS.[3]

Levonorgestrel IUS

Two levonorgestrel IUSs (**Table 3**) are fully subsidised without restriction in New Zealand.[23] These are:

- a levonorgestrel 52 mg device (Mirena®) which is indicated for contraception for 5 years.[4] In addition, this intrauterine system is also indicated and approved in New Zealand for:
  1) the treatment of idiopathic menorrhagia provided there is no underlying pathology; and
  2) the prevention of endometrial hyperplasia during oestrogen replacement therapy;
- a levonorgestrel 13.5 mg device (Jaydess®) which is indicated for contraception for up to 3 years.[5]

The narrower insertion tube and smaller device size of Jaydess® compared with Mirena® (**Table 3**) may be a consideration for women who have not had a vaginal birth or who have a smaller endometrial cavity.[4, 5, 29] Both systems have a reservoir on their stem which slowly releases levonorgestrel directly to the endometrium. Neither device should be used for emergency contraception.

Mechanism of action: Both Mirena® and Jaydess® primarily work by thickening the cervical mucus which prevents sperm from traveling up into the uterus.[30] In addition, local progestogenic effects within the uterine cavity cause decidualisation and atrophy of the endometrium, providing a decrease in menstrual flow.[31]

Efficacy: Both Mirena® and Jaydess® provide similarly effective contraception (**Table 2**).[4, 5, 32] When inserted according to the manufacturer's insertion instructions, Mirena® has a failure rate of approximately 0.2% at 1 year and a cumulative failure rate of approximately 0.7% at 5 years;[4] Jaydess® has a failure rate of approximately 0.4% at 1 year and a cumulative failure rate of approximately 0.9% at 3 years.[5]

Side effects: Common side effects associated with either Jaydess® or Mirena® are shown in **Table 3**. Hormone-related side effects, such as breast tenderness and mood changes, associated with these IUSs have been shown to be no different from those associated with the use of a copper IUD.[33]

In the first few months of use of either device, the initial bleeding pattern may include spotting, shorter or longer periods, or irregular bleeding.[4, 5] However, the number of bleeding days should decrease over time. Jaydess® is less likely to cause amenorrhoea than Mirena®.[4, 5, 32]

Details relating to the risk of perforations and cervical shock associated with IUDs/IUSs are outlined below.

WHO data suggest there is a small increased risk of pelvic infection (1.6 cases per 1000 woman-years of use) in the first 20 days after insertion, often relating to asymptomatic and unrecognised sexually transmitted infections (STIs).[2, 34] After the first 20 days, the rate of pelvic inflammatory disease was similar in users of an IUD to that expected in the general population not using an IUD.[2]

Non-contraceptive benefits: Both Mirena® and Jaydess® reduce menstrual bleeding; however, the extent of the reduction is greater in patients fitted with Mirena®.[4] In New Zealand, only Mirena® is indicated for the treatment of heavy menstrual bleeding.[4] See section on "Women with heavy bleeding" below. In addition, Mirena® is indicated for the prevention of endometrial hyperplasia during oestrogen replacement therapy.[4]

Patient screening: Before insertion, the woman must be informed of the efficacy, risks, and side effects of the Mirena® or Jaydess®.[2, 4, 5] These IUSs do not protect against STIs, and all women should be advised that additional barrier methods of contraception should be used if they are at risk of STIs.

A careful clinical history and physical examination are essential to identify any contraindications to their use prior to insertion.[2, 9] There are few contraindications to IUS use.[4, 5] The United Kingdom Medical Eligibility Criteria for Contraceptive use (UKMEC) is a useful and easily accessible guide which outlines eligibility criteria for the use of IUSs.[35]

Insertion: Mirena® and Jaydess® should only be inserted by physicians/healthcare professionals who are experienced in inserting IUDs and/or have undergone training relating to the insertion procedure.[4, 5]

IUSs can be inserted at any time in the menstrual cycle if there is reasonable certainty that the woman is not pregnant.[4, 5, 36] Immediate contraceptive cover is given if the IUS is inserted within seven days of the onset of menstruation. At other times in the cycle, additional contraception will be needed for seven days post insertion.[36] Either of these devices can be replaced by a new IUS at any time in the cycle. Mirena®/Jaydess® can also be inserted immediately after a first trimester abortion.[36] The IUS can also be inserted immediately post-delivery*, or at 6 weeks.[37]

*Unapproved use

Table 3. Comparison of Jaydess® and Mirena®[4, 5, 43]

	Jaydess®[12]	Mirena®[11]
	28 mm horizontal width Silver ring 30 mm vertical length	32 mm horizontal width 32 mm vertical length
Indication	Contraception	Contraception Idiopathic menorrhagia provided there is no underlying pathology Prevention of endometrial hyperplasia
Total levonorgestrel in reservoir	13.5 mg	52 mg
Estimated mean dissolution rate of levonorgestrel	6 µg/24 hours over 3 years	15 µg/24 hours over 5 years
Approved duration of use for contraception	3 years	5 years
Dimensions of T-frame	28 x 30 mm	32 x 32 mm
Inserter tube width	3.8 mm	4.4 mm
Colour of removal threads	Brown	Brown
Failure at 1 year	0.4%	0.2%
Visible on ultrasound and X-ray	Yes (with silver ring on stem to distinguish from Mirena®)	Yes
Rate of amenorrhoea	6% at 1 year 12% at 3 years	18.6% at 1 year 30–40% at 5 years
Adverse events	Hormonal side effects with both IUSs can include headache, acne, breast tenderness, mood changes, and irregular bleeding If these occur, most will resolve with continued use of the IUSs	
Additional benefits	Reduces heavy menstrual bleeding, but not approved for this indication	Reduces heavy menstrual bleeding, and is approved for this indication

Patient resources:

Information on Mirena® for patients is available from:
https://www.medsafe.govt.nz/consumers/cmi/m/Mirena.pdf

https://www.healthnavigator.org.nz/media/18421/by11252-mirena-patient-booklet-a5_final.pdf

Information on Jaydess® for patients is available from:
https://www.healthnavigator.org.nz/media/11887/by9401_jaydess-patient-booklet_final_officeprint.pdf

https://www.medsafe.govt.nz/consumers/cmi/j/jaydess.pdf

Copper IUD

Copper IUDs available and fully funded in New Zealand are:[3]

- Choice Load 375
- Choice TT380 Standard and Short

Mechanism of action: The copper IUD prevents fertilisation through a cytotoxic inflammatory reaction that is spermicidal.[38] In addition, its endometrial inflammatory effect prevents implantation should fertilisation occur.[39]

Indications: Licensed indications for copper IUDs are for ongoing contraception as well as emergency contraception provided it is inserted into the uterine cavity after unprotected intercourse up to 5 days after the estimated date of ovulation (day 19 in a 28-day cycle; day 21 in a 30-day cycle). The copper IUD may then either be removed after the next period or used as ongoing contraception.[6, 40] Copper IUDs can be used in clinical scenarios where the use of hormonal contraceptives is not recommended, such as in women with previous breast cancer.[9]

Efficacy: Copper IUDs are highly effective, with an estimated failure rate with typical use of <1% after 1 year of use.[3, 8]

Duration of use: Copper IUDs are long acting, and effective for up to 10 years depending on the device.[9] If inserted over the age of 40 years, they may be left *in situ* until the menopause.[40]

Side effects: Although copper IUDs typically do not change menstrual frequency, currently available products can increase menstrual flow and cramping-type abdominal pain.[9, 39-42] Bleeding and cramping typically decrease over the first 6 months of use, and most women report being satisfied with this contraceptive method.[9, 41, 42]

See comments in later sections regarding risk of perforations with IUDs.

Insertion: These devices should only be inserted by physicians/healthcare professionals who are experienced in inserting copper IUDs and/or have undergone training relating to the insertion procedure of the devices.[6]

The copper IUD can be inserted at any time in the menstrual cycle if there is reasonable certainty that the woman is not pregnant.[6] It is immediately effective. Copper IUDs can be inserted immediately (within 10 minutes) post-abortion, or vaginal delivery.[37]

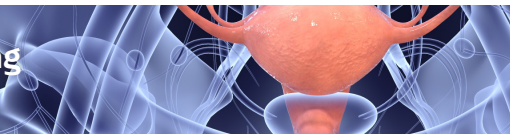
Patient resources:

Information on copper IUDs for patients is available from:
https://www.mhcs.health.nsw.gov.au/publications/8700/oth-8700-eng.pdf/@@display-file/file/oth-8700-eng.pdf

https://www.familyplanning.org.nz/advice/contraception/intra-uterine-device-iud

Resources for healthcare professionals for IUDs

- Family Planning provides Contraceptive Counselling and LARC insertions and removals for all eligible healthcare professionals.[52] https://www.familyplanning.org.nz/courses
- A continuing professional development online ecourse on IUDs is available from the University of Auckland's Goodfellow Unit.



Management of problems associated with intra-uterine contraception

Perforation

Uterine perforation is a rare risk associated with IUC use.[44, 45] Perforation or a penetration of the uterine corpus or cervix occurs most often during insertion of an IUD, although it may not be detected until sometime later.[4, 5]

In the European Active Surveillance Study for Intrauterine Devices involving 61,448 women who were new users of levonorgestrel-releasing IUSs and copper-IUDs, an analysis at 12 months found the overall perforation rate was 1.4 per 1000 insertions for users of levonorgestrel-releasing IUSs and 1.1 per 1000 insertions for copper IUD users.[45] The strongest risk factors for uterine perforation were breastfeeding at time of insertion and a time since last delivery of less than 36 weeks, with no differences between women using levonorgestrel-releasing IUSs or copper IUDs.[45] Patients of more experienced clinicians were less likely to suffer perforation, regardless of IUC type.[45]

Excessive pain or bleeding during insertion, or lost strings may be indicative of a perforation. In the event of a perforation, an ultrasound or X-ray is typically performed to determine the degree of perforation or to locate the device, which should be removed as soon as possible.[9, 46]

The perforation usually heals without complications, and a further attempt at insertion can be made no less than 4 weeks later.[40]

Vasovagal collapse/cervical shock

Cervical stimulation during insertion of IUCs can rarely cause a vasovagal reaction, bradycardia, and other arrhythmias.[36] In healthy women, vasovagal incidents usually resolve with simple resuscitation measures; rarely, bradycardia persists and treatment with intravenous or intramuscular atropine is required.[36]

Expulsions

Partial or complete expulsions of IUCs may occur, with the expulsion rates for Mirena® and Jaydess® being similar to those of other IUCs.[4, 5, 36] Partially expelled IUCs should be removed and a new IUC inserted, provided pregnancy has been excluded and no other contraindications exist.[4, 5]

Ectopic pregnancy

The overall risk of ectopic pregnancy is reduced with use of an IUC when compared to using no contraception.[3, 47, 48] If pregnancy occurs with an IUC *in situ*, there is an increased risk of an ectopic pregnancy occurring, with some studies indicating that half of the pregnancies that occurred were ectopic [3, 47] However, the absolute risk of ectopic pregnancy with a IUC is low. For example, the overall incidence of ectopic pregnancy with Jaydess® is approximately 0.11 per 100 women-years.[5] This rate is lower than in women not using any contraception (0.3-0.5 per 100 women-years).[5] Similarly, in clinical trials, the ectopic pregnancy rate with Mirena® was approximately 0.1% per year. In a large, prospective, cohort study with an observation period of 1 year, the ectopic pregnancy rate with Mirena® was 0.02%.[4] This rate is lower than in women not using any contraception (0.3–0.5 % per year).[4]

Users of IUCs should be informed about symptoms of ectopic pregnancy.[3, 47] The possibility of ectopic pregnancy should be considered in individuals with an intrauterine method who present with abdominal pain especially in connection with missed periods or if an amenorrhoeic individual starts bleeding. If a pregnancy test is positive, an ultrasound scan should be urgently carried out to locate the pregnancy.[3, 47]

Management of possible pain

Expectation or fear of possible pain can be a reason given by women not insert an IUC.[3] However, studies suggest that the majority of individuals report that pain during IUC fitting is mild (visual analogue score 1-3/10) or moderate (score 4-6/10) rather than severe (7-10/10), even without the use of analgesia.[49, 50]

The FSRH recommends working in partnership with users to establish the best strategies for reducing anxiety and the most effective interventions for minimising pain at IUC insertion.[51] FSRH considers it crucial that it is the patient's informed decision to use intrauterine contraception.[51] The insertion procedure should be carried out by trained healthcare professionals who are mindful of the patient experience and understand that a minority of individuals do report severe pain associated with the procedure.[51] The FSRH recommend that healthcare professionals should create a reassuring, supportive environment, offer appropriate analgesia (and referral on to another provider if they cannot offer this), and ensure that the patient is aware that they can request that the procedure stops at any time.[51]

In New Zealand, pre-insertion oral analgesia (paracetamol and/or ibuprofen) is recommended by the Ministry of Health.[3] However, FSRH did not find the evidence to support pre-insertion analgesia to be helpful for IUD insertion pain, although it does support the use of oral analgesia for post-insertion pain.[51] Positive reinforcement, distraction, and controlling apprehension are important aspects of expectation and pain management of IUC insertion.[3]

EXPERT COMMENT

IUDs/IUSs provide very effective contraception, and for women not wishing a hormonal method, the copper IUD is an excellent choice. Ensuring that a woman is not pregnant is important before insertion takes place. The FSRH table (see below) offers useful advice.[37] A pelvic examination is required to determine the position of the uterus and a tenaculum applied to the cervix will help straighten the canal during insertion. Routine STI swabs are not required. Taking the history will clarify the need for pre-insertion swabs but should not delay insertion as long as the woman can be easily contacted and treated.

Routine 6-week post-insertion checks are no longer thought necessary. Women should be taught to check for the strings of their device and advised to see a health professional if these seem to be longer or not felt, or if the plastic stem is palpable. It is now recommended that patients using a menstrual cup with an IUS should check their IUS threads after a period. The suction should be gently released before cup removal so that the threads will not get caught between the cup and vaginal wall.

The risk of expulsion is around 1 in 20 and is highest in the first year of use. No action is needed if strings are not visible as long as an ultrasound scan shows the IUD/S is in position in the uterus. A plain abdominal X-ray is recommended, to rule out perforation, if the device is not in the uterus. Devices do not need to be removed if a woman develops pelvic inflammatory disease as long as there is response to antibiotic treatment.

The FSRH supports extended use until menopause of a copper IUD fitted from the age of 40 years or a Mirena® fitted at 45 years. They do not specifically endorse other extended use, although they agree that review of the evidence supports the use of the copper TT380 IUD for 12 years and the Mirena® IUS for 7 years for contraception. Both the FDA and Europe have now approved Mirena for up to 8 years' contraception with efficacy remaining high at more than 99% during years 6 to 8 of use; recommending it be replaced or removed after the end of the eighth year.*

**The reviewer's thoughts and opinions are their own. Bayer does not recommend any usage of its products outside of the New Zealand Data Sheet. Mirena is registered in New Zealand for use for up to 5 years.*

Criteria for excluding pregnancy (adapted from UK Selected Practice Recommendations for Contraceptive Use)[53]

Health professionals can be 'reasonably certain' that a woman is not currently pregnant if any one or more of the following criteria are met and there are no symptoms or signs of pregnancy:

- She has not had intercourse since last normal menses
- She has been correctly and consistently using a reliable method of contraception (including condoms)
- She is within the first 7 days of the onset of a normal menstrual period
- She is not breastfeeding and less than 4 weeks from giving birth
- She is fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months' postpartum
- She is within the first 7 days post-abortion or miscarriage
- A negative pregnancy test, if available, adds weight to the exclusion of pregnancy, but only if ≥3 weeks since the last episode of unprotected sexual intercourse

Levonorgestrel implants

The subcutaneous levonorgestrel implant (Jadelle®) is fully funded for use as a contraceptive method for long-term use (up to 5 years) in New Zealand.[7]

Jadelle® consists of two implants which are inserted subdermally.[7, 54] Each implant contains 75 mg levonorgestrel. The release rate of levonorgestrel is about 100 µg/day at one month after insertion, declining to about 40 µg/day within 1 year, to about 30 µg/day within 3 years and to about 25 µg/day within 5 years.[7]

Mechanism of action: A levonorgestrel implant primarily prevents ovulation.[7, 55, 56] In addition, it alters cervical mucus thus preventing passage of sperm into the uterus.

Effectiveness: Jadelle® provides very effective contraception, with an estimated failure rate with typical use of <0.1% within the first year.[8] Satisfaction with the levonorgestrel implants is generally high.[42]

Patient screening: A Jadelle® implant can be inserted any time as long as the woman is not pregnant.[7] A complete medical and family history should be taken. The most recent UKMEC guidance should be referred to when assessing a woman's eligibility for any contraceptive method including the progestogen-only implant.[20]

Contraindications to use of Jadelle® include: known or suspected pregnancy, active venous thromboembolic disorder, presence or history of severe hepatic disease with liver function values above normal, presence or history of liver tumours (benign or malignant), known or suspected sex hormone-dependent malignancies, and undiagnosed vaginal bleeding.[7]

Insertion and removal: Jadelle® implants are about 43 mm in length and 2.5 mm in diameter.[7] Jadelle® implants are inserted under local anaesthesia in a subdermal position, just beneath the skin, in a narrow V shape on the inside of the upper non-dominant arm. A disposable, sterile trocar should be used, and the implants introduced one at a time.[7] Training is required for the insertion and removal procedures, which should preferably be done by a healthcare professional.[7]

Before insertion of Jadelle®, the woman must be informed of its associated efficacy, risks, side effects, and bleeding pattern changes.[7] This discussion should include the information that a small proportion of women (1.5%) experienced adverse effects when Jadelle® is removed, including multiple or long incisions, pain, difficult removals, and/or the requirement for additional visits. These problems typically occur when the implant has been inserted deeper than the advised subdermal placement.

In women who have not used hormonal contraception in the past month, Jadelle® should be inserted within 7 days from the onset of menstrual bleeding.[7]

If the implants are inserted at any other time, pregnancy must be reliably excluded before insertion and an additional non-hormonal contraceptive method used for at least 7 days after the insertion. The ideal time for inserting a levonorgestrel implant in women currently using combined oral contraceptive is on the day after the last active tablet. The FSRH also provides advice for women starting the progestogen-only implant.[55]

Jadelle® implants may be removed at any time of the menstrual cycle for medical or personal reasons, but they must be removed 5 years from insertion at the latest. Return to fertility is immediate and another contraceptive method should be used if pregnancy is not planned.[7]

Adverse events: Jadelle® implants affect the menstrual bleeding pattern in most women, with irregular, prolonged, and intermenstrual bleeding, spotting, and amenorrhoea being reported.[7]

In general, patterns of bleeding became more stable with increased time.[7, 57] If bleeding is persistent or problematic, pharmacological management may be required. A combined oral contraceptive is usually the first-line treatment to reduce uncontrolled bleeding in patients using a levonorgestrel implant.[9]

A New Zealand study reported that 18% of women who had a Jadelle® implant inserted in a New Zealand Family Planning Clinic had it removed within 1 year of insertion.[57] Similar rates have been reported in other studies in other countries with levonorgestrel implants.[8, 58, 59] The commonest reason for removal was bleeding.[57] In women who had a Jadelle® implant, 34% reported regular period-like bleeding, 27% had irregular bleeding, 22% had amenorrhoea, and the rest of the women reported bleeding patterns such as heavy bleeding or bleeding every two weeks.[57]

The FSRH advise that although some women do report changes in weight, mood, headache, and libido when using the progestogen-only implant, there is no evidence of a causal association.[55] There is no requirement of routine follow-up of the woman with a levonorgestrel implant, but women should be encouraged to return at any time to discuss problems or change their contraceptive method.[55] Women should be advised to return if: they cannot feel their implant or if it appears to have changed shape; they notice any skin changes or pain around the site of the implant; they become pregnant; or they develop any condition that may contraindicate continuation of the method.[55]

Expulsion of implant: Expulsion of an implant may occur before the incision has healed, if the implant was improperly inserted (e.g., very near the skin surface or too close to the incision), or if the insertion site is infected.[7]

The expelled implant should be replaced with a new, sterile implant.

Concomitant medication: Levonorgestrel implants are not a suitable contraceptive method for women using enzyme-inducing medication.[7, 9, 55] The effectiveness of levonorgestrel implants is reduced when women are taking medicines that induce microsomal enzymes (e.g., phenytoin, barbiturates, primidone, carbamazepine, rifampicin, and efavirenz).[7, 9, 55]

Patient resources:

Information on Jadelle® for patients is available from:

https://www.healthnavigator.org.nz/media/14801/jadelle-patient-booklet.pdf

https://www.medsafe.govt.nz/consumers/cmi/j/jadelle.pdf

EXPERT COMMENT

The Jadelle® implant is a very effective contraceptive and has the added benefit of relieving period pain. The FSRH advises that there is no direct evidence that supports earlier replacement for women with high BMI.[55] Women should be advised to seek help early if they have troublesome bleeding. The FSRH advises that after exclusion of other causes of bleeding, implant users with problematic bleeding *who are medically eligible* can be offered a 3-month trial of additional use of combined oral contraception/ contraceptive (outside the product licence) or a 5-day course of mefenamic acid.

There has been a change to the Medsafe Jadelle® document supporting immediate insertion after delivery even if the woman is breastfeeding as research has shown no harmful effects. The position of the insertion site has had various changes over the years. Initially it was recommended that the implant insertion site should be in the groove between the biceps and the triceps muscle. However, to avoid the large blood vessels and nerves that lie deeper in the connective tissue between these muscles, the advice was changed to recommend implant insertion over the biceps 8–10 cm (3-4 inches) above the medial epicondyle of the humerus. A cadaver study then subsequently found even fewer neurovascular structures over the triceps muscle and FSRH recommended placement over the triceps muscle.[60] Although the implant referred to in the FSRH is the one rod Nexplanon®, the NZ Family Planning training document now advises "arm flexed at elbow with hand under head – four finger breadths above elbow crease and behind sulcus, over triceps muscle". Personal communication with Bayer has been that their recommendation for Jadelle® insertion has not changed. The Jadelle data sheet advice is that the implants are inserted in the inner aspect of the upper left arm in right-handed women and in the right arm in left-handed women, approximately 8 cm above the fold in the elbow.[7]

The comment from the cadaver study authors was that the exact site of implant insertion is less important than assuring a superficial placement (to facilitate localisation and removal and avoid injury to deep structures).[60] However, placement in a region free of major neurovascular structures further mitigates risks in the event of incorrect deep subdermal placement is obviously very important. If an implant is inserted deeper into muscle, it can then move out of the area. Implants that are not palpable at time of removal need to be referred to an interventional radiologist for removal under ultrasound scan guidance. Accident Compensation Corporation can be approached to pay for this removal.

LARCs in specific populations

Young and/or nulliparous women

Despite concerns about the difficulty of inserting IUSs in young or nulliparous women, a study involving young females aged 13-24 years (59% of whom were nulliparous) indicated that the device was inserted successfully at the first attempt in 96.2%, with no perforations detected within the first 6 months.[61]

Data from the CHOICE project indicates that continuation rates are high for nulliparous and adolescents who use LARCs, indicating a high level of satisfaction for this form of contraception.[62]

Awareness and knowledge of LARCs among young people also appears to be low.[63, 64] It is therefore vital that comprehensive information and counselling is specifically directed towards the needs and concerns of young and/or nulliparous women to enable them to make an informed contraceptive choice.[65] Given the effectiveness of LARCs, they must be included in the recommended range of options available when informing and counselling this patient population.[3, 17, 22]

Women with heavy bleeding

International guidelines recommend a levonorgestrel-releasing IUS as a first-line option for eligible women with heavy bleeding.[19, 66-68]

Both Mirena® and Jaydess® reduce menstrual bleeding; however, the extent of reduction is greater in patients fitted with Mirena®.[4] In New Zealand, only Mirena® is indicated for the treatment of heavy bleeding.[4] In women who have heavy menstrual bleeding with no underlying cause, Mirena® reduces heavy bleeding by 71-95% at the end of six months.[4]

A copper IUD may initially result in heavier and more painful menstrual bleeding.[9, 39-42] While this typically improves after the first three months, a copper IUD may not be the ideal contraceptive in women who already have heavy, painful menstrual bleeding.[9]

Women with obesity

As mechanisms of action of IUSs/IUDs are based on local effects and do not rely on systemic drug levels, a woman's weight would not be expected to affect contraceptive effectiveness of IUS/IUDs.[69-72]

Studies have not reported any evidence of impaired contraceptive effectiveness in IUC users with obesity, either with the copper IUD or the levonorgestrel-releasing IUSs.[72] Consequently, for women with obesity without coexistent medical conditions, evidence-based guidelines do not place any restrictions on the use of IUCs in this patient population.[20, 71] In particular, the UKMEC assign both copper IUDs and levonorgestrel-releasing IUSs a category 1 classification (i.e., no restriction to their use) in women with a body mass index (BMI) ≥30 kg/m^2 (**Table 4**).[20]

There has been some concern regarding the efficacy of progestogen-only implants in heavier women.[55] However, there is considerable variation in serum levonorgestrel concentrations and in individual response, and so serum concentrations alone are not predictive of the risk of pregnancy in an individual woman,[7, 71, 73] with studies indicating that obesity does not impact the efficacy of progestogen-only implants.[73] According to the evidence-based UKMEC guidance, obesity alone does not restrict the use of a progestogen-only implant.[20]

Women with multiple cardiovascular risk factors/ cardiovascular disease

The risks associated with pregnancy in women with multiple cardiovascular risk factors (e.g., smoking, diabetes, hypertension, obesity, and dyslipidaemias) or with cardiovascular disease vary widely and depend on the woman's cardiac diagnosis and her individual risk factors.[74-76] Contraception for this group of women needs to be patient-focused and take into consideration the risk factors of the individual patient.[76]

UKMEC classifications for women with multiple cardiovascular risk factors are shown in **Table 4**.[20] In particular, copper IUDs can be used in women with higher cardiovascular risk and the advantages of levonorgestrel IUSs or progestogen-only implants generally outweigh their theoretical or proven risks.[9, 20]

Table 4. United Kingdom medical eligibility criteria in specific patient populations[20]

	Copper intrauterine devices	Levonorgestrel intrauterine system	Progestogen-only implants	Combined hormonal contraception*
Women with obesity				
BMI ≥30–34 kg/m^2	1	1	1	2
BMI ≥35 kg/m^2	1	1	1	3
Multiple risk factors for cardiovascular disease (such as smoking, diabetes, hypertension, obesity and dyslipidaemias)	1	2	2	3
Venous thromboembolism (VTE)**				
History of VTE	1	2	2	4
Current VTE (on anticoagulants)	1	2	2	4
Smoking				
Age <35 years	1	1	1	2
Age ≥35 years				
<15 cigarettes/day	1	1	1	3
≥15 cigarettes/day	1	1	1	4
Stopped smoking <1 year	1	1	1	3
Stopped smoking ≥1 year	1	1	1	2

BMI = body mass index.
1=no restriction to use;
2=advantages generally outweigh the theoretical or proven risks;
3=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 other more appropriate methods are not available or not acceptable;
4=represents an unacceptable health risk if used.
* includes combined oral contraception, transdermal patch and vaginal rings.
** VTE includes deep vein thrombosis and pulmonary embolism of any aetiology.

After pregnancy/abortion

International guidelines recommend that services providing care to pregnant women should discuss all appropriate methods of contraception, including LARCs, to women before they are discharged from the service.[19, 77, 78] Sexual activity and fertility may return quickly after childbirth/abortion, and it is important that effective methods of contraception are used. The NZ guidance on contraction reflects similar advice that women should be offered contraception immediately after delivery.[3]

NZ studies have also shown that compared with other contraceptive use, when a LARC is inserted immediately post-abortion, there was a decrease in repeat abortion.[79]

Emergency contraception

Two methods of emergency contraception are licensed for use in New Zealand; oral levonorgestrel 1.5 mg (Postinor®)[80] and the copper IUD.[40] The copper IUD is the more effective method of emergency contraception.[40, 53, 81, 82] Copper IUDs have the added advantage of providing ongoing contraception. Although a recent randomised trial indicated that Mirena® could provide effective emergency contraception,[83] the FSRH has said that due to data limitations, it cannot yet be recommended in this situation.[84]

Menopausal women

There is now updated FSRH guidance regarding when contraception is no longer required for women entering menopause.[85] This recommends that a single-serum follicle stimulating hormone (FSH) level can be used to determine the need for ongoing contraception for patients using a levonorgestrel IUS, contraceptive implant, or progestogen-only pills who have been amenorrhoeic for at least 12 months since turning 50 years. If FSH is >30 IU/L, contraception is only required for one more year. If FSH is ≤30 IU/L, contraception is still required, and the FSH can be rechecked in a further year if required. Alternatively, patients can continue their progestogen-only method of contraception, provided they remain medically eligible, until the age of 55 years, after which the risk of conception is negligible.[85]

EXPERT COMMENTARY

There are few contraindications for LARC use and the FSRH UKMEC provides easily accessible advice regarding the suitability of LARCs for women with various medical conditions.[35 76, 77] The FSRH guidelines advise that contraceptive counselling should be made available to women in the antenatal period to enable them to choose the method they wish to use after childbirth. Intrauterine contraception and progestogen-only implants can be inserted immediately after delivery, and maternity services should ensure that there are sufficient numbers of staff able to provide these forms of contraception so that women can initiate them immediately after childbirth. For women who are breastfeeding, progestogen-only methods have no adverse effects on lactation, infant growth, or development.[7, 77]

TAKE HOME MESSAGES

- Appropriate contraceptive options vary depending on the specific needs, preferences, and co-morbidities of each patient.
- LARCs may be recommended as a first-line choice for women of all ages, including adolescents.
- There are few contraindications for LARC use.
- Mirena® should be considered above other contraceptive methods for women with heavy menstrual bleeding.
- The narrower insertion tube and smaller device size of Jaydess® may be a consideration for women who have not had a vaginal birth or who have a smaller endometrial cavity.
- The FSRH UKMEC provides easily accessible advice regarding the suitability of LARCs for women with various medical conditions.
- Contraceptive education and counselling are important to ensure maximum persistence with the chosen contraceptive method.

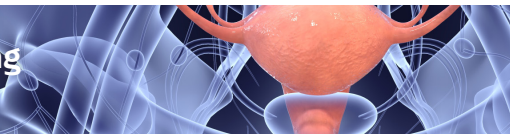
EXPERT'S FINAL COMMENTS

Two barriers to LARC use have been lack of training for primary healthcare practitioners and the ability to deliver a same day service for women. GPs in some areas may organise for their practices to be listed on the contracted service provider list. Prior training in LARC provision is required and includes Family Planning online theory training and practical insertion and removal training available at some hospital clinics. Reimbursement for services may be available for eligible patients/providers. Providing a LARC for women the same day as requested avoids loss to follow up and the risk of unintended pregnancy, as does provision immediately post abortion and delivery.

STI screening is not considered necessary for IUD/S use except for those women at high risk. In addition, LARCs can be inserted at any time in the menstrual cycle, as long as pregnancy can be reasonably excluded. The copper IUD is the most effective post-coital contraceptive and needs to be more widely considered for this purpose.

Helpful websites regarding LARC use are:

- FSRH UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) Faculty of Sexual and Reproductive Healthcare (FSRH). UK medical eligibility criteria for contraceptive use. 2019.
- FSRH clinical guideline: intrauterine contraception. 2019. https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/.
- Faculty of Sexual and Reproductive Healthcare. FSRH clinical guidance: progestogen-only implants. 2014. www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014. Accessed April 21, 2020.
- FSRH Guideline – Contraception After Pregnancy. 2017 Faculty of Sexual and Reproductive Healthcare. FSRH guideline: contraception after pregnancy 2017.



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