Part 5 - Intra-Uterine Device Fitting

Introduction

1. This paper sets out the specification for an Enhanced Service for insertion of Intra-Uterine Device (IUD). These include the Copper Intra-uterine Device (Cu-IUD) and the Levonorgestrel Intra-uterine Device (LNG-IUD).

Background

- 2. Intrauterine contraception is highly efficacious with very low failure rates. It is more cost-effective than shorter acting methods due to lower typical use failure rates and licenced durations of use of up to 10 years¹.
 - i) Copper IUDs are the most effective non-hormonal method of contraception available. They are also the most effective method of emergency contraception in suitable women.²
 - ii) The Levonorgestrel intrauterine device (LNG-IUD) is available as 52mg LNG-IUD (Mirena, Levosert, Benilexa), 19.5mg LNG-IUD (Kyleena) and 13.5mg LNG-IUD (Jaydess).
 - iii) A 52mg LNG-IUD has additional non-contraceptive benefits of decreasing menstrual loss and is recommended by the Royal College of Obstetricians and Gynaecologists (RCOG)³ for the management of menorrhagia.
 - iv) A 52mg LNG-IUD can also act as endometrial protection in HRT⁴ for up to 5 years (outside product licence) as recommended by the FSRH.¹
 - v) Familiarity with the UK Medical Eligibility Criteria for Contraceptive use (UKMEC) for intrauterine methods is advised.¹
 - vi) The FSRH guidance recommends medical and sexual history taking, including assessment for STI screening, as part of the routine assessment of suitability for IUD use.¹
 - vii) The FSRH guidance describes good practice for the counselling of individuals prior to use of an IUD.¹

4. SPC Mirena: <u>Mirena 20 micrograms/24 hours intrauterine delivery system - Summary of Product</u> <u>Characteristics (SmPC) - (emc) (medicines.org.uk)</u>

^{1.} FSRH Clinical Guideline: Intrauterine Contraception March 2023 (Amended July 2023)

^{2.} FSRH Clinical Guideline: Emergency Contraception (March 2017, amended July 2023)

^{3.} RCOG. Guidelines for the initial management of menorrhagia. London: RCOG, 1998

viii) FSRH Guidance recommends that health professionals offering IUD insertion should hold the FSRH Letter of Competence (LoC) in Intrauterine Techniques or equivalent recognised competencies. Perforation risk is related to the competence of the health care professional. IUD fitting is not undertaken by all general medical practitioners and maintaining expertise can be difficult. Requirements for recertification, including a minimum number of insertion procedures, are detailed.¹

Aims

- 3. The aims of this service are to:
 - (i) ensure that the full range of contraceptive options is provided by General practice to patients, supporting the SG aim of providing care close to home.
 - (ii) Increase availability and access to IUD insertion as a method of long-acting contraception within Primary Care.
 - (iii) ensure ready availability of post-coital IUD fitting for emergency contraception as a means of reducing unwanted pregnancies.
 - (iv) increase availability of LNG-IUD in the management of menorrhagia and the menopause within Primary Care.

Service outline

- 4. This enhanced service includes:
 - (i) **Counselling, fitting, monitoring, checking and removal** of IUD as appropriate and in accordance with the product licence with reference to the Summary of Product Characteristics (SmPC) for each device.
 - (ii) **Production of an up-to-date register of patients** fitted with an IUD. This will include all patients fitted with an IUD, documenting the device fitted, whether the device was fitted in primary or secondary care. This is to facilitate clinical audit and follow up of women when their device has expired.
 - (iii) **Practitioners to undertake regular continual professional development (CPD)** in the topic of sexual health, including learning on new devices and fitting techniques.
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 - 3. RCOG. Guidelines for the initial management of menorrhagia. London: RCOG, 1998

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(iv) **Provision of adequate equipment**.

- a. An appropriate room fitted with a suitable couch, examination light, and adequate space and equipment for resuscitation.
- b. Hand washing facilities, sterile consumables and instruments.
- c. Medical devices that come into contact with the patient must either be "single use" or be reprocessed at the Central Decontamination Unit (CDU) at Ayrshire Central Hospital. Local decontamination of these devices is not permitted. Re-use of Single Use devices is not permitted under any circumstances.
- d. Practices must implement all relevant Infection Control policies contained in the NHS Ayrshire and Arran Control of Infection Manual.
- e. An appropriately trained assistant needs to be present to support the patient, and assist the doctor during the procedure and in the event of an emergency.¹
- (v) **The provision of public health information** on safer sex practices and appropriate **sexual health screening** where indicated.
- (vi) Assessment to ensure that an IUD is the most appropriate method of contraception based on medical evidence, locally recognised clinical guidelines, patient choice, sexual history, and risk assessment including an assessment of pregnancy and STI risk with tests taken in accordance with FSRH guidelines.
- (vii) **Follow up** Post-insertion review as required for assessment of problems such as not being able to feel the threads, abnormal bleeding or pain. Routine annual checks are not required, but mechanisms should be in place to ensure timely review should a woman present with a pregnancy concern, or requesting removal of the device for any reason.
- (viii) **Provision of information.** Appropriate verbal and written information about all contraceptive options should be provided at the time of counselling to ensure informed choice, including effectiveness, duration of use, side effects, complications and those symptoms that require urgent assessment in accordance with FSRH guidance.

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(ix) **Production of an appropriate clinical record.**

The patient's clinical, reproductive and sexual history; the counselling process; STI screening if applicable; valid consent¹; the pelvic examination; the insertion procedure and any complications; the type and batch number of the IUD; advice about additional contraceptive requirements, and follow-up arrangements should be adequately recorded.

If the patient is not registered with the provider of the enhanced service, the provider must ensure that the patient's registered practice is given all appropriate clinical details for inclusion into the patient's notes after obtaining explicit consent from the patient.

- (x) **Use of LNG-IUD for the management of menorrhagia** in primary care as part of a care pathway developed and agreed with local gynaecology colleagues. This is to ensure these devices are used for the correct patients and the approved indications.
- (xi) **Use of LNG-IUD for the management of menopausal symptoms with HRT** in primary care as part of a care pathway developed and agreed with local sexual health colleagues. This is to ensure these devices are used for the correct patients and the approved indications.

Governance

5. **Practitioners undertaking these procedures should have undertaken appropriate training.**

- (i) Training should be based on modern, authoritative medical opinion, for example, the current requirements set down by the Faculty of Sexual & Reproductive Healthcare (FSRH) for the Letter of Competence in intrauterine techniques (LoC IUT).
- (ii) Training should involve demonstration of clinical skills in counselling for IUD, knowledge of issues relevant to IUD use, problem management, demonstration of examination skills in assessing the pelvic organs, observation of insertion and removal, followed by at least the minimum number of supervised insertion procedures recommended to achieve competence.
- (iii) It is recommended that a minimum of one health care professional working within the practice providing the ES holds a current FSRH LoC IUT.

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(iv)Reaccreditation / recertification is expected in accordance with modern, authoritative medical opinion, for example, the current requirements set down by the Faculty of Sexual & Reproductive Healthcare (FSRH) for the Letter of Competence in intrauterine techniques (LoC IUT).^{1.}

At the time of writing, the FSRH requirement for reaccreditation included: demonstration of a minimum of two continuing professional development (CPD) credits relevant to IUT, completion of the e-SRH module 15, evidence of BLS and anaphylaxis update training, and demonstration of a minimum of 12 insertion procedures using at least two different types of coil in a 12 month period within 24 months of recertification. FSRH recertification is required every 5 years.

- 6. **Appraisal.** Clinicians who have previously provided services similar to the proposed enhanced service, for example during specialist Gynaecology training, and who demonstrate at appraisal and revalidation that they have such continuing clinical experience, training and competence as is necessary to enable them to provide the enhanced service (*by being considered equivalent to the requirements set down by the FSRH*) shall be deemed professionally qualified to do so.
- 7. **Adverse events** should be recognised, documented, discussed within the team and reflected upon. Learning should be shared where deemed appropriate.
- 8. **Audit** of clinical standards or documentation is recommended to inform appraisal discussion.

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