Public Health Service
General Practice

Intrauterine Contraceptive Device/Intrauterine System (IUD/IUS): Fitting, Checking, Problem Solving and Removal of Intrauterine Devices (for contraceptive and non-contraceptive purposes)

SERVICE SPECIFICATION

Service	**Fitting, Checking, Problem Solving and Removal of Intrauterine Devices (for contraceptive and non-contraceptive purposes) in General Practice settings**
Authority Lead	**Devon County Council – Julia Loveluck, Torbay Council – Sarah Aston**
Period	**1 April 2016 – 31 March 2018 (with the option to extend by two separate 12 month periods)**
Date of Review	**March 2017**

1. Population Needs

1.1 National/local context and evidence base

Improving sexual health is a public health priority. The *Public Health Outcomes Framework for England 2013-2016* (Department of Health 2012) set the national and local strategic direction for sexual health and one of the three principal indicators for sexual and reproductive sexual health is a continuing fall in the rate of births to women under the age of 18.
Further significant benefits to public health could be achieved by enabling women of all ages to control their fertility through access to a full range of contraceptive choices and abortion services

A population survey by the Office of National Statistics (ONS 2008) revealed 4% of women aged between 15-54 use an intrauterine device (IUD) as their method of contraception with a further 3% identifying use of a progestogen bearing intrauterine system (IUS). Some of the IUD users may be misclassified.

IUD usage was examined by NICE (CG30, October 2005) and increased provision has been recommended on grounds of its high clinical effectiveness with very low failure rates as there is minimal compliance requirement. NICE quotes five year cumulative failure rates of <20/1000 for IUDs and <10/1000 for the IUS. IUDs should have a minimum of 380mm copper and those with banded arms have evidence of superior efficacy and longer licenses. The NICE LARC guidance -published in September 2014 confirms that these recommendations remain unchanged.

NICE recommended increasing uptake to reduce unintended pregnancy and calculated cost effectiveness to be greater than that for combined oral contraception at any point for an IUD and from year two for an IUS. Against this the cost per pregnancy averted in the first year was sufficiently low such as to recommend usage for any period of intended use.
NICE guidance on Heavy Menstrual Bleeding (CG44, January 2007) additionally recommended that an IUS should be considered for first line medical management of heavy menstrual bleeding in women with heavy cyclical bleeding. This may avoid the need for gynaecological referral and provide effective management of a problem with significant quality of life impact.

There are now three IUS devices. The well-established Mirena® provides high intrauterine

levels of progestogen and has high efficacy for endometrial opposition. It has a 5 year license for contraception and heavy menstrual bleeding and it is also licensed for 4 years as the progestogenic component of an HRT regime (Mirena Summary of Product Characteristics), and is widely used in gynaecological practice. The Levosert® became available in 2015 and is identical in composition to Mirena®, but it has a different frame and introducer and is consequently slightly wider and needs a two-handed technique. It is only licensed for contraception for three years and for heavy menstrual bleeding. It does not have a license for endometrial protection. The other IUS is Jaydess® which is on a smaller frame and has a lower dose of progestogen. It has a 3 year license for contraception and Is not licensed for heavy menstrual bleeding or the progestogenic component of HRT.

An IUD is the most effective method of post coital contraception and expert opinion is that it should be offered even when the patient presents within the licensed use of emergency hormonal contraception (FSRH 2011, updated 2012).

Women considering use of any contraceptive method should receive information concerning its mode of action, efficacy, side effects, complications, failure rate, return to fertility, procedure required and any risks inherent in this. Written information using appropriate language should be provided. (NICECG30, October 2005, updated September 2014).

Complication rates associated with fitting have been shown to be inversely linked to the skill of the fitter. Training and competency assessment is therefore mandatory. The standard applied is that of the Letter of Competence of the Faculty of Sexual and Reproductive Healthcare (LoC IUT of the FSRH). The qualifications of the FSRH are now open to nurses as well as doctors and the LoCs are also now open to doctors and nurses without the DFSRH, as stand-alone qualifications. These qualifications are accredited by the Royal College of Nurses (RCN) and the Royal College of General Practitioners (RCGP).

A minimum activity level of 12 insertions a year is recommended to maintain competency. A minimum of 10 hours education in reproductive health issues of which at least two should concentrate on the use of intrauterine devices are required for every five year reaccreditation cycle.

2. Key Service Outcomes

2.1 Insert any locally agreed outcomes and quality requirements

It is expected that the service outlined in this specification will contribute to:

- Increased long acting reversible contraception (LARC) uptake and continued use, particularly in under 25s.
- A reduction in the number of unplanned pregnancies.
- A reduction in the under 18 conception rate.
- A reduction in the number of terminations of unplanned pregnancies.
- A reduction in repeat terminations.

3. Scope

3.1 Aims and objectives of service

This specification for the insertion, removal and management of an intrauterine contraceptive device (IUD) or intrauterine system (IUS) is designed to:

- Ensure the availability of IUD/IUS through primary care, as part of a range of contraceptive options offered by the practice.
- Promote IUD/IUS as an effective Long Acting Reversible Contraceptive (LARC) method of contraception.
- Increase uptake and ongoing use of IUD/IUS thereby contribute to reducing unplanned conceptions and particularly teenage pregnancies.
- Provision of accessible and timely post-coital fittings for emergency contraception as another means of reducing unplanned conceptions.
- Raise awareness of the benefits of IUD/IUS by providing high quality advice, support and information on the full range of contraception methods to all women using or seeking contraception.

3.2 Service description/pathway

The requirement of the service includes:

- Pre-insertion counselling, fitting, monitoring, checking and removal of IUD as appropriate following current best practice guidance, within the practice (see 4.1 & 4.2).
- The fitting of a copper-bearing IUD for emergency contraception as clinically indicated or appropriate referral.
- The maintenance of an up-to-date register of patients fitted with an IUD/IUS, including the type of device fitted. This is to be used for audit purposes, and to enable the primary care team to target these patients for health care follow-up.
- A requirement from the contractor to assure that all clinicians carrying out the fitting of IUD/IUS meet the required accreditation standards (see 3.2.1).
- A recorded sexual history and risk assessment for the presence of sexually transmitted and other infections, to determine the need for Chlamydia screening and other testing prior to the insertion of the IUD/IUS. Patients who are found to be Chlamydia positive should be referred for screening for other sexually transmitted infections in accordance with recommended national standards and for partner management.
- Pregnancy testing equipment for appropriate use prior to IUD insertion.
- Provision of advice on the use of condoms and reducing the risk of acquiring sexually transmitted infections.

The provision of adequate equipment to undertake IUD/IUS fitting and removal:

- an appropriate room fitted with a couch and adequate space and equipment for

resuscitation;

- Oxygen and Atropine (which can be administered IM) should be easily availably
- selection of vaginal specula and cervical dilators;
- cervical anaesthesia should be considered and the fitter decide whether or not to use it;
- an appropriately trained assistant must be present to support the patient and assist the clinician during the procedure.

The provision of written information at the time of the counselling and fitting with information on follow-up. This should include an alert for those symptoms that will require urgent assessment.

A follow-up appointment at three to six weeks after IUD/IUS insertion to exclude infection, perforation or expulsion, or pregnancy for intra uterine devices fitted for emergency contraception. Arrangements should be in place to assess abnormal bleeding or pain urgently. There is no evidence that annual review is beneficial.

A fully informed discussion on the nature and purpose of the proposed treatment or intervention, any associated risks and the form in which the patient consents should be clearly written in the patient's lifelong medical record. Implied consent (non-verbal) or verbal consent is sufficient for procedures such as insertion and removal of IUD/IUS.

The maintenance of detailed records regarding the patient's clinical history, the counselling process, the results of any Chlamydia screening, the pelvic examination, problems with insertion, the type and batch number of the device and follow-up arrangements in the lifelong patient records.

3.2.1 **Training and Accreditation Standards for IUD/IUS Fitters**

3.2.1.1 Clinicians should be competent in Basic Life Support and anaphylaxis management and, as for other areas of clinical practice, have a responsibility for ensuring that their skills are regularly updated. Practitioners carrying out the service outlined in this specification must:

- Demonstrate evidence of initial training
- Demonstrate a continuing sustained level of activity
- Conduct regular audits
- Be appraised on what they do

3.2.1.2 The standard applied for both doctors and nurses is that of the Faculty of Sexual and Reproductive Healthcare (LoC IUT of the FSRH). This qualification is accredited by the RCGP and the RCN and has replaced other qualifications and qualifications should be re-certified every 5 years.(GPIUD/IUS 2&3)

3.2.1.3 Local certificates of equivalence are longer be issued by Faculty Registered Trainers in the Devon County Council or Torbay council areas. Clinicians who are accredited to fit and remove IUD's/IUS as part of this public health commissioned service are required to hold a current Faculty of Letter of Competence. Certificates of equivalence that have been issued recently will remain valid for a five year period from the date of issue, at which point the clinician must convert to a Faculty LoC IUT.

3.2.1.4 Practices will be required to maintain an up-to-date register of all registered patients

that undergo fitting or removal of an IUD/IUS, within the practice. This will include details of the device fitted, duration of use, reasons for removal and complications or significant events. Annual data detailing the number of accredited fitters within the practice and the number of fittings/removals that each accredited fitter has undertaken in the preceding twelve month period, will be submitted to commissioners. Practices are encouraged to model their service delivery to ensure that clinicians are able to undertake a minimum of 12 fittings per annum in line with FSRH standards.

3.2.1.5 Individual clinicians who fit IUD/IUS are expected to keep a log of experience. Information on the quality outcome indicators (Appendix GP IUD/IUS 1) should be held by the practice and available to the commissioner as part of an audit process.

3.2.1.6 GP's who delegate the task of IUD/IUS removal to Registered Nurses who are not accredited IUD/IUS fitters must be confident that the nurse has received appropriate training and experience/skills to undertake the task. This training should be provided by someone who currently holds a LoC IUT.

3.3 Population covered

The service will cover the populations of Devon County Council and Torbay Council geographical areas.

3.4 Any acceptance and exclusion criteria

This specification covers the use of IUD/IUS for both contraceptive and non-contraceptive purposes. Devon County Council and Torbay Council are responsible for the collection of data and for the payment of GPs for this service. The commissioning of the fitting and removal of IUS for non-contraceptive purposes remains the responsibility of the relevant Clinical Commissioning Group. (see 3.6).

3.5 Interdependencies with other services

To meet the requirements of this specification the provider will be expected to have close working relationships with all relevant services, agencies and disciplines as appropriate.

3.6. Intra-uterine devices fitted for non-contraception/medical indications

The local Public Health team undertake to manage the reporting and payment processes associated with IUD/IUS fitting and removal activity, for both contraception and non-contraception purposes. Practices are required to submit quarterly data disaggregated by contraception and non-contraception activity. The local Public Health team will invoice the relevant Clinical Commissioning Group quarterly, for re-imbursement of payments associated with non-contraception fitting activity.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

The service will be provided in compliance with:

Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Unit Guidance and Clinical Standards:

- Intrauterine Contraception, Clinical Effectiveness Unit Nov April 2015 (updated June 2015). http://www.fsrh.org/pdfs/CEUGuidanceIntrauterineContraception.pdf

- Emergency Contraception, Clinical Effectiveness Unit August 2011, updated January 2012. (http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf).

- FSRH Training Requirements for Letter of Competence IUT (http://www.fsrh.org/pdfs/IUT Training requirements pdf).

- NICE 2005, Long Acting Reversible Contraception. Clinical Guideline 30. (www.nice.org.uk/Guidance/CG30). (updated September 2014)

- NICE 2007, Heavy Menstrual Bleeding Investigation and Treatment. Clinical Guideline 44. (www.nice.org.uk/Guidance/CG44).

4.2 Applicable local standards

The service will be provided in compliance with:

- Fraser Guidelines - young people under the age of 16 years presenting for sexual health services will be encouraged to involve their parents or guardians. This process should be clearly documented, signed and dated by the assessing clinician.

- Young people under the age of 13 or where abuse is suspected will be managed according to Devon and Torbay Safeguarding Children Boards policy and guidance (http://www.devonsafeguardingchildren.org/)

- Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health (Department of Health 2004)

- The Mental Capacity Act 2005

- Local Devon (https://new.devon.gov.uk/devonsafeguardingadultsboard/) and Torbay (http://www.torbaycaretrust.nhs.uk/ourservices/SafeguardingAdults/Pages/Default.aspx) safeguarding policy and guidance for working with vulnerable adults

- Infection control policies and procedures compliant with national guidelines.

4.2.1 Patient Safety and Incident Reporting

The Provider/Supplier must act in an open and transparent way in relation to services provided to service users/patients. Robert Francis QC statement that, "a relentless focus on the patient's best interests and the obligation to keep patients safe and protected from substandard care" is the basis for expecting openness, transparency and candour in the relationships covered in this specification and contract.

Serious incidents requiring reporting which occur in GP Practices are notifiable to NHS England, as outlined in the GP commissioning contract. The purpose of reporting incidents is for the identification of trends, specific incidents of concern or emerging risks to patient safety. Information will be treated confidentially and sensitively.

Incidents that occur, in the course of the counselling, fitting, or removing of contraceptive

devices under this specification, are reportable to NHS England and/or local CCG. NHS England will inform the local Public Health Commissioner of the outcome of these incidents, as well as any investigation that takes place.

Serious incidents that have been reported to NHS England and/or local CCG should be notified by the supplier to the local PH Commissioner, as soon as reasonably practicable, in line with the requirements of the main Public Health Services contract.

Reflective Practice:

In the circumstances where an incident has been reported to NHS England and/or local CCG and local Public Health commissioners and does not give rise to an investigation, the practitioner may wish to debrief with a lead sexual health clinician within the Practice team. Where the practitioner feels he or she would benefit from additional objectivity, or where there is no readily available lead clinician, the practitioner may contact the Local Faculty Programme Training Director in the specialist Contraception and Sexual Health Service for their local area (i.e.) Torbay Sexual Medicines Service or Northern Devon Healthcare Foundation Trust. The importance of reflective practice is frequently noted in literature and is commonly regarded as an essential component of competent practice. Neither NHS England nor the Public Health Team views the reporting of incidents as characteristic of unsafe clinical practice.

The contract document contains further information about clinical governance.

Quality Assurance of Public Health Commissioned Services:

As part of the annual public health audit of accredited GP/Nurse fitters in primary care, fitters will be required to identify any known complications or significant events that have occurred in that period. They will be asked to supply brief details of the event, learning from the incident and any change to practice as a result.

5. Location of Provider Premises

The Provider's Premises are located at: GP Practice Premises

Acknowledgement: Dr Clare Seamark, Faculty of Sexual and Reproductive Healthcare Regional Training Adviser (Southwest), for the clinical scrutiny of this service specification.

QUALITY OUTCOMES INDICATORS

(N.B. Activity and performance targets may be altered in-year)

For the Fitting, Checking, Problem Solving and Removal of Intrauterine Devices in General Practice Settings				
Data Quality Indicator	**Data Quality Threshold**	**Method of Measurement**	**Milestone Date**	**Consequence**
GP or nurse fitters who are signed up to fit or remove devices under this specification meet the requirements of the Faculty of Sexual and Reproductive Healthcare (LoC IUT of the FSRH) and have undertaken appropriate accreditation (see 3.2.1.2)	A full record of all procedures and a log of experience are maintained by each individual fitter signed up to the specification.	Aggregated data detailing the number of patients fitted with an IUCD for either contraception or non-contraception indications is available to the local Public Health commissioner (see 3.2.1.4)	Submission of quarterly data disaggregated by contraception and non-contraception activity Report total numbers of devices fitted/removed by individual fitter as part of the local Public Health "Annual Fitters Audit"	Joint Review Process
Significant incidents that occur in the course of the counselling, fitting, or removing of contraceptive devices are reported to NHS England and/or local CCG in accordance with existing requirements and to the Public Health Commissioner as soon as is practicable (see 4.2.1)	A full record of all procedures and a log of experience are maintained by each individual fitter signed up to the specification.	Details of significant incidents that occur, in the course of the counselling, fitting, or removing of contraceptive devices under this specification are available to the local Public Health commissioner	Report the details of the significant event to the local Public Health Commissioner in your area as soon as is practicable The outcome of any significant event escalated to NHS England and/or local CCG is reported in the local Public Health "Annual Fitters Audit"	Joint Review Process

TRAINING REQUIREMENTS FOR DOCTORS AND NURSES FOR INTRAUTERINE TECHNIQUES		
LoC IUT linked to Faculty Qualification	**Stand-alone LoC IUT**	**Local Equivalence Certificate**
Current DFSRH/NDFSRH/MFSRH/FFSRH	FSRH eKA - online assessment of sexual & reproductive healthcare knowledge	Theoretical grounding in sexual & reproductive healthcare and in active practice
Basic Life Support	Basic Life Support	Basic Life Support
Anaphylaxis update	Anaphylaxis update	Anaphylaxis update
e-SRH-module 18 **http://www.e-lfh.org.uk/projects/e-srh/index.html** freely available to NHS staff	e-SRH-module 18 **http://www.e-lfh.org.uk/projects/e-srh/index.html** freely available to NHS staff	e-SRH-module 18 **http://www.e-lfh.org.uk/projects/e-srh/index.html** freely available to NHS staff
Training with Faculty Registered Trainer (FRT) This starts with theoretical and model uterus training. The practical training then includes:- Demonstration of insertion techniques by FRT followed by a minimum of 7 satisfactory insertions (must include both a 'gold-standard' copper IUD and a hormonal IUS)	Training with Faculty Registered Trainer (FRT) This starts with theoretical and model uterus training. The practical training then includes:- Demonstration of insertion techniques by FRT followed by a minimum of 7 satisfactory insertions (must include both a 'gold-standard' copper IUD and a hormonal IUS)	Training with Faculty Registered Trainer (FRT) This starts with theoretical and model uterus training. The practical training then includes:- Demonstration of insertion techniques by FRT followed by a minimum of 7 satisfactory insertions (must include both a 'gold-standard' copper IUD and a hormonal IUS)
Apply with fee to FSRH for LoC IUT. The qualification can then be re-certified every 5 years.	Apply with fee to FSRH for LOC IUT and probably become Associate of FSRH- allows involvement with FSRH and will automatically lead to ability to re-certificate every 5 years.	Local Equivalence Certificate issued by FRT Commitment by Trainee to keep up-to-date and undertake equivalent CPD as if holding a LoC and undertake e-SRH module 18 at least every 5 years.

Evidence needed - for this training includes up-to-date certificates for Basic Life Support and Anaphylaxis Management. For the LoC either the possession of DFSRH/NDFSRH/MFSRH/FFSRH or certificate of passing the FSRH eKA. All candidates should also undertake e-SRH Module 18 and have proof of this.

Experienced Fitters - Need the qualifications and experience as above, but they can self-certify the model uterus training and up to 5 previous insertions and only need two satisfactory insertions witnessed by a FRT (must include both a 'gold-standard' copper IUD and a hormonal IUS).

Fees - there are fees associated with FSRH qualifications and the eKA. 2014 fees eKA £75 per attempt, one off fee for LoC £50. Fee to become Associate FSRH £75 per year (or £250 for LoC without becoming Associate). Fees for the practical training will generally be charged.

REACCREDITATION REQUIREMENTS FOR DOCTORS AND NURSES FOR INTRAUTERINE TECHNIQUES		
DFSRH/MFSRH/FFSRH & LOC IUT	**Stand-alone LoC IUT & Associate FSRH**	**Local Certificate of Equivalence**
Maintain primary qualification. Min 10 hours Sexual & reproductive health updates in 5 years- at least 2 hours of which should be on SDI as required by FSRH. A **minimum** of 5 CPD credits gained from attendance at: Courses in core topics directly related to Sexual and Reproductive Health and Courses relating to consultation skills. A **maximum** of 5 CPD credits may be acquired for other activities such as: reading articles; completing CME modules; audit and research.	Min 10 hours Sexual & reproductive health updates in 5 years- at least 2 hours of which should be on IUT as required by FSRH. Re-certification will be by the FSRH on completion of forms and submission of evidence.	Min 10 hours Sexual & reproductive health updates in 5 years- at least 2 hours of which should be on IUT. Health professional should maintain their own records and they should be available for scrutiny by the commissioners.
Basic Life Support and anaphylaxis	Basic Life Support and anaphylaxis	Basic Life Support and anaphylaxis
e-SRH-module 18	e-SRH-module 18	e-SRH-module 18
A log of insertions covering a twelve-month period within twenty four months of the date of recertification. This log will need to show a minimum of twelve insertions over twelve months of at least two different types of intrauterine method in conscious women.	A log of insertions covering a twelve-month period within twenty four months of the date of recertification. This log will need to show a minimum of twelve insertions over twelve months of at least two different types of intrauterine method in conscious women.	A log of insertions covering a twelve-month period within twenty four months of the date of recertification. This log will need to show a minimum of twelve insertions over twelve months of at least two different types of intrauterine method in conscious women.

Evidence- Those holding DFSRH/NDFSRH/MFSRH/FFSRH or are an Associate of FSRH with a stand-alone LoC IUT will be re-certified by the FSRH. Those holding *a current* Local Equivalence certificate should retain all their certificates and logs for local inspection.

Please note that the Local Equivalence Certificate will no longer be issued by Faculty Registered trainers in the Devon County Council or Torbay Council areas and fitters are now required to re-accredit through the Faculty LoC route

For further information on training or accreditation - details available at FSRH.org or:

Devon County Council area:
Contact your local FSRH General Training Programme Director via the Training section of the Northern Devon Healthcare Trust sexual health website:
http://thecentresexualhealth.org/professionals/training

Torbay Council area:
Contact your local FSRH General Training Programme Director via:
Torbay Sexual Medicine Service, Circus Health Centre, Abbey Road, Torquay TQ2 5YH
Tel 01803 656500