Public Health Service
General Practice

Fitting, Checking, Problem Solving and Removal of Sub-Dermal Contraceptive Implants

SERVICE SPECIFICATION

Service	**Fitting, Checking, Problem Solving and Removal of Sub-Dermal Contraceptive Implants (updated 6 April 2017)**
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 2018**

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 includes one of the three principal indicators for sexual and reproductive sexual health which 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.

The National Institute for Health and Clinical Excellence (NICE) published clinical guidance on the effectiveness and appropriate use of long-acting reversible contraception (LARC) in October 2005. This Guideline endorsed the use of Long acting Reversible Contraception as the most cost effective methods for reducing the number of unplanned pregnancies. The NICE LARC guidance published in September 2014 confirms that these recommendations remain unchanged (*NICE Guideline CG30, October 2005*). A review of studies of contraceptive efficacy reported a one-year Pearl index of 0-0.6 per 100 for the progestogen contraceptive implant. (*Mansour D et al. Efficacy of Contraceptive Methods: a review of the literature. European Journal of Contraception and Reproductive Healthcare. February 2010;15:4-16*).

Women have identified that they want help from healthcare professionals to make informed choices, reassurance to overcome concerns about LARC, particularly efficacy, length of action (side effects, return to fertility), insertion and removal. Most of all they want to hear that LARC is safe and easy, reliable and hassle-free and different but normal. (*Glasier A, et al (2008). Attitudes of women in Scotland to contraception: A qualitative study to explore the acceptability of long acting methods. Journal of Family Planning and Reproductive Health Care, **34**(4): 213–217*).

Since 2010 the contraceptive implant has been under the brand name Nexplanon® (which replaced Implanon®). Nexplanon® and Implanon® are bioequivalent and the main changes relate to the application device, insertion technique and that the device can now be located by X-ray. Contraceptive implants are one of two areas of contraceptive provision with relatively high levels of litigation. There are three types of incident associated with contraceptive implants that recur in legal cases in a range of countries; non-insertion, deep

insertion and nerve injury. (*Rowlands S, (2010). Legal aspects of contraceptive implants. Journal of Family Planning and Reproductive Health Care, 36(4): 243-248*).

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 a contraceptive sub-dermal implant is designed to:

- Provide an accessible contraceptive implant insertion and removal service in general practice as part of a range of contraception choices for women.
- Promote contraceptive implant as an effective Long Acting Reversible Contraceptive (LARC) method of contraception.
- Increase uptake and ongoing use of contraceptive implants thereby contribute to reducing unplanned conceptions and particularly teenage pregnancies.
- Raise awareness of the benefits of contraceptive implants by providing high quality advice, support and information on the full range of contraception methods to all women using or seeking contraception, and particularly to women aged under 25.

3.2 Service description/pathway

The requirement of the service includes:

- Pre-insertion counselling, fitting, monitoring, checking and removal of contraceptive implants as appropriate, following current best practice guidance within the practice (Appendix GP SDI 2).
- The maintenance of an up-to-date register of all registered patients that undergo fitting or removal of a contraceptive implant 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.

- A requirement from the contractor to assure that all that individual clinicians undertaking the fitting and removal of contraceptive implants are appropriately trained and meet the required accreditation standards

- A recorded sexual history and risk assessment to ensure that the contraceptive implant is the most appropriate method of contraception based on medical evidence, clinical guidelines, sexual history and practice.

- Risk assessment to exclude the risk of pregnancy at the time of counselling and whether or not emergency contraception/pregnancy testing is required. Patients should be referred for screening for sexually transmitted infections based on sexual history and in accordance with recommended national standards. This should include an offer of Chlamydia Screening to 15 to 24 year olds as part of either the local Devon or Torbay Chlamydia Screening Programme and provision of advice on the use of condoms and reducing the risk of acquiring sexually transmitted infections.

- The provision of the necessary equipment is required for implant fitting and removal. This includes an appropriate room with a couch and adequate space with equipment for resuscitation, and the facility for local anaesthesia, the provision of sterile surgical instruments and other consumables. An assistant may be present but it is not absolutely necessary as it is for an IUD/IUS fitting.

- The provision of appropriate verbal and written information about all contraceptive options should be provided at the time of counselling to ensure informed choice. The effectiveness, duration of use, side effects and those symptoms that require urgent assessment should be reinforced at fitting, so that the patient has a thorough understanding of implant use.

- A follow up is recommended for those in whom there could be any chance of pregnancy occurring and in the very young users. Routine annual checks are not required however arrangements should be in place to review clients experiencing problems in a timely fashion. Arrangements should be in place to ensure ease of access for women requesting removal of the implant for any reason including problems or at expiry of the device. The implant is licensed for three years at which point it will need to be exchanged or alternative contraception provided. The device can be removed at the woman's convenience.

- Maintenance of adequate records including patient's clinical, reproductive and sexual history, the counselling process, the results of any STI screening, problems with insertion, the type and batch number of the implant, expiry date of the device and follow up arrangements. If the patient is not registered with the GP provider practice, the clinician who fits the device 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.

3.2.1 **Training and Accreditation Standards for Sub-dermal Implant (SDI) Fitters**

Clinicians should be competent in Basic Life Support (including 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 Letter of Competence of the Faculty of Sexual and Reproductive Healthcare (LoC SDI 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 (Appendix GP SD1 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 contraceptive SDI's 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 SDI.

3.2.1.4 Practices will be required to submit annual data detailing the number of accredited SDI fitters within the practice and the number of fittings and removals that each accredited fitter has undertaken in the preceding twelve month period, within the practice. Practices are encouraged to model their service delivery to ensure that clinicians are able to undertake a minimum of 6 procedures per annum in line with FSRH standards, of which one must be an insertion and one a removal).

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

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

None other than in those women where the contraceptive implant is clinically contraindicated.

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 Any activity planning assumptions

Fitting/Insertion of sub-dermal contraceptive implants:
Payment for the fitting/insertion of sub-dermal contraceptive implants will be at the ***GP tariff rate*** for ***the first 6 devices fitted within the practice in a contract year***.

All other devices that are fitted or removed during the remainder of the contract year will be at the Nurse tariff rate.

4. Applicable Service Standards

4.1 Applicable national standards e.g. National Institute of Clinical Excellence (NICE)

The service will be provided in compliance with:

- FSRH Guideline: Contraception after Pregnancy. FSRH: January 2017.
https://www.fsrh.org/news/new-fsrh-guideline--contraception-after-pregnancy/

- FSRH Guideline: Emergency Contraception. FSRH: 14 March 2017
https://www.fsrh.org/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

- Progestogen-only Implants, Clinical Effectiveness Unit Feb 2014.
https://www.fsrh.org/documents/cec-ceu-guidance-implants-feb-2014/

- FSRH Training Requirements for Letter of Competence IUT
https://www.fsrh.org/recertification/recertification-requirements-for-letters-of-competence-loc-iut/

- NICE Contraception Quality Standard (QS129). NICE: September 2016.
https://www.nice.org.uk/guidance/qs129

- NICE Public Health Guideline (PH51). Contraception services for under 25's: Recommendation 5 Seeking Consent and Ensuring Confidentiality. NICE: March 2014.
https://www.nice.org.uk/guidance/ph51/chapter/1-recommendations

- Department of Health (2004). 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
http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/publicationspolicyandguidance/DH_4086960

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/)

- 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

- The Mental Capacity Act 2005. (https://new.devon.gov.uk/adultsocialcareandhealth/guide/mca-practice-guidance/part-21-consent-to-having-sex/)

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 (November 2015)

Review and update of national and local standards: Julia Loveluck – Senior Public Health Officer Sexual Health, Devon County Council (April 2017)

GP SDI 1

QUALITY OUTCOMES INDICATORS

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

For the Fitting, Checking, Problem Solving and Removal of Contraceptive Sub-Dermal Implants 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 SDI 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 SDI is available to the local Public Health commissioner (see 3.2.1.4)	Submission of quarterly activity data 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 SDI's		
LoC linked to Faculty Qualification	**Stand-alone LoC**	**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 17 **http://www.e-lfh.org.uk/projects/e-srh/index.html** freely available to NHS staff	e-SRH-module 17 **http://www.e-lfh.org.uk/projects/e-srh/index.html** freely available to NHS staff	e-SRH-module 17 **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 arm training. The practical training then includes:- Demonstration of insertion & removal techniques by FRT followed by 2 satisfactory insertions and 2 satisfactory removals by the applicant.	Training with Faculty Registered Trainer (FRT) This starts with theoretical and model arm training. The practical training then includes:- Demonstration of insertion & removal techniques by FRT followed by 2 satisfactory insertions and 2 satisfactory removals by the applicant.	Training with Faculty Registered Trainer (FRT) This starts with theoretical and model arm training. The practical training then includes:- Demonstration of insertion & removal techniques by FRT followed by 2 satisfactory insertions and 2 satisfactory removals by the applicant.
Apply with fee to FSRH for LoC. The qualification can then be re-certified every 5 years	Apply with fee to FSRH 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 17 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 17 and have proof of this.

Experienced Fitters - Need the qualifications and experience as above, but they can self-certify the model arm training and up to 6 previous insertions and 6 removals and only need one satisfactory insertion and one satisfactory removal witnessed by a FRT.

Fees- there are fees associated with FSRH qualifications and the eKA. There is a one off fee on first obtaining a LoC. Fees for the practical training may also be charged.

GP SDI 3

REACCREDITATION REQUIREMENTS FOR DOCTORS AND NURSES FOR SDI's		
DFSRH/MFSRH/FFSRH	**Stand-alone LoC SDI & 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 SDI 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 SDI. 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 17	e-SRH-module 17	e-SRH-module 17
A log of procedures covering a twelve-month period within twenty four months of the date of recertification. This log will need to show a minimum of six procedures to include at least one insertion and one removal	**A log of procedures** covering a twelve-month period within twenty four months of the date of recertification. This log will need to show a minimum of six procedures to include at least one insertion and one removal	**A log of procedures** covering a twelve-month period within twenty four months of the date of recertification. This log will need to show a minimum of six procedures to include at least one insertion and one removal

Evidence- Those holding DFSRH/NDFSRH/MFSRH/FFSRH or are an Associate of FSRH with a stand-alone LoC IUT SDI 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