Document Control

Title

Protocol for the management of females who attend the Sexual & Reproductive Health Service requesting Sub-Dermal progestogen-only contraceptive implant insertion (Nexplanon)

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Version	Date Issued	Status	Comment / Changes / Approval
1.0	19.01.12	Final	First proposal ratified
2.1	19.07.12		Amended to reflect nurse-led clinics and need to use PGDs for patients not known in advance
2.2	04.09.12		Further amendment following initial draft of PGD meeting
2.3	18.09.14		Amendments to authors listed. Amended to include skin assessment and core assessment in examination section. References updated. Typing errors and format amended. Nurse to supply wound care management, written advice. Child Protection change to read safeguarding. UKMEC reference added.
2.4	08.10.14		Amendment, migraine with and without aura removed as exclusion from significant medical history.
2.5	11.06.15		Quick start implants with follow up, pregnancy testing added. Confirmed pregnancy added to exclusion.
2.6	19.07.17		EC information updated. Supporting information updated. Girls/Women changed patients. Safeguarding updated. St Johns Wort included. Reference PGD and PSD updated. Approved DTC July 2017. Updated authors.
2.7	04.12.18		Amendment – removal of statement reference written consent Change from Nexplanon to Progestogen-only implant. Change nurse to healthcare professional.
3.0	16/06/20	Final	Add in unexplained bleeding, current or past breast cancer, liver disease or cancer. Add in table on switching from other hormonal methods. Change child protection to safeguarding. Change advice on bleeding pattern on implant. Updated insertion site as per SPC guidelines. Advice updated, patients should be advised to report if they are ever unable to feel their implant.
4.0	17/06/20	Final	Approved at Devon Sexual Health Governance

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<tr><td colspan="2">Distribution List
Devon Sexual Health, 31 Sidwell St, Exeter</td><td colspan="2">Distribution Method
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1. Purpose

1.1. This Protocol is for the use by staff employed by Northern Devon Healthcare Trust who have achieved the agreed clinical competencies to work under it.

2. Presenting Symptoms

2.1. Patients requesting a progestogen only-implant.

Situation 1: Unknown patient presents requesting progestogen-only implant. The patient will be counselled about the method and arrange an appropriate appointment for fitting.

Situation 2: The healthcare practitioner will counsel the patient about the method prior to fitting the progestogen-only implant as part of the same consultation under PGD (PGD Pathway).

Situation 3: Named patient attends for initial counselling for progestogen-only implant with appropriately trained practitioner. Patient Specific Directive (PSD) put in place prior to fitting. The fitting is undertaken during separate consultation.

3. History

3.1. Significant medical history

Refer to UKMeC if there are any concomitant medical condition and discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which thehealthcare professional is unsure or uncertain.

3.2. Any medication

The medical practitioner will always check any medication being taken for interactions with the progestogen-only implant or Lidocaine (for guidance see current British National Formulary (BNF) or North and East Devon Formulary and Referral, available on BOB.

3.3. Special considerations

Has the patient taken Ulipristal acetate (UPA-EC) the last five days? It is recommended by the Faculty guideline development group that the Progestogen-only implant is avoided for five days after UPA – EC to avoid compromising the ability of UPA-EC to delay ovulation

3.4. Any current drugs that induce liver enzymes or that have been taken in the previous 28 days

Consider DMPA/IUC as an alternative method or inform the patient to use condoms until 28 days after stopping treatment.

Examples of liver enzyme inducing drugs are:

- Anticonvulsant drugs: Carbamazepine, Oxcarbazepine, Phenytoin, Phenobarbital, Primidone, Topiramate
- Antituberculosis drugs: Rifampicin and Rifabutin
- Antifungal drugs: Griseofulvin
- Protease inhibitors: Atazanavir, Lopinavir, Ritonavir, Darunavir
- Non-nucleoside reverse transcriptase inhibitors: Efavirenz, Nevirapine
- Others: Modafinil, St John's Wort (hypericum), Tacrolimus, Bosetan, barbiturates

Consult BNF for full list

3.5. Any allergies

Progestogen, Etonogestrol or any excipient in Nexplanon, local anaesthetic or adhesive plasters.

3.6. Possibility of pregnancy

Confirmed pregnancy is exclusion to fitting an implant
A pregnancy test, if available, adds weight to the exclusion of pregnancy, but only if ≥3 weeks since the last episode of unprotected sexual intercourse.

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
- She is within the first seven days of the onset of a normal menstrual period
- She is within four weeks postpartum for non-lactating women
- She is within the first seven days post-abortion or miscarriage
- She is fully or nearly fully breastfeeding, amenorrhoeic, and less than six months postpartum

Health professionals should also consider if a woman is at risk of becoming pregnant as a result of unprotected sexual intercourse within the last seven days.

3.7. Exclusion criteria

- Confirmed pregnancy
- Unexplained vaginal bleeding
- Current or past breast cancer
- Severe decompensated liver disease
- Liver carcinoma
- The patient is taking or has started enzyme inducing medication since the recent initial consultation (see current British National Formulary (BJF) or North and East Devon Formulary and Referral advice (available on intranet) or the FSRH CEU "Drug interactions with hormonal contraception" guidance 2017
- Any patient who has taken Ulipristal Acetate in the last five days

Any concerns should be discussed with senior healthcare practitioner

4. Counselling

4.1. Mode of Action

Primarily inhibits ovulation, but also alters cervical mucus preventing sperm penetration and normal endometrial development.

4.2. Efficacy

Provides effective contraception for three years. Overall pregnancy rate is <1 in 1000 over three years of use. Pregnancies due to true method failure are extremely rare. Rapid return to fertility after removal. Will require immediate contraception cover after removal as drug concentrations can be undetectable within 24 hours of removal. 94% of women will ovulate within the first three weeks of removal

4.3. Timing of insertion

FSRH guidance advises that a patient may start the progestogen-only implant up to and including Day 5 of the menstrual cycle without the need for additional contraceptive protection.
The patient may start the Progestogen-only implant at any other time if it is reasonably certain that she is not pregnant. She should then use extra contraceptive protection for the first 7 days. The patient should be advised to do a pregnancy test no sooner than three weeks after the last unprotected sexual intercourse.
For advice on switching from hormonal methods or replacing a progestogen only implant see appendix B.

4.4. Side effects

The nurse will discuss the possible side effects as listed in the Summary of Product Characteristics (SPC)

- Very commonly reported (>1/10): acne, headaches, weight change
- Other possible side effects (1/10-1/100): mood changes, abdominal pain, decreased libido, dizziness, breast tenderness, hair loss, hot flushes, ovarian cyst

4.5. Effect on bleeding patterns

Fewer than one-quarter of women using the progestogen-only implant will have regular bleeds. Infrequent bleeding is the most common pattern (approximately one-third); around one-fifth of women experience no bleeding; and approximately one-quarter have prolonged or frequent bleeding. Altered bleeding patterns are likely to remain irregular.

It may be possible to prescribe additional hormonal medication in some instances to control the bleeding. Patients should be encouraged to attend seeking help for unacceptable bleeding to help aid Nexplanon compliance.

4.6. Explanation of the fitting procedure and after effects

Simple minor procedure used to fit implant in non-dominant arm (usually). Local anaesthetic used during the procedure. Analgesics after the procedure are not usually required. A small steri-strip, gauze and bandage are normally applied. The bandage can be removed the same day and the plaster in three to five days. It is advisable to keep the wound dry during this time.

Occasionally there may be some bruising or infection at the site. There will be a small scar where the implant was inserted and/or removed.
Patients should be advised to report if they are ever unable to feel their implant.

Very rarely it may be difficult to remove the implant, but ordinarily it is a simple procedure similar to insertion. Implants can be refitted into the same arm. Written and verbal explanations of wound care advice to be given.

4.7. Current contraception

Document current and past methods of contraception.

4.8. Safeguarding

If a patient is 13-18 years of age: reassure confidentiality and ensure no safeguarding issues, assess and document Fraser competency. Complete the <16 template. Discuss with safeguarding leads if any concerns.

Ensure no safeguarding concerns for patients over 18 years of age also.

5. Examination

Prior to the fit the skin should be assessed for rashes, dermatitis, and eczema or similar. If there is severe eczema at the insertion site consider treating this before insertion of the implant.

A pregnancy test should be performed as indicated by the history.

6. Referral Pathway

If the patient does not meet the criteria for fitting a sub-dermal progestogen-only implant then the patient must be referred for further assessment on same day if possible, or as soon as is feasible.
Consider bridging with an alternative method if possible and appropriate if fitting cannot be done that day.

7. Treatment Pathway

Nexplanon may be inserted only by healthcare practitioners who have been specifically trained to the standard of Faculty of Sexual and Reproductive Health (FSRH) Letter of Competence (LoC) in Sub-Dermal Implant (SDI) insertion and who are approved to work to the Trust's PGD for Local Anaesthetic and Nexplanon.

7.1. Fitting progestogen-only Implant (Nexplanon) as per PSD or PGD

The nurse will usually fit the progestogen-only implant in the non-dominant arm.

• The woman's arm should be flexed at the elbow with her hand underneath her head (or as close as possible) during insertion and removal of the implant.

• The implant should be inserted subdermally, just under the skin at the inner side of the non-dominant upper arm. The updated insertion site is overlying the triceps muscle about 8-10 cm from the medial epicondyle of the humerus and 3-5 cm posterior to the sulcus (groove) between the biceps and triceps muscles. There is no need to replace implants inserted in accordance with the previous implant instructions, unless there are concerns.

Where possible the patient and practitioner should palpate the implant after insertion to ensure is present.

7.2. They will record in the Electronic Patient Record (using the correct template):

- The name of the Health Care Assistant/Nurse assisting with the procedure
- Batch No and expiry date of the local anaesthetic used and the implant.
- That the implant is palpable, and in which arm
- They will give advice about wound aftercare
- They will give specific advice about additional precautions and pregnancy testing as required
- They will give a reminder card and inform the GP (if the patient is agreeable)
- They will make sure that the patient understands that the service will not be sending reminders at three years, but that the patient is welcome to return at any time, particularly if experiencing any problems
- Following Levonorgestrel Emergency Hormonal Contraception LNG-EC quick start of contraception including implants should be offered. Implant fitting should be delayed for 5days after use of Ulipristal emergency contraception. Advise and offer a follow up pregnancy test four weeks after fitting implant.

8. Discharge Pathway

8.1. Before discharge:

- Reaffirm patient's contact details
- Document the consultation as per treatment pathway
- The patient 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.
- Encourage the patient to return if they develop problematic bleeding.

8.2. Ensure as indicated that:

- The patient has understood the information given as per treatment pathway

8.3. Patient follow up:

- As per Treatment Pathway

8.4. Further advice

- Routine cervical screening to be encouraged as per national guidelines
- If appropriate the nurse will encourage the woman to stop smoking
- Breast awareness should be encouraged
- Full STI screening to be offered as per national guidelines.

9. Documents consulted to prepare this protocol

- Fraser Guidelines/Gillick Competence (Gillick v West Norfolk and Wisbech Area Health Authority 1985 3 All ER 402-437)
- Infections post Nexplanon insertion, R Partridge and J Bush (2013) J fam plan Reprod Healthcare (2013: 40: 75 doi: 10.1136/jfprhc-2013-100774
- Safeguarding Children, Northern Devon Healthcare Trust, v2 January 2017
- Safeguarding Adults, Northern Devon Healthcare NHS Trust, v5 Jan 2016.doc (approved at Safeguarding Adult Board 28.01.2016)
- Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit CEU Statement (September 2010) Nexplanon (Update November 2010 change to Progestogen-only implants February 2014
- Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit CEU guidance (March 2017) Emergency Contraception
- National Institute for Health and Clinical Excellence, Long Acting Contraception (clinical guideline No. 30)
- http://www.nice.org.uk/nicemedia/pdf/ (addendum to Clinical Guideline 30, Long-acting reversible contraception)
- UK Medical Eligibility Criteria for Contraception use (UKMEC 2009)
- https://www.gov.uk/drug-safety-update/nexplanon-etonogestrel-contraceptive-implants-reports-of-device-in-vasculature-and-lung

10. APPENDIX A – Training Competency Form

The registered health professional named below, being employees of Northern Devon Healthcare Trust based at ……. have received training and are competent to operate under this protocol

11. Appendix B. Table from FSRH guidance on switching from hormonal methods to Progestogen only implant

NAME *(please print)*	PROFESSIONAL TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE