Cheshire & Merseyside
sexualhealthnetwork

CMSHN Draft Protocol **September 2012**

CONTRACEPTIVE IMPLANT

Efficacy

The pregnancy rate associated with use of a POI is very low < 1 in 1000 over 3 years. Most pregnancies with an implant have occurred when the client was already pregnant prior to insertion of the implant or has not observed contraceptive cover after initial fitting.

Side Effects

- Bleeding: Altered bleeding patterns are common among women using a POI. Women should be advised that 20% of users will have no bleeding while almost 50% will have infrequent, frequent or prolonged bleeding and bleeding patterns are likely to remain irregular.
- Weight change, mood change, loss of libido: Women should be advised that there is no evidence of a causal association between use of the POI and the above three symptoms.
- Acne: Women should be advised that acne may improve, occur or worsen during the use of a POI.
- Headache: There is no evidence of causal association between use of a POI and headache
- Migraine: Women who develop new symptoms of migraine with aura whilst using POI should be advised to seek medical advice as medical investigation may be appropriate.

Assessment of Client Suitability

A medical history (including sexual history) and a clinical assessment together with consideration of the recommendations in the UK Medical Eligibility Criteria (UKMEC) should be used to assess the use of the POI.

Blood pressure and BMI should be recorded.

Assessment of method suitability for the client

- Efficacy and failure rate discussed and written method information should be given
- Procedure fully explained and demonstration implant shown
- Decision to proceed taken by client and clinician
- **All clients should be counselled and given the opportunity to take time to consider all their contraceptive options, and possible side effects, including changes to bleeding patterns, before POI insertion**
- Further appointment made by client for insertion if required.

Documentation

- The full visit history should be completed or updated as required.
- Written method information including contact number is given to client
- Prescription is recorded
- Site of implant, batch number and expiry date of medication recorded
- Record of implant site and date due for removal given to client
- Nurse supplying where appropriate under patient group direction
- GP notified of prescription, if permission is given for correspondence

Post- Insertion instructions & follow up arrangements

- Advised additional contraception for seven days if necessary.
- Wound care instructions should be given at time of insertion.
- Advised to take simple analgesia if required.
- Routine post-insertion follow up is not necessary. Women should be advised to return at any time to discuss problems or if they want to change their contraceptive method.
- Women should be advised to specifically return if they: cannot feel the implant; notice any change in shape or changes to the skin around the site of the implant; experience any pain; become pregnant or develop any condition that would contraindicate its use.
- It should be documented that the implant is palpated in situ post insertion

Management of Bleeding Problems with POI in situ

- A sexual history should be taken from women who experience unacceptable bleeding while using the POI to establish STI risk
- Consider a pregnancy test if there is any concern regarding risk of conception and timing of fitting.
- Investigation for gynaecological pathology may be clinically indicated, ie, inspection of the cervix is recommended to exclude local causes.
- Only perform a cervical smear test if it is due.

If other pathology is excluded or treated, the client can be reassured that irregular bleeding patterns is an expected side effect of POI, but she should report any further changes.
There is very little evidence supporting the use of any particular drug regimen in the management of persistent unacceptable bleeding patterns with POI use. Mefenamic acid or ethinylestradiol (alone or as a COC) may be used if there are no contraindications.

Timing of insertion of subdermal implant

- **First use**

POI can be inserted up to and including day 5 of cycle without additional contraceptive precautions.
POI can be inserted after day 5 if reasonably certain the woman is not pregnant. See Appendix !.
A careful history should be taken to ensure that the women has not had unprotected intercourse

since last menses and has been correctly and consistently using a reliable method of contraception. Additional contraceptive precautions should be used for 7 days.

- **Following abortion or miscarriage**

If inserted within 5 days of surgical or second part of a medical abortion - no additional precautions required.
If started beyond 5 days after event then 7 days of additional contraceptive precautions is required.

- **Postpartum**

If inserted up to day 21, no additional contraceptive cover is required.
If started after day 21, 7 days of additional contraceptive precautions is required.

- **Breast feeding**

POI is safe and licensed to insert in breast feeding mothers. Timing of insertion as above.

- **Switching from another method**

Ensure adequate contraceptive cover from previous method continues for 7 days post insertion of POI.

Timing of Removal

POIs work by preventing ovulation. Contraceptive cover is present until the device is removed, irrespective of when last sexual intercourse occurred. Any sexual intercourse after removal must be covered by an alternative method of contraception if pregnancy is to be avoided.

If a POI is removed prior to its licence limit (3 years) and another implant reinserted immediately, there is no need for additional contraceptive precautions.

Insertion and Removal

- Health professionals who insert and remove POI should be appropriately trained should maintain competencies and attend regular updates.
- An aseptic technique should be used for the insertion and removal of POI. Skin preparation should be per local infection control guidance
- Appropriate anaesthesia should be injected prior to insertion and removal of a POI.
- Please ensure to check that implant is present in the loading device before insertion
- It should be documented that the implant is palpated in situ post insertion

Lost POI

If the implant is impalpable, no attempt should be made to remove it. The client should be referred for ultrasound location.

Deeply inserted implants may need to be removed by an expert.

Although Nexplanon is radio-opaque and can be seen on X-Ray, CT and MRI, ultrasound remains the recommended first line imaging technique for locating a non palpable or deep POI.

APPENDIX 1

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 7 days of the onset of a normal menstrual period
- She is within 4 weeks postpartum for non-lactating women
- She is within the first 7 days post-abortion or miscarriage
- She is fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months postpartum

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.

UKMEC	DEFINITION OF CATEGORY
CATEGORY 1	A condition for which there is no restriction for the use of the contraceptive method.
CATEGORY 2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
CATEGORY 3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method.
CATEGORY 4	A condition which represents an unacceptable health risk if the contraceptive method is used.

UKMEC TABLE – IMPLANT

COMMON REVERSIBLE METHODS
I = Initiation, C = Continuation

Condition	UKMEC CATEGORY
Personal characteristics & reproductive history	
PREGNANCY	n/a
AGE	1
PARITY	1
BREASTFEEDING	1
POSTPARTUM (non breastfeeding women)	1
a) < 21 days	1

b) > 21 days	1	
POST ABORTION		
a) First trimester	1	
b) Second trimester	1	
c) Immediate post septic abortion	1	
PAST ECTOPIC PREGNANCY	1	
HISTORY OF PELVIC SURGERY (including caesarean section) (see also postpartum section)	1	
SMOKING		
a) Age < 35 years	1	
b) Age ≥35 years	1	
OBESITY	1	
Cardiovascular disease		
MULTIPLE RISK FACTORS FOR ARTERIAL CARDIOVASCULAR DISEASE (such as older age, smoking, diabetes and hypertension)	2	
HYPERTENSION		
a) Adequately controlled hypertension	1	
b) Consistently elevated blood pressure levels (properly taken measurements) i. systolic ≥140 to 159mmHg or diastolic ≥ 90 to 94 mmHg ii. systolic ≥160 or diastolic ≥ 95mmHg	 1 1	
c) Vascular disease	2	
HISTORY OF HIGH BLOOD PRESSURE DURING PREGNANCY (where current BP is normal)	1	
VENOUS THROMBO-EMBOLISM (VTE) (including deep vein thrombosis and pulmonary embolism)		
a) History of VTE	2	
b) Current VTE (on anticoagulants	2	
c) Family history of VTE	1	
d) Major surgery i. *With* prolonged immobilisation ii. *Without* prolonged immobilisation	 2 1	
e) Minor surgery *without* immobilisation	1	
f) Immobility (unrelated to surgery) eg: wheelchair use, debilitating illness)	1	
KNOWN THROMBOGENIC MUTATIONS (eg: Factor V Leiden; Prothrombin mutation; Protein S, Protein C and Antithrombin deficiencies)	2	
Condition	UKMEC CATEGORY	
SUPERFICIAL VENOUS THROMBOSIS		
a) Varicose veins	1	
b) Superficial thrombophlebitis	1	
CURRENT AND HISTORY OF ISCHAEMIC HEART DISEASE	I	C
	2	3
STROKE (history of cerebrovascular accident)	I	C
	2	3
KNOWN HYPERLIPIDAEMIAS (screening is NOT necessary for safe use of contraceptive methods)	2	
VALVULAR AND CONGENITAL HEART DISEASE		
a) Uncomplicated	1	
b) Complicated (e.g. with pulmonary hypertension, trial fibrillation, or a history of subacute bacterial endocarditis)	1	
Neurological conditions		
HEADACHES		
a) Non migrainous (mild or severe)	1	
b) Migraine without aura at any age	2	
c) Migraine with aura at any age	2	
d) Past history (≥ 5 years ago) of migraine with aura at any age	2	
EPILEPSY – be aware of potential drug interactions	1	
Depressive disorders		
DEPRESSIVE DISORDERS	1	
Reproductive tract infections and disorders		
VAGINAL BLEEDING PATTERNS		

a) Irregular pattern *without* heavy bleeding	2
b) Heavy or prolonged bleeding (includes regular and irregular patterns)	2
UNEXPLAINED VAGINAL BLEEDING (suspicious for serious condition) before evaluation	3
ENDOMETRIOSIS	1
BENIGN OVARIAN TUMOURS (including cysts)	1
SEVERE DYSMENORRHOEA	1
GESTATIONAL TROPHOBLASTIC NEOPLASIA (GTN) (includes hydatidiform mole, invasive mole, placental site trophoblastic tumour)	
a) Decreasing or undetectable β-hCG levels	1
b) Persistently elevated β-hCG levels	1
CERVICAL ECTROPION	1
CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)	1
CERVICAL CANCER (awaiting treatment)	2
Condition	UKMEC CATEGORY
BREAST DISEASE	
a) Undiagnosed mass	2
b) Benign breast disease	1
c) Family history of cancer	1
d) Carriers of known gene mutations associated with breast cancer (eg: BRCA1)	2
e) Breast cancer i. Current ii. Past and no evidence of current disease for 5 years	 4 3
ENDOMETRIAL CANCER	1
OVARIAN CANCER	1
UTERINE FIBROIDS	1
PELVIC INFLAMMATORY DISEASE (past or current)	1
STIs	1
HIV/AIDS	
HIGH RISK OF HIV	1
HIV INFECTED	
a) Not using anti-retroviral therapy	1
b) Using anti-retroviral therapy – be aware of potential drug interactions	1-2
AIDS AND USING HAART	2
Condition	UKMEC CATEGORY
Other infections	
SCHISTOSOMIASIS	1
TUBERCULOSIS	1
MALARIA	1
Endocrine conditions	
DIABETES	
a) History of gestational diabetes	1
b) Non vascular disease i. non insulin dependent ii. insulin dependent	 2 2
c) Nephropathy/retinopathy/neuropathy	2
d) Other vascular disease or diabetes of >20 years' duration	2
THYROID DISORDERS	1
Gastrointestinal conditions	
GALL BLADDER DISEASE	
a) Symptomatic	2
b) Asymptomatic	2
HISTORY OF CHOLESTASIS	
a) Pregnancy related	1
b) Past COC related	2
VIRAL HEPATITIS	
a) Acute or flare	1
b) Carrier	1

c) Chronic	1
CIRRHOSIS	
a) Mild (compensated without complications)	1
b) Severe (decompensated)	3
LIVER TUMOURS	
a) Benign i) Focular nodular hyperplasia ii) Hepatocellular (adenoma)	 2 3
b) Malignant (hepatoma)	3
INFLAMMATORY BOWEL DISEASE (includes Crohn's disease, Ulcerative colitis)	1
Anaemias	
THALASSAEMIA	1
SICKLE CELL DISEASE	1
IRON DEFICIENCY ANAEMIA	1
RAYNAUD'S DISEASE	
a) Primary	1
b) Secondary i. *without* lupus anticoagulant ii. *with* lupus anticoagulant	 1 2
RHEUMATIC DISEASES	
SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) **People with SLE are at an increased risk of ischaemic heart disease, stroke and venous thromboembolism and this is reflected in the categories given.**	
a) Positive (or unknown) antiphospholipid antibodies	3
b) Severe thrombocytopenia	2
c) Immunosuppressive	2
d) None of the above	2
DRUG INTERACTIONS	
ANTIRETROVIRAL THERAPY **This section relates to the SAFETY of contraceptive use in women using these antiretroviral. EFFECTIVENESS may be reduced and pregnancy itself may have a negative impact on health for some women with certain medical conditions**	
a) Nucleoside reverse transcriptase inhibitors b) Non-nucleoside reverse transcriptase inhibitors c) Ritonavir-boosted protease inhibitors	1 2 2
ANTICONVULSANT THERAPY	
This section relates to the SAFETY of contraceptive use in women using these anticonvulsants. EFFECTIVENESS may be reduced and pregnancy itself may have a negative impact on health for some women with certain medical conditions	
Certain anticonvulsants and progestogen-only contraception: Although the interaction of certain anticonvulsants with implants is not harmful to women, it is likely to reduce the effectiveness of implants. If a woman on certain anticonvulsants decides to use an implant **THE CONSISTENT USE OF CONDOMS IS RECOMMENDED*. Use of other contraceptives should be encouraged for women who are long-term users of any of these anticonvulsant drugs.**	
a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine) b) Lamotrigine	2* 1
ANTIMICROBIAL THERAPY **This section relates to the SAFETY of contraceptive use in women using these antimicrobials. EFFECTIVENESS may be reduced and pregnancy itself may have a negative impact on health for some women with certain medical conditions**	

Rifampicin or rifabutin therapy and progestogen-only contraception: Although the interaction of rifampicin or rifabutin with implants is not harmful to women, it is likely to reduce the effectiveness of implants.. If a woman on rifampicin or rifabutin decides to use an implant **THE CONSISTENT USE OF CONDOMS IS RECOMMENDED*. Use of other contraceptives should be encouraged for women who are long-term users of rifampicin or rifabutin**..	
a) Broad spectrum antibiotics	1
b) Antifungals	1
c) Antiparasitics	1
d) Rifampicin or rifabutin therapy	2*

Local deep implant removers list – from drug company

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Please check who else is trained in our area.

References: please expand abreviations & check ref list is exactly the same as on other documents

Croxatto HB, Makarainen L. The pharmacodynamics and efficacy of Implanon. An overview of data. Contraception 1998: 58; 91S-97S.

FFPRHC Guidance (July 2004). Contraceptive choices for breastfeeding women

Journal of Family Planning and Reproductive Health Care 2004: **30**(3) 181

FFPRHC Guidance (April 2005) Drug interactions with hormonal contraception
Journal of Family Planning and Reproductive Health Care 2005; 31(2): 139–151

Faculty of Family Planning and Reproductive Health Care UK Medical Eligibility Criteria for contraceptive use (UKMEC 2005/6)

UKMEC Criteria for Contraceptive Use November 2009 (updated May 2010)

FSRH Guidance (April 2008 – updated January 2009) Progestogen Only Implants

FSRH CEU Statement Nexplanon (Sept 2010 updated Nov 2010)

FSRH Guidance (Jan 2011) Drug Interactions Hormonal Contraception

The UKMEC for Contraceptive Use Summary Sheets (May 2010)

With sincere thanks to the West of Scotland Sexual Health Managed Clinical Network for sharing their guidelines and protocols http://www.centralsexualhealth.org/west-of-scotland-managed-clinical-network