CONTRACEPTION
PROTOCOLS

BORDERS SEXUAL HEALTH

A Wylie, November 2010
(Review Date November 2011)

(Adapted from NHS Grampian Protocols – S Brechin)
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STATEMENT

The rationale for these protocols is to summarise the large amount of evidence-based published information on contraceptive use. This document includes both hormonal and non-hormonal methods of contraception:

- **Hormonal contraception**: combined hormonal pills, patch and ring, progestogen-only pills, injectable, implant, intrauterine system and emergency contraception

- **Non-hormonal contraception**: male and female condoms, diaphragms and cervical caps, male and female sterilisation

The objective of this document is to provide evidence-based guidance on the SAFE AND EFFECTIVE USE OF CONTRACEPTION BY WOMEN AND MEN OF REPRODUCTIVE AGE.

This document can be used as a reference by all healthcare professionals and other professionals throughout NHS Borders who are involved in discussing and/or prescribing contraception.

National evidence-based guidance from the Faculty of Sexual and Reproductive Health (FSRH), the World Health Organisation (WHO), the Royal College of Obstetricians and Gynaecologists (RCOG) the British Association for Sexual Health and HIV (BASHH), the National Institute for Clinical Excellence (NICE) and the Scottish Intercollegiate. These protocols are based on national evidence-based guidance (page 70) but have been adapted to reflect local provision of services in NHS Borders and care pathways should be followed were provision cannot be facilitated locally. In particular, national guidance from the FSRH has been used extensively in developing this single guidance document. The FSRH guidance documents used extensively in this guidance (available at www.fsrh.org) were developed by the FSRH Clinical Effectiveness Unit (Director Dr Susan Brechin) using a systematic review of the literature; multidisciplinary groups of experts which included client/user representatives. They have been independently peer reviewed.

This document updates and replaces previous informal protocols on contraceptive use which have been used widely by nurses and doctors within Borders Sexual Health. These previous protocols have been used by medical and nursing staff within the Department of Sexual and Reproductive Health as a point of reference.

These protocols do not replace the clinical advice which can be sought from any of the clinical team at Borders Sexual Health.
If you wish to discuss a clinical problem telephone us on: 01896 663700.
COMBINED HORMONAL CONTRACEPTION (PILLS AND PATCH)

- Combined hormonal contraception (CHC) can be used safely by the majority of women from menarche to age 50 years when no other risk factors are present.

- User preference and concerns should be considered when counselling about the benefits, potential harms, and correct use. Most evidence relates to combined oral contraceptive (COC) use but this evidence is extrapolated to patch use also.

- A first line COC is usually a monophasic pill with 30 micrograms of ethinylestradiol and levonorgestrel or norethisterone (e.g. Microgynon 30 is Borders Sexual Health pill of first choice). If a woman has previously used a combined oral contraceptive pill (COC) with desogestrel or gestodene (e.g. Marvelon, Mercilon, Femodene) and wishes to use this again or specifically requests this pill and she may do so after counselling about the increased venous thromboembolic risks.

- Women may consider using a 20 microgram pill first-line but there is no evidence that the reduced dose of EE has any beneficial effects and may indeed lead to breakthrough bleeding. It is recommended that women aged over 40 years should use the lowest dose of pill possible and this should be discussed when starting the method or reviewing pill use in women aged over 40 years.

- There are no benefits in using a bi-phasic or triphasic COC. Women using these pills should be reviewed at follow-up and discussion should take place about switching to a first-line pill.

- There is no evidence that one COC is better than another in terms of bleeding patterns and the patch and pill appear to be similar. Figures 4 & 5, Pages 53 and 54 outlines the management of unscheduled bleeding in women using hormonal contraception.

- Women using non-liver enzyme inducing antibiotics short term (< 3 weeks) should be advised to use condoms in addition for the duration of the antibiotic regime and for 7 days after or until 7 consecutive pills have been taken. The pill free interval may need to be omitted. After 3 weeks use of a non-liver enzyme inducing antibiotic gut flora have returned to normal and condoms are no longer required as additional contraceptive protection.

- Women using liver-enzyme inducing medications short term (e.g. single dose of rifampicin for meningitis prophylaxis) should be advised to use condoms in addition to combined hormonal contraception and for at least 4 weeks after the liver enzyme inducer is stopped.

- Women using liver-enzyme inducing medications long term (e.g. anti-epileptic medication, anti-retrovirals, rifampicin, St John’s Wort) should be advised that the efficacy of combined hormonal contraception is reduced and an alternative contraceptive method which is not altered with use of liver enzyme inducing medication should be considered (e.g. injectable, copper intrauterine device or levonorgestrel intrauterine releasing system).

- It should be noted that Dianette (35 micrograms of EE and 3 mg of cyproterone acetate) is not licensed solely as a contraceptive. It is licensed to be used by women with moderate to severe acne which has failed to respond to medical treatment; moderate hirsuitism and should be used short term. Once symptoms improve or resolve an alternative COC can be used. The VTE risk is increased with Dianette.
• There is no evidence that pills containing third generation progestogen (desogestrel or gestodene) are better for the skin than second generation pills (norethisterone or levonorgestrel). There is some evidence that estrogen dominant pills (e.g. Cilest) may improve acne. All COCs increase sex hormone binding globulin (SHBG) and can reduce free testosterone and may improve acne or hair growth.

• In NHS Borders the use of a combined hormonal contraceptive patch can be offered to women who are demonstrated to have problems with pill compliance, nausea with the COC or problems with GI absorption with COC. The risk benefit profile for patch us is the same as for COC. The patch is a second line combined method.

N.B. The patch may be less reliable in women weighing over 90kg.

• In addition, the combined vaginal ring has been approved for specialist use in NHS Borders. This may be offered 2nd line to women who have difficulty remembering pills, want a longer acting method or want the better cycle control offered by a combined method.

• Yasmin is not in the Borders Formulary and is not recommended for routine use.

<table>
<thead>
<tr>
<th>MEDICAL ELIGIBILITY CRITERIA should be assessed before considering combined hormonal contraceptive use to ensure the woman has no conditions where use is not recommended. The full UKMEC categories can be viewed and downloaded from the Faculty of Sexual and Reproductive Health at <a href="http://www.fsrh.org">www.fsrh.org</a> Categories where use may be restricted only are outlined below.</th>
</tr>
</thead>
</table>
| **UKMEC 3**  
Risks generally outweigh benefits but use can be considered with expert clinical judgement and/or referral to a specialist contraceptive provider |
| **UKMEC 4**  
Unacceptable health risk and should not be used |
| Breastfeeding between 6 weeks and 6 months postpartum and fully or almost fully breastfeeding |
| Postpartum < 21 days postpartum |
| Smoking aged ≥35 years and smoking less than 15 cigarettes per day, or stopped smoking less than 1 year ago |
| Obesity BMI 35 to 39 kg/m² |
| Cardiovascular disease multiple risk factors for arterial cardiovascular disease |
| Hypertension elevated BP > 140 to 159 mmHg systolic or > 90 to 94 mmHg diastolic Family history of VTE in a first degree relative aged ≤45 years |
| Immobility (unrelated to surgery) e.g. wheelchair use, Known hyperlipidaemias |
| Migraine headaches without aura in women aged ≥35 years; or a past history of migraine with aura at any age |
| Breast disease past history of breast cancer and no evidence of recurrence for 5 years carriers of known gene mutations associated with breast cancer (e.g. BRCA1); or past history and no evidence of current disease for 5 years |
| Diabetes with nephropathy / retinopathy / neuropathy; or other vascular disease or diabetes of > 20 years' duration The category will given will depend on disease severity |
| Gallbladder disease symptomatic medically treated or current |
| History of cholestasis past COC-related |
| Cirrhosis mild compensated disease |
| Drugs which induce liver enzymes for example rifampicin, rifabutin, St John's Wort, griseofulvin, and certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine) |
| Breastfeeding < 6 weeks postpartum |
| Smoking aged ≥35 years and smoking more than 15 cigarettes per day |
| Obesity BMI ≥ 40 kg/m² |
| Cardiovascular disease multiple risk factors for arterial cardiovascular disease |
| Hypertension BP 160mmHg systolic and/ or > 95 mmHg diastolic; or vascular disease |
| VTE current (on anticoagulants) or past history |
| Major surgery with prolonged immobilisation |
| Known thrombogenic mutations |
| Current and history of ischaemic heart disease |
| Stroke |
| Valvular and congenital heart disease complicated by pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis |
| Migraine headaches with aura at any age |
| Gestational trophoblastic neoplasm when hCG is abnormal |
| Breast disease current breast cancer |
| Diabetes with nephropathy, retinopathy, neuropathy or other vascular disease, or diabetes of > 20 years duration. The category given will depend on disease severity |
| Viral hepatitis active disease |
| Cirrhosis severe decompensated disease |
| Liver tumours benign and malignant |
| Raynaud's disease secondary with lupus anticoagulant and thus a tendency to thrombosis |
**NuvaRing®**

Nuvaring® is a combined hormonal contraceptive vaginal ring releasing 15 μg/day ethinylestradiol and 120 μg/day of etonogestrel. It is latex free. The contraindications are the same for other combined methods. It is placed (anywhere) in the vagina and kept in place for 3 weeks and then removed for one week. A new ring is placed in the vagina for the next cycle of 3 weeks in, 1 week out and so on.

The SMC approved it for use earlier this year (2010) and it has been included on the Borders Formulary for specialist use.

**Who is the NuvaRing® suitable for?**
- women who find it difficult to remember pills daily but who don’t want a LARC method
- women who want the good cycle control provided by a combined method
- women who have GI absorption problems

**Pros**
- good cycle control (better than COC)
- longer acting method
- lower systemic levels E2 levels than COC

**Cons**
- may cause vaginitis
- needs to be kept in fridge until dispensed therefore only able to give 3 months supply at a time.
- efficacy reduced if ring removed or expelled for more than 3 hours
- almost double price of Evra
- more expensive than LARC

At first visit enquiry and documentation should be made about:

- Medical conditions (past and present)
- Specific enquiry about migraine and cardiovascular risk factors (smoking, obesity, hypertension, thrombophilia, previous VTE and hyperlipidaemia)
- Drug use (prescription and non-prescription)
- Relevant family history
- Smear history
- Record blood pressure (BP) and Body Mass Index (BMI)

At follow up visits documentation should be made about:

- Update medical history (migraine, smoking, VTE)
- Check bleeding pattern
- Assess STI risk and discuss safer sex
- Record BP
- Record BMI
- Assess compliance and discuss use (e.g. tricyling)

**POINTS TO COVER WHEN COUNSELLING about combined hormonal contraception**

**POTENTIAL RISKS**

- Women should be counselled that the risk of myocardial infarction with combined hormonal contraceptive use is very small but is increased for non-smokers and smokers.

- All COCs increase the risk of venous thromboembolism ‡, myocardial infarction and ischaemic stroke but the absolute risk is small.

- Any increase in the risk of breast cancer associated with use is likely to be small, is in addition to the background risk and is reduced to no increased risk 10 years after stopping. New data suggests no increased risk of breast cancer.

- There may be a very small increase in the risk of cervical cancer with use which increases with increasing duration of use. New data suggest increased risk with ≥ 8 years use (the rate is 38 per 100 000 woman years). No need to stop combined hormonal contraception if there is an abnormal smear.

<table>
<thead>
<tr>
<th>Circumstance</th>
<th>Risk of VTE per 100 000 woman years  ‡ (Absolute risk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women not using COC</td>
<td>5</td>
</tr>
<tr>
<td>Women using COCs containing norethisterone or levonorgestrel</td>
<td>15</td>
</tr>
<tr>
<td>Women using COCs containing desogestrel or gestodene</td>
<td>25</td>
</tr>
<tr>
<td>Women who are pregnant</td>
<td>60</td>
</tr>
</tbody>
</table>

‡ Absolute VTE risk associated with combined oral contraceptive pill (COC) use and non-use
NON-CONTRACEPTIVE BENEFITS

- Menstrual pain and blood loss may be reduced.
- The incidence of functional ovarian cysts and benign ovarian tumours is reduced.
- The risk of ovarian and endometrial cancer is reduced by at least 50% during use and for at least 15 years after stopping.
- The risk of colorectal cancer is reduced.
- Evidence suggests an overall reduction in all cancer risk of approximately 12% with COC use.
- Improvement in symptoms of acne vulgaris.

INFORMATION ON USE for women when first using the combined oral contraceptive pill

When used consistently and correctly COC is > 99% effective at preventing pregnancy

One pill should be taken daily for 21 days followed by 7 pill free days. Women may choose to take more than one packet of pills continuously followed by a 7 day pill free interval (unlicensed).

COC may be started up to and including day 5 of the menstrual cycle to provide immediate contraceptive protection. COC can be started at other times if it is reasonably certain a woman is not pregnant but additional barrier contraception is required for the first 7 days of pill taking.

If vomiting occurs within 2 hours of pill-taking another pill should be taken as soon as possible. With persistent vomiting or severe diarrhoea for > 24 hours instructions for missed pills (Figure 1, Page 46) should be followed.

If taking non-liver enzyme inducing antibiotics women should be advised to use condoms during antibiotic use and for 7 days after the antibiotic is stopped. If there are fewer than 7 pills remaining in the packet the pill free interval should be omitted. If a non-liver enzyme inducing antibiotic has been used for ≥3 weeks additional barrier contraception is no longer required.

Missing pills is not encouraged but one pill can be missed any time without loss of contraceptive protection. If more than one pill is missed then condoms or abstinence is advised until seven consecutive pills are taken (See Figure 1, Page 50).

Serious symptoms which require immediate medical advice include chest pain, breathlessness, coughing up blood, painful leg swelling, weakness or numbness of an arm or leg, unusual headaches or migraines that are worse than usual, sudden problems with speech or eye sight, jaundice, severe abdominal pains. Temporary side effects such as headaches, nausea, breast tenderness, and mood changes usually settle within a few months. Irregular bleeding is common in the first few months.

If given any new medication ask if this will interact with the COC. If you have to go to hospital for an operation, or if you have an accident which affects the movement of your legs you should tell the doctor you are taking the COC.
INSTRUCTIONS FOR USE of a combined hormonal contraceptive patch

When used consistently and correctly the patch is > 99% effective at preventing pregnancy. Apply patch to skin (abdomen, thigh, buttoc, upper arm) once a week for 3 consecutive weeks followed by a patch free week. Patches can be continued without patch free week to avoid bleeding for up to 6 weeks (licensed).

A patch can be continued for up to 9 days before contraceptive protection is lost.

Patch may be started up to and including day 5 of the menstrual cycle without the need for additional barrier contraception.

It can be started at other times if it is reasonably certain a woman is not pregnant but additional barrier contraception is required if or the first 7 days of using the patch (i.e. one patch).

If taking antibiotics women advised to use condoms during antibiotic use and for 7 days after the antibiotic is stopped. If there is less than 1 week of patch use left, then the patch free interval should be omitted. If a non-liver enzyme inducing antibiotic has been used for ≥3 weeks additional barrier contraception is no longer required.

If taking non-liver enzyme inducing antibiotics women should be advised to use condoms during antibiotic use and for 7 days after the antibiotic is stopped. If there are fewer than 7 days of patch use remaining in the packet the patch free interval should be omitted. If a non-liver enzyme inducing antibiotic has been used for ≥3 weeks additional barrier contraception is no longer required.

Serious symptoms which require immediate medical advice include chest pain, breathlessness, coughing up blood, painful leg swelling, weakness or numbness of an arm or leg, unusual headaches or migraines that are worse than usual, sudden problems with speech or eye sight, jaundice, severe abdominal pains. If you have to go to hospital for an operation, or if you have an accident which affects the movement of your legs you should tell the doctor you are taking the COC.

Temporary side effects such as headaches, nauseas, breast tenderness, and mood changes usually settle within a few months. Irregular bleeding is common in the first few months. If given any new medication ask if this will interact with the patch.
Instructions for using the combined hormonal vaginal ring  Nuvaring®

The ring should be placed in your vagina for 3 consecutive weeks followed by 1 ring free week. After you ring free week, you should insert a new ring in your vagina. You should have a withdrawal bleed in your ring free week.

The ring should not be removed from your vagina during the 3 consecutive weeks. It stays in place during sex.
The ring should be compressed and then inserted into your vagina until comfortable. The exact position is not important.
It can be removed (for the ring free week) by hooking your forefinger under the ring and pulling it out. It should be disposed in normal household waste.

The ring may be started up to and including day 5 of the menstrual cycle without the need for additional barrier methods.
It can be started at any other time if it is reasonably certain a woman is not pregnant but additional barrier contraception is required for 7 days.

If the ring comes out for more than 3 hours, rinse it in tepid water and put it back in your vagina. You will need to use condoms for 7 days.

The ring needs to be kept in the pharmacy fridge until it is given to you, so you will only be given 3 months supply at a time. You should keep it at room temperature.

Serious symptoms which require immediate medical advice include chest pain, breathlessness, coughing up blood, painful leg swelling, weakness or numbness of an arm or leg, unusual headaches or migraines that are worse than usual, sudden problems with speech or eye sight, jaundice, severe abdominal pains. If you have to go to hospital for an operation, or if you have an accident which affects the movement of your legs you should tell the doctor you are taking the combined hormonal contraceptive.

Temporary side effects such as headaches, nauseas, breast tenderness, and mood changes usually settle within a few months. Irregular bleeding is common in the first few months.

If given any new medication ask if this will interact with the ring.
Antibiotics may interact with the effectiveness of the ring, so use condoms whilst you are taking antibiotics and for 7 days after. If there are less than 7 days of ring use left, omit your ring free period and insert a new ring.

FOLLOW UP OF WOMEN using combined hormonal contraception

Women should be encouraged to use a combined hormonal contraceptive (pill, patch or ring) for at least 3 months before considering an alternative unless she has serious side effects (as above).

A follow up at 3 months allows an assessment of BP, problems and re-instruction if required. In the absence of special problems up to 12 months supply of combined hormonal contraception can be given at follow up.

Women should be encouraged to return at anytime if any problems arise.
### WHEN TO START combined hormonal contraception

<table>
<thead>
<tr>
<th>Circumstances for COC start</th>
<th>When to start COC</th>
<th>Additional contraceptive protection required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women having menstrual cycles</td>
<td>Start COC up to and including day 5. At any other time if it is reasonably certain that she is not pregnant.</td>
<td>None or For 7 days</td>
</tr>
<tr>
<td>Women who are amenorrhoeic</td>
<td>COC can be started at any time, if it is reasonably certain she is not pregnant.</td>
<td>For 7 days</td>
</tr>
<tr>
<td>Postpartum (not breastfeeding)</td>
<td>Start COC on day 21 postpartum if vaginal delivery and no additional risk factors for VTE. If she is &gt; 21 days postpartum and her menstrual cycles have returned she can start COC as for other women having menstrual cycles. If she is &gt; 21 days postpartum and her menstrual cycles have not returned treat as amenorrhoeic.</td>
<td>None or For 7 days</td>
</tr>
<tr>
<td>Postpartum (breastfeeding)</td>
<td>If she is &gt; 6 months postpartum and her menstrual cycles have returned she can start COC as for other women having menstrual cycles.</td>
<td>None or for 7 days</td>
</tr>
<tr>
<td>Post-abortion</td>
<td>She can start COCs within 5 days of surgical or medical abortion at gestations &lt; 24 weeks to provide immediate contraceptive protection.</td>
<td>None</td>
</tr>
<tr>
<td>Switching from other hormonal methods (other than the IUS)</td>
<td>COC can be started immediately if she has been using her hormonal method consistently and correctly, or if it is reasonably certain she is not pregnant. There is no need to wait for her next menstrual period. If her previous method was an injectable or an implant (which inhibit ovulation), she can start COC anytime up to when the repeat injection is due or the implant is removed.</td>
<td>None</td>
</tr>
<tr>
<td>Switching from a non-hormonal method (other than the IUD)</td>
<td>Start COC up to and including day 5 of the menstrual cycle At any other time if it is reasonable certain that she is not pregnant.</td>
<td>None or For 7 days</td>
</tr>
<tr>
<td>Switching from an intrauterine device or system</td>
<td>Ideally start COC at least 7 days before removal of an intrauterine method so that contraceptive protection is maintained. <strong>NB:</strong> To prevent risk of pregnancy at the time of removing an intrauterine method avoid unprotected sex 7 days prior to removal. If started on the day of removal.</td>
<td>None or For 7 days</td>
</tr>
</tbody>
</table>
ADVICE ON MISSED combined hormonal contraceptive pills

- Seven pills taken consecutively will inhibit ovulation the remaining pills in a packet maintain anovulation.
- Seven pills are missed every month (in the pill free week) without losing the contraceptive effect, as long as all other pills are taken consistently and correctly.
- The most risky time to miss pills is in week one (any days 1-7) because they are preceded by a seven day pill free week. This is why emergency contraception may be indicated.
- Missed pills in week three are only risky if the woman does not omit her pill free week or ensure that it is no longer than 7 days.
- Missed pills in week 2 are rarely an indication for emergency contraception.
- If the woman is anxious and has attended the clinic EC may still be given even if not fulfilling the recommendations outlined below. Manage women individually.

SEE FIGURE 1: Advice for missed Combined Oral contraceptive pills (Page 50 )

<table>
<thead>
<tr>
<th>Week of pill taking</th>
<th>*Pills missed</th>
<th>Emergency contraceptive use</th>
<th>Condom use</th>
<th>Advice for COC taking</th>
</tr>
</thead>
</table>
| Week 1-3            | One 20 μg pill | Not indicated               | Condoms or abstinence are not advised | 1. Take the missed pill as soon as remembered.  
2. She may take two pills on the same day (one at the moment of remembering and the other at the usual time) or even at the same time.  
3. Continue pill taking as usual. |
|                     | One or two 30 – 35 μg pills |             |                        |          |
|                     | Two or more 20 μg pills | Indicated if pills are missed in the first week and UPSI occurred in the pill free week or in the first week of pill taking. * | Condoms or abstinence advised until seven consecutive pills have been taken | 1-3 as above.  
AND  
if missed pills are in week 3 omit the pill free interval. |
|                     | Three or more 30 – 35 μg pills |             |                        |          |
|                     | If pill packet started late (extending pill free interval) |             |                        |          |
|                     | - two or more days late for 20μg pills |             |                        |          |
|                     | - three or more days late for 30 – 35 μg pills |             |                        |          |

*If a woman is unsure which COC she is using treat as for 20 μg pills
**PROGESTOGEN-ONLY PILLS**

*Traditional* progestogen-only pills contain norethisterone, levonorgestrel or etynodiol diacetate. The desogestrel-only pill is one of the new generation of POPs. Progestogen-only pills currently in use at Borders Sexual Health are listed below.

<table>
<thead>
<tr>
<th>Brand Name (Manufacturer)</th>
<th>Type of progestogen</th>
<th>Dose of progestogen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TRADITIONAL POPs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Micronor</td>
<td>Norethisterone</td>
<td>350mcg</td>
</tr>
<tr>
<td>Noriday</td>
<td>Norethisterone</td>
<td>350mcg</td>
</tr>
<tr>
<td>Norgeston</td>
<td>Levonorgestrel</td>
<td>30mcg</td>
</tr>
<tr>
<td><strong>DESOGESTREL-ONLY POP</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerazette</td>
<td>Desogestrel</td>
<td>75mcg</td>
</tr>
</tbody>
</table>

**CLINICAL ASSESSMENT of women requesting progestogen-only pills**

MEDICAL ELIGIBILITY CRITERIA should be assessed before considering POP use to ensure the woman has no conditions where use is not recommended. The full UKMEC categories can be viewed and downloaded from the Faculty of Sexual and Reproductive Health at [www.fsrh.org](http://www.fsrh.org). Categories where use may be restricted (UKMEC 3 & 4) only are outlined below.

**UKMEC 3 (the risks may outweigh the advantages but use of a POP may be considered. A decision about use requires clinical judgement and/or referral to a specialist contraceptive provider)**

The initiation of a POP in women with: a history of breast cancer *(no evidence of disease in the last 5 years)*; gestational trophoblastic neoplasia *(abnormal serum hCG)*; active viral hepatitis; severe decompensated cirrhosis; liver tumours *(benign and malignant)*; use of liver enzyme inducing medication.

The continuation of a POP by women with: the occurrence of new symptoms or having a new diagnosis of ischaemic heart disease, stroke, venous thromboembolism or migraine with aura.

**UKMEC 4 (poses an unacceptable health risk and POP should not be used)**

Current breast cancer *(within last 5 years).*

Notably women may use POP if they have or have had an ectopic pregnancy; ovarian cyst; venous thromboembolism; stroke; ischaemic heart disease; or migraine with aura (UKMEC category 2 benefits outweigh risks).
At first visit enquiry and documentation should be made about:

- Medical conditions (past and present)
- Drug use (prescription and non-prescription)
- Relevant family history
- Smear history
- Record blood pressure (BP) and Body Mass Index (BMI) as part of a more general health check

At follow up visits documentation should be made about:

- Update medical history, drug history, family history
- Assess bleeding pattern
- Assess compliance and discuss use

Blood pressure and an assessment of weight can be documented before starting a progestogen-only pill but this should be seen as part of a more general health check.

An individual assessment of the risk of sexually transmitted infections (STIs) will inform decisions about the need for barrier methods in addition, and appropriate testing for STIs.

**POINTS TO COVER WHEN COUNSELLING on progestogen-only pills use**

- Traditional progestogen-only pills (containing norethisterone, levonorgestrel or etynodiol diacetate) work by altering cervical mucus to prevent sperm penetration and for some women ovulation is also inhibited.

- The desogestrel-only pill alters cervical mucus but the primary mode of action is inhibition of ovulation.

- If used consistently progestogen-only pills are more than 99% effective at preventing pregnancy. There are no data to suggest that some progestogen-only pills are better at preventing pregnancy than others.

- Women should be advised to take ONE progestogen-only pill at the same time every day and without a pill free interval. Women under the age of 35 years.

- Women under the age of 35 years should be offered the desogestrel – only pill as first line, due to its greater contraceptive efficacy as younger women are more fertile. Women over the age of 35 years may be offered one of the traditional POPs.

- Some women may consider that the desogestrel-only pill, with the 12 hours window will improve pill taking and they should be supported in this choice.

- There is no evidence that the efficacy of progestogen-only pills (traditional or desogestrel-only) is reduced in women who weigh more than 70kg and therefore the licensed use of ONE pill per day is recommended.

- If a woman vomits within 2 hours of pill taking another pill should be taken as soon as possible.
- Women using **liver-enzyme inducing medications short term** (e.g. single dose of rifampicin for meningitis prophylaxis) should be advised to use condoms in addition to progestogen-only pills and for at least 4 weeks after the liver enzyme inducer is stopped.

- Women using **liver-enzyme inducing medications long term** (e.g. anti-epileptic medication, anti-retrovirals, treatment for tuberculosis, St John’s Wort) should be advised that the efficacy of progestogen-only pills is reduced and an alternative contraceptive method not altered with use of liver enzyme inducing medication should be considered (e.g. injectable, copper intrauterine device or levonorgestrel intrauterine releasing system).

- Women can be advised that the efficacy of progestogen-only pills is NOT reduced by use of **non-liver enzyme inducing antibiotics** and additional contraceptive protection is not required.

- Changes in bleeding patterns is common with POPs: 2 in 10 women have no bleeding; 4 in 10 women have a regular bleeding; and 4 in 10 women have irregular bleeding. *Figure 4, Page 53* outlines the management of unscheduled bleeding in women using hormonal contraception.

- Women can be advised that there is no evidence of a causal association between progestogen-only pill use and weight change, depression, headache, cardiovascular disease (myocardial infarction, venous thromboembolism and stroke) or breast cancer.
WHEN TO START a progestogen-only pill

No additional contraceptive protection is required if progestogen-only pills are started:

- up to and including day 5 of the menstrual cycle.
- up to and including day 21 postpartum.
- at the time of an abortion or miscarriage (< 24 weeks gestation) or within 5 days.

If a POP is started outside these times condoms or abstinence is advised for 48 hours.

ADVICE ON MISSED progestogen-only pills

*Traditional* POPs should be taken every 24 hours. However, there is a 3 hour window where efficacy is not reduced if taken up to 27 hours since the last pill. If taken after this time or not at all missed pill rules should be followed (see Figure 2, Page 51).

For desogestrel-only pills advice is to take at the same time every day however, the window for late pills is up to 12 hours. Therefore if it is more than 36 hours since the last desogestrel-only pill was taken missed pills rules should be followed.

For all POPs (traditional and desogestrel-only) abstinence or barrier contraception is required for 48 hours after the pills have been restarted and the effect on cervical mucus is restored.

ONGOING USE AND FOLLOW-UP for women using progestogen-only pills

In the absence of special problems, women can be given up to 12 months of progestogen-only pills at first and follow-up visits. Annual BP checks are NOT a requirement but may be carried out as part of a more general health check. Follow up should be tailored to the individual and women may return at any time if problems arise.

We advise that the progestogen-only pill can be continued until the age of 55 years when natural loss of fertility can be assumed. If women do not wish to continue alternatively she can continue POP and have FSH concentrations checked on two occasions one to two months apart; if both measurements are >30IU/L this is suggestive of ovarian failure; she may continue with progestogen-only pill or barrier contraception for one further year (or 2 years if <50 years).

MANAGING BLEEDING in women using a progestogen-only pill

Women who have a change in bleeding patterns when using a progestogen-only pill need to be investigated to exclude sexually transmitted infections, pregnancy or gynaecological pathology.

There is no evidence that changing the type and dose of progestogen will improve bleeding but this may help some individuals. After exclusion of other causes if bleeding patterns are still unacceptable an alternative contraceptive may need to be considered.

Figure 4, Page 53 outlines the management of unscheduled bleeding in women using hormonal contraception.
The most commonly used injectable in the UK depot medroxyprogesterone acetate (DMPA). The other progestogen-only injectable contraceptive available in the UK is norethisterone enantate (NET-EN) which is only licensed for up to two injections (for women whose partners have undergone vasectomy, until vasectomy is effective). Information on NET-EN will be included when relevant otherwise all information is regarding DMPA. A subcutaneous preparation of DMPA has been developed for self-administration. UK marketing authorisation was obtained in October 2005 but it is not yet currently available.

In settings where progestogen-only injectable contraception is given the FSRH outlines emergency equipment which should be available (see table on Page 24).

**CLINICAL ASSESSMENT before use of progestogen-only injectable contraception**

**MEDICAL ELIGIBILITY CRITERIA** should be assessed before considering progestogen-only contraceptive use to ensure the woman has no conditions where use is not recommended. The full UKMEC categories can be viewed and downloaded from the Faculty of Sexual and Reproductive Health at [www.fsrh.org](http://www.fsrh.org). Categories where use may be restricted only are outlined below.

### UKMEC 3 (the risks may outweigh the advantages but use of a POP may be considered. A decision about use requires clinical judgement and/or referral to a specialist contraceptive provider).

- Significant multiple risk factors for arterial cardiovascular disease
- Vascular disease
- **Venous thromboembolism (VTE)** *Current VTE (on anticoagulants)*
- **Ischaemic heart disease** *(on anticoagulants)*
- **Stroke** *(history of cerebrovascular accident)*
- **Headaches** *Migraine with aura, at any age (continuation)*
- **Unexplained vaginal bleeding** *(suspicious for serious underlying condition) before evaluation*
- **Gestational trophoblastic Neoplasia (GTN)** *(Includes hydatidiform mole, invasive mole, placental site trophoblastic tumour) hCG abnormal*
- **Breast cancer** *Past and no evidence of current disease for 5 years*
- **Diabetes** *Other vascular disease or diabetes of >20 years’ duration*
- **Viral hepatitis** *Active*
- **Cirrhosis** *Severe (decompensated)*
- **Liver tumours**

### UKMEC 4 (poses an unacceptable health risk and POP should not be used)

- current breast cancer (within last 5 years)
At first visit enquiry and documentation should be made about:

- Medical conditions (past and present)
- Specific enquiry about cardiovascular risk factors (smoking, obesity, hypertension, hyperlipidaemia, etc)
- Drug use (prescription and non-prescription)
- Relevant family history (osteoporosis)
- Smear history
- Record blood pressure (BP) and Body Mass Index (BMI)

At follow up visits documentation should be made about:

- Update medical history, drug history and family history
- Check bleeding pattern

Annual BP check is not essential for safe use as this is a progestogen-only method but may be performed as part of a more general health check.

An individual assessment of the risk of sexually transmitted infections (STIs) will inform decisions about the need for barrier methods in addition, and appropriate testing for STIs.

**POINTS TO COVER WHEN COUNSELLING on the progestogen-only injectable**

- The progestogen-only injectable acts primarily by inhibition of ovulation.
- The pregnancy rate with the progestogen-only injectable is < 4 in 1000 over 2 years.
- The efficacy of the progestogen-only injectable is **NOT** reduced by antibiotics or liver-enzyme inducing drugs (such as some anti-epileptics, antiretrovirals, St Johns Wort) and injections can be continued at the usual 12 week injection interval.
- Women should be counselled about the possible bleeding patterns which may with a progestogen-only injectable, in particular up to 70% of users are amenorrhoeic in the first year of use. See Figures 4 & 5, Pages 53 and 54 the management of unscheduled bleeding in women using hormonal contraception.
- The use of the progestogen-only injectable is associated with weight gain. *There is no evidence of a causal association with depressive mood or headache.*
- There can be a delay in return to fertility of up to 1 year in after discontinuation but no reduction in fertility.
- Use of the progestogen-only injectable is associated with a small loss of bone mineral density which is usually recovered after discontinuation. There is no evidence of an increased risk of fracture. *(Progestogen-only injectables may be used as a first-line contraceptive for women under the age of 18 years after other methods have been considered).*
- Consider if woman has multiple risk factors for osteoporosis (e.g. previous or present anorexia, high dose steroids, family history of osteoporosis, malabsorption).
WHEN TO START the progestogen-only injectable

In order to provide immediate contraceptive protection a progestogen-only injectable can be given:

- up to and including day 5 of the menstrual cycle
- within 21 days of delivery (vaginal or operative)
- At the time of surgical abortion, the second part of a medical abortion, or after a spontaneous pregnancy loss (first, second or third trimester) or within 5 days

If started at other times an additional method of contraception (such as condoms) is required for 7 days.

USE & FOLLOW UP of women using progestogen-only injectable contraception

In general women should be advised to attend for repeat injections of DMPA every 12 weeks and it is licensed to be given up to 12 weeks and 5 days. If a woman attends late the DMPA protocol can be followed but women should be managed on an individual basis. Ovulation is very unlikely up to 14 weeks since the last injection and therefore an injection can be given up to 14 weeks since the last injection WITHOUT THE NEED FOR ADDITIONAL CONTRACEPTIVE PROTECTION. If a woman presents after 14 weeks an assessment should be made of her risk of pregnancy as a result of intercourse from 14+1 weeks (Figure 3, Page 52).

LOCAL POLICY FOR BONE SCANS IN WOMEN USING DMPA

For women who wish to continue using a progestogen-only injectable a discussion about the risks and benefits should be carried out every couple of years. Women with significant lifestyle and/or medical risk factors for osteoporosis may need to consider other methods of contraception.

In NHS Borders, along with NHS Lothian, we do not recommend routine bone scans unless requested after specialist review.

MANAGING PROBLEMS associated with progestogen-only injectable use

Women who experience unacceptable bleeding whilst using the progestogen-only injectable should be assessed for STI risk (in particular Chlamydia) and consideration given to the possibility of gynaecological pathology (Figures 4, Pages 53 management of unscheduled bleeding in women using hormonal contraception).

If bleeding is unacceptable and the woman wishes to continue with this method the use of mefenamic acid or ethinylestradiol (as combined oral contraception) may be indicated as a short term treatment if there are no contraindications for use (unlicensed use).

Locally we use Microgynon 30 for 9 consecutive weeks (3 packets). If estrogen is contraindicated mefenamic acid 500mg twice or three times daily can be used to reduce a bleeding episode.
PROGESTOGEN-ONLY SUBDERMAL IMPLANTS

Implanon® will shortly be replaced by Nexplanon®. Nexplanon® contains etonorgestrel and barium (to allow x-ray imaging). The Nexplanon® implant comprises a single subdermal rod and is licensed for three years’ use. Each implant contains 68mg of ENG dispersed in a membrane of ethylene vinyl acetate. The etonorgestrel implant in inserted into the medial aspect of the upper arm approximately 8 to 10 cm above the medial epicondyle.

Other progestogen-only implants (not available in the UK) include: Norplant, a six rod (36mg each) levonorgestrel implant which was discontinued in the UK in 1999; and Jadelle which consists of two rods each containing 75mg of levonorgestrel. Both are licensed for 5 years’ continuous use. UK clinicians may still see women with these implants; particular women who are continuing with use or who had insertion outside the UK.

CLINICAL ASSESSMENT of women requesting a progestogen-only implant

MEDICAL ELIGIBILITY CRITERIA should be assessed before considering contraceptive use to progestogen-only ensure the woman has no conditions where use is not recommended. The full UKMEC categories can be viewed and downloaded from the Faculty of Sexual and Reproductive Health at www.fsrh.org. Categories where use may be restricted only are outlined below.

UKMEC 3 (the risks may outweigh the advantages but use of a POP may be considered. A decision about use requires clinical judgement and/or referral to a specialist contraceptive provider).

- Current VTE (on anticoagulants)
- Current/arising ischaemic heart disease (continuation)
- Stroke (continuation)
- Migraine headaches with aura at any age (continuation)
- Unexplained vaginal bleeding suspicious for serious condition
- Gestational trophoblastic neoplasia when hCG is abnormal
- Breast disease past history of breast cancer and no evidence of recurrence for 5 years
- Viral hepatitis active disease
- Benign and malignant liver tumours
- Cirrhosis severe decompensated disease
- Drugs which induce liver enzymes for example rifampicin, rifabutin, St John’s Wort, griseofulvin, and certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)

UKMEC 4 (poses an unacceptable health risk and POP should not be used)

- Current breast cancer (within last 5 years)
DOCUMENTATION when counselling/inserting a progestogen-only implant

At first visit enquiry and documentation should be made about:

- Medical conditions (past and present)
- Drug use (prescription and non-prescription)
- Relevant family history (osteoporosis)
- Smear history
- Record blood pressure (BP) and Body Mass Index (BMI)

An individual assessment of the risk of sexually transmitted infections (STIs) will inform decisions about the need for barrier methods in addition, and appropriate testing for STIs.

Annual follow up is not required.

POINTS TO COVER IN COUNSELLING about use of a progestogen-only implant

- The primary mode of action of the progestogen-only implant is prevention of ovulation.
- The duration of use for the progestogen-only implant is three years.
- The pregnancy rate associated with the use of a progestogen-only implant is very low (less than 1 in 1000 over 3 years).
- The ectopic pregnancy risk is reduced when using a progestogen-only implant compared to no contraception.
- Women with a BMI over 30kg/m² can use progestogen-only implants without restriction or a reduction in contraceptive efficacy for the licensed duration of use.
- There is no evidence of a delay in fertility following removal of a progestogen-only implant.
- Bleeding patterns are likely to change during use of a progestogen-only implant. 20% of users will have no bleeding; almost 50% will have infrequent, frequent or prolonged bleeding. Bleeding patterns are likely to remain irregular over time.
- Clinicians should be aware that early discontinuation of progestogen-only implants is common. This is often due to bleeding. See Figure 4, Page 53 the management of unscheduled bleeding in women using hormonal contraception.
- There is no evidence of a causal association between the use of a progestogen-only implant and weight change, mood change, loss of libido, or headaches.
- Acne may improve, occur, or worsen during use of a progestogen-only implant.
- There is little, or no, increase in risk of venous thromboembolism associated with use of a progestogen-only implant.
- There is no evidence of a clinically significant effect on bone mineral density with use of a progestogen-only implant.
• Women using **liver enzyme-inducing drugs short term (< 3 weeks)** may continue with the progestogen-only implant. Additional contraception (e.g. condoms) should be used until 4 weeks after the liver enzyme-inducer has been stopped. Alternative contraception should be chosen if liver enzyme-inducing drugs are to be used long-term.

• **Non-liver enzyme inducing antibiotics** do **NOT** reduce efficacy of implants.

**TIMING OF INSERTION**

In order to provide immediate contraceptive protection the progestogen-only implants should be inserted:

- up to and including day 5 of the menstrual cycle.
- up to and including day 21 postpartum.
- at the time of abortion or miscarriage (< 24 weeks gestation) or within 5 days.

If an implant is started outside these times condoms or abstinence is advised for 7 days.

**FOLLOW UP of women using a progestogen-only implant**

**Routine follow-up visits are not required.** Women should be advised to return at any time to discuss problems or if she wants to change her method. An annual BP check is not required.

**Consider the need for a pregnancy test** at 3-4 weeks especially if insertion outwith days 1 -5 of cycle and any risk pregnancy in that cycle prior to insertion (or the first 7 days after insertion).

**Women should be advised to specifically return if they:** cannot feel the implant; notice any change in shape or any changes to the skin around the site of the implant; experience any pain; become pregnant; or develop any condition that would contraindicate use.

**MANAGING PROBLEMS associated with progestogen-only implants**

A sexual history should be taken from women who experience **unacceptable bleeding** while using the progestogen-only implant to establish STI risk * and/or be investigated for gynaecological pathology if clinically indicated. See Figure 4, Page 53 the management of women with unscheduled bleeding using hormonal contraception.

• Locally women who experience **unacceptable bleeding** while using the progestogen-only implant who have had gynaecological problems excluded may be offered or **ethinylestradiol** (Microgonon 30) for up to 3 months either continually or as the normal cyclical regimen then stop. A withdrawal bleed would be expected when stopping (unlicensed use).

• Review patient after this time. It may be reasonable to continue with COC + Implant long term if this is her preference (unlicensed).

* Women under the age of 25 years should be tested for chlamydial infection.
If ethinylestradiol is contraindicated a progestogen-only pill has been used but although this does help some women there is no evidence for this as a treatment option. There is limited evidence for mefenamic acid 500mg twice or three times daily on heavy days of bleeding. No treatments have been shown to be very effective after cessation in the long term bleeding patterns.

There is no evidence of a **teratogenic effect** of a progestogen-only implant if a woman becomes pregnant.

### INSERTION AND REMOVAL PROCEDURE

The implant should be inserted into the subcutaneous layer **8 to 10 cm above the elbow crease** in the non-dominant arm. Insert under aseptic conditions using sterile gloves and a sterile pack should be used for the procedure. The skin should be cleaned with **antiseptic solution**. The use of sterile water is **not recommended**. Appropriate **local anaesthesia** should be injected prior to insertion and removal of progestogen-only implants (see below). **Prophylactic antibiotics for endocarditis for insertion and removal** are NOT required. **Emergency equipment** (Page 24) must be available in all settings where subdermal contraception is inserted and removed and local referral protocols must be in place for women who require further medical input.

The Summary of Product Characteristics (SPC) recommends the use of 2ml (1%) lidocaine injected just under the skin along the ‘insertion canal’ for insertion and the use 0.5ml to 1ml (1%) lidocaine injected at the site for removal. There is little evidence to provide recommendations other than that provided in the Summary of Product Characteristics. However, from clinical experience of staff working in Sexual and Reproductive Health there appears to be a consensus for using for:

<table>
<thead>
<tr>
<th>INSERTION</th>
<th>REMOVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2ml of 1% of plain lidocaine</td>
<td>2-4ml of 1% of plain lidocaine</td>
</tr>
</tbody>
</table>

**(Maximum daily dose of lidocaine is 200mg** (1% solution 100mg per 10ml= 20ml per day)**

**Fertility** is restored quickly after progestogen-only implant removal and effective contraception is required if pregnancy is not desired. Women should be advised that **abstinence, additional contraceptive protection or emergency contraception is NOT required** prior to progestogen-only implant removal if they return within 3 years and there is to be immediate replacement of another implant or they are starting another method of contraception.
COMPILATIONS WITH REMOVAL

If at the time of planned removal you cannot palpate the progestogen-only implant the woman should be referred to Borders Sexual Health for assessment and onward referral, if necessary, to the regional specialist for removal impalpable Implants. The regional specialist for NHS Borders area for removal impalpable Implants under U/S control is:

Dr Kate Weaver,
Well Woman and Family Planning Services,
18 Dean Terrace,
Edinburgh. EH4 1NL
Telephone: 0131 332 7941

The incidence of complications at implant removal is low (1.3%). Complications include broken implant, migration of implant, and difficulty locating the implant. Methods such as ultrasound or magnetic resonance imaging (MRI) can be used to locate the device.

EMERGENCY EQUIPMENT

The FSRHC ‘Service Standards for Resuscitation in Sexual Health Services’ recommends training and regular updates in resuscitation for all staff dealing with emergencies which may arise during implant procedures. The recommendations for emergency resuscitation, emergency packs and service standards are summarised here.

<table>
<thead>
<tr>
<th>BASIC RESUSCITATION MEASURES</th>
<th>EQUIPMENT</th>
<th>MEDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Display clear algorithms regarding emergency procedures and emergency telephone numbers</td>
<td>Essential</td>
<td>Essential</td>
</tr>
<tr>
<td>Adequate training of all staff in basic life support</td>
<td>Sphygmomanometer</td>
<td>Atropine for intravenous use (0.6 mg/ml) for the management of persistent bradycardia</td>
</tr>
<tr>
<td>Abandon procedure, lower head and/or raise legs</td>
<td>Pocket mask and one way valve</td>
<td>Adrenaline for intramuscular use 1:1000 (1milligram/ml) for the management of anaphylaxis</td>
</tr>
<tr>
<td>Assistant to monitor pulse and BP</td>
<td>Appropriate selection of needles and syringes, tape, latex -free gloves, sharps box, scissors, saline flush</td>
<td></td>
</tr>
<tr>
<td>Ensure clear airway</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arrange transfer if no improvement</td>
<td>Desirable (Accessible if available)</td>
<td>Desirable</td>
</tr>
<tr>
<td>Oxygen mask with reservoir bag</td>
<td>Automated external defibrillator</td>
<td>Diazepam</td>
</tr>
<tr>
<td>Suction</td>
<td>Adjustable couch with easy access</td>
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</tbody>
</table>
INTRAUTERINE CONTRACEPTION

Intrauterine methods are long acting reversible contraception (LARC) and failure rates for most intrauterine contraceptives are very low (1 to 2%). Failure rates for the levonorgestrel-releasing intrauterine system (LNG-IUS) are similar to those for Cu-IUDs. Women may choose between a Cu-IUD or a LNG-IUS. Women with menorrhagia may opt for a LNG-IUS which is also licensed to manage idiopathic menorrhagia (5 years duration). The LNG-IUS is licensed for 5 years duration for contraception but only 4 years as the progestogen component of HRT.

The placement of copper on the arms of framed devices (banded devices such as TT380 Slimline and TCu380 Quickload) improves efficacy.

<table>
<thead>
<tr>
<th>Devices currently in use at BSH</th>
<th>Copper content (mm²)</th>
<th>Recommended duration of use (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEVONORGESTREL-RELEASING (Mirena)</td>
<td>Not applicable</td>
<td>5 years (contraception and idiopathic menorrhagia)</td>
</tr>
<tr>
<td>COPPER DEVICES FRAMED</td>
<td></td>
<td>4 years (endometrial protection)</td>
</tr>
<tr>
<td>COPPER SLEEVES (BANDED DEVICES)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The recommended first choice Cu-IUD is a TCu380S – two are available:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TT380 Slimline (rigid introducer)</td>
<td>380</td>
<td>10</td>
</tr>
<tr>
<td>TCu380 A QuickLoad (soft flexible introducer)</td>
<td>380</td>
<td>10</td>
</tr>
<tr>
<td>COPPER ON THE STEM ONLY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nova-T380</td>
<td>380</td>
<td>5</td>
</tr>
<tr>
<td>Flexi-T300</td>
<td>300</td>
<td>5</td>
</tr>
</tbody>
</table>

Our practical experience at Borders Sexual Health has led us to use the TT380 Slimline as the banded device of choice. It does, however, have a rigid introducer and can be difficult to use if the uterus is acutely anteverted or retroverted. The Quickload has a soft flexible introducer and can be used easily particularly if the uterus is anteverted or retroverted.
The Nova T380® has been compared to the TCu380S over 5 years. There were twice as many pregnancies with the Nova T380®, as the trial was small the difference was statistically significant at the end of the first year of use only.

The Nova T380® is now the Cu-IUD of second choice for use at BSH. It can be used if the cervical os appears to narrow and there is no facility for cervical dilatation. The mechanism for insertion is slightly different for the NovaT380®.

A FlexiT300 can be useful as emergency contraception. It should not be used for ongoing contraception as there were reports of the threads detaching from the device. It may be useful as emergency contraception, especially in nulliparous young women due to its small frame and narrow introducer. Two smaller versions of framed IUDs are available in the UK. The MiniTT380 Slimline® (a smaller version of the TT380 Slimline®) and a shorter version of the Multiload 375. Neither has been adequately assessed in clinical trials. A Cochrane review identified comparable failure rates for a framed (TCu380A) and a frameless device (GyneFix) but the efficacy of the frameless device may be compromised by an increase rate of expulsion. A retained GyneFix is particularly effective up to 5 year of use. The Multiload is not a first line choice as it does not have copper sleeves on the horizontal arms. Also, there may be difficulty and discomfort to the woman on removal of the device which may have become embedded in the endometrium.

**CLINICAL of difficulties with ASSESSMENT of women considering intrauterine contraception**

**MEDICAL ELIGIBILITY CRITERIA** should be assessed before considering intrauterine contraceptive use to ensure the woman has no conditions where use is not recommended. The full UKMEC categories can be viewed and downloaded from the Faculty of Sexual and Reproductive Health at www.fsrh.org. Categories where use may be restricted only are outlined below.

<table>
<thead>
<tr>
<th>UKMEC Category 3 (risks outweigh benefits. A decision about use requires clinical judgement and/or referral to a specialist contraceptive provider)</th>
<th>UKMEC Category 4 (unacceptable risk)</th>
<th>Where Cu-IUD and LNG-IUS are given different UKMEC categories</th>
</tr>
</thead>
</table>

*Initiation* of the method in women with unexplained vaginal bleeding. Gestational trophoblastic neoplasia when serum hCG concentrations are abnormal. Initiation of the method in women with cervical cancer awaiting treatment or with endometrial cancer. Uterine fibroids or uterine anatomical abnormalities distorting the uterine cavity. Initiation of intrauterine methods in women with current pelvic inflammatory disease or purulent cervicitis. Initiation of intrauterine methods in women with known pelvic tuberculosis. | A UKMEC category 1 is given for a Cu-IUD and a category 3 is given for the LNG-IUS due to the progestogen content for the following medical conditions:

*Continuation* of LNG-IUS if a new diagnosis of ischaemic heart disease is made or if new symptoms of migraine with aura occur at any age. Past history of breast cancer with no recurrence in last 5 years. Active viral hepatitis, severe decompensated cirrhosis or liver tumours (benign or malignant). |

A UKMEC category 1 given for a Cu-IUD and a category 4 is given for the LNG-IUS due to the progestogen content for the following medical conditions:

Current breast cancer.
**DOCUMENTATION**

At first visit enquiry and documentation should be made about:

- Medical conditions (past and present)
- Drug use (prescription and non-prescription)
- Relevant family history (osteoporosis)
- Smear history
- Record blood pressure (BP) and Body Mass Index (BMI)

An individual assessment of the risk of sexually transmitted infections (STIs) will inform decisions about the need for appropriate testing for STIs before or at the time of insertion.

Annual follow up is not required but women can re-attend at anytime if they have any concerns about the method.

**DURATION OF USE AND CHOICE**

Intrauterine devices with the longest duration of use are generally preferred as they reduce the risk of infection, perforation and expulsion associated with reinsertion.

All Cu-IUDs are licensed for at least 5 years use and some are recommended for longer use.

- The **TT380 Slimline** has been studied to 5 years use but because of the clinical performance compared to the TCu380A it is licensed for **10 years** use.

- A Cu-IUD inserted when a woman is 40 years or over can be retained until the menopause is confirmed which may be > 10 years. Retain the Cu-IUD until 1 year after the last menstrual period if this occurs after the age of 50 years and for 2 years if this occurs before the age of 50 years.

- The LNG-IUS is licensed for 5 years use as contraception and for idiopathic menorrhagia and licensed for 4 years to provide endometrial protection.

The Nice Guideline on Long Acting Reversible Contraception (LARC) recommends that women who have the LNG-IUS inserted at or after the age of 45 years and are **amenorrhoeic** may retain the LNG-IUS until the menopause. Randomised trials show the LNG-IUS provides effective contraception for up to 7 years and the LNG-IUS can be used for this duration of use in women aged 45 years or over at insertion.

Amenorrhoea with LNG-IUS use does not reliably indicate anovulation. Women aged 45 years or more at the time of LNG-IUS insertion are counselled about the likely contraceptive efficacy and the risks of removal and replacement. Women may opt to continue with the LNG-IUS until no longer required or until the menopause can be confirmed.
POUNTS TO COVER WHEN CounSELLING before use of intrauterine contraception

- **Mode of action** of a Cu-IUD is primarily preventing fertilization and the LNG-IUS is to prevent sperm penetration and implantation
- **Failure rates** at 5 years use are low 2% for Cu-IUDs (380mm²) and 1% for LNG-IUS
- **Uterine perforation** is uncommon (up to 2 per 1000 insertions)
- **Expulsion** occurs in around 1 in 20 women, is most common in the first year of use and particularly within 3 months of insertion
- The risk of ectopic pregnancy is reduced with intrauterine contraception when compared to using no contraception. If you suspect you are pregnant while using an intrauterine method it is important to do a pregnancy test and seek urgent medical advice to identify if the pregnancy is intra- or extrauterine.
- There is no delay in return to fertility after removal of intrauterine contraception
- There is an increase in the risk of pelvic infection in the 20 days following insertion of intrauterine contraception but risk is the same as the non-IUD using population thereafter
- **Bleeding and pain** are common causes of discontinuation. Spotting, light bleeding, heavy or prolonged bleeding are common in the first 3 to 6 months of Cu-IUD use. Irregular bleeding and spotting is common in the first 6 months after insertion of the LNG-IUS. By 1 year after LNG-IUS insertion amenorrhoea or oligomenorrhoea is usual. See Figure 4 management of unscheduled bleeding in women using hormonal contraception Page 53.
- **Hormonal side effects** can be due to due to systemic absorption of progestogen but few women discontinue for this reason and these are not significantly different from Cu-IUD users
- **Insertion procedure** and likely discomfort during and after intrauterine contraceptive insertion should be discussed with women and oral analgesia can be advised before insertion

TIMING OF INSERTION of intrauterine contraception

At Borders Sexual Health our normal routine for intrauterine method insertion is to see the woman for an initial assessment and counselling. Medical history is taken and Chlamydia screening performed as appropriate. Thereafter she is given the next available appointment for insertion and asked to abstain or continue with her current reliable contraception until the device is fitted.

A Cu-IUD can be inserted at any time in the menstrual cycle if it is reasonably certain the woman is not pregnant. A Cu-IUD will provide immediate contraceptive protection. As for emergency contraceptive use a Cu-IUD can be inserted up to 5 days after the expected date of ovulation (i.e. up to day 19 of a regular 28 days cycle) or up to 5 days after the first episode of unprotected sex.

The LNG-IUS can be inserted at any time in the menstrual cycle if it is reasonably certain the woman is not pregnant and the clinician is reasonably certain there has been no risk of conception. Unless the LNG-IUS is inserted within the first 5 days of menstrual cycle condoms or abstinence is advised for 7 days after insertion.
<table>
<thead>
<tr>
<th>Circumstances when intrauterine contraception can be inserted</th>
<th>Recommendations for timing of insertion</th>
</tr>
</thead>
<tbody>
<tr>
<td>In all circumstances</td>
<td>A Cu-IUD can be inserted at <em>any time in the menstrual cycle</em> if it is reasonably certain the woman is not pregnant. A Cu-IUD is effective immediately. The LNG-IUS can be inserted at <em>any time in the menstrual cycle</em> if it is reasonably certain the woman is not pregnant and the clinician is reasonably certain there is no risk of conception. Condoms or abstinence should be advised for 7 days after inserting the LNG-IUS unless inserted in the first 5 days of the cycle.</td>
</tr>
<tr>
<td>Postpartum <em>(Including post-caesarean section and breastfeeding)</em></td>
<td>Insert from 4 weeks postpartum as above</td>
</tr>
<tr>
<td>Following abortion</td>
<td>Ideally insert at the time of a first or second trimester surgical abortion for immediate contraceptive effect. Following medical or surgical abortion ideally insert within the first 48 hours or delay until 4 weeks postabortion. However, waiting until 4 or more weeks post-termination may put women at risk of pregnancy. After counselling and when intrauterine contraception is the preferred method it can be inserted by an experience clinicians anytime post abortion if there is no concern that the pregnancy is ongoing.</td>
</tr>
<tr>
<td>Changing from another method of contraception</td>
<td>If changing intrauterine devices abstain or use condoms for 7 days before in case a new device cannot be inserted following removal of the existing device. Intrauterine contraception can be inserted at anytime if another method of contraception has been used consistently and correctly. Insert anytime if it is reasonably certain that she is not pregnant. There is no need to wait for the next menstrual period or withdrawal bleed. A Cu-IUD is effective immediately. Condoms or abstinence may need to be advised for 7 days after inserting the LNG-IUS unless the current contraceptive method is still effective (for example &lt; 12 weeks since last progestogen-only injection; within 3 years of insertion of a subdermal implant; no later than day one of the hormone free interval for pills or patch).</td>
</tr>
</tbody>
</table>

**STI SCREEN AND TREAT prior to using intrauterine contraception**

- **A self obtained low vaginal swab** (or endocervical swab) should be performed to identify *Chlamydia trachomatis* by women deemed to be at higher risk of STI before routine IUD insertion:
  - aged <25 years
  - any age with a new sexual partner or more than one partner in the last year
  - requesting testing

- If a woman is found to have *Chlamydia trachomatis* treat with **Azithromycin 1g stat** orally (or Doxycycline 100mg BD for 7 days) prior to IUD insertion.

- Arrange treatment of partner or contacts and refer or advise regarding partner notification.

- No specific time delay between treatment of asymptomatic STIs and IUD insertion is recommended and indeed in asymptomatic women IUD can be inserted and treatment can be given at the same time if necessary.

- For **emergency IUD** insertion a SOLVS can be performed at the time of IUD insertion. If a woman is deemed at higher risk of STI prophylactic antibiotics should be given at insertion (Azithromycin 1g stat orally to cover CT and consider in addition CEFIXIME 400mgs stat orally to cover GC).

- A full sexual health screen can be offered if **high risk, symptomatic or requested** (Gonorrhoea, Trichomonas, HIV, Hepatitis B & C & Syphilis).

- There is **NO indication to test for (via HVS) or treat other lower genital tract organisms** or delay insertion in asymptomatic women attending for insertion of intrauterine contraception.

- The growth of **commensals and other organisms** does **NOT** require treatment if no pus cells. **Group B Streptococcus** with no pus cells does **NOT** require treatment unless symptoms of vaginitis. In this case patients who have Group B, (A, C or G) should be treated with penicillin.

  **NB:** See “Borders GP STI Testing Kit “ and guidance.

**ANTIBIOTICS for ENDOCARDITIS PROPHYLAXIS**

Transient bacteraemia following removal and replacement of intrauterine contraception was identified in 13% of women but does not necessarily indicate a risk for endocarditis. A recent review by NICE suggests the evidence for use of antibiotics even for people at risk of endocarditis during interventional procedures is poor. Recommendations from the American Heart Association and a guideline from the British Society for Antimicrobial Therapy that antibiotic prophylaxis is not required for insertion or removal of intrauterine contraception even in women at risk of endocarditis. The NICE guideline supports these previous guidelines.

**Prophylactic antibiotics are NOT REQUIRED for insertion or removal of intrauterine contraception even in women at risk for endocarditis**
PROCEDURES FOR INSERTION of intrauterine contraception

Clinicians fitting intrauterine contraceptive insertions should be appropriately trained, maintain competence and attended regular updates in dealing with emergencies. An appropriate trained assistant should be present during insertion of intrauterine contraception.

- A bimanual pelvic examination should be performed before inserting intrauterine contraception.
- Aseptic technique should be used.
- The cervix should be stabilised with an appropriate forceps to allow assessment of the length of the uterine cavity and to ensure fundal placement of the device.

Documentation should be made in the case notes to record appropriate pre and post insertion counselling, the insertion procedure and the type of device inserted.

Emergency equipment must be available in all settings where intrauterine contraception is being inserted and local referral protocols must be in place for women who require further medical input (Page 24).

ONGOING MANAGEMENT of women using intrauterine contraception

Women should be given information (oral and written) about the device inserted and duration of use.

Women should be advised on how to check for the intrauterine contraceptive and its threads and advised that if they are unable to feel them it may be that the device has been expelled. Alternative contraception should then be used until they seek medical advice.

A follow up appointment after the next menses or at 6 weeks after insertion is recommended, or sooner if the woman has any concerns. If the woman is happy with the method at follow up, there are no problems identified and she can feel her own threads there is no indication for examination unless the woman specifically requests this.

Annual review and speculum examination is not generally required. Women should be advised to seek medical help at any time if they develop symptoms of pelvic infection, pain, persistent menstrual abnormalities, missed period, non-palpable threads or can feel the stem of the device.
<table>
<thead>
<tr>
<th>Problems associated with intrauterine contraception</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspected perforation at the time of insertion</td>
<td>The procedure should be stopped and vital signs (blood pressure and pulse rate) and level of discomfort monitored until stable. An ultrasound scan and/or plain abdominal X-ray to locate the device if it has been left <em>in situ</em> should be arranged as soon as possible. REFER GYNAE, at Borders General Hospital.</td>
</tr>
<tr>
<td>‘Lost threads’</td>
<td>Advise women to use another method (condoms or abstinence) until medical review. Consider the need for emergency hormonal contraception. If no threads are seen and uterine placement of the intrauterine method cannot be confirmed clinically, an ultrasound scan should be arranged to locate the device and alternative contraception recommended until this information is available. If an ultrasound scan cannot locate the intrauterine method and there is no definite evidence of expulsion, a plain abdominal X-ray should be arranged to identify an extra-uterine device. At the BGH, an X-ray will be done if device not seen on U/S. If the intrauterine method is not confirmed on an ultrasound scan clinicians should not assume it has been expelled until a negative X-ray is obtained (unless the woman has witnessed expulsion). Hysteroscopy is not readily available in all settings but can be useful if the ultrasound scan is equivocal. Surgical retrieval of an extrauterine device is advised.</td>
</tr>
<tr>
<td>Abnormal bleeding</td>
<td>Gynaecological pathology and infections should be excluded if abnormal bleeding persists beyond the first 6 months following insertion of intrauterine contraception. Women using the LNG-IUS who present with a change in pattern of bleeding should be advised to return for further investigation to exclude infections, pregnancy and gynaecological pathology. For women using a Cu-IUD non-steroidal anti-inflammatory drugs can be used to treat spotting, light bleeding heavy or prolonged menstruation. In addition anti-fibrinolytics (such as tranexamic acid) may be used for heavy or prolonged menstruation.</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Most pregnancies in women using intrauterine contraception will be intrauterine but an ectopic pregnancy must be excluded. Women who become pregnant with an intrauterine contraception <em>in situ</em> should be informed of the increased risks of second trimester miscarriage, preterm delivery and infection if the intrauterine method is left <em>in situ</em>. Removal would reduce adverse outcomes but is associated with a small risk of miscarriage. If the threads are visible, or can easily be retrieved from the endocervical canal, the intrauterine contraceptive should be removed up to 12 weeks gestation. If there is no evidence that the intrauterine method was expelled prior to pregnancy, it should be sought at delivery or termination and, if not identified, a plain abdominal X-ray should be arranged to determine if the intrauterine method is extra-uterine.</td>
</tr>
<tr>
<td>Suspected pelvic inflammatory disease (PID)</td>
<td>For women using intrauterine contraception with symptoms and signs suggestive of pelvic infection appropriate antibiotics should be started. There is no need to remove the intrauterine method unless symptoms fail to resolve within the following 72 hours or unless the woman wishes removal. All women with confirmed or suspected PID should be followed up to ensure: resolution of symptoms and signs, their partner has also been treated when appropriate completion of the course of antibiotics, STI risk assessment, counselling regarding safer sex and partner notification.</td>
</tr>
<tr>
<td>Suspected actinomyces-like organism (ALOs)</td>
<td>Intrauterine contraceptive users with ALOs detected on a swab who have no symptoms should be advised there is no reason to remove the intrauterine method unless signs or symptoms of infection occur. There is no indication for follow-up screening. If symptoms of pelvic pain occur women should be advised to seek medical advice. Other causes of infection (in particular STIs) should be considered and it may be appropriate to remove the intrauterine method.</td>
</tr>
</tbody>
</table>
INSERTION PROCEDURE

For complicated insertions (such as previous failed attempt, acutely anteverted or retroverted uterus, or where cervical dilation may be required) women can be referred to Dr Wylie’s IUD Clinic, Borders Sexual Health where we have access to paracervical block. We do, however, not have direct access to U/S and women requiring U/S will need to be referred to Department of Radiology at Borders General Hospital (BGH).

PLEASE NOTE:

If a woman attends General Practice with lost threads an urgent scan appointment can be obtained by contacting X-Ray Department at Borders General Hospital.

She should be advised about using an alternative contraceptive and her need for emergency contraception assessed.
EMERGENCY CONTRACEPTION

Emergency Contraception (EC) provides women with a safe means of preventing pregnancy following unprotected sexual intercourse or potential contraceptive failure. Alternative terms such as ‘post coital contraception’ or ‘the morning after pill’ are often confusing and ‘emergency contraception’ is the preferred term. Currently, women in the UK can be offered an oral hormonal method (levonorgestrel) or a copper-bearing intrauterine device (IUD) for emergency contraception.

There is no time in the menstrual cycle when there is no risk of pregnancy following unprotected sexual intercourse (UPSI). This is especially true if the cycle is irregular or if there is uncertainty about the date of the last menstrual period (LMP). Only 30% of women have their fertile period (defined as six fertile days during the menstrual cycle) within the days of the menstrual cycle identified by clinical guidelines. Women should be advised that timing of fertility can be highly unpredictable. Nevertheless, the probability of pregnancy in the first 3 days of the cycle appears to be negligible.

<table>
<thead>
<tr>
<th>Day of cycle</th>
<th>Expected pregnancy risk associated with a single act of UPSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days 1-9</td>
<td>2-3%</td>
</tr>
<tr>
<td>Days 10 - 17</td>
<td>20-30%</td>
</tr>
<tr>
<td>Days 18-28</td>
<td>2-3%</td>
</tr>
</tbody>
</table>

Risk of pregnancy following potential contraceptive failure is difficult to define. Each woman will need to be counselled individually.

EC may be required in a range of clinical situations:

- following consensual sex where no contraception was used;
- mistake with oral contraception;
- following rape or sexual assault;
- when using the withdrawal method;
- following ejaculation onto the external genitalia;
- when a condom bursts, is dislodged or incorrectly used;
- or if a diaphragm or cap is incorrectly inserted, damaged, dislodged or removed within 6 hours of sex.
- potential contraceptive failures and indications for EC use are summarised in a later section.

AVAILABLE EMERGENCY CONTRACEPTIVES

Levonorgestrel emergency contraception has been licensed in the UK since 1999 and is available on prescription and as a purchasable medicine at pharmacies. In Borders Sexual Health we use **Levonelle 1500** which has become the standard formulation issued on prescription. In Community Pharmacies, the generic name for levonorgestrel EC is **Levonelle One-Step** (as a single 1.5mg dose of LNG).

A copper IUD can be used as emergency contraception and at least 300mm² of copper is required. Ideally a 380mm² device should be used in case the woman wishes to continue this method.

**Ulipristal acetate (ellaOne®)** has been approved for use in NHS Borders since Autumn 2010. It is as effective as Levonorgestrel and may be used up to 120 hours after unprotected sex.
CLINICAL ASSESSMENT of women requesting emergency contraception

It is important for the clinician to take an accurate history to assess the risk of pregnancy and the need for EC in each case. Enquiry should cover:

- the most likely date of ovulation based on the date of the last menstrual period and the usual cycle length
- when the first episode of unprotected sex occurred
- details of further episodes of UPSI
- details of potential contraceptive failure (e.g. missed pills - how many and when, has she has UPSI)
- was the sex consensual
- assess risk of STI
- Fraser competency if aged < 16 years

The clinician should summarise evidence of effectiveness and the need for EC in each woman’s individual circumstance to allow her to make an informed choice regarding its use. Clinical judgement should then allow a decision to be made regarding the need for EC in an individual case – but a pragmatic approach is often required.

The UK Medical Eligibility Criteria for Contraceptive Use advises that there are no medical contraindications to levonorgestrel EC. The only absolute contraindication is the rare porphyria. Use will not have an effect on an existing pregnancy. For a full list of eligibility criteria for use of Cu-IUD see chapter on intrauterine methods. Use of a Cu-IUD for EC carries the same contraindications as routine Cu-IUD insertion.

Risk of sexually transmitted infections, previous ectopic pregnancy, young age, and nulliparity are NOT contraindications to emergency Cu-IUD use. There are no drugs which reduce the efficacy of emergency CU-IUD use and therefore CU-IUDs are the preferred option for women using liver-enzyme inducing drugs. A sexual history should be taken from all women attending for EC to assess risk of sexually transmitted infections.
The mode of action of levonorgestrel EC is incompletely understood but is thought to be due primarily to inhibition of ovulation rather than inhibition of implantation. A randomised trial showed that use of levonorgestrel in the follicular phase (pre-ovulation) interferes with the ovulatory process. When levonorgestrel was given before the luteinising hormone (LH) surge (when follicles were <15mm in size), follicular rupture was prevented or ovulatory dysfunction (absent LH peak or LH peak after follicular rupture) was apparent in the subsequent 5 days in around 80% of women. Thus, if taken prior to ovulation, levonorgestrel can inhibit ovulation for 5 to 7 days, by which time any sperm in the upper reproductive tract have lost their fertilising ability.

Levonorgestrel is NOT ABORTIFACIENT and will not interrupt an existing pregnancy; limited epidemiological data indicate no adverse effects on the fetus. Levonorgestrel should be given as a single 1.5mg dose as soon as possible after unprotected sex, and within 72 hours and can prevent up to 84% of expected pregnancies.

**USE OF LEVONORGESTREL WITHIN 72 HOURS**

Use is licensed within 72 hours of unprotected sex or potential contraceptive failure. If used within this time frame it can reduce the expected pregnancy risk by 84%.

<table>
<thead>
<tr>
<th>EC option</th>
<th>% of expected pregnancies prevented</th>
</tr>
</thead>
<tbody>
<tr>
<td>POEC within 72 hours <em>(licensed)</em></td>
<td>84%</td>
</tr>
<tr>
<td>POEC between 73 and 120 hours <em>(unlicensed)</em></td>
<td>63%</td>
</tr>
<tr>
<td>Mifepristone up to 120 hours <em>(unlicensed)</em></td>
<td>85%</td>
</tr>
<tr>
<td>Cu-IUD</td>
<td>99%</td>
</tr>
</tbody>
</table>

**USE OF LEVONORGESTREL BEYOND 72 HOURS**

A large randomised controlled trial provided evidence that levonorgestrel continues to reduce the expected pregnancy rate if taken between 73 and 120 hours after unprotected sex. The data added weight to the theory that levonorgestrel does not suddenly stop working beyond 72 hours. No data have been identified relating to use of levonorgestrel for EC beyond 120 hours. Use of levonorgestrel beyond 72 hours remains outside the product licence.

Levonorgestrel EC may be considered between 73 and 120 hours after unprotected sex, but women should be informed of: the limited evidence of efficacy; that such use is outside product licence; and the alternative of an IUD.
USE OF LEVONORGESTREL MORE THAN ONCE IN A CYCLE

Hormonal EC can be used more than once in a cycle. The Summary of Product Characteristics states that repeated administration of levonorgestrel is not recommended because of disturbances to the cycle. Giving repeat doses of levonorgestrel prior to the LH surge may be effective and further unprotected sex may be an indication for repeat levonorgestrel use. Repeated use will not induce abortion if the woman is already pregnant.

No data were identified regarding a minimum time interval between successive EC treatments. The consensus view was that unprotected sex within 12 hours of a dose of EC does not require further treatment with EC.

DRUG INTERACTIONS RELEVANT TO POEC USE

Liver enzyme inducing drugs

Liver enzyme inducers (including some anticonvulsants, antiretroviral, rifampicin and the herbal remedy St John’s Wort) may reduce the efficacy of POEC by increasing the metabolism of levonorgestrel. There is no licensed use of Levonelle 1500 in an increased dose. Recommendations for POEC use by women using liver enzyme inducers who refused to use a Cu-IUD is to increase the dose by 100%. When levonorgestrel is used as 1.5mg tablets (Levonelle One-Step or Levonelle 1500) a dose of 3 mg (two tablets) should be taken at first presentation and within 72 hours of unprotected sex. This advice is based on clinical judgement, taking into consideration the consequences of an unintended pregnancy.

Non-liver enzyme-inducing antibiotics

The efficacy of POEC is NOT reduced by non-liver enzyme inducing antibiotics as, unlike estrogens, progestogens do not undergo significant re-absorption in the bowel.

Other drugs

Caution is advised when prescribing oral EC for women using the anticoagulant drugs phenindione and warfarin. It has been observed that anticoagulant effects may be altered following levonorgestrel use. Women should be advised about potential drug interactions and attention should be paid to their anticoagulation monitoring.
### AFTER CARE AND FOLLOW UP AFTER POEC USE

**Vomiting** following levonorgestrel administration is unusual, occurring in only 1% of women. Nausea is reported more frequently (14%). **Women who experience vomiting within 2 hours of administration of levonorgestrel EC should be advised to return as soon as possible for a repeat dose.**

A Cu-IUD should be considered for a woman experiencing persistent vomiting with oral EC.

**Disturbances to the cycle** are common after levonorgestrel EC. In a World Health Organisation (WHO) trial, 16% of women experienced bleeding (unrelated to expected menstruation) in the 7 days following treatment. Around half of women menstruated a few days earlier or a few days later than their expected time. It may be difficult to differentiate between non-menstrual bleeding in the early days after EC and actual menstruation. Clinicians and women should always err on the side of caution, and undertake pregnancy testing if there is any doubt that menstruation has followed EC use. Following levonorgestrel EC, over 80% of women menstruate before, or within 2 days after, their expected date; and 95% menstruate within 7 days after their expected date.

**Women should be advised to have a pregnancy test if menstruation is delayed by more than 7 days, or is lighter than usual.**

**Ectopic pregnancies** have been identified following administration of levonorgestrel EC in case series. However, the overall risk does not appear to be increased following levonorgestrel EC. There is insufficient post-marketing data to allow accurate assessment of risk. Clinicians and women should be alert to the possibility of an ectopic pregnancy, but the risk is likely to be small. EC can be used by women with a previous ectopic pregnancy.

### ONGOING CONTRACEPTION AFTER POEC USE

**Levonorgestrel EC does not provide contraceptive cover for the remainder of the cycle and effective contraception or abstinence must be advised.**

After EC use because of unprotected sex, clinicians and women should discuss initiating a regular method of contraception. This can be started at any time in the cycle if it is *reasonably certain* that the woman is not pregnant. It would be appropriate to initiate a regular method of contraception immediately if abstinence, or condom use, is unlikely.

After EC use because of 'missed pills', women should be advised to resume hormonal contraception within 12 hours of taking levonorgestrel EC.

### ADVANCE PROVISION OF POEC

'Advance provision' of EC refers to provision in advance of need. The FSRH supports the advance provision of hormonal EC for women attending family planning and sexual health services. Randomised trials have shown that advance supply to selected women is safe and effective. Increasing the uptake of EC may reduce the rate of unintended pregnancies without increasing the number of women having unprotected sex. Women who had advance supply at home were more likely to use EC when required, without compromising regular contraceptive use or sexual behaviour. Interviews with women who had received EC in advance highlighted that while advance supplies were seen as useful, they were not considered an alternative to other forms of contraception. A population-based study did not show that providing sexually active women with EC in advance of need had any impact on abortion rates. **Consider advance provision for any women who may be at risk (e.g. for women relying on barrier methods or travelling abroad).**
Ulipristal acetate is a progesterone receptor modulator that is licensed for use for emergency contraception (EC), up to 120 hours after unprotected intercourse. The Borders joint formulary and Scottish medicines consortium has approved ulipristal acetate (ellaOne®) for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse (UPSI) or recognised contraceptive failure.

A meta-analysis of two randomised controlled trials (RCT) comparing UPA to 1.5 mg levonorgestrel, showed that it significantly reduced the risk of pregnancy in women, amongst women presenting for EC after unprotected intercourse.¹ Compared to levonorgestrel, ulipristal almost halved the risk of pregnancy when taken within 120 hours (5 days) of unprotected intercourse. If used within 24 hours of intercourse the risk of pregnancy was reduced by almost two-thirds compared with levonorgestrel. The copper intrauterine device (IUD) can also be used as an emergency contraceptive up to 5 days after unprotected intercourse or ovulation and is thought to be the most effective method of emergency contraception.

Due to cost considerations, women who receive advance supplies of EC with condoms/other barrier methods, should only be given Levonorgestrel (levonelle).

**Indications for use:**
Ulipristal acetate 30 mg (ellaOne®) is indicated in the following circumstances:

1. Women who present to sexual health service requesting EC within 120 hours of UPSI, who decline an IUD.
2. Complete or partial expulsion of IUD/IUS * or if mid-contraception cycle removal of an IUD/IUS is deemed necessary and UPSI has occurred in the last 7 days (and women decline insertion of another IUD)

**Consider use in following circumstances:**
(following discussion with patient about unknown interactions of ulipristal acetate on progestogen containing contraception * see below)

1. Missed combined oral contraceptive pills (COC P) *(two or more 20mcg COCP, or three or more 30-55 mcg COCP in the first seven days of pill taking and who have had unprotected sex in week 1 or the pill free interval).
2. Missed progestogen only pills (POP)* (one or more POPs have been missed or taken >3 pills hours late (>12 hours late for Cerazette®) and UPSI has occurred in the 2 days following this.
3. Late injection of contraceptive progestogen-injection * (>14 weeks from the previous injection for medroxyprogesterone acetate or >10 weeks for norethisterone enantate) and UPSI has occurred.
4. Situations involving contraceptive patch or vaginal ring when EC would be considered (e.g. patch off > 24hrs or ring removed > 3 hrs and unprotected sex)
Generally avoid use of Ulipristal acetate (ellaOne ®) in the following circumstances:

1. Women who present > 120 hours of UPSI. Consideration should be given to inserting an IUD.
2. Women who have more than one episode of UPSI in that cycle. Consideration should be given to inserting an IUD.
3. Women using enzyme inducing drugs (including St John’s Wort) and drugs that may have possible interactions (antacids, antivirals, ulcer healing drugs). Consideration should be given to inserting an IUD.
4. Women who have received levonorgestrel EC (levonelle ®) in the same cycle. Consideration should be given to inserting an IUD.

(A doctor may however reasonably consider use of ulipristal acetate in above circumstances on an individual patient basis, if judged to be in best interests of patient, patient declines alternative methods of EC and following discussion with patient about unlicensed use and uncertain effects of ulipristal acetate on an early pregnancy)

Avoid Use
1. Women with significant hepatic or renal impairment
2. Women with uncontrolled severe asthma

Dosing
Ulipristal acetate treatment consists of one tablet (30mg) to be taken orally as soon as possible, but no later than 120 hours (5 days) after unprotected intercourse or contraceptive failure. It can be taken at any moment during the menstrual cycle, if one is reasonably certain that the woman is not already pregnant. If vomiting occurs within 3 hours of intake, another tablet should be taken.

Adverse effects
In an RCT, adverse events were reported by a similar proportion of women taking ulipristal acetate or levonorgestrel (just over half of women of women). The majority of these were mild to moderate in intensity. The most frequently reported adverse events were similar for both ulipristal acetate or levonorgestrel and included headache, dysmenorrhoea, nausea, fatigue, dizziness and abdominal pain.

Breastfeeding
It is not known whether ulipristal is excreted in breast milk so breastfeeding women are advised not to breastfeed and to discard expressed milk for 36 hours after treatment. Since breastfeeding itself confers some protection against pregnancy (the extent depending on the frequency of breastfeeds and the amount of supplementation with artificial milk or solids) it may be sensible to give lactating women levonorgestrel rather than ulipristal acetate.

Ongoing contraception
Interactions with hormonal contraception have not been studied but ulipristal acetate (progesterone receptor modulator) could in theory reduce the efficacy of progestogen-containing contraceptives. The manufacturer advises abstinence/condoms for the remainder of the menstrual cycle in which ulipristal acetate is used. However, based upon its half life, ulipristal acetate should be is virtually eliminated by 7 days. Given the significantly increased risk of pregnancy, if further UPSI occurs in that cycle, all women attending for EC should be advised to start effective contraception immediately.
**Women not already using hormonal contraception**

In the absence of evidence, it would seem reasonable that women who are not already on hormonal contraception should commence this the next day. The manufacturer advises abstinence/condoms for the remainder of the menstrual cycle in which ulipristal acetate is used. As a minimum, it would seem reasonable to advise women to abstain/ use condoms together with hormonal contraception for 14* days (*based upon expert opinion only of 7 days to eliminate plus further 7 days for ovarian quiescence on hormonal contraception = 14 days)

**Women currently using hormonal contraception**

In the absence of evidence, it would seem reasonable that women who are currently using a hormonal method of contraception (and who have taken ulipristal acetate as EC for missed pills), should be advised to continue their hormonal method. The manufacturer advises abstinence/condoms for the remainder of the menstrual cycle in which ulipristal acetate is used. As a minimum, it would seem reasonable to advise women to abstain/ use condoms together with hormonal contraception for 14* days (*based upon expert opinion only of 7 days to eliminate plus further 7 days for ovarian quiescence on hormonal contraception = 14 days)

**Safety and Pregnancy**

There have only been a small number of women who have opted to continue with a pregnancy that has occurred before, or despite, taking ulipristal acetate. Whilst the outcome of the small number of babies born in this group has been good, clearly ulipristal acetate is a new drug and so a European registry has been established to follow up the outcome of births occurring after ulipristal acetate administration. The local suppliers of ulipristal acetate should be contacted if pregnancy is diagnosed after use of ulipristal acetate.

**References**


Check list:

☐ <= 120 hours of UPSI and declines IUD
☐ SINGLE episode UPSI this cycle
☐ not had levonorgestrel EC this cycle
☐ can be reasonably certain patient is not already pregnant
☐ not taking drugs that would interact (antacids, antivirals, ulcer healing drugs, enzyme inducers)
☐ not significant hepatic or renal impairment
☐ not severe uncontrolled asthma
☐ not breastfeeding

Counsel:

☐ mode of action is to prevent ovulation. Possible effect on endometrium to make implantation less likely (unproven).
☐ uncertain effect if patient would continue with a pregnancy. No harmful effect in small number of births worldwide. Follow up of any birth would be advised (European registry established).
☐ next menses may be delayed by on average few days. Pregnancy test advised if next menses more than one week late.
☐ importance of ongoing contraception as higher risk of pregnancy if more sex this cycle.
☐ ideally condoms /abstinence for rest of cycle (advised by manufacturer) but as a minimum 14 days* and pregnancy testing.
☐ hormonal contraception may be commenced with condoms /abstinence for rest of cycle (advised by manufacturer) but as a minimum 14 days* and pregnancy testing.
☐ if vomit within 3 hours- need another dose of ulipristal acetate.
☐ common side effects are same as for levonorgestrel (headache, dysmenorrhoea, nausea, fatigue, dizziness and abdominal pain).

* based on expert opinion only. (Ulipristal virtually eliminated by 7 days so further 7 days to maintain ovarian quiescence with hormonal contraception = 14 days)

SIGNATURE ...........................................
PRINT NAME ....................................... 
GRADE ............................................

UPA Counselling
May 2010-05-06 STC version 01

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COPPER IUD AS EMERGENCY CONTRACEPTION

It is widely accepted that Cu-IUDs work by inhibiting fertilisation by direct toxicity primarily by impairing gamete viability before fertilisation. However, a Cu-IUD has both pre-and post-fertilisation effects which contribute to efficacy as EC. An inflammatory reaction within the endometrium may have an anti-implantation effect should fertilisation occur.

A Cu-IUD is effective immediately after insertion. If fertilisation has already occurred, it is accepted that there is an anti-implantation effect, although an IUD is NOT ABORTIFACIENT. This is supported by a Judicial Review in 2002 which ruled that pregnancy begins at implantation, not at fertilisation.

A copper IUD can be inserted up to 5 days after the first episode of unprotected sex. If the timing of ovulation can be estimated, insertion can be beyond 5 days of unprotected sex, as long as it does not occur beyond 5 days after ovulation. Approximately 99% of expected pregnancies will be prevented.

CHOICE OF Cu-IUD FOR EMERGENCY CONTRACEPTION

A Cu-IUD (or advice on how to obtain one) should be offered to all women attending for EC even if presenting within 72 hours of unprotected sex.

Ideally, an emergency IUD should be fitted at first presentation, but insertion can be offered later, at the woman’s convenience. In this case, levonorgestrel EC should be given in the interim.

If facilities are unavailable locally for emergency Cu-IUD insertion, referral mechanisms should facilitate timely access to a specialist who can provide this service. Clinicians can refer women directly to Borders Sexual Health by telephoning 01896 663700.

There is no provision for IUD insertion at Borders Sexual Health Friday to Sunday, so please phone Ward 16 at BGH, if required. If the woman attends within 72 hours of unprotected sex we usually advise Levonelle is given in the event that the woman fails to attend for her Cu-IUD insertion appointment.

Devices which are narrower and have shorter stems such as the Flexi T 300 or a Nova T380 are suitable for emergency contraception. Nevertheless, if a woman is considering keeping the device or may consider this for long term a banded Cu-IUD containing at least 380mm² of copper (TT 380 Slimline) should be used as an emergency IUD. These banded devices have the lowest failure rates and longest duration of use if continued to be used as a longer term method.

The levonorgestrel releasing intrauterine system (LNG-IUS) is ineffective as emergency contraception and should not be used.
TESTING FOR STI PRIOR TO INSERTION OF EMERGENCY Cu-IUD

- A self obtained low vaginal swab (SOLVS) should be performed to identify Chlamydia. Some women will also require testing for Gonorrhoea.
- Women deemed to be at higher risk of STI:
  - aged <25 years
  - any age with a new sexual partner or more than one partner in the last year
  - requesting testing
- If a woman is at higher risk of STI give prophylactic antibiotics at the time of insertion to cover Chlamydia as a minimum Azithromycin 1g stat orally or Doxycycline 100mg BD for 7 days and consider if there is an indication to cover Gonorrhoea (CEFIXIME 400mgs stat).
- Arrange treatment of partner or contacts and refer or advise regarding partner notification.
- A full sexual health screen can be offered if high risk, symptomatic or requested (Gonorrhoea, Trichomonas, HIV, Hepatitis B & C & Syphilis).


AFTER CARE AND FOLLOW UP AFTER Cu-IUD EMERGENCY USE

Women should be advised that a small increase in pelvic infection occurs in the 20 days following IUD insertion, but the risk is the same as for the non-IUD-using population thereafter.

An emergency IUD can be removed anytime after the next menstruation (within 3 weeks) if no unprotected sex has occurred since menses or if hormonal contraception was started within the first 5 days of that cycle.

ONGOING CONTRACEPTION AFTER Cu-IUD EMERGENCY USE

A woman having an emergency Cu-IUD inserted may choose to keep it in place as a regular method of contraception. She should be advised to return 3 to 6 weeks after insertion for a check to exclude infection, perforation or expulsion.

IUD-users should be counselled about when to seek medical advice: if they develop symptoms of pelvic infection, pain, persistent menstrual abnormalities, missed period, or non-palpable threads.

MIFEPRISTONE AS EMERGENCY CONTRACEPTION

Many large trials have shown that the progestogen antagonist, mifepristone, provides very safe and effective emergency contraception. The use of mifepristone as emergency contraception however, is not licensed.

Mifepristone is one of the drugs used to induce medical abortion and is only available from hospitals and specially licensed Sexual Health Clinics.

It is not currently available in Borders Sexual Health as emergency contraception.
- Used consistently and correctly male condoms are up to 98% effective at preventing pregnancy and female condoms up to 95% effective.

- In general evidence supports the use of condoms to reduce the risk of STI transmission however, even with correct and consistent use transmission may occur. Female condoms are at least as good as male condoms at preventing STIs.

- Men and women with latex sensitivity or allergy can use polyurethane or deproteinised latex condoms.

- Condoms lubricated with non-spermicidal lubricant are recommended for use.

- Additional lubricant should be recommended for use with condoms for anal sex to reduce the risk of breakage. Lubricant increases the risk of slippage and should not be routinely recommended or supplied for vaginal sex.

- Non-oil based lubricants are recommended as they can be used safely with latex and non-latex condoms.

- An advance provision of emergency contraception should be offered to women using condoms as the sole method of contraception.

- Condom users should be made aware of the risk of pregnancy and sexually transmitted infections should a condom fail.

- Offer testing for sexually transmitted infection after a condom has burst. Although STI testing can be done at the time of presentation it is recommended at 2 and 12 weeks after a condom failure.

- Post exposure prophylaxis for HIV should be considered if the person presents within 72 hours of a condom failure with an HIV positive partner. The risks may outweigh benefits and a risk assessment is required before initiating treatment.

**NB:** See “Borders STI Management Guidelines”.

- Refer to the fpa leaflet on male and female condoms to back up the verbal information given about male and female condom use.

- **Emergency contraception** can be used to reduce the risk of pregnancy and should be taken as soon as possible after a condom accident or unprotected sex.

**AN ADVANCE PROVISION OF EMERGENCY HORMONAL CONTRACEPTION CAN BE OFFERED TO WOMEN RELYING ON CONDOMS FOR CONTRACEPTION**
DIAPHRAGMS AND CERVICAL CAPS

When used consistently and correctly and with spermicide diaphragms and cervical caps are estimated to be between 92 and 96% effective at preventing pregnancy and the contraceptive sponge is estimated to be between 80 and 90% effective at preventing pregnancy. GYGEL II is the only spermicide available at present in the UK.

There is limited evidence on the use of diaphragms, cervical caps or contraceptive sponge in reducing the risk of sexually transmitted infections. There may be some protection against cervical intraepithelial neoplasia (CIN) with diaphragms. The use of a diaphragm, cervical cap or contraceptive sponge by women who have or at high risk of HIV or AIDS is not generally recommended.

Women with sensitivity to latex proteins can use a silicone diaphragm or cervical cap or a polyurethane female condom. For women with a history of toxic shock syndrome the use of diaphragms, cervical caps and contraceptive sponge is not generally recommend

- Initial assessment of diaphragm and cervical caps should be done by a competent health professional

- All methods can be inserted anytime before intercourse

- The use of spermicide is recommended when using diaphragms and cervical caps

- If intercourse is repeated or occurs ≥ 3 hours after insertion more spermicide is required and should be inserted with an applicator or as a pessary without removing the diaphragm or cervical cap

- The diaphragm or cervical cap must be left in situ for at least 6 hours after the last episode of intercourse. Sperm in the lower reproductive tract are unlikely to be alive after 6 hours

- Oil-based lubricants can damage latex and women should be advised to avoid use when using latex diaphragms or cervical caps

- Women should be advised to check diaphragm or cervical cap regularly for tears, holes or cracks

- There is no evidence that a colour change or change in shape of the outer ring of a diaphragm reduces efficacy

- Women should be advised on the use of emergency contraception should female barrier methods be used incorrectly

- Women should be advised to attend for a review of contraception if they have:
  - any problems with the method
  - lost or gained more than 3kgs (7lbs)
  - had a pregnancy
  - had gynae surgery e.g. pelvic floor repair

AN ADVANCE PROVISION OF EMERGENCY HORMONAL CONTRACEPTION CAN BE OFFERED TO WOMEN RELYING ON FEMALE BARRIER METHODS FOR CONTRACEPTION
<table>
<thead>
<tr>
<th>TYPE OF BARRIER METHOD</th>
<th>DESCRIPTION</th>
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</thead>
</table>
| **DIAPHRAGMS**         | *Available in different sizes from 60 to 95mm (in 5mm increments).*  
  *Initial fitting by a competent health professional is required*  
  *Maximum duration of use recommended after insertion is 30 hours.* |
| Coil spring            | Has a soft flexible rim, which does not form an arc when folded.  
  This diaphragm may be used for women with average vaginal muscle tone. |
| Arcing spring          | Has a firm rim, which causes the diaphragm to fold at two hinged points, and form an arc. The firm rim makes it easier to place the diaphragm in the posterior fornix.  
  It can be used in women with a retroverted uterus, a rectocele, cystocele or lax vaginal muscle tone. |
| Flat spring            | Has a more delicate and thinner rim than the coil spring diaphragm.  
  It may be used in women with firm muscle tone. |
| Arcing spring or coil spring types | Wide seal rim diaphragm has flexible flange attached to the inner edge of the rim. The flange is approximately 1.5cm wide and intended to hold spermicide in place inside the diaphragm and to create a better seal between the diaphragm and the vaginal wall. |
| **CERVICAL CAPS**      | *Available in different sizes as noted below*  
  *Initial fitting by a competent health professional is required*  
  *Maximum duration of use recommended after insertion is 30 hours (48 hours for a silicone cervical cap).* |
| FemCap                 | Shaped like an American sailors hat. It has a dome, which covers the cervix. The circular rim fits into the fornices of the vaginal vault. The posterior brim adhered to the walls of the vagina and is designed to funnel ejaculate into a groove between the dome and the brim. This also acts as a reservoir for spermicide.  
  Available in 3 sizes 22mm for nulliparous women, 26mm for parous women who have not had a vaginal delivery and 30mm for parous women who have had at least one vaginal delivery. The second generation of FemCap has a strap to facilitate removal. |
| **FEMALE CONDOM**      | *No fitting required*  
  *(Polyurethane)*  
  This is a loose fitting sheath with two flexible polyurethane rings one at either end. It sits within the vagina. At the closed end of the tube the ring is not fixed but facilitates insertion and acts as an internal anchor. At the open end the flexible ring lies outside the vagina. The Femidom is lubricated with non-spermicidal lubricant. |
Counselling and advice on sterilisation procedures should be provided to women and men within the context of a service providing a full range of information and access to other long-term reversible methods of contraception. This should include information on the advantages and disadvantages and relative failures.

Women should be informed that vasectomy carries a lower failure rate and that there is less risk related to the procedure.

Women, particularly those at increased risk from conditions such as previous abdominal surgery or obesity, should be informed of the risks of laparoscopy and the chances of laparotomy being necessary if there are problems with the laparoscopy.

Women should be informed that tubal occlusion is associated with a failure rate estimated at 1 in 200 (lifetime risk) and 2-3 per 1000 after 10 years. Pregnancy can occur several years after the procedure. The longest period of follow-up data available for the most common method used in the UK, the Filshie clip, suggests a failure rate after ten years of two or three per 1000 procedures.

Ectopic pregnancy risk is reduced compared to women using no method but women should be informed that, if tubal occlusion fails, the resulting pregnancy may be ectopic.

Although women requesting sterilisation should understand that the procedure is intended to be permanent, they should be given information about the success rates associated with reversal, should this procedure be necessary. Reversal of sterilisation is done privately.

Women should be reassured that tubal occlusion is not associated with an increased risk of heavier or longer periods when performed after 30 years of age. There is an association with subsequent increased hysterectomy rate; although there is no evidence that tubal occlusion leads to problems that require hysterectomy. Obviously women discontinuing hormonal contraception may find that their periods become heavier and more painful.

Hysteroscopic methods of tubal occlusion are still under evaluation and should only be used within the present guidance system for new surgical interventions.

PLEASE NOTE:

Refer women requesting sterilisation directly to Gynaecology Department at Borders General Hospital.
Men should be informed that vasectomy has an associated failure rate of 1 in 2000 and that pregnancies can occur several years after vasectomy.

The majority of vasectomies are performed under local anaesthetic.

Although men requesting vasectomy should understand that the procedure is intended to be permanent, they should be given information on the success rates associated with reversal should this procedure be necessary. They should also be informed that reversal operations or assisted reproduction procedures are rarely provided within the NHS.

Men should be advised to use effective contraception until azospermia has been confirmed. The way in which azospermia is confirmed will depend on local protocols. This is arranged by Surgical Department, Borders General Hospital.

Men requesting vasectomy can be reassured that there is no increase in testicular cancer or heart disease associated with vasectomy. The association, in some reports, of an increased risk of being diagnosed with prostate cancer is at present considered to be non-causative.

Men should be informed about the possibility of chronic testicular pain after vasectomy.

**PLEASE NOTE:**

Men requesting vasectomy may be referred to Surgical Outpatients Department, Borders General Hospital.
If ONE or TWO pills have been missed at anytime

OR

If ONE pill is missed when using Loestrin 20, Mercilon, Femodette

CONTINUING CONTRACEPTIVE COVER:

She should take the most recent missed pill as soon as she remembers.

She should continue taking the remaining pills daily at her usual time. *

MINIMISING THE RISK OF PREGNANCY

She does not require emergency contraception

MINIMISING THE RISK OF PREGNANCY

* Depending on when she remembers her missed pill she may take two pills on the same day (one at the moment of remembering and the other at the regular time) or even at the same time.

If THREE or more pills have been missed at anytime

OR

If TWO or more pills missed when using Loestrin 20, Mercilon, Femodette

CONTINUING CONTRACEPTIVE COVER:

She should take the most recent missed pill as soon as she remembers.

She should continue taking the remaining pills daily at her usual time. *

She should be advised to use condoms or abstain from sex until she has taken pills for 7 days in a row.

MINIMISING THE RISK OF PREGNANCY

Extending the pill-free interval is risky therefore:

If pills are missed in the first week of pill taking

EMERGENCY CONTRACEPTION should be considered if she had unprotected sex in the pill-free interval or in the first week of pill taking

If pills are missed in the second week of pill taking (pills 8-14)

NB. After seven consecutive pills have been taken seven can be missed (as occurs in the pill free interval) without the need for EC

If pills are missed in the third week of pill taking

She should OMIT THE PILL FREE INTERVAL by finishing the pills in her current pack and starting a new pack the next day
### Figure 2: Advice for missed progestogen-only pills

#### How late is the missed progestogen-only pill?

<table>
<thead>
<tr>
<th>MORE than 3* hours late</th>
<th>LESS than 3* hours late</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take a pill as soon as you remember. If you have missed more than one pill just take one.</td>
<td>Take it as soon as you remember, and take the next one at the usual time. You are protected against pregnancy.</td>
</tr>
<tr>
<td>Take your usual pill at the usual time. This may mean taking two pills in one day. This is not harmful.</td>
<td></td>
</tr>
<tr>
<td>You are not protected against pregnancy. Continue to take your pills as usual but you also need to use an extra method, such as the condom for the next two days.</td>
<td></td>
</tr>
</tbody>
</table>

* 12 hours if you are taking the progesterone-only pill Cerazette
Figure 3: Advice for late Depo Medroxyprogesterone acetate Injection  
(If a woman presents > 14 weeks since her last DMPA injection)

Note: Women should be encouraged to attend every 12 weeks for repeat DMPA (licensed use). Evidence supports the continued contraceptive efficacy of the method should the woman present any time up to exactly 14 weeks since her last injection. A repeat injection can be given and no additional contraceptive protection is required.

<table>
<thead>
<tr>
<th>Timing of DMPA</th>
<th>Has unprotected sex occurred?</th>
<th>Can the injection be given?</th>
<th>Is EC indicated?</th>
<th>Is additional contraception required?</th>
<th>Should a pregnancy test be performed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>When an injection is overdue (&gt; 14 weeks since last injection)</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes for the next 7 days</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Yes, but only in the last 3 days</td>
<td>Yes</td>
<td>Yes, should offer progestogen-only emergency contraception or a copper intrauterine device</td>
<td>Yes for the next 7 days</td>
<td>Yes 28 days later</td>
</tr>
<tr>
<td></td>
<td>Yes, but only in the last 4-5 days</td>
<td>Yes</td>
<td>Yes, should offer a copper intrauterine device</td>
<td>No, if opts for a Cu-IUD</td>
<td>Yes 28 days later</td>
</tr>
<tr>
<td></td>
<td>Yes more than 5 days ago</td>
<td>No</td>
<td>No</td>
<td>Yes for 28 days, if a pregnancy test is negative she can have DMPA + abstain or condoms for 7 days</td>
<td>Yes, at the initial presentation and repeat before the injection and 4 weeks after the injection. If she fails to attend a PT should be performed before the next injection is given.</td>
</tr>
</tbody>
</table>
Figure 4: Management of unscheduled bleeding (Investigation)

- **Take a medical history to assess:**
  - woman’s concerns
  - correct use of the method
  - use of interacting medication
  - other symptoms (pain, dyspareunia, heavy bleeding, postcoital bleeding)
  - illness which may affect absorption of orally administered hormones
  - possibility of pregnancy
- **Exclude sexually transmitted infection**
- **Check she is up to date with smears**

Manage any issues identified above

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**Less than 3 months since starting the method**

All of the above checked and confirmed/excluded

Examination and investigation **not** necessary unless requested by woman

Reassure and arrange follow up

If requested medical management can be considered (see figure 4)

*Note: LNG-IUS users with pain, discharge or lost threads in addition to bleeding require investigation to exclude expulsion, perforation or infection*

Follow up arranged

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**More than 3 months use with persistent bleeding; new symptoms; or a changed bleeding pattern**

**Other symptoms** such as pain, dyspareunia, heavy bleeding, postcoital bleeding.

**Aged over 45 years.**

**Speculum examination to assess cervix** (e.g. polyps, ectopy)

**Normal findings**

**Clinical findings refer/manage appropriately**

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**Persistent bleeding at follow up**

Or

**After failed medical treatment**

**No other symptoms**

Reassure

Consider medical therapy Figure 4.

**Symptoms (pain, dyspareunia, heavy bleeding)**

Age over 45 years

Consider further assessment (endometrial assessment such as with ultrasound scan, biopsy, hysteroscopy) depending on age and likelihood of pathology.
May try a different POP although there is no evidence that changing the progestogen type or increasing the dose improves bleeding.

No evidence that desogestrel-only pills have better bleeding patterns than traditional POPs.

No evidence to support the use of two POPs per day to improve bleeding.

In general consider:

Consider an alternative contraceptive method after full discussion about expected bleeding patterns.

In general continue with the same pill for at least 3 months as bleeding may settle in this time.

Use a COC with a dose of EE to provide the best cycle control.

May consider increasing the EE dose up to a maximum of 35 micrograms.

May try a different COC but no evidence one better than any other in terms of cycle control.

No evidence changing progestogen dose or type improves cycle control but may help on an individual basis.

A first-line COC (30 to 35 micrograms of ethinylestradiol with levonorgestrel or norethisterone) may be considered for up to 3 months continuously or in the usual cyclical regimen (unlicensed).

No evidence reducing injection interval for depot medroxyprogesterone acetate improves bleeding (but anecdotally may help).

Mefenamic acid 500mg twice or three times daily for 5 days for women with bleeding on DMPA to reduce the duration of the bleeding interval, no long term benefit.

Figure 5: Management of unscheduled bleeding (Treatment)
Medical therapy options for women using hormonal contraception with unscheduled bleeding
(based on expert clinical judgment of the multidisciplinary group developing this guidance)
There are two classes of drugs which reduce the efficacy of hormonal contraception: liver enzyme inducing drugs and non liver enzyme inducing antibiotics.

**Liver Enzyme- Inducing Drugs**
These drugs increase the enzyme activity in the liver and cause increased breakdown of oestrogen and progestogen and therefore reduce contraceptive efficacy. Liver enzyme inducing drugs are a problem with combined and some progestogen only methods.

**Liver Enzyme Inducing Drugs**
The following drugs induce liver enzymes.
1. **Anti-epileptic**
   Carbamezepine, Oxycarbamezepine, Phenytoin, Phenobarbitone, Primidone, Topiramate.
2. **Antibiotic**
   Rifampicin and Rifabutin
3. **Antifungal**
   Griseofulvin
4. **Antiretroviral**
   Amprenavir, Atazanavir, Nelfinavir, Lopinavir, Saquinavir, Ritonavir, Efavirenz, Nevirapine
5. **CNS**
   Modafil

(The following drugs are also enzyme inducers but are not thought to reduce contraceptive efficacy: Lanzoprazole, Tacrolimus, Bosentan, Terbinafine).

**CONTRACEPTIVE ADVICE FOR WOMEN USING ENZYME INDUCING DRUGS**

**Combined hormonal contraception**

**Combined oral contraception (COC)**
Use a COC with at least 50 μg ethinylestradiol daily. This can be taken as a 30 μg COC plus a 20 μg COC or as two 30 μg COCs.
Additional contraceptive protection, such as condoms, is required when taking liver enzyme-inducers and for 4 weeks after they are stopped.
Information should be given on the use of alternative methods which are unaffected by liver enzyme-inducers.
If additional contraception fails or is not used emergency contraception may be indicated.
Combined contraceptive patch
Use one patch per week as for women not using liver enzyme-inducers. Additional contraceptive protection, such as condoms, is required when taking liver enzyme-inducers and for 4 weeks after they are stopped. Information should be given on the use of alternative contraceptive methods if liver enzyme-inducers are to be used long term. If additional contraception fails or is not used emergency contraception may be indicated.

Progestogen-only contraception

Progestogen-only pills (POPs)
Advise alternative contraceptive methods.

Progestogen-only implants
May continue with progestogen-only implants with additional contraceptive protection, such as condoms, when taking liver enzyme-inducers, and for 4 weeks after they are stopped. Information should be given on the use of alternative contraceptive methods if liver enzyme-inducing drugs are to be used long term e.g. antiretrovirals.

Note: Implanon should not be used in HIV positive women on longterm ARVs.

Progestogen-only injectables
Progestogen-only injectables are unaffected by liver enzyme-inducers. Continue with the usual injection interval of 12 weeks for depot medroxyprogesterone acetate and 8 weeks for norethisterone enanthate.

Progestogen-only emergency contraception
Take a total dose of 2.25 mg levonorgestrel, or two tablets Levonelle, as a single dose as soon as possible and within 72 hours contraception of unprotected sex. Consider the use of a copper IUD, which is unaffected.

Levonorgestrel-releasing intrauterine system
No additional contraceptive protection required.

Non-hormonal methods
IUD, condoms, female barrier methods - No additional contraceptive protection required.

Non liver enzyme inducing Antibiotics:
These antibiotics reduce colonic bacteria thus reducing the conversion of inactive metabolites of ethinyl oestradiol to active metabolites, which are reabsorbed into the circulation. Antibiotics are only a problem with combined methods.
CONTRACEPTIVE ADVICE FOR WOMEN USING NON ENZYME INDUCING ANTIBIOTICS

Combined hormonal contraception

Combined oral contraception (COC)

Established COC user:
When taking a short course (<3 weeks) of any non-liver enzyme-inducing antibiotic additional contraceptive protection, such as condoms, is advised during the treatment and for 7 days after the antibiotic has been stopped.
If fewer than seven pills are left in the packet after antibiotics have stopped the pill-free interval should be omitted or any inactive pills discarded.
When any non-liver enzyme-inducing antibiotic is taken for ≥3 weeks additional contraceptive protection is no longer required. If a new antibiotic is prescribed, however, advice is as for short courses.

New COC user:
When starting a COC if currently taking a short course (<3 weeks) of any non-liver enzyme-inducing antibiotic additional contraceptive protection, such as condoms, is advised during the treatment and for 7 days after the antibiotic is stopped.
When starting a COC if any non-liver enzyme-inducing antibiotic has been taken for ≥3 weeks additional contraceptive protection is not required.

Combined contraceptive patch

Established contraceptive patch users:
If taking a short course (<3 weeks) of any non-liver enzyme-inducing antibiotic (except tetracycline) additional contraceptive protection, such as condoms, is advised during the treatment and for 7 days after the antibiotic is stopped.
If there are fewer than 7 days remaining before the usual patch-free week another patch should be applied (when due for changing) so that the patch-free week is delayed by 7 days.
When any non-liver enzyme-inducing antibiotic is taken for ≥3 weeks additional contraceptive protection is no longer required. If a new antibiotic is prescribed, however, advice is as for short courses.

New patch user:
When starting a contraceptive patch if currently taking a short course (<3 weeks) of any non-liver enzyme-inducing antibiotic additional contraceptive protection, such as condoms, is advised during the treatment and for 7 days after the antibiotic is stopped.
When starting a contraceptive patch if any non-liver enzyme-inducing antibiotic has been taken for ≥3 weeks additional contraceptive protection is not required.

Progestogen-only methods
Efficacy of progestogen-only methods (including emergency contraception) is not reduced by non-liver enzyme-inducing antibiotics.

Non-hormonal contraception
Efficacy unaffected.
Evidence-based used in the development of these protocols and proformas


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