



# Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit

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## FFPRHC Guidance (January 2004)

# The Copper Intrauterine Device as Long-term Contraception

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This Guidance provides information for clinicians providing women with copper-bearing intrauterine devices as long-term contraception. A key to the grades of recommendations, based on levels of evidence, is given at the end of this document. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this Guidance and evidence tables summarising the research basis of the recommendations are available on the Faculty website ([www.ffprhc.org.uk](http://www.ffprhc.org.uk)). Abbreviations (in alphabetical order) used include: acquired immune deficiency syndrome (AIDS); actinomyces-like organisms (ALOs); automated external defibrillator (AED); blood pressure (BP); *British National Formulary* (BNF); confidence interval (CI); copper-bearing intrauterine contraceptive device (IUD); emergency contraception (EC); Faculty Aid to Continuing Professional Development Topic (FACT); levonorgestrel-releasing intrauterine system (IUS); human immunodeficiency virus (HIV); Medicines and Healthcare products Regulatory Agency (MHRA); non-steroidal anti-inflammatory drugs (NSAIDs); odds ratio (OR); pelvic inflammatory disease (PID); relative risk (RR); Royal College of Obstetricians and Gynaecologists (RCOG); Scottish Intercollegiate Guidelines Network (SIGN); sexually transmitted infection (STI); termination of pregnancy (TOP); World Health Organization (WHO); WHO *Medical Eligibility Criteria* (WHOMEC); WHO *Selected Practice Recommendations* (WHOSPR).

### What is intrauterine contraception?

This Guidance provides recommendations and good practice points regarding the use of a copper intrauterine device for long-term contraception, the accepted abbreviation for which is IUD. The use of an IUD as emergency contraception (EC) was covered in previous Guidance.<sup>1</sup> The IUD is a safe and effective method of contraception. Although use in the UK has increased in recent years, only 5% of contraceptive users aged 16–49 years currently use an IUD.<sup>2</sup> A balanced approach to counselling by clinicians may allay myths and unfounded fears and further increase IUD use.<sup>3</sup>

### What should a clinician assess before inserting an IUD?

Women considering an IUD should be counselled regarding all contraceptive options, including the alternative levonorgestrel-releasing intrauterine system (IUS). Clinical history taking, including sexual history, should allow a clinician to discuss her individual sexual health risks with each woman. Examination and testing for sexually transmitted infections (STIs) (*Chlamydia trachomatis* and *Neisseria gonorrhoea*) may then be offered and performed if appropriate.

Who is medically eligible to use an IUD?

**1 After counselling, an IUD is a safe contraceptive choice for the majority of women (Grade C).**

The World Health Organization *Medical Eligibility Criteria for Contraceptive Use* (WHOMEC)<sup>4</sup> provides evidence-based recommendations to enable women to choose a method of contraception without unnecessary medical contraindications. For most women, the benefits of IUD use outweigh risks (WHO 1, 'unrestricted use' and WHO 2, 'benefits generally outweigh risks') (Table 1). There are few circumstances where WHOMEC recommends that risks usually outweigh benefits (WHO 3) or that an IUD should not be used (WHO 4) (Table 1). This Guidance endorses WHOMEC unless otherwise stated. Outlined below are

conditions where this Guidance suggests a less restrictive approach compared to WHOMEC.

*Women at risk of sexually transmitted infections (STIs)*

**2 After counselling about other contraceptive methods, women who are assessed as at higher risk of STI may still choose to use an IUD (Grade C).**

WHOMEC recommends that risks of using an IUD generally outweigh benefits for women who are at increased risk of STIs, such as those with multiple sexual partners (WHO 3).<sup>4</sup> Although women may have risk factors for STI most will not have infection. The risk of pelvic inflammatory disease (PID) due to IUD use is unknown. The risk of PID in the month following IUD insertion did not increase significantly, even in the presence of *C. trachomatis*, compared to women without infection [relative risk (RR) 1.7; 95% CI 0.4–7.5].<sup>5</sup> The Clinical Effectiveness Unit (CEU) recommends that, after counselling regarding other methods, women who are at a higher risk of STI may still choose an IUD. Safer sex and condom use in addition should be promoted.

*Women with PID currently or within the last 3 months*

**✓ After considering other contraceptive methods, a woman may use an IUD within 3 months of treated pelvic infection, provided she has no signs and symptoms.**

WHOMEC recommends that an IUD should not be inserted when a woman has PID currently or within the last 3 months (WHO 4).<sup>4</sup> The CEU considers that after discussing other contraceptive methods, if no other method is acceptable and pregnancy risk is substantial, a clinician may insert an IUD provided the woman has no abnormal signs and symptoms suggestive of PID following treatment and her partner has been appropriately tested and treated. Safer sex and condom use in addition should be promoted.

**Table 1** Medical eligibility criteria for IUD use adapted from the WHO Medical Eligibility Criteria for Contraceptive Use<sup>4</sup>

Unrestricted use (WHO 1)	Benefits generally outweigh the risks (WHO 2)
Age – 20 years and over	Menarche to under 20 years
Parous women	Nulliparous women
Postpartum – four or more weeks postpartum in women who are breastfeeding, not breastfeeding or post-Caesarean section	Less than 48 hours postpartum in women who are breastfeeding, not breastfeeding or post-Caesarean section
First-trimester TOP	Second-trimester TOP
Past ectopic pregnancy	Anatomical abnormalities (including cervical stenosis, cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion
History of pelvic surgery	Complicated valvular heart disease <sup>a</sup>
Smoking – any age and amount	Heavy or prolonged bleeding (includes regular and irregular patterns) in the absence of significant pathology
Obesity – BMI 30 or more	Continuation with unexplained vaginal bleeding before evaluation
Multiple risk factors for cardiovascular disease	Endometriosis
Hypertension	Severe dysmenorrhoea
VTE	Continuation by women with cervical cancer awaiting treatment, endometrial cancer or ovarian cancer
Superficial venous thrombosis	Uterine fibroids without distortion of the uterine cavity
Current ischaemic heart disease	Past PID without subsequent pregnancy
Known hyperlipidaemias	Vaginitis without purulent cervicitis
Uncomplicated valvular heart disease <sup>a</sup>	Continuation in women with current PID or within the last 3 months <sup>b</sup>
Headaches including migraine	Women at high risk of HIV, who are HIV-positive or have AIDS, or women with an increased risk of STI <sup>c</sup>
Epilepsy	Treated PID or STI within the last 3 months <sup>d</sup>
Irregular bleeding (without heavy bleeding)	Anaemia
Benign ovarian tumour	Thalassaemia
Cervical ectropion	Sickle cell disease
Cervical intraepithelial neoplasia	Iron deficiency anaemia
Breast disease (benign and malignant)	
Past PID with subsequent pregnancy	
Schistosomiasis	
Non-pelvic TB	
Diabetes	
Thyroid disease	
Gallbladder disease	
History of cholestasis	
Viral hepatitis	
Cirrhosis	
Liver tumours	
Commonly used drugs which affect liver enzymes	
Antibiotics	
Risks usually outweigh the benefits (WHO 3)	Unacceptable health risk, should not be used (WHO 4)
Postpartum insertion between 48 hours and 4 weeks postpartum in women who are breastfeeding, not breastfeeding or post-Caesarean section	Pregnancy
Current benign gestational trophoblastic disease	Puerperal sepsis
Ovarian cancer	Immediate post-septic abortion
Continuation in women with known pelvic TB	Distorted uterine cavity (any congenital or acquired abnormality distorting the uterine cavity in a manner that is incompatible with IUD insertion) including uterine fibroids
	Insertion before evaluation of unexplained vaginal bleeding which is suspicious for serious conditions
	Current malignant gestational trophoblastic disease
	Insertion in women with cervical cancer who are awaiting treatment, or endometrial cancer
	Insertion for women with a current STI or PID
	Insertion in women with known pelvic TB

<sup>a</sup>Women with previous endocarditis or with a prosthetic heart valve require intravenous antibiotic prophylaxis to protect against bacterial endocarditis for IUD insertion and removal.<sup>22</sup>

<sup>b</sup>For IUD users with PID, appropriate antibiotics should be started. There is no need to remove the IUD unless symptoms fail to resolve.<sup>12</sup>

<sup>c</sup>Women who are HIV-positive may be offered an IUD after testing for bacterial STIs.

<sup>d</sup>After considering other contraceptive methods, a woman may use an IUD within 3 months of treated PID, provided she has no signs and symptoms. AIDS, acquired immune deficiency syndrome; BMI, body mass index; CIN, cervical intraepithelial neoplasia; HIV, human immunodeficiency virus; PID, pelvic inflammatory disease; STI, sexually transmitted infection; TB, tuberculosis; TOP, termination of pregnancy; VTE, venous thromboembolism.

### Women who are HIV-positive

#### **3 Women who are HIV-positive may be offered an IUD after testing for bacterial STIs (Grade B).**

WHOMEC recommends that risks of IUD use outweigh benefits for women at risk of contracting the human immunodeficiency virus (HIV), those who are HIV-positive, or who have acquired immune deficiency syndrome (AIDS).<sup>4</sup> This advice was based on theoretical concerns regarding increased rates of PID and HIV transmission but may deny women a long-term, reversible method of contraception which is unaffected by liver enzyme-inducing drugs. Much of the evidence is based on African cohort studies, which may be less relevant to UK practice. HIV status did not affect rates of PID following IUD insertion.<sup>6</sup> Prospective cohort studies did not show significant differences in viral shedding<sup>7</sup> or any increase in female-to-male transmission with IUD use.<sup>8</sup> One

cross-sectional study suggested increased acquisition of HIV for women using an IUD,<sup>9</sup> but two subsequent studies did not support this.<sup>10,11</sup> The CEU considers that women in the UK who are HIV-positive may use an IUD. Risk assessment and testing for STIs prior to IUD insertion is recommended.

*Are there any drugs that may interact with an IUD?*

#### **4 There are no drugs that are known to affect IUD use and efficacy (Grade C).**

Summaries of Product Characteristics suggest some anti-inflammatory medications may affect IUD action. No published evidence was identified of any effects of anti-inflammatory drugs (non-steroidal, corticosteroids, cyclo-oxygenase inhibitors) on IUD efficacy. No evidence was identified regarding the use of warfarin or heparin on IUD insertion and use.

Which examinations, investigations and treatments are required prior to inserting an IUD?

The WHO *Selected Practice Recommendations for Contraceptive Use* (WHOSPR)<sup>12</sup> provides recommendations on examinations and tests which should be performed before providing an IUD. This Guidance endorses the WHOSPR unless otherwise stated. Haemoglobin measurement is not recommended routinely prior to IUD insertion.

#### Bimanual pelvic examination

### 5 A bimanual pelvic examination should be performed before inserting an IUD (Grade C).

A bimanual pelvic examination to assess the size, shape and position of the uterus should be performed prior to IUD insertion.<sup>12</sup>

#### Testing for STI

### 6 STI risk assessment (history and examination) should be performed for all women considering an IUD (Grade C).

### 7 Women assessed to have a higher risk of STI should be offered testing for *C. trachomatis* (as a minimum) prior to IUD insertion (Grade C).

✓ Women assessed to have a higher risk of STI may also be offered testing for *N. gonorrhoea* prior to IUD insertion, depending on its local prevalence.

✓ There is no indication to test for other lower genital tract organisms in asymptomatic women attending for IUD insertion.

✓ Ideally, for women assessed as at higher risk of STI, the results of tests should be available and appropriate treatment provided prior to IUD insertion.

✓ For women assessed as at higher risk of STI, if results are not available and IUD insertion cannot be delayed, the use of prophylactic antibiotics may be considered.

WHOSPR recommends risk assessment (clinical history and physical examination) and testing for STIs and HIV prior to IUD insertion.<sup>12</sup> The validity of risk assessments in different clinical settings has not been confirmed but risk may be assessed individually, taking into consideration local prevalence of STIs, the woman's age and her sexual activity. A large UK sample of women aged 16–24 years attending family planning, general practice, genitourinary medicine, antenatal clinics and termination services identified a prevalence of *C. trachomatis* of 9.8–11.2%.<sup>13</sup> A UK pilot study in women attending for IUD insertion identified *C. trachomatis* in 4% (95% CI 2%–8%).<sup>14</sup>

For women undergoing uterine instrumentation, including IUD insertion, the Royal College of Obstetricians and Gynaecologists (RCOG) recommended that sexually active women aged less than 35 years should be screened for infection.<sup>15</sup> More recently, the Scottish Intercollegiate Guidelines Network (SIGN)<sup>16</sup> recommended testing for *C. trachomatis* in all sexually active women aged less than 25 years having an IUD inserted. Women who are widowed, divorced or separated comprise 4% of IUD users<sup>2</sup> and may embark upon new sexual relationships. SIGN also recognises that sexual activity, as well as age, is an

important risk factor for STI and recommend testing for women aged over 25 years with two or more partners, or a change of sexual partner, in the last year who are having an IUD inserted. Clinicians should involve all women considering an IUD in assessing their own risk of STI and their need for testing. Following this, appropriate STI testing should be offered to those who want it.

STI testing prior to IUD insertion should cover *C. trachomatis*, as a minimum. Testing for *N. gonorrhoea* may be included depending on age, STI risk and local prevalence. There is no indication to test routinely for other lower genital tract organisms in asymptomatic women attending for IUD insertion, since the results would not affect management.

Ideally, STI testing should be performed in advance of insertion to allow infection to be identified and treated. However, no evidence was identified to suggest that this decreases the incidence of post-insertion PID. A prospective cohort study showed that 10% of women (95% CI 1%–33%) with unsuspected *C. trachomatis* at the time of IUD insertion developed pelvic infection post-insertion.<sup>17</sup> A cohort study suggested that when women had *C. trachomatis* identified at the time of IUD insertion, risk of PID in the following month was not increased significantly compared to women without *C. trachomatis* (RR 1.7; 95% CI 0.4–7.5).<sup>5</sup> Women with *N. gonorrhoea* at the time of IUD insertion, however, were at an eight-fold increased risk of developing PID compared to non-infected women (RR 8.3; 95% CI 2.4–28.8). A systematic review<sup>18</sup> highlighted the lack of good-quality evidence to identify the risk of PID following IUD insertion in the presence of *C. trachomatis* or *N. gonorrhoea* compared to women not having an IUD inserted. For women assessed at higher risk of STI, if results are not available prior to insertion, the use of prophylactic antibiotics may be considered if IUD insertion cannot be delayed.

#### Measurement of pulse and blood pressure

### ✓ Pulse rate should be measured and documented post-IUD insertion.

WHOSPR does not recommend routine blood pressure (BP) measurement before IUD insertion.<sup>12</sup> UK practice varies regarding measurement of BP and pulse rate before and after IUD insertion but the CEU advises that a post-insertion measurement of pulse rate is good practice. When bradycardia is associated with clinical signs and symptoms (pallor, light-headedness, nausea) BP should also be measured and recorded.

#### Prophylaxis to prevent pelvic infection

### 8 Prophylactic antibiotics are not recommended for routine IUD insertion (Grade A).

A meta-analysis concluded that the use of prophylaxis prior to IUD insertion did not confer benefit<sup>19</sup> and the WHOSPR does not recommend prophylactic antibiotics routinely for IUD insertion.<sup>12</sup> WHOSPR recommends that prophylaxis may be considered in settings of high STI prevalence and limited testing, but this is not relevant to UK practice. Prophylactic antibiotics may be considered for women who are at increased risk of STI if an IUD is to be inserted prior to results of tests being available.

#### Prophylaxis to prevent bacterial endocarditis

### 9 Women with previous endocarditis or with a prosthetic heart valve require intravenous antibiotic prophylaxis to protect against bacterial endocarditis during IUD insertion or removal (Grade C).

✓ **When prophylaxis against bacterial endocarditis is required, clinicians should refer to the BNF for the most up-to-date regimen and ensure the IUD procedure takes place in an appropriate setting.**

Women with valvular heart disease can safely use an IUD but prophylaxis against bacterial endocarditis may be required at the time of insertion.<sup>4</sup> A small study identified transient bacteraemia from vaginal organisms in 13% of women within 10 minutes of IUD insertion.<sup>20</sup> Conflicting advice is provided by the American Heart Association<sup>21</sup> and the *British National Formulary* (BNF)<sup>22</sup> The CEU considers that the BNF guidance should be adopted. There is no advice specifically relating to IUD insertion. For gynaecological procedures, the BNF<sup>22</sup> recommends antibiotic prophylaxis only for women with prosthetic valves or who have had endocarditis previously. In these circumstances an intravenous regimen is advised. In the absence of specific guidance, the CEU considers that such prophylaxis should be used for both insertion and removal.

### What do women need to know when considering an IUD?

#### Mode of action

**10 Women should be informed that the primary mode of action of an IUD is prevention of fertilisation (Grade B).**

It is widely accepted that IUDs work primarily by inhibiting fertilisation due to direct toxicity.<sup>23,24</sup> A systematic review on mechanisms of action of IUDs showed that pre- and post-fertilisation effects contribute to efficacy.<sup>25</sup> An inflammatory reaction within the endometrium may have an anti-implantation effect should fertilisation occur but an IUD is not an abortifacient.<sup>26,27</sup> Alterations in the copper content of cervical mucus are seen, which may inhibit sperm penetration.<sup>28–30</sup>

#### Efficacy

**11 Women should be advised of the low failure rate of IUDs, i.e. around 1% (Grade C).**

**12 IUDs containing at least 300 mm<sup>2</sup> of copper should be used as they have the lowest failure rates (Grade A).**

✓ **IUDs such as T-Safe Cu380A represent a reversible alternative to female sterilisation.**

There are few systematic reviews of randomised trials that allow a direct comparison of pregnancy rates with different devices. Factors such as a woman's sexual activity and age may be important in determining efficacy but are often not investigated fully in clinical trials. Experience of the inserter may also be important.<sup>31</sup>

WHO states that an IUD (in particular the T-Safe<sup>®</sup> Cu380A) is a very effective method, with 0.6–0.8 pregnancies per 100 women in the first 12 months of use.<sup>4</sup> Three of the largest WHO randomised trials investigated T-Safe<sup>®</sup> Cu220C, Multiload<sup>®</sup> Cu250, Nova-T<sup>®</sup> and T-Safe Cu380A devices in parous women recruited from 24 centres in 14 countries.<sup>32</sup> The T-Safe Cu380A had the lowest cumulative pregnancy rate. A follow-up study included 7159 woman-years for the T-Safe Cu380A and 17 098 woman-years for the T-Safe

Cu220C.<sup>33</sup> The T-Safe Cu380A had a significantly lower cumulative pregnancy rate after 8 years (2.2 per 100 woman-years). Indirect comparisons with 10-year failure rates for tubal sterilisation<sup>34</sup> (1.9 per 100 woman-years) suggest that T-Safe Cu380A may be an effective alternative to sterilisation. The WHO studies included parous women only. The 1-year failure rate for T-Safe Cu380A in nulliparous women was 1 per 100 woman-years.<sup>35</sup> An adaptation of the T-Safe Cu380A (T-Cu380S Slimline<sup>®</sup>) has not been shown to alter pregnancy rates.<sup>36</sup>

A 3-year randomised trial compared T-Safe Cu380A with Multiload<sup>®</sup> Cu375 in parous women. Pregnancy rates were low for both devices, but significantly less for the T-Safe Cu380A (1.6 compared to 2.9 per 100 woman-years).<sup>37</sup> A review of four studies comparing Multiload Cu375 with T-Safe Cu380A in parous women also identified lower pregnancy rates for T-Safe Cu380A.<sup>38</sup> Phase III clinical trials of Nova-T<sup>®</sup> 380 identified similar cumulative pregnancy rates of 1.9 per 100 woman-years at 5 years.<sup>39,40</sup>

A Cochrane Review<sup>41</sup> included three trials<sup>42–44</sup> with over 5800 parous women using a T-Safe Cu380A or a frameless device (GyneFix<sup>®</sup>). In a WHO trial<sup>43</sup> the risk of pregnancy was lower with GyneFix between Years 2 and 6 [RR 0.53; 95% CI 0.32–0.91], but pregnancy rates for the whole 6 years were similar.<sup>41</sup> Frameless devices appear to have a lower pregnancy rate in later years, although the absolute difference is small.

T-Safe Cu380A has also been compared with Cu-Safe<sup>®</sup> 300 in 600 women and had a lower pregnancy rate but this was not statistically significant.<sup>45</sup>

Studies have shown a five-fold decrease in pregnancy rates when the copper content increases from 200 to 350 mm<sup>2</sup> (2.2 vs 0.44 per 100 woman-years).<sup>46</sup> With a fall in pregnancy rates, the risk of ectopic pregnancy is also reduced by a factor of five as copper dose increases (0.08 vs 0.015 per 100 woman-years),<sup>46</sup> thus IUDs containing at least 300 mm<sup>2</sup> of copper should be used.

#### Duration of IUD use

**13 IUDs with the longest licensed duration of use should be used to minimise the established risks associated with re-insertion (Grade C).**

✓ **Women should be given information on the device inserted and its licensed duration of use to avoid unnecessary early removal. This information should also be documented in the case notes.**

Clinical trials show that most of the widely used copper IUDs are effective for at least 5 years and many are effective for longer (Table 2).<sup>22,47</sup> Currently, the T-Safe Cu380A is the only device licensed for up to 8 years' use, although clinical trial data suggest it appears effective up to 12 years.<sup>33</sup> The Gyne<sup>®</sup> T380 is no longer available in the UK but women with this device may continue to use it for its 10-year licensed duration.<sup>22</sup> It is accepted UK practice to recommend that a copper IUD inserted at age 40 years or over may be retained beyond the licensed duration until contraception is no longer required.<sup>48,49</sup>

#### Pelvic infection

**14 Women should be advised that a small increase in risk of pelvic infection occurs in the 20 days following IUD insertion but the risk is the same as the non-IUD-using population thereafter (Grade A).**

**Table 2** IUDs currently available in the UK

Device (manufacturer)	Copper dose (mm <sup>2</sup> )	Suitable with a minimum uterine length (cm)	Net BNF price <sup>22</sup>	Licensed duration of use (years)
T-Safe® Cu380A (FP Sales)	380	6.5	£9.40	8
Multiload® Cu375 (Organon)	375	6	£9.24	5
Nova-T® 380 (Schering Health)	380	6.5	£13.50	5
Flexi-T® 300 (FP Sales)	300	5	£8.65	5
GyneFix® (FP Sales)	330	All uterine sizes	£24.75	5
Multiload® Cu250 (Organon)	250	6	£7.13	3
Multiload® Cu250 Short (Organon)	250	5	£7.13	3

The Gyne-T® 380 (Janssen-Cilag) is not available in the UK now, however some women may still be using this device. It can be used until the licensed duration of use (10 years) is attained.

BNF, *British National Formulary*.

**15 Women should be informed of the symptoms of pelvic infection and advised how and where to seek medical help if these occur, particularly in the first 3–4 weeks after insertion (Grade C).**

A review of 12 randomised and one non-randomised WHO trial,<sup>50,18</sup> covering 22 908 IUD insertions and over 51 399 woman-years of follow up, identified a low overall rate of PID of 1.6 per 1000 woman-years. After adjusting for confounding factors, although a six-fold increase in the risk of PID was identified in the 20 days following IUD insertion, the overall risk was low. Beyond the first 3 weeks, the risk was very low and remained low for up to 8 years. Women should be advised to look out for symptoms of PID, especially in the 3–4 weeks after insertion.<sup>12</sup>

*Ectopic pregnancy*

**16 Women should be informed that the overall risk of ectopic pregnancy is reduced with IUD use compared to using no contraception (Grade B).**

A meta-analysis of case-control studies showed no increased risk of ectopic pregnancy with current IUD use [adjusted odds ratio (OR) 1.06; 95% CI 0.91–1.24].<sup>51</sup> Past use of IUD was associated with an increased risk of ectopic pregnancy (OR 1.4; 95% CI 1.23–1.59). However, there are limitations in how well case-control studies can assess such risks. Since the IUD is a very effective method of contraception, the absolute risk of pregnancy is very low. The annual ectopic pregnancy rate for IUD users is 0.02 per 100 woman-years, compared to 0.3–0.5 per 100 woman-years for those not using contraception.<sup>52,53,46</sup> Alternative contraceptive methods which inhibit ovulation will, however, reduce the risk of ectopic pregnancy to a greater degree.

*Fertility*

**17 Women may be informed that previous use of an IUD does not affect fertility (Grade C).**

A case-control study found that previous IUD use in nulliparous women did not increase the risk of tubal occlusion and infertility, whereas infection with *C. trachomatis* did.<sup>54</sup> A cohort study compared parous IUD users and non-users and showed no difference in fertility after discontinuation of contraception.<sup>55</sup> Data for nulliparous women from this same cohort study suggested that long-term IUD use was associated with fertility impairment.<sup>56</sup> This finding could be explained by bias (IUD users differed from non-IUD users in that they were older, had higher rates of previous miscarriage, termination and ectopic pregnancy) or confounding factors (STIs may have accounted for these findings rather than the IUD itself).<sup>57</sup> Overall return to

fertility and pregnancy outcomes were good following IUD removal in a prospective study from New Zealand.<sup>58</sup> A randomised study showed that the mean time to pregnancy following IUD removal was 3 months.<sup>59</sup> This was also shown in a more recent multicentre prospective study.<sup>60</sup> The balance of evidence suggests that the use of an IUD does not affect return to fertility.

*Expulsion*

**18 Women should be advised that the most likely cause of IUD failure is expulsion. The risk of this happening is around 1 in 20 and is most common in the first year of use, particularly within 3 months of insertion (Grade B).**

Expulsion of an IUD occurs in approximately 1 in 20 women, and is most common in the first 3 months after insertion and usually during menstruation.<sup>61</sup> A meta-analysis<sup>41</sup> of three clinical trials<sup>42–44</sup> investigated expulsion for GyneFix and T-Safe Cu380A. There is insufficient evidence that the reported problems of early expulsion with GyneFix have been overcome.<sup>42</sup>

*Perforation*

**19 Women may be informed that uterine perforation occurs in fewer than 1 in 1000 insertions (Grade B).**

Uterine perforation occurs in fewer than 1 in 1000 insertions.<sup>31,61</sup> A Cochrane Review<sup>41</sup> included a total experience of over 23 000 women-years. No perforations were reported in two trials,<sup>42,43</sup> which represented around 5000 insertions. Further trials<sup>62</sup> and audits of personal practice<sup>63</sup> also support low perforation rates.

*Check for IUD threads*

**✓ Women should be offered instruction on how to check for the IUD 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 medical advice has been sought.**

Each IUD user should be offered instruction on how she (or her partner) can check for IUD threads, or the stem of the IUD, after each menstruation (or alternatively at regular intervals). If threads are present and menstruation has not been missed, an IUD is assumed normally placed. If threads are not present, women should be advised to use condoms until a clinician is able to determine that the IUD is intrauterine. Hormonal EC may be indicated.

*Menstrual abnormalities*

**20 Women should be informed that menstrual abnormalities (including spotting, light bleeding, heavy or longer menstrual periods) are common in the first 3–6 months of IUD use (Grade C).**

**21 Women should be informed that unacceptable bleeding is one of the most common reasons for requesting IUD removal (Grade B).**

✓ **Women should be advised to seek medical advice, to exclude infection and gynaecological pathology, if menstrual abnormalities persist beyond the initial 6 months of use.**

Although IUDs do not affect ovulation, the luteal phase of the cycle is shorter<sup>64</sup> and the onset of menstrual bleeding occurs earlier.<sup>64,65</sup> Menstrual abnormalities, including spotting and light bleeding or heavy or longer periods, are common in the first 3–6 months of IUD use<sup>12</sup> and persist in a minority of women. These bleeding patterns are not harmful and usually decrease over time, but women should be advised to seek medical advice, to exclude gynaecological pathology and infection, if bleeding problems persist.<sup>12</sup> Studies have shown that menstrual bleeding alone and bleeding with pain are the most common reasons cited for requesting IUD removal.<sup>40,61</sup> No differences were identified in rates of removal for bleeding alone or bleeding with pain between GyneFix and T-Safe Cu380A.<sup>41</sup>

*Dysmenorrhoea and pain*

**22 Women should be informed that dysmenorrhoea is a common reason for requesting IUD removal (Grade B).**

Women should be counselled fully regarding pain associated with IUD use. A Cochrane Review of framed and frameless devices<sup>41</sup> was unable to identify whether frameless devices were less likely to cause pain in nulliparous women (because only parous women were included in the randomised trials reviewed).

**Table 3** Recommendations for timing of IUD insertion

Circumstances when IUD can be inserted	Recommendations for timing of IUD insertion
Women with regular menses	If pregnancy can be excluded an IUD can be inserted at any time during the menstrual cycle. Pregnancy can be reasonably excluded if there are no symptoms or signs of pregnancy and any of the following criteria are met: <ul style="list-style-type: none"> <li>– no sexual intercourse since last normal menses</li> <li>– correct and consistent use of a reliable method of contraception</li> <li>– within 7 days of starting normal menses</li> </ul> Up to 5 days after the first episode of sexual intercourse in a menstrual cycle or up to 5 days after the earliest calculated time of ovulation in a regular cycle <sup>a</sup>
Women who are amenorrhoeic	Any time at the woman's convenience, if it is reasonably certain that she is not pregnant (as above)
Women who are postpartum	For women who are fully or nearly fully breastfeeding, amenorrhoeic and less than 6 months postpartum (including Caesarean section) an IUD can be inserted within 48 hours of delivery <sup>b</sup> or 4 or more weeks postpartum <sup>c</sup>
Following termination of pregnancy	At the time of a first- or second-trimester surgical TOP. <sup>d</sup> Following medical or surgical termination suggested within the first 48 hours otherwise wait until 4 or more weeks post-termination <sup>e</sup>
Switching from another method of contraception	Any time if it is reasonably certain that the woman is not pregnant (as above). There is no need to wait for the next menstrual period

<sup>a</sup>An IUD can be inserted up to 5 days after the first episode of unprotected sex or up to 5 days after the earliest expected date of ovulation.

<sup>b</sup>The risk of uterine perforation is increased if an IUD is inserted between 49 hours and up to 4 weeks postpartum.

<sup>c</sup>Evidence suggests an IUD may be inserted from 4 weeks postpartum.

<sup>d</sup>The risk of expulsion is greater when an IUD is inserted immediately following second-trimester TOP but the benefits generally outweigh risks.

<sup>e</sup>Advice regarding IUD insertion following medical TOP is in keeping with postpartum insertion.

IUD, intrauterine device; TOP, termination of pregnancy.

*Endometrial and cervical cancer*

**23 Women may be informed that there is no evidence of an increase in reproductive tract cancer with IUD use (Grade B).**

A systematic review of non-contraceptive benefits of IUD suggested a reduction in the risk of endometrial cancer (RR 0.51; 95% CI 0.3–0.8).<sup>66</sup> Most studies are case-control<sup>67–73</sup> and, as always, should be interpreted with caution. No effect on risk of cervical cancer was shown.<sup>66</sup>

**When should an IUD be inserted?**

**24 An IUD can be inserted at any time in the menstrual cycle if it is reasonably certain the woman is not pregnant (Grade C).**

WHO has advised that pregnancy can be reasonably excluded if a woman has no symptoms or signs of pregnancy and meets any of the following criteria: no intercourse since last normal menses; correct and consistent use of a reliable method of contraception; is within 7 days of the start of normal menses; is within 4 weeks postpartum (for non-lactating women); is within the first 7 days post-abortion or miscarriage; is fully or nearly fully breastfeeding, amenorrhoeic and less than 6 months postpartum;<sup>12</sup> or is within 5 days of the earliest expected date of ovulation. Having reasonably excluded pregnancy, an IUD may be inserted at any time during the menstrual cycle<sup>12</sup> (Table 3).

*Postpartum*

**25 An IUD may be inserted safely 4 or more weeks postpartum (Grade C).**

Established practice in the UK has been to delay insertion until 6–8 weeks postpartum. WHOMEC, however, recommends that the benefits of IUD use 4 or more weeks after delivery outweigh any risks (WHO 1).<sup>4</sup> This unrestricted use includes women who are breastfeeding,

not breastfeeding or who are post-Caesarean section. WHOMEc suggests an increased risk of uterine perforation if an IUD is inserted between 48 hours and 4 weeks postpartum and therefore the risks of insertion during this time generally outweigh the benefits (WHO 3). A review of studies involving postpartum insertion provided 2-year follow-up data on 6816 woman-months of experience following insertion between 4 and 8 weeks postpartum and 19 733 woman-months of experience following insertion more than 8 weeks postpartum.<sup>74</sup> No perforations were identified and discontinuation rates were similar in the two groups, suggesting an IUD can be inserted safely after 4 weeks postpartum.

WHOMEc suggests an increased risk of expulsion if an IUD is inserted within the first 48 hours postpartum but the benefits of immediate IUD insertion generally outweigh the risks (WHO 2). A non-randomised, prospective study included 734 breastfeeding women with a mean time of insertion of a T-Safe Cu380A of 47.6 days postpartum (SD 9.9). It showed an expulsion rate at 12 months of 5.6 per 100 insertions.<sup>75</sup>

Women with current puerperal sepsis should be advised against insertion of an IUD (WHO 4).

There is no increase in copper levels in breast milk with an IUD and breastfeeding women may use it.<sup>76,77</sup>

*Following termination of pregnancy*

**26 An IUD can be inserted safely immediately following a first-trimester or second-trimester TOP (Grade C).**

Insertion of an IUD immediately following induced abortion has advantages in that the woman is known not to be pregnant, her motivation for effective contraception is likely to be high, and she is present in a health care setting. Systematic reviews show that the insertion of an IUD at the time of surgical abortion is safe and practical.<sup>19</sup> However, these multicentre trials employed IUDs that are rarely used currently in the UK (Lippes Loop®, Copper 7® and T-Safe® Cu200). Expulsion rates were higher after second-trimester abortion than after earlier procedures. Delaying insertion following second-trimester termination of pregnancy (TOP) was advised, but no timescale was given.<sup>19</sup> WHOMEc recommends that an IUD can be inserted immediately following induced (or spontaneous) first-trimester abortion (WHO 1) and, although risk of expulsion following a second-trimester abortion is higher, generally the benefits of IUD insertion still outweigh the risks (WHO 2).

Case-control studies show the risk of uterine perforation following IUD insertion within 30 days of a TOP is low<sup>78</sup> and only three perforations were identified in

2348 such insertions in a WHO study.<sup>79</sup> Re-admission rates for pelvic infection were not increased by IUD insertion immediately following a first-trimester TOP.<sup>80</sup>

There are few data specifically relating to IUD insertion following medical TOP. The CEU suggests that an IUD may be inserted immediately (i.e. within 48 hours) following first- or second-trimester medical TOP. Otherwise, insertion should be delayed until 4 weeks following medical TOP (as for postpartum insertions).

**What procedures and documentation are required for IUD insertion?**

RCOG guidelines on gynaecological examinations<sup>81</sup> recommend that all patients should give verbal consent before pelvic examination; patients should be provided with private, warm and comfortable changing facilities.

*Chaperones*

**27 A chaperone should be offered to all women having a pelvic examination and the offer documented in the case notes, together with the chaperone's identity, if accepted (Grade C).**

A chaperone (who need not be a trained health professional) should be offered for any gynaecological examination, irrespective of the gender of the clinician.<sup>81</sup> The presence and identity of the chaperone should be documented in the case notes, as should the offer of a chaperone, in instances where this offer is declined.

*Assistants*

**28 An appropriately trained assistant should be present during IUD insertion to help in the event of an emergency (Grade C).**

A survey of experienced family planning doctors suggested that only 75% always have an assistant for IUD insertion.<sup>82</sup> Medical emergencies (such as vasovagal attack and anaphylaxis) may occur during IUD insertion. An assistant, who is appropriately qualified and trained to deal with likely emergencies, should be present when inserting an IUD.

*Emergency equipment for IUD insertion*

**29 Emergency equipment must be available in all settings where IUDs are inserted and local referral protocols must be in place for patients requiring further medical input (Grade C).**

**Table 4** Emergencies and IUD fitting: resuscitation measures and contents of an emergency pack

Basic resuscitation measures	Recommended equipment	Essential medication
Display clear algorithms regarding emergency procedures and emergency telephone numbers	<b>Essential</b> Sphygmomanometer	Atropine for intravenous use (0.6 mg/ml) for the management of persistent bradycardia
Adequate training of all staff in basic life support	Pocket mask and one-way valve	Adrenaline for intramuscular use 1:1000 (1 mg/ml) for the management of anaphylaxis
Abandon procedure, lower head and/or raise legs	Oxygen mask with reservoir bag	Oxygen
Assistant to monitor pulse and blood pressure	Appropriate selection of needles and syringes, tape, gloves, sharps box, scissors, saline flush	
Ensure clear airway		
Give oxygen	<b>Non-essential</b>	
Arrange transfer if no improvement	The following equipment should be accessible if available: Automated external defibrillator Suction	

**30 Clinicians involved in IUD insertions should be trained and attend regular updates in dealing with likely emergencies (Grade C).**

A Faculty Aid to Continuing Professional Development Topic (FACT)<sup>83</sup> and the Resuscitation Council UK<sup>84</sup> provide guidance on management of common medical emergencies. Vasovagal episodes, bradycardia, anaphylaxis or epileptic seizures may occur during IUD insertion. Basic resuscitation equipment for managing the airway and administering drugs should be accessible (Table 4).

The Resuscitation Council (UK) has provided *Guidance for Clinical Practice and Training in Primary Care*.<sup>85</sup> Sexual and Reproductive Health Care services may be provided in primary care and these Guidelines may be relevant. All members of the primary health care team who have contact with patients, including reception staff, should be trained and equipped to a level appropriate for their expected role, to resuscitate patients who suffer cardiac arrest in the community. The minimum standard should be proficiency in basic life support. One individual should be responsible for the co-ordination of resuscitation services within the clinical setting and a named individual should also be responsible for maintaining all emergency equipment and drugs. Current resuscitation guidelines emphasise the use of oxygen, which should be available wherever possible. The Resuscitation Council also recommend that every health care practice, wherever and whenever sick patients are seen, should be equipped with an automated external defibrillator (AED). If an AED is available in clinical settings, staff should be trained to operate this equipment. Clinicians should be aware of local protocols, which should be clearly displayed in clinical areas, to reflect the type and location of setting and ease of referral in an emergency.<sup>86</sup>

*Documentation of IUD insertion*

**31 Details of pre-insertion counselling and the insertion procedure should be clearly documented in patient records (Grade C).**

The Faculty of Family Planning and Reproductive Health Care (FFPRHC) document entitled 'Maintaining good medical practice for those working in family planning and reproductive health care' highlights good clinical care and record keeping.<sup>86</sup> Information recorded should be relevant and manageable within the time of a consultation and suggestions for minimum documentation have been published.<sup>87</sup>

*Cervical cleansing*

**✓ Cleansing the ectocervix prior to IUD insertion is not essential.**

The effect of cleansing the cervix has not been assessed. A recent survey of experienced family planning doctors showed that 94% clean the cervix prior to IUD insertion.<sup>82</sup> No evidence was identified that cleansing the cervix affects infection rates. None of the standard cleansing agents are effective bacteriologically against *C. trachomatis* or *N. gonorrhoea*. Clinicians may however choose to remove any mucus or debris from the cervix.

*Sterile gloves*

**✓ A 'no-touch' technique should be used when sounding the uterine cavity and inserting an IUD. Sterile gloves are not required.**

Gloves should be worn on both hands for pelvic examination.<sup>81</sup> There is no recommendation regarding sterile gloves for IUD insertion. If a 'no touch' technique is used (i.e. one whereby anything that is to be inserted into the uterine cavity is held only by the handle) sterile gloves are unnecessary. Gloves should be changed after the pelvic examination and before proceeding to uterine instrumentation to avoid contaminating other surfaces.

*Cervical priming*

Case reports, but no randomised trials, have described the use of prostaglandins for cervical priming pre-IUD insertion.<sup>88</sup> Randomised trials have shown that misoprostol improves the ease with which the cervix can be dilated and reduces complications in premenopausal women,<sup>89</sup> postmenopausal women<sup>89,90</sup> and nulliparous women<sup>91</sup> undergoing operative hysteroscopy.

*Analgesia and anaesthesia*

**✓ Pain relief prior to, and during, IUD insertion should be discussed with women and administered appropriately.**

**✓ The use of topical anaesthesia or intracervical block for IUD procedures should be discussed with women and provided if requested.**

There is a lack of randomised controlled trials investigating the use of oral analgesia or topical or intracervical anaesthesia during IUD insertion. The experience of immediate post-insertion pain appears to be independent of age, parity or day of cycle but related to expected pain and cervical resistance.<sup>92</sup> Topical local anaesthetic gel has been shown in small randomised studies to reduce pain during tenaculum placement<sup>93</sup> and at the time of IUD insertion.<sup>94,95</sup> In a survey of clinicians, topical gel was the most commonly used method of anaesthesia for IUD insertion.<sup>82</sup>

*Use of forceps and assessing length of the uterine cavity*

**32 A pair of forceps (such as Allis or tenaculum) should be used, and an assessment of the length of the uterine cavity made, to reduce the risk of perforation and facilitate fundal placement of the IUD (Grade C).**

An appropriate type of forceps (such as Allis or tenaculum) should be used to stabilise the cervix in order to reduce the risk of perforation and enable fundal placement of the IUD. An assessment of the length of the uterine cavity is consistently advised to reduce the risk of perforation and to facilitate fundal placement of the IUD.<sup>87,96</sup> This is particularly important for women with small uterine cavities (<6 cm) for whom small devices, such as Flexi-T<sup>®</sup> 300, would be most suitable (Table 2).

**Who can insert an IUD?**

The prescriber holds ultimate responsibility for a device or medication prescribed and has a responsibility to report any defect noted to the Medicines and Healthcare products Regulatory Agency (MHRA).

*Training requirements*

**33 Clinicians who insert IUDs are responsible for ensuring that they are appropriately trained and maintain their clinical competence (Grade C).**



The FFPRHC has specific training requirements for doctors wishing to obtain a letter of competence in intrauterine techniques (LoC IUT). A multicentre randomised trial<sup>97</sup> and a prospective cohort study<sup>98</sup> support IUD insertion by any appropriately trained clinician. The Royal College of Nursing outlines training requirements for nurses wishing to insert IUDs.<sup>99</sup> Competence in gynaecological examination and the assessment, management and investigation of women with IUD problems are required for all clinicians inserting IUDs. Recertification should ensure continuing competence. The LoC IUT should be updated every 5 years, with at least 2 hours of relevant continuing education and a log of at least 12 insertions in 12 months or six in 6 months using at least two different types of device in unanaesthetised patients. A large prospective study, which included 17 469 Multiload Cu375 insertions by 1699 doctors, showed that doctors inserting fewer than 10 IUDs in a 6-year period reported significantly more perforations than those inserting between 10 and 100 IUDs.<sup>31</sup>

### What follow-up is required following IUD insertion?

**34 A follow-up visit should be advised after the first menses, or 3–6 weeks, after IUD insertion (Grade C).**

**35 Women should be advised to seek medical help at any time if they develop symptoms of pelvic infection, pain, persistent menstrual abnormalities, missed period or non-palpable threads (Grade C).**

The WHOSPR recommends a follow-up visit after the first menses, or 3–6 weeks after insertion,<sup>12</sup> to exclude infection, perforation or expulsion. A woman should also be advised to return at any time to discuss problems, or if she wants to change her method. Women should be counselled about when and why to seek medical advice.

### How are IUD problems managed?

#### *Suspected perforation*

**✓ If uterine perforation at insertion is suspected, the procedure should be stopped and vital signs and level of discomfort monitored until stable. Urgent and specific follow-up should be arranged to include ultrasound scan and/or plain abdominal X-ray to locate the device if it has been left in situ.**

A study from New Zealand of almost 17 500 insertions reported an incidence of perforation of 1.6 per 1000 insertions.<sup>31</sup> Of the 28 perforation events reported, 27 were related to IUD insertion and one was related to the uterine sound prior to insertion of the device. This reported incidence is almost certainly an underestimate, as events not requiring hospital treatment may not have been reported. An older study, using an international dataset of over 21 500 insertions, estimated the perforation rate to be 1.9–3.6 per 1000 insertions.<sup>100</sup> The analysis suggested previous Caesarean section as a risk factor. The little evidence that is available suggests that the risk of serious sequelae from uterine perforation with a sound in non-pregnant women is low, that surgical intervention is seldom needed, and that conservative management is appropriate. There is no evidence to provide guidance on the time interval after which it would be appropriate to repeat an attempt at IUD insertion following suspected perforation. On a pragmatic basis, a 6-week interval after an

asymptomatic, suspected perforation would seem reasonable.

#### *'Lost threads'*

**36 IUD retrievers (such as Emmett and Retrieve) can be effective in locating threads (Grade A).**

**✓ If no threads are seen and uterine placement of the IUD cannot be confirmed clinically, an ultrasound scan should be arranged to locate the device and alternative contraception recommended.**

**✓ If an ultrasound scan cannot locate the IUD and there is no definite evidence of expulsion, a plain abdominal X-ray should be arranged to identify an extrauterine device.**

If no threads are visible on speculum examination and uterine placement of the IUD cannot be confirmed clinically, some clinicians may prefer to refer women immediately for an ultrasound scan to locate the device. If no threads are seen, IUD thread retrievers (Retrieve<sup>®</sup> or Emmett<sup>®</sup>) have been shown in a randomised trial to assist in thread retrieval.<sup>101</sup> In this same study prior to randomisation, the use of Spencer Wells forceps for initial exploration of the endocervical canal was useful in identifying lost threads.<sup>101</sup> Experienced clinicians may attempt to use a sound to identify if the IUD is lying within the endocervical canal, or within the uterine cavity, but the accuracy of this procedure is unknown. Care should be taken not to displace the device. If the IUD is confirmed as intrauterine, it can be retained or consideration given to replacement. The risk of infection when changing a device whose threads are not palpable, but which is still within its lifespan, must be discussed.

If the IUD is not visible on ultrasound scan, a plain abdominal X-ray should be arranged to determine if the IUD is extrauterine. An IUD should not be assumed 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 IUD is advised.

#### *Abnormal bleeding*

**37 Gynaecological pathology and infection should be excluded if abnormal bleeding persists beyond the first 6 months following IUD insertion (Grade C).**

**38 NSAIDs (mefenamic acid) can be used to treat spotting, light bleeding and heavy or prolonged menstruation. Antifibrinolytics (tranexamic acid) may be used for heavy or prolonged menstruation (Grade A).**

WHOSPR recommends a short course of non-steroidal anti-inflammatory drugs (NSAIDs), taken during the days of bleeding, to treat spotting or light bleeding.<sup>12</sup> Heavier and longer menstrual bleeding can be treated with NSAIDs (mefenamic acid) or antifibrinolytics (tranexamic acid). This approach is supported by small clinical trials.<sup>102–104</sup> Gynaecological pathology, pregnancy and infection should be excluded if abnormal bleeding persists. A cohort study showed that complaints of bleeding are not associated with a misplaced device on ultrasound scan but this should be considered in women with persistent bleeding.<sup>105</sup>

## Pregnancy

**39 Most pregnancies occurring in women using an IUD will be intrauterine, but ectopic pregnancy must be excluded (Grade C).**

**40 Women who become pregnant whilst using an IUD should be informed of the increased risks of second-trimester miscarriage, preterm delivery and infection if the IUD is left in situ (Grade B).**

**41 Women who are pregnant with an IUD in situ, and who wish to continue with the pregnancy, should be informed that, when possible, IUD removal would reduce adverse outcomes. However, removal itself carries a small risk of miscarriage (Grade C).**

**42 Whether or not the IUD is removed, a pregnant woman should be advised to seek medical care if she develops heavy bleeding, cramping pain, abnormal vaginal discharge or fever (Grade C).**

**✓ If there is no evidence that the IUD was expelled prior to pregnancy, it should be sought at delivery or TOP and, if not identified, a plain abdominal X-ray should be arranged to determine if the IUD is extrauterine.**

WHOSPR provides recommendations on the management of women using an IUD who become pregnant.<sup>12</sup> Approximately 6% of pregnancies occurring in women using an IUD are ectopic.<sup>52</sup> If diagnosis is in any doubt, ectopic pregnancy must be excluded.<sup>12</sup>

Women with an intrauterine pregnancy and an IUD in situ should be advised of an increased risk of second-trimester miscarriage, preterm delivery and infection if the IUD is retained.<sup>106</sup> Removal of the IUD reduces these risks, but entails a small risk of miscarriage. If IUD threads are visible on speculum examination, or can easily be retrieved from the endocervical canal, the IUD should be removed by gently pulling on the threads. The WHOSPR does not provide a cut-off of gestational age for IUD removal, but this has traditionally been up to 12 weeks, since the gestation sac is believed to occupy the whole of the uterine cavity beyond this time. Threads are more likely to be visible in the first trimester. Those visible in the second trimester are perhaps due to an IUD that is lying at the lower pole of the uterus or within the endocervical canal. Whether the IUD is removed or not, advice should be given to return if heavy bleeding, cramping pain, abnormal vaginal discharge or fever occurs. If threads cannot be seen or easily retrieved, an ultrasound scan should be arranged to assess the location of the IUD. If the IUD is not seen on the scan then this suggests expulsion. However, expulsion should not be assumed and, if the IUD is not identified at delivery or TOP, an X-ray should be performed to determine if the IUD is extrauterine.

## Removal of an IUD

**43 An IUD should be removed during or after the menstruation following sterilisation (Grade C).**

**✓ When switching to a hormonal contraceptive, this should be initiated prior to IUD removal to maintain contraceptive protection.**

**✓ For women who wish to become pregnant, an IUD can be removed at any time in the menstrual cycle**

**✓ An IUD can be removed at any time in the cycle if it is to be replaced immediately with another IUD. However, women should be advised to use condoms or abstain from sexual intercourse for 7 days before the exchange, in case a new IUD cannot be inserted immediately.**

**✓ An IUD can be replaced by an IUS at any time in the menstrual cycle but women should be advised to use condoms or abstain from sexual intercourse for 7 days before removal of the IUD and for a further 7 days after insertion of the IUS.**

Advice regarding IUD removal varies with the reason. The primary mode of action of an IUD is prevention of fertilisation. Ovulation still occurs, and with the untimely removal of an IUD an ovum could potentially be fertilised and implant. If sexual intercourse with no additional contraception has occurred in the preceding 7 days, removal of the device may leave the woman at risk of pregnancy. Women should therefore be advised to use condoms or abstain from sexual intercourse for 7 days before IUD removal, even when reinsertion is planned. When sexual intercourse has occurred in the preceding 7 days, the need for IUD removal and use of EC should be discussed.

No evidence was identified regarding the optimal timing of pregnancy following IUD removal. A small, 10-year retrospective study investigated the outcomes of pregnancies occurring in women who became pregnant whilst using an IUD.<sup>107</sup> The numbers included were very small but no evidence of fetal malformations was identified.

## Presence of actinomyces-like organisms

**44 Symptomatic IUD users with ALOs detected on a cervical smear should be advised there is no reason to remove the IUD unless signs or symptoms of infection occur (Grade B).**

*Actinomyces israeli* are commensals of the female genital tract. They may be identified on cervical smears, but this is not diagnostic or predictive of any disease.<sup>108–111</sup> Actinomyces-like organisms (ALOs) are found in women with<sup>112</sup> and without<sup>113–116</sup> an IUD. The role of ALOs in infection in IUD users is unclear.<sup>117</sup> Limited evidence suggests that the IUD should be removed in a symptomatic woman, with appropriate antibiotic treatment provided and referral to GUM or gynaecology.<sup>117</sup> There is no evidence to support the routine removal of an IUD in an asymptomatic woman with ALOs or to support periodic ALO screening.<sup>118</sup> Previous recommendations suggest follow-up every 6 months for a woman retaining her IUD.<sup>119</sup> However, currently there is little evidence to support routine follow-up unless symptoms occur. A 2-year follow-up of asymptomatic women with untreated ALOs who retained their IUDs did not identify PID in any women.<sup>114</sup> More common causes of pelvic pain, such as STIs, should be investigated and managed appropriately.

## Pelvic inflammatory disease

**45 For IUD users with PID, appropriate antibiotics should be started. There is no need to remove the IUD unless symptoms fail to resolve (Grade B).**

For IUD users with clinical PID, testing for relevant organisms and appropriate antibiotics should be initiated.

WHOSPR recommends that there is no need to remove the IUD.<sup>12</sup> However, if the woman wishes IUD removal, it should be removed after antibiotic treatment has started. If intercourse without additional contraception occurred, EC may be indicated. If the condition does not improve within 72 hours, generally the course would be to review the diagnosis, remove the IUD and continue antibiotics. All women with confirmed or suspected PID should be followed up to ensure: resolution of symptoms and signs; treatment of their partner when appropriate; completion of the course of antibiotics; STI risk assessment; counselling regarding safer sex; and partner notification.

#### Postmenopausal removal

✓ **Postmenopausal women should be advised to have their IUDs removed 1 year after their LMP if this occurs when they are over the age of 50 years, and 2 years after their LMP if aged less than 50 years.**

It is generally accepted that an IUD can be removed 1 year after the last menstrual period (LMP) in a woman over the age of 50 years and 2 years after the LMP in women under the age of 50 years. It is advised that IUDs are removed, rather than left in situ, after the menopause. Cases of ALOs, endometrial cancer and pyometra have been reported in postmenopausal women with IUDs. If the IUD cannot be removed easily in an outpatient setting, consideration should be given to the benefits and risks of hysteroscopy versus retention of the IUD.

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This Guidance was developed by the Clinical Effectiveness Unit (CEU) of the Faculty of Family Planning and Reproductive Health Care (FFPRHC): Gillian Penney (Director), Susan Brechin (Unit Co-ordinator) and Alison de Souza (Research Assistant) in consultation with the Clinical Effectiveness Committee, which includes service user representation and an Expert Group of health care professionals involved in family planning and reproductive health care. The Expert Group comprised: Urszula Bankowska (Consultant in Sexual and Reproductive Health Care, The Sandyford Initiative, Glasgow); Toni Belfield (Director of Medical Information, fpa, London); Maggie Gormley (Clinical Nurse Specialist, Margaret Pyke Centre, London); Mary Olliver (Head of Reproductive Health, Winchester and Eastleigh Healthcare NHS Trust/Education Committee Member); Naomi Hampton (Consultant in Sexual and Reproductive Health Care, Ealing Primary Care Trust, London/Education Committee Member); Ruth Howlett-Shipley (Specialist Registrar in Public Health Medicine, South West Region/Trainee Member of the CEU); Sarah Hughes (Consultant in Contraception and Sexual Health, Victoria Health Centre, Nottingham); Noel Mack (General Practitioner, Kemnay Health Centre, Aberdeenshire); Paul O'Brien (Senior Clinical Medical Officer, Westside Contraceptive Services, Westminster Primary Care Trust, London); Sam Rowlands (Clinical Director, bpas, London); Karen Trewinnard (Staff Grade Doctor, Ella Gordon Unit, St Mary's Hospital, Portsmouth).

This guidance is also available online at [www.ffprhc.uk](http://www.ffprhc.uk). Evidence tables are available on the FFPRHC website. These summarise relevant published evidence on IUDs for long-term contraception, which was identified and appraised in the development of this Guidance. The clinical recommendations within this Guidance (i.e. the text appearing within the red and blue boxes) are based on evidence whenever possible.

Grades of Recommendations	
<b>A</b>	Evidence based on randomised-controlled trials (RCTs)
<b>B</b>	Evidence based on other robust experimental or observational studies
<b>C</b>	Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities
✓	Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

Electronic searches were performed for: MEDLINE (Ovid version) (1996–2003); EMBASE (1996–2003); PubMed (1996–2003); the Cochrane Library (to September 2003) and the US National Guideline Clearing House. The searches were performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library was searched for systematic reviews, meta-analyses and controlled trials relevant to copper-bearing intrauterine contraception. Previously existing guidelines from the FFPRHC, the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and reference lists of identified publications were also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications were appraised according to standard methodological checklists before conclusions were considered as evidence. Evidence was graded as above, using a scheme similar to that adopted by the RCOG and other guideline development organisations.