Letters to the Editor

Full-term pregnancy with Implanon® *in situ*

An 18-year-old nulliparous woman who had had no bleeding since the insertion of an etonogestrel subdermal contraceptive implant (Implanon®) 4 months earlier had a positive pregnancy test. The implant was easily palpable and correctly sited. An ultrasound scan showed the gestation was 27±2 weeks.

Review of the patient's general practitioner (GP) records indicated that the Implanon had been inadvertently inserted when she was already pregnant. She had not regained regular menstruation since stopping depot medroxyprogesterone acetate contraceptive injections (Depo-Provera®) 6 months previously and switching to condoms. At the time of fitting she denied any sexual intercourse since splitting up with her boyfriend 6 weeks previously. She had had two negative pregnancy tests, one on the day of fitting.

Her GP (H.P.) referred her to a specialist contraception clinic for removal of the implant, where she attended 3 weeks after the pregnancy diagnosis (now 30 weeks' gestation). The patient said she was happy with the implant and would wish to use it again after delivery, and she asked if it had to be removed. The doctor in the clinic (H.C.) discussed with the patient the lack of evidence about the correct course of action, and explained that progestogens in pregnancy have not been linked with fetal abnormality. In addition, it was unlikely that the rate of progestogen release from the implant would be altered in pregnancy and there was no reason to expect the low blood levels of progestogen to interfere with labour or delivery. Use of Implanon during lactation is standard (although the patient planned to bottle-feed). Keeping the implant in place therefore seemed to be an option.

The GP informed the manufacturers of Implanon (Organon), who of course recommended removal. After discussion it was agreed that it was reasonable for the implant to be left in place, giving the patient the opportunity to return if she changed her mind and decided she wanted it removed. Informal discussion with a few colleagues indicated the majority would advise removal but could not give any clear reason why.

The patient had a spontaneous labour and normal delivery of a healthy baby girl weighing 3.3 kg at 40+2 weeks' gestation. At routine follow-up at 6 weeks the baby was being bottle-fed and showed no signs of abnormality. The mother was healthy and the implant still had nearly 2.5 years of its licensed life left.

What would other readers have advised in this situation?

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Acknowledgement
The patient gave her consent to the publication of this report.

Chlamydia rates in postcoital IUD recipients

Swab results were checked for 105 recipients of a postcoital intrauterine device (IUD) in Sheffield, UK in 2004. Only one chlamydia result was positive.

A computer-generated list was used to identify all recipients of a postcoital IUD in Central Health Clinic, Sheffield in 2004. Paper notes were then obtained and checked. The age range of recipients was 13–52 years; 54 were aged under 25 years. All received pre-IUD counselling, including discussion regarding infection/sexually transmitted infections (STIs). All recipients were recorded as having had endocervical swabs for gonorrhoea and chlamydia. Results were checked both on computer and in the notes. One client was excluded because of recent antibiotics (within 2 weeks of the swabs). One set of results could not be found. One result was positive for chlamydia and 102 results were negative.

One positive chlamydia result was less than the figure expected from local and national prevalence figures of 3–12%.[1,2]

Risk of infection can be discussed in the consultation to exclude those who are symptomatic for pelvic inflammatory disease or at high risk of acquiring an STI. We believe pre-IUD counselling helps clients most at risk of chlamydial infection to choose not to have an IUD fitted, even if the patient withholds relevant information (the informed user being a sensible user). A prospective study of all clients considering a postcoital IUD would be valuable to explore this impression further.

Our study supports research findings that prophylactic antibiotics are not cost effective.[3]

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Mirena® IUS and ovarian function

"Accurate, up-to date information is essential to enable users to make an informed and voluntary choice of contraceptive method", declared the National Institute for Health and Clinical Excellence (NICE) guidelines,[1] which also stated that "User satisfaction and successful use of contraception depend on adequate knowledge and accurate perceptions of the method".

At present there is strong evidence that the frequency of functional ovarian cysts is increased in the presence of the levonorgestrel-releasing intrauterine system (LNG-IUS). Some of the studies showed that as many as 30% of women identified ovarian cysts 3 months after LNG-IUS insertion.[2] According to the NICE guidelines, "The incomplete suppression of ovarian activity in LNG-IUS users is a recipe not only for erratic bleeding, but also for the development of ovarian follicular cysts".[1] As stated in the Summary of Product Characteristics for the Mirena® IUS, functional ovarian cysts have been diagnosed in about 10–12% of patients.[3] In most cases they are small and asymptomatic, and disappear spontaneously.

The FFPRHC Guidance published in April 2004[4] stated that: "Women may be reassured that although ovarian cysts occur in LNG-IUS users, there is no significant increased risk compared to IUD users". The NICE guidelines published in October 20051 asserted that: "Development of ovarian follicular cysts … occurs in 20% of women using the LNG-IUS". But according to these NICE guidelines there is no need to inform patients about this risk prior to IUS insertion.

"The LNG-IUS is a suitable option for most women who need contraception and/or treatment for menorrhagia" stated the FFPRHC Guidance.[4] According to the NICE guidelines, the IUS is becoming one of the most cost effective, close to an ideal contraceptive device with high efficacy, ease of use and almost no absolute contraindications (except current malignancies or genital/pelvic infection). "The IUS may be used by adolescents … nulliparous women …women of all ages may use the IUS".[1] It is likely that the frequency of IUS use will significantly increase from its current level (1%).[1] Indeed, our service is actively promoting long-acting reversible contraception and the IUS in particular.

Future IUS users are more likely to have no menstrual or pelvic pain problems prior to IUS insertion and they are highly likely to develop them later, which will have an important impact on the IUS discontinuation rate and the overall cost effectiveness. At present, up to 60% of women will stop using the IUS within 5 years. The most common reasons for discontinuation are unacceptable vaginal bleeding and pain.[1]

Cost effectiveness and utility for the patient are also affected by the way IUS-induced ovarian cysts are investigated. Functional ovarian cysts are infrequent in women not using hormonal contraception or in women on combined oral contraception.[5,6] Currently, the typical IUS user is over 30 years old. Westhof and Clark found that women aged 30–34 years had the highest rate of admission for functional cysts: 142/100 000 woman-years.[7]

While there are Royal College of Obstetricians and Gynaecologists (RCOG) guidelines for the management of ovarian cysts in postmenopausal women,[8] there is currently no nationally agreed algorithm for the management of ovarian cysts in premenopausal women.

There is also no absolute opinion on the place of routine ultrasound investigations for LNG-IUS users: some studies recommend it and some do not, as ovarian cysts have a high rate of spontaneous resolution.[5] It is, for example, unclear how long one should wait for resolution of the cyst, when the scan should be performed and how frequently it is to be repeated. This was not an issue in the past when IUS use was infrequent. The new generation of IUS users may not be prepared to cope with functional ovarian cysts. The likelihood of increased IUS use will make the development of algorithms for the management of functional ovarian cysts and/or pelvic pain a high priority. As Sturridge and Guillebaud declared in 1996, "the unique unwanted non-contraceptive effects of the system, including possible development of functional ovarian cysts, and the relationship between menstrual bleeding pattern and ovarian function, also require better understanding, in order to offer appropriate patient counselling and maximise acceptability and continuation of use of the method".[9] Although this statement was originally made in 1996, it is even more appropriate for 2006.

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Reply

Thank you for the opportunity to respond to the letter from Dr Elena Valarche on ovarian cysts and the levonorgestrel-releasing intrauterine system (LNG-IUS) (Mirena®).

Based on the evidence, Faculty of Family Planning and Reproductive Health Care Guidance stated that "women may be reassured that although ovarian cysts occur in levonorgestrel-releasing intrauterine system (LNG-IUS) users, there is no significant increased risk compared to copper-bearing intrauterine device users (Grade A)".[1] A systematic review did not identify an increased risk of ovarian cysts in LNG-IUS users at 5 years compared to copper-bearing intrauterine device users (RR 1.5; 95% CI 0.51–4.4).[2]

Guidelines from NICE on 'Long-acting reversible contraception'[3] state that ovarian follicular cysts occur in 20% of women using the LNG-IUS; however, these are almost always asymptomatic. In addition, spontaneous resolution of ovarian cysts in women using the LNG-IUS has been reported.[4] Only one non-comparative study has reported that women discontinue with the LNG-IUS as a result of the development of ovarian cysts.[5] The CEU supports the counselling of women on potential risks and benefits of contraceptive methods.

The CEU acknowledges that there is a lack of clear guidance on the management of functional ovarian cysts in women using the LNG-IUS. Moreover, there is little evidence on the management of all women of reproductive age with functional ovarian cysts and further research would be of benefit. The CEU is updating Guidance on the IUD and the LNG-IUS later this year. All new evidence will be identified and reviewed. However, at present there is no evidence to suggest that women with a LNG-IUS should be reviewed and/or scanned to identify ovarian cysts.

The CEU could find no evidence to support the statement that easier access to scanning facilities would improve the care of women presenting with pelvic pain in primary care. The aetiology of pelvic pain in women of reproductive age may be due to many underlying causes, both physical and psychological, and allowing easier access to scan facilities may not be appropriate.

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Emergency contraception and the LNG-IUS

The Faculty Guidance document from the CEU on 'Emergency contraception' (April 2006 issue) is comprehensive, and does provide sound practical guidelines on the subject.[1]

It is surprising that no mention is made that the levonorgestrel-releasing intrauterine system (LNG-IUS) is not suitable and not licensed for emergency contraception.[2] It would have been appropriate to emphasise that there is no research evidence available on the effectiveness of the LNG-IUS for use for emergency contraception.

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Reply

Thank you for the opportunity to respond to the letter from Dr Bhathena regarding the CEU Guidance on 'Emergency contraception' (April 2006).[1] I note that Dr Bhathena works in India; it is very encouraging to see that CEU Guidance is being used and proving helpful to colleagues internationally. Dr Bhathena points out that our emergency contraception Guidance does not explicitly state that the levonorgestrel-releasing intrauterine system (LNG-IUS) is unlicensed and unsuitable for emergency contraception. Previous CEU Guidance addressed 'The levonorgestrel-releasing intrauterine system in contraception and reproductive health' (April 2004).[2] This Guidance included an explicit recommendation: "The LNG-IUS is not effective as emergency contraception (Grade C)".

I agree with Dr Bhathena that it would have been helpful to readers if this recommendation had also been included in the 'Emergency contraception' Guidance. This point will be incorporated in any future revision of the Guidance.

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CEU Guidance on emergency contraception

Clearly the 'CEU Guidance' series has established itself as the final arbiter in 'small print' contraceptive advice in the UK today. I found the recent summary on emergency contraception[1] both timely and comprehensive. However, there are three points I would like to take issue with, two of which have considerable bearing on my current practice.

In 'EBM' Box 7 you state that "IUDs with banded copper on the arms and containing at least *380 mm² of copper* have the lowest failure rates and *should be the first choice*, particularly if the woman intends to continue the IUD as contraception". I imagine this advice was taken from the recent National Institute for Clinical Excellence (NICE) report on long-acting reversible contraception. Only the TCu380A (or its 'look-a-likes') and the Flexi-T 380 (currently not listed in the *British National Formulary*) would satisfy these criteria from the IUDs available in the UK today.

Previous advice from the CEU[2] had been to use any device with >300 mm² of copper and I do not know of any evidence-based medicine that has shown any copper IUD to be superior to another for *emergency* contraception. Many of us find it hard enough to promote the use of IUDs to young teenagers and nullips in these circumstances and do not welcome the suggestion that to use a Nova-T 380 would be suboptimal treatment.

The second point is one of omission. Reference 5 in your article refers to '*PRODIGY Guidance – Contraception – emergency* [Accessed 16 January 2006]'. The PRODIGY list of indications for emergency contraception includes discussion about the contraceptive patch, which surely for completeness should be included in your 'Table 1'.

My final reservation concerns 'off-licence use'. In several of your 'Good Practice Point boxes' you make the comment that the advice is 'outside the product licence' In the 2003 Guidance[2] use 'more than once in a cycle' was listed in this category but in the current advice this is no longer mentioned. Had the product licence been changed in this respect?

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Reply

Thank you for the opportunity to respond to the letter from Dr Terry McCarthy regarding the CEU Guidance on emergency contraception.[1] Dr McCarthy has studied the recommendations in detail and given careful consideration as to their implications for his own practice. It is very rewarding to the CEU team to know that clinicians are using the Guidance in this way.