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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.