


Reply
In response to the letter from Drs Pittrof, Rubenstein and Sauer we would like to make the following points:

1. There is clear evidence that ulipristal acetate (UPA) is more effective than levonorgestrel (LNG). Biomedical studies have shown that when given at mid-cycle (when risk of pregnancy is highest) UPA is able to delay ovulation whereas LNG is no better than placebo.1,2 Studies have also demonstrated that UPA has endometrial effects (which may or may not contribute to its efficacy) whereas LNG does not.3,4 The recent randomised controlled trial and meta-analysis of studies comparing UPA with LNG for emergency contraception (EC) that we published in the Lancet showed that UPA reduces the risk of pregnancy by almost one half compared to LNG.5

2. A Cochrane review actually concluded that mifepristone plus estradiol (≥25 mg) were significantly more effective than LNG for preventing pregnancy when used for EC.7

3. As regards the possible effect of UPA if taken in pregnancy, we observed in our study that there were pregnancies in women treated with UPA that were judged to have occurred well before treatment, that continued after UPA treatment.1,6 Furthermore, the miscarriage rate in women who received UPA was similar to that in women who had LNG and no different from that observed in the general population of pregnant women.1,6 Whilst there have been a small number of normal births in women who received UPA, clearly UPA is a new drug and so it is only appropriate that a European registry pregnancy registry has been established to collect more information on effect on ongoing pregnancy.

4. We discussed the possible interaction of a progestosterone receptor modulator (PRM) with hormonal contraception in our commentary on this Journal7 and concluded that further research is required, because the requirement to abstain or use barrier methods for the remainder of the monophasic cycle is not supported.

5. Drs Pittrof, Rubenstein and Sauer express concern that women who cannot access National Health Service abortion services may try to procure UPA from a pharmacy. We commented on this in our Journal7 and concluded that further research is required, because the requirement to abstain or use barrier methods for the remainder of the monophasic cycle is not supported.

6. We disagree with the point made in the letter that a woman who has used UPA in the past is ‘less able to use it successfully’. We feel that a study conducted over the Christmas period, when workload is not typical, for such a short period of time may not truly reflect patient flow. In fact the observed improvement may not be related to the change in process at all. Evaluating such a change immediately is unlikely to record the true effect of the change. Finally, in relation to the methods used in the study, the practice would have been to introduce further bias and complicates the statistics.

In conclusion, we welcome a paper that aims to improve care at the time of the crisis studying ways to reduce waiting time, but should guard against overenthusiastic claims.

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References
suggest that this was not in the patients' best interests given that it contradicts the advice of the RCOG and the Charing Cross Hospital GTN website.

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References

Resolution of localised lipoatrophy at the site of Implanon® insertion
I have previously reported a 40-year-old woman who had an Implanon® implanted into her right upper arm. At the site of the Implanon in the middle of the inner aspect of her right upper arm it was noticed at the time of implant removal 3 years later that she had a localised area of lipoatrophy extending approximately 2 cm either side of the implant along a length of approximately 15 cm extending above and below the end of the implant. In this 4 x 15 cm area there was virtually no subcutaneous fat. The lipoatrophy had been present since the time of implantation and had had no effect on the patient who had to have the area of lipoatrophy demonstrated to her.

Six months after removal the area of lipoatrophy had completely resolved and the patient remains asymptomatic. Both arms looked the same with return of the subcutaneous fat on the affected side. It has been suggested that lipoatrophy might have been caused by topical steroids being used but a review of the patient records shows they have not been prescribed over the last 8 years and the resolution of the lipoatrophy after removal of the implant does not support this.

I suggest that localised lipoatrophy is added to the rare side effects described for Implanon and that the possibility of it developing, even if it is reversible, further motivates correct placement of the implant.

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References

Reply
Dr Lindsay should be commended for reporting1 and following up on this case;2 indeed, confined adverse events should be followed up and the information collated used to assess causality or the relationship between the drug and the event.

In the case reported by Dr Lindsay, causality cannot be fully established and, as such, the event of localised lipoatrophy cannot be classified as caused by Implanon®. The fact that, at the 6-month follow-up assessment after implant removal the event had resolved is not enough to establish causality.

When we applied the Naranjo Scale to this case the maximum score we achieved was two out of a possible ten.3 The Naranjo Scale is a questionnaire designed by Naranjo et al. for determining the likelihood of whether an adverse drug event is actually due to the drug rather than the result of other factors such as pre-existing condition.4

The score of two suggests the relationship is possible; however, it is too low to classify this event as definite or probable. Therefore Dr Lindsay’s conclusion regarding this event in our opinion is not valid. Furthermore, the patient’s pre-existing autoimmune condition is still a confounding or alternative explanation as previously mentioned in our letter.4 Excluding the use of steroids is very important in assessing this case, as it provides valuable information; however, the evaluation of all the information gathered so far is not adequate to allow Implanon to be classified as a definite or probable cause of this event.

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References

Use of an expired Cu-IUD
I was ready to fit an intrauterine device (IUD) in the CASH clinic when the nurse announced that the expiry date of the Flexi-T 300® was 6 months previous. Having already opened the pack, I continued to fit the IUD to save National Health Service (NHS) money. The nurse advised me that many years ago at an update conference I had heard an expert panel state that it is safe to use an IUD up to a year after the expiry date. Common sense dictates that an expired Cu-IUD is not the same as expired sandwiches, for example.

Shortly after this episode occurred I was on annual leave. During my holiday, one of my colleagues contacted the patient and subsequently replaced the IUD, informing the patient that there was a risk of pregnancy. I was surprised at this since I am aware that there are a number of problems associated with IUD fitting and removal per se. One could argue that the IUD could have been left in situ for 4.5 years instead of the normal 5 years.

I would be interested to know whether any other Journal readers have used an expired IUD and, if so, what the outcome was. Was my colleague right to replace the IUD on this occasion?

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Reply
I would like to respond to Dr Yadava’s letter1 on behalf of Williams Medical Supplies, a manufacturer of copper intrauterine devices (IUDs). Most Cu-IUDs have an expiry date of around 4 years. This is because sterility can be guaranteed over this time frame. Once the expiry date has passed, the product is no longer guaranteed to be sterile and therefore we would not recommend fitting an expired IUD in a patient because of potential infection concerns. If an expired product is fitted by mistake, then there are two courses of possible action. One would be to undertake close patient observation over an agreed time span to ensure infection has not occurred. The second option would be to remove the IUD and fit a new one that is within its expiry date.

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Reference

Reply
I would like to respond to Dr Yadava’s letter1 on behalf of the Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Healthcare. We are not aware of any evidence or...