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Reply

In response to the letter[1] 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 greatest), UPA is able to delay ovulation whereas LNG is no better than placebo.[2,3] Studies have also demonstrated that UPA has endometrial effects (which may or may not contribute to its efficacy) whereas LNG does not.[4,5] 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.[6]
2. A Cochrane review actually concluded that mid-doses of mifepristone (>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 early 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.[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. 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 pregnancy registry has been established to collect more information on effect on ongoing pregnancy.
4. We discussed the possible interaction of a progesterone receptor modulator (PRM) with hormonal contraception in our commentary in this Journal[8] and concluded that further research is required, because the requirement to abstain or use barrier methods for the remainder of the month is not evidence based.
5. Drs Pittrof, Rubenstein and Sauer express concern that women who cannot access National Health Service abortion services may try to procure several doses of UPA from different clinics with the intention of trying to induce an abortion (unproven effect), or sell the product on the 'black market' at 'real' value. This course of action seems unlikely since a woman could more easily purchase an effective treatment (mifepristone and misoprostol) over the Internet, at an affordable price (www. womenonweb.org).[9]

As we discussed in our commentary[8] in this Journal, UPA does by virtue of the fact that it is a PRM raise issues for service delivery and for 'bridging' contraception. However, in spite of these challenges, we believe that contraceptive service providers will judge the evidence for themselves, and welcome UPA as an advance in EC that is more likely to help women avoid an unintended pregnancy than LNG.

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Self-triage and clinic waiting times

We would like to thank Drs Hitchings and Barton[1] for concluding that self-triage can effectively reduce clinic times as in our clinical experience this appears to the case. Their paper describes a significant reduced waiting time from 40 to 23 minutes (expressed as median).[1] However, we are unsure if the methods used in this survey are robust enough to conclude this.

First, the paper does not clearly define its research question;[2] this then impacts on the methods it uses. For example, if the research question was "Does self-triage reduce waiting times?" then a method that measures waiting time would have been more appropriate. Alternatively, a questionnaire would have been better if the paper set out to find out "Is self-triage acceptable to patients in SRH?".

Whilst acknowledging that the ideal methodology may not have been possible, we do think the actual design of the survey could have been improved. The original power calculation is not included, so it is not clear if the sample is adequate to demonstrate a significant result. This calculation is important even for a pilot study, a descriptor for this study that is hidden in the discussion. It is stated that the study was prospective, though the description of the data collection is not adequate to support this. 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. Also, 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 of discarding incomplete forms will introduce further bias and complicates the statistics.

In conclusion, we welcome a paper that aims to put patients at the centre of their care by studying ways to reduce waiting time, but would guard against overenthusiastic claims.

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Combined pill and GTD

I have read the new UK *Medical Eligibility Criteria for Contraceptive Use* (UKMEC) guidelines[1] and am surprised and concerned that the recommendations regarding hormonal contraception, particularly the combined oral contraceptive pill (COC) and gestational trophoblastic disease (GTD), have been changed. It used to be recommended that the COC was not taken until the beta-human chorionic gonadotropin (ß-hCG) levels had fallen to normal following evacuation of a hydatiform mole.[2] The new (2009) guidelines state the COC can be started whilst the ß-hHCG levels are decreasing, persistently elevated and in the presence of malignant disease. The accompanying notes suggest that starting the COC in this situation may decrease the requirement for chemotherapy (by promoting a more rapid reduction in ß-hCG levels). This advice differs to that given by the Royal College of Obstetricians and Gynaecologists (RCOG), the Patient UK website (a common source of information for both general practitioners and patients) and the Charing Cross Hospital gestational trophoblastic neoplasia (GTN) website, which recommend that hormonal methods [and intrauterine devices (IUDs)] are not used until the ß-hCG level has returned to normal.

I am puzzled by the new advice given by UKMEC. The references given in the 2009 guidelines all predate, and are very similar, to those in the 2006 guidelines. Why has the advice changed? I am aware of the paper in *Contraception*[3] suggesting that both the COC and IUDs can be used in women with GTN. This paper also quotes some publications suggesting that COC use reduces the risk of women developing post molar trophoblastic disease, however it is not quoted by UKMEC 2009.

Professionals and patients become confused when contradictory advice is given. As a specialty we should be more aware of this than most following the problems that have arisen after various 'pill scares'. I would be interested to hear why UKMEC have changed their guidance but

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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Reply

In response to Dr Robinson's letter[1] we can say that the use of combined hormonal contraception (CHC) in women with gestational trophoblastic disease (GTD) was extensively reviewed by a multidisciplinary working group of worldwide experts for the WHO Medical Eligibility Criteria (WHOMEC) update in 2009. As a result of this systematic review of published evidence, and taking into account the opinion of experts, a decision was made to advise a Category 1 (unrestricted use) for the use of CHC in women with GTD with decreasing or undetectable levels or indeed with persistently elevated levels or malignant disease.

It is recognised that management of GTD varies worldwide. Nevertheless, based on evidence around risks, there is no good published evidence that use of CHC in women with GTD worsens outcomes.

The UK Medical Eligibility Criteria (UKMEC) Consensus Group, which included a variety of health professionals (including representation from the Royal College of Obstetricians and Gynaecologists, the Faculty of Sexual and Reproductive Healthcare, and general practice), agreed to uphold the new WHOMEC Category 1 for CHC use by women with GTD and persistently elevated serum human chorionic gonadotropin (hCG) levels or malignant disease. The UKMEC Consensus Group could find no evidence to support a Category 3 for the use of intrauterine contraception in women with decreasing or undetectable serum levels of hCG. As there is no evidence that use of intrauterine contraception by women with GTD and decreasing or undetectable serum levels of hCG poses any risk, a Category 1 was given as in the UKMEC 2005. The Gaffield review paper[2] was published after the review of evidence in preparation of the UKMEC update and therefore was not quoted.

It is clear that any guideline such as UKMEC needs to be taken as a guide and should not replace clinical judgment. Expert opinion and discussion with specialists should be sought in complex and rare situations such as women with GTD. Best attempts can be made to ensure coherence of guidance across colleges in the UK but this requires reciprocal arrangements from all colleges to ensure advice reflects evidence and opinion.

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Resolution of localised lipoatrophy at the site of Implanon© insertion

I have previously reported a 40-year-old woman who had had an Implanon© implanted into her right upper arm.[1] 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 and along a length of approximately 15 cm extending above and below the ends of the implant. In this 4 × 15 cm area there was virtually no subcutaneous fat. The lipoatrophy had been asymptomatic 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[2] the lipoatrophy might have been due to the use of topical steroids 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 suggest Implanon as a cause.

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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1 Lindsay P. Localised lipoatrophy at the site of Implanon© insertion [Letter]. *J Fam Plann Reprod Health Care* 2009; **35**: 266.
2 Mohlala B, Falowo F. Reply to "Localised lipoatrophy at the site of Implanon© insertion" [Letter]. *J Fam Plann Reprod Health Care* 2009; **35**: 266.

Reply

Dr Lindsay should be commended for reporting[1] and following up on this case;[2] indeed all 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.[3]

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, this provided 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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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 money, confident in the knowledge 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 letter[1] 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 the product's 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
1 Yadava RP. Use of an expired Cu-IUD [Letter]. *J Fam Plann Reprod Health Care* 2010; **36**: 107.

Reply

I would like to respond to Dr Yadava's letter[1] on behalf of the Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Healthcare. We are not aware of any evidence or