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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