## Risk of VTE among users of oral contraceptives

We have recently reviewed two studies,[1] a cohort study conducted in Denmark,[2] and a case-control study conducted in The Netherlands,[3] in which it was claimed that the risk of venous thromboembolism (VTE) among users of oral contraceptives (OCs) containing desogestrel, gestodene, drospirenone and cyproterone is greater than among users of levonorgestrel-containing OCs. We concluded that in both studies the comparisons among the progestogens were not valid due to methodological limitations.

The Danish study linked prescription data recorded in one national registry to hospital discharge diagnoses of VTE recorded in another registry. The investigators stated that in an earlier validation study 10% of the diagnoses documented between 1994 and 1998 "were uncertain". In the study under review they acknowledged that they relied on the "final discharge diagnoses as reported", and that they were unable to "evaluate the validity of each included diagnosis of [VTE]".[2]

Since publication of our review new information has come to light that bears on the validity of the registry-recorded diagnoses. In a cohort study that included 27 178 men and 29 876 women aged 50–64 years, Severinsen and her colleagues examined the medical records of 1100 cases of registry-recorded VTE.[4] The diagnosis was incorrect in 25% of cases diagnosed in hospital wards, and in 69% of cases diagnosed in emergency departments; the latter cases constituted 41% of the total. Incorrect diagnoses were more commonly recorded among women than among men. A stratified analysis did not show an impact of age on diagnostic precision.

It is difficult to reconcile the findings of Severinsen *et al*. with the assumption that the diagnosis was uncertain in about 10% of the cases of VTE,[2] even though that estimate was made among women of fertile age. Based on the wording used by the authors it can be assumed that the VTE incidence rates among the compared OCs were based on all VTE diagnoses – including VTE diagnosed in emergency departments. If so, Severinsen's results suggest that the diagnosis was not only uncertain, but in at least 40% of the cases it was wrong. If the analysis was based only on hospital ward cases, the diagnosis was incorrect in about 29% of the female patients.

Relative to levonorgestrel the relative risks for the compared OCs were small (<2), and the major diagnostic imprecision suggested by Severinsen's data would be sufficient to nullify the findings. It obliges Lidegaard to verify the diagnoses in his study.

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## Critique of a Danish cohort study on hormonal contraception and VTE

Thanks to Samuel Shapiro and Jürgen Dinger (S&D) for their altruistic interest in and concern for possible bias and confounding in two recently published studies on use of oral contraceptives (OCs) and the risk of venous thromboembolism (VTE), as detailed in their review article[1] in the January 2010 issue of the *Journal of Family Planning and Reproductive Health Care*. One of the two studies under discussion was a national Danish cohort study.[2]

The two authors' concern is to question whether bias and confounding could explain how different types of progestogens in OCs seem to play a differential role in the risk of VTE. However, S&D don't stop with questioning. They actually conclude first that the results of both studies are invalid, and second that the best scientific evidence (taking all studies into account) is that the progestogen type in the combined OC has no influence on the risk of VTE.

These rather bombastic conclusions necessitate a validation of each of their points of concern for the Danish cohort study.

### Control for duration of use

S&D correctly state that the risk of VTE is highest during the first months of use. It is also correct that some (in fact few, however) short-term users of OC with levonorgestrel (LNG) might have used the pill for a longer period (before our study window started in 1995), namely the small fraction of the LNG short-term users beginning their short use in the beginning of 1995. While this potential left censoring bias could influence users of OC with LNG more than users of OC with drospirenone, it also applies to users of the third-generation progestogens, desogestrel and gestodene. However, the risk estimates for third-generation OCs was 82% and 86% higher than the risk estimates for OCs with LNG, a risk ratio even higher than for OCs with the fourth-generation drospirenone. That should not be the case, if the concern of S&D had any substantial significance. The magnitude of misclassification of the short-term LNG users was in the order of 0.22 (per cent of short-term users) × 0.023 (proportion of short-term users who were recorded within the first 3 months of 1995) = 0.005 or about a half per cent. In addition, we stratified for (adjusted for) length of use when comparing the different types of progestogens, thereby eliminating all other differences (other than the small fraction of short-term users starting their short-term use in 1995) concerning length of use between different OC types. Therefore, it is very unlikely that this small misclassification of short-term users starting their short-term use in the beginning of 1995 would have had a substantial influence on our estimates.

Thereafter S&D argue that the risk in short-term users of OCs with LNG should have been three times higher than for long-term users. Our analysis demonstrated, however, that the risk among short-term users (all products considered together) was about 50% higher in the first year. Not more. With these national cohort data, their calculation, anticipating this three-fold difference, is far too high.

As indicated in our paper,[2] a large number of studies with different designs have assessed a possible differential effect of different progestogens to influence women's VTE risk. The vast majority of these studies have found a consistently higher risk with OCs containing desogestrel and gestodene than for OCs containing LNG.

So the present two new studies are in accordance with the available scientific evidence. In addition, the different impact of the different progestogens on the so-called Activated Protein C sensitivity ratio gives us a probable mechanism through which these different progestogens exert their differential influence on the coagulation system.

In conclusion, well-sized and well-conducted newer epidemiological studies consistently find a higher risk of VTE with the newer progestogen types as compared with the older types. The fact that differently designed studies conducted at different times in different countries find the same differential risk between different progestogen types increases the probability that this difference is real and not due to bias and confounding as S&D suggest.

Next S&D argue that when operating with length of use one has to consider only the length of the last use. Had we done so, S&D could have argued that our missing data on previous use had flawed our effort to exclude bias due to attrition of susceptible individuals, as this attrition is in effect according to the total length of use and not only according to the last length of use.

### Confounding

Next S&D argue that our missing control for obesity (BMI) "was a major defect in the Danish study". Now, adiposity is a well-established risk factor for VTE. A risk factor is, however, not the same as a confounder, which in addition to being a risk factor also has to be associated with use of OCs in general, and differentially with different OC types, if the considerations of S&D are to be valid. The fact is that there is no association between OC use and adiposity, and no significant difference in the frequency of adiposity in users of different types of OC (as documented in our paper).[2] Therefore, the increased risk of VTE in users of OC with third- and fourth-generation OCs as compared with OCs containing LNG cannot be explained by our missing control for adiposity.

Conversely, it is true that the frequency of adiposity increased in the general population during the study period. Therefore we adjusted our estimates for calendar year, thereby eliminating this potential time-trend bias.

S&D further speculate that women at an increased risk of VTE should preferentially be prescribed newer OCs, in particular OCs containing drospirenone. Our data demonstrate the opposite. The use of medication for hypertension, diabetes, hyperlipidaemia and heart disease was actually lower in users of drospirenone than in users of LNG. Consequently, this speculation does not seem to be very relevant.

Finally, S&D postulate that the decreasing risk of VTE with increasing length of education was unexpected, and therefore an indicator of selection bias, women educated for a short time being more prone to be diagnosed with VTE in case of symptoms than women with a longer education. This assumption is unlikely. All diseases I am aware of (with the one exception of multiple sclerosis), including thrombotic diseases, decrease in frequency with increasing length of education. Referral to hospital and subsequent diagnostic investigations are free in Denmark. Therefore, there is no reason to believe in any selection bias according to length of education. As our trend confirms a previously proven general trend towards unhealthier lifestyle and more morbidity with decreasing length of education, this finding only strengthens the validity of our results.

### Other issues

S&D postulate that the diagnoses in the National Register of Patients have not been validated. This

is wrong. We went through all the VTE diagnoses during the period 1994–1998 in women aged 15–44 years and found 10% with an uncertain diagnosis (this was clearly stated in the paper).

Initially, S&D make a rather unusual complaint, namely that large observational studies nearly always find significant associations, even if the association is small. Is that really a critique? Meaning that if we had done a smaller study then the quality would improve? The quality in large samples is first of all that one is able to separate the contribution from different axes of OC use; the length of use, the estrogen dose, the progestogen type, the dose and the route of administration. Other scientists would consider this to be a strength rather than a weakness.

**Conclusion**

Scientific critique is always welcome, and bias and confounding in observational studies are difficult to exclude completely. Some of the suggestions made by S&D are theoretically valid but seem of little or no quantitative significance. When several large-scale, independent epidemiological studies generate the same results, one also has to consider the possibility that these results are actually true.

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## Reply

We thank Professor Lidegaard for his comments.[1] As stated[2] with regard to his study,[3] "The investigators are to be congratulated for conducting such a large study that also adjusted for the confounder information assessable in the Danish registries". We also believe that additional subanalyses might improve the interpretability of the findings. We address Professor Lidegaard's comments in the paragraphs that follow.

**Previous studies**

Relevant references to studies of the risk of venous thromboembolism (VTE) in users of desogestrel and gestodene, as compared with levonorgestrel (LNG), were provided in our review,[4] and a further detailed consideration of the "large number of studies" at issue would fall outside the scope of this response. Readers interested in the topic may also wish to refer to the judgement of the High Court of Justice[5] in the UK. It is not primarily the court's conclusion that is of interest here but the comprehensive documentation of methodological details and arguments that were scrutinised during more than 12 weeks of hearings with expert witnesses on the strengths and weaknesses of all relevant studies on this topic published until 2002.

**The Danish cohort study**

Professor Lidegaard questions the relevance and quantitative impact of our criticisms.[4] In response, we first consider the validity of the diagnosis of VTE in the Danish registry data.

**Validation**

In their publication,[3] Lidegaard and his colleagues "clearly stated" that "the registry approach did not permit us to evaluate the validity of each included diagnosis of [VTE]" and that they relied on the "final discharge diagnosis as reported". The statement now made, that they "went through all the VTE diagnoses … and found 10% with an uncertain diagnosis…"[1] is misleading: that estimate was made in an earlier study.[6] As indicated in our Letter to the Editor in this issue of the Journal,[7] Severinsen and colleagues[8] have now reported that in Denmark registry-recorded diagnoses of VTE were incorrect in at least 40% of cases aged 50–64 years (in 40% the diagnosis could be ruled out, and in 5% it was uncertain) – or about 29% in female hospital-ward cases. It is unlikely that the discrepancy with the 10% rate of "uncertainty" identified by Lidegaard can be explained by age, and it obliges him to verify the diagnoses in his study. If VTE was incorrectly diagnosed as commonly as is suggested by Severinsen's data, the interpretation of the small risk estimates must be questioned.

The remainder of our response follows Lidegaard's sequence.

**Left censorship**

Lidegaard acknowledges that left censorship may have distorted the data for LNG more than for drospirenone. In fact, since drospirenone was only introduced in Denmark in 2001, for this compound there was no left censorship, and no distortion. Desogestrel and gestodene were introduced in Denmark in the first and second half of the 1980s, respectively, whereas LNG has been available since the first half of the 1970s. In addition, the market shares of desogestrel and gestodene were more or less stable between 1995 and 2005,[9] while the use of LNG declined. Inevitably, therefore, the distorting effect of left censorship was more marked for LNG than for desogestrel or gestodene.

While Lidegaard acknowledges left censorship, his calculation of its potential impact is misleading for a number of reasons. Here, however, we confine our response just to one of them. Lidegaard states that "about a half per cent" of "short-term levonorgestrel users" were misclassified. This misses the point. In the first study year (1995) all *long-term users* (100%) were misclassified as *short-term users*. As approximately 14% of the total LNG exposure stems from 1995[9] it has to be assumed that in that year approximately 57 000 woman-years of LNG use were classified as short-term use (0.14 × 411 099; see Table 2 in Lidegaard's publication). This number probably represents more than 60% of the total short-term exposures (0.22 × 411 099; Table 1). We therefore disagree with Lidegaard "that it is very unlikely" that this misclassification "had a substantial influence" on the risk estimates.

**Risk of VTE among short-term OC users**

As the duration of oral contraceptive (OC) use was misclassified, the risk of VTE for short-term users was underestimated in the Danish study. In an earlier study[6] Lidegaard observed a three-fold higher relative risk increase for the first year of use relative to the following years. That study identified VTE from the same source (the Danish patient registry) but the information on OC use was derived from a different source: it was reported by the patients, and there was no left censorship. Moreover, it is not only short-term use that is at issue: in a valid comparison *similar durations of use*, whether short- or long-term, should have been compared among users of the different OCs.

**Total vs current duration of OC use**

With regard to the total duration of all episodes of OC use versus duration of the current episode only, we reiterate that multiple studies have demonstrated that the risk of VTE is no longer increased within a few months of stopping current use. It is only the duration of such use that is relevant. The need to have data on all episodes of OC use is not in order to sum all durations, but in order to be able to compare starters with starters, re-starters with re-starters, and switchers with switchers, as illustrated in Figure 1.

A comparison along these lines would also minimise any "bias due to attrition of susceptible individuals",[1] mentioned by Lidegaard. In addition, the requirement that starters should be compared with starters could readily have been met in the Danish study. Had follow-up commenced in 2001, the study would have started after the introduction of all the relevant progestogens and had women who used OCs between 1995 and 2000 been excluded, for practical purposes that objective would have been accomplished.

**Confounding by obesity and other risk factors**

Lidegaard claims that he has documented that there was "no significant difference in the frequency of adiposity in users of different types of OC."[1] In his study he had no data on obesity,[3] and his claim is based on data from a different study covering the time from 1994 to 1998.[6] Those data do not preclude the possibility that preferential prescribing of selected OCs occurred after 1998, and there is evidence that it did occur. In a recent study, drospirenone – a progestogen that is also an aldosterone antagonist – was preferentially prescribed to women with a high body mass index (BMI).[10] That study also demonstrated that the combination of obesity with other risk factors (e.g. family history) led to a multiplicative increase in the risk of VTE. Since the Danish study lacked data on BMI, confounding from that source was not ruled out. Lidegaard acknowledges the increase in the prevalence of obesity that occurred between 1995 and 2005,[1,11] as well as the decline in the use of LNG.[9] He nevertheless claims that adjustment for calendar year eliminated confounding due to obesity. Both the increase in obesity and the decline in the use of LNG were substantial. Thus

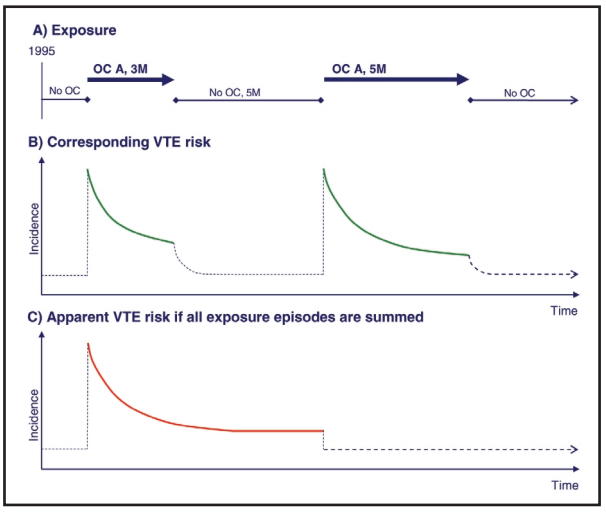


**Figure 1** Time patterns of venous thromboembolism (VTE) occurrence based on a hypothetical example of two exposure episodes to the same oral contraceptive (OC), lasting 3 and 5 months (M), and separated by a 5-month interval of non-use: Real and apparent VTE risks if individual episodes of OC use are analysed separately or summed

adjustment using time-trend data as a surrogate for obesity could possibly have reduced confounding, but it would not have eliminated it, especially since its effect in combination with other risk factors is multiplicative.

With regard to possible confounding from other sources, VTE was more frequently diagnosed in women who only completed primary school. Socioeconomic status was thus a determinant of VTE risk, and the possibility that this factor may have reflected detection bias was not evaluated. With regard to other potential confounders Lidegaard mentioned that allowance for treated diabetes, heart disease, hypertension and hyperlipidaemia did not affect the findings. Only heart disease and diabetes are risk factors for VTE; hypertension and hyperlipidaemia are not. As for other factors, the Danish study did not evaluate potential confounding due to a family history of VTE, recent surgery, trauma or immobilisation.

**Confounding by indication**

We stated that in the past there has been a general tendency to prescribe the most recently introduced OCs to women thought to be at increased risk of VTE. In a former publication[6] Lidegaard has agreed: "In many countries including Denmark … many gynecologists and general practitioners have prescribed these new pills to women at anticipated increased thrombotic risks". He has also stated that the risk of VTE conferred by "Family disposition, BMI, smoking, and years of schooling are probably the most important confounders to adjust for to account for prescribing bias".

**Study size**

We repeat that in the presence of systematic bias, a large study will more readily produce statistically significant results than a small one. Statistical significance, however, does not equate causation, and in a large study a biased or confounded association may nevertheless be "significant".

**Conclusion**

We are aware that *ex-post facto* criticism of studies conducted by others is easier than doing better oneself. We would welcome an opportunity to discuss with Professor Lidegaard details of additional subanalyses that might shed light on the issues raised in his publication, and in this correspondence. However, we reiterate that in our view the Danish comparison of selected progestogens with LNG was not valid.

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## LNG may still be the best oral EC option

The last two issues of this Journal each included a commentary[1,2] on the progesterone receptor modulator (PRM), ulipristal acetate (UPA). Both commentaries concluded that UPA is more effective for emergency contraception (EC) than levonorgestrel (LNG). Now, as the key studies have been published, it is possible to assess the possible merits of providing UPA rather than LNG oral EC.

At present there remain good reasons to be cautious about the claims that UPA is the superior emergency contraceptive:

1. Both studies comparing LNG and UPA found no significant difference in pregnancy rates when used for EC. The recently published randomised controlled trial (RCT)[3] was designed as a non-inferiority study and a previous RCT[4] also showed non-inferiority for UPA. None of the studies were powered to provide the answer as to which is the better method of EC. There are two reasons why a non-inferiority design was chosen: (i) it is cheaper as a smaller sample size is required and (ii) it is all that is required for drug licensing. Analysis of the combined data of both studies showed that UPA showed significantly reduced pregnancy rates for UPA as compared to LNG. A meta-analysis does not replace a sufficiently powered single study such as the World Health Organization (WHO) multicentre RCT.[5] The WHO study also compared a PRM (10 mg mifepristone) with LNG. It was powered to find a difference but did not find one.
2. The primary outcome of the recently published RCT[3] was pregnancy rate, which was not statistically different for LNG and UPA. Pregnancy prevention rates are listed on ClinicalTrials.gov (No. NCT00551616) as a secondary outcome. The results were presented at a conference[6] but were not reported in the recent publication.[3] Pregnancy prevention rates are not observed but calculated and are much less robust than pregnancy. In theory, randomisation should have ensured that pregnancy risks in the LNG and UPA groups will have been similar, and different pregnancy prevention rates should also be apparent in different pregnancy rates. As we do not know if a power calculation was performed for secondary outcomes we cannot assess the likelihood of a type 1 error (i.e. finding something which is not there).

Even if UPA is more effective than LNG for EC used under trial conditions, there are good reasons (costs aside) to remain cautious about the use of UPA:

1. Post-implantation use of LNG has not been associated with any harm to an early pregnancy. This still needs to be shown for UPA.
2. Information provided on ClinicalTrials.gov (No. NCT00551616) explains that the recent[3] study specifically excluded women who intended to use hormonal or used contraception during the current cycle. While the same criteria were used for the WHO multicentre trial[5] it is unlikely that the use of hormonal contraception started at the time of LNG EC would reduce the effectiveness of EC or vice versa. This is important as there is a high risk of subsequent conception in the current cycle in women receiving EC.[7] In a commentary in the January 2010 issue of this Journal, Cameron and Glasier[8] appear to suggest that hormonal contraception can also be started at the time of UPA EC. This may not be the case, as there are at least theoretical reasons why the combination of a progestogen and a PRM at the same time might cancel each other out. As the use of hormonal contraception was specifically excluded in the recent RCT it is only possible to speculate how UPA and hormonal contraception affect each other. The serum half-life of UPA may only be 32.4 hours[9] but its biological effects last a lot longer. When given in the immediate pre-ovulation period it prevents ovulation for 5 or more days in 59% of cases.[10] Similarly, it might affect the effectiveness of hormonal contraception for an uncertain period of time. While we know that there are no adverse interactions between LNG and hormonal contraception, we cannot even estimate the effect of UPA on the effectiveness of 'quickstart' hormonal contraception and vice versa.
3. UPA is a cousin of mifepristone, and it is at least conceivable that women may access it under the pretext of EC with the intention of terminating an early pregnancy. UPA (30 mg) (ellaOne®) taken as EC does not appear to interrupt a pregnancy, and the same number of pre-EC pregnancies occurred in the UPA and LNG arms of the recently published RCT.[3] It will, however, not be long before it will become common knowledge that to get more than one dose of ellaOne one will need to present to more than one clinic. This may be an attractive proposition for women who cannot access a termination on the National Health Service. A drug that can induce abortions would also have a real value on the black market. To prevent this we should consider pregnancy testing prior to administration of ellaOne under direct supervision.

The purpose of EC is to prevent unplanned pregnancy. In most cases this can best be achieved if EC can be combined with ongoing contraception. As this has not been studied we do not know how the combination of UPA and hormonal contraception will affect the effectiveness of EC or ongoing contraception. At least for the combination of EC with LNG with an immediate depot medroxyprogesterone acetate (DMPA) start there is strong evidence of reduced pregnancy rates.[11] Even now for the purpose of prevention of unplanned pregnancy in women presenting for EC, LNG plus 'quickstart' DMPA remains the most evidence-based approach for women who do not wish to have an intrauterine device fitted.

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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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1 *UK Medical Eligibility Criteria for Contraceptive Use (UKMEC 2009).* 2009. http://www.fsrh.org/admin/uploads/UKMEC2009.pdf [Accessed 10 February 2010].
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3 Gaffield ME, Kapp N, Curtis KM. COC and IUD use amongst women with gestational trophoblastic disease. *Contraception* 2009; **80**: 363–371.

## 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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**References**
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2 Gaffield ME, Kapp N, Curtis KM. COC and IUD use amongst women with gestational trophoblastic disease. *Contraception* 2009; **80**: 363–371.

## 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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**References**
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

recommendation that intrauterine devices (IUDs) are safe to use after the manufacturer's expiry date. Guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) on the safe use of medical devices advises checking before use whether a device is within its expiry or use-by date.[2]

Training material from Family Health International states that the expiration date printed on IUD packaging indicates the date when the sterile packaging expires, not the date when the IUD's effectiveness expires.[3] Even in the resource-constrained settings for which this information is intended, it is advised that an IUD is used only if the sterile package has not expired.

Therefore, Dr Yadava's patient was probably not at increased risk of pregnancy but she may have been at increased risk of infection. In the event of inadvertent insertion of an expired IUD, the patient should be informed of the error and advised of the risks of retaining or replacing the IUD. If the IUD has only recently expired or if the IUD has been inserted without any infective complications, then the risks of replacing the IUD may outweigh the benefits.

Confusion has possibly arisen because in contraceptive literature the term 'expiry date' is often used to describe the limit of an IUD's recommended duration of use. This 'expiry date' can be exceeded in women who are over the age of 40 years at the time of insertion.[4]

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**References**
1 Yadava RP. Use of an expired Cu-IUD [Letter]. *J Fam Plann Reprod Health Care* 2010; **36**: 107.
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## Correspondence about the recent article on "Nurse Training in Sexual and Reproductive Health"

The Journal has received a number of letters written in response to the Personal View article entitled "Nurse training in sexual and reproductive health" by Shelley Mehigan, Wendy Moore and Linda Hayes that appeared in the January 2010 issue of the Journal. The very fact that this article has attracted the greatest number of letters of any article published in the Journal in recent years is evidence of the article's timeliness and relevance to many of the Journal's readers. The individual letters received by the time this Journal issue went to press, and the response from Shelley Mehigan and Wendy Moore, are reproduced here in full.

## Letters

I would like to thank the authors of the article[1] on nurse training in sexual and reproductive health in the January 2010 issue of this Journal for very clearly setting out the current situation regarding nurse training in this specialty and the history to the situation.

I agree with the authors that post-registration training in contraception and sexual health has been an area of concern for some years now. Certainly when I joined the Faculty Associate Members Working Group 3 years ago this was one of the main issues on our agenda. We set out to look at whether nurses could do the Faculty Diploma (the DFFP as it was known as then) along with doctors. This was not possible as it is a medical diploma and qualification. This has come full circle and will be revisited. A lot of work has taken place within this group, including attempting to map current training provided across the country.

- **Recruitment.** As a Senior Nurse Manager in a service employing over 60 SRH nurses I find the lack of standardisation of training difficult when recruiting; to ascertain from applications whether the candidate has completed a recognised training or a skills course can be difficult, in addition 'recognised' courses can vary significantly. From the nurse's point of view there seem to be enthusiastic candidates who have not attended recognised contraception and sexual health courses but who are keen to move into the specialty and it seems some nurses are having difficulty in knowing exactly which training is required by employers and/or accessing the training.
- **Access to training.** From the nurse's position, to undertake a contraception and sexual health course at a Higher Education Institute (HEI) can take 3–9 months to complete. Managers are reluctant to give study leave to enable nurses to access the training, and nurses are struggling to balance the demands of their job with lengthy assignments. In some instances, after 6 months two modules have been completed and the nurse is trained in contraception; however, yet another module is required to complete cervical cytology screening and yet another for management of sexually transmitted infections (STIs).
- **Multidisciplinary training.** I believe that training in contraception and sexual health should be multidisciplinary. Nurses and doctors should be able to access the same training and undergo the same assessment; it would follow on that standard accreditation is required. The Faculty has welcomed Associate Members with the AMNG working group and with Associate Members represented on other committees. If the Faculty could extend accreditation to clinicians other than doctors this could address many of the issues, although this is currently not possible.
- **Standardised training.** The content of the training must be standardised and it is vital that training from all providers and HEIs is *up to date*, *evidence-based* and reviewed by practising experts in SRH. The course should cover contraception and sexual health to meet the needs of integrated services. Cytology training and updating is another area that would benefit from standardising across disciplines.
- The new e-learning for the DFSRH will be *accessible* for all to learn in their own time and at their own pace. Assessment would be standard. The Course of 5 may be richer for having doctors and nurses training together. I believe the *clinical placement and clinical assessment* is a very important part of the SRH nurse training and I would not like to see it reduced. This part of the assessment is not undertaken by HEIs but by local SRH departments. Therefore this could continue whether or not the nurse is doing a university-accredited course. Locally we provide clinical placements of 12–14 weeks with usually one session a week. If this can be provided with longer sessions over a shorter time period then the clinical training could be completed in several weeks.
- Many post-registered nurses are not doing the contraception and sexual health training as part of a pathway to get a degree, but to achieve the competencies required to work in the area. For those nurses who choose to do it as part of a degree or masters, a standardised course should be available at HEIs but I would recommend that the course includes the same basic content as the standard training accessed by doctors and nurses (i.e. the e-learning, Course of 5 and clinical placement).
- **Accreditation** needs to be addressed urgently in view of the Royal College of Nursing (RCN) changes. We plan in future to provide accreditation as a Department of SRH to nurses trained in subdermal implants (SDIs). However, this has implications for those who wish to become primary trainers for their medical colleagues.

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I am corresponding in response to the article[1] in the Journal on nurse training in SRH, and want to say that I totally agree with all of the points the authors raised in this article.

I am the lead nurse for sexual health in Northamptonshire Healthcare Foundation NHS Trust with 27 family planning (FP) nurses and 23 genitourinary medicine (GUM)/HIV nurses. Training, education and development of their roles is one of my key responsibilities.

In the days of the English National Board (ENB), as the authors quite rightly say, we knew the standards required. Currently we support FP students on courses at De Montfort University Leicester and are very satisfied with this course in terms of standards and support from tutors, and so on. However, there have been students from other areas where we have been less than impressed with the course offered.

I think the proposal to link in with the DFSRH standards is an excellent progression, particularly as nurses take on such an integral advanced role in this specialty. With advanced practice, I as a manager like to know that when a new member of staff has attended specific courses, it is at the level required to carry out the job competently and safely.

I welcome involvement in these new initiatives.

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1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

I was most interested to read the nurse training article[1] in the Journal.

I have a particular interest in nurse training as one of my roles at The Margaret Pyke Centre is Nurse Trainer for inserting and removing subdermal implants. I am also training to be a Faculty Nurse Trainer for Doctors in this specialty.

It seems to me that the Royal College of Nursing (RCN) are implementing policies that positively discourage Nurse Trainees, by the large increase in accreditation and re-accreditation fees. Primary care trust budgets seem to be so tight that they are not providing the money for the fees, so that the only way for a nurse to obtain accreditation is to pay for it herself. The nurses that I have trained have had difficulty in affording the fee of £35 (£75 for non-RCN members), so you can imagine the extra difficulty that a fee of £300 (£400 for non-members) is going to cause. It is definitely going to reduce the number of nurses coming forward for the programme. Furthermore, this disincentive to increasing the pool of competent people is contrary to the stated policy of promoting long-acting reversible contraception (LARC).

I shall be writing to the RCN to highlight this issue and ask them to reconsider the change. If they are not prepared to do so, are there other possible avenues to achieving a recognisable accreditation for nurses without a significant financial penalty?

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1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

I have just read the excellent article[1] in the January 2010 issue of the Journal on the subject of nurse training. The article clearly documents concerns I have had for several years relating to national standards for post-registration nurse education in contraception and sexual health.

I was involved in the provision of contraception and sexual health courses for over 20 years at City University and Surrey University before I become involved with the rollout of non-medical prescribing .I was also the education lead on the Royal College of Nursing (RCN) Family Planning Forum Executive Committee from 1998 to 2000, and would add that before the demise of the National Boards in 2002 we were concerned about the variation of training provision across different university providers. It was at this time that the Board Course No. 8103 came into being and the ENB R71 was developed by some providers as it was felt that the 8103 was not fit for their purpose. All this is now boring history but I suspect that some providers have for some time not drastically changed their CASH training! I fully support the need to rectify the confusing situation and revolutionise post-registration nurse training in this field.

Can I ask that when looking at levels of training, consideration be given to the Knowledge and Skills Framework, career progression and remuneration of nurses so that specialist nurses undertaking more advanced roles are suitably rewarded!

If I can provide any input into the development of this training please ask. Although I retired from my academic job at Surrey University in 2008, I still work part time in the CASH service in North Surrey and mentor CASH students from Surrey University.

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1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

Firstly, congratulations for publishing a very interesting article[1] on nurse training in the January 2010 issue of the Journal.

I wholeheartedly agree with the authors that there is no standard training for nurses to gain the CASH qualification, and standards from universities vary considerably across the country. It will be very interesting to see how the Band 5 trainee nurses at Margaret Pyke progress with the e-SRH modules and whether this will indeed provide a turning point for nurse education in CASH.

What I find a little more disturbing is the price hike by the Royal College of Nursing (RCN) for accreditation for subdermal implants and intrauterine devices: this is somewhat shocking in today's current economic climate. How are nurses expected to find this kind of money? I have actively encouraged training for appropriate primary care staff in these skills and encouraged them to seek accreditation but with many practice nurses not receiving Agenda for Change pay and advised to do this training by their managers but not given financial backing by their employers (most practice nurses not employed by NHS) this has to be a grave mistake by the RCN. As CASH nurses trying to encourage the uptake of long-acting reversible contraception (LARC) and make it easily accessible this is yet another barrier.

I am well aware that the RCN has external accreditors and they are probably paid for the work they do, but £300 per member? I will have to seriously reconsider whether I renew my certificate when it expires later this year.

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**Reference**
1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

I thought I would submit my comments on the article[1] in the January 2010 issue of the Journal on nurse training.

I am in agreement with the authors about the fact that we need to try to standardise the course in some way. I feel that it would be lovely if we could use the Faculty training in some way but I am aware that they do deal only with doctors.

I have thought that if all the universities could get together and decide to produce a examination paper that every student undertakes, then even if the lectures and practicals differed then the standardisation of the examination would be the same for all students and at least we would be able to say that an individual student has achieved a certain level.

I am aware that this may be impossible but it does seem like a good way forward.

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1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

I absolutely agree with what the authors said in their recent article[1] on nurse training and I believe that they should continue to explore the option of the Faculty supporting nurse education and accrediting nurse training. This could be done by a separate but affiliated nurses group.

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I read the article[1] on nurse training in the January 2010 issue of the Journal with interest and I agree that things have become inconsistent since the demise of the English National Board (ENB).

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Having read the article[1] on nurse training in SRH in the January 2010 issue of the Journal, I absolutely agree with the authors that there should be standardised training not only for sexual health, but for all the other tasks and skills that nurses need to know these days. Coming out of university with a degree does not equip nurses with any specialised skills. Therefore having a course that 'adds on' to a degree and is the same anywhere in the UK has to be the way forward. E-learning is brilliant and would equip nurses, especially practice nurses, to at least be able to have some knowledge of family planning and STIs, even if they didn't want to do more in-depth study.

As a Practice Nurse Facilitator I am always being asked where nurses can find training and I have very little to offer.

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**Reference**
1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

Having read the recent article[1] on nurse training in this Journal, I am wholeheartedly behind the authors' efforts to both standardise and make accessible sexual and reproductive health (SRH) education. In this day and age I feel that e-learning is an entirely appropriate and cost-effective approach for core learning with the other three DFSRH elements ensuring consistency across all clinicians working in this area. Working with practice nurses I can clearly see benefits for this as follows:

1. Less time away from the workplace.
2. Recognition of the expertise and status of practice nurses working in this area which in many GP practices is a nurse-led service.
3. With more clinicians completing a standardised curriculum comes more accessibility to a pool of appropriately qualified mentors in practice to ensure proper succession planning and choice for accessing the clinical placements.
4. Safe and evidence-based practice that is equitable for patients.
5. Free access via e-learning for theory to support Level 1 sexual health service delivery will provide a taster for new nurses and other clinicians to ensure consistent delivery of the wider sexual health agenda and also ensure a standardised preparation for those who intend to go further.

With regard to the accreditation, I would favour the Faculty option with the university option second until the Faculty is able to take this on. Why would we want to share a training pathway and not see the output given equitable and consistent accreditation?

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**Reference**
1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

I am responding to the article[1] on nurse training in the January 2010 issue of the Journal. I cannot begin to say how much I relate to the issues covered in this article and agree with the views expressed by its authors.

Here in Hull we have had real problems recruiting family planning (FP) nurses for several years and rely heavily on sessional bank nurses (whose main employment is elsewhere) to maintain a service. Similar problems recruiting suitably qualified FP doctors has meant that we have significantly developed the role of FP nurses to compensate – extended roles, patient group directions (PGDs), prescribing, and so on – which current university FP training has not really kept

pace with, and consequently we have had to develop our own training packages and competencies.

We are a service working towards full integration with genitourinary medicine (GUM) and have some 'one-stop' clinics at present. To do this we have trained all our GUM nurses to give emergency hormonal contraception and feel that the only way forward is to bring nurses into the service in GUM on Band 5 and second to do FP training once basic GUM competencies have been achieved. We have also very successfully 'fast tracked' one Band 6 nurse recruited from the substance misuse services to become a dual-trained sexual health nurse with her main remit in FP after failing to recruit FP trained nurses on several consecutive occasions.

We currently second nurses onto the Foundation in FP and Practical Aspects of FP (three semesters total) at the University of Hull but are looking at running our own alternatives to this, not only to fulfill our own needs but also to meet the requirements of primary care nurses (most of whom are not FP trained) who need to be trained up quickly to provide long-acting reversible contraception (LARC) methods in response to our high teen pregnancy rate. Our plan was to adapt the FSRH course as the authors mentioned in their article. I personally would be very grateful for any contacts that the authors have at either of the pilot sites – why reinvent the wheel?!

I would be more than happy to work on this with the authors, as I feel very strongly about this issue and would love to be involved in finding a solution that the whole country could benefit from.

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1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

The problems around post-registration training, since the demise of the National Boards in 2002, are succinctly summarised by Mehigan *et al*. in their recent article[1] in this Journal. This includes the subsequent lack of standardised training and a nationally recognised post-registration qualification in sexual and reproductive health (SRH). With the variety of university courses in SRH, it is indeed difficult for employers and service users to have confidence in knowing what the nurse has achieved in terms of theoretical and practical exposure within the discipline.

National accreditation of nurses' competence through the National Boards, with university courses built around recognised clinical curricula, enabled nurses to demonstrate their competence in SRH to employers and patients alike. The Faculty of Sexual and Reproductive Healthcare acknowledged the contribution of nurses to the field of SRH by opening up membership to them.

I support the option proffered by the authors, namely exploring the possibility of the Faculty supporting and accrediting nurse training. The universities would once again be able to develop their courses around recognised curricula. I suspect many of them will welcome the return of standardisation in post-registration SRH education, reducing any ambivalence they may have about developing new courses.

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Thank you to the three correspondents in the Personal View article[1] on nurse training in sexual and reproductive health.

The extraordinary situation of there being no national standards for nurse training in England needs to be highlighted and emphasised whenever possible in the hope that someone, somewhere will see fit to reinstate an English National Board (ENB) equivalent.

With regard to training in sexual health, I feel that the Faculty has a great opportunity to positively move this situation forward. Having been a member of the Nurses' Working Group for a number of years, I am only too well aware that changes within the Faculty are extremely difficult but feel not impossible.

Multidisciplinary work is now the norm and it seems that merging nurse training with that of the doctors has to be the most reasonable way forward. The two professions are very different with different training needs but there is a point where the merging of core sexual and reproductive health training could be perfectly possible and definitely pragmatic with health care as it is at the moment.

Another point highlighted in this article is the Royal College of Nursing (RCN) raising the price of accreditation to a degree that suggests a nurse has the take home pay of a banker. What is their justification for this? Clearly it will be the individual nurse paying this rather than her primary care trust, which anyway are all pleading poverty. Presumably many nurses will vote with their feet and prefer not to accredit themselves at the very moment that the National Institute for Health and Clinical Excellence (NICE) guidelines are promoting long-acting reversible contraception (LARC); procedures requiring training and accreditation. Is it possible for another organisation to set up an accreditation process?

After 40 years in this area of work I feel that there have been many opportunities for nurse self-development that have not only been good for the individual but also the patients and the organisations for which we nurses work. The issue of standards is crucial, and the fact that the nurses' union is the only body looking at them is concerning.

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**Reference**
1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

I would like to congratulate the authors on their excellent Personal View article[1] on nurse training in sexual and reproductive health (SRH) that appeared in the January 2010 issue of this Journal.

SRH nursing appears to have gone full circle. During the last 33 years many courses have been open to doctors, nurses, midwives and health visitors, with examinations and diplomas being presented to successful candidates. Also nurses have struggled to be accepted in multidisciplinary teams and this is now well established.

Globally since the late 1960s, nurses/midwives with the appropriate recognised training have extended their roles in order to meet the needs of their communities and professional development. This has been supported by their medical colleagues.

I totally agree there is a lack of national recognised post-registration training in advanced knowledge and clinical skills of SRH.

The Faculty is globally recognised for academic expertise and development of standards of care and training. Surely now it is time for the Faculty to yet again approach the Chairman and Council of the Royal College of Obstetricians and Gynaecologists (RCOG) to make a special case to pioneer accrediting post-registration nurses in SRH?

The Royal College of Nursing (RCN) is not the appropriate professional body to accredit some courses and study days at an over-rated price for members/non-members.

Today families have to move around the country to seek employment. Surely potential employees have the right to a set of National Standards in SRH for their clients/patients. This should be a question for the Department of Health.

I have spent the last 30 years contributing to this field, and feel very strongly that it must not be just pushed under the carpet by a small number of medical and nursing colleagues.

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**Reference**
1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

In response to the recent article[1] on sexual and reproductive health (SRH) education for nurses, I would like to provide a higher education institute (HEI) perspective. As an educator and course deliverer, I would welcome professional bodies developing National Standards for SRH education and training, identifying roles and the core competencies for such roles.

If commissioners were required to fund only professionally badged courses, HEIs and other training providers would be forced to develop education and training programmes to meet these standards in order to attract students. HEIs must also find alternative ways of delivering such courses to increase access for training.

One key driver for commissioners and service deliverers would be that if staff were undertaking roles without such core competencies stated within their professional bodies' National Standards then they may be leaving themselves open to litigation. In following the model cited in the article would be an example of best practice, offering an opportunity to standardise SRH education and training, allowing HEIs the opportunity to accredit such courses.

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1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

I would like to respond on behalf of the Scottish SRH Lead Nurse Forum to the Mehigan *et al*. article[1] on nurse training in sexual and reproductive health (SRH) that appeared in the January 2010 issue of the Journal.

1. We would endorse the view that standardisation of core SRH theory and practice education, which is evidence based and regularly reviewed by SRH experts, is desirable and ultimately in the best interests of patients and employers. This allows for a transfer of skills when practitioners move location within the UK.
2. We would endorse the view that evidence of formal accreditation for learning is important as a means of quality assurance and governance. Currently in Scotland all accreditation is provided by Higher Education Institutes (HEIs). Employers would expect to fill posts with candidates who could provide evidence of accreditation in SRH from an HEI or, if a novice in SRH, candidates who are prepared to undertake HEI SRH modules.

3. In 2008 the Scottish SRH Lead Nurse Forum (representing each of the Scottish regions) formed a collaboration with the leads for SRH in each of the Scottish HEIs with a view to producing a Career and Education Framework for sexual health nursing. This work was supported and published by NHS Education Scotland (NES) in 2009. The Career and Education Framework is based on the Knowledge and Skills Framework (KSF),[2] the NHS Career Framework for Health[3] and the Scottish Credit and Qualifications Framework (SCQF).[4]
4. The intention in 2010 is to review current course content in order to provide recipients and employers with a standard content and level of delivery aimed at equipping nurses to work within modernised and integrated sexual health services. Clearly the Faculty's standards will be taken into account as we determine this. We are also considering future demand and capacity. We intend to agree how many courses are needed (including new modules/courses), what formats, content and level, and who is best equipped to provide these in future to ensure sufficient and high-quality access across Scotland with choice for practitioners and employers.
5. Since the Faculty e-learning material has only just been launched there has not been time to assess where it will fit in the overall picture of SRH training and education for both specialist and non-specialist nurses. It does need to be clearly 'badged' in terms of accreditation if it is not to get lost among some of the other online training resources aimed, in particular, at practice nurses. We plan to assess it against the NES Competency Record Book for sexual health nursing.[5]
6. We look forward to the outcome of the current pilot exercises in The Margaret Pyke Centre and Reading. Our general feeling is that it would be retrograde to suggest that nurses undertake courses of this magnitude without formal accreditation from a UK body.
7. Currently in Scotland there is still a small cohort of nurses who use 'credit points' obtained from HEI sexual health modules to count towards the achievement of a degree. As the profession becomes wholly degree educated this will no longer be an issue.
8. There is concern that there has been too little consideration of the implications for assessed practice for nurses if we were to adopt the e-FSRH theory component without having access to the full accredited DFSRH. We would encourage the Faculty to consider the possibility of nurses being able to qualify for the Diploma, which would then act as a benchmark.
9. Removing HEIs from the provision of assessed practice puts the onus on employers to manage this along with all governance aspects of training staff who are not employed within the organisation (e.g. registration checks). This is not impossible but very difficult for areas with low staff numbers.
10. We favour multidisciplinary training in core SRH.

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1 Mehigan S, Moore W, Hayes L, Nurse training in sexual and reproductive health care. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.
2 Scottish Executive Health Department. T*he NHS Knowledge and Skills Framework (NHS KSF) and the Development and Review Process*. Edinburgh, UK: Scottish Executive Health Department, 2004.
3 Skills for Health. *The Career Framework for Health*. 2006. http://www.skillsforhealth.org.uk [Accessed 2 March 2010].
4 The Scottish Credit and Qualifications Framework: The Level Descriptors. http://www.SCQF.org.uk [Accessed 2 March 2010].
5 NHS Education for Scotland (NES). *Competency Record Book: A Route to Enhanced Competence in Sexual and Reproductive Health Nursing* (post-registration and pre-specialist level). 2007.

## RCN response

The Royal College of Nursing (RCN) would like to make the following points in response to the article[1] on nurse training in sexual and reproductive health by Shelley Mehigan *et al*. published in the January 2010 issue of the Journal.

The article states that "the RCN removed the specialist sexual health adviser post which was a detrimental and backward step". We fundamentally disagree with this view. The RCN places a firm emphasis on public health. Sexual health nurses have seats on the public health forum and this is working well, with clear programmes of work being developed around sexual health issues. We believe this model provides a broader perspective than simply having one Sexual Health Adviser.

Second, RCN accreditation is provided to external organisations seeking accreditation for events, resources and courses. The fee is in two bandings: a lower rate for National Health Service (NHS) Trusts and not-for–profit organisations, and a higher rate for for-profit companies. There is no differential made between applicants who are RCN members and those who are not.

Evaluation of our accreditation service shows that the reason organisers from various organisations apply for accreditation is that they wish to associate their names with the RCN's high standards and commitment to professional development. We have evidence to show that employers who know that RCN-accredited events are educationally robust, focused on nursing practice and evidence-based are more likely to release their staff to attend RCN-accredited events.

There is a difference in the cost of accreditation for members and non-members seeking to be accredited for fitting IUTs/IUSs and SDIs. Membership of the RCN is open to all nurses, and is a matter of personal choice. However, in common with all membership organisations, the RCN offers membership benefits such as this reduced fee.

In terms of education, it is accepted that there is a lack of consistency in the content of many professional programmes since the National Boards ceased to exist. To address this, and to contribute to quality of care in practice, the RCN has developed a number of standards and competency frameworks to provide an evidence-based benchmark in order that programmes, or an individual's experience, might be mapped against the evidence and current best practice. The processes used by the RCN Accreditation Unit are robust and supported by experts in the relevant fields of practice.

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**Reference**
1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.

## Authors' response to corespondence about Nurse Training in SRH

We would like to thank all those who responded to our article.[1] As Journal readers will see, most respondents are in agreement with our concerns and are supportive of the suggestions we made as to how nurse training in SRH might be delivered in the future. In addition to the written responses we have heard from a number of people who have expressed the same views verbally.

In specific response to the letter from the Royal College of Nursing (RCN),[2] we were surprised to read their comment about the current situation being better than "simply having one Sexual Health Adviser". The sexual health (and previous family planning forum) was one of the longest established and most active forums within the RCN, with up to seven representative members on the steering group supported by an adviser who was qualified and experienced in the field. We are aware of instances now of members being unable to get answers from people with sexual health knowledge or qualifications to concerns about which they have contacted the public health team. We would repeat our concern, namely that since most Level 1 sexual health care is delivered in general practice, and many practice nurses are members of the Medical Defence Union (MDU) in preference to the RCN, this has implications for the cost incurred for accreditation.

We are delighted that the National Support Team for Sexual Health and Sexual Health Policy Team at the Department of Health (DH) has recently appointed Anita Weston (formerly Nurse Adviser for Sexual Health at the DH) to undertake a 4-month project on 'Nurse Education in Sexual Health'. The aim of this project is to bring together the various pieces of work and educational initiatives that a number of organisations in the field have developed, and to consider an overall nationally recognised and standardised educational pathway for nursing in sexual and reproductive health in England.

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1 Mehigan S, Moore W, Hayes L. Nurse training in sexual and reproductive health. *J Fam Plann Reprod Health Care* 2010; **36**: 5–6.
2 Davies J. RCN response [Letter]. *J Fam Plann Reprod Health Care* 2010; **36:** 111.

## LETTERS TO THE EDITOR

Letters to the Editor are welcome and generally should not exceed 600 words or cite more than five references. For comments on material published in the most recent issue of the Journal, correspondence should be received within 4 weeks of dispatch of that Journal to be in time for inclusion in the next issue. When submitting letters correspondents should include their job title, a maximum of two qualifications and their address(es). A statement on competing interests should also be submitted for all letters. Letters may be submitted to the Editor or the Journal Editorial Office (details on page 50).