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Editor's Note: Missed pill correspondence

Interested readers may wish to note that there has been a letter[1] from the Clinical Effectiveness Unit (CEU) published in the *Lancet*, in response to the April Editorial[2] by Diana Mansour and Ian Fraser.

The main points of this letter can be summarised as follows: The authors believe that most women know the name and type of their pill and would be able to apply the recommendations. They believe having different rules for 20 and 30 μg ethinylestradiol pills minimises intervention and inconvenience for the maximum number of women. They state a pill has been missed only when 24 hours have elapsed after the scheduled time. They did not review the three studies cited by Mansour and Fraser as suggesting caution about extending the pill-free interval beyond 7 days; two were published after the World Health Organization recommendations were developed. Finally, the Faculty of Family Planning and Reproductive Health Care's philosophy is to be guided by evidence, not fear of litigation.

A comment in response to the letter has been placed on the *Lancet's* website.[3] For our readers' convenience, we have permission to reproduce it in full below.

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1 Penney G, Brechin S, Glasier A, Bigrigg A. Missed contraceptive pill recommendations. *Lancet* 2005; **366**: 1264. DOI: 10.1016/S0140-6736(05)67522-8.
2 Mansour D, Fraser IS. Missed contraceptive pills and the critical pill-free interval. *Lancet* 2005; **365**: 1670–1671.
3 http://www.thelancet.com/journals/lancet/article/PIIS0140673605675228/comments?action=view&totalComments=1.

Comment on *Lancet website*: Missed pill guidelines

Dear Sir

In the same week that the Faculty of Family Planning's Clinical Effectiveness Unit (CEU) stated that "we assume that most women know the name and type of their pill",[1] a paper in the *Journal of Family Planning and Reproductive Health Care* showed that 41% of a group of educated women were not even sure whether they were taking a high- or a low-dose pill.[2] In the same issue of that Journal, Thurrock Primary Care Trust explained that they felt they could not use the new guidelines in their area because their clients "would have difficulty following the new advice".[3]

There have been letters to that Journal pointing out the deficiencies of the CEU's guidelines on missed pills, over the last 6 months, yet the widespread concerns are simply being ignored by the Faculty. Is it a valid excuse to say that papers that suggest their guidelines are unsafe were published after the WHO recommendations? Why did the CEU not take those findings into account when considering important new guidelines?

Competing Interests: None.

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3 Willis C, Whitwell I. Missed pill guidelines (Letter). *J Fam Plann Reprod Health Care* 2005; **31**: 336; author reply, 336.

Interested readers should refer to the *Lancet's* website for any further responses or comments.

DMPA and BMD

Following the Committee on Safety of Medicines (CSM) advice for prescribers of depot medroxyprogesterone acetate (DMPA) in November 2004, there has been continued discussion regarding its effects on bone mineral density (BMD), and what this may mean long term for bone health and fracture risk.

To examine women's views and knowledge regarding this issue we produced a short anonymous questionnaire for women using DMPA who attend contraception and sexual health clinics in Newcastle-upon-Tyne. It was given to all women prior to their consultation appointment at three clinics between January and June 2005.

All 64 patients to whom the questionnaire was given completed it, and their ages ranged from 17 to 46 (mean, 25.8) years. They had been using DMPA for between 3 months and 9 years (mean duration of use, 2.6 years).

Of these patients, 53 (83%) were aware of the possible effects of DMPA on BMD, and all of these women felt that their concerns had been discussed. Four of these patients (all in their twenties) were considering a change of contraception following reading about the CSM advice in the media or as a result of discussing this issue with a health care professional. One woman was definitely going to change her method of contraception to a progestogen-only implant.

Those women who were not considering a change to their contraception (i.e. 90.5% of those aware of the link with reduced BMD) cited various reasons for continuing DMPA including:

- the potential reversibility of BMD changes
- researching the topic themselves and finding the evidence weak
- belief that they were not at risk of osteoporosis
- worrying about forgetting pills
- concern related to side effects with other forms of contraception.

There were 11 patients who stated that they were not aware of any effects DMPA may have on bone health. This was 17% of the sample, which is rather concerning. All the patients said they had been given a Family Planning Association leaflet on injectables before or at the start of DMPA use, which highlights the importance of ensuring patient understanding within the consultation rather than relying on written information which may not be read, understood or retained. All the women in this group had the effects of DMPA on BMD discussed with them after completion of the questionnaire and all decided to continue using this method of contraception.

As health professionals, it is easy to presume that women attending for repeat prescriptions are aware of issues regarding their contraceptive method. However, patient choice can only be informed if it is based on current evidence, even if this involves sharing uncertainty regarding guidance.

From this small audit only one woman planned to change her contraceptive method from DMPA, although four others were considering a change (8% of the total). We do not know, however, how many women have chosen to start other birth control methods in the light of this information or those who have discontinued DMPA and are now using less effective methods. Overall DMPA still remains a popular choice for women wanting a highly effective yet reversible method of contraception, and the majority of established users surveyed wish to continue its use.

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Audit of documentation of female sterilisation

We read with great interest the paper by Anderson *et al*. on documentation of preoperative counseling for female sterilisation: a complete audit cycle[1] in which the authors have provided evidence on the usefulness of a standardised proforma in the documentation of counselling women requesting sterilisation. Their documentation was fully compliant with the Royal College of Obstetricians and Gynaecologist (RCOG)'s guidelines[2] only when a standardised proforma was used during the counselling.

A recently completed re-audit of documentation of female sterilisation carried out in our department has identified areas where there is room for further improvement in our practice. It is our experience that the awareness of the standards set out in the RCOG's guidelines was not enough on its own to facilitate changes towards improving the quality of communication and to ensure that our documentation process was fully compliant with the RCOG's guidelines.

Sterilisation is a major cause of litigation involving gynaecological practice, accounting for 25% of all claims notified to the Medical Defence Union.[3] In order to minimise the risk of litigation, the need for adequate documentation and the use of a checklist as an important part of informed consent procedures was identified in a previous study.[4]

The present authors have now demonstrated that the introduction of a standardised proforma can significantly improve the level of compliance with the RCOG's guidelines by improving the quality of documentation.[1]

If our ultimate goal is to improve the quality of care and thereby reduce the high level of complaints and litigation associated with female sterilisation, then the available evidence would suggest that units providing the female sterilisation service should seriously consider the use of a standardised proforma that would ensure that a consistent and adequate information as recommended by the RCOG is provided to all patients requesting sterilisation.

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3 Yunus D, Sarkar PK. Re-audit on medical record keeping in female sterilization. East Lancashire Hospitals NHS Trust, June 2005.
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Effective copper surface area of IUDs

Many providers of intrauterine devices (IUDs) wrongly believe that the nominal surface area of copper IUDs equals the effective copper surface area. The reality is different, however. This letter explains the situation.

Studies suggest that a good contraceptive efficacy is obtained with IUDs having a copper surface area of 200 mm^2. Failure rates of the T-Safe® TCu200 are of the order of 3.0 at 2 years. When the copper surface area is increased to 380 mm^2, failure rates are usually less than 1.5 at 2 years. No additional reduction in failure rate is seen when the copper surface area is increased further.

These clinical studies were conducted with copper IUDs provided with a copper wire wound around the stem of the IUD. It is important to distinguish between IUDs with copper wire and the ones that have copper sleeves or a combination of the two. The remark by Kosonen is important: "Only in the case of sleeves is the nominal and the effective surface area the same. When copper wire is used, that part of the wire lying against the plastic body is ineffective and should not be calculated as a part of the effective surface area".[1] Other researchers confirm these findings: "The portions of the wire winding in contact with the plastic surface give off hardly any copper".[2] Chantler writes: "It has been shown that there is negligible corrosion of the copper in contact with the plastic core and that this area should be discounted in the calculation of the active surface area of the copper".[3] The effective copper surface area of the TCu200 IUD is only 120 mm^2 and of the T-safe® TCu380A IUD 252 mm^2 (Figure 1). This research also showed that copper release is lower the more the winding of the copper wire is tighter. This is the case with high-load copper IUDs such as Multiload® Cu375 and TCu380A. One could conclude that 40% of the copper wire is 'ineffective'.

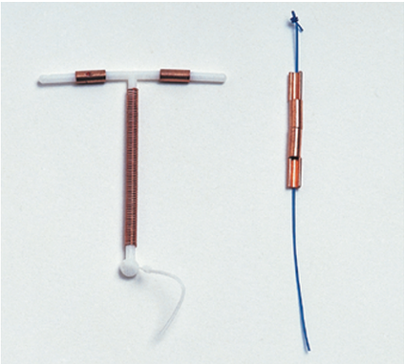

Figure 1 *T-safe® TCu380A IUD (left) and GyneFix® 200 IUD (right)*

With the frameless GyneFix® IUD, all surface areas are exposed to the uterine environment. This is a fundamental difference compared to conventional IUDs. Copper-release studies with the standard GyneFix 330® IUD removed after more than 10 years of use have shown that the copper surface area decreases very little over that period, only 7% after 12 years of use (Contrel, manufacturer's data on file). This could explain the high efficacy of the small GyneFix® 200 IUD (Figure 1), less than 1.0 at 3 years of use,[4] and the absence of increase in annual pregnancy rate with GyneFix as the surface area of the GyneFix IUD decreases very little over time. The copper content of the GyneFix 200 is 280 mg, which is higher than the copper content of TCu380A (244.7 mg of copper) having a lifespan of at least 10 years.

The smaller the size of the GyneFix the less the effect on menstrual blood loss. Women wearing the small GyneFix 200 IUD report a similar bleeding pattern when compared with the bleeding pattern before insertion of the IUD.[5] At the same time, the small surface area optimises tolerance. This could be important since abnormal bleeding and pain are the two major reasons for IUD discontinuation.

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Statement on competing interests
Dirk Wildemeersch is a Belgian gynaecologist and Medical Director of Contrel Research, a company which was established to manage clinical research and to develop and study innovative drug delivery technologies, aimed at finding improved methods for prevention and treatment of gynaecological conditions, improvements to birth control methods, and higher levels of safety, user acceptability, compliance and quality of life for women. Contrel Research manufactures and distributes GyneFix® and FibroPlant® IUDs.

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Inappropriate advertising?

I was shocked to see the Emotional Bliss advertisement in the last issue of the Journal (*J Fam Plann Reprod Health Care* 2005; **31**: 301). I do not feel that such advertisements conform to the ethical medical standards of a scientific journal. I fully understand that commercials are essential to finance the publication of a journal but advertisements of sex toys are totally out of character of a scientific journal.

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Reply

I was sorry to hear that Dr Qureshi objected to this advertisement. Many of the readers of this journal are necessarily involved in psychosexual therapy as part of their professional activities. In 2004, the journal published a special supplement about parenthood, emotional well-being and sexuality in which an advertisement for the firm Emotional Bliss appeared and was welcomed by the readership. Our readers are mainly concerned with contraception and reproductive health and, because of this, they treat more women than men. The commonest sexual problem in women is loss or lack of libido. Whatever a therapist's personal feelings about the use of sexual aids, it has been shown that they are a useful adjunct to treatment for sexual responsiveness in many women. The Journal's Editorial Board believes that enabling doctors and therapists to recommend a safe and discrete source for sexual aids assists the women that they are treating.

Anne Szarewski, PhD, FFFP
Editor-in-Chief, Journal of Family Planning and Reproductive Health Care (on behalf of the Editorial Board)

ERRATA

Chlamydia screening in general practice: views of professionals on the key elements of a successful programme, Ma R, Clarke A, *J Fam Plann Reprod Health Care* 2005; **31**(4): 302–306

The Journal wishes to apologise for any inconvenience or embarrassment caused to Dr Aileen Clarke that might have resulted from her name appearing in print as Aileen Clark within this article and on the contents page of the journal issue.

Community-based distribution and contraception usage in Iran, Jahanfar S, Ghodsi M, Shahpoorian F, Jamshidi R, *J Fam Plann Reprod Health Care* 2005; **31**(3): 194–197

Unfortunately the details printed in the article for one of the contributing authors, Dr Zahra Ghodsy, were incorrect. The correct information is as follows: Dr Zahra Ghodsy, Azad University of Toyserkan, Hamedan, Iran. The Journal wishes to apologise unreservedly to Dr Ghodsy for any inconvenience and embarrassment this inadvertent error might have caused.

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