



LETTERS

EID use and normal 7-day PPIs first emerged in the 50–100 µg pill era! Indeed, in the Mayo Clinic-based collected series,⁷ 16/25 women who, despite allegedly good pill-taking, conceived on enzyme-inducers were taking 50 µg pills; and the remaining nine were taking 100 µg pills (with mestranol!).

Please, may we have our tricycle back?

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- 2 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Faculty Statement from the CEU on a New Publication WHO Selected Practice Recommendations for Contraceptive Use Update. Missed pills: new recommendations. *J Fam Plann Reprod Health Care* 2005; **31**: 153–155.
- 3 Spona J, Elstein M, Feichtinger W, Sullivan H, Ludicke F, Muller U, et al. Shorter pill-free interval in combined oral contraceptives decreases follicular development. *Contraception* 1996; **54**: 71–77.
- 4 Guillebaud J. *Contraception: Your Questions Answered*. Edinburgh, UK: Churchill Livingstone, 1985: 142.
- 5 Sullivan H, Furniss H, Spona J, Elstein M. Effect of 21-day and 24-day oral contraceptive regimens containing gestodene (60 microg) and ethynodiol diol (15 microg) on ovarian activity. *Fertil Steril* 1999; **72**: 115–120.
- 6 World Health Organization (WHO). *Medical Eligibility Criteria for Contraceptive Use* (3rd edn). Geneva, Switzerland: WHO, 2004. <http://www.who.int/reproductive-health/publications/mec/index.htm>.
- 7 Coulam CB, Annegers JF. Do anticonvulsants reduce the effectiveness of oral contraceptives? *Epilepsia* 1979; **20**: 519–525.

Reply

We welcome the opportunity to respond to these comments on our FFPRHC Guidance on 'Drug interactions with hormonal contraception' published in the April issue of the Journal.¹ Your correspondent draws attention to a paper by Spona *et al.* which provides some evidence to support a reduction in the pill-free interval in women taking concurrent liver enzyme-inducers.² As explained in our response to your correspondent, Graham Davies, we failed to identify this paper during our systematic review for the 'Drug interactions' Guidance; but did identify it during development of our subsequent Guidance on 'The use of contraception outside the terms of the product licence'.³

Within the limits of our resources, the CEU always endeavours to undertake a fully comprehensive and systematic literature search in the preparation of Guidance. Nevertheless, relevant papers occasionally are missed by the search strategies used. We are always grateful to Faculty members for alerting us to evidence that we may have overlooked. Such evidence will be taken into account when Guidance is updated.

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Missed pill guidelines

We manage a family planning contraception service for the under-25s in South West Essex, and we are writing to express our service's concerns about the new missed pill guidelines. Our young service users often lead chaotic lifestyles with

subsequent chaotic pill taking. By promoting the new advice we feel that we would be giving them further leeway to miss pills, which could result in an increase in unwanted pregnancies. Some of our service users have poor literacy skills and would have difficulty following the new advice in the fpa leaflet. They have to rely on a clear explanation of pill taking from staff, and the old advice is a lot easier to explain verbally. At present the fpa leaflet advice contradicts that given in the patient information leaflets provided by the pill manufacturers. We understand that the manufacturers advice is unlikely to change since this would involve new product licences being sought. Our concerns were discussed at Thurrock PCT's Medicine Management Committee last month and it was decided that at present all contraception providers working for the PCT should continue to adhere to the former missed pill advice. This recommendation is to be taken to the South West Essex Medicine Management Committee.

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Reply

We welcome the opportunity to respond to these comments on the 'new missed pill rules' published by the WHO¹ and endorsed in our Faculty Statement published in the April 2005 issue of the Journal.² Your correspondents' main points are: that young people often have chaotic lifestyles and chaotic pill-taking routines (and that the 'new rules' appear to promote greater leeway and laxity); and that the 'new rules' are at odds with information in the patient information leaflets provided by manufacturers.

We acknowledge the lifestyle factors that influence contraceptive choices for young people. The new 'missed pill rules' do not negate or contradict the responsibility of clinicians caring for young people to promote the fundamental importance of regular, disciplined, pill-taking routines. Pragmatic measures, such as use of the alarm call facility on a mobile phone, can assist young people in maintaining the necessary routine. We do not believe that evidence-based missed pill rules, which minimise unnecessary interventions for the maximum number of women, condone or reinforce poor pill-taking routines. If a young woman has a lifestyle that is incompatible with regular pill taking, then she needs a user-independent method of contraception, not 'stricter' missed pill rules.

We also acknowledge that the new WHO recommendations differ from the advice given in manufacturers' leaflets. However, the problem of conflicting information from different sources is not new. Advice given in different manufacturers' leaflets varies in some details, as does advice in the *British National Formulary*. Achievement of uniformity and consistency was one of the reasons given by the WHO for publishing the new advice.

We disagree that the new advice is more difficult than the old to explain verbally to an individual patient. Each woman need only be given the 'rules' that apply to her own pill formulation (20 µg or ≥30 µg ethynodiol diol); there are fewer circumstances in which she must adopt any special measures (only if she has missed 'two for twenty' or 'three for thirty' pills); and there are fewer circumstances in which emergency contraception must be considered (only if pills have been missed in Week 1 of the pill-taking cycle).

Thus, the CEU stands by their endorsement of the WHO's 'missed pill rules'. Nevertheless, an individual clinician managing an individual patient may choose to give different advice tailored to individual circumstances, or based on his/her own interpretation of available evidence.

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Preoperative counselling for female sterilisation

I read with great interest the article by Philip Owen and colleagues on 'Documentation of preoperative counselling for female sterilisation'.¹ A similar audit was conducted recently in the Department of Obstetrics and Gynaecology, Nobles Hospital, Isle of Man and included 81 cases which were admitted for sterilisation between October 2002 and September 2004. The auditable standards were obtained from the Clinical Guidelines No. 4 of the Royal College of Obstetricians and Gynaecologists (RCOG), (published in January 2004) and the RCOG Consent Advice 3 (published in October 2004). Data were collected retrospectively from the case notes.

The results of the audit were as follows:

- Discussion regarding vasectomy was recorded in 60% of the case notes.
- Discussion regarding Implanon® was recorded in 60% of the case notes.
- Discussion regarding Mirena® was recorded in 84% of the case notes.
- Discussion regarding Depo-Provera® was recorded in 54% of the case notes.
- Discussion regarding the failure rate was recorded in 95% of the case notes.
- Discussion regarding risks specific to laparoscopy and risk of minilaparotomy were recorded in 89% of the case notes.
- Discussion regarding the risk of ectopic pregnancy in cases of failure was recorded in 85% of the case notes.
- Discussion regarding irreversibility was recorded in 94% of the case notes. However, discussion regarding the reversal procedure and its success rates were only recorded in 1% of the case notes.
- Advice regarding use of effective contraception until the next period was recorded in 19% of the case notes.

It was concluded that documentation of preoperative counselling for female sterilisation needs to be improved. It was recommended that a 'tick box' proforma should be used, and to do a re-audit in 12 months' time to check whether the introduction of the proforma has resulted in an improvement of documentation.

The female sterilisation procedure is very commonly performed and has the potential to attract complaints and litigation. I have a few comments to make regarding the sample proforma that was included in the article.

The Consent Advice 3 of the RCOG recommends that the procedure should be called a laparoscopic tubal occlusion. Moreover, the risk of death (which is 1 in 12 000 procedures performed) should be mentioned. During the preprocedure discussion it is difficult to emphasise the irreversibility of the procedure whilst at the same time talking about the reversal procedures and their success rates.