LETTERS

EID use and normal 7-day PFIs 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 mestrano!)

Please, may we have our tricycle back?

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References

- 1 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. FFRHC Guidance (April 2005). Drug interactions with hormonal contraception. *J Fam Plann Reprod Health Care* 2005; **31**: 139–150.
- 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 ethinylestradiol (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 FFRHC 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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References

- 1 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. FFRHC Guidance (April 2005). Drug interactions with hormonal contraception. *J Fam Plann Reprod Health Care* 2005; **31**: 139–150.
- 2 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.
- 3 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. FFRHC Guidance (July 2005). The use of contraception outside the terms of the product licence. *J Fam Plann Reprod Health Care* 2005; **31**: 225–242.

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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Ivy Whitwell, Qualifications?

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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 ethinylestradiol); 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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References

- 1 World Health Organization (WHO). *Selected Practice Recommendations for Contraceptive Use* (2nd edn). Geneva, Switzerland: WHO, 2005. http://www.who.int/reproductive-health/publications/spr_2/index.html [Accessed 19 August 2005].
- 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.

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 periods 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.

I would be grateful for the authors' thoughts on this matter.

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Reference

- 1 Anderson J, Gunn E, Hunter M, Owen P. Documentation of preoperative counselling for female sterilization: a complete audit cycle. *J Fam Plann Reprod Health Care* 2005; **31**: 24-25.

Reply

Dr Qureshi's interest in our article is most welcome. The results of the audit from Dr Qureshi's unit suggest that the introduction of a standardised proforma might be expected to improve compliance with RCOG guideline recommendations.

As regards to whether the procedure is called 'laparoscopic tubal occlusion' or 'laparoscopic sterilisation', whilst the former may be more precise, the latter is likely to be more easily recognised as an identifiable procedure by most of our patients. Preoperative counselling is an exercise in communication and we should strive to use the terminology that is most easily understood by our patients.

The publication of the consent advice from the RCOG postdated our audit, so quoting a risk of dying from the procedure was not included as an auditable standard. Whilst there should be no difficulty in explaining that the procedure must be considered irreversible, I agree that to then discuss the availability and results of sterilisation reversal seems contradictory. This latter dilemma is not an issue locally since our Health Board do not permit us to perform sterilisation reversal procedures.

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Pelvic examination for detecting ovarian cancer

I was very disappointed to read Gill Wakley's website review in the last issue of the Journal.¹ Have we finally abandoned clinical common sense on the altar of guidelines and evidence-based medicine?

Nobody with any sense would advise a pelvic examination as a means of detection of ovarian cancer. The main reason for performing a bimanual examination prior to taking a smear is to enable that examination to be easier and more comfortable for the patient. It enables the smear taker to choose the correct speculum (extra long, virgin, etc.) and hopefully to locate the cervix at the first attempt. How else would one know that the uterus was sharply retroverted and the cervix anterior behind the pubic symphysis? Repeatedly opening and closing the speculum in an attempt to find the cervix is very uncomfortable (I have been on the receiving end!). If one can locate the cervix first time, the procedure is much easier for everybody. I have lost count of the number of women who have said: "Is that all? Last time it took much longer".

A bad experience having a smear taken is often a reason for patients declining further screening.

Of course, all sorts of valuable information can be gained by a pelvic examination. Discomfort can prompt tactful questioning about dyspareunia, which is often not presented as a symptom. If the uterus is enlarged, direct questions about menorrhagia may elicit symptoms that have not been directly complained about. I have even found the odd retained tampon that may account for symptoms. As a hospital gynaecologist, I have on several occasions seen women referred with retained tampons that had not been detected as a speculum often pushes the tampon out of the way but does not discover it.

Then, of course, if one did find an ovarian cyst, would it not be better for the woman if it were found and acted on regardless of whether it is malignant?

I will continue to advise trainees that I think the bimanual examination is part of the taking of a smear ... but then I don't write the guidelines!

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Reference

- 1 Wakley G. NLH primary care question answering service [Website Review]. *J Fam Plann Reprod Health Care* 2005; **31**: 212.

Reply

There appear to be two main issues raised in this letter.

First, the website review is reporting the answer to a specific question. Dr Devonald raises another question by suggesting that the guidelines for taking a cervical smear should be altered to include a digital vaginal examination to establish the position of the cervix, before inserting the speculum. This would make an excellent question for the NELM primary care question service, namely: 'By how much does a prior vaginal digital examination impair the accuracy of a cervical smear sample?' If the answer is that it does not, then there are training implications for the many nurses who take cervical smears but have not been trained to carry out a digital vaginal examination.

Second, Dr Devonald goes on to suggest that although it cannot reliably detect ovarian cancer, a pelvic examination is useful. But useful for what?

An examination on a patient without symptoms is a screening test and it is quite clear from the literature that a pelvic examination fails the criteria for a screening test.^{1,2} For example, it does not identify reliably, at an early stage, conditions that can be treated to prevent progression. It may do harm by identifying conditions that are not significant and expose the patient to unnecessary further investigations. It may do harm by giving false reassurance of normality.

As a preliminary investigation of a patient with symptoms, it may sometimes be useful, but is not accurate enough to preclude further investigation of symptoms by other means such as ultrasound or laparoscopy.^{3,4}

A large number of questions and answers now appear in the women's health section of this NELM service,⁵ many of which health professionals will find instructive and useful, as they are based on real clinical problems.

Gill Wakley, MD, MFFP

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References

- 1 Cochrane AL, Holland WW. Validation of screening procedures. *Br Med Bull* 1971; **27**: 3-8.
- 2 Grover SR, Quinn MA. Is there any value in bimanual pelvic examination as a screening test? *Med J Aust* 1995; **162**: 408-410.
- 3 Carter J, Fowler J, Carson L, Carlson J, Twigg LB. How accurate is the pelvic examination as compared to transvaginal sonography? A prospective, comparative study. *J Reprod Med* 1994; **39**: 32-34.
- 4 Nezhat C, Santolaya J, Nezhat FR. Comparison of transvaginal sonography and bimanual pelvic examination in patients with laparoscopically confirmed endometriosis. *J Am Assoc Gynecol Laparosc* 1994; **1**: 127-130.
- 5 <http://www.nelh.nhs.uk/>.

Copying clinic letters to patients

I read with interest Anna Glasier's contribution to Personal View in the April edition of the Journal.¹

Whilst noting that she found it difficult to draw precise conclusions from her small project, I should like to add our own findings from a more

general patient population to support her impressions.

We conducted an audit into the system for 'Copying Letters to Patients', which had been set up at Barnsley Hospital NHS Foundation Trust in response to the Department of Health Initiative first noted in the NHS Plan.² Our findings mirrored those of Anna Glasier in that patients were enthusiastic about the initiative but that medical, nursing and administrative staff were much less so.

Eighty-five case notes were reviewed as an unselected sample of patients attending a first outpatient appointment in General Medicine, Orthopaedics, Rheumatology or General Surgery. Confirmation of a wish to receive a copy letter was present in 40 cases and all of these patients were asked to complete a questionnaire by post on their satisfaction or otherwise after receiving the copy letter. Some 130 clinical and administrative staff were asked to complete a similar questionnaire. Both patients and staff were also allowed the opportunity in the questionnaire to comment by means of free text.

Staff were generally critical, regarding the initiative as time consuming, bureaucratic and a duplication of time and effort, potentially leading to increased work from telephone calls from patients who had not understood some of the medical terms used in the letter. Patients were correspondingly enthusiastic, with the majority saying that the copy letters helped them to understand their condition or illness and what would happen to them next, as well as being a reminder of what was said during their consultation. Only one patient said that they had noticed a factual error in the letter and all remarked that they could understand the medical terminology used.

The outcomes are so similar to Anna Glasier's findings that I would conclude that the nature of the information being sent to the patient has little bearing on their satisfaction at having received it. The highly personal nature detailing a sexual health consultation appears to be no more or less inhibitory to its formal documentation than a history taken that does not require such intimate detail to be recorded.

Equally striking was the suspicion and uncertainty with which staff approached this issue.

Our personal view is that in terms of this initiative staff appear to have a common hesitant approach but that patients are more sophisticated in their wish to understand their own personal health information than their health worker carers give them credit for.

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References

- 1 Glasier A, Gebbie A, Cowan F. Is it helpful to send copies of clinic letters to women following consultations in sexual health? *J Fam Plann Reprod Health Care* 2005; **31**: 101-102.
- 2 Department of Health. *The NHS Plan*. London, UK: Stationery Office, 2000.

Invisible contraception?

I thought others might be interested to hear a comment passed on to me in my family planning clinic today. My client noticed her friend's Implanon® rod glowing under UV lighting while they were in a nightclub. It didn't put her off having one fitted herself, but maybe we should warn people that their 'invisible' contraceptive method may be seen in these circumstances.

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