

## LETTERS

# Letters to the Editor

## Practice-based commissioning

Richard Ma raises some very interesting points in his commentary about practice-based commissioning (PBC) and its impact on sexual health services in this issue of the Journal.<sup>1</sup> In my view, he is right to encourage sexual health providers to start thinking now about the opportunities that the new arrangements may provide for developing a more integrated service that encompasses contraception, abortion and STI provision in a community setting. A major barrier to doing so is the 1967 Abortion Act, which states that abortions can only take place in NHS hospitals or in licensed premises. However, a creative collaboration with a local acute trust may overcome this difficulty, as is already the case in some places.

While PBC does present opportunities for new partnerships and improved patient pathways, there are also risks associated with it. For example, some GP practices do not see the need for dedicated contraceptive services, and with the increased influence that general practice will have on the shape of services this may mean that community contraceptive clinics are no longer commissioned to provide services.

Where this happens, as is highly likely in some areas, there will be a major loss of expertise, which will have far reaching consequences for contraceptive services not only now but in the future. It will destroy the three-level model for sexual health services that is the basis of the National Strategy for Sexual Health and HIV. The already greatly stretched training capacity, which is unable to meet current needs, will be further reduced. And professionals providing Level 1 and 2 services will no longer have the support they need from family planning consultants and specialist family planning nurses. Above all, many women will no longer have access to a full range of contraceptive methods because their general practice does not provide them.

When the Government's proposals for changing the emphasis of primary care trusts (PCTs) away from providing services to commissioning were first announced, the indication was that PCTs would no longer provide any services at all. This created major concerns for sexual health services because of the lack of alternative providers (other than for some specific services in some parts of the country) and fears about fragmentation of services. The Government has now clarified the situation: PCTs will continue to employ clinical staff and any decisions about divestment of services will be made locally by the PCT. Such decisions will be taken in the light of the White Paper on health outside hospitals. We can only hope that the White Paper will create an environment in which the networks and collaboration between different components of a comprehensive sexual health service can flourish.

PCTs have a vital role in ensuring the health and well-being of their populations, and sexual health services are vital to improving health and reducing health inequalities. As PBC is implemented, the partnership between general practice and PCTs will be crucial in ensuring that adequate resources are allocated to improving and developing sexual health services. Above all, we need to maintain the pressure on PCTs to give sexual health the priority it deserves.

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### Reference

- 1 Ma R. Practice-based commissioning and sexual reproductive health services: opportunities and threats. *J Fam Plann Reprod Health Care* 2006; 32: 7-9.

## NICE Guidance on LARC

I welcome the useful advice in the National Institute for Health and Clinical Excellence (NICE) long-acting reversible contraception (LARC) Guidance and am pleased to see that it states that all progestogen-only methods may be used by women who have migraine with or without aura.<sup>1</sup> However, although this broad recommendation is applied to injectable contraceptives and subdermal implants, it is unclear for the levonorgestrel intrauterine system (LNG-IUS).

The Guidance notes an increase in headache incidence with IUS use and that "In the current WHO-MEC recommendations, the LNG-IUS is assigned to (WHO) category '2' for initiation and category '3' for continuation in women who have migraine with focal symptoms at any age". Although the subsequent recommendation by NICE is that "progestogen-only methods, including the IUS, may be used by women who have migraine with or without aura", it is unclear to me if NICE is suggesting that the WHO-MEC guidance does or does not apply.

I understand the potential concern of increased headache reported in LNG-IUS users. However, there are no data to support that its use is associated with an increase in aura. Although it is recognised that women who have migraine, particularly with aura, and take combined oral contraceptive pills are at increased risk of ischaemic stroke,<sup>2</sup> this is not the case for progestogen-only contraception.<sup>3-5</sup> Hence, progestogen-only contraception can be used by women with any type of migraine, irrespective of whether aura is present before, or develops after, commencing the method.<sup>6</sup> Clearly, it may be worth considering stopping the method to assess whether or not symptoms improve, but this should be on clinical grounds, not on safety. Hence I recommend that both NICE and WHO should consider migraine aura to be WHO Category 2 for both initiation and continuation of all progestogen-only methods.

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- 1 National Institute for Health and Clinical Excellence. *Long-acting Reversible Contraception: The Effective and Appropriate Use of Long-acting Reversible Contraception*. London, UK: Royal College of Obstetricians and Gynaecologists Press, 2005.
- 2 Etminan M, Takkouche B, Isoma FC, Samii A. Risk of ischaemic stroke in people with migraine: systematic review and meta-analysis of observational studies. *BMJ* 2005; 330: 63-65.
- 3 Tzourio C, Tehindrazanarivo A, Iglésias S, Alépérovitch A, Chedru F, d'Angle-Chatillon J, et al. Case-control study of migraine and risk of ischaemic stroke in young women. *BMJ* 1995; 310: 830-833.
- 4 Cardiovascular disease and use of oral and injectable progestogen-only contraceptives and combined injectable contraceptives. Results of an international, multicenter, case-control study. World Health Organization Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. *Contraception* 1998; 57: 315-324.
- 5 Heinemann LA, Assmann A, DoMinh T, Garbe E. Oral progestogen-only contraceptives and cardiovascular risk: results from the Transnational Study on Oral Contraceptives and the Health of Young Women. *Eur Contracept Reprod Health Care* 1999; 4: 67-73.
- 6 MacGregor EA, Guillebaud J. Combined oral contraceptives, migraine and ischaemic stroke. Clinical and Scientific Committee of the Faculty of Family Planning and Reproductive Health Care and the Family Planning Association. *Br J Fam Plann* 1998; 24: 55-60.

## Emergency contraception and liver enzyme-inducing drugs

The CEU Guidance on drug interactions with hormonal contraception<sup>1</sup> includes discussion on progestogen-only emergency contraception in women using liver enzyme-inducing drugs. In Table 2 of page 145 I read: "Take a total dose of 2.25 mg levonorgestrel as a single dose as soon as possible and within 72 hours of unprotected sex". The authors stated on page 146: "The most recent

BNF, however, supports taking 2.25 mg LNG as a single dose at first presentation. The CEU was unable to identify any new data to support a single dose of 2.25 mg LNG".

The *British National Formulary (BNF)*, Volumes 49 and 50 of March 2005 and September 2005 reported, under interactions on pages 407 and 412, respectively, the following: "For emergency contraception in patients on liver enzyme-inducing drugs, 1.5 mg levonorgestrel is taken immediately and 750 µg taken 12 hours later".<sup>2,3</sup>

A previous CEU Guidance on emergency contraception in women taking liver enzyme-inducing drugs<sup>4</sup> made the same recommendations as *BNF* Volumes 49 and 50. *BNF* states in the preface on page iii that the current edition must always be used when making clinical decisions.<sup>3</sup>

Please clarify this discrepancy.

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### References

- 1 Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. *FFPRHC Guidance* (April 2005). Drug interactions with hormonal contraception. *J Fam Plann Reprod Health Care* 2005; 31: 139-150.
- 2 *British National Formulary*, Vol. 49. London, UK: British Medical Association and Royal Pharmaceutical Association of Great Britain, March 2005.
- 3 *British National Formulary*, Vol. 50. London, UK: British Medical Association and Royal Pharmaceutical Association of Great Britain, September 2005.
- 4 Stephen G, Brechin S, Penney G. The members' enquiry service: frequently asked questions. *J Fam Plann Reprod Health Care* 2005; 31: 65-66.

## Reply

Thank you for the opportunity to respond to the letter from Dr Nader Al-Hassan regarding apparent inconsistencies within our CEU Guidance on drug interactions with hormonal contraception.<sup>1</sup> I share Dr Al-Hassan's frustrations about conflicting guidance from different sources. As Dr Al-Hassan says, in our 2003 CEU Guidance on emergency contraception<sup>2</sup> we recommended a regimen of levonorgestrel 2.25 mg as a divided dose for women taking concurrent enzyme-inducing drugs; in our 2005 Guidance on drug interactions with hormonal contraception we recommend 2.25 mg as a single dose. There is no research evidence about the most appropriate emergency contraception regimen for women taking concurrent enzyme-inducers and our recommendation in the drug interactions Guidance was, in fact, based on the advice in the volume of the *BNF* that was current at the time of writing. In our Guidance we refer to Volume 48 of the *BNF* (September 2004). Page 407 of that volume contains the advice on interactions with hormonal emergency contraception: "the dose of levonorgestrel should be increased to 2.25 mg taken as a single dose". We note that in an earlier volume (Volume 43) and in a later volume (Volume 49) the *BNF* does recommend a divided dose in this circumstance. We do not know the reason why the *BNF* has altered its advice from a divided dose to a single dose, and back again, in successive volumes. However, on the basis of available data, we doubt that the difference in regimen makes any difference to efficacy.

The CEU is currently updating our Guidance on emergency contraception for publication in the April 2006 issue of this Journal. We will again be reviewing available evidence in developing an updated recommendation on concurrent emergency contraception and enzyme-inducers.

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- 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. FFRHC Guidance (April 2003). Emergency contraception. *J Fam Plann Reprod Health Care* 2003; **29**(2): 9-16.

### Editor's Note: Missed pill correspondence

Interested readers may wish to note that there has been a letter<sup>1</sup> from the Clinical Effectiveness Unit (CEU) published in the *Lancet*, in response to the April Editorial<sup>2</sup> 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.<sup>3</sup> For our readers' convenience, we have permission to reproduce it in full below.

## References

- 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",<sup>1</sup> 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.<sup>2</sup> 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".<sup>3</sup>

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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## References

- 1 Penney G, Brechin S, Glasier A, Bigrigg A. Missed contraceptive pill recommendations. *Lancet* 2005; **366**: 1264.
- 2 van der Westhuizen M, Hall D. Are affluent, well-educated, career-orientated women knowledgeable users of the oral contraceptive pill? *J Fam Plann Reprod Health Care* 2005; **31**: 307-309.
- 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<sup>1</sup> 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<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

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.<sup>1</sup>

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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