

## Letters

**Service standards for sexual health**

Madam

We fail to understand why Dr Stephen Searle<sup>1</sup> feels that implementing the Faculty's Service Standards<sup>2</sup> should detract from our level of client care. If a service has a clear chaperone policy or protocol then the amount of actual documentation required is minimal. An entry in the case notes 'chaperone declined' or 'chaperone: Nurse Smith' should suffice to indicate adherence with the policy.

In Abacus Clinics in Liverpool we established a chaperone policy in 2001 in response to guidance from the General Medical Council<sup>3</sup> and the Royal College of Obstetricians and Gynaecologists.<sup>4</sup> This followed a lengthy in-house discussion and required a significant 'culture change' for a predominantly female staff who previously viewed the offer of a chaperone as a purely gender issue with medico-legal implications. Some felt that the offer of a chaperone would alarm clients and make them suspicious of the clinician. There were concerns about the chaos that would ensue in busy clinics if all clients wanted a chaperone. In the event, these fears were unfounded. A review of staff perspectives on the policy a year after its introduction showed that the majority of staff felt that less than 5% of clients accepted a chaperone when offered. It was felt that the reason for requesting a chaperone had more to do with relieving the client's anxiety about the examination rather than concerns about unprofessional behaviour by the clinician. Whilst only 18% of staff members stated that they always offered a chaperone, up to 80% usually or sometimes did so. The main reason given for not offering a chaperone was that they simply forgot to do so because it was a change to their previous routine practice. Those who did offer documented the offer on most occasions. There was no evidence to suggest that implementing the policy had a significant detrimental effect on clinic times or workload.

Documentation relating to practical procedures, e.g. fitting an intrauterine device (IUD), may be more time consuming but it is important, not just for medico-legal reasons, but for ensuring continuity of good clinical care and risk management. Perhaps the devil is in the detail. It is up to us as clinicians to decide what is and what is not essential documentation. Following an audit<sup>5</sup> of relevant case notes within our service, carried out in 2000, we established a minimum standard<sup>6</sup> for documentation relating to IUD insertion acceptable to all our clinicians. In our experience staff have been happy to implement these standards, accepting them as a useful aid to maintaining good clinical care.

Standards achieved by consensus should serve to protect both client and clinician.

**Laraine Murray**, RGN, Dip. Health Education Nursing Studies

*Family Planning Nurse, Abacus Clinics for Contraception and Reproductive Health Care, Liverpool, UK*

**James T McVicker**, MRCGP, MFFP

*Associate Specialist, Abacus Clinics for Contraception and Reproductive Health Care, North Liverpool PCT, 40-46 Dale Street, Liverpool L2 5SF, UK*

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- 1 Searle S. Service standards for sexual health (Letter). *J Fam Plann Reprod Health Care* 2004; **30**(2): 131.
- 2 Faculty of Family Planning and Reproductive Health Care (FFPRHC). *Service Standards for Sexual Health Services*. London, UK: FFPRHC, September 2003. <http://www.ffprhc.org.uk>.
- 3 General Medical Council (GMC). *Standards on Intimate Examinations*. London, UK: GMC, December 2001. <http://www.gmc-uk.org>.
- 4 Royal College of Obstetricians and Gynaecologists (RCOG). *Intimate Examinations. Report of a Working Party*. London, UK: RCOG, September 1997. <http://www.rcog.org.uk>.
- 5 Murray L. A review of staff attitudes to the implementation of a chaperone policy in a large community based contraception and reproductive health care service. Unpublished audit.
- 6 Kasliwal AP, Webb AMC. Intrauterine device insertions: setting our standards. *J Fam Plann Reprod Health Care* 2002; **28**(3): 157-158.

Madam

I would like to respond to the letter by Stephen Searle in the April 2004 issue of the Journal on behalf of the Clinical Standards Committee of the Faculty.<sup>1</sup> The reason d'être of the National Health Service, and for all who work in it, is to provide high-quality, continuously improving, patient-centred care. In a relatively short space of time clinical governance has become a pre-eminent tool in enabling this to happen.

Whilst the number of publications on this subject is almost overwhelming, the basic principles applied to clinical practice should ensure the delivery of good care. The service standards are produced by the Faculty with the object of interpreting national guidance and directives and incorporating these with core clinical governance principles to provide specialty-specific standards. They are intended to aid clinicians in patient care. Clear record keeping is fundamental to, and an integral part of, patient care. To view it as reactive bureaucracy, which is only necessary to protect in cases of legal action for poor practice, is surely to miss the point. Rather, good record keeping is a fundamental part of each episode of patient care.

Clearly formation of standards is a rapidly developing area. The documents produced by the Clinical Standards Committee have short review cycles so that views can be included commensurate with this progression. Further, the Committee always welcomes comments and suggestions. It is to be hoped that these will inform the refinement of the standards at review thus maximising their usefulness.

**Christine Robinson**, FRCOG, MFFP

*Chair of the Clinical Standards Committee, Faculty of Family Planning and Reproductive Health Care, London, UK*

## Reference

- 1 Searle S. Service standards for sexual health (Letter). *J Fam Plann Reprod Health Care* 2004; **30**(2): 131.

**IUD insertion following medical TOP**

Madam

We found the FFPRHC Guidance on 'The copper intrauterine device as long-term contraception'<sup>1</sup> most informative but were surprised by the lack of data relating to intrauterine device (IUD) insertion following medical termination of pregnancy (TOP) (Section 26). Our district general hospital performs more than 300 medical TOPs annually up to 83 days' gestation. All women are screened for sexually transmitted infections and there is a 96% complete miscarriage rate.<sup>2</sup> In a proportion of cases abortion occurs or completes at home in the first few days following the administration of misoprostol. If abortion occurs in hospital, contraception such as oral contraceptives or Depo-Provera<sup>®</sup> is commenced immediately by the nursing staff. Women are then reviewed in a weekly specialist family planning clinic approximately 7-10 days after their termination procedure. This review ensures that the termination is complete and allows the patient's physical and emotional status to be assessed. IUDs or implants are inserted at this visit. Occasionally at this review appointment bleeding is still continuing and further misoprostol is required to expel all products of conception. Another appointment is then made 1 week later for the IUD fitting.

Since January 2000, 55 copper IUDs have been inserted between 4 and 30 (average, 11) days following medical TOP. The majority were Gyne T380<sup>®</sup> or Nova T380<sup>®</sup> IUDs but included two GyneFix<sup>®</sup> IUDs in 2000 and two Flexi-T300<sup>®</sup> IUDs in 2003. The two women whose copper IUDs were fitted at 29 and 30 days post-TOP had had continued problems with bleeding and required further doses of misoprostol. Thirty Mirena<sup>®</sup> intrauterine systems (IUS) were also inserted 6-16 (average, 10) days following medical TOP. There have been no difficulties or immediate complications with insertions using this policy.

In 2001, a Mirena IUS was partially expelled

20 days after insertion and a new IUS was refitted without incident. Two women have conceived with copper IUDs in situ 4 and 6 months after insertions. One subsequently miscarried and the second has had a further TOP. A third woman had an ectopic pregnancy 14 months after IUD fitting.

We consider that the Guidance of the Clinical Effectiveness Unit (CEU) that IUDs should be fitted within 48 hours or after 4 weeks for women undergoing first-trimester medical TOP is too restrictive. The first-trimester postabortal uterus does not appear to behave like a postpartum uterus. In practice many women would not wish to be examined within the first 48 hours when the bleeding may be heavier and in some women the uterus may not be completely empty. Waiting for 4 weeks (presumably until after the next menses) requires women to arrange a further appointment that they may have difficulty keeping and also denies them efficient contraception for the first month after TOP.

We suggest that a review appointment, usually at 7-10 days post-medical TOP, allows safe insertion of both copper IUDs and Mirena IUS and should be promoted.

**N Selvakumari**, DFFP

*Staff Grade, Maternity & Women's Health Care, Royal Bolton Hospital, Bolton, UK*

**E Stevenson**, MFFP

*Clinical Assistant, Maternity & Women's Health Care, Royal Bolton Hospital, Bolton, UK*

**M Cooper**, DFFP

*Clinical Assistant, Maternity & Women's Health Care, Royal Bolton Hospital, Bolton, UK*

**M Tasker**, MFFP

*Consultant Gynaecologist, Maternity & Women's Health Care, Royal Bolton Hospital, Minerva Road, Farnworth, Bolton BL4 0JR, UK*

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- 1 FFPRHC Clinical Effectiveness Unit. FFPRHC Guidance (January 2004). The copper intrauterine device as long-term contraception. *J Fam Plann Reprod Health Care* 2004; **30**(1): 29-42.
- 2 Basu R, Gundlach T, Tasker M. Mifepristone and misoprostol for medical termination of pregnancy: the effectiveness of a flexible regimen. *J Fam Plann Reprod Health Care* 2003; **29**(3): 139-141.

**Reply**

Madam

The FFPRHC Clinical Effectiveness Unit (CEU) provides evidence-based Guidance documents on contraceptive and reproductive health topics. The recent Guidance document 'The intrauterine device as long-term contraception'<sup>1</sup> was developed using best available evidence from a systematic literature review, the collective knowledge of the multidisciplinary expert group and subsequent peer review. Despite a large number of medical abortions performed each year in England, Wales and Scotland, there is a lack of published evidence on the timing of intrauterine contraceptive insertion following medical abortion.

The insertion of intrauterine contraception immediately following abortion clearly has advantages. The insertion of intrauterine contraception at the time of surgical abortion is practical and safe.<sup>2</sup> The World Health Organization (WHO) *Medical Eligibility Criteria for Contraceptive Use* (WHOMEC)<sup>3</sup> recommends that intrauterine contraception can be inserted immediately following induced or spontaneous first-trimester abortion (WHO 1: unrestricted use). Although the risk of expulsion of an intrauterine device (IUD) following second-trimester abortion is increased,<sup>2</sup> WHOMEC recommends that the benefits still outweigh the risks (WHO 2).<sup>3</sup> Although WHOMEC does not provide recommendations regarding insertion of intrauterine contraception in the weeks following abortion, evidence from case-control studies showed low perforation rates with insertion within 30 days of abortion.<sup>4</sup>

Issues surrounding the insertion of intrauterine contraception postpartum, when the uterus is involuting, are clearly different from first-trimester abortion but may be more similar to second-trimester abortion. However, in the absence of evidence the CEU advised that, as for postpartum insertion, following medical abortion the insertion of intrauterine contraception should be within the first 48 hours or delayed until 4 or more weeks after abortion. This advice from the CEU may be too restrictive but until more

published evidence is available an alternative recommendation cannot be made. The CEU would certainly encourage groups to publish their case series of post-abortion IUD insertions (Level III evidence) to increase the evidence base.

**Susan Brechin, MRCOG, MFPP**

*Co-Ordinator, Clinical Effectiveness Unit, Faculty of Family Planning and Reproductive Health Care, Room 63, Aberdeen Maternity Hospital, Cornhill Road, Aberdeen AB25 2ZD, UK*

## JOURNAL CLUB

**Implanon – the single-rod subdermal contraceptive implant.** Newton J, Newton P. *J Drug Eval* 2003; **1**(6): 177–218. Parthenon Publishing Group. ISSN 1479-1137

This relatively new journal is primarily aimed at pharmaceutical physicians, but its Editor-in-Chief, Professor Ronald Mann, hopes it will also be useful to clinicians. Each issue is devoted to examining a single drug, with the intention of doing so in an independent and comprehensive manner. The Editor-in-Chief writes an 'executive summary' derived from the review.

Authors are selected on the basis of their extensive clinical experience, but are professionals who are not directly or indirectly associated with the manufacturer in a way that would prejudice independence of view and a declaration of 'conflict of interest' is required to be signed by each author.

The definition for a systematic review was given in an article in the journal in January 2004:<sup>1</sup> 'A critical synthesis of research evidence, which involves analysis of all available and relevant evidence in a systematic, objective and robust manner.' However, this article is not so much a systematic review as a monograph, the definition of which is 'a scholarly book, article or pamphlet on a specific and usually narrow subject'. In many ways it demonstrates the reasons why having specified guidelines is a good idea.

### 1. What is the research question?

This is not stated explicitly. It could be to answer the question: 'Is this contraceptive method acceptable, effective and safe?' If so, then to a large degree the question is answered, but the answers need to be extracted from a large mass of data. If the question was 'What is known so far about this method of contraception?', then again most of the answers are there, but see the caveats highlighted below.

### 2. Why was the review needed?

The last review of Implanon that I could find was in 1999,<sup>2</sup> so another is due. This paper is cited twice in this journal (references 29 and 56).

### 3. Is there a protocol outlining the review specifications? How were sources of literature identified?

The authors do not give their inclusion criteria or their searching protocol, so that it is not possible to judge for degree of bias in selection of papers or the reason for exclusion of papers. I found, on a superficial search, a list of 159 research articles on Implanon – but looking at the abstracts of some of them (it is very time consuming doing a systematic review!) several are obviously not suitable for a review article and some are repeated references.

### 4. Is there an assessment of the methodological quality of the articles included in the review?

The review includes a summary of the paper by Edwards and Moore<sup>2</sup> that did spell out the inclusion criteria for the studies in that paper (up to 1999). I could not find a similar list of inclusion criteria for papers published after that date, although there only appear to be eight citations after that date.

### 5. Was a data extraction form used? Was there any independent data extraction?

This is unknown but seems unlikely with only two named authors.

### 6. Were the data summarised and tabulated with synthesis of results?

Much of the data were summarised but is difficult to access in a systematic way.

### 7. Is the interpretation valid and the implications for practice considered?

The implications for practice are not contentious and contain no surprises.

In summary, this article may provide a useful resource for those who want information on Implanon gathered together and presented with supporting references. However, clinicians might also want to look at a health technology assessment produced for the National Health Service research and development programme in 2000<sup>3</sup> that is easily found from the National electronic Library of Medicine (NeLM).<sup>4</sup> Neither this nor a review from the Centre for Reviews and Dissemination<sup>5</sup> of an economical analysis of Implanon are cited. A Cochrane Review protocol has been developed: 'Subdermal implantable contraceptives versus other forms of reversible contraceptives as effective methods of preventing pregnancy', so a systematic review will be available in due course.

### References

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- 2 JE Edwards, A Moore. Implanon: a review of clinical studies. *Br J Fam Plann* 1999; **4**: 3–16.
- 3 French R, Cowan FM, Mansour DJA, et al. Implantable contraceptives (subdermal implants and hormonally impregnated systems) versus other forms of reversible contraception: two systematic reviews to assess relative effectiveness, tolerability and cost-effectiveness. *Health Technol Assess* 2000; **4**(7): i–vi, 1–107. <http://www.ncchta.org>.
- 4 <http://www.nelh.nhs.uk/>.
- 5 <http://agatha.york.ac.uk/online/nhseed/20008111.htm>.

Reviewed by **Gill Wakley, MD, MFPP**

*Visiting Professor in Primary Care Development, Staffordshire University and Freelance General Practitioner and Writer, Abergavenny, UK*

**Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia. randomized trial 5-year follow-up.** Hurskainen R, Teperi J, Rissanen P, et al. *JAMA* 2004; **291**: 1456–1463

This study is from all five university hospitals of Finland. In some countries the levonorgestrel-releasing intrauterine system (LNG-IUS) is licensed and/or being used to treat menorrhagia. The commonest indication for hysterectomy is menorrhagia, so it is important to consider whether possible alternatives to surgery are effective and cost-effective.

This study gives the 5-year results of a previously published 1-year study.<sup>1</sup> Of 236 women referred to the hospitals with menorrhagia, 119 were randomised for LNG-IUS treatment and 117 for hysterectomy. Only 12 women failed to complete the 5-year follow-up. The Health-Related Quality of Life (HRQL) was measured using the five-dimensional EuroQol system and the RAND 36-item system. The Spielberger Anxiety Inventory, the Beck Depression Inventory and the McCoy Sex Scale were all assessed. Overall satisfaction was assessed by a five-level question.

Cost analysis was calculated taking account of medical treatment, sick leave, and so on based

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- 3 World Health Organization (WHO). *Medical Eligibility Criteria for Contraceptive Use*. Geneva, Switzerland: WHO, 2000.
- 4 Heartwell S, Schlesselman S. Risk of uterine perforation among users of intrauterine devices. *Obstet Gynecol* 1993; **61**: 135.

on Finnish costs. Results at 5 years showed that the two groups did not differ substantially in terms of the HRQL; 94% of the LNG-IUS group and 93% of the hysterectomy group were satisfied or very satisfied. The haemoglobin and serum ferritin levels were significantly higher at 5 years than at base line, with no substantial difference between the groups. However, 50 (42%) women in the group allocated to the LNG-IUS eventually underwent hysterectomy. Of the 57 women with an LNG-IUS in situ at 5 years, 75% reported amenorrhoea or oligomenorrhoea and 19% reported irregular bleeding. In the group allocated to hysterectomy, 109/117 had hysterectomy. Complications included three bladder perforations and one bowel perforation.

The average total cost was US\$2817 in the LNG-IUS group and US\$4660 in the hysterectomy group, i.e. the LNG-IUS costs were 40% less. When hysterectomy costs are placed at 20% less or placed higher than USA costs, the LNG-IUS costs were still considerably less.

In Finland the use of hysterectomy has been falling while the use of the LNG-IUS has been increasing. The authors conclude the LNG-IUS may improve HRQL at relatively low cost despite the need for some women to eventually require hysterectomy.

The study certainly confirms the LNG-IUS as an effective treatment for menorrhagia. This being the case it is puzzling why *Clinical Evidence*<sup>2</sup> describes it as being of 'unknown effectiveness'. All the more surprising when their own supporting literature review amply confirms its effectiveness! Probably their failure to endorse the LNG-IUS is because there has never been a randomised controlled trial of the LNG-IUS versus placebo, which of course can never occur.

### References

- 1 Hurskainen R, Teperi J, Rissanen P, et al. Quality of life and cost-effectiveness of levonorgestrel-releasing intrauterine system versus hysterectomy for treatment of menorrhagia. *Lancet* 2002; **357**: 273–277.
- 2 Godlee F (exec. ed.). *Clinical Evidence Concise*. 9th Issue. *Women's Health Section*. London, UK: BMJ Publishing Group, June 2003; 393. <http://www.nelh.nhs.uk/clinicalevidence>.

Reviewed by **Michael Cox, FRCOG, MFPP**

*Consultant Obstetrician and Gynaecologist (Retired), Nuneaton, UK*

**Preconception care practice and beliefs of primary care workers.** Heyes T, Long S, Mathers N. *Fam Pract* 2004; **21**: 22–27

The authors explored the views of health practitioners working in primary care in Barnsley Health Authority (in the north of England) about preconception care. They obtained a response rate of 61% from general practitioners (GPs), practice nurses, health visitors and midwives in July 2000. Most of those who replied were providing preconception care on an opportunistic basis and infrequently. Few general practices had any written policy. The respondents agreed that advice on smoking, drug use, folic acid, genetic counselling, chronic disease, alcohol and screening was important. Screening advice included rubella, genital infections, hepatitis, human immunodeficiency virus and cervical screening. They felt that advice about diet, exercise, supplements, food safety, occupational hazards and state benefits were less important. Giving preconception advice was not a high