

a rota that exceeded the limit on hours, 45% routinely exceeded their contracted hours, and a similar proportion slept for less than four hours during their nights on call. These figures, rather than establishing that anaesthetists reject shift systems, surely indicate that there is an urgent need for the wider implementation of such arrangements to reduce the over intense, unsafe working practices that put both patients and doctors at risk.

It is notable that most respondents wished to base hours and the class of additional duty hours on the intensity of their workload and to determine maximum lengths of shifts locally. This is entirely in accordance with the new deal and is exactly how partial and full shifts are being implemented in many units. Successful shifts are those that have been designed by juniors and consultants who know the local patterns of workload, tested, adjusted, and discussed with all parties (juniors, seniors, medical staffing officers, and nurses). Inflexibility has been the downfall of many potentially successful shifts. The guidelines on the length of the shifts are not, as the author suggests, rigid. In certain patterns, shifts longer than the often quoted 16 hours are acceptable—for example, when the shift type is changing from night to day, or vice versa. In partial shifts, where the doctor works only one night at a time (with days or half days off before and after a night on call) this change occurs daily. I commend the document *Shifting Work Practices* to all those who have no experience of such working patterns or who dislike the shift patterns that they are working.<sup>2</sup>

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1 Mackenzie P. Anaesthetists in training do not want new deal. *BMJ* 1995;311:331-2. (29 July.)

2 Junior Doctors Committee. *Shifting work practices: a guide to partial shifts*. London: BMA, 1994.

## Polymyalgia rheumatica and giant cell arteritis

EDITOR.—The quaint belief that more of something good must be better has plagued the rational use of corticosteroids over the years but is not the guiding principle for most other forms of treatment. John Ferris and Robert Lamb suggest that high starting doses for the treatment of giant cell arteritis are necessary to prevent blindness, but produce no evidence that lower starting doses are less effective.<sup>1</sup> This is understandable because no such evidence exists, as became apparent from a review of the literature done in my department.<sup>2</sup> We also reported our experience with 96 patients with giant cell arteritis. The starting dose of prednisolone was 20 mg daily for 77 of these, none of whom had any ocular complication of their arteritis. Higher doses were given to the remaining 19 patients, one of whom developed some visual loss, probably related to giant cell arteritis, four weeks after starting treatment.

The incidence of blindness after the start of corticosteroid treatment is so low that little is likely to be achieved by large randomised controlled studies as suggested by Ferris and Lamb. I believe that we should continue to use lower starting doses, as advocated by Gillian Pountain and Brian Hazleman,<sup>3</sup> who seem to have adopted the reasonable suggestions for the management of polymyalgia rheumatica and giant cell arteritis published in the *Drug and Therapeutics Bulletin*.<sup>4</sup> The main cause of death and morbidity in giant cell arteritis is the corticosteroid treatment.<sup>5</sup>

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- 1 Ferris J, Lamb R. Polymyalgia rheumatica and giant cell arteritis. *BMJ* 1995;311:455. (12 August.)
- 2 Myles AB, Perera T, Ridley MG. Prevention of blindness in giant cell arteritis by corticosteroid treatment. *Br J Rheumatol* 1992;31:103-5.
- 3 Pountain G, Hazleman B. Polymyalgia and giant cell arteritis. *BMJ* 1995;310:1057-9. (22 April.)
- 4 The management of polymyalgia rheumatica and giant cell arteritis. *Drug Ther Bull* 1993;31:65-8.
- 5 Rubinow A, Brandt KD, Cohen AS, Sack B. Iatrogenic morbidity accompanying suppression of temporal arteritis by adrenal corticosteroids. *Ann Ophthalmol* 1984;16:258-65.

## Combined oral contraceptives and thromboembolism

EDITOR.—It is understandable that last week's *BMJ* should devote considerable space to the Committee on Safety of Medicines' recent advice<sup>1</sup> on combined oral contraceptives and venous thromboembolism.<sup>2-6</sup> I doubt, however, whether your readers will be enlightened by some of the views expressed in it. In particular, the excess risk of venous thromboembolism with combined oral contraceptives containing desogestrel or gestodene is 15 per 100 000 users per year, not 15 per 100 000 women.

The committee's decision to advise doctors, pharmacists, and the public about the increased risk of thromboembolism with combined oral contraceptives containing desogestrel or gestodene was based on the results of three studies. Contrary to assertions in the *BMJ* and elsewhere, none were preliminary findings. The World Health Organisation's study and that of Dr Hershel Jick (based on the general practice research database) have been submitted for publication; Professor Spitzer provided the committee with an abstract prepared for the December meeting of the British Pharmacological Society. None of the authors have retracted their publications. All indicate that there is an increased risk of venous thromboembolism associated with combined oral contraceptives containing desogestrel or gestodene compared with other combined oral contraceptives. As with all studies of this type, considerable care was taken to assess whether the results could be due to chance, confounding, or bias. The Committee on Safety of Medicines considered these possibilities but concluded that none could explain the overall observations.

Several of your commentators indicated that the adverse effects of combined oral contraceptives containing desogestrel or gestodene on thromboembolism might be "counterbalanced" by their favourable effects on blood lipids and hence acute myocardial infarction.<sup>7</sup> Some go further and suggest that, from the available epidemiological data, this "seems likely." The committee examined this proposition with considerable care. Firstly, there is uncertainty whether their biochemical effects on blood lipids can be extrapolated to clinical outcomes on myocardial infarction and stroke.<sup>7</sup> Secondly, neither of the two (not three) epidemiological studies that attempted to examine the effect on myocardial infarction was of sufficient size to address the issue. Indeed Professor Spitzer indicated at a meeting on 10 October 1995 that it would take a further one to two years before he could answer the question. In addition, one study showed no difference between combined oral contraceptives containing desogestrel or gestodene and other combined oral contraceptives with respect to stroke. Thirdly, acute myocardial infarction attributable to combined oral contraceptives predominantly occurs in older women aged 35 to 40 years and particularly those who are smokers. The thinly veiled suggestion that the committee should ignore the results of the present studies in order to acquire further data on acute myocardial infarction over the next 12 to 24 months is not one likely to appeal to many British women or their doctors.

Several of your commentators also criticise the

committee for acting in haste. Over the past few years we have kept a close watch on the safety of combined oral contraceptives containing "third generation" progestogens but until recently had no cause for concern. In mid-July, however, we became aware of the preliminary results of the WHO's study and, at a meeting to discuss this, it was suggested that additional analyses might clarify the issues it raised. At the same time the Medicines Control Agency asked Professor Spitzer to expedite the analysis of his transnational study.<sup>8</sup> Furthermore, the Medicines Control Agency explored with Dr Hershel Jick the possibility of his undertaking a separate study based on the general practice research database. The results of these two latter studies became available in late September-early October together with the final report of the WHO's investigation as it related to venous thromboembolism. This chronology shows that the committee and the Medicines Control Agency behaved responsibly and without undue haste. It also shows that the committee acted with reasonable promptness once the situation became clear.

Professor Spitzer expressed surprise that the committee's advice was based on unpublished data not subjected to peer review.<sup>5</sup> Such criticism is frankly absurd. The committee spends much (if not most) of its time examining data that has been neither published nor peer reviewed, in the form of pharmaceutical companies' product licence applications and postmarketing safety reports. Indeed, one of the responsibilities of the committee (and of its subcommittees) is to take on the critical role typically adopted by reviewers of scientific journals.

It would obviously be advantageous if there were simultaneous publication of studies forming the subject of a combined oral contraceptives "Dear Doctor/Pharmacist" letter. Since 1980 successive chairmen have written 10 such letters on drug safety issues, of which eight have been based on data that have been wholly or partially unpublished. The committee would be failing in its duty to the profession and the public if it did not communicate important drug safety information promptly. It will continue to do so.

Finally, I fully appreciate from reports in the media, and the contents of my postbag, the irritation of doctors who first learnt of new concerns on the safety of combined oral contraceptives from the press and their patients. Unfortunately, conventional technology still does not guarantee that 190 000 doctors and pharmacists will read of such matters before they appear in the media. The suggestion in my local newspaper (the *Newcastle Journal*) that I should let them know by telephone smacks of innocence rather than practicality. Nevertheless, I apologise unreservedly for any embarrassment that the late arrival of my letter may unwittingly have caused and we are reviewing our procedures to see how this might be avoided in the future. I am sure, however, that the practical advice issued jointly by the Family Planning Association and the Faculty of Family Planning will help prescribers during the next few weeks and months.

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1 Committee on Safety of Medicines. *Combined oral contraceptives and thromboembolism*. London: CSM, 1995.

2 Guillebaud J. Advising women on which pill to take. *BMJ* 1995;311:1111-2. (28 October.)

3 Macrea K, Kay C. Third generation oral contraceptive pills. *BMJ* 1995;311:1112. (28 October.)

4 Carnall D. Controversy rages over new contraceptive data. *BMJ* 1995;311:1117-8.

5 Spitzer WO. Data from transnational study of oral contraceptives have been misused. *BMJ* 1995;311:1162. (28 October.)

6 Craft N. Clots of trouble. *BMJ* 1995;311:1172-3.

7 Wilde MJ, Balfour JA. Gestodene: a review of its pharmacology, efficacy and tolerability in combined contraceptive preparations. *Drugs* 1995;50:364-95.

8 Spitzer WO, Thorogood M, Heinemann L. Trinational case-control study of oral contraceptives and health. *Pharmacoepidemiology and Drug Safety* 1993;2:21-31.