

for most patients, and such a practice will produce recurrence of symptoms with much suffering. It may also be a dangerous action in women with depression responsive to oestrogen. This approach might be used to justify a study of the pharmacokinetics of implants, but we would argue that this is inhumane management of individual patients.

We would agree that there is currently no evidence that such high oestradiol concentrations are dangerous, but we need more information about those patients who seem to need increasingly frequent hormone implants. On the other hand, we do know that treatment with percutaneous oestradiol produces a greater density in vertebral and femoral bone than does oral treatment. This difference is directly related to oestradiol concentrations.¹ Indeed, in a prospective study we found an 8% increase in spinal bone density and a significant correlation between the incremental increase in vertebral bone density and the oestradiol concentrations achieved after one year of treatment with percutaneous implants (unpublished data).

Oestrogen replacement therapy in postmenopausal women is probably the most important advance in preventive medicine in the Western world for half a century. There is much evidence that oestradiol implants, by virtue of the higher oestradiol concentrations achieved, are the most effective and acceptable mode of hormone replacement therapy. The occasional finding of supra-physiological concentrations of oestradiol does not encourage us to change this view.

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Communicating with Asian patients

SIR,—Ms Kathryn A Stevens and Dr R P Fletcher's article on communicating with Asian patients is both timely and relevant to everyday clinical practice in our multicultural society.¹

Their finding that 30% of patients could read no language is consistent with the results of our survey of a random sample of 337 Asian women aged between 16 and 80 living in Leicester. Of these women (who were mainly Gujarati speaking), 193 (57%) could read their main language only a little or hardly at all, and 74 (37%) of a group of 200 women shown a bilingual leaflet on contraceptive methods were unable to read it.²

Other authors have advocated the use of videos for different groups of Asians—the elderly,³ women at home,⁴ and antenatal patients.⁵ I have recently found a videotape viewed at home to be successful in persuading Asian women who have never had a cervical smear test to attend for this procedure (unpublished data). This multilingual videotape and others—on diet for Asian diabetics and on organ transplantation—are available from the Leicestershire Health Education Video Unit, Clinical Sciences Building, Leicester Royal Infirmary, PO Box 65, Leicester LE2 7LX (telephone 0533 550461).

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Rules for drug trials

SIR,—Professor Ian Oswald criticised the design of the two dose parallel group multicentre trial of the antianxiety agent suriclone for not having a placebo control group,¹ but it may well not be necessary if the hypothesis testing in the study relates to trying to identify differences between the two doses rather than whether one or both is an effective antianxiety agent. A placebo group is, therefore, not mandatory on all occasions in clinical trials. There may well be an adequate number of placebo controlled studies in progress or in planning for this product.

I would be interested to know, for antidepressants, what statistical power Professor Oswald would require to show satisfactorily that an active antidepressant was not significantly different from amitriptyline. I know of no study that adequately shows that an antidepressant is more effective than another except perhaps in subgroup analyses.

I agree that in order to determine satisfactorily whether a compound possesses antidepressant activity a placebo controlled comparison must be undertaken. Until recently in the United Kingdom most of Professor Oswald's colleagues were refusing to accept a placebo comparison in a double blind study.

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Complementary medicine

SIR,—In his item on complementary medicine Mr David Aldridge suggests that a European Community directive to review all drugs and remedies by the end of 1990 is likely to speed a decision on the usefulness of homoeopathic and other such remedies.¹ That will be a difficult objective to achieve, particularly where the effect is weak and the disorder is spontaneously variable and strongly responsive to placebos.

A recent example was the paper by Dr Peter Fisher and colleagues on the effect of homoeopathic treatment of fibrositis.² Publication of that paper was a serious error of judgment on the part of the distinguished authors and of the *BMJ*. It states that a double blind crossover trial showed that a

tincture of the leaves of poison oak diluted to 10⁻¹² was beneficial for patients with fibrositis. There is a great merit in publishing pragmatic results without reference to theory or rationale. In this situation, however, it would be necessary to postulate some form of energy hitherto unknown in physics to explain the systemic effect of any compound in such dilution. This is, of course, possible but there is a much simpler explanation. The alternative is that the blindness of the trial had been inadvertently breached. In the most innocent of trials it has been everyone's experience that it is extraordinarily difficult to keep a secret secret and free of hints. This is such a serious problem that it becomes apparent that most so called blind trials are in fact transparent since the placebo effect varies with the active effect.

I find it extraordinary that the *BMJ* should publish this paper without comment so soon after the similar Benveniste affair in *Nature*. That paper³ was accompanied by an editorial and followed by a special investigation by the journal of the blindness of the experiments which revealed many possible alternative explanations.^{4,5} In the paper by Dr Fisher and colleagues we are told nothing of any checks on blindness, of the role of the homoeopath, or of any differences of result depending on the direction of the crossover. These criticisms do not cast doubt on the honesty and competence of the authors. The criticism points to the problem of accepting any double blind trials at face value.

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AUTHORS' REPLY.—We find it strange that Professor Wall should wish to suppress publication of a study just because the treatment involved is homoeopathic. Of course, there is the possibility of type 2 as well as type 1 error, and the mathematical chances are known, but we cannot think of any way in which the double blindness of the study could have been breached. The homoeopathic doctor assessed the patients' suitability for treatment but had nothing to do with its administration or assessment of its efficacy. The treatment code was not broken until after completion of the study.

It is also absurd to suggest that we should not publish results without reference to rationale: the mode of action of penicillamine in rheumatoid arthritis is unknown, but it is a valuable treatment. We reject any suggestion that we should investigate only orthodox treatments; we are prepared to use all methods of relieving pain but always take steps to evaluate their usefulness. Professor Wall has himself made an important contribution to the understanding of acupuncture,¹ and it would be interesting to learn how he would investigate the alleged clinical effects of homoeopathic medicines.

Dr Hedley Berry² and Drs A E Davies and R W Davey³ raise several points which we could not adequately address in our short paper. Our trial design was quite different from that of Dr Berry.⁴ Our patients were selected not only by conventional diagnostic criteria but also by criteria for homoeopathic remedy and we tested *Rhus toxicodendron* only in patients with the appropriate criteria for response to it. It is not true to say that treatment does not relieve pain. Changes in pain and sleep showed a highly significant difference, 53 of 60 possible differences showing improvement during