

tions for behaviour disturbances in dementia, methodological difficulties have meant that randomised, controlled trials are largely limited to the use of antipsychotic drugs—the most commonly used preparations. Schneider *et al* conducted a meta-analysis of double blind, placebo controlled trials of antipsychotic drugs in dementia.⁵ They concluded that there was reliable and significant evidence for the efficacy of these compounds. Agitation, hallucinations, delusions, suspiciousness, and aggression were the symptoms most likely to respond to treatment. Small doses of antipsychotic medication may be effective—for example, haloperidol 0.0125–1 mg daily or thioridazine 5–10 mg daily. Antipsychotic drugs seem to be more effective than benzodiazepines.² Hypnotics are widely used but should be reserved for specific disturbances in sleep. Other preparations, such as selective serotonin reuptake inhibitors and anticonvulsants, may be of benefit for behaviour disturbances, although this may have to be determined empirically as controlled trials are lacking.

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Authors' reply

EDITOR,—Like McAllister-Williams and Ferrier, and Tarbuck, we were also concerned about the media coverage of our recent article. We feel this matter was treated with an air of hysteria not justified by the content of our paper. We too would be concerned about the introduction of legislation to control neuroleptic prescribing, and at no point in our article do we advocate this.

Various authors (McAllister-Williams and Ferrier, and Thacker and Jones) have questioned our methodology and interpretation. Our selection of homes was geographical. It was simply a survey of prescribing levels using the only available (American) guidelines, which roughly mirror recommendations in the British National Formulary.

Cameron *et al* state that 90% of their patients have disturbed behaviour. This may reflect staff tolerance of behaviour rather than showing a need for medication. Their commonly reported problems (agitation and nocturnal restlessness) could be akathisia, a common side effect.

However, the most important issue is whether neuroleptics should be used. Studies have shown that neuroleptics have limited effects—18% benefit compared with placebo.¹ These studies were too short, at 6 weeks, to show ongoing benefit or to show side effects which develop later, such as tardive dyskinesia, Parkinsonism, and akathisia. Discontinuation studies, after the American legislation, suggest that there is often no need for ongoing medication.² Some commonly used neuroleptics have a high incidence of cholinergic effects, which may aggravate confusion and lead to many other side effects.

Documentation of behaviour problems should, indeed, be routine within long term care

settings. As Tobiansky and Blanchard point out, environmental factors, physical problems, and staff tolerance must be addressed before medication is considered. Should drugs with considerable morbidity and, indeed, mortality^{3,4} be used simply because a patient is noisy, as suggested by Cameron?

If neuroleptics must be used, then it should be for as short a period as possible. We must remain aware of the potential for side effects, often not attributed to the drugs, when patients are being managed in non-hospital settings.

We hope that our article will contribute to the debate regarding neuroleptic prescribing in elderly people and, by raising various issues, help lead to more appropriate use.

We believe, along with Tarbuck, and Tobiansky and Blanchard, that the way to improve on prescribing levels in nursing homes is through education and training of staff and the primary care team. Drug use should not be the first choice in the management of behavioural difficulties.

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Costs and getting ethical approval deter doctors from participating in multicentre trials

EDITOR,—Many questions in medicine can be answered only if large numbers of patients are studied, and multicentre trials are normally necessary for this. The research committee of the British Thoracic Society, which has conducted many multicentre trials,¹ designed two studies on the prevention and treatment of osteoporosis by hormone replacement therapy and/or etidronate and/or calcium in asthmatic patients taking corticosteroids. Height, weight, activity status, fractures, and (if available) results of bone densitometry were recorded annually for five years. Lateral radiographs of the thoracolumbar spine were obtained at entry and at five years, or sooner if symptoms of vertebral collapse developed. The costs of densitometry and copying the radiographs were reimbursed by the society, but funding was not provided for the radiography or drugs. Ninety six physicians agreed to enter patients into one (17) or both (79) studies.

After two years, recruitment was so slow and the number of physicians withdrawing their participation so high that we decided to investigate. We sent a questionnaire to the 60 physicians who had withdrawn or had not entered patients. Note was also taken of any difficulties reported by the 36 who had entered patients. Table 1 gives the reasons for withdrawal. Pressure of work and difficulty in finding patients are not new reasons for not participating in the society's trials, but difficulty in obtaining approval from the local research ethics committee and local objections to costs have not previously been so evident.¹ Objections on grounds of cost arose from the

Table 1—Reasons for physicians withdrawing from studies*

Reason	No
Pressure of work	26
Difficulty in obtaining local ethical approval	17
Local objections about costs	15
Difficulty finding patients	10
Scientific doubts	2

*Several physicians cited more than one reason.

radiology directorate (seven), pharmacy (seven), local research ethics committee (six), and general practice or family health services authority (three). Thirteen of the 36 active participants had had to overcome objections from their local research ethics committee of the sort that had caused others to withdraw, and seven had had to overcome problems with costs raised by their hospital or in general practice.

A national ethical body exists for community based multicentre research.² If a similar arrangement existed for hospital based multicentre trials then probably fewer physicians would have withdrawn because of the delays and frustrations occasioned by multiple submissions and exchanging correspondence with their local research ethics committees. The NHS reforms, particularly the purchaser-provider split, have increased concern about costs. Even local research ethics committees raised costs as objections, which is surely beyond their remit.^{3,4}

Difficulties with local research ethics committees and increased awareness of costs seem to have deterred participation in these studies. We agree with Smyth *et al* that a new approach to funding multicentre studies is required⁵ and recommend the establishment of a national ethical body for hospital based multicentre research.

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Diazepam is more useful than magnesium for immediate control of eclampsia

EDITOR,—Lelia Duley criticises our suggestion that diazepam should be used for the immediate control of active eclampsia.^{1,2} We did not argue that diazepam should be used because it is more readily available or that it should be used rather than magnesium to prevent further fits. Our point was that it controls active eclampsia more rapidly because it can be prepared and given more easily. We believe that in a patient who is