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

having fits, small delays in controlling the fits can lead to a worse outcome for both the mother and the fetus.

Duley advises that doctors should be taught how to use magnesium. We agree, but the fact remains that most junior obstetricians will rarely be required to treat a patient with eclamptic fits. With the introduction of structured training, some trainees will receive their certificate of specialist training without managing a single case. In contrast, most doctors learn how to control non-eclamptic fits with diazepam during the preregistration year. It seems logical that this experience will enable trainee obstetricians to use diazepam safely and confidently in emergencies. Despite being experienced obstetricians who are familiar with magnesium, we have to review the protocol before using it. This is not the case for diazepam, which comes in a formulation that is ready to use. Interestingly, one of the women in Crowther's study who was allocated to receive magnesium died of a cardiac arrest immediately after the infusion, "presumably as a result of too rapid an injection."³ Furthermore, examination of the two reports that Duley cites in support of magnesium to prevent recurrent fits shows that immediate control of active eclampsia was not their focus.^{3,4}

Diazepam is effective at arresting convulsions,³ the excess of recurrent fits with diazepam occurs after the first hour,³ and maternal morbidity is otherwise the same for diazepam and magnesium.⁴ We conclude that diazepam is a good drug for the immediate control of eclampsia and that magnesium is better to prevent recurrent fits.

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Screening for diabetic retinopathy

Diabetic patients should continue to be assessed by direct ophthalmoscopy

EDITOR,—There has been much discussion in the *BMJ* recently about the merits and shortcomings of various modes of screening for diabetic retinopathy.¹⁻³ Many diabetologists and general practitioners are now confused about the value of regular direct ophthalmoscopy for their diabetic patients because of its perceived poor sensitivity.

This is of great concern, and we think that a clearer distinction must be made between screening for any retinopathy and screening for sight threatening retinopathy (that is, proliferative retinopathy or macular oedema). Although J P O'Hare and colleagues allude to the problem and give figures for both,³ most published figures for sensitivity and specificity refer to screening for sight threatening retinopathy.^{1,2} While it is true that no treatment is necessary for retinopathy that is not sight threatening and purists might argue that screening for a condition that does not have an effective treatment is not justified, the efficacy of laser photocoagulation for sight threatening retinopathy depends on

both accurate and timely diagnosis of this treatable subset of the condition. However, little if any research has been carried out on the best means of following up patients who are known to have retinopathy that is not yet sight threatening. With regard to maculopathy, the detection of retinal thickening close to the fovea requires considerable skill, and measuring visual acuity has been shown to have no significant beneficial effect on sensitivity while lowering specificity.²

Therefore, since there is no perfect way of screening for sight threatening retinopathy and since, at any time, about 70% of the diabetic population does not have retinopathy, we suggest that all patients with appreciable retinopathy (defined as more than six to eight microaneurysms, or any haemorrhage or exudate or cotton-wool spots, or any new vessels) should be referred for a thorough assessment by an ophthalmologist. This will allow follow up visits to be scheduled on the basis of known prognostic indicators.⁴

Laser photocoagulation is much better at preserving visual function than at restoring loss. If the progression of the microvasculopathy is monitored by someone who is experienced in treating sight threatening retinopathy the decision of when to treat is within that person's control and the optimal time is more likely to be identified.

Organised community screening programmes for diabetic retinopathy (at whatever stage) are not yet available nationwide. Until they are, doctors caring for diabetic patients should continue to perform direct ophthalmoscopy through dilated pupils to detect any signs of this frequently asymptomatic cause of visual morbidity.

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True costs are different from those given in paper

EDITOR,—I believe that there are problems with the costing used in J P O'Hare and colleagues' study of the effect of adding retinal photography to screening for diabetic retinopathy.¹

Firstly, no detail of the method is given. The figure of £12.50 for the cost of adding photography first appears in the discussion, and it would be useful to know what it includes (for example, labour, materials, capital for camera and van).

Secondly, the cost per patient whose sight is saved is based on dividing the extra cost of adding photography to the screening of 3500 patients (at £12.50 per patient this is £43 750) by the total number of patients whose sight is saved (this being regarded as equivalent to the number given laser treatment). Table 1, however, shows that the sensitivity of referral is increased by only 8% by adding photography (65% to

73%) or by 19% by adding photographs reviewed by a specialist (65% to 84%). The extra cost of photography should be divided only by the number of extra patients whose sight is saved by the extra referrals. If 100-125 patients need referral, only 8-10 would be added by photography; if the proportion requiring laser treatment is similar (50% or 40%, based on 50 from 100 or 125) then the number of extra patients whose sight was saved would be about four (three to five, ranging from 40% of 8 to 50% of 10). This is because the general practitioners and optometrists (combined) were already referring most of the patients who needed referral. When the marginal cost of £43 750 is divided by the marginal number of patients whose sight was saved (four) the true cost of adding photography is shown to be £10 937.50 per patient whose sight is saved. The paper's "key message" box is therefore misleading.

It would have been more useful to consider separately the cost per referral for each screening method (general practitioner, optometrist, and photography) and to turn the question round—that is, to ask what screening by a general practitioner or optometrist adds to screening by photography with a specialist reporting on the photographs. Only screening by an optician is competitive (75% v 75%), and the choice then depends on a comparison of costs. Adding photography to examination by an optician improves sensitivity by 13% (75% to 88%), and that requires marginal analysis with the costs being based on the optician taking the photographs; there will be a reduced capital cost (camera only) and reduced labour cost, especially since diabetic patients are entitled to free annual eye checks. The NHS therefore already incurs most of the cost of screening by an optician, and the marginal cost of photography would be low.

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Authors' reply

EDITOR,—P M Hart and colleagues' statement that doctors caring for diabetic patients should continue to perform direct ophthalmoscopy is a message that needs to be supported. Our paper provides evidence that, in an organised community screening programme, combining ophthalmoscopy and retinal photography improves performance, and our experience is that it enhances the skills of the doctors undertaking ophthalmoscopy and their referral at the most appropriate stage to the ophthalmologist.

N R Waugh raises interesting points about marginal costs for photography. The figure of £12.50 for the screening service includes the photographer's and clinical specialist's salaries, film costs, camera and vehicle maintenance, and a depreciation element for the capital replacement of camera and van. The cost per patient whose sight was saved was calculated by use of combined modalities in an organised screening service on the assumption that the total package was necessary to achieve a sufficiently high sensitivity. Clearly if only the additional value of one modality (whether ophthalmoscopy or fundal photography) is assessed the marginal costs for the other seem high. A fuller analysis of costs for the different modalities has been made in previous studies,¹ and our paper did not attempt to repeat this.