Letters

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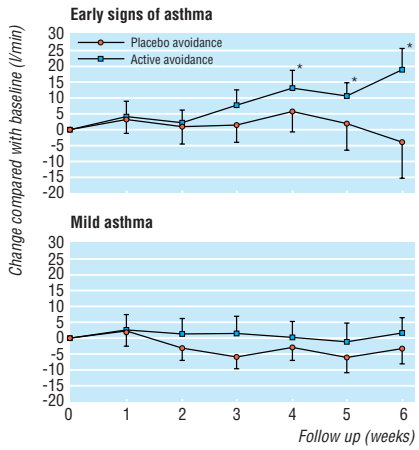
Control of house dust mite in managing asthma

Effectiveness of measures depends on stage of asthma

EDITOR—In their meta-analysis Gøtzsche et al concluded that measures to control house dust mites are not clinically effective in patients with asthma who are sensitive to mites.[1] In the accompanying editorial Strachan commented that this was probably because several control measures used in the included studies did not result in a (relevant) reduction in concentrations of house dust mite allergens. Improvements in clinical condition are consequently not to be expected. Some studies in the meta-analysis found clinical effects while others did not.[1] This may not be a result of effectively reducing allergen concentrations but of measuring different groups of asthmatic patients in different stages of disease. We believe that early treatment of mild asthma might have more impact than treating mild to moderate asthma.

We investigated the (clinical) effects of a combined allergen avoidance strategy (use of covers on mattresses and bedding that are impenetrable to house dust mites and use of benzyl benzoate (Acarosan) on living room and bedroom floors) in two groups of subjects allergic to house dust mites. One group had some early signs of asthma[2] but no diagnosis and the other had a confirmed diagnosis of mild asthma.[3] In the subjects without diagnosed asthma, peak flow rates and symptom scores stabilised during follow up (figure (top)), suggesting that the onset of asthma may have been delayed. The subjects with mild asthma showed no clinical effects during the same follow up (figure (bottom)), although allergen concentrations were reduced, especially on mattresses (10-fold, $P = 0.0001$).[3]



Morning peak flow rates in subjects with allergy to house dust mites and early signs of asthma or confirmed mild asthma during placebo and active strategies to avoid allergens. *P<0.05

We hypothesise that allergen avoidance has more impact as an early preventive measure than as treatment of mild asthma. In established asthma small amounts of allergen may be sufficient to trigger a deterioration in the condition. Furthermore, allergen concentrations will need to be reduced for some time to reverse the already developed process of inflammation. In allergic patients who have not yet develped asthma a reduction in allergen load might prevent further development of the disease as the process of inflammation can probably be slowed down at this early stage. The fact that avoidance measures are more effective in children than in adults supports this idea.[4] Thus allergen avoidance measures need to be applied in an early stage of the disease (secondary or even primary prevention[5]) to be clinically effective.

In summary, we believe that the conclusion of Gøtzsche et al covers only one aspect. Measures to control house dust mite might be effective in patients in the early stages of asthma and might therefore be recommended as an early intervention.

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Competing interests: None declared.

1 Gøtzsche PC, Hammarquist C, Burr M. House dust mite control measures in the management of asthma: meta-analysis. *BMJ* 1998;317:1105-10. (24 October.)
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Peak expiratory flow rates in populations are not valid measure of asthma

EDITOR—The fact that Gøtzsche et al found that measures to eradicate house dust mite had no significant effect on the severity of asthma is not surprising as they used peak expiratory flow rate as one of their principal measures of severity.[1] The enormous heterogeneity of peak expiratory flow rates makes them poor measures of asthma severity when studying populations. Gregg and Nunn's results from mini-Wright peak flow meters show wide variation between people, age and height explaining only 30% of the variation in peak flow rates.[2,3] Peak expiratory flow rate nevertheless remains a useful measure for self monitoring of asthma.

In addition to the important distinction made by Strachan between efficacy and clinical effectiveness in efforts to reduce house dust mite,[4] the measure of clinical effectiveness should be valid. I suggest that failure to distinguish between two population distributions of peak expiratory flow rate does not provide a valid measure of asthma.

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Competing interests: None declared.

1 Gøtzsche PC, Hammarquist C, Burr M. House dust mite control measures in the management of asthma: meta-analysis. *BMJ* 1998;317:1105-10. (24 October.)
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Conclusions of meta-analysis are wrong

EDITOR—Gøtzsche et al performed a meta-analysis of the published controlled trials of avoiding dust mite allergen in the treatment of asthma.[1] Several past approaches for decreasing mites in houses are known to be ineffective—for example, vacuuming carpets and using acaricidal foams and HEPA (high efficiency particulate air) air cleaners.[1,2] Gøtzsche et al concede that in 12 of the 23 studies the avoidance measures did not decrease mite allergen concentrations. In addition, five studies did not measure whether exposure to dust mite changed. To include all these studies in one analysis as if they were comparable to controlled trials in which mite allergen concentrations had been decreased significantly is equivalent to analysing the effectiveness of inhaled steroids in studies in which actuation failed to deliver the drug. Indeed, many of the older

"avoidance" studies included have so little insight into the factors that influence mite allergen in a house that it is amusing to reread them today.[1]

Gøtzsche et al state that the results were the same for the studies in which successful reduction in exposure to mite allergen was achieved, which is strikingly different from the conclusion of three groups who analysed the same studies.[3] Each of these reports concluded that the evidence strongly favoured using physical avoidance measures in treating children with asthma and mite allergy. Five controlled trials of allergen avoidance have achieved a prolonged (≥6 months) decrease in allergen concentration (references 11, 19, and 23 in the meta-analysis).[4 5] The active avoidance group in four of the studies showed significant improvement. Gøtzsche et al restricted their calculations to two outcomes (symptoms and morning peak flow), although these were not the primary outcomes of the successful studies. Thus, they did not include the controlled trial by Ehnert and her colleagues in Berlin, which produced the most convincing decrease in mite allergen concentration and highly significant decrease in bronchial hyperreactivity (see figures 2 and 3[1]).

Allergic patients who are removed from an environment with high mite concentrations improve clinically and in terms of bronchial reactivity.[2] The question has always been whether the same effect can be achieved in homes. Gøtzsche et al reached a negative conclusion by including studies that had no effect, or unknown effects, on mite allergen concentrations and imposing an analysis that was simplistic and unrelated to the successful results. The correct conclusions are, firstly, that reducing mite allergen concentrations in a humid climate is not easy and requires an understanding of the factors that influence mite growth and, secondly, that four of the five controlled trials with a prolonged decrease in these concentrations have achieved impressive clinical results.

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Competing interests: TAEP-M and MDC have received support for research on indoor allergens from Allergy Control Products (Ridgefield, CT) and from S C Johnson Wax (Racine, WI). Both companies manufacture products used for allergen avoidance.

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Power dressing is important in meta-analysis

Editor—The paper by Gøtzsche et al[1] highlights a recurring problem with systematic review and meta-analysis—namely, ignoring or paying lip service to the importance of power. The continued publication of articles with inadequate power in social and health science journals has been noted on many occasions,[2–4] without any apparent effect.[3] Articles of inadequate power are, however, often combined into meta-analyses with scant regard to their power. The power of a study is the probability that it will lead to significant results.[2] For example, in a recent systematic review of the literature examining the prevention of pregnancy nine of the 15 articles included had low statistical power.[5] Given this low statistical power, should these articles have been included?

In the study by Gøtzsche et al the main result is that 41 out of 113 patients exposed to treatment interventions improved compared with 38 out of 117 in the control groups. If we imagine this had been run as a single experiment with this number of subjects and perform a χ^2 test on the results, the results will indeed be non-significant ($\chi^2 = 1.27$, $P = 0.161$, $\phi = 0.076$). Suppose that we had originally believed that the effect size of treatment would be small—that is, about 0.1^2—then an adequate sample with a power of 0.8 to detect a significant difference would be 785 subjects for the 0.05 level and 1168 for the 0.01 level.

To put it another way, the power of the study by Gøtzsche et al to detect a significant difference of a small effect size is inadequate. It is also inadequate to detect a medium effect size. Given that this is the case, would it be published if it were a single study, and should it be published because it is a meta-analysis?

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Authors' reply

Editor—Our conclusion was: "Current chemical and physical methods for eradicating mites or reducing exposure to mites seem to be ineffective and cannot be recommended as prophylactic treatment for asthma patients who are sensitive to mites." This conclusion is still valid as none of the correspondents have provided data to the contrary.

The hypothesis by Cloosterman and van Schayck that avoidance measures might be more effective if they are applied early is interesting. However, as they suggest, it needs further testing. Their trial included only 29 patients, and forced expiratory volume in 1 second at baseline was already as high as 99% of the predicted values.

Morrison's comment that peak flow is highly variable is less relevant. Any variation can be overcome if the sample size is big enough, and the difference in peak flow we found corresponded to only −3 l/min (95% confidence interval −25 to 19 l/min). This does not suggest we missed any worthwhile effect.

Contrary to the statements of Platts-Mills et al, we quoted odds ratios for five end points (not just two), and we included the paper of Ehnert et al as reference 11. As we stated, there was no overall effect on bronchial hyperreactivity. Platts-Mills et al claim that physical avoidance measures have an effect. They refer to a small study by Murray and Ferguson of 20 patients, which we excluded as it is not a randomised trial. Furthermore, they refer to a conference abstract. We are aware of this trial and of other trials, and these will be included in the updated Cochrane version of our review.[1] We agree with Platts-Mills et al that removing patients from an environment with a high mite concentration may be beneficial. We also wish to point out that vote counting (four out of five studies give positive results) is a notoriously unreliable method.[2]

Muncer's comment is relevant to those planning trials but not to a meta-analysis, which is a retrospective systematic review of what has been done. A meta-analysis is therefore always informative, whatever the power might be.

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1 Hammarquist C, Burr ML, Gøtzsche PC. House dust mites and control measures in the management of asthma (Cochrane review). In: Cochrane Collaboration. *Cochrane Library*. Issue 3. Oxford: Update Software, 1998.
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More thoughts prompted by the Bristol case

Damned if you do and damned if you don't?

Editor—I can readily identify myself as one of the two consultants principally concerned with the case of whistleblowing or professional assassination reported anonymously as a personal view.[1] Many of the problems we had with reporting poor performance should be resolved if the new formal procedures and assessments of the General Medical Council (GMC) work. However, the

central issue of a practitioner's first responsibility being to protect patients from underperforming colleagues by speaking out remains. It will be difficult to reassure doctors about the consequences to themselves of so reporting if, later, accusations of malice or personal motives are cited. The alternative of anonymous reporting is unacceptable since it would then be easier to make malicious accusations and it is normal in law for people making accusations to be available for cross examination by the accused.

A major problem is for doctors to know at what point a level of failure is significant. In my case, questions from general practitioners, requests for second opinions, and complaints from junior doctors who were willing to cite the cases that worried them were sufficient for me to act. The subsequent process of suspension is clearly damaging to a doctor, but the decision must be taken exclusively by the management as part of a risk assessment. The preliminary screening in the GMC's new procedure should probably be the stage at which a decision can be made on the evidence provided to suspend the practitioner or permit him or her to continue at work while being investigated; the screeners will become familiar with accepted standards in each specialty.

My experience of the management's independent assessment was wholly unsatisfactory: we were not told who carried it out but simply that "the frequency and degree [of errors that we reported] could be considered acceptable medical practice." Such assessments probably explain why Tomlin reports that in only two of 28 cases that he surveyed was fault proved against the accused doctors.[2] Neither were we told of any advice given to our colleague to modify his practice. This is unsatisfactory, since those making complaints have no feedback and cannot evaluate their own actions. I would recommend that this aspect was addressed in the formal GMC procedure so that there is an evolving and published set of standards.

Sometimes in professional work we have to do what we think is our best and take partially informed criticism on the chin. That is what I have learnt from blowing the whistle.

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1 Whistleblowing or character assassination. *BMJ* 1998;316:1756-7. (6 June.)
2 The aftermath of the Bristol case [letters]. *BMJ* 1998;317:811-6. (19 September.)

Doctors must accept inevitable consequences of ageing

Editor—The letters published after the trauma of the Bristol case[1] omitted one aspect of paramount importance—that consultants can be expected to perform complex procedures up to the age of 65 or until they retire. Most consultants achieve their peak professional and physical performance in their late 40s to middle 50s. A physical deterioration (which can affect performance, stamina, and confidence) follows, at a variable rate. Clinicians with insight adapt their practice, but competitive and macho individuals may refuse to accept that others in their department, hospital, or specialty are better.

Paradoxically, as eyesight and the spine deteriorate, clinical knowledge continues to accrue. Why does the profession not recognise this by negotiating contracts that allow clinicians to withdraw from the most complex, tiring work as they age? They might then increase their outpatient consultations, undergraduate and postgraduate teaching, or management or other related activities without financial penalty.

To achieve a debate on this matter, I put forward a motion to last year's annual representative meeting of the BMA. Although only two motions related to the consultant contract, neither was taken. When I asked why, a member of the Central Consultants and Specialists Committee said, "They were not going to have conference tell the consultants what to do." Such attitudes are the basis of the Bristol case and other disasters.

As a profession we must accept that there are inevitable consequences of ageing. Our patients should be protected from them, both in the NHS and in private practice.

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1 The aftermath of the Bristol case [letters]. *BMJ* 1998;317:811-6. (19 September.)

Fear of hypercapnia is leading to inadequate oxygen treatment

Editor—Patients with proved hypoxaemia who are receiving a fractional inspired oxygen concentration of only 24-35% can be found in wards throughout the United Kingdom. Even this is overstating the case since masks often do not deliver the set oxygen concentration,[1 2] and an ill fitting facemask with a resultant increase in entrained room air will further reduce the inspired oxygen concentration.[3] I was therefore delighted by Bateman and Leach's statement that "Inadequate oxygen accounts for more deaths than can be justified by the relatively small risks associated with high dose oxygen."[4] It was disappointing then to find that most of the article dealt with oxygen delivery systems designed to deliver a low percentage of oxygen. It was also frustrating to read a recommendation that the maximum permissible inspired oxygen concentration is 60% in a non-arrested hypoxaemic patient. A subsequent article in the ABC of Oxygen again stated that 24-28% oxygen should be used for patients with chronic obstructive airways disease until arterial gas analysis is available because of the possibility of hypercapnia.[5] This fear has been successfully transmitted to generations of medical students, who have subsequently been unable to bring themselves to adequately treat documented hypoxaemia.

In intensive care respiratory depression can be treated by instituting or increasing mechanical ventilation, a treatment not immediately available to most respiratory physicians. Over 15 years, I have seen a small number of patients who exhibited moderate and gradual rises in partial pressure of carbon dioxide because of loss of hypoxic drive. In no case did the hypercapnia constitute a risk to life or an acute emergency. Hypoxaemia, however, is responsible for many cardiorespiratory arrests and does represent a sudden and profound risk to life. The standard thinking on oxygen therapy and chronic lung disease requires a change in emphasis. We should highlight statements such as that with which Bateman and Leach finish their article: "Failure to correct hypoxaemia for fear of causing hypoventilation and carbon dioxide retention is unacceptable clinical practice."[4]

I would also like to question their view that the use of nasal prongs can ever be associated with adequate humidification. Many patients receiving oxygen have increased bronchial secretions due to acute respiratory infection or chronic lung disease. We should be recommending the best humidification possible. This requires a face mask and a circuit with a humidification chamber, preferably heated.

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Having practice pharmacists is not only way of reducing prescribing costs

Editor—Wells advocates employing a practice pharmacist to control prescribing costs in general practice.[1] This can be achieved by other, less costly, means. The latest prescribing analysis and cost (PACT) data for the non-fundholding practice (about 8500 patients) where I work show that our prescribing costs are 26% below the national equivalent, marginally better than those of Wells's practice (24% below the national equivalent). Our generic prescribing rate is 80%, and the number of items prescribed is 31% below the national equivalent. This has been achieved by means of computer aided

generic prescribing, a practice formulary, and prescribing protocols and guidelines.

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1 Wells WDE. Having a practice pharmacist can reduce prescribing costs. *BMJ* 1998;317; 473. (15 August.)

Thalassaemia among Asians in Britain

Thalassaemia Society is working to improve awareness

EDITOR—Gill and Modell quote incidence figures for thalassaemia in the United Kingdom.[1] However, the paper by Varawalla et al indicates that up to 1 in 7 Asians in the United Kingdom may be carriers.[2] There have been no large epidemiological studies to provide a true picture (incidence varies according to religion, marriage practices, and culture).

They are correct that awareness levels are unacceptably low, and our survey carried out in November 1996 of Asians in England showed that only 5% were aware of thalassaemia. We have calculated the cost of supporting a patient from birth to 30 years. Figures vary depending on the calculation method and whether the cost of borrowing to the state is considered. Accordingly, we feel that it is safer to quote a range of between £250 000 and £1 000 000.

It is true that the Cypriot community in particular has benefited from having health education available both in Cyprus and the United Kingdom. The message has been reinforced by the church in Cyprus and this community's frequent travel to Cyprus. In India, however, thalassaemia education such as that at the Wadia Hospital in Bombay (World Health Organisation project) may not have any impact on people living here, who may not originate from the catchment area.

Modell et al looked at the use of nurse facilitators to enhance screening.[3] It would be interesting to know the background of the practitioners. The Thalassaemia Society is running a project over three years to increase awareness of thalassaemia in Asians as well as increase testing before conception in primary care. We have found that in those areas where public awareness needs to be increased there are a higher number of ethnic minority practitioners.

The society also acts as an information and resource centre for primary care workers. Our health education material has the advantage of having community involvement and sensitivity. Information is also available on our website (www.ukts.org). With increased emphasis on health improvement programmes, the time is right for primary care groups to respond positively to screening.

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1 Gill PS, Modell B. Thalassaemia in Britain: a tale of two communities. *BMJ* 1998;317:761-2. (19 September.)
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Authors' reply

EDITOR—We agree that no large studies exist of the prevalence of thalassaemia among British Asians. We therefore used the most comprehensive data sources available to base our figures on.[1] These were calculated by applying the Hardy-Weinberg equation to, firstly, the 88 affected pregnancies in Indian parents recorded in the UK Thalassaemia register and the UK register of prenatal diagnoses in the 10 years 1983-92,[2] and, secondly, the roughly 153 870 births to parents of Indian origin in the same 10 years.[1] The result is an average gene frequency of 0.0225 (2.25%) corresponding to an average β thalassaemia carrier frequency of 4.5%. Of course, there are wide variations: some groups of East African Asians have a higher prevalence (probably up to 6%), while Punjabi Sikhs have around a 3% prevalence. However, 4.5% carrier prevalence is a good estimate. Underlying assumptions and economic models certainly affect estimated treatment costs: those used for the estimate we quote are available for scrutiny in the public domain.[3]

Of course it would be interesting to know if there is a relation between practitioners' ethnic origin and screening activity. It was not possible to disentangle this in the study as most practitioners from minority ethnic groups work in inner city areas where large proportions of ethnic minority communities reside.[4] We agree with Lakhani that services have to be provided to meet the needs of this community.

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Costs incurred by one severely ill Jehovah's Witness could run one unit in Africa for one year

EDITOR—Minerva reports that a Jehovah's Witness survived emergency surgery for a leaking abdominal aneurysm despite having a postoperative haemoglobin concentration of only 30 g/l; he spent 14 weeks in hospital.[1] Those of us who work in rural Africa can only wonder how much it cost in the face of claims of rationing and cost cutting in the NHS. Such a stay must easily have cost a six figure sum.

Here in Uganda for £250 000 a year we can treat 25 000 outpatients and 7000 inpatients, conduct over 1000 deliveries, and perform 1500 operations. We run a community health programme for 500 000 people. The costs incurred by this one patient might run our unit for a whole year. Will the time come when a religious group will be charged the costs of keeping its members alive? Ethically one may feel that one should do everything, whatever the cost; at the end of the financial year, however, elective surgery that could be life improving has to be cancelled.

The choice is easy here in Uganda. When a child who has severe anaemia from malaria with hookworm infestation and undernutrition comes in the choice is simple: he or she has a transfusion or dies.

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1 Minerva. *BMJ* 1998;317:690. (5 September.)

How do two meta-analyses of similar data reach opposite conclusions?

EDITOR—In their meta-analysis Fahey et al concluded that treatment with antibiotics made no significant difference to the resolution of acute cough,[1] although they found a trend favouring antibiotics. The Cochrane meta-analysis on treatment of acute bronchitis concluded that antibiotics have a modest beneficial effect.[2] Eight of the nine studies extracted were the same in both meta-analyses, and 90% of the 750 patients were used in both.

How can two meta-analyses based on the same studies come to opposite conclusions? In Fahey et al's study the outcome measures were resolution of cough and clinical improvement on re-examination. In the Cochrane meta-analysis, four outcomes showed significant differences between antibiotic treatment and placebo. The patients were less likely to report feeling unwell at a follow up visit (two studies), to show no improvement on assessment by a doctor (four studies), and to have abnormal lung findings (two studies) and had a more rapid return to work or usual activities (five studies). The two meta-analyses agreed in finding no significant difference in the proportion of patients with resolution of cough at follow up. Both agreed that side effects were significantly higher in the antibiotic groups.

The search strategy and the inclusion and exclusion criteria do not seem to explain the differences in conclusion. The answer may lie in the objective and the choice of outcome measures in the two analyses. The objective in Fahey et al's meta-

analysis was to assess whether antibiotic treatment for acute cough is effective; that in the Cochrane group's meta-analysis was to determine whether antibiotic treatment is associated with any improved outcomes in patients with a clinical diagnosis of acute bronchitis. In our opinion the two main questions in evaluations such as this should be: Which outcome measures are the most clinically relevant? and Are the differences that are found to be significant also clinically important? As the choice of outcome measures may be crucial for the main conclusion, the choice should be explicit early in the study and be well substantiated. Meta-analyses based on small studies are not easy to interpret, and conclusions should be drawn with caution.

This example shows that in meta-analyses too there is an element of subjectivity in the research question posed, the choice of outcome measures, and the evaluation of whether significant differences also are clinically important.

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1 Fahey T, Stocks N, Thomas T. Quantitative systematic review of randomised controlled trials comparing antibiotic with placebo for acute cough in adults. *BMJ* 1998;316:906-10. (21 March.)
2 Becker L, Glazier R, McIsaac W, Smucny J. Antibiotics for acute bronchitis (Cochrane review). In: Cochrane Collaboration. *Cochrane Library*. Issue 1. Oxford: Update Software, 1999.

Management of drug budgets

Neurologists do not have confidence in Glasgow's method of managing drugs budget

Editor—As the local neurologists implementing the introduction of new drugs into neurological practice we take issue with the process described in Beard et al's article about systems and strategies for managing the drugs budget in Glasgow.[1] We recognise the importance of pragmatism and sound economic analysis in meeting the challenge of increasing drug costs to the NHS. However, we have no confidence in the methods currently implemented by the Glasgow area drugs and therapeutics committee in the assessment of new drugs.

It was made clear to us that if we did not participate in "pragmatic outcome studies" our patients would not have access to new treatments. For this reason we reluctantly agreed to provide limited reports to the drugs and therapeutics committee. These studies have been open label, uncontrolled, and of small numbers of patients. The criteria for assessing sufficient cost effectiveness, which the committee requires to justify subsequent funding, were not defined or explained to us at any stage. At best these studies might produce grade 4 data (as defined by United States Agency for Health Care Policy and Research[2]).

We regard it as crucial that the responsibility for funding decisions is seen to lie where it does, in fact, lie. The current strategy whereby "if hospital specialists cannot show that a treatment provides measurable and worthwhile benefit it will not be purchased" has the effect of shifting perceived responsibility for funding decisions away from the purchaser towards the clinician. We do not disagree with the concept of cost benefit or cost utility analysis (in distinction to cost effectiveness analysis) in evaluating new drugs, and would take part in such studies if they were adequately resourced and constructed in a manner that would produce new and useful data.

We cannot endorse Beard et al's view that other health boards should follow the example of Glasgow—an example that the authors themselves recognise may lead to "postcode prescribing." Beard et al's paper shows the urgent need to advance national policies for introducing new drugs into clinical practice. We trust that such policies will begin to emerge with leadership from the Department of Health, the royal colleges, specialist societies, and the National Institute for Clinical Excellence. Such guidance should promote equity of access to treatment, appropriate use of drugs, and scientifically sound economic analysis of benefit.

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1 Beard K, Forrester E, Lee A, Burns H, Brodie MJ. Systems and strategies for managing the drugs budget in Glasgow. *BMJ* 1998;317:1378-81. (14 November.)
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Local and national coordination are needed

Editor—The article by Beard et al on the management of drug budgets clarifies that the initial motive in setting up the strategy was financial.[1] Reducing costs without sacrificing quality of care is a laudable aim, but how it is to be achieved? What should be the role of local advisory bodies in achieving it?

If we are to avoid confusion and problems we must differentiate between what is best achieved locally and what should be coordinated nationally. Monitoring of doctors' prescribing habits is a local function and should be addressed as such. Dissemination of information to both doctors and patients must be coordinated nationally if conflicting advice is not to be given. Local priorities will, however, probably be identified for local implementation. Monitoring of prescribing and dissemination of agreed information thus clearly provide roles for the local advisory committee.

The introduction of new drugs seems the most contentious area. The concept that a local advisory board is going to produce definitive information from a small open uncontrolled study is ludicrous, and for this to be going on throughout the country, coordinated only locally, is a waste of time, effort, and funds. It is the duty of the Medicines Control Agency to assess the data, and then a national decision should be made regarding an introduction to the NHS. The role of the local advisory committee should then be to ensure the coordinated introduction of these policies locally. They may well include restriction because of financial pressures, but this should be clearly stated.

At present in Glasgow the most respected neurological unit in the city is advising general practitioners and patients to prescribe donepezil to patients with Alzheimer's disease, and permission is apparently refused by the local prescribing adviser while the outcome of a local study is awaited. There is no surer way of undermining the faith of patients in their doctors and the NHS.

A national strategy should be developed that outlines the role of local prescribing advisers and places many of the roles outlined in the paper on a national footing, possibly as an extension of the role of the Medicines Control Agency. At present the cost of ill judged and uncoordinated advice as measured by the dissatisfaction of patients and doctors may turn out to be greater than any savings apparently achieved in local drug budgets.

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Patients who are eligible but not randomised should be included as additional comparative arm in study

Editor—Peto and Baigent state that we need to find ways of making trials much simpler and larger.[1] We agree and have a suggestion based on 20 years' experience.[2]

Everyone is familiar with inclusion and exclusion criteria for randomised controlled trials. With rare exceptions, however, those patients who are eligible but not randomised are a forgotten part of the population; this presents a potentially large problem for all trials. The principal investigators of randomised controlled trials often find that the number of patients being entered into a trial by a particular contributor is not related to the size of the population served by that doctor. There are many reasons for this: purported logistic problems of data entry, inconvenience for patients, patients' unwillingness to accept

randomisation, non-specific unsuitability of patients for the trial, etc. The doctor's inability or unwillingness to offer the trial to all eligible patients provides the circumstances in which clinical selection bias is likely to have occurred.

We recommend that in all trials there should be an absolute requirement that the "eligible but not randomised" group of patients should be included in the documentation process as an additional comparative arm in the study. To investigate the possibility that clinical selection has biased the trial results, this group should be compared with the true control group. If the outcome results are similar then we may predict that the result of the trial will apply to the general population. By contrast, if the outcome results are different then selection bias has clearly occurred, such that the applicability of the trial results to an unselected population must be questioned.

Furthermore, routine documentation of all patients being cared for in departments and units undertaking randomised trials would confer some additional benefit. For example, the larger number of patients being documented and followed up would allow variance between treatments and between outcomes achieved by different doctors to be recognised. The study of such variances will complement the results of randomised controlled trials as we search for reliable new knowledge.

Insisting that all eligible patients be documented would have several consequences: the size of the eligible but not randomised group would be minimised; the size of the trial itself would be maximised; and the results of the trial would be more readily applicable to the population at large. This strategy would help in the recruitment of the necessary numbers of patients for meaningful results and reduce the time taken to complete the trial. Achieving both these objectives would enhance the value of all trials.

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Patients' understanding of randomised controlled trials depends on their education

Editor—We appreciated Featherstone and Donovan's report about patients' perspectives of participation in a randomised controlled trial.[1] We recently investigated the ability of 40 middle aged and elderly caregivers to understand and retain information about randomised controlled trials in patients with Alzheimer's disease.

Eighteen caregivers were men and 22 women, and their mean age was 64 (SD 6) (range 50-76). They had had a mean of 6 (3) years of schooling (range 5-17), and their mean score in the minimental state examination was 29 (1) (range 25-30). They were given information in a semistructured manner, including information sheets. Twenty eight of them could not explain why placebo, randomisation, and double blind procedures were used. Furthermore, eight of them could not recall anything other than a vague idea of participation in an "experiment" and the possible use of a placebo for some unknown reason. Using a four step scale to rate competency to participate in a randomised controlled trial on the basis of understanding information we found a significant positive correlation between competency and degree of education.

We agree that accurate information does not ensure understanding of the features of randomised controlled trials. Our results are similar to those of Featherstone and Donovan, in that 30% (6/20) of their subjects and 20% (8/40) of ours were unaware of the influence of chance. However, Featherstone and Donovan did not report the degree of education of their subjects. We wonder whether awareness of randomisation and degree of education were correlated in their subjects. We hope that cross cultural studies will contribute further to our hypothesis that the understanding of information based on a scientific standard for obtaining consent to randomised controlled trials is strictly linked to social and cultural background. The large discrepancy between the complexity of methods for randomised controlled trials and the poor education of many potential participants should be highlighted in discussions of issues surrounding informed consent.

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1 Featherstone K, Donovan L. Random allocation or allocation at random? Patients' perspectives of participation in a randomised controlled trial. *BMJ* 1998;317:1177-80. (31 October.)

Review on bladder cancer

New rather than old TNM staging system should have been used

Editor—The review on bladder cancer includes an incorrect diagram of the TNM staging system and neglects any reference to the hope of improved outcomes with concurrent radiation and chemotherapy.[1] The diagram shows the previous TNM (fourth edition) T categories[2] rather than the new (fifth edition) system.[3] The new system categorises all muscle invasion without perivesical invasion as T2. T2a is invasion of the "inner half" and T2b is invasion of the "outer half." Any perivesical invasion leads to T3 categorisation, which is also subcategorised: T3a is microscopic invasion beyond the muscle; T3b is an "extravesical mass."

The review summarises the evidence for little useful effect of either neoadjuvant or adjuvant chemotherapy in patients with muscle invasive bladder cancer managed surgically. It neglects, however, one promising avenue of multimodality treatment: concurrent chemotherapy and radiation. Several studies show that this approach has survival rates and local control rates comparable to those in surgically managed patients but conserves good bladder function in most patients.[4,5] Completion of randomised controlled trials to evaluate this approach is essential.

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Author's reply

Editor—The reason why I used the fourth edition of the TNM system instead of the fifth is that all the cases referred to were staged according to the fourth or previous versions. This is because of the time period in which the patients were recruited in the different trials. For recent and future trials the European Organisation for Research and Treatment of Cancer Genito-Urinary Cancer Cooperative Group will use the fifth edition, although it does not agree completely with the revisions.[1]

My review was intended more for general practitioners than for medical specialists and is therefore not fully detailed. I did not mention concurrent chemotherapy and radiation, or review brachytherapy and many urinary diversions either. In my view, concurrent chemotherapy and radiation is still not standard treatment. At least four reports in the literature (of 840 patients in randomised trials treated with sequential or concurrent chemotherapy and radiotherapy) did not show survival benefit.[2] I agree with Millar that randomised controlled trials to evaluate this combined modality must be completed.

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Use of health services by children

Study does not rule out effect of social class

EDITOR—In a secondary analysis of the British general household survey, Cooper et al conclude that the use of health services by children and young people is equitable in terms of social class status.[1] It is difficult either to agree or to disagree with them, since the results of the logistic regression analysis in table 3 do not include any details of their main social class variable (socioeconomic group of the head of family unit). We are told only that this variable was not significant and were not offered P values, odds ratios, or confidence intervals. The practice of presenting results only for variables that are statistically significant ($P < 0.05$) is adopted throughout table 3. We are surprised that the *BMJ* found this acceptable, since it ignores the journal's own published statistical guidelines.[2]

Cooper et al found a significant association between socioeconomic group and inpatient admissions in their univariate model (table 1), and a significant association between housing tenure and inpatient admissions in their logistic regression model (table 3). One would expect there to be a strong link between socioeconomic group and housing tenure, with a higher proportion of people from lower socioeconomic groups living in local authority housing. The logistic regression model does not include both housing tenure and socioeconomic group simultaneously since these variables would provide very similar information. Cooper et al themselves claim that both socioeconomic group and housing tenure are measures of social class. Therefore, all the indications are that inpatient admissions for children are indeed related to social class, after adjustment for morbidity, with higher admission rates among the lower social classes.

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1 Cooper H, Smaje C, Arber S. Use of health services by children and young people according to ethnicity and social class: secondary analysis of a national survey. *BMJ* 1998;317:1047-51. (17 October.)
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Motivation for consultations may explain differential referral patterns

EDITOR—The use of health services by children and young people is an area that has been neglected. Cooper et al's study goes some way to redressing this imbalance.[1] Their assertion, however, that children and young people from ethnic minority groups may experience poor quality consultations in primary care and discrimination in referral to hospital services may be unfounded.

Data from the Camden and Islington Young People and Health Study suggest an alternative explanation for these patterns.[2] This was a self complete questionnaire based survey of 993 students aged 15 and 16, attending eight secondary schools in inner London. We were able to explore young people's own reports of use of general practitioners' services, in contrast to Cooper et al who rely on parental reports for those aged under 16.

In our sample, Asian and black young people were significantly more likely to report "excellent" self rated health and similar levels of longstanding limiting illness to their white counterparts. They were also more likely to report going to the general practitioner by themselves. Asian young people expressed less concern about the confidentiality of general practitioners' services. Asian and black young people were less likely to list their parents as a source of general health advice or to include parents or friends as potential sources of help or advice about drugs, alcohol, and sex.

Increased consultation rates among 15 and 16 year olds from ethnic minorities may therefore be accounted for by this group's reliance on their family doctor for health advice. Although this cannot fully explain the consultation patterns described by Cooper et al, it does highlight the need to gather more information about patients' motivation for consultation as well as their frequency. Children, young people, and young adults have different motivations for consulting their general practitioner, which aggregating data for young people aged 0-19 will mask. As young people have been shown to have distinct, yet unmet, primary healthcare needs,[3 4] future research should concentrate on young people's own experience of primary health care.

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Different data collection methods can lead to different findings

EDITOR—The findings by Cooper et al about ethnicity and use of health services in the United Kingdom[1] are the opposite of my findings in the Netherlands. On the basis of data from the First Dutch National survey of morbidity and interventions in general practice, used in a regression analysis, socioeconomic status contributed significantly whereas ethnicity of the child did not contribute to the variation in the use of general practitioners.[2] A detailed analysis matching a child from an ethnic minority to a socioeconomically comparable Dutch child showed that consultation rates of general practitioners did not differ by ethnic origin, but the types of illness presented did.

I do not think that the Netherlands differs from the United Kingdom in this respect. The contradicting results may be explained by differences in the methods of data collection. Cooper et al's study used self reported data based on retrospective interviews (it is not clear whether these were written or oral interviews), whereas my study used registrations with general practitioners. I compared both methods for consultation data of the same children and period. I found that consultation data reported by parents from lower socioeconomic classes and ethnic minorities deviated more from the general practitioner registration than data reported by parents from higher socioeconomic classes.[3] The self reported data by parents of lower socioeconomic classes and ethnic minorities may thus be less reliable.

Regarding the measurement of perceived health status, Cooper et al used a measurement that was too crude. Since experiences and behaviour with regard to illness are culturally bound, the complex process of illness behaviour cannot be captured with a few standardised questions.

The measurement of socioeconomic status—occupation of the head of the family—is dubious. The parents' education (especially the mother's) may have lead to different results, since the mother often decides to consult the general practitioner. Even more problematic is the measurement of socioeconomic status if ethnic minorities are to be compared with the white population, taking into account unemployment rates and numbers of one parent families.

Cooper et al did not analyse the non-response group their study. The absolute numbers of non-white participants are small, and extrapolation of the results is therefore not appropriate. People from lower socioeconomic classes refuse participation in surveys more often. Also, people from ethnic minorities may have other characteristics that lead to greater non-response.

Large scale population surveys are important, but more emphasis should be put on the measurement of different concepts before it can be assessed whether equity has been achieved.

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Objective measures of health status are essential

EDITOR—In their secondary analysis of the British general household survey Cooper et al found that south Asian children and young people used the services of general practitioners significantly more often than their white counterparts, but utilisation of hospital outpatient and inpatient services was significantly lower among all children and young people from ethnic minorities than among their white counterparts.[1]

Cooper et al attempted to adjust for differences in health status among different ethnic groups using data based on reports from the children or their parents. Ethnicity has, however, been shown to be a significant predictor of differences in self reported health, and in one study, Asian patients were less satisfied and perceived as less sharing in the doctor patient relationship compared with other ethnic groups, even though they had better health or health of equal status compared with white people.[2] This observation might account for Cooper et al's findings. Before it can be concluded that children and young people from ethnic minority groups received a poorer quality of health care, data based on objective measures of health status are essential.

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Hospital care is not necessarily superior to primary care

EDITOR—In their article, Cooper et al showed that Asian children are more likely to consult their general practitioners but less likely to be seen in hospital outpatient departments or be admitted as inpatients than white children.[1] Only one interpretation of this finding is offered, namely, that children of Asian origin receive health care of poorer quality because of bias and discrimination by their general practitioners. While this may one possible interpretation, it has some obvious flaws. First, it implies that a visit to hospital equates with high quality medical care whereas consultation with the general practitioner is somehow inferior. Second, there are other equally likely interpretations of Cooper et al's data.

Perhaps, through frequent contact with their patients, general practitioners of Asian children have a better knowledge of their patients and are better able to meet their health needs without making (possibly inappropriate) referrals to hospital. Alternatively, white children's parents may pressurise their general practitioners into early hospital referral because of their own perception that hospitals will offer higher quality service. It would be have been prudent of the authors to offer other interpretations of the data and not fall into the trap of assuming that hospital care is necessarily superior to primary care.

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1 Cooper H, Smaje C, Arber S. Use of health services by children and young people according to ethnicity and social class: secondary analysis of a national survey. *BMJ* 1998;317:1047-51. (17 October.)

Authors' reply

EDITOR—Given the unexpected and striking nature of our findings, it is unsurprising that comments focus on methodology and interpretation. Our population sample covers 20 473 children, including 2155 from ethnic minority groups. There are no larger or better quality population based British data than the General Household Survey.[1]

In separate analyses for ages 0-9 and 10-19, social class of the head of the family unit was not statistically significant ($P < 0.05$) in predicting the use of general practitioner, outpatient, or inpatient services when ethnicity and age were included in models. Housing tenure was, however, significant ($P < 0.01$) for inpatient use when added to these models. This addresses Reid and Sturdy's criticism—housing tenure is not providing the same information as class. Rogers and Karlsen believe that aggregating data for 0-19 year olds masks differences among age groups, but separate analyses for younger and older children show comparable findings by class and ethnicity as for the aggregate 0-19 group. General Household Survey data for ages 16 and above are collected from young people themselves, removing potential error if young people attend general practitioners without their parents. Bruijnzeels comments that our measure of socioeconomic status is inadequate, but our table 3 included a measure of family work status that distinguished family structure and parental employment; this variable was not significant in any utilisation models but was a major predictor of children's health status.[2]

Little is known in Britain about ethnicity and the meaning of health, therefore both Bruijnzeels and Leung are right that minority ethnic groups may interpret questions about self assessed health status differently from white parents. However, less error is likely for reported outpatient visits in the past three months and inpatient stays in the past year—certainly not sufficient to explain our findings of such low use of inpatient and outpatient services by children from minority ethnic groups.

The interpretation and policy implications of our findings are of paramount importance. We agree with Bragonier that hospital care is not necessarily superior to primary care. As he suggested, parents from ethnic minorities may put less pressure on general practitioners for hospital referral than white parents. This probably reflects more fundamental underlying language and communication difficulties between general practitioners and parents from ethnic minorities, which we found in recent qualitative research[3] and which needs further investigation. Alternatively, referral rates may vary between general practitioners; parents from ethnic minorities may be registered with general practitioners with a low propensity to refer, which may also relate to ethnic status of general practitioners and area of residence. This is a priority for research using administrative data from general practitioners and hospitals.

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