Letters

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Effect of adding selegiline to levodopa in early, mild Parkinson's disease

Formal systematic review of data on patients in all relevant trials is required

EDITOR—The increased death rate with selegiline in the Parkinson's Disease Research Group's trial highlights the problem of interpreting the results of a small trial in isolation. Ben-Shlomo et al emphasised the internal consistency of this finding,[1] which is not surprising because much of the original data were reanalysed. The hazard ratio was lower than in the original report (1.32 *v* 1.57), which suggests that the trial might have stopped on a random high.

There is no formal systematic review of all unconfounded randomised trials comparing long term selegiline with control treatment in patients with early Parkinson's disease. One attempt by the manufacturers of selegiline did not say which trials were included.[2] I found three such trials in the Cochrane controlled trials register, with follow up ranging from 2.5 to 8.2 years—that is, after the increase in deaths with selegiline started in the Parkinson's Disease Research Group's trial.[3–5] Two trials did not start levodopa treatment for the first few months, unlike the Parkinson's Disease Research Group's trial, but most patients had been taking levodopa for several years at the end of follow up.[3 4] In one trial all patients were switched to selegiline treatment after 1.5 years, which would dilute any treatment effect.[3]

I performed a meta-analysis of the number of deaths at the last available follow up (figure). This is simplistic because of unequal follow up periods in the selegiline and control arms in some trials, but the results did not change after accounting for this. The results are based on under 2000 patients and show a non-significant 16% increase in the relative risk of death with selegiline (lower than that seen in the Parkinson's Disease Research Group's trial). None of the other trials showed a trend against selegiline, but the confidence intervals were wide and compatible with an excess of deaths. There was no evidence of heterogeneity among the trials.

The Parkinson's Disease Research Group's trial found more falls and possible dementia in those who died in the selegiline arm, but this is difficult to interpret without similar data for survivors. Dementia is a poor prognostic factor and is probably associated with a greater risk of falling. Rather than selegiline causing dementia, it might be that, by chance and despite randomisation, more patients in the selegiline arm had a propensity to develop dementia.

This crude meta-analysis suggests that selegiline is unlikely to reduce mortality, but whether it increases mortality remains unclear. A formal systematic review of all relevant trials using data on individual patients data to assess survival, disability, and the risk of dementia is needed. This will require close collaboration between all the trialists. Unfortunately, a recent meta-analysis[6] considered only survival and did not include the two largest trials.[1 3]

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1 Ben-Schlomo Y, Churchyard A, Head J, Hurwitz B, Overstall P, Ockelford J, et al. Investigation by Parkinson's Disease Research Group of United Kingdom into excess mortality seen with combined levodopa and selegiline treatment in patients with early, mild Parkinson's disease: further results of randomised trial and confidential inquiry. *BMJ* 1998;316:1191-6 (18 April.).
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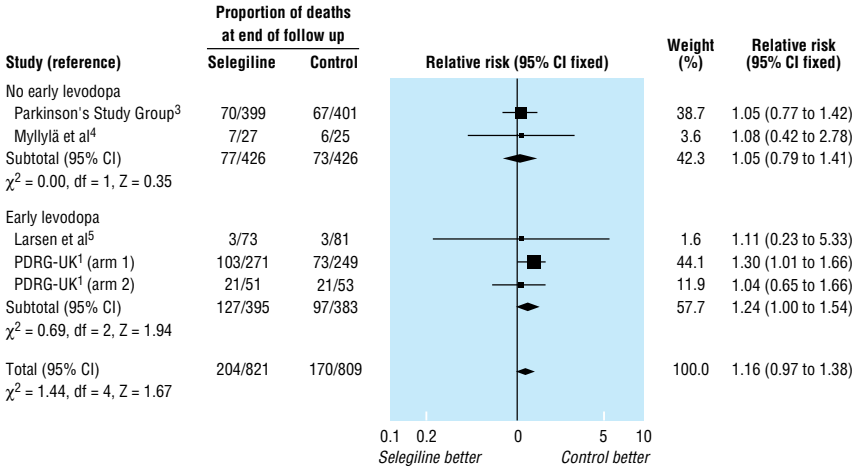

Effect of long term selegiline and control treatment in early, mild Parkinson's disease on death at end of follow up. PDRG-UK=Parkinson's Disease Research Group of the United Kingdom

Evidence is insufficient to show that combined treatment increases mortality

EDITOR—The conclusions of the Parkinson's Disease Research Group of the United Kingdom in its interim analysis of 1995 that levodopa and selegiline treatment is associated with increased mortality were premature as no significant differences in mortality were found after an additional 21 months of follow up (6.8 years in total; hazard ratio 1.32 (95% confidence interval 0.98 to 1.79)).[1] Moreover, when the results were analysed according to an on treatment approach no significant differences in the overall mortality were found between the groups in the interim or in the last analysis.[1] Furthermore, no difference was found in mortality between the patients randomised to receive bromocriptine (one of the three original study arms) and those to receive selegiline and levodopa, although the authors did not mention this in the final report. No significant differences were found in the causes of death between the groups.

Two main problems that may have caused biases in the study have been discussed in the literature. Firstly, patients were allowed to be rerandomised to another group after their original randomisation. Secondly, patients still receiving the original treatment, rerandomised patients, and those withdrawn from the study regardless of how

Proportions of deaths and overall mortality in 11 clinical studies of treatment of Parkinson's disease with selegiline

Study	**Selegiline**	**No selegiline**
Olanow et al 1998[2]*	14/297	17/292
Caraceni et al 1997[3]	25/155	25/156
Di Rocco et al 1996[4]	30/109	40/67
Rinne et al†	3/30	10/30
Parkinson's Study Group 1998[5]	70/399	67/401
Birkmayer et al 1985[6]	118/564	114/377
Ben-Shlomo et al 1998[1]	103/271	73/249
Total	363/1825 (19.9%)	346/1572 (22%)

*Meta-analysis of 5 trials.
†Submitted for publication.

long before and what kind of treatment they had received since withdrawal were included in the analysis. Furthermore, mortality curves became separate between the second and third year of follow up, after which they progressed in parallel. This phenomenon is difficult to explain with any relevant biological mechanism; thus the observed difference could be due to problems in study design.

We performed a meta-analysis on the binary data of all available clinical studies since data on individual patients were not available from all studies (table). Overall, 363 out of 1825 patients given selegiline died (19.9%) compared with 346 out of 1572 who were not given selegiline (22%). In fact, mortality was significantly lower in the group given selegiline (hazard ratio 0.82 (0.69 to 0.97); P = 0.02).

Given the possibility of a biased study design and methodological limitations of the study by the Parkinson's Disease Research Group and the fact that no other clinical study has reported similar findings, there is not enough evidence to claim that the combination of selegiline and levodopa increases mortality in patients with Parkinson's disease.

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Anaesthetists consume 3% of trust expenditure but affect 60% of trust income

EDITOR—The letters on the Audit Commission's report *Anaesthesia under Examination*[1] from those working in anaesthesia have been predictable, varying from those from apoplectic sceptics[2] to the welcoming.[3 4] Having read these and attended the Audit Commission's day in London, we think that the letters are misinformed and based on an incorrect premise.

Firstly, the Audit Commission's report must be considered in context. It was commissioned in 1996 by the chief executives of NHS trusts to provide information on anaesthetists—a group that consumed 3% of trust expenditure but affected 60% of trust income. The report cannot be read without account being taken of the bias implicit in the facts of who the report was written for and who would pay for it. In fact, it looked at the perioperative period, when many workers are involved. As a result of this underlying direction to the Audit Commission's investigation, any conclusions drawn for anaesthetists from the report must be treated with caution.

At the presentation by the Audit Commission on the day, discussion showed that even in an ideal system, exemplified by that at Central Middlesex Hospital, which incorporated maximum anaesthetic flexibility, the difficulty was not among the anaesthetic group. Clearly, until the surgeons cooperated positively, and more fully, with the scheduling and organisation of operating lists, little benefit would be gained by creating new working arrangements for the anaesthetic group. Their ideal system had an appreciable cost, which was not taken into account by the commission but which a systems management analysis might have been able to quantify. We concluded that anaesthetists, consuming 3% of trust expenditure but affecting 60% of trust income, showed high productivity compared with other groups. The report did not, of itself, show a need to increase the productivity of anaesthetists, which was the Audit Commission's starting premise.

As part of the 3% that affect 60% of the income, we wondered why the value added by our specialty was not more appreciated. Stigmatising a linchpin group would demotivate them, leading to decreased output and productivity. On the other hand, expansion of this group and ensuring that its pivotal role was appreciated and valued would be a more obvious way to increase hospital activities on which so much of the hospital's income depends.

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Extrapolation of trial results suggests that aspirin is useful in intermittent claudication

EDITOR—In their evidence based guidelines Eccles et al conclude that aspirin is unlikely to have a beneficial effect on the incidence of major cardiovascular events in patients with intermittent claudication.[1] In contrast, an editorial by Fowkes et al suggests that aspirin may be effective, and thus warranted, even in asymptomatic peripheral vascular disease.[2]

Surprisingly, these opposite statements are both claimed to draw largely on the work of the Antiplatelet Trialists' Collaboration.[3] Only four studies, however, have specifically compared aspirin with placebo in peripheral vascular disease, in a total of 494 patients given aspirin and 484 controls given placebo; 56 events occurred in the aspirin group and 56 in the placebo group, and the relative risk reductions with aspirin ranged from 24% to −90% in the different trials.[3] The number of randomised trials is therefore too small to lead to a conclusion about the efficacy of aspirin in peripheral vascular disease.

On the other hand, the thrombosis prevention trial has shown that aspirin is efficacious in the primary prevention of cardiac ischaemic events in patients with a relatively low risk profile (1% yearly incidence of events in the control group *v* an average 9% in the controls in the intermittent claudication trials).[4] The benefits of antiplatelet treatment are larger when the risk of vascular events is higher, while bleeding is likely to be the same.[2 4] Intermittent claudication is associated with a twofold to fivefold increased relative risk of ischaemic cardiovascular disease.[2] Thus the suggestion that aspirin is not effective in reducing the first occurrence of ischaemic cardiovascular disease in peripheral vascular disease seems unlikely. This controversy is reminiscent of that about the effectiveness of aspirin in the secondary prevention of myocardial infarction, when only a meta-analysis of six randomised trials, in over 10 000 patients, showed the efficacy of aspirin.[5]

Insufficient data are available on antiplatelet treatment, particularly with aspirin, in peripheral vascular disease, and new trials will probably show a considerable benefit from treatment. A precise definition of aspirin's effects in peripheral vascular disease will help to clarify the reported advantage with clopidogrel, an antiplatelet drug recently registered in Europe.

We agree with Eccles et al that there is no direct evidence for the efficacy of aspirin in intermittent claudication, but as clinicians we feel uncomfortable not to prescribe aspirin in patients with a high cardiovascular risk profile.[2] Treatment recommendations in

grey areas in which insufficient randomised evidence is available may reasonably come from the extrapolation of results obtained in similar categories of patients.

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1 Eccles M, Freemantle N, Massun J, North of England Aspirin Guideline Development Group. North of England evidence based guideline development project: guideline on the use of aspirin as secondary prophylaxis for vascular disease in primary care. *BMJ* 1998;316:1303-9. (25 April.)
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Doctors are ethically obliged to advise patients to quit smoking

EDITOR—Butler et al studied smokers and their perceptions of doctors' advice on quitting smoking[1]; their study concluded with a discouraging message for doctors who provide such advice. Doctors should consider other evidence when deciding whether to give advice to smokers on quitting. Contrary to Butler et al's findings, quantitative surveys have shown that most smokers want to be given advice about quitting.[2] Even if the opinions of the smokers in this study are representative, we still believe that doctors should not be discouraged from giving advice on quitting.

Advice from doctors is a cost effective intervention. Although brief advice enables only 2% of smokers to quit, it only costs £100 ($160) per success. This is 20 times more cost effective than nicotine replacement treatment (about £2000 per success).[3] In high risk groups such as pregnant women, patients who have had a myocardial infarction, and men at high risk of ischaemic heart disease, the efficacy of brief advice is much greater.[3]

The Framingham risk equation[4] shows that the reduction in the risk of cardiovascular disease from quitting smoking is equivalent to the reduction in risk achieved by the combination of lowering blood cholesterol concentration by 30% and lowering diastolic blood pressure by 15 mm Hg. In practice, these targets are difficult and costly to attain; smokers are much more likely to require drug treatment to lower their blood pressure or cholesterol concentrations.[5]

The management of risk factors in smokers, such as blood pressure and cholesterol, will impose a huge cost on the NHS and the taxpayer. By respecting patients' wishes not to be informed about quitting and by protecting the rights of smokers to continue smoking, which increases a society's burden of smoking related diseases, fewer economic resources will be available to non-smoking taxpayers, whose rights will therefore be infringed.

Doctors have an ethical obligation to educate their patients about smoking and should not hesitate to routinely provide advice on quitting. The development of potentially better ways of giving advice, such as Butler et al's suggestion of tailoring advice to individuals, should be encouraged but these methods need to be tested for their efficacy and cost effectiveness.

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Preventing headache after lumbar puncture

Most doctors are unaware of features of headache after lumbar puncture

EDITOR—Serpell et al's survey of lumbar puncture practice in the United Kingdom reminds us that small (22-26 gauge), atraumatic needles, which reduce the incidence of headache after lumbar puncture, are not being routinely used.[1] The incidence of headache after lumbar puncture is roughly 35% with 20 gauge standard needles, 5% with 22 gauge atraumatic needles, and 1% with 25 gauge atraumatic needles.[2] Adequate cerebrospinal fluid can be obtained by aspirating with smaller needles. The cost of an atraumatic (Whitacre or Sprotte) needle is about £4, compared with £1 for the standard (Quincke) needle. Using 22 gauge atraumatic needles would therefore cost £10 per headache prevented. A third of headaches after lumbar puncture are described as severe, prolonged, or debilitating and unresponsive to simple measures.[3] Prolonged headache after lumbar puncture can lead to subdural haematoma.[4]

The authors mention that epidural blood patching is a successful way of treating persistent headache after lumbar puncture. Epidural blood patching is widely used by anaesthetists for the more severe headache after lumbar puncture caused accidentally by large 16 gauge or 18 gauge epidural needles.[5]

I conducted an audit at a district general hospital that performs about 150 lumbar punctures annually. Only three out of 26 doctors were aware of the option of epidural blood patching for headache after lumbar puncture (eight junior house officers, 10 middle grade doctors, and eight consultant or staff grade doctors were surveyed). In addition, less than half (of all grades) were able to state correctly the characteristic features of headache after lumbar puncture—fronto-occipital distribution, relief when the patient lies down, onset up to several days after dural puncture, and duration up to several weeks. Clearly, these points still need to be disseminated to all those who perform and teach how to perform lumbar puncture. This is an important message that is equally relevant to surgeons, obstetricians, and general practitioners who encounter headache after lumbar puncture or spinal or epidural anaesthesia.

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1 Serpell MG, Haldane GJ, Jamieson DRS, Carson D. Prevention of headache after lumbar puncture: questionnaire survey of neurologists and neurosurgeons in the United Kingdom. *BMJ* 1998;316:1709-10. (6 June.)
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Optimism generally quoted for epidural blood patching is unwarranted

EDITOR—Serpell et al stated that epidural blood patching has a success rate of 90% with only minor short term sequelae.[1] Although epidural blood patches are regarded by many as the preferred treatment for persistent headache after lumbar puncture and success rates of 97.5% have been quoted,[2] others have found a much lower success rate (61-68%).[3] A recent North American survey of the management of dural puncture during epidural analgesia given during labour concluded that the expressed optimism about the efficacy of epidural blood patching was not supported by the evidence available; 44% of centres reported cases of persistent headache after lumbar puncture after two or more epidural blood patches.[4]

We have performed a retrospective audit of obstetric epidurals at the Royal Surrey County Hospital over five years. The aim was to determine the efficacy of epidural blood patching in the management of headache after inadvertent lumbar puncture with a 16 gauge Tuohy needle in the obstetric population. During that time 55 lumbar punctures occurred and epidural blood patching was performed on 62 occasions in 48 patients. Our results showed that only a third of patients (16) obtained complete and permanent relief after treatment with one epidural blood patch; a further 24 obtained partial

relief. Fourteen patients required a second epidural blood patch, which was completely successful in only seven.

Although in our experience failure backache was the only complication seen, other complications reported include neck pain, leg pain, paraesthesia, cranial nerve palsies, raised temperature, bradycardia, meningism, haematoma, and pneumocephalus.[2 5] The optimism generally quoted for epidural blood patching in the treatment of headache after lumbar puncture is unwarranted, and not all sequelae are minor.

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Evidence must come from randomised trials put together systematically

EDITOR—Serpell et al report their survey of methods used to prevent headaches after lumbar puncture.[1] Others have shown a similar diversity of practice with respect to needle types and techniques, the use of prophylactic bed rest and fluids, and the treatment of established headaches after lumbar puncture with various drugs or epidural blood patching.[2 3] Such variation in practice usually implies a lack of reliable evidence for particular interventions, and this is certainly the case for lumbar puncture. Serpell et al, however, have relied on a non-systematic review of atraumatic versus bevelled needles; the results of a single trial of smaller versus larger needles when many other trials also address this issue; a non-randomised comparison of bed rest versus early mobilisation; a non-randomised observational study of different orientations of bevelled needles; and their own assertion that positioning the patient upright makes lumbar puncture easier.[1]

Randomised trials are the least biased way of assessing the effectiveness of interventions and provide the best evidence on which to base practice. There are many trials assessing various methods to reduce headache after lumbar puncture. Several of these trials are methodologically flawed, with potentially biased results. Others are fairly small and so provide inaccurate or inconclusive results.

The best way to sort out which interventions are clearly effective, which are clearly ineffective, and which have uncertain effects is to perform systematic reviews of all the available evidence from properly randomised trials. This evidence needs to be gathered from trials among patients undergoing lumbar puncture for diagnostic purposes, for spinal anaesthesia, and for myelography. An overview of randomised trials of different types of needles in the prevention of headache after lumbar puncture showed that smaller gauge needles were better than larger gauge needles and that atraumatic needles were better than bevelled needles.[4] The strategy for identifying trials was, however, limited, and only patients undergoing spinal anaesthesia were included. There are no systematic reviews of prophylactic bed rest or fluid supplements after lumbar puncture, or of the various drug treatments and interventions such as epidural blood patching used to treat established headache after lumbar puncture.

Until the evidence from randomised trials has been put together systematically and made widely available, there will no doubt continue to be selective quoting of individual trial results and of unreliable non-randomised observational studies, with resulting diversity in the practice of lumbar puncture.

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1 Serpell MG, Haldane GJ, Jamieson DRS, Carson D. Prevention of headache after lumbar puncture: questionnaire survey of neurologists and neurosurgeons in United Kingdom. *BMJ* 1998;316:1709-10. (6 June.)
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Authors' reply

EDITOR—Sharma highlights the fact that headache after lumbar puncture may go unrecognised, never mind untreated. This is an important point to rectify; all clinicians who perform lumbar puncture should be fully aware of and able to manage the possible resultant sequelae.

Williams et al suggest that epidural blood patching may not be as effective as commonly perceived. But the other treatments of established headache after lumbar puncture are not renowned for their effectiveness either, and the consequences of not treating it can be catastrophic.[1 2] Comparative studies of the various treatments need to be done.

Sudlow is critical of our references. As there are no systematic reviews on any of the various aspects that may affect the incidence of headache after lumbar puncture (except for that by Halpern and Preston, which she says is flawed), we must rely on the evidence available. The number of good quality trials that conclude that atraumatic needles are better than bevelled needles is compelling. Anaesthetists as a group probably do more lumbar punctures in their role of performing spinal anaesthesia than any other specialty. The effects of lumbar puncture on morbidity are usually closely monitored. Atraumatic needles have largely replaced bevelled needles in most practices; for these personal observations to induce such a widespread change in practice must surely speak for itself.[3] We are confident that these conclusions will be borne out when such a review is done. We acknowledge that patients undergoing myelography or diagnostic lumbar puncture are a different population from those undergoing spinal anaesthesia, but it would be reasonable to assume that the same mechanisms for headache are involved, particularly if the results of the investigations are normal.

We accept the limitations of our other references, but they are the best currently available. Our assertion that positioning the patient upright makes lumbar puncture easier is based on our analysis of a randomised study (not cited in our paper owing to the limit of five references) which showed that spinal anaesthesia was quicker to perform in the upright than in the lateral position (115 *v* 240 seconds, $P < 0.001$).[4]

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Trial of mammography in women under 50 is ethical

EDITOR—In a news item about the Medical Research Council being cleared of engaging in unethical research practices, Nicholson refers to the United Kingdom Coordinating Committee on Cancer Research trial of mammography in women under 50. He states that "it is unethical to continue to fund this trial and it should be reviewed to get the consent of all those involved."[1] As the principal investigators for this trial, which is jointly funded by the Medical Research Council, the Cancer Research Campaign, and the Department of Health, we would like to clarify the issue.

The trial has been running since 1991 and has been approved by the local research ethics committees in each of the 23 centres that are already participating. Approval has also been obtained from a multicentre research ethics committee to recruit additional centres. The control group for the trial comprises a random sample of women similar to those who have been invited for screening. These women are monitored to determine the incidence of cancer and have the same access to care as does the general population. The trial design, while differing from that of randomised trials of treatment,

has been used in other screening trials. It was decided on after careful consideration, and the design satisfied the ethics committees referred to above.

We do not believe that we are failing to take the issue of informed consent seriously. We also are unable to see how the fact that women in our control group are not informed that they are taking part in a study can bias the results. Indeed, if we did inform the women in the control group this is would be likely to introduce a volunteer bias (that is, those agreeing to participate might have a different risk).

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1 Kmietowicz Z. MRC cleared of unethical research practices. *BMJ* 1998;316:1628. (30 May.)

Fraud

Fair and efficient system of investigating alleged misconduct can be devised

EDITOR—Only one of the five papers on dealing with research misconduct in the United Kingdom (that by Riis) mentions the pharmaceutical industry and the national medicines regulatory agencies—and only as an aside.[1] Licences for drugs are granted on studies conducted by pharmaceutical companies and assessed by the regulators, so fraud endangers safety.

In the United Kingdom the pharmaceutical industry has been responsible for uncovering misconduct and fraud. The initial evidence is usually obtained by the company's clinical research associates who monitor the centres. Fraud can include falsification of data (even phantom patients) and the ethics review process.

A company loses on average about £650 000 ($1m) a day in delay in registering a new drug. In addition, conducting a trial to good clinical practice standards costs about £20 000 ($32 000) a patient. Thus if a 25-patient study has to be repeated and 100 days are lost a company can lose over £1m ($1.6m); in the case of a 400-patient study requiring two years from start to finish it can lose about £500m ($800m). In addition, the reputation of the company is at stake. In the United Kingdom companies hand over the evidence that they have gathered about fraud to the institution where the person works and lets it act. If officers of medical schools or district general hospitals were to find themselves facing a bill of £500m plus legal costs, they would soon devise a fair and efficient system of investigating alleged misconduct.

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1 Riis P. Dealing with research misconduct in the United Kingdom: honest advice from Denmark. *BMJ* 1998;316: 1733. (6 June.)

Pharmaceutical industry follows guidelines on conduct of research

EDITOR—We welcome the articles on research misconduct but would like to draw attention to two issues.[1] Firstly, some of the articles imply that there are few, if any, guidelines in the United Kingdom for the conduct of research. In fact, detailed guidelines which include information on the protection of patients and the validity of data have been followed by the pharmaceutical industry for some time. A European Commission directive (91/507/EC), which has been in effect since July 1991, requires all clinical trials to be conducted in accordance with the principles of good clinical research practice, as described in a 1990 Committee for Proprietary Medicinal Products guideline.[2] Recently, the international conference on harmonisation produced a single guideline for the European Union, Japan, and the United States, which is being reviewed by the European parliament and is due to be enacted in a European Union directive. Since the late 1980s pharmaceutical companies have incorporated these guidelines into their own working practices and have made every effort to follow them. The industry has been active in drawing the attention of the General Medical Council to cases of suspected fraud, and most companies now have comprehensive procedures in place for dealing with these cases.

Secondly, several of the articles call for the establishment of an independent agency to formalise the maintenance of research standards. In October 1996 the UK Medicines Control Agency formed a division to ensure good clinical practice and to monitor compliance, inspections, and enforcement. The agency is carrying out an inspection programme to ensure that the standards contained in the guidelines described above are upheld.

We hope that future articles on clinical research in the *BMJ* will consider the role of the pharmaceutical industry and that groups developing guidelines to combat research fraud will base their recommendations on existing guidelines rather than try to work in isolation.

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1 Rennie D; Evans I; Farthing MJG; Chantler C, Chantler S; Riis P. Dealing with research misconduct in the United Kingdom. *BMJ* 1998;316:1726-33. (6 June.)
2 Committee for Proprietary Medicinal Products. *Good clinical practice*. Brussels: CPMP, 1991. (Part of the European Medicines Evaluation Agency, London.)

In NHS appointments, research output should not be used as yardstick of ability

EDITOR—I was not surprised that my description of some of the reasons why fraudulent research is offered for publication[1] was not cited in the many articles about poor performance and fraud in the 6 June issue of the *BMJ*, but, 10 years after it was published, the problems outlined have not changed. In summary they are that research output is used as a yardstick of performance in NHS appointments and that this yardstick outweighs all others, especially in the appointment of trainees to specialist registrar posts.

I still vividly recall my attempts to secure a post as a senior registrar in anaesthetics in the mid-1980s. I was (I thought) a more than competent trainee, willing to work hard, and reasonably pleasant. Yet time and again, when I applied for non-research jobs my lack of publications was a stumbling block. Presumably this was the problem of the trainee with whom Bowie collaborated.[2] Similarly, after appointment to a career post, discretionary points exist on most pay scales, often awarded partly on the basis of publications.

Academic departments retain funding, award tenure, and make appointments largely on the basis of research published, albeit with lip service being paid to an assessment of quality. Excellence in teaching seems an irrelevance. Is it any wonder that people embellish or even invent results?

To my shame, I am now spending some of my spare time inventing and helping with modest projects to give my trainees help up the career ladder, and I will doubtless embellish my modest curriculum vitae for the hunt for discretionary points that marks the winter season in each trust. Research is the life blood of advance in medicine. It is essential. It is too important to be left to amateur researchers and trainees whose motives might be less than pure.

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1 Skinner AC. Fraud in medicine. *BMJ* 1988;296:574.
2 Bowie C. Was the paper I wrote a fraud? *BMJ* 1998;316: 1755-6. (6 June.)

Validating research retrospectively is difficult

EDITOR—Bowie highlights problems of attempting to confirm retrospectively that research was carried out by contacting patients long after the assessment.[1] Do patients remember having been contacted and assessed?

To shed some light on this, the first 10 contactable community treated patients on the Tees stroke register who were still living at home were telephoned. Each had initially been assessed at home soon after the stroke by a research doctor, three weeks later by a research nurse during a telephone call, and six months after the stroke with a self completed postal questionnaire. None of the 10 had more than these three contacts with the stroke register, the last being on average over two years previously. All had given written consent, and all the assessments had been completed. All 10 patients were telephoned, and they or their carer, or both, were asked whether they remembered each of the three assessments had taken place. The table shows the results. Whether the patients would have answered similarly over

Responses of 10 patients with stroke who were telephoned and asked whether they remembered having been examined and telephoned and having answered self completed questionnaire at least two years previously

Case	Examined	Telephoned	Questionnaire
1	Yes	Yes/uncertain	Yes
2	Yes	Yes/uncertain	Yes
3	Yes	Uncertain	No
4	No	Yes	No
5	Yes	No	Yes
6	Yes	No/uncertain	Yes
7	Yes	No	Uncertain
8	Uncertain	Yes/uncertain	Yes
9	Yes	No/uncertain	Yes
10	No	No	No

six years after the event is a matter of conjecture.

I concluded that telephone assessments are unlikely to be remembered and that trying to check whether one was carried out by contacting the patient or carer is of no benefit. You may not be able to differentiate whether some, none, or all of the claimed assessments were performed. Bowie's failure to find even one person who remembered the telephone assessment is not evidence that they did not occur. Even if some patients remembered, that still would not be evidence that all the assessments occurred.

When doing prospective assessments the only means of confirming whether a patient is alive on the day of the assessment is by telephoning the patient or carer; thus a possible way of checking whether previous assessments were done is to check whether the patient was alive at the time of the claimed assessment. A person who goes to the trouble of determining whether a patient is alive and obtaining his or her contact number (about half the work of doing a telephone assessment) probably does the assessment.

Ideally, in retrospective attempts to confirm that a study was undertaken the original paper copies (or computer database) could be compared with general practice or hospital records for consistency. This, however, has implications for long term storage of records, security, and confidentiality. A better way of preventing potential fraud is for co-authors to carry out an ongoing review of the methods and preliminary results at the time of the study.

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1 Bowie C. Was the paper I wrote a fraud? *BMJ* 1998;316: 1755-6. (6 June.)

Some aspects do not fall within remit of bodies examining fraud

Editor—Several papers in the issue of 6 June were about fraud in publication. The medical and scientific professions as a whole deplore fraud and are now making serious efforts to eradicate it. There are, however, other practices, which I regard as "parafraud." Parafraud includes:

- authors not publishing results that do not support their hypotheses;
- authors not doing crucial control experiments;
- authors claiming authorship of papers towards which they have not made any contribution;
- authors leaving out some results of experiments arbitrarily;
- referees recommending rejection of papers for publication without specifying reasons and relevant references, or rejecting work that may yield results throwing into doubt the value of their own work;
- referees recommending that grants not be given to fund research by competitors;
- authors misquoting other authors deliberately or accidentally;
- referees not reading manuscripts or submissions for grants with sufficient attention to assess them seriously;
- authors not answering questions at meetings or in correspondence;
- authors ignoring findings inimical to, or preceding, their own;
- authors being unwilling to discuss their own published research.

Several other examples of parafraud exist.[1 2] Of course, the extent of these practices is unknown, but my experience is that most of them are regarded as acceptable by the academic community. Their influence on the body of knowledge is unknowable but may be large. Unfortunately, they do not fall within the remit of bodies examining fraud.

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1 Hillman H. Fraud verses carelessness. *Nature* 1987;326: 736.
2 Hillman H. Parafraud in biology. *Science Engineering Ethics* 1997;3:121-36.

Fraud at conferences needs to be addressed

Editor—I was very interested to read the 6 June issue which dealt with scientific fraud; however, none of the articles addressed the issue of fraud at scientific meetings.[1–4] Most researchers at the cutting edge of their specialty regard these meetings, particularly international conferences, as their main opportunity to present their data and have their abstract published.

I recently attended a conference in Europe to which a previously unknown presenter had submitted no fewer than 16 abstracts; 12 of these had been accepted by the scientific committee, and one had been awarded a prize for best poster on the basis of the abstract. It subsequently transpired that most of the data contained in the abstract had been plagiarised from other studies or simply invented and, interestingly, the presenter was unable to display any of his posters, claiming that they had been lost in transit. This situation raises questions about the rigour with which abstracts submitted to scientific meetings are reviewed and the processes used for final selection.

It is astonishing that the scientific committee was not able to detect the fraud perpetrated by an investigator who had no reputation in his area of research and who had submitted abstracts containing numbers of patients that, in some cases, were greatly in excess of anything previously reported. Committees must bring scientific objectivity to the process of the selection of abstracts even though they may also be considering the number of submissions that they accept in order to maximise attendance at a conference. Conversely, institutional or other external funding for conference attendance is frequently dependent on the acceptance of an abstract, so the dynamics of submission and selection are complex. It is unfair to researchers who have submitted genuine abstracts and have had them rejected to see fraud paraded at a conference.

In the same way that journal editors have been working together internationally for some years to achieve uniformity in the submission and review of research papers, I would suggest that a similar code of practice should be developed by the organisers of scientific conferences. Doing this would go a long way towards removing concerns about perverse incentives for selecting abstracts.

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1 Smith R. The need for a national body for research misconduct. *BMJ* 1998;316:1686-7. (6 June.)
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4 Bowie C. Was the paper I wrote a fraud? *BMJ* 1998;316: 1755-6. (6 June.)

Calcium channel blockers: Is the jury still out?"

Editor—Stanton's editorial on calcium channel blockers[1] is based on an incomplete review of the available evidence. I found three additional published randomised controlled trials in which calcium channel blockers were compared with other drugs for the treatment of hypertension in predominantly non-diabetic patients.[2–4] The study group on long term antihypertensive therapy[2] compared an angiotensin converting enzyme inhibitor, delapril, with dihydropyridine calcium channel blockers; the cardiovascular study in the elderly compared the combination of chlorthalidone and atenolol with nifedipine in an elderly hypertensive population (I have been kindly provided with 12 year outcome data for the individual drugs by Casiglia)[3]; and the verapamil in hypertension and atherosclerosis study compared chlorthalidone with verapamil.[4] If the total cardiovascular events (stroke, coronary heart disease, and congestive heart failure) are combined for the other drugs compared with the calcium channel blockers, all six trials show a trend towards a benefit for the other drug; the overall odds

ratio is 0.50 (99% confidence interval 0.35 to 0.72). Can all of these trials be discounted as the result of random error?

It is important to be certain that data from all relevant trials are included. Relevant data have been collected in the treatment of mild hypertension study,[5] and should be included, but the authors have refused to provide it.

Many doctors prescribe calcium channel blockers as first line drugs for hypertension, presumably with the assumption that the overall benefits for the patient will be better than with a thiazide, β blocker, or angiotensin converting enzyme inhibitor. The chances that calcium channel blockers, particularly dihydropyridines, will be associated with better outcomes than other antihypertensive classes is small, whereas the chances that they will be associated with worse outcomes is substantial. Doctors should therefore act on the basis of this growing evidence, and begin to change their prescribing habits accordingly.

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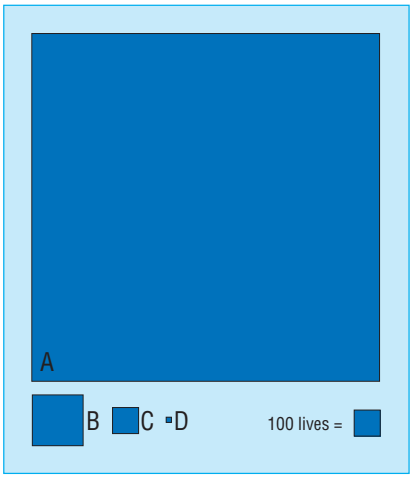
Secondary prevention in coronary heart disease

Cost effectiveness of treatment must be borne in mind

Editor—Campbell et al surveyed the true rates of treatment with various forms of secondary prophylaxis in patients with coronary heart disease, at least in those general practices that participated.[1] The authors do not consider the utilitarian argument that it is best to do the greatest good for the greatest number. The figure shows the number of lives saved per £100 000 spent on drugs for secondary prevention, based on the approximate number of patient years of treatment needed to save one life. If "all bad things" are considered[2] then aspirin (after the first five weeks)[3] and simvastatin[4] will both prevent about one bad thing for every 30-40 years of patient use, but £100 000 of aspirin (half a 300 mg tablet a day) will prevent about 1300 events, while £100 000 of simvastatin (20 mg a day) will prevent only eight.

I do not argue that we should abandon secondary prevention with lipid lowering agents, but we should concentrate on doing the easy and most cost effective things well. By these criteria, aspirin, then β blocking drugs and angiotensin converting enzyme inhibitors, in suitable cases are orders of magnitude more important than statins.



Areas of squares represent number of lives saved by spending £100 000 on each of four drugs after myocardial infarction. A: soluble aspirin 150 mg daily in first five weeks; B: soluble aspirin 150 mg daily long term; C: atenolol 50 mg daily; D: simvastatin 20 mg daily.

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1 Campbell NC, Thain J, Deans HG, Ritchie LD, Rawles JM, Squair JL. Secondary prevention in coronary heart disease: baseline survey of provision in general practice. *BMJ* 1998;316:1430-4. (9 May.)
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Payment for chronic disease management should include coronary heart disease

Editor—Campbell et al have confirmed that secondary prevention of coronary heart disease in Scotland is inadequate but have gone on to show that the situation can be improved by proper organisation within general practice.[1]

When the banding system of health promotion in general practice was abolished the requirement for general practitioners to provide coronary secondary prevention was also abolished; the long term care of diabetic and asthmatic patients, however, was ensured by separate payments for chronic disease management for these conditions. Local medical committees were charged with setting up health promotion committees, to which all general practitioners had to submit their own protocols for health promotion, which might include coronary disease. No guidance was given about what these protocols should cover or how they should be structured. No way of monitoring their performance or outcomes has ever been proposed.

The Coronary Prevention Group has been lobbying the BMA's General Practitioners Committee to negotiate for the inclusion of coronary disease in the specific payment scheme for chronic disease management. There are four justifications for this approach: secondary prevention of coronary disease is effective[2]; secondary prevention of coronary disease in general practice is far more cost effective than primary prevention[3]; secondary prevention is not currently being provided adequately in the United Kingdom[4 5]; and paying general practitioners to provide secondary prevention is likely to improve that provision. Plenty of evidence supports the first three of these justifications, but the Coronary Prevention Group was unable to find any evidence to support its belief that paying general practitioners to perform chronic disease management was effective. Campbell et al have now provided that evidence.

The Coronary Prevention Group strongly believes that improved secondary prevention of coronary disease would best be served by general practitioners' representatives negotiating with the government for coronary heart disease to be included in the payment scheme for chronic disease management, funded by new money. We would encourage all general practitioners to lobby their representatives on the General Practitioners Committee for this to happen.

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The Bristol affair

"Dispatches" programme was painstakingly researched and did not attract writ for defamation

Editor—It was my programme in March 1996 about the Bristol heart surgery tragedy, for Channel 4's current affairs series *Dispatches*, that prompted the General Medical Council (GMC) to investigate what, it subsequently became clear, was the medical scandal of the century. Since then I and my colleagues have continued to report on these cases. I wish to reply to Dunn's allegations about media reporting of the tragedy; I

am, presumably, one of those whom he pronounces guilty of "using a sustained stream of biased, misleading, and often inaccurate information."[1]

According to Dunn, bereaved parents should direct their grief and anger over the death of their children towards people like me, rather than the surgeons who operated on the children and have since been found guilty of serious professional misconduct. "Shoot the messenger" is the age old response of those who dislike the message.

The *Dispatches* programme was researched painstakingly over many months to ensure the accuracy of the story it told. Had it been "misleading" or "inaccurate" it would surely have attracted a writ for defamation from one or more of the three doctors who were named. However, no writ followed the original programme or any of the four documentaries and dozens of shorter reports that HTV has produced since.

Dunn complains that the views of the three doctors have received inadequate attention in the media. I have personally written many letters to James Wisheart, Janardin Dhasmana, and John Roylance, seeking to report their views. None of them has taken up my offer, which remains open. Their refusal to contribute notwithstanding, HTV reported the defence they made at the GMC. Interviews with lay supporters—which we have also broadcast—are, ultimately, no substitute for the doctors' own words.

It is for the GMC to defend its disciplinary practices, but I would point out that only one of the three doctors found guilty of serious professional misconduct, Dr Roylance, has exercised his right to appeal to the Privy Council. If Mr Wisheart or Mr Dhasmana had genuine reason to think that he had been treated "unfairly" by his peers, as Dunn suggests, surely he would have followed suit.

In revealing and reporting this serious lapse by the medical profession, HTV and its colleagues have illuminated an area of life that has been dark for far too long. Dunn should look closer to home for people to blame if the public does not like what we showed them and demands reform.

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GMC made grave error in taking the case on

Editor—I felt honoured to be elected to the General Medical Council (GMC) and to contribute to the formulation of *Good Medical Practice*.[1] I admired Sir Donald Irvine's enunciation of clear principles as he steered this through the council as chair of the standards committee.

It was therefore with surprise and growing uneasiness that I watched the events of the Bristol case unfold. It is difficult to comment on a judgment of the professional conduct committee without having read the evidence, but I found it hard to understand how the committee could be absolutely sure that the doctors were guilty of serious professional misconduct. Doctors often disagree about the best method of management. Is Sir Donald sending the right message to the public in this complex area? As a member of the GMC it seemed wrong to criticise, so I did nothing at the time, but my conscience troubled me. So many people whom I did not know supported me when I was the victim of an injustice, so why was I silent? Peter Dunn was one of my expert paediatric witnesses during the inquiry into my competence in 1986,[2] and I respect his integrity and judgment.[3]

Doctors are trained to look at the facts, weigh the evidence, and reach a conclusion about how best to treat a patient. In many aspects of our work there is not enough scientific evidence on which to make a proper judgment, and we do our best. Dealing with uncertainty is part of our everyday experience.

Just as doctors disagree, so do lawyers. But surely in a case as sensitive and difficult as this it would have been prudent for the president to step down as chair of the professional conduct committee if, as Dunn states, the defence lawyers accused him of bias.

I think that the GMC made a grave error in taking on this case and in arranging to try Dr John Roylance at the same time as the two cardiac surgeons. How could he be guilty of anything until a decision had been reached about their conduct?

The perception among many people, medical and lay, is that these doctors were made scapegoats as a way of satisfying the government that doctors were capable of regulating themselves as a profession. If this perception is correct then a grave miscarriage of justice has occurred and incalculable damage been done to self regulation, the medical profession, and the parents whose children were patients in Bristol.

I believe in self regulation, in professional integrity, and in providing a good service to patients. Our credibility will be undermined if we lose our scientific objectivity and sacrifice our dedicated colleagues to satisfy ill founded fears of some members of the public and the short term aims of politicians.

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1 General Medical Council. *Good medical practice.* London: GMC, 1995.
2 Savage W. *A savage enquiry: who controls childbirth?* London: Virago, 1986.
3 Dunn PM. The Wisheart affair: paediatric cardiological services in Bristol, 1990-5. *BMJ* 1998;317:1144-5. (24 October.)

Committee of inquiry should include a cardiac surgeon

Editor—Dunn's article highlighting many concerns that follow from the Wisheart affair is a breath of fresh air, though the questions raised will not make the work of the Kennedy inquiry any easier.[1] The hype inspired by the media proved a disservice to the profession and may well have clouded the judgment of the professional conduct committee of the General Medical Council (GMC). So far the previously vociferous media have ignored Dunn's article, and it would seem that they do not wish to challenge their earlier often erroneous comments with the facts.

I hope that the Kennedy committee of inquiry will include a cardiac surgeon; if it does not the problems beset by the professional conduct committee will be compounded.

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League tables of in vitro fertilisation clinics misinform patients

Editor—Marshall and Spiegelhalter have done a valuable service in questioning the reliability of the Human Fertilisation and Embryology Authority's league tables of in vitro fertilisation clinics.[1] Unfortunately, the tables are probably even less reliable than these authors suggest.

The authority reports adjusted life birth rates, which are based mostly on the female patient's age. As the method of adjustment is unpublished one cannot judge whether the various factors are weighted correctly. Moreover, this adjustment does not embody all factors affecting outcome. These include an accurate record of the number of previous cycles of in vitro fertilisation, basal follicle stimulating hormone concentrations, amount of gonadotrophin needed before eggs are collected, total ovarian response, and number of embryos transferred. Some clinics attempt to reduce the incidence of triplet pregnancy by transferring only two embryos except where prognosis is known to be poor. Others try to increase success, but also increase risks, by routinely transferring three embryos.

Commercial interests are involved in practising in vitro fertilisation. Most patients are forced into the competitive private sector because of inadequate NHS funding. There is commercial pressure on NHS clinics too, because they are less viable if purchasers believe that they have poorer success rates than others. Many clinics therefore unreasonably exclude women whose prognosis is regarded as unfavourable. This may improve league results, but is detrimental to women whose only chance of a baby is to have in vitro fertilisation. Pressure to be

high in the league table also inhibits research—for example, clinics are increasingly reluctant to undertake controlled trials investigating potential improvements because these may affect their results adversely.

Evidence also suggests that the existence of league tables discourages some clinics from reporting their results fully to the Human Fertilisation and Embryology Authority. Some may abandon individual in vitro fertilisation cycles early when a poor response is anticipated and convert the patient to gamete intrafallopian transfer, which is unregulated. Competition to succeed at all costs also accounts for too many patients receiving three embryos. This has led to unacceptable rates of triplet pregnancy, with its high cost to the patient and NHS alike.

The Human Fertilisation an Embryology Authority repeatedly claims that it is "not producing leagues tables" (Ruth Deech, Human Fertilisation and Embryology Authority press release, 2 Dec 1997). The tables are certainly perceived as such. The authority has a statutory duty to maintain adequate public information The current tables misinform and damage the interests of patients in different ways. Re-evaluation of this important issue is needed.

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1 Marshall EC, Spiegelhalter DJ. Reliability of league tables of in vitro fertilisation clinics: retrospective analysis of live birth rates. *BMJ* 1998;316:1701-5. (6 June.)

Information systems introduced carefully can aid clinicians

Editor—The article by Simpson and Gordon on clinical information technology is free of jargon and relevant.[1] It is also realistic. I have seen three software systems come and go in the trust where I am based. All were management tools; clinicians were merely encouraged to believe in them. Then four years ago I had the opportunity to purchase an early version of a medical information management system (the Advanced Medical Information Guidance and Organisational System manufactured by AVC Multimedia, Norwich); this system essentially duplicates case records in an electronic form and allows users to search for information throughout the system. Soon the whole of our large inner city psychiatry directorate (which is spread across four sites) will be on one network.

The essence of good psychiatric practice is multidisciplinary teamwork. With our system I can view the records of other members of the team, some of whom have stopped using paper records. My laptop computer contains my entire caseload. I take it with me to meetings with representatives of social services, to day centres, and to local general practitioners' surgeries to discuss clients who we have in common. Before the current system it would have taken a secretary several hours just to list all of a local practitioner's patients, now it takes a minute. Care plans are updated weekly, directly on the system.

It is important to know why one system works and another fails. The key is, as Simpson and Gordon say, to keep it focused on the patient. Clinicians intuitively feel ownership of a "bottom up" approach. However, there also needs to be a financial commitment as terminals have to be available throughout the various clinical environments and offices. Also, enthusiasm is no substitute for proper management of the system. Our information technology manager is a clinician (nurse): "street credibility" is important if professionals are to be convinced that the initial pain of introducing information technology is worth the long term gains. Of course, staff must be properly trained. We have found that a "cascade" approach works best [2]; we identify one person from each clinical area or discipline and train him or her. This person trains another group of staff and they, in turn, train another group.

Clinicians need to see instant benefits from the system and must not be asked to enter data twice. Lastly, software development is vital. Like Simpson and Gordon we have been able to generate information of relevance both to clinicians and managers from one system.

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1 Simpson K, Gordon M. The anatomy of a clinical information system. *BMJ* 1998;316:1655-8. (30 May.)
2 Johnson M. The development of a mental health clinical information system within an inner city psychiatry directorate *Br J Healthcare Comput Information Manage* 1997;14: 26-9.

We need to develop scoring systems to determine clinical need

Editor—I know little about New Zealand and even less about spin doctoring. I wish, however, to dispel some myths about waiting lists that have been quoted as fact in recent letters.[1]

Myth 1). "Waiting lists are a form of rationing." They are not a form of rationing; they are the result of our failure to ration when demand exceeds supply. A waiting list is a backlog, nothing more. If it is regarded as a form of rationing it will continue to expand indefinitely or until the rate at which patients die while waiting equals the difference between the rate at which patients are referred and the rate at which they can be treated.

Myth 2). "Priority is based on clinical grounds." Not so. Priority is based on listing order or waiting time. As a cardiac surgeon, I operate a simple clinical priority system in my waiting list. My efforts to implement this are, however, in direct conflict with the misguided government directive aimed at limiting waiting times. As soon as patients have been waiting for 18 months I have to give them priority over all but the most dire emergencies. Patients waiting for urgent cardiac surgery who are not actually occupying hospital beds get an extremely rough deal under the present system.

The only logical way to manage the shortfall between demand and supply is rationing on the basis of clinical need. This will require the development of scoring systems that express clinical need as a quantitative measurement. I read in another letter, "We fear further manipulation of lists on the basis of points scored rather than clinical need."[2] If the New Zealand scoring system is not a measurement of clinical need then it needs to be altered so that it is.

New Zealand's health system may be far from ideal. At least the New Zealanders have faced up to their problems in a rational way and have produced a system to manage the situation, even though it may be imperfect. So far we in Britain have steadfastly failed to face the problem. Until we do so, waiting lists will continue to grow indefinitely according to the elementary principles of supply and demand, and no amount of spin doctoring or government directives can prevent this.

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1 Padwell A. Most New Zealanders believe their public health service has deteriorated. *BMJ* 1998;316:1321. (25 April.)
2 Nicholls MG, Richards AM, Moller PW, Elliott JM, Begg EJ. Health authorities in New Zealand have spin doctors to produce good news. *BMJ* 1998;316:1321. (25 April.)

Ethical commentaries must be based on sound science

Editor—It is unfortunate that the scientific basis of Savulescu's commentary on the ethics of the study by Parkins et al, in which infants were exposed to 15% oxygen, is so weak.[1] Savulescu states that evidence exists that exposure to hypoxia is related to sudden infant death; he refers to a study in piglets to support his assertion.[2] In fact, this study he cites shows no such thing. Parkins et al cogently explain the scarcity of evidence on the effects of exposure to 15% oxygen.

Savulescu also argues that piglets should be used as a model for infants. He is clearly unaware of the important differences that exist between species in terms of ventilatory responses to hypoxia; this is an area of debate in respiratory physiology.[3] For example, the depressant effect of hypoxia on the respiratory system of many animals is thought to be due to an action of hypoxia on the central nervous system. In contrast, the depressant effect of hypoxia in humans is thought to be due to an action on the carotid body.[3] It is misleading therefore to extrapolate all studies in animals to humans.

Savulescu discusses the possibility that hypobaric hypoxia somehow differs from isobaric hypoxia. There is no evidence in humans that barometric pressure affects ventilatory responses over and above the reduction in the partial pressure of oxygen.[4] Birds might be expected to show some differences in ventilatory responses since they possess aerodynamic valves which prevent inspired air from being shunted past the gas exchange surfaces. The efficiency of these valves depends on gas density, and thus efficiency might be reduced in hypobaria. However, studies in ducks show minimal differences between hypobaric hypoxia and isobaric hypoxia.[5]

The fact that seems to have been overlooked is that an inspired oxygen fraction of 15% is equivalent to breathing air at an altitude of about 2300 metres (7000 feet). Many cities, such as Pretoria and Mexico City, are at or near this altitude, and many infants live in and visit these places. The ethical arguments about studying infants exposed to mild hypoxia might be elaborate. However, it follows that the same ethical issues must then apply to allowing infants to visit, reside in, or even be born in cities at high altitude. It is perhaps at this point that many of the ethical arguments become untenable.

Parkins et al's study was interesting, necessary, safe, and ethical. The real lesson of Savulescu's commentary is that proper discussion of ethical issues in research needs good acquaintance with the underlying science.

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1 Parkins KJ, Poets CF, O'Brien LM, Stebbens VA, Southall DP. Effect of exposure to 15% oxygen on breathing patterns and oxygen saturation in infants: interventional study. *BMJ* 1998;316:887-94. [With commentaries by Savulescu J; Hughes V.] (21 March.)
2 Waters KA, Beardsmore CS, Paquette J, Meehan B, Cote A, Moss IR. Respiratory responses to rapid-onset, repetitive vs continuous hypoxia in piglets. *Respir Physiol* 1996;105:135-42.
3 Robbins PA. Hypoxic ventilatory decline: site of action. *J Appl Physiol* 1995:79:373-4.
4 Loeppky JA, Scotto P, Roach RC. Acute ventilatory response to simulated altitude, normobaric hypoxia, and hypobaria. *Aviat Space Environ Med* 1996;67:1019-22.
5 Shams H, Powell FL, Hempleman SC. Effects of normobaric and hypobaric hypoxia on ventilation and arterial blood gases in ducks. *Respir Physiol* 1990;80: 163-170.

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Educational resource pack exists to help staff listen to what concerns children

Editor—Hart and Chesson emphasise the importance and feasibility of soliciting the views of children and young people on their healthcare experiences and needs.[1] Staff must raise awareness that children and young people may have different concerns from those of adults and that recognising children's anxieties is important but not always easy. This can leave clinicians and managers unsure how to start improving their practice or believing that only experts can communicate with, or understand what is likely to be important for, children. In an attempt to improve the tools available on listening to children, Action for Sick Children has published an educational resource pack that provides insight into children's views on these subjects.[2] The publication is based on the responses of groups of children to structured questions relating to their perception of healthcare delivery. The material is developed into a training pack, including slides and suggestions for discussion in tutorial groups and for use in various ways with different clinical and managerial practitioners. One of the most striking effects of using the pack is the universal recall that adults viewing the material have of their own childhood experiences and the recognition that these have a lifelong effect on attitudes to illness and use of health care. For those who have become aware of the need to listen to children but are unsure about how to start, this type of material provides an introduction that does not depend on prolonged paediatric experience or expert psychology training and can apply to any healthcare setting. A further project currently involves specific groups of children looking at environmental as well as clinical issues that they perceive as relevant to their needs. Other "young consumer surveys" have been reported in relation to quality and audit; plenty of material is available that could be used to allow health care to be more child friendly in all the healthcare encounters that children and young people have.

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*Una MacFadyen is a member of the Action for Sick Children project steering group.

1 Hart C, Chesson R. Children as consumers. *BMJ* 1998;316:1600-3. (23 May.)
2 Davies-Jones C. Pictures of healthcare—a child's eye view. London: Action for Sick Children, 1997.

Several issues need to be considered before all patients are followed up by telephone

Editor—Pal found that telephone follow up of outpatients can be effective for patients,[1] but several issues need to be considered before his results can be generalised.

Firstly, a detailed clinical assessment and investigations were undertaken to determine the patients' suitability for follow up by telephone. It is important to take into account the extra time and resources devoted to this assessment, as it might partially account for the acceptability of subsequent follow up by telephone. Secondly, it is unclear how many patients were found to be unsuitable and were excluded in the initial assessment; hence the proportion of patients suitable for follow up by telephone is unknown. If the proportion is small the extra effort devoted to the initial assessment would become relatively important. Thirdly, all the general practitioners seemed to agree to prescribe new treatments. This might not apply to other districts or to specialties such as ophthalmology, dermatology, and rheumatology, in which physical signs may be relatively more important than symptoms in the assessment of follow up patients.

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1 Pal B. Following up outpatients by telephone: pilot study. *BMJ* 1998;316:1647. (30 May.)

Corrections

Odds ratios should be avoided when events are common

Several errors occurred in this letter by Douglas G Altman et al (7 November, p 1318). The last sentence should end "surely it makes sense also to report the relative risk when this differs markedly from the odds ratio" (not "surely it makes no sense ...." as printed). Also, the first name of the second author is Jonathan, not Jonathon, and the second author of reference 2 is Bero LA, not Dero LA.

Systematic review of trials comparing antibiotic with placebo for acute cough in adults

An editorial error occurred in the last letter in this cluster, by Tom Fahey and Nigel Stocks (10 October, p 1015). The first sentence should have read: "Cates bases his criticism on manipulation of the pooled effect estimates and attributing the non-significant trend towards antibiotic as evidence of efficacy."